Standard Operating Procedures

Human Research Protection Program

University of Maryland College Park

July 23, 2025

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1. **Purpose**

   The purpose of this Standard Operating Procedure is to describe the Institution and its commitment to the Human Research Protection Program (HRPP).

2. **Policy**

   The Institution is committed to the human research protection program through establishment and funding of an Institutional Review Board (IRB) operating in full compliance with Health and Human Services regulations and 45CFR46.

   a. The Institution is comprised of The University of Maryland College Park (UMD).
   b. The Institution is committed to ensuring the existence and evolution of premier educational programs, high quality research, which is conducted with integrity, consistent with ethical standards, and with respect for all individuals and groups (HRPP Policies 1.004 and 2.010).
      i. The UMD IRB Leadership (Director - HRPP, IRB Chairs, and Quality Assurance Program Manager) meet with the Vice President for Research (VPR) on an annual basis to review and discuss the following:
         1. Resources needed for maintenance and growth of the UMD HRPP (space, personnel, equipment, etc.)
         2. Analysis of previous fiscal year caseload, quality assurance audit reports, summary of Quality Improvement activities (including issues identified and solutions implemented), and research community education initiatives.
         3. Comparison of AAHRPP Accredited peer institutions using the AAHRPP Annual Report.
         4. Annual surveys of the UMD research community and IRB Members requesting feedback on process, education, communication, and suggestions for areas of improvement.
   c. The IRB has been authorized by the Institutional Official (IO) to review and approve all human subject research conducted by the faculty, students, staff or other institutional representatives regardless of where the research is conducted, unless the IRB accepts the review and approval of another duly constituted IRB through a reliance agreement.
   d. UMD may conduct FDA regulated research. If UMD does conduct FDA regulated research; the UMD IRB will ensure appropriate expertise is present to review the research. If the UMD IRB is unable to procure appropriate expertise to review the FDA regulated research:
      i. It will reach out to the University of Maryland, Baltimore campus to discuss reliance on their IRB review process; or
      ii. It will not conduct the review.

1. **Purpose**

   The purpose of this SOP is to describe the agreement with the Department of Health and Human Services (DHHS) Office of Human Research Protection (OHRP) through the Federalwide Assurance (FWA).

2. **Policy**

   It is the policy of the IRB that this Institution will file and maintain an agreement with OHRP through an FWA. This Institution has declared that all institutional components listed under the UMCP FWA (#00005856) must comply with this assurance.

   a. The Institution has determined that all FEDERALLY FUNDED human subject research will be governed by the DHHS regulations at 45CFR46 (Common Rule).
   b. The Institution has "unchecked the box" on its FWA and taken a flexible approach to non-federally funded, non-federally regulated research. This means that the UMD IRB Standard Operating Procedures, which may include elements of 45CFR46, will govern the review of these projects.
   c. The Institution has determined that all its activities related to human subject research, regardless of funding source, will be guided by the ethical principles found in the Belmont Report.
   d. The Institution has designated establishment and registration of one IRB with provisions for sufficient meeting space and staff to support the IRB's review and recordkeeping duties (HRPP Policies 1.005 and 2.003).
      i. IRB-01 (IRB00000474 – University of Maryland College Park – IRB #1)
   e. The Institution will maintain a list of IRB members identified by name, earned degree, representative capacity, as well as maintenance of current curriculum vitae for each IRB member.
   f. The Institution will update its IRB Registration every three (3) years and within 90 days of changes to the IRB contact person list on the Registration or the IRB Chairperson.
   g. The Institution has established HRPP written policies and procedures as required under DHHS regulations at 45CFR46.108. The January 21, 2019, Revised Common Rule applies to all research approved before and after this date.
      i. The IRB will conduct initial and continuing review of research (at intervals appropriate to the degree of risk, but not less than once per year when required or justified). The investigator and the Institution will be provided written (electronic) notification of the findings and actions taken by the IRB (HRPP Policies: 3.002, 3.003, 3.004, 3.005, and 11.001). The IRB will determine which protocols require review more often than annually (HRPP Policy 3.010) and which protocols require verification from sources other than the investigators that no material changes have occurred since the previous IRB review.
      ii. The IRB shall ensure that proposed changes in approved research protocols are reported promptly and are not initiated without IRB review and approval, except when necessary to eliminate immediate risk to the participant (HRPP Policies: 12.001, 13.001, 14.001).
      iii. The IRB shall have the authority to observe, or have a third party observe, the consent process and research activities.

iv. The IRB shall ensure prompt reporting to the IRB, appropriate institutional officials, and in the case of federally funded projects, federal regulatory officials (OHRP, National Science Foundation, National Institutes of Health, and other Departments or Agencies) (HRPP Policy 14.002):
    1. All incidences of unanticipated problems involving risks to participants or others
    2. Any serious or continuing non-compliance with federal or IRB requirements
    3. Suspension or termination of IRB Approval

v. The IRB shall require confirmation by a qualified IRB Office staff member that a research protocol qualifies for Exempt status (HRPP Policy 4.001)

1. **Purpose**

   The purpose of this SOP is to describe the vision, mission, and values for UMD.

2. **Policy**

   UMD has developed a comprehensive vision, mission, and values statement.

   a. Vision

   During the next decade, the University of Maryland will enhance its standing as a world-class, preeminent institution of higher education.

   The University will achieve this goal through an unwavering commitment to excellence in all it undertakes.

   The University will attract a diverse student body that possesses the ability and passion for learning. Innovative and relevant programs, whether within or built upon traditional disciplines in the arts and sciences, will prepare students to be engaged and self-realized citizens and leaders in a complex, democratic society.

   The University will foster research, scholarship, and arts programs noted for their quality, creativity, and impact, and provide affordable access.

   As befits its proximity to the nation's capital, the University will expand its international influence and address great and challenging problems of our time. Taking maximum advantage of its special location, the University will be a world center for creation and refinement of knowledge; advancement in science and technology, humanities, and social sciences; global leadership; and innovative production in the creative and performing arts.

3. **Mission Summary**

   Achieving excellence in teaching, research, and public service within a supportive, respectful and inclusive environment is central to the mission and identity of the University of Maryland, College Park (UMD). As the flagship campus and a national leader in higher education, UMD strives to provide exceptional and affordable instruction for Maryland's most promising students, regardless of income. A pre-eminent locus of scholarship, the university builds and maintains a world class capacity in the sciences, arts, and humanities to support ground-breaking discoveries that address the most pressing global challenges and inspire the human imagination. As one of the country's first land-grant institutions, UMD uses its research, educational, cultural, and technological strengths in partnership with state, federal, private, and non-profit sectors to promote economic development and improve quality of life in the State of Maryland. Diversity amongst our students, faculty, and staff is essential to this mission. Accordingly, ensuring equal educational opportunity; hiring and retaining a diverse and exceptional faculty and staff; recruiting and graduating talented students from

traditionally underrepresented groups; and providing a supportive climate for their well-being are top institutional priorities.

The full Mission Statement can be viewed here: https://provost.umd.edu/mission-vision

1. **Purpose**

   The purpose of this SOP is to describe the vision, mission, and values for the UMD HRPP.

2. **Policy**

   The IRB has developed a comprehensive vision, mission, and values statement.

   a. **Vision**

   The HRPP for UMD, hereafter referred to as the "Institution" and affiliates will be a nationally known HRPP where:

   i. Investigators will conduct research with the highest thought, technical skill, and care.
   ii. Investigators will adhere to high standards of research ethics, comply with all applicable federal, state, and local laws and regulations, and always consider the rights and welfare of research participants.
   iii. IRB Members and Staff will keep abreast of the latest developments in the ethics and regulation of human participant research and will perform thorough and consistent review of research projects.

   b. **Mission**

   The mission of the HRPP is to ensure the protection of human participants who choose to participate in research conducted by investigators at the Institution and affiliates that is part of a broader framework of the responsible conduct of research.

   c. **Values**

   i. Faculty, staff, and students, and others who serve as investigators will emphasize the conduct of quality research, which is carried out with scientific integrity and in an ethical manner.
   ii. Investigators will respect all individuals and groups served by this Institution

   d. **Components**

   i. **Office of Research Administration**

   Office of Research Administration (ORA) is the pre-award and non-financial post-award administration office for the University of Maryland. ORA works to facilitate the submission of all sponsored project proposals on behalf of UMD and helps researchers and business officers administer projects when contracts and grants are awarded to UMD. ORA and the UMD HRPO work together to confirm human subject research approvals and perform grant congruency checks if needed.

   ii. **Office of General Counsel**

The Office of General Counsel (OGC) is the in-house law firm for UMD. Administrators, faculty and staff members consult with an OGC attorney when legal issues arise during the course of university activities or business. OGC helps university clients fulfill their educational, research, and entrepreneurial missions in accord with the many legal and policy requirements applicable to public research universities. The UMD HRPO will consult with OGC if interpretation of regulations and policy is needed, to confirm if research is complying with state and local laws, and if guidance is needed during review of serious non-compliance. A member of OGC serves as an ex-officio member of the UMD IRB.

iii. **Disclosure Office**

The Disclosure Office provides faculty, students, trainees and staff with support, education, and resources needed to ensure a culture of integrity. The UMD HRPO will work with the Disclosure Office if a conflict of interest (COI) is identified in an IRB application. Both offices will discuss any needed additions to the COI management plan in order to properly inform and protect participants.

iv. **Institutional Leaders**

Institutional leaders are the Institution Official, components in the Office of the President, the Office of the Vice President for Research, and Deans. The UMD HRPO will communicate with UMD leadership when necessary, such as cases of serious non-compliance, major policy changes, and/or major changes in operation.

1. **Purpose**

   The purpose of this SOP is to describe the IRB charter, appointments, and administrative structure.

2. **Policy**

   It is the policy of the IRB that the structure and composition of the IRB be in full accordance with the Health and Human Services policies and 45CFR46.

   a. **IRB Charter**

   The UMD IRB is a duly constituted IRB, which has established membership in full accordance with the requirements of Health and Human Services regulations at 45CFR46.107.

   b. **Institutional Official**

   The President has appointed the Vice President for Research to serve as the Institutional Official (IO) in accordance with the provisions of the Federal Wide Assurance (FWA #00005856). The IO appoints the officers of the IRB and all IRB Members.

   c. **HRPP Director**

   The HRPP Director (Director) reports to the IO, including on matters concerning compliance with 45CFR46 and HRPP policies and procedures. The IO has delegated responsibility for the daily operation of the HRPP to the Director who has a continuous appointment. The Director is primarily involved in the development of HRPP policies and procedures, revision of IRB forms, compliance issues, conflict resolution, and continuing education of both IRB members and investigators.

   d. **IRB Chair/Co-Chair**

   The IRB Chair and/or Co-Chair works closely with the Director. The IRB Chair and/or Co-Chair is primarily involved in conducting IRB meetings, reviewing and approving expedited transactions, reviewing adverse events and serious problems, continuing education of IRB members and investigators, as well as serving as a resource for investigators and IRB Members regarding issues related to University and federal policies. The IRB Chair and/or Co-Chair's term of service is at the discretion of the IO. The IRB Chair and/or Co-Chair has a direct line to the IO and the President as necessary.

   e. **Human Research Protections Office (HRPO)**

   The HRPO within the HRPP serves at the administrative office for the IRB. The Quality Assurance Program Manager, IRB Specialist, IRB Analyst, and IRB Graduate Assistant positions, are hired and operate under the direction of the Director.

   f. **Administrative Structure**

   The IRB has direct access to the HRPP Director, IO, and President.

1. **Purpose**

   The purpose of this SOP is to describe the authority granted by UMD to the IRB operating in the HRPP.

2. **Policy**

   It is the policy of the IRB that the Institution provide sufficient resources and decisional autonomy for the IRB to carry out its duties independently of the Institution in full accordance with Health and Human Services policies at 45CFR46.

   a. UMD through its President, authorizes the IRB to independently review and approve all human participant research conducted or supported by the faculty, students, staff, or other representatives of UMD, when such research is part of their institutional responsibilities regardless of where the research is conducted unless the IRB accepts the review and approval of another duly constituted IRB with a FWA for research conducted at other study sites.

   b. The Vice President for Research (VPR) will serve as the IO.

   c. The IRB, which is housed administratively within the Division of Research's HRPO, shall exercise its authority in full accordance with the HRPP policies and procedures included in this SOP, which includes elements of Health and Human Services regulations At 45CFR46. This authority includes review and approval of *exempt* research under 45CFR46.104; research which qualifies for *expedited review* under 45CFR46.110; and research which requires review by the fully convened IRB. The IRB has the empowerment, flexibility and discretion to raise the standards of protection above those afforded to research participants in 45CFR46 as it deems appropriate and necessary, although it may not lower the protections below those afforded by 45CFR46.

   d. IRB Members are to report any attempts to unduly influence their decisions to the IRB Chair and/or Co-Chair, the HRPP Director, or the Vice President for Research. The IRB Chair and/or Co-Chair, in consultation with the HRPP Director and the Vice President for Research, will investigate the allegations, and if true, will take any needed corrective action.

   e. The Institution's HRPP policy will apply 45CFR46, including Subpart A, B, C, and D, to all human subject research regardless of funding, with exceptions noted in HRPP Policy 5.003 (Section 2.3). Subpart B is intended to apply to all human subject research including that performed in the social and behavioral sciences as noted in HRPP Policy 5.002 (Section 2.2).

      i. Human subject research that would fall under the purview of the FDA may be reviewed at UMD if appropriate expertise can be identified to serve on the IRB. If the UMD IRB does not have the appropriate expertise to review the FDA regulated research, it will not conduct the review.

      ii. In the event that UMD conducts or reviews FDA funded human subject research, all contracts and/or other funding agreements will require the sponsor to provide both routine and urgent safety data and safety monitoring reports to the UMD IRB Office as indicated in the data and safety monitoring plan approved by the IRB. All contracts and/or

funding agreements will require that the sponsor promptly (within 30 days) reports to the UMD IRB Office any findings that could:

1. Affect the safety of participants.
2. Influence the conduct of the study or alter the IRB's approval to continue the study.

f. Per Health and Human Services regulations at 45CFR46.112 the institution acknowledges that research, which has been approved by the IRB, may be subject to further appropriate review by the IO, or his/her designee. However, no official may approve research if it has not been approved by the IRB. In addition, any attempt to unduly influence the IRB from both within and outside the Institution is strictly prohibited and must be reported to the IO or the President who will take appropriate action.

g. Approval of research by the IRB can be overturned by the IO or his/her designee. The reasons for administrative disapproval of research by the IO or his/her designee shall be provided in writing to the IRB. The IRB will notify the Principal Investigator (PI) of any disapproval in writing and provide the reason(s) for disapproval.

1. **Purpose**

   The purpose of this SOP is to describe UMD IRB membership requirements and responsibilities.

2. **Policy**

   It is the policy of UMD that the IRB will include an appropriately diverse mixture of backgrounds and experiences in accordance with the Health and Human Services regulations under 45CFR46.107. The IRB will adhere to the following policy:

   a. The IRB will have at least five (5) members. Members will be appointed for revolving one-year terms.
   b. Members will represent varying academic disciplines and have the necessary credentials to provide an appropriate review of submitted protocols. The IRB will represent the diversity of the community in order to provide guidance on varying perspectives and sensitivities. The IRB will be sufficiently qualified through experience, expertise, and diversity to provide appropriate review of research with a primary focus on protection of human subjects.
   c. The IRB will include at least one member that is not affiliated with the Institution. The unaffiliated member must not: 1) have a professional relationship with the Institution as an employee, consultant, volunteer faculty, or student, and 2) be a family member (1st and 2nd degree relative), which has a professional relationship with the Institution.
   d. The IRB will include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas.
   e. The IRB will have a non-voting representative from the Institution's Office of General Counsel serving in an *ex-officio* capacity to offer legal counsel to the IRB.
      i. When legal conflicts arise, the Office of General Counsel will provide a legal opinion and resolution to the IRB.
   f. The IRB will include one or more members who are knowledgeable about, and experienced in, working with vulnerable populations, including, but not limited to: children, prisoners, differently abled individuals, cognitively impaired individuals, etc.
   g. In situations where a prisoner is involved in research under IRB review and the IRB does not already have a member with appropriate background and experience to serve in the capacity of prisoner representative, the IRB will include an ad-hoc prisoner representative to serve in that capacity. This individual must have a close working knowledge, understanding, and appreciation of the prison conditions in the facility where the research will be conducted from the perspective of the prisoner.
   h. Where IRB members have conflicts of interest pertaining to the research to be reviewed, members must be absent themselves from the meeting room before the final review, discussion, and vote, except where requested by the IRB to be present to provide information. IRB members with conflicts of interest must not participate in all types of reviews, including initial review, continuing review, review of modifications, review of unanticipated problems involving risks to participants or others, and review of non-compliance.

IRB members also may not serve as reviewers for research in which they have a conflicting interest when asked to review protocol transactions using the expedited review process.

i. Individuals who are responsible for business development are prohibited from serving as IRB members or ex-officio IRB members and carrying out day-to-day operations of the review process.

j. When review of a proposal requires expertise that is not available on the IRB, at its discretion, the IRB will request assistance from an expert consultant. These individuals have access to all documents submitted to the IRB relevant to the protocol under review and may participate in the deliberations and make recommendations on the project but will not vote (HRPP Policy 2.003).

k. Alternates are appointed and function in the same manner as the primary IRB members. The alternate's expertise is comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the primary member is unable to attend a convened IRB meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member would receive.

l. The IRB roster identifies the primary member(s) for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the primary member is absent. The IRB minutes will document when an alternate member replaces a primary member.

m. IRB members are expected to be fully engaged in the HRPP and will be involved in carrying out the following responsibilities (when requested by the IRB Chair or designee):
   i. Serving as a primary or secondary reviewer for initial applications.
   ii. Serving as a primary or secondary reviewer for continuing review applications.
   iii. Serving as a primary or secondary reviewer for internal unanticipated problems involving risks to participants or others.
   iv. Serving as a primary reviewer for external adverse events or serious problems.
   v. Serving as a primary or secondary reviewer for amendments to protocol documents or consent documents.
   vi. Serving as a primary reviewer for incidents of non-compliance.
   vii. Serving as an expedited reviewer.
   viii. Acknowledging protocol deviations.
   ix. Completing continuing education.

n. When IRB membership changes, the Director – HRPP or designee will work with the IO or designee to send an appointment letter to the member leaving or joining the IRB. The Director – HRPP or designee will also update the IRB Member Roster accordingly.

o. The IRB Member Roster must remain current and identify members sufficiently to describe each member's primary anticipated contributions to IRB deliberations. The list must contain the following information about members:
   i. Name
   ii. Earned degrees

iii. Affiliated or non-affiliated status
iv. Status as a scientist (physician, social-behavioral scientist, other-scientist, non-scientist). For the purposes of this IRB Member Roster, members will research experience are designated as scientists (including graduate student members). Research experience includes training in research (e.g. doctoral degrees with a research-based thesis) and previous or current conduct of research. Graduate students being trained in research fields will be designated as scientists).
v. Indications of experience, such as board certifications or licenses sufficient to describe each member's primary anticipated contributions to IRB deliberations.
vi. Representative capacities of each IRB member. Specifically: prisoner representative, knowledgeable about or experienced working with minors, pregnant women, cognitively impaired individuals, and other vulnerable populations.
vii. Role on the IRB (Chair, Co-Chair, etc.)
viii. Voting status (ex-officio members do not vote)
ix. Alternate status (including primary member)
x. Affiliation status with UMD

p. The IRB Member Roster is confidential and is not posted publicly. The names of IRB members who reviewed specific protocols will not be released.

1. **Purpose**

   The purpose of this SOP is to describe the structure of the IRB Meetings and IRB Member responsibilities.

2. **Policy**

   It is policy of the IRB that the structure of IRB Meetings and responsibilities of IRB members are clearly defined.

   a. IRB meeting dates are determined at the end of each calendar year.

   b. Three (3) weeks prior to the scheduled IRB Meeting, an IRB staff member sends the RSVP notices to each board member requesting their attendance. The members are officially notified of the date, time, and location of the IRB Meeting. This information can also be found on the IRB website and IRB electronic submission system.

   c. Ten (10) to fourteen (14) days prior to the IRB Meeting, IRB applications and supporting materials will be posted on the electronic submission system for IRB Members to access, review, and provide written feedback.

      i. For initial reviews by a convened IRB, all members are provided with:

         1. The full protocol or a protocol summary containing the relevant information needed to determine whether the proposed research fulfilled the criteria for approval. This includes all supporting documentation (surveys, questionnaires, interview materials, etc.).
         2. Informed consent document.
         3. Recruitment materials.
         4. DHHS-approved protocol (when one exists).

      ii. Primary and Secondary IRB Member reviewers perform an in-depth review of all pertinent documentation. All other IRB Members review all materials provided in enough depth to discuss the information at the convened meeting. When conducting reviews using the expedited process, the reviewer has access to and reviews all submitted information including, at a minimum, all information the convened IRB would have received.

   d. The IRB has a minimum of five (5) regular voting members, plus one (1) non-voting ex-officio member serving as a legal representative.

   e. A quorum will be established in accordance with federal requirements. If quorum is not met or lost, the meeting will be postponed and re-convened as soon as possible (HRPP Policy 2.011).

      i. Quorum is defined as the minimum number of IRB members that must be present at the IRB Meeting to make an action/vote valid. A majority must be present. For example, if fourteen (14) members are on the IRB Member roster, quorum is defined as eight (8) voting members present at the IRB Meeting (inclusive of at least one (1) non-scientist member).

   f. IRB Members will serve as Primary or Secondary reviewers. A Primary and Secondary reviewer will be assigned to all initial reviews and table reviews. A Primary reviewer will be assigned to amendment and continuing reviews.

   g. IRB Members will review and vote on IRB policies as required (HRPP Policy 2.013).

h. Individuals may be invited to attend IRB meetings as guests under the following conditions:
   i. Guest attendance is at the discretion of the IRB Chair.
   ii. Guests may be asked to leave at any time.
   iii. Guests will be asked to state the purpose of their visit for the IRB Meeting Minutes.
   iv. Guests attending a meeting where a proposed protocol has been submitted will be asked to provide information about a proposed study and answer any question the IRB may have regarding the protocol under review.
   v. All requests for visitors to attend an IRB meeting must be directed to the IRB Chair. The request must include the name(s) of the visitor(s), the rationale for the visit, and the proposed visit date. The IRB Chair may approve the request. The IRB Chair may also refer the request to the next IRB meeting for discussion.
   vi. If the request is granted, the visit will be required to sign a Confidentiality Agreement and may be required to leave the room during any discussion as necessary.

1. **Purpose**

   The purpose of this SOP is to describe the identification, appointment, and role of IRB consultants.

2. **Policy**

   It is the policy of the IRB that services of expert consultants will be obtained as needed.

   a. Either before or during the review of a protocol, the IRB, assigned IRB reviewer, or the IRB itself, will determine if there is a need for appointment of an expert consultant, either scientist or non-scientist, in accordance with the provisions of 45CFR46.107(e). Depending on the nature and magnitude of the problem or concern, the IRB may seek more than one (1) consultant.

   b. Consultants will be selected from within the Institution, as well as from outside the Institution based upon the required expertise.

      i. The IRB Chair will table a protocol to another meeting, or obtain consultation if there is not appropriate scientific, scholarly, or representational expertise.

   c. Consultants generally will produce written reviews, and they may participate in the IRB's discussion of the protocol.

   d. Written reviews will be accessible to all IRB reviewers.

   e. Consultants who attend an IRB Meeting may not vote and are excused upon conclusion of discussion of the protocol in question.

   f. Potential consultants will be queried and asked to sign an attestation by the IRB Chair before the meeting as to whether they have any potential conflicts of interest[1] with the relevant investigators or funding agencies. If they do, they will be excused and another consultant found.

   g. When the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, the IRB Chair or Director will ensure that one or more individuals who are knowledgeable about, or experienced in, working with such participants will be present at the meeting.

[1] Conflicts of interest shall mean situations where a consultant's direct or indirect interests (financial or otherwise) may compromise, or have the appearance of compromising, the consultant's professional judgement or behavior in carrying out his or her obligations to the UMD IRB.

1. **Purpose**

   The purpose of this SOP is to describe the orientation and initial training for new IRB Members and Human Research Protection Program (HRPP) staff.

2. **Policy**

   It is the policy of the IRB to provide new IRB members and HRPP staff with an orientation and initial training that includes the information necessary to facilitate the performance of assigned responsibilities.

   a. All new IRB Members and HRPP staff will participate in orientation. The orientation is conducted by an IRB Specialist and/or the Director - HRPP. HRPP policies and procedures are reviewed and explained. New IRB Members and HRPP staff will have time to ask questions. IRB Member Orientation Materials are available in a shared, online file that is accessible at all times.

   b. Orientation materials will include access to and review of the following:
      i. Code of Federal Regulations: 45CFR46
      ii. Belmont Report
      iii. Overview of Federalwide Assurance (FWA 00005856)
      iv. Overview of IRB Member reviewer resources & guidance documents
      v. IRB Member Handbook
      vi. Electronic Submission System guidance
      vii. Limited IRB Membership Roster (contact info and expertise only)

   c. All IRB Members and staff are required to complete CITI (Collaborative Institutional Training Initiative) Training. IRB Members are required to complete the IRB Member Training Modules and HRPP Staff are required to complete the Biomedical or Social and Behavioral Research – Basic Modules. A minimum passing score of 80% is required to obtain CITI certification. HRPP staff are also required to complete the COI Mini Course, Responsible Conduct of Research Course and are encouraged to complete any optional courses that are available.

1. **Purpose**

   The purpose of this SOP is to describe the identification and management of IRB member conflict of interest (COI).

2. **Policy**

   It is the policy of the IRB to identify and appropriately manage all IRB Member potential conflicts of interest.

   a. Upon receipt of IRB meeting materials, all IRB Members must notify the IRB Chair or Co-Chair of a COI in advance of the upcoming meeting or upon assignment as an expedited, primary, or secondary reviewer. If the IRB Member is uncertain if a potential COI exists, they are encouraged to consult with an IRB Chair or Director.

   b. Prior to the beginning of each meeting, IRB Members will be asked to declare any COI related to the protocols under review, which have not already been declared.

   c. The individual can be a member of the IRB; however, they cannot participate in the review and approval process for any project in which they have a COI. A protocol will not be assigned to a conflicted IRB Member. When the member has a conflicting interest, they will not be present during the final discussion and vote and may only be present at the beginning of the discussion to provide information if requested by the IRB. They must be absent from the meeting room during the subsequent discussion and voting phases of the review and may not participate in the vote. The absent IRB Member is not counted towards a quorum when the vote on the protocol in question is taken. The IRB Meeting Minutes will reflect whether these requirements have been met.

   d. The following constitutes IRB Member conflict of interest:

      i. The IRB Member (or immediate family member, as defined below) serves as a Principal Investigator (PI) and is, accordingly, listed on the IRB application, or has served as a scientific advisor to the PI.

         1. Immediate family member: Parent(s), or spouse of parent, spouse, biological or adopted child, or anyone that may be claimed as a dependent under the Internal Revenue Code.

      ii. The IRB Member (or an immediate family member) is an advisor (e.g. thesis/dissertation committee member) or a direct supervisor of trainee's (e.g. graduate or undergraduate) research.

      iii. The IRB Member (or an immediate family member) has received payments in excess of $0 including salary, consulting fees, royalty, or licensing payments from intellectual property, honoraria and/or gifts from the commercial company sponsoring the research, or their representative(s) or with a company with a financial interest in the product or service being test over the past 12 months or anticipates receiving such a payments during the next 12 months.

      iv. The IRB Member (or an immediate family member) holds a paid or unpaid position as director, officer, partner, trustee, or any other significant position (e.g. scientific advisory board/consultant) in the company sponsoring the research or with a company with a financial interest in the product or service being tested.

v. The IRB Member (or an immediate family member) holds patent rights or royalties from such rights whose value may be affected by the outcome of the research, including royalties under any royalty-sharing agreements involving UMD.
vi. The IRB Member (or an immediate family member) has a financial interest (as defined above in items ii, iii, iv, v) in a company which has a marketed product, or is in the process of developing a new product, which is, or will be, in direct market competition with the product in the protocol under IRB review.
vii. The IRB Member (or an immediate family member) has a personal relationship or a conflict with any investigator listed on the protocol, which would potentially cause the IRB Member to be perceived as less than objective in their review.
viii. The IRB Member (or immediate family member) has an ownership interest or compensation related to the research whose value may be affected by the outcome of the research.

e. The IRB Meeting minutes will record the name of the IRB Member with the COI and indicate that they were recused and did not vote.

1. **Purpose**

   The purpose of this SOP is to describe the IRB program of continuing education for IRB Members and HRPP staff.

2. **Policy**

   It is the policy of the IRB to provide IRB Members and HRPP staff with ongoing education concerning new regulation, new OHRP guidance documents, Association for the Accreditation of Human Research Protections Programs (AAHRPP) accreditation standards, issues in the field of research ethics, OHRP compliance citations, and other subjects of interest, which are related to human participant protections.

   a. CITI Certification is valid for three (3) years. When re-certification is required, IRB Members and HRPP staff must complete continuing education modules available through the CITI training program. Guidance will be found on the UMD IRB website.
   b. The IRB website is regularly updated and maintains links to OHRP and other resources of interest to IRB Members and HRPP staff. IRB Members and HRPP staff are encouraged to access these resources for current issues relating to human participant research protection.
   c. IRB Members and HRPP staff are provided educational materials at each Board meeting. These materials may be current journal articles addressing issues of human participant research; new or updated guidance issued by OHRP; or other items of interest.
   d. Publication of new books on research ethics and protection of human participants will be made available to IRB Members and HRPP staff.
   e. The IRB Chair and Members may attend conferences on human research protections for the purposes of continuing education.
   f. HRPP staff are offered the opportunity, on a rotational basis, to attend regional and national conferences on human research protections. HRPP staff also attend a number of virtual webinars throughout the year as topics of interest arise through PRIMR, AAHRPP, OHRP, etc.
   g. HRPP staff members are required to obtain Certification for IRB Professionals (CIP) obtained through passing a national examination (PRIMR).

1. **Purpose**

   The purpose of this SOP is to describe the evaluation of the performance of IRB Members.

2. **Policy**

   It is the policy of the IRB to carry out evaluations of IRB Members and provide feedback as necessary to individual IRB Members.

   a. IRB Members are evaluated on an annual basis by the IRB Chairs, QA Program Manager, and Director through completion of a Self-Evaluation Survey and internal performance assessment. The results of the Self Evaluation Survey are provided to the Board in aggregate at a convened IRB Meeting. Members also receive an individualized summary of performance.

   b. Performance assessment is based upon meeting attendance records, thoroughness of reviews, participation in IRB discussions, and service on subcommittees.

   c. IRB Members are chosen by, and serve at the discretion of, the IO in consultation with the IRB Chair and Director. Members who do not adequately fulfill their responsibilities as judged by the IRB Chair may be asked to step down from IRB membership by the IO. Members missing three (3) meetings in a one-year period may be removed from the IRB. A warning notice may be sent after the second (2nd) absence. IRB Members may be granted an extended leave due to medical, personal, or professional reasons, the return to complete their term.

   d. If an IRB Member's performance is determined to be deficient, the IRB Chair will discuss his/her concerns with the member and seek a satisfactory resolution.

   e. Any IRB Member whose contribution to the IRB is determined to be deficient can have his/her appointment termination by the IO upon recommendation by the IRB Chair.

   f. If an IRB Member's appointment is termination, the IO will notify the member in writing. The IO, at his/her discretion, may notify the IRB Member's supervisor or other administrative officials.

   g. Upon request of individual IRB Members, the Director and/or IRB Chair will write letters of recommendation, which attest to the quality and value of the member's service on the IRB.

   h. The IRB Chair is chosen from existing members of the IRB by the IO. The Chair should be a tenured faculty member of UMCP. The Chair is evaluated on an annual basis by the IO and the Director.

   i. The HRPP staff members are annually evaluated by the Director, who is in turn evaluated by the IO or his/her designee.

   j. Alternate IRB Members are chosen on the basis of availability and specialty need. They are listed on the IRB membership roster. When in attendance, alternates will receive the same project material all other IRB Members receive.

   k. The Director, IRB Chair, and IO meet annually to discuss whether provided resources are sufficient for the human research protection process to be effective.

1. **Purpose**

   The purpose of this SOP is to describe the requirements for IRB Members to maintain the confidentiality of project reviews.

2. **Policy**

   It is the policy of the IRB to maintain strict confidentiality of all reviews and other actions.

   a. All IRB Members will keep confidential all projects and other information pertaining to research reviewed by the IRB, which is unavailable to non-IRB members. Confidentiality requirements are reviewed with IRB Members during orientation.

   b. All printed IRB review material must be secured in a locked personal file cabinet or disposed of in a manner which preserves confidentiality. When meeting in person, IRB material should not be left unsecured in the IRB meeting room. Materials are left in the room at the end of the meeting for proper disposal/shredding by IRB staff.

   c. All electronically downloaded and/or saved IRB documents must be properly destroyed/deleted from IRB members' electronic devices after the end of the IRB meeting. Destruction of these electronic documents must take place whether meeting in person or online.

   d. Projects without a proprietary information/confidentiality restriction may be discussed with expert internal or external consultants. In such cases, the IRB office should be notified. Confidentiality should be safeguarded by assigned consultants.

   e. In the case of protocols with a proprietary information/confidentiality restriction, which require consultation with an internal or external consultant, the IRB office should be notified in advance and approval obtained from the IRB Chair/Co-Chair or Director – HRPP. Confidentiality should be safeguarded by assigned consultants.

1. **Purpose**

   The purpose of this SOP is to describe IRB reviewer assignment for full board meetings and expedited review.

2. **Policy**

   It is the policy of the IRB to assign reviewers who have the necessary scientific/scholarly expertise in the area of the research under review.

   a. An HRPO staff member (analyst, specialist, etc.), in consultation with the IRB Chair, Director or designee, will assign reviewers for full board meetings.
   b. At least one (1) of the IRB members attending the full board meeting must have the necessary scientific/scholarly expertise in the area of research under review, or the services of an expert consultant can be used.
   c. The IRB Chair/Co-Chair and IRB members are able to review and approved projects qualifying for expedited review.
   d. IRB member reviewers have access to the following transaction documentation, as applicable (initial/amendment/continuing review):
      i. The full protocol or a project summary containing the relevant information needed to determine whether the proposed research fulfilled the criteria for approval.
      ii. Initial application/Amendment application/Continuing Review application.
      iii. Consent/assent documents.
      iv. Recruitment materials.
      v. DHHS-approved protocol (if applicable).
      vi. Sponsor protocol/investigator brochure (if applicable).
   e. If an IRB member requires additional information to complete their review, they may contact the investigator directly or may contact the HRPO to make a request of the investigator.
   f. IRB member reviewers will use the Criteria for Approval Guidance document as a guide for completing their review.
   g. All IRB members are provided with and review the above material. During the IRB meeting, the assigned reviewer(s) lead the IRB through the completion of the applicable regulatory criteria for approval.
   h. When conducting expedited review of Continuing Review applications, the IRB Chair/Co-Chair or IRB Member reviewer receives access to all of the material reviewed by the reviewer(s) during initial application review. The reviewer applies the regulatory criteria for approval and generates modifications to the PI if necessary and/or indicates approval.
   i. When conducting expedited review of Amendment applications, the IRB Chair/Co-Chair or IRB Member reviewer receives access to all of the material reviewed by the reviewer(s) during initial application review. The reviewer applies the regulatory criteria for approval and generates modifications to the PI if necessary and/or indicates approval.

j. For full board review of project modifications/tabled project, the primary reviewer presents an overview of the modifications and leads the IRB through the completion of the regulatory criteria for approval. All IRB members receive the complete project which includes a complete history of the project along with the request modification materials.

1. **Policy**

   The purpose of this SOP is to describe the procedures for submission of review by IRB members and to describe the process by which determination letters are developed and distributed.

2. **Purpose**

   It is the policy of the IRB to encourage IRB member reviewers to submit comments regarding the IRB application, its associated documents and other pertinent issues. Comments will be submitted through the IRB electronic submission system. IRB members who will not be present at the meeting may also submit their comments through the IRB electronic submission system. IRB member comments become part of the project review record.

   a. Reviews are summarized and presented at the IRB meeting.
   b. Significant deficiencies and/or major points of clarification, which require revision of the IRB application, should be described fully, sequentially, and referenced to sections of the IRB application. The detailed protocol should be referenced as necessary, if applicable.
   c. Significant deficiencies (i.e. errors, inadequate explanations, non-disclosure of pertinent information such as risk(s), and excessively high readability level) should be described sequentially according to the section of the consent form (i.e. elements of consent outlined in 45CFR46).
   d. It is not necessary to comment on format or standardized elements. The HRPO staff will add any listed and necessary prescriptive changes to the determination letter.
   e. IRB member reviewers should refrain from editorializing relative to either the application or the consent/assent document.
   f. If an IRB member wishes to assist an investigator in carrying out revisions for minor improvement of language, this assistance should be conducted via a post-IRB review consultation. The IRB determination letter should refer to this consultation as the mechanism by which further details will be provided.
   g. IRB determination letters, which reflect the decisions of the IRB, are developed by the HRPO staff in consultation the IRB Chair/Co-Chair and/or Director. The PI will receive the determination letter within five (5) days of the IRB Meeting.
   h. IRB determination letters must be written in a clear, explanatory, and facilitative fashion in order to assist investigators in understanding the rationale for any IRB concerns and mandated changes to the project, consent/assent documents, and supporting documents.
   i. If the IRB approves research with conditions:
      i. Substantive changes or requirements, requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB.
      ii. Minor or prescriptive changes or requirements may be reviewed for approval by the IRB Chair/Co-Chair, or designated IRB member reviewer.
      iii. The date of approval for minor or proscriptive changes is the date the “Approved with Specific Changes” determination letter is published in the IRB electronic submission system.

UNIVERSITY OF MARYLAND	**Policy #: 2.011** **Title:** IRB Quorum and Voting Requirements **Section:** *IRB Membership & Standard Operating Procedures*
Human Research Protections Policies and Procedures Institutional Review Board	Date: December 5, 2017 Revised: January 30, 2024

1. **Purpose**

   The purpose of this SOP is to describe quorum and voting requirements.

2. **Policy**

   It is the policy of the IRB to conduct full board meetings in compliance with Health and Human Services regulations at 45CFR46.108(b).

   a. A full board meeting cannot be convened without the presence of a quorum. A duly constituted quorum must include: a simple majority of the voting membership. The minutes reflect what capacity each member is serving for that meeting. The IRB Analyst/Specialist has the responsibility to monitor the members present at the convened meetings in order to determine that quorum has been established and remains so throughout the meeting.
      i. Quorum is defined as the minimum number of IRB members that must be present at the IRB meeting to make an action/vote valid. For example, if 14 members are on the IRB Member roster, quorum is defined as 8 voting members present at the IRB meeting (inclusive of at least one non-scientist member).

   b. When the IRB reviews any projects, amendments, unanticipated problems involving risks to participants or others, adverse events, or compliance issues related to research involving prisoners, a prisoner representative must be present in accordance with 45CFR46.304(b) (HRPP Policy 5.003).

   c. IRB members who abstain from voting (recorded as an abstention) are included in the quorum.

   d. Any IRB member who has a conflict of interest will be recused in accordance with Health and Human Services regulations 45CFR46.107(d). IRB members with a conflict of interest are prohibited from participating in the discussion or from voting and will only provide information upon request from the IRB (HRPP Policy 3.007).

   e. If attendance at a convened full board meeting falls below a quorum, the meeting will be adjourned at the earliest possible time, but in no case, later than ten (10) business days after the adjourned meeting.

   f. No motion shall pass unless a simple majority of the IRB members, which constitute a quorum, are present (in person, audio or video conference, or web with video exchange) during the discussion and vote in favor of the motion. If a member must leave the meeting temporarily before the vote is taken, the vote can be delayed. Voting by absentee is not permitted. If a motion fails to pass by a simple majority vote, other motions will be entertained. If no further motions are made, the project or issue under discussion shall automatically be deemed to have been tabled and shall be referred, as needed, to an IRB subcommittee for further consideration.

   g. The general attendance at convened meetings of at least one member who represents the general perspective of participants, one member who is unaffiliated with the institution and one member who is a non-scientist will be documented in the minutes.
      ii. The member representing the general perspective of the participants, the unaffiliated member, and non-scientific member may be represented by one person or they may be represented by two or three different persons.
      iii. It is not required the unaffiliated member(s) be present at each meeting.

iv. A non-scientist member must be present at each meeting in order to constitute quorum.

h. At the discretion of the of the IRB Chair, voting may be by written ballot, a show of hands, electronic polling or voice vote. The official meeting minutes will record, without individual identification, the number of votes to approve, disapprove, table, or abstain.

i. Whenever an issue arises during an IRB meeting, the minority opinion will be included in the minutes of the meeting. Any additional controverted issues will be included in the minutes as well.

UNIVERSITY OF MARYLAND	**Policy #: 2.012** **Title:** IRB Minutes **Section:** *IRB Membership & Standard Operating Procedures*
Human Research Protections Policies and Procedures Institutional Review Board	Date: December 5, 2017 Revised: June 16, 2025

1. **Purpose**

   The purpose of this SOP is to describe the requirements for minutes of IRB meetings. The minutes include the basis for requiring changes in the research as well as the basis for disapproving the research.

2. **Policy**

   It is the policy of the IRB to maintain minutes of IRB meetings in accordance with Health and Human Services regulations at 45CFR46.115(a)(2).

   a. The IRB minutes will include 1) core minutes and 2) determination letters to investigators. Determination letters reflect the final determination of the IRB and are an official component of the meeting minutes.
   b. The core IRB minutes will identify the IRB members who are present, IRB alternates who are serving to replace an IRB primary member, IRB alternates who are non-voting and present, consultants, administrative staff present, and any guests in attendance at the meeting. If a consultant is present at the convened meeting, the name of the consultant, and a brief description of the consultant's expertise, and documentation that the consultant did not vote with the IRB on the study.
   c. The core IRB minutes will include 1) names of the IRB members who have a conflict of interest and are recused (absent) from the discussion and the vote, and 2) a notation indicating that conflict of interest was the reason for the absence.
   d. The core IRB minutes will include the names of IRB members who do not have a conflict of interest but are absent from the room at the time of the vote.
   e. The core IRB minutes will include vote counts for all board actions (e.g. for, against, abstain, etc).
   f. The core IRB minutes will include a written summary of the discussion and resolution of controverted issues. A controverted issue is clarified for the purposes of this policy as one which generated a contentious discussion among IRB members regarding a human subject protection issue. Examples include, but are not limited to:
      i. Concerns over the acceptability of the risk-benefit relationship of the research.
      ii. Concerns over additional protections for a vulnerable participant population and whether the project meets the requirements of Subpart C or D.
      iii. Concerns over the investigator's qualifications.
      iv. Justification of deletion or substantive modification of information concerning risks or alternative procedures contained in the consent document.
      v. Concerns related to noncompliance.
   g. The core IRB minutes will include a determination of when continuing review is required more often than annually, as required by the Health and Human Services regulations at 45CFR46.109(e). This determination will be based on factors such as: the risk determination, inclusion of a vulnerable populations, a history of non-compliance, etc.
   h. The core IRB minutes will include the length of time of an approval for both full board and expedited projects.
   i. The core IRB minutes will include specific comments relevant to the inclusion of certain (e.g. vulnerable) populations.

j. The core IRB minutes will include an IRB determination of which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review. This determination will be based on a history of non-compliance as well as other factors the IRB deems appropriate.
k. The core IRB minutes will include determinations and protocol-specific findings justifying determinations for waiving or altering the consent process, research involving pregnant women, fetuses, and neonates, research involving prisoners, children, and individuals with diminished capacity to consent.

3. In addition to the review of pending applications, IRB meeting minutes will include information regarding expedited approvals, modifications, continuing reviews, exempt determinations, and any other business appropriate for IRB meetings.

4. The IRB determination letters sent to investigators will include the following:
   a. The basis for requiring changes in or disapproving an application.
   b. IRB required modifications of the initial application, detail protocol, consent/assent documents, requested clarifications, and additional information.
   c. IRB required modifications of amendments to the IRB application and consent/assent documents.
   d. IRB required actions in response to reports of unanticipated problems involving risk to participants or others.
   e. Documentation of compliance with the requirements of Health and Human Services regulations at 45CFR46 Subparts B, C, and D as applicable, including documentation of determinations required by the regulations and the protocol-specific findings justifying those determinations.
   f. Documentation of compliance with Health and Human Services regulations at 45CFR46.111(b), which require additional protections for vulnerable participants, such as decisionally impaired persons, economically or socially disadvantaged persons, and terminally ill patients.
   g. Documentation of IRB determinations involving waivers or alterations of informed consent, in accordance with Health and Human Services regulations at 45CFR46.116(f) including protocol-specific findings justifying those determinations (HRPP Policy 9.006).
   h. Documentation of IRB determinations involving a waiver of the requirement to obtain a signed consent form in accordance with Health and Human Services regulations at 45CFR46.117(c)(1)(2).

5. Copies of the core IRB minutes are distributed to IRB members electronically through email or the electronic system of record. The core IRB minutes are also available for review by the IO and other administrators as appropriate.

6. The IO and all IRB members have access to complete copies of the IRB minutes, which include the appended IRB determination letters. The letters are also kept on file in the electronic system of record and can be reviewed as requested.

7. The complete IRB minutes will be provided, after consultation with the UMD Office of General Counsel, to OHRP, auditing officials, and the courts in accordance with all applicable federal, state, and institutional requirements.

1. **Purpose**

   The purpose of this SOP is to describe the review and approval process for HRPP policies.

2. **Policy**

   It is the policy of the IRB to continually, and at least annually assess the adequacy of existent policies and the need for new policies as the field of research ethics and human subject protection evolves.

   a. Proposed HRPP policies, which impact significantly the IRB review system, investigators, and the Institution will be reviewed and approved by the IRB with the Chair acting as designated signatory, the Director, the IO, and in some cases the President. HRPP internal administrative policies will be given to the IRB for their information, but do not require formal approval.
   b. When a draft policy is scheduled for review at the IRB meeting, all members of the IRB will be given a copy of the draft policy approximately one week in advance of the meeting.
   c. All IRB members will be invited to attend the meeting at which the policy will be reviewed.
   d. All IRB members have access to the policy documents and be able to voice their opinions and suggest modifications. IRB members may provide written statements in support of their vote or ask other IRB members to express their opinions at the meeting.
   e. IRB Member comments will be taken into consideration when making adjustments to the policy. If there is disagreement on modifications, the IRB Chair and Director will make the final determination.
   f. If necessary, an IRB subcommittee will be assigned a policy for review, presentation and discussion at a future IRB meeting.
   g. Standard Operating Procedures (SOP) are posted on the HRPP website and accessible. The UMD human subject research community is informed of SOP changes via the IRBNews listserv.

1. **Purpose**

   The purpose of this SOP is to describe the maintenance and composition of IRB records.

2. **Policy**

   It is the policy of the IRB that records will be maintained in full accordance with Health and Human Services regulations at 45CFR46.

   a. Under Health and Human Services regulations at 45CFR46.115, the IRB will maintain documentation of all IRB activities.

   b. Where appropriate, the IRB office will maintain all records, reports, and other required documents as specified by federal regulations and UMD policies on record retention. The following documentation will be maintained for a minimum of three (3) years following the closure of the IRB approved project:

      i. Copies of all research protocols reviewed.
      ii. Scientific evaluations, if any, which accompanied the protocols.
      iii. Progress reports submitted by the research investigators.
      iv. Reports of injuries to participants.
      v. Reports of unanticipated problems involving risk to participants (including adverse event reports) and documentation of IRB review of these reports.
      vi. Documentation of non-compliance and corrective action plans.
      vii. Data and safety monitoring reports (if applicable).
      viii. Minutes of IRB meetings.
      ix. Records of continuing review activities.
      x. Copies of all correspondence between the IRB, the IRB office, and the research investigator
      xi. List of IRB members and alternates. A resume or curriculum vitae for each IRB member is kept on file in the IRB Office.
      xii. Consent documents.
      xiii. Statements of significant new findings provided to participants.
      xiv. Records pertaining to research, which is conducted, must be stored securely in the IRB office or IRB system of record, and must be retained for at least three (3) years after completion of the research. Paper records will be stored at the State Records Facility or UMD IRB office for at least three (3) years after project closure. Electronic records will be stored in perpetuity in the electronic submission system.

   c. The IRB project files (paper and electronic) will include:

      i. IRB application.
      ii. Detailed protocol (if applicable).
      iii. Federal grant application (accessible through UMD Office of Research Administration).
      iv. Approved informed consent/assent documents (as applicable).

v. Initial IRB determination letter to the PI, including citations of appropriate federal regulations utilized during IRB review of research involving pregnant women (45CFR46 Subpart B), prisoners (45CFR46 Subpart C), and/or children (45CFR46 Subpart D).
vi. PI response to IRB determination letter(s).
vii. Further correspondence regarding IRB review of the application.
viii. Final IRB approval letter. The letter must include documentation of approvals under Health and Human Services regulations for exempt status (45CFR46.104) and expedited status (45CFR46.110).
ix. For protocols receiving an exempt determination, the file will include documentation of the exemption. Documentation of verified exempt determinations consists of a reviewer's citation of a specific exempt category or categories. The exempt determination is reported at the next convened IRB meeting and documented in the IRB minutes (HRPP Policy 4.001).
x. IRB approved recruitment materials and copies of the IRB approved project materials.
xi. All requests for changes and the correspondence pertaining to the request. Copies of the modified IRB project documents associated with the request.
xii. All continuing reviews and the correspondence pertaining to the request. Copies of the consent documents approved in conjunction with the continuing review.

d. IRB records for initial and continuing review by the expedited process must include: the specific permissible category or categories, a description of actions taken by the reviewer, the approval period, and any determinations required by the regulations including protocol-specific findings supporting those determinations.
e. IRB records (expedited or full board review process) must document any determinations required by the regulations and protocol-specific findings supporting these determinations, including:
i. Waiver or alteration of the consent process.
ii. Research involving pregnant women, fetuses and neonates.
iii. Research involving prisoners.
iv. Research involving children.
f. All interim progress reports (if applicable).
g. Reports of unanticipated problems (internal adverse events, internal fatal adverse events, external adverse events, and unanticipated problems involving risks to participants or others) and the correspondence pertaining to the reports. Copies of supporting documentation will be included with the reports.
h. Incidents of non-compliance, including documentation of investigations, correspondence, and reports to institutional officials and OHRP, where appropriate.
i. Results from correspondence regarding the findings (HRPP Policy 7.001).
j. When following DHHS requirements: Records must include the rationale for conducting continuing review on research that would otherwise not require continuing review.
k. Records must also include the rationale for an expedited reviewer's determination that research appearing on the expedited review list presents greater than minimal risk.

l. Records must include documentation specifying the responsibilities that a relying organization and an organization operating an IRB each will undertake to ensure compliance with the requirements of the Common Rule (HRPP Policy 3.012).
m. The project file is maintained on the electronic system of record.
n. Existing paper copies of IRB projects that remain open after implementation of the electronic system of record will be maintained in the IRB office until the project is completed or terminated. Once completed or terminated, the paper files will either be sent to the State Records Archive or maintained in the IRB office for at least three (3) years. After which, they will be destroyed.
o. The electronic submission system maintains all relevant project and review information including the following:
    i. IRB project number.
    ii. Project title.
    iii. Review category and review path (exempt, expedited, full board).
    iv. Date project was received, date of full board meeting(s), approval, closure, continuing review, date for reminders, date of requested modifications.
    v. Status of the project (approved, disapproved, pending review, pending response from PI, tabled, terminated, withdrawn, closed).
    vi. PIs name and contact information.
    vii. Special considerations (video/audio recording, radioactive materials, etc.).
    viii. Need for ancillary reviews (biosafety committee, dive safety committee, etc.).
    ix. Funding source.
    x. Investigator status (faculty, student, staff, etc.).
    xi. Project type.
    xii. Number of participants to be enrolled.
    xiii. Description of subject population.
    xiv. Requested waivers (HIPAA, consent, etc.).
p. The electronic system of record maintains investigator training records for each submitted project.

1. **Purpose**

   The purpose of this SOP is to describe activities requiring IRB approval.

2. **Definitions**

   a. **Research** is defined by DHHS regulations at 45CFR46.102(l) as "systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities."

   b. The **Belmont Report** provides further clarification of "research" as follows: "… the term 'research' designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships)."

   c. **Human Subject** is defined by DHHS regulations at 45CFR46.102(e)(1) as, "a living individual about whom an investigator (whether professional or student) conducting research, i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens; or ii) obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

   d. **Clinical Investigation** is defined by FDA regulations as any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under Section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these Sections of the act, but the results of , which are intended to be submitted later to, or held for inspection by the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include, experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies. An experiment, as defined in 21CFR312, includes any use of a drug other than the use of a marketed (approved) drug in the course of medical practice.

   e. **Human Subject** is defined by the FDA as an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. In the case of a medical device, a human subject also means a human on whose specimen an investigational device is used.

   f. **Systematic Investigation**, for the purposes of this policy, is an activity that involves a prospective research plan that incorporates data collection, either quantitative or qualitative, and data analysis in order to answer a research question.

g. **Intervention** includes both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

h. **Interaction** includes communication or interpersonal contact between investigator and subject. It also includes interaction with identifiable, private information.

i. **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

j. **Individually Identifiable Information** is information where the identity of the participant is or may be readily ascertainable by the investigator or associated with the information.

k. Investigations designed to develop or contribute to **Generalizable Knowledge** are those designed to draw general conclusions (i.e. knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings (publish, present outside of the institute) intended to contribute to the field of study.

l. **Human Subject Research** for the purposes of this policy is defined as an activity that meets the definitions of "research" and involves "human subjects" as defined either by HHS regulations or by FDA regulations.

3. **Policy**

IRB approval is required for all research involving human subjects as defined above, which is conducted by faculty, students, staff, or others under the jurisdiction of the IRB, (i.e. research performed on the premises of UMD, as well as research involving human subjects conducted elsewhere by investigators as part of their institutional responsibilities, unless the investigation is conducted under a separate cooperative research agreement.)

When reviewing research involving human subjects, the IRB will apply 45CFR46 in accordance with HRPP Policy 1.002. The IRB does not review activities which do not meet the aforementioned definitions under Section 2 above.

4. **Classification of Human Subject Research**

a. **Social Science, Behavioral and Education Research (SBER)**

SBER includes all research performed with intent to develop generalizable knowledge (i.e. test a hypothesis and draw conclusions) about behaviors, attitudes, and interactions among and between individuals, groups, and cultures. Generally, this category of research has no intent of producing a diagnostic, preventative, or therapeutic benefit from the research. There may, or may not, be any prospect of direct benefit to human subjects within SBER.

Types of research involving human subjects that fall under the SBER classification, may include:

1. Qualitative social science research
2. Ethnographic research
3. Observational research
4. Survey research
5. Interview/focus group research
6. Education research
7. Criminal justice research
8. Other (for example, a project may study how individuals respond to certain engineering techniques or interact with a graphical user interface)

b. **Biomedical Research**

Biomedical research at UMD, generally, but not exclusively, refers to clinical/patient-oriented investigations, biomedical engineering research, and exercise science and nutrition studies research.

5. **Not Human Subject Research**

a. **Scholarly and Journalistic Activities (oral history/journalism/biography/etc.)**

These projects include the collection and use of information, that focus directly on the specific individuals about whom the information is collected [45CFR46.102(l)(1)].

b. **Public Health Surveillance Activities**

These projects include the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority [45CFR46.102(l)(2)].

c. **Criminal Justice Collection Activities**

These projects include the collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes [45CFR46.102(l)(3)].

d. **Intelligence Community Support Activities**

These projects include authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions [45CFR46.102(l)(4)].

e. **Quality Improvement**
These projects include the collection and analysis of information intended to improve an existing process or program. There is no intent to contribute to generalizable knowledge.

f. **Student Projects**
These projects include the collection and analysis of information intended to complete coursework for a grade or presented within the academic confines of the institution only. There is no intent to contribute to generalizable knowledge. The student's instructor/advisor/supervisor is responsible for providing appropriate oversight of the project and should consult with the UMD HRPP as needed.

6. **Human Subject Research Determination**
Any individual who is unsure if a proposed activity constitutes "research involving human subjects" should complete a Human Subject Research Determination application in the IRB electronic submission system. HRPO staff will review the application and determine whether the proposed activity is subject to 45CFR46 and any other requirements dictated by a federal sponsor. If not, the HRPO will generate and provide an official determination to the investigator indicating the project does not meet the definition of human subject research. If the project does meet the definition of human subject research, the investigator will be instructed to complete and submit the necessary IRB application.

If there is a question concerning whether an investigator is engaged in research or not, the UMD HRPO will consult with the OHRP.

7. **Review Path**
The project review path (exempt, expedited, full board) will be determined by HRPO staff or in consultation with an IRB member or an IRB Chair. This includes reporting of findings that could affect the safety of participants or influence the conduct of the study. The OHRP Human Subject Regulation Decision Charts will be used as needed in determining the review path: https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html

8. **Sponsored Research**
   a. The University agrees to follow the research protocol, applicable state and federal law, and UMD's ethical standards.
   b. The sponsor agrees to follow UMD's policies and procedures regarding the dissemination and publication of findings from sponsored research.
   c. When participant safety could be directly affected by study results after the study has ended, UMD will have a written agreement with the sponsor that the researcher or UMD will be notified of the results in order to consider informing participants

1. **Purpose**

The purpose of this SOP is to describe the ethical principles, which govern research under the jurisdiction of the UMD IRB.

2. **Policy**

It is the policy of the UMD IRB that all research which is reviewed and approved by the Board and conducted under its jurisdiction will generally conform to the following guidance documents: 1) The Nuremburg Code and 2) The Belmont Report. Health and Human Services regulations at 45CFR46 reflect the basic ethical principles for the conduct of human subject research found in these documents.

All researchers, participating personnel, and IRB members are charged with upholding the ethical principles contained in the aforementioned guidance documents as they apply to the research project in question. The IRB project, consent documents, and IRB review process is designed to support IRB members and investigators to ensure that research reflects the highest possible ethical standards (HRPP Policy 3.004).

a. **The Nuremburg Code**

The Nuremburg Code contains ten (10) basic ethical principles, which are presented in abbreviated form below:

i. Obtain voluntary consent of the participant.
ii. Design the study to yield results for the good of society, otherwise unobtainable through other means.
iii. Base studies involving humans on animal experiments.
iv. Avoid physical and mental suffering and injury to the participant or others.
v. Do not conduct the study if death or disabling injury is an expected result.
vi. The degree of risk should never exceed the humanitarian importance of the problem to be solved by the research.
vii. Protect the participant from injury disability or death.
viii. Be scientifically qualified to conduct the study.
ix. Allow the participant to withdraw at any time.
x. Be prepared to stop the study when continuation is likely to result in injury, disability, or death to the participant.

b. **The Belmont Report**

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research released the “Belmont Report: Ethical Principals and Guidelines for the Protection of Human Subjects of Research”. The three basic ethical principles described in the Belmont Report are:

i. **Respect for Persons**

The ethical principle of respect for persons has two components: Acceptance of individual autonomy and protection of those with diminished autonomy.

Autonomous individuals demonstrate the ability to make informed choices and act on the choices. These choices must be acknowledged and accepted by others as a demonstration of respect, as long as those choices are not harmful to others. Conversely, it must also be recognized that some individuals may be incapable of making informed choices and require special protection. The principle of respect for persons in the research context is demonstrated through the process of informed consent, including the process of assent and proxy (legally authorized representatives) consent for potential participants requiring special protections.

xi. **Beneficence**

The principle of beneficence is defined in two ways: (1) do not harm, and (2) maximize the potential benefits and minimize all potential harms (e.g. risks) related to research participation. While there is an imperative that no harm comes to the participant, it should be recognized that there is potential for harm due to unknown factors associated with the research. To minimize this risk, the potential benefits for the participant and society must be determined and maximized.

xii. **Justice**

The principle of justice implies a sense of "fairness". Justice occurs when the burdens and benefits are equally carried by all. To achieve justice in the research context, recruitment of potential participants must occur without discrimination, bias, or undue influence in order to distribute the burdens and benefits of research equitably for individual and society.

1. **Purpose**

   The purpose of this SOP is to describe the IRB deadlines, submission materials, and the IRB pre-review process.

2. **Policy**

   It is the policy of the UMD IRB that all human subject research applications include, as applicable, the submission materials outlined in the sections below and undergo pre-review by UMD IRB staff.

3. **IRB Deadlines**

   Application forms and application guidance can be found on the UMD IRB website and in the electronic submission system. Submission deadlines and IRB meeting dates can be found on the UMD IRB website and the electronic submission system. Protocols requiring Full Board review must be submitted by the published submission deadline to be considered for placement on the next IRB meeting agenda. Incomplete applications may result in the delay of IRB review.

4. **Initial Application Materials Submission**

   a. **Initial Application**

      Follow guidance in the electronic submission system to complete the IRB application.

   b. **Informed Consent Documentation**

      The consent and assent process and documents must be appropriate for the proposed study population (e.g. adult, parent, minor, etc). DHHS Consent Guidance.

   c. **Participant Recruitment Materials**

      Copies of all advertisements, flyers, email, transcripts of broadcast materials and other recruitment materials must be provided for IRB review.

   d. **Description of Performance Site(s) for Non-Institutional Sites**

      Performance sites are defined as (1) sites where institutional investigators or staff interact with participants, collect data, or solicit consent, or (2) sites over which the IRB has responsibility. Performance sites do not include other sites participating in a multi-center study which have an IRB. All performance sites must be identified.

   e. **Other Relevant Materials**

      i. Copies of all research measures (surveys, questionnaires, interview questions, focus group questions, etc.) and other materials presented to participants must be submitted for IRB review.

      ii. Where applicable and/or upon request, a copy of the detailed protocol and a copy of the grant narrative pertaining to human subject research activities.

5. **IRB Office Pre-review**

   Each new project created in the electronic submission system will be assigned a project (“IRB”) number. Subsequent transactions under this project will be connected to this project (“IRB”) number.

All projects submitted for IRB review are screened by IRB staff. Specifically, the project application will be screened to determine:

a. All required application materials have been submitted and are complete.
b. All personnel listed on the application have completed the required human subject training course. See HRPP Policy 3.009.
c. The PI and research team members will receive notification through the electronic submission system to correct errors, provide missing documents, or provide additional information as necessary.
d. The IRB Office staff will determine, with the advice of the IRB Chair/Co-Chair if needed, whether a project - qualifies for expedited or full board review. An IRB Chair/Co-Chair or IRB Member will be assigned as a reviewer for Expedited transactions. IRB Members will be assigned as reviewers for projects requiring full board review.

1. **Purpose**

   The purpose of this SOP is to describe the criteria required for IRB approval of projects reviewed by either the expedited or full board process.

2. **Policy**

   It is the policy of the IRB that all expedited and full board research projects will undergo a rigorous review which will allow a determination that the project meets 1) the criteria specified in Health and Human Services regulations at 45CFR46.111 and 2) IRB HRPP Policies and Procedures. 45CFR46.111 criteria are listed as follows and are the reference guide for all IRB reviews.

   a. In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:
      i. Risks to subjects are minimized: (a) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
         1. Sound research design is a plan that guides data collection and analysis to answer a research question or solve a problem. It helps avoid bias, confusion, and resource waste. The goal of a sound research design is to provide credible results. When human subjects are involved in research, sound research design includes procedures that do not unnecessarily expose subjects to risks and whatever risks are present are outweighed by potential benefits.
      ii. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
      iii. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, cognitively impaired individuals, or economically or educationally disadvantaged persons.
      iv. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45CFR46.117.
      v. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45CFR46.117.
      vi. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

vii. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

3. **Criteria for IRB Approval**

a. **Purpose of the Study**

The IRB will determine if the background and literature citations support the stated purpose of the study. See HRPP Policy 3.006.

b. **Study Population**

The IRB will examine the characteristics of the proposed subject sample to determine if the eligibility criteria is appropriate with respect to the nature and goals of the research and the selection of subjects is equitable without bias or discrimination. Factors to be considered include, number of subjects, age range, gender identity, race/ethnicity, health status, etc. Any proposed exclusion criteria must be scientifically justified by the investigator. In particular, the following items will be examined during review:

i. Accrual: The IRB must be assured that the number of participants to be enrolled is sufficient for the purpose of the study and adequate justification for the number is provided.
ii. Sex: The IRB must be assured that the proposed distribution is suitable for the purpose of the study and appropriate justification for eligibility is provided. Women of childbearing potential and pregnant women should not be excluded from participation unless adequate justification is provided.
iii. Age Range: Appropriate justification must be provided for the proposed age range as well as for the inclusion or exclusion of certain age groups. For example, minors, elderly, etc.
iv. Race and Ethnicity: The proposed distribution of participants by race and/or ethnicity must be suitable for the purpose of the study. Appropriate justification for the inclusion or exclusion of persons or groups must be provided.
v. Vulnerable Populations: The IRB will determine if inclusion of vulnerable populations is appropriate and meets the requirements of any relevant subpart under 45CFR46. For instance, Subpart B – Pregnant women and neonates (HRPP Policy 5.002), Subpart C – Prisoners (HRPP Policy 5.003), Subpart D – Children/Minors (HRPP Policy 5.004). The IRB will determine if appropriate protections are in place for cognitively impaired individuals (HRPP Policy 5.005) as well as other vulnerable populations.
vi. Eligibility Criteria: The IRB will determine if the provided inclusion and exclusion criteria are appropriate for the purpose of this project.

c. **Methods and Procedures**

The IRB will review the experimental design in order to be assured that potential risks to participants are minimized and the potential benefits are maximized by utilization of procedures consistent with sound research design and which do not unnecessarily expose participants to risk (HRPP Policy 3.006). The IRB must determine if

the interventions and follow-up activities are appropriate for the stated purpose of the research and, whenever appropriate, procedures are used which will already be performed on the participants for diagnostic or treatment purposes. Interventions and procedures considered standard of care must be clearly identified.

d. **Deception**

The IRB accepts the need for certain types of behavioral and social science projects to employ strategies that include either deception and/or the withholding of information. Employment of such strategies must be adequately justified in the IRB application. In general, deception is not acceptable, if, in the judgement of the IRB, the participant would have declined to participate had they been informed of the true purpose of the research. Studies using deception and/or withholding of information as part of their experimental design must meet all requirements of 45CFR46.116(f), described below, and include a post-study debriefing.

In the event a project employs the use of deception, the investigator must:

i. Provide justification for the deception.
ii. Describe the manner of deception and/or how deception will take place.
iii. Note whether the deception results in any increased risk to participants.
iv. Describe how any additional risks would be minimized.
v. Provide a post-study debriefing that includes an apology for use of deception and allowing participants the option to withdraw their data from the study.

e. **Data Storage and Confidentiality**

The IRB will review the methods to be used to protect confidentiality and will ensure that appropriate protections are in place in consideration of the nature of the research, the vulnerability of the participant population, and the risk associated with a breach of confidentiality.

If research data with participant identifiers will be made available to persons other than the listed investigators, sponsor, or federal agency, the IRB will review the justification for sharing this data and determine acceptability in accordance with all applicable regulations, including the HIPAA Privacy Rule (HRPP Policies 10.001 and 10.002).

If the research involves the collection of sensitive information where a breach of confidentiality would constitute a serious risk, the IRB will consider the need for a Certificate of Confidentiality (HRPP Policy 3.011) if the project is not funded by the National Institutes for Health.

f. **Risk – Benefit Assessment**

i. **Potential Risks:** Both immediate and latent (delayed) risks of any procedure involving human subjects will be review by the IRB to ensure that risks to participants are identified and minimized. The estimated probability, severity, average duration, and reversibility of any potential harm will be considered according

to available empirical data. Furthermore, since vulnerable populations may be at greater risk than others, the IRB will take into consideration the potential risk characterization of the participant group and ensure that additional appropriate protections are in place.

ii. **Risk Classification:** Risk is classified as 1) minimal, or 2) greater than minimal. The IRB will review carefully the risk classification of the research, as it will determine the type of IRB review and interim review requirements.

iii. **Minimal Risk:** "The probability (of occurrence) and magnitude (seriousness) of harm or discomfort (e.g. physical, psychological, social) associated with the research are not greater than those ordinarily encountered in daily life (of healthy persons in the general population) or during the performance of routine physical or psychological examinations or tests."

A uniform standard of minimal risk based upon the daily life of a normal, average, healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests they would be expected to encounter will normally be used for research involving adults. However, under these circumstances, application of the minimal risk classification will be based upon a consideration of the risks inherent in each participant's life thereby resulting in a relative standard of minimal risk which is more stringent. Factors such as age, repetitive procedures, and vulnerability will be considered in determining if a study qualifies as minimal risk.

When research involves children, a uniform standard of minimal risk also will be used, which is based upon the daily life a normal, average, healthy child living in a safe environment or the performance of routine psychological and medical examinations they would be expected to encounter as part of a standard well-child examinations.

iv. **Minimization of Risk:** The IRB will review data and safety monitoring that must fit the design, nature, and risk profile of the research. In some cases, the research will required a data and safety monitoring plan. The IRB will determine whether or not a research project requires review more often than annually (HRPP Policy 3.010) and will establish appropriate reporting and/or monitoring procedures that may include observation of the consent process, observation or ongoing research, or review of research records (HRPP Policy 7.001).

The IRB will also determine whether a research project requires verification from sources other than the investigators that no material changes have occurred since the previous IRB review (HRPP Policy 3.010).

v. **Potential Benefits:** The IRB will review the anticipated benefits to both the participant and to society. In addition, the IRB will consider whether the benefits are maximized to the greatest extent possible through proper protocol design. Financial or other forms of compensation are not considered a benefit to be derived

from research participation. Although the participant may consider financial compensation a desirable outcome, this fact will not be used in the risk-benefit analysis.

vi. **Alternatives to Participation:** The IRB will review the alternatives outside of the research context that are available and may be of reasonable benefit to the participant.

g. **Risk – Benefit Analysis**

The IRB will examine the relationship of the risks to benefits identified in the application. The following is a series of principles which the IRB will take into consideration:

i. In research involving the study of efficacy and safety of a therapeutic or diagnostic method, where there is the potential for participants to receive a direct health benefit (e.g. clinical research), the risk-benefit relationship must be at least as favorable as that presented by alternate standard therapies available to the participant in the non-research context.

ii. In research involving a combination of a standard therapy (used solely for the benefit of the participant and not part of the research project) with specified research procedures, the anticipated benefits of the therapy must not be used to justify exposing participants to the risks associated with the research procedures. Conversely, only the risks associated with the research procedures should be used in determining an acceptable risk-benefit relationship.

iii. In research that has no likelihood or intent of producing a diagnostic, preventative, or therapeutic benefit to the subject (e.g. behavioral research and non-clinical biomedical research), the potential risk to the participant must be outweighed or balanced by the potential benefit to the participant and/or by the potential benefit to society.

h. **Participant Financial Obligations:** The IRB will review the financial obligations of the participant relative to participating in the study. The IRB application should clearly identify who will be financially responsible for research-related interventions or procedures, as well as other potential costs of participation (e.g. travel, childcare, food).

i. **Compensation for Participation:** The IRB will review the amount of compensation offered for participation (monetary and all other forms) in order to ensure that it is not coercive and is fair (HRPP Policy 3.015).

j. **Conflict of Interest:** The IRB will review potential conflicts of interest of the investigators in conjunction with the Disclosure Office (HRPP Policy 3.007). This review will be based upon the Board's charge to ensure protection of the rights and welfare of human subjects. This charge includes the authority to:

i. Ensure disclosure in the consent document of any financial interests of the investigators, which are judged by the IRB to be material to the participant's decision whether or not to participate in research.

ii. Ensure there is an appropriate plan for monitoring of the research, which may involve observation of the consent process, auditing of records, and interim reporting of research results to the IRB.
iii. Require informed consent be obtained by a qualified individual other than the principal investigator. If the IRB finds that the conflict of interest management plan requires additional measures, the Board will alter the management plan in accordance with its charge and forward the revised plan to the Disclosure Office.

k. **Participant Identification and Recruitment:** The IRB will review the method of prospective participant identification and recruitment in order to be assured it is ethically and legally acceptable (HRPP Policy 3.016). Advertisements used to recruit participants are considered an extension of the recruitment and informed consent processes, and therefore, must be reviewed by the IRB.

l. **Informed Consent:** The IRB will review both the consent form and the process of informed consent as described in the IRB application to ensure that consent will be sought only under appropriate circumstances, which allow the prospective participant engage in thoughtful decision making. Specifically, the IRB will determine the following:
   i. The process of consent/assent is appropriate in consideration of the nature of the research, risks of the research, and characteristics of the participant population (HRPP Policy 9.002).
   ii. All required consent/assent documents contain the elements of informed consent required by DHHS regulations (HRPP Policy 9.002 and 9.004).
   iii. Documentation of informed consent conforms to HRPP Policy 9.002.
   iv. When following DHHS regulations, the consent document begins with a concise and focused presentation of key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.
      1. Key information, such as rationale for why the research is being conducted, why the participant is being asked to participate, and what the research activities entail, is included in the Purpose section of the consent form.
      2. A concise presentation of this material should include short statements of key information contained within the Purpose section of the consent document before a more detailed description is included within the Procedures section of the consent document.

m. **Investigator Qualifications:** The IRB will review that the investigator has the appropriate qualifications and licensure (if applicable) to carry out the procedures involving human subjects with an acceptable degree of risk. The investigator and anyone on the research team who will interact with human subjects must complete the required human subject research training listed on the UMD IRB website. The investigator must have adequate facilities and equipment to conduct the research with an acceptable degree of risk.

The principal investigator must be affiliated with UMD. For student projects, the student may act as the principal investigator, however the faculty advisor must be listed on the project, have completed the required human subject research training, and sign the application.

If the faculty advisor of the graduate student has left UMD for another institution, they may continue to act in this capacity for up to one (1) year. After which a new faculty advisor must be identified and added to the project.

n. **Scientific and Scholarly Merit and Resource Review**: The IRB must ensure that the research has undergone appropriate scientific and scholarly merit and resource review (HRPP Policy 3.006). This is conducted by the IRB Chair or Designated IRB Member reviewer.

4. **IRB of Record:** If UMD is the lead site for a multi-institutional project and data are collected and analyzed at UMD, or reportable events tracked at UMD, then a copy of the IRB approval letter from all relying sites must be provided. If additional sites are added after approval of this application, then letter of IRB approval must be submitted as they become available.

   Letters of support/agreement may be requested from study sites not associated with the institution (such as schools, nursing homes, prison, etc.) stating that the site administrator is aware of the study and will allow the institutional PI and study personnel to utilize their stie to conduct the study.

5. **IRB Reviewer Guidance:** All IRB Members have access to guidance documents that outline the Criteria for Approval and any required Subpart determinations that must be made to complete their reviews.

6. **Office of Research Administration (ORA):** All proposals for funding must be submitted to the Office of Research Administration. If human subjects are involved, ORA will inform the PI to contact the IRB Office. It is the responsibility of the PI to secure IRB Approval.
   a. **"118 Letter"**
      Requested by the PI when subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. The PI will submit a request for a "118 Letter" from the IRB through the electronic submission system and the IRB will provide this letter on letterhead signed by the Director – HRPP.
   b. **"Prior to IRB Account Approval Form"**
      Requested by the PI when an account must be established by ORA for activities prior to human subject research activities. For example, purchasing equipment, conducting research activities not involving human subjects, etc. The PI is required to provide a brief budget and justification for the prior to IRB approval budget and will provide a date by which IRB approval will be obtained in order to access the remaining funds. ORA will confirm IRB approval with the UMD IRB Office prior to releasing funds related to human subject research.

7. **Additional Administrative Review:** Human research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. Those officials cannot, however, approve any research project unless it is first approved by the IRB. When a study is considered controversial, particularly from a community-based standpoint, the IRB Chair will forward a copy of the project to the IO or their designee and the PI will be so notified.

1. **Purpose**

   The purpose of this SOP is to describe the IRB initial review categories.

2. **Policy**

   It is the policy of the IRB that applications submitted to the UMD IRB Office will be assigned a review path of administrative review, exempt review, expedited review, or full board review in accordance with Health and Human Services regulations at 45CFR46.

3. **Administrative Review**

   The following transactions are reviewed and administratively reviewed and acknowledged by IRB Office staff. Clarifications and modifications will be requested as needed prior to the final determination.

   a. Human Subject Research Determination application.
   b. 118 Letter request.
   c. Minor updates/changes submitted as an Amendment.

4. **Exempt Review**

   a. If a project involves activities presenting no greater than minimal risk to participants and these activities fall within the categories described at 45CFR46.110(d)(1-8), the project will receive an exempt determination from either an IRB Analyst, IRB Specialist, IRB Chair, or Designated IRB Member reviewer once any required modifications have been adequately addressed.

5. **Expedited Review**

   a. If a project involves activities presenting no greater than minimal risk to participants and these activities fall within the categories outlined by the Notice published in the Federal Register by the Secretary of HHS [noted within 45CFR46.110(a)] the project will be placed on a expedited review path and final approval will be determined by an IRB Chair or Designated IRB Member reviewer once any required modifications have been adequately addressed.
   b. Projects receiving expedited review will not require continuing review unless an IRB Chair or Designated IRB Member reviewer provided adequate justification for its requirement.
   c. Expedited review procedures may be used for amendments involving research activities presenting no greater than minimal risk.

6. **Full Board Review**

   a. If a project does not meet the criteria outline in the exempt or expedited review categories and/or presents greater than minimal risk to participants, it will be assigned to the next available IRB Meeting Agenda.
   b. If an IRB Chair or Designated IRB Member reviewer reviews a project using expedited review procedures, but determines during the review that it would benefit from a Full Board review, it will be assigned to the next available IRB Meeting Agenda.

c. **IRB Determinations**

i. **Approval**: No modifications are required and the investigators will be notified they can begin the project.

ii. **Approval with Specific Changes**: The IRB has enough information to know what it is approving. The investigators will be notified as to the nature of the required modifications or prescriptive changes. Once any required modifications or prescriptive changes have been adequately addressed, an IRB Chair or Designated IRB Member reviewer will complete the approval process and the investigators will be notified.

iii. **Tabled**: The IRB does not have enough information to know what it is approving. The investigators will be notified as to the nature of the missing information, significant amount of modifications, clarifications, and/or serious concerns the IRB review noted. An IRB Chair and/or Designated IRB Member reviewer may be assigned to discuss the tabled project with the investigators.

Once the investigators submit the required materials from the tabled determination letter, the previously tabled project will be assigned to the next available IRB Meeting agenda in adherence with published submission deadlines for full board meetings. Whenever possible, the two IRB Member reviewers who performed the initial review will be assigned to review the investigators response to the table determination letter. When that is not possible, IRB Member reviewers are encouraged to consult as needed, with the previous reviewers to resolve any concerns that may still exist. Additionally, the investigators may be invited to the next IRB Meeting to be available for questions.

iv. **Disapproved**: This determination is applied to projects that have serious design flaws, are designed in such a way that participants will be placed at unnecessary risk, or do not have an appropriate risk to benefit ratio. The investigators will be notified of the IRB determination and an IRB Chair or IRB Member may be assigned to discuss the project with the investigators. The investigators may submit a new project application after the IRB comments have been taken into consideration and they have consulted with an IRB-designated mentor with appropriate expertise.

1. **Purpose**

   The purpose of this SOP is to describe the requirements for scientific and scholarly merit review of research projects submitted to the IRB for review.

2. **Policy**

   It is the policy of the IRB that all research projects applications must undergo a scientific or scholarly merit review and resource review per HHS regulations at 45CFR46.111(a)(1)(i) and 45CFR46.115(a)(1).

3. **Review Paths**

   a. **Expedited**: Scientific merit review is conducted by an IRB Chair or Designated IRB Member review and is documented through the use of Expedited review checklists.

   b. **Full Board Review:** Scientific merit is conducted by the primary and, if assigned, secondary reviewer and documented through the use of IRB Reviewer worksheets and the overall IRB discussion in the meeting minutes.

4. **Scientific and Scholarly Merit Requirements**

   The IRB Chairs, Designated IRB Member reviewer or IRB Member will evaluate the scientific and scholarly validity of a proposed study. The IRB has broad-based disciplinary expertise, which allows a judgement to be made that the proposed research meets the following criteria in consideration of the need to satisfy scientific and scholarly merit requirements:

   a. The research uses procedures consistent with sound research design.
   b. The research design will allow the proposed research question to be answered.
   c. The knowledge to be gained from the research is sufficiently important from the research or training perspective.
   d. The risk benefit relationship is acceptable.

5. **Ancillary Reviews (if applicable)**

   The UMD IRB will instruct the PI to engage with the following institutional regulatory committees if the IRB application deems it necessary.

   a. **Institutional Biosafety Committee (IBC)**

      At UMD, the IBC consists of the Chairperson, faculty, and community representatives. Two community members with no UMD affiliation other than membership on the IBC, are required and appointed to represent the interest of the surrounding community with respect to health and the protection of the environment. The IBC represents collective expertise and research experience in recombinant DNA, infectious agents and biological safety in experiments, which may pose potential risks to human health or to the environment.

The IBC is responsible for ensuring that research conducted at UMD is in compliance with the National Institutes of Health Guidelines for Research involving Recombinant DNA, drafting campus biosafety policies and procedures as well as reviewing individual research proposals for biosafety concerns.

b. **Radiation Safety Committee (RSC)**

The RSC operates under the auspices of the Department of Environmental Safety at UMD. The RSC is charged with assessing that all experimental or research uses of radioactive materials and/or ionizing radiation in or on human beings conform to the currently accepted radiation protection regulations and practices, and the UMD Radioactive Material License on file with the Maryland Health and Human Services System.

1. **Purpose**

The purpose of this SOP is to describe the IRB, Office of Research Administration (ORA), and Disclosure Office review process for determining PI conflict of interest (COI). The Disclosure Office is responsible for applying the University Policy on Conflict of Interest and Conflict of Commitment.

2. **Policy**

It is the policy of the IRB that the Principal Investigator, the responsible party for the research, declares all possible conflicts of interest including significant financial interests. These policies and procedures apply to all financial conflicts of interest and are guided by Code of Federal Regulations (42CFR50 – Subpart F). This is to promote objectivity in research to ensure conflicts of interest do not adversely affect the protection of participants or the credibility of UMD's HRPP. Actual or perceived conflicts of interest should be eliminated where feasible, and effectively disclosed and managed when elimination is not feasible.

a. The IRB Application includes a COI Disclosure section for the PI and research team members.
b. When it is determined that the PI or other key personnel have a conflict of interest, financial or otherwise, related to the research, the individual must describe the conflict and the management plan approved by the UMD COI Committee.
c. The UMD COI Committee will perform its review prior to IRB review. The IRB Application must include a copy of the approved COI management plan.
d. The IRB or the Designated IRB Member reviewer will review the COI and approved management plan in terms of the IRB's obligation to ensure protection of the rights and welfare of human participants. This charge includes authority to:
    i. Ensure disclosure in the consent documents of any conflicts of interest of the PI or research team members that are judged by the IRB to be material to the subject's decision whether or not to participate in the research.
    ii. Ensure there is an appropriate plan for monitoring of the research, which may involve observation of the consent process, auditing of records, and interim reporting of research results to the IRB.
    iii. Require informed consent be obtained by a qualified individual other than the principal investigator.
e. The IRB will forward the results of the IRB review, including any required modifications to the management plan, back to the UMD Disclosure Office. The UMD Disclosure Office will review and approve the modified COI management plan. It should be noted that the UMD Disclosure Office may not remove any IRB required modifications to the management plan within the authority of the IRB as specified under HRPP Policy 3.007(d)(i-iii).

1. **Purpose**

   The purpose of this SOP is to describe the qualifications and responsibilities of personnel involved in the conduct of human subject research.

2. **Policy**

   It is the policy of the IRB that all personnel involved in the conduct of human subject research must possess the required experience, skills and appropriate licensure (if applicable).

3. **Qualifications**

   All research personnel list on the IRB application or interacting with human subjects or identifiable data from human subjects, must have completed human subjects research (HSR) protection training. The standard at UMD is the completion of the HSR course(s) through the CITI program (HRPP Policy 3.009). Non-UMD personnel may link equivalent HSR training records or complete training through the CITI program under the UMD account. The IRB will not approve new projects, changes or annual reviews of existing projects until all listed research personnel in the IRB application have provided records of HSR training completion.

4. **Research Personnel Classification**

   a. **Principal Investigator (PI)**

      This individual assumes overall responsibility for the study design, development and submission of the IRB application; obtaining informed consent/assent from participants by all authorized personnel listed on the application; the conduct of the research; and the publication of the findings.

      Only one (1) individual may be listed as PI for an IRB application.

      Students may function as PI and therefore may be listed on the application as PI. However, the student's UMD faculty advisor must be listed on the application as the supervising investigator. UMD staff members cannot take the place of the student's UMD faculty advisor and cannot supervise the student.

   b. **Supervising Investigator(s) & Other Key Personnel**

      These individuals assume shared responsibility for the project design and contribute substantively to the development and submission of the IRB application, obtaining informed consent/assent from participants, the conduct of the research, and the publication of the findings.

   c. **Participating Personnel**

      These individuals are faculty or graduate students who have a limited or no role in project design. These personnel typically do not participate in the development and submission of the IRB application.

Regardless of their specific duties on the project, participating personnel must have sufficient knowledge about the application and study design to effectively perform their perspective project role.

d. **Lead PI – Multi-site**

When the researcher is the lead PI of a multi-site study, the IRB evaluates whether the management of information that is relevant to the protection of participants is adequate (HRPP Policy 3.012). The IRB application must include a description of how the following is managed:

i. Unanticipated projects involving risks to participants or others
ii. Interim results
iii. Project modifications
iv. Reporting to other site
v. Description of the consent process. If an external entity is contracted to obtain consent, the firm must have its own IRB.

1. **Purpose**

   The purpose of this SOP is to describe the training requirements for all personnel involved in conducting human subject research.

2. **Policy**

   It is the policy of the UMD IRB that all personnel involved in the conduct of exempt and non-exempt human subject research (HSR) must receive training in human subject research protections.

3. **Collaborative Institutional Training Initiative [CITI]**

   Human subject research protections training is primarily accomplished through this web-based training program. Researchers may take either of the following required courses, as applicable: *Social & Behavioral Research - Basic/Refresher Course*; or *Biomedical Research – Basic/Refresher Course*.

   Individual test scores are confidential. Those who have access to individual test scores include, the webmaster, staff supporting the training software, and IRB staff in order to confirm that a passing score of 80% was achieved. There will be no further disclosure of individually identifiable quiz results or aggregate institutionally identifiable results beyond that mentioned above.

   Training completion expires after three (3) years at which time the researcher must take the Refresher course to remain in compliance. CITI training and guidance on how to complete CITI training can be found on the UMD IRB website.

4. **CIRTification**

   Human subject research protections training designed specifically especially for community partners is available through this web-based training program. This training is for those involved in the research activities outlined in the approved IRB application, but is designed for non-academic personnel (business associates, local government representatives, school system representatives, etc.) **NOTE: This training DOES NOT replace the required CITI training for UMD investigators and researchers.**

5. **Student Research**

   All graduate and undergraduate students conducting exempt and non-exempt HSR who have responsibility for project design and integrally involved in data collection must complete the one of the two Basic CITI courses.

6. **External Investigators**

   The UMD IRB will accept certificates of HSR training from other institutions when research personnel include external investigators or subcontract recipients who have completed HSR training elsewhere and are under the legal jurisdiction of that institution with respect to compliance with federal regulations. A copy of any certification must be provided with the IRB application.

7. **New Research Personnel**

   All new UMD employees serving as investigators, faculty advisors, or participating personnel must complete CITI training prior to addition as personnel to any research study. The UMD IRB will accept certificates of training from prior institutions if the training is equivalent to CITI course offerings and it has been completed within the past three (3) years.

8. **Additional Training Requirements**

   a. **Belmont Report**: All research personnel are expected to read the Belmont Report, which is posted on the OHRP website [www.hhs.gov/ohrp].

   b. **UMD IRB SOP**: All research personnel are expected to be reasonably familiar with UMD IRB Standard Operating Procedures and know where to access them for guidance [research.umd.edu/irb].

   c. **Code of Federal Regulations - 45CFR46**: All research personnel are expected to be reasonably familiar with the requirements of Health and Human Services regulations at 45CFR46, which can be accessed on the OHRP website [www.hhs.gov/ohrp].

   d. **HIPAA Training (if applicable):** All research personnel who interact with protected health information for research purposes must complete HIPAA training, which is hosted by the University of Maryland, Baltimore and be accessed on the UMD IRB website.

1. **Purpose**

   The purpose of this SOP is to describe the criteria that the IRB will use at both initial and continuing review in determining the need for 1) IRB review more frequent that annually; 2) increased monitoring; and 3) verification from other sources other than the researchers that no material changes have occurred since previous IRB review.

2. **Policy**

   It is the policy of the UMD IRB that all non-exempt research will be assessed at both initial and continuing review in accordance with the requirements set forth by HHS regulations at 45CFR46.108(3)(i) and 45CFR46.109(e)(f).

3. **Increased Monitoring and/or Interim Continuing Review**

   a. Unless specifically waived by the IRB, research that meets any of the following criteria will require review more often than annually:
      i. Significant risk to research participants (e.g., death, permanent or long-lasting disability or morbidity, severe toxicity) without the possibility of direct benefit to the participants.
      ii. The involvement of especially vulnerable populations likely to be subject to coercion (e.g., institutionalized psychiatric patients, incarcerated minors); or
      iii. A history of serious or continuing non-compliance on the part of the PI.

   b. The following factors will determine which studies require review more frequently than on an annual basis:
      i. The probability and magnitude of anticipated risks to participants.
      ii. The likely medical condition of the proposed participants.
      iii. The overall qualifications of the PI and other members of the research team.
      iv. The specific experience of the PI and other members of the research team in conducting similar research.
      v. The nature and frequency of adverse events observed in similar research at this and other institutions.
      vi. The novelty of the research creating unanticipated adverse events and/or serious problems more likely; and/or
      vii. Any other factors that the UMD IRB deems relevant.

   c. When the IRB determines the need for increased monitoring, this may be accomplished by either: 1) submission of interim reports by the PI; or 2) auditing of investigator records by the IRB staff. The PI will be notified of these requirements in writing.

   d. If the IRB determines the need for more frequent continuing review, the PI will be notified in writing and the IRB approval period will be set accordingly. Based on the criteria outlined in 3(a) and 3(b) above, the IRB will determine whether the research shall be reviewed more often than annually.

4. **Independent Verification**

The following circumstances may require verification from sources other than the researchers that no material changes have occurred since the previous IRB review:

a. History of non-compliance
b. Recurrent delays in submitting amendments
c. High number of IRB approval expirations
d. Failure to respond to IRB review letters or other correspondence in a timely manner.

When the IRB determines that verification from sources other than the researchers is necessary, the Quality Assurance Program Manager will perform the verification by conducting a Quality Assurance Review (HRPP Policy 7.001).

1. **Purpose**

   The purpose of this SOP is to describe the process for applying for a Certificate of Confidentiality from the National Institutes of Health (NIH). **Please Note**: NIH-funded research meeting specific criteria are automatically granted a Certificate of Confidentiality and do not need to apply for one.

2. **Policy**

   It is the policy of the IRB that a Certificate of Confidentiality may be required for certain research projects where the potential for disclosure of sensitive, personally identifiable information creates significant risk of harm to the participant.

3. **Issuance**

   a. Certificates are issued by the NIH for the purpose of protecting identifiable research information from compelled disclosure. The certificate allows the researchers and others who have access to research records to refuse to disclose identifiable information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.
   b. Federal funding of the research is not a prerequisite.
   c. A certificate does not prevent voluntary disclosures such as a limited disclosure to protect the participant or others from serious harm, as in cases of child abuse.
   d. A research project cannot rely on a certificate to withhold data if the participant consents in writing to the disclosure.

4. **Applicable Research**

   a. The project must be categorized as research (HRPP Policy 3.001).
   b. The research must be IRB approved.
   c. The information collected must be “sensitive” (e.g. disclosure would result in significant harm to the participant) and within the NIH mission or HHS health-related research mission.
   d. Personally identifiable information is collected during the research.
   e. The investigator and/or IRB determine that a certificate is necessary to minimize risk to participants.
   f. Certificates are issued for single, well-defined projects rather than groups or classes of projects. Occasionally a certificate can be issued for cooperative multi-site projects. A coordinating center or “lead” institution must ensure that all participating institutions conform to the application assurances and inform participants appropriately about the certificate, its protections, and circumstances in which voluntary disclosures would be made.
   g. NIH funded researchers are automatically issued a certificate of confidentiality through their award. Other DHHS agencies (FDA, CDC, SAMSHA, HRSA, HIS) issue certificates of confidentiality for research they fund.

5. **Sensitive Research Categories**
    a. Information related to sexual attitudes, preferences, or practices.
    b. Information related to the use of alcohol, drugs, or other addictive substances.
    c. Information pertaining to illegal conduct.
    d. Information that, if released, could damage a participant's financial standing, employability, or reputation within the community.
    e. Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.
    f. Information pertaining to an individual's psychological well-being or mental health.
    g. Genetic information.

6. **Application Process**
    a. Principal Investigators conducting research that collects sensitive information from human subjects may apply for a certificate of confidentiality from the NIH.
    b. In addition to the completed application, the PI will be required to provide documentation of IRB approval and a copy of the informed consent form(s) as it would read if a certificate of confidentiality is obtained (e.g., explains the certificate, its protections and the circumstances in which voluntary disclosures might be made).
    c. Both the PI and Institutional Official a required to sign the certificate application.
    d. Detailed application instructions and further information may be found on the NIH website.

7. **Information Disclosure When:**
    a. Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.
    b. Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
    c. Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
    d. Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human participants in research.

8. **Automatically Covered Research**
    Examples of research automatically covered by a certificate of confidentiality include:

    a. Biomedical, behavioral, clinical or other research, including exempt research, except where the information obtained is recorded in such a manner that human participants cannot be identified or the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants.

b. The collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual.
c. The generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human participants can be identified or the identity of the human participants can readily be ascertained.
d. Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

9. **Participant Awareness**

Written materials require that when research is covered by a certificate of confidentiality, researchers must inform participants (for example, in the consent document) of the protections and limitations of certificates of confidentiality.

a. For studies that were previously issued a Certificate and notified participants of the protections provided by that Certificate, NIH does not expect participants to be notified that the protections afforded by the Certificate have changed, although IRBs may determine whether it is appropriate to inform participants.
b. If part of the study cohort was recruited prior to issuance of the Certificate, but are no longer activity participating in the study, NIH does not expect participants consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that participants who were previously consented to be re-contacted to be informed of the Certificate, although IRBs may determine whether it is appropriate to inform participants.
c. Researchers conducting research covered by a certificate of confidentiality, even if the research is not federally funded, must ensure that if identifiable, sensitive information is provided to other researchers or organizations, the other researcher or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.

1. **Purpose**

The purpose of this SOP is to describe the conditions and relevant procedures for the following:

a. The UMD IRB will rely on an external IRB review and approval of cooperative research.
b. The UMD IRB will act as the IRB of record for cooperative research;
c. The UMD IRB will execute Individual Investigator Agreements for external researchers working on research reviewed by the UMD IRB.
d. The UMD IRB may accept Exempt determinations by an external IRB.
e. Policies and Procedures the UMD IRB will follow based on federal funding source.

2. **Definitions**

a. **Cooperative Research** is research that involves more than one institution.
b. **Reliance Agreement** (or 'Authorization Agreement') is an agreement used to document respective authorities, roles, responsibilities, and communication between an organization providing the ethical review and a participating organization relying on a reviewing IRB.
c. **Relying Institution** is a Participating Institution the cedes IRB review to a Reviewing IRB.

3. **Policy**

It is the policy of the UMD IRB that, if UMD investigators are participating in cooperative research, the UMD IRB may enter into a reliance agreement, rely on the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort in accordance with Health and Human Services regulations at 45CFR46.114.

a. All non-exempt cooperative research studies involving an AAHRPP accredited institution are eligible for a reliance agreement with UMD.
b. Non-exempt cooperative research projects involving a non-AAHRPP accredited institution may be eligible for a reliance agreement with UMD. Eligibility for a reliance agreement will be determined on a case-by-case basis by the IRB Specialist and/or Director of the HRPP. The process that will be used to evaluate whether research is being reviewed appropriately and complies with applicable laws and regulations may include:
    i. Reviewing any relevant IRB applications and related materials (i.e., consent documents, recruitment materials, etc.) for the study in which the agreement is being sought;
    ii. Reviewing the external IRB's website to ensure compliance with appropriate policies and procedures and ethical standards;
    iii. Confirming that appropriate training requirements are enforced by the reviewing IRB. The extent of the review of the non-accredited IRB may vary, depending on the risk to participants in the research.

4. **SMART IRB**

The UMD IRB has adopted the Standard Operating Procedures of the SMART IRB initiative. Please see Appendix A to view the SMART IRB SOPs.

a. SMART IRB SOPs will be followed when engaging with institutions who also follow SMART IRB SOPs.
b. The UMD IRB will have the discretion to execute a reliance agreement outside of the SMART IRB system if one or more of the following cases apply:
    i. No federal funding
    ii. Reviewed through the Expedited review path. NOTE: Exempt protocols do not require reliance agreements.
    iii. Reviewing or Relying institution is not a SMART IRB participant. When UMD is the relying institution, this will be assessed on a case-by-case basis to ensure appropriate oversight.

5. **UMD IRB to Rely on an External IRB**

a. **Conditions for UMD IRB to Rely on an External IRB**
    i. UMD faculty, staff, or students are engaged in human subject research in collaboration with an external institution under the authority of the IRB of that institution.
    ii. The external IRB has accepted full responsibility to protect the rights and welfare of all participants enrolled within its institution, in accordance with Health and Human Services regulations at 45CFR46.
    iii. The UMD IRB agrees to comply by the determinations and requirements of the external/reviewing IRB. UMD IRB officials must not approve research subject to a reliance agreement if it has not been approved by the Reviewing IRB.
    iv. The external IRB has a Federalwide Assurance (FWA) approved by the Office of Human Research Protections (OHRP).

b. **The UMD IRB will require the following documentation via email and/or the UMD IRB's reliance platform, for example the Online Research System (ORS) of SMART IRB, to determine the UMD IRB's willingness to rely on an external IRB for the review of the cooperative research**:
    i. A copy of the reviewing IRB's Approval Letter.
    ii. A summary of UMD investigator roles and responsibilities to confirm engagement in human subject research activities.
    iii. A copy of each UMD investigators' human subject research training certificate.
    iv. Confirmation of any conflicts of interest (COI) related to the study collaboration. If a COI exists, a copy of the approved Management Plan must be provided.
    v. Project funding source/entity.

c. **UMD procedures to review and establish reliance on an external IRB:**
   i. All requests to rely on an external IRB will be reviewed by the IRB Specialist, Director of the HRPP, Vice President for Research, or designee.
   ii. All accepted reliance agreements will be signed by the Director of the HRPP, Vice President for Research, or their designee.
   iii. When necessary, additional reviews, such as scientific review or conflict of interest review, will be conducted by UMD prior to establishing reliance. When appropriate, the results of this review will be communicated to the external reviewing IRB through the established reliance contact at the external IRB.
   iv. The UMD IRB will provide the reviewing IRB with requested information about local requirements or local research context issues relevant to the IRB's determination when requested. This information will be delivered via email to the established reliance contact at the external IRB and/or through the external IRB's reliance platform, for example the Online Reliance System of SMART IRB.
   v. The UMD IRB will request that all researchers and research staff disclose any conflicts of interest according to the process agreed upon between the researcher's institution and the reviewing IRB. Researchers and staff must comply with any conflict-of-interest management plan that may result.

d. **UMD IRB, as the Relying Institution, will ensure the following:**
   i. UMD researchers comply with the determinations and requirements of the Reviewing IRB, including requirements related to initial and continuing review, record keeping and reporting, and promptly reporting any proposed changes to the research to the Reviewing IRB per their policies and procedures.
   ii. UMD researchers may not implement changes to the research without prior IRB approval, except where necessary to eliminate apparent immediate hazards to the participants.
   iii. UMD researchers will not enroll participants in research prior to approval by the reviewing IRB and will meet all other applicable requirements for the study.
   iv. UMD researchers, when responsible for enrolling participants, will obtain, document, and maintain records of consent for each participant or each participant's legally authorized representative.
   v. UMD researchers, when applicable, will provide the reviewing IRB with any data safety monitoring reports they receive, according to the Reviewing IRB's policies and procedures.
   vi. All unanticipated problems, participants complaints, protocol deviations, and other events will be reported to the external IRB no later than two weeks from their receipt from UMD researchers, in order to allow the external IRB to make required determinations for unanticipated problems involving risks to participants or others. This information will be delivered via email to the established reliance contact at the external IRB and/or through the external IRB's reliance platform, for example the Online Reliance System of SMART IRB.

e. The IRB Specialist or designee, will be the established point of contact at the UMD IRB for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions when using an external IRB for review. The IRB Specialist will also maintain the Reliance Agreements page on the UMD IRB website to ensure researchers are aware of which activities are eligible for external IRB review and the process to request a reliance agreement. Questions regarding reliance agreements and the execution process may be directed to the following shared email inbox relianceagreements@umd.edu to ensure timely responses.

f. All collected documentation will be stored in the relevant folder and/or noted on the Reliance Agreement Tracking Sheet stored on the UMD IRB Office shared drive. The Tracking Sheet is managed by the IRB Specialist, Director - HRPP, and/or their designee.

6. **UMD acting as IRB of Record**
   a. Conditions for UMD to serve as the IRB of Record
      i. Both UMD and relying institutions' researchers have agreed to conduct the research in accordance with the approved IRB application and meet all training requirements.
      ii. The relying institution has agreed to cede all responsibilities to protect the rights and welfare of all participants enrolled within its institution to the researchers listed on the approved UMD IRB protocol, in accordance with Health and Human Services regulations at 45CFR46.
      iii. The relying institution ensures appropriate monitoring of research, which includes conducting UMD IRB-directed audits upon request, and ensures cooperation of relying institution's investigators with any audit or investigation by Reviewing IRB.
      iv. The relying institution has a Federalwide Assurance (FWA) approved by OHRP.

   b. **The UMD IRB will require the following documentation via email and/or the UMD IRB's reliance platform, for example the Online Reliance System (ORS) of SMART IRB, to determine the UMD IRB's willingness to serve as the Reviewing IRB for the cooperative research**:
      i. A copy of the UMD IRB Approval Letter.
      ii. A summary of external investigator roles and responsibilities to confirm engagement in human subject research activities.
      iii. A copy of external investigator human subject research training certificate.
      iv. Confirmation of any conflicts of interest (COI) related to the study collaboration. If a COI exists, a copy of the approved Management Plan must be provided.
      v. Project funding source/entity.

   c. **UMD procedures to review and establish reliance as the Reviewing IRB**:
      i. All requests to rely on UMD IRB review will be reviewed by the IRB Specialist, Director of the HRPP, Vice President for Research, or designee. All accepted reliance agreements will be signed by the Director of the HRPP, Vice President for Research, or their designee.

d. **UMD IRB, as the Reviewing IRB, will ensure the following**:

i. The UMD IRB will review the addition of research sites during the initial review or during the submission of an amendment to previously approved protocols. If a relying institution's researchers are added during the initial approval process, the reliance agreement process will not commence until the initial IRB approval is granted by the UMD IRB. If a relying institution's researchers are added through an amendment, the reliance agreement process will begin as soon as the amendment is acknowledged or approved. Changes to the overall protocol and/or relying site documents will be reviewed in accordance with existing UMD IRB policies and procedures.

ii. The UMD IRB will provide any requested IRB documentation to the relying institution in order to abide by their institution's policies and procedures.

iii. IRB applications or other related materials contain a description of any laws relevant to the study being reviewed by the IRB, when research is conducted in another state or country. Information about relevant laws may be provided in a local context form, or other ways as required.

iv. The UMD IRB will request that the relying investigator(s) or institution's reliance contact provide any conflict of interest disclosures prior to finalizing the agreement. Disclosures can be provided via email to the IRB Specialist or designee and/or the UMD IRB's reliance platform, for example the Online Reliance System of SMART IRB.

v. All unanticipated problems, participants complaints, protocol deviations, and other events will be reported by the relying IRB to the UMD IRB no later than two weeks from their receipt, in order to allow the UMD IRB to make required determinations for unanticipated problems involving risks to participants or others. This information will be delivered via email to the established reliance contact at the UMD IRB and/or through the UMD IRB's reliance platform, for example the Online Reliance System of SMART IRB. Any unanticipated problems, participant complaints, protocol deviations, and other events that are determined by the UMD IRB to involve risks to participants or others will be reported to the relying IRB no later than one week from the date of determination.

vi. The UMD IRB will communicate the suspension or termination of IRB approval to the Overall PI, Site Investigator, and the Relying Institution within 48 hours of the suspension or termination. A notice of suspension or termination of IRB approval will be provided through email or other means as deemed appropriate, for example the Online Reliance System of SMART IRB.

vii. The UMD IRB will make any official decisions and relevant IRB records, including but not limited to minutes, determination/approval letters, consent documents, and other records that document the IRB's determinations, to the relying organization upon request.

viii. Any relevant or updated policies will be provided to the relying organization, including HRPP staff, and researchers and research staff as appropriate. These relevant or updated policies will be provided to the relying organization via email or through other means as deemed appropriate, for example the Online Reliance System of SMART IRB.

e. The IRB Specialist or designee will be the established point of contact at the UMD IRB for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the IRB. External communication regarding reliance agreements may be directed to an following shared email in box relianceagreements@umd.edu to ensure timely responses to questions.

f. All collected documentation will be noted on the Reliance Agreement Tracking Sheet stored on the UMD IRB Office shared drive. This Tracking Sheet is managed by the IRB Specialist and/or Director of the HRPP.

7. **Conditions for External Researcher without Institutional Affiliation (Individual Investigator Agreements)**
   a. For researchers that will be engaged in human subject research that do not have an affiliated IRB or whose IRB does not have a Federalwide Assurance (FWA) will be permitted to rely on UMD IRB through the use of an Individual Investigator Agreement.

   b. For researchers that will be engaged in human subject research that are affiliated with an institution with a Federalwide Assurance (FWA) but are not acting as an agent of the institution will be permitted to rely on the UMD IRB through the use of an Individual Investigator Agreement (IIA).

   c. The Individual Investigator will be required to review:
      i. The Belmont Report.
      ii. The U. S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45CFR46.
      iii. The FWA and the applicable Terms of the FWA for UMD.
      iv. The relevant institutional policies and procedures for the protection of human subjects. This includes appropriately documented completion of human subject research training.

   d. The Individual Investigator understands and will comply with all standards and requirements of the UMD IRB, comply with all other applicable federal, international, state, and local laws, regulations and policies that may provide additional protection for human subjects, and will abide by all determinations of the UMD IRB and will accept the final authority and decisions of the UMD IRB, including but not limited to directives to terminate participation in designated research activities.

   e. The principal investigator will contact the IRB Office at relianceagreements@umd.edu to request an Individual Investigator Agreement (IIA). After confirming the Individual Investigator is engaged in human subject research under a non-exempt UMD IRB project, the IRB Specialist or designee will draft the IIA document and send it to the PI and Individual Investigator. The PI and Individual Investigator will review and sign the document, return it along with documentation of human subject research training completion to the IRB Specialist, who will then route for signature by the Vice President for Research or Director of the

HRPP. Final signed versions will be sent to the PI and Individual Investigator and stored on the UMD IRB shared drive.

f. All collected documentation for Individual Investigator Agreements will be noted on the Reliance Agreement Tracking Sheet stored on the UMD IRB Office shared drive. This Tracking Sheet is managed by the IRB Specialist or designee.

8. **Conditions to accept external exempt determinations**

Federal regulations require reliance agreements for collaborative non-exempt human subject research. This policy outlines the conditions in which UMD IRB may enter into a reliance agreement for an exempt study or may accept an external IRB's exempt determination and the procedures to do so.

a. UMD IRB does not enter typically into reliance agreements for exempt study collaborations; however the IRB Specialist and/or Director of the Human Research Protection Office will consider entering into a reliance agreement if an external IRB requires it.
b. If UMD investigators are engaged in research deemed exempt by an external IRB, the UMD IRB may accept the external IRB's exempt determination. The IRB Specialist and/or Director of the Human Research Protection Office will consider accepting an external exempt determination if they determine that the research meets Exempt criteria. The determination will be made based on the submitted study materials on a case-by-case basis and will be documented in a tracking sheet stored on the UMD IRB Shared Drive.
c. Should UMD IRB decline to accept an external exempt determination, UMD investigators will submit the study for an exempt determination by UMD IRB. The submission should detail the UMD investigators' role in the project and include all relevant study materials such as non-UMD consent forms and non-UMD determinations.

9. **Relevant Policies Based on the Federal Funding Source of Cooperative Research:**
   a. Conditions when following Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations:
      i. The UMD IRB, when serving as the IRB of Record, will determine whether the relying organization applies its FWA to some or all research via the Local Context Form, and ensure the IRB review is consistent with requirements in the relying organization's FWA.
      ii. The Reviewing IRB will be responsible for obtaining any additional approvals from DHHS when the research involves pregnant women, fetuses, and neonates; or children; or prisoners, unless otherwise determined by the Reviewing IRB and Relying Institution(s).

   b. Relevant policies when following National Institutes of Health (NIH) policies:
      i. The requirement for single IRB review applies to awardees in the United States and participating research sites in the United States.

ii. The requirement for single IRB review does not apply to organizations outside the United States.
iii. Awardee organizations are responsible for ensuring authorization agreements are in place, and that documentation is maintained.
iv. The Reviewing IRB is responsible for meeting the additional requirements of the NIH Genomic Data Sharing Policy, unless otherwise determined by the Reviewing IRB and Relying Institution(s).
v. Participating sites are expected to rely on the single IRB, though they may conduct their own review in accordance with NIH policy on exceptions from single IRB review.

c. Relevant policies when UMD serves as the IRB of Record for a Department of Defense (DoD)-covered research study:
    i. Please refer to HRPP Policy 15.004.

d. Relevant policies when following Department of Energy (DOE) requirements:
    i. Please refer to HRPP Policy 15.005.

1. **Purpose**

   The purpose of this SOP is to describe the requirements for retention and security of research records.

2. **Policy**

   It is the policy of the UMD IRB that the research record maintained by the IRB and PI must: 1) contain an accurate and complete account of the conduct of the study; 2) be maintained and stored securely; and 3) be retained for the required amount of time following completion of the research in accordance with DHHS regulations under 45CFR46.115(b), and sponsor requirements as applicable.

   This policy also applies UMD Policy Records Retention Schedule [https://purchase.umd.edu/administrative-services/records-retention/umd-records-retention-schedule]. Item 84 pertains to investigator record retention. Item 197 refers to IRB record retention.

3. **Research Record**

   The research record must include, but is not limited to:

   a. Initial Application: 1) IRB Application; 2) detailed protocol (if applicable); 3) funding proposal (if applicable); 4) consent documents (if applicable); 5) supporting documentation
   b. Applications for continuing review and corresponding documents.
   c. Requests for change (amendment) to the project and/or consent documents.
   d. Reports of adverse events and unanticipated problems involving risk to the participant or others.
   e. Deviation reports and resolution.
   f. Incidents of non-compliance and resolution.
   g. IRB correspondence with the research team
   h. Any other project-related documentation not covered by the above. The PI will also maintain copies of sponsor contracts and correspondence (if applicable) and subject files that should contain: 1) signed consent documents; 2) laboratory results; 3) other applicable information.

4. **Security of Research Records**

   a. All research records must be maintained and stored securely, in a manner that protects participants privacy and confidentiality by preventing unauthorized access (e.g. locked cabinets, password protected electronic devices; digital encryption; restricting access to identifiable information, etc).
   b. All research databases must comply with UMD Information Security policies and procedures relating to the safeguarding of electronic confidential information [https://it.umd.edu/security]
   c. Records are accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.

5. **Retention of Research Records**

   a. Social science, behavioral, educational, and biomedical research records must be retained for at least

seven (7) years beyond the termination of the project, or longer as required by sponsors. However, research data should be de-identified as soon as possible. This includes destroying links to identifiable research data.

b. If the investigator resigns from UMD before the end of the designated period, the department of record must maintain the research records unless otherwise specified. The investigator, however, may have a copy of the research records in accordance with applicable UMD records policies.
c. If a project is cancelled without participant enrollment, records are retained for at least three (3) year after cancellation.
d. If a project continues after a sponsor cancels funding, the investigator shall attest in writing the following to cancelling sponsor's HRPP:
    1. At time of funding cancellation, all participant data has been de-identified or destroyed, or some/all of the data is being retained in the protective manner authorized in writing by the IRB.
    2. At sponsor's request after funding cancellation, which may be before or after the federally required three (3) year retention period for research records, all participant data has been de-identified or destroyed, or some/all data is being retained in the protective manner authorized in writing by the IRB.
    3. At time of study completion or closure, all participant data has been de-identified or destroyed, or some/all data is being retained in the protective manner authorized in writing by the IR

1. **Purpose**

   The purpose of this SOP is to describe the procedure a PI may take to express disagreement with IRB decisions.

2. **Policy**

   It is the policy of the IRB that a PI has the right to disagree with IRB decisions and may seek resolution. However, appeals of disapproved projects will not be considered.

   a. The results of the IRB expedited or full board review will be conveyed to the PI by the IRB staff through written electronic correspondence. Individual IRB members should not discuss the results of the IRB review with the PI unless agreed upon by the IRB Chair and majority of IRB members.

      i. If a PI disagrees with the IRB's written decision, they are encouraged to contact the HRPO and/or the IRB chair and provide a written response detailing justification for the disagreement.
      ii. If the disagreement is related to a substantive human protection issue and the project was reviewed by the fully convened IRB, the project will referred back to the fully convened IRB. The PI may be invited to attend the IRB Meeting to address any questions generated by the members.
      iii. If the disagreement does not represent a substantive human protection issue, the IRB Chair will seek a resolution.
      iv. Appeals of disapproved projects will not be considered.

   b. Any PI who believes there is a conflict of interest on the part of any IRB member relative to his/her project is encouraged to contact the IRB Chair, Institutional Official, and/or Director of the HRPP. All necessary steps will be taken to immediately resolve the problem.

   c. Investigators who have concerns or suggestions regarding the institution's human research protection program (HRPP) should convey them to the Institutional Official or other responsible part (e.g. Dean, Department Chair, Director – HRPP) regarding the issue, where appropriate. The Institutional Official or designee will investigate the issue, and where deemed necessary, convene the parties involved to form a response to the investigator to make necessary procedural or policy modifications, as warranted. In addition, the IRB Chair or Director of the HRPP will be available to address investigators' questions, concerns, and suggestions.

1. **Purpose**

   The purpose of this SOP is to describe compensation for research participants.

2. **Policy**

   It is the policy of the IRB that compensation for research participants may be acceptable if: 1) the possibility of coercion or undue influence is minimized, and 2) the compensation is considered a recruitment incentive, not a benefit, in accordance with Health and Human Services regulations at 45CFR46.116.

3. **Requirements**

   a. Compensation for participation is not an obligation of the researcher toward the participant. Compensation may be offered but is not required.

   b. Participation in research should not require financial sacrifice but should be revenue neutral for participants.

   c. Compensation should not be used as a "benefit" to offset risks (either quantitative or qualitative) associated with the research.

   d. Generally, compensation should be based on the premise that participation in research requires time and effort from the participant. Compensation, when offered, should be based on a reasonable consideration of the duration of time spent in preparation for, participation in, and recovery from, research interventions, in addition to the effort expended during the research activities.

      Interventions are understood to include such elements as procedures performed, visits to a clinic or research setting, phone interviews, or surveys completed. If appropriate, such compensation should include all parties involved. For example, if a family member is required to transport a participant home after a research visit, their time may be compensated.

   e. Compensation above these levels must be justified by the PI and must comply with enumerated principles.

   f. In order to minimize the risk that cumulative compensation for prolonged participation could unduly influence participation, the compensation plan should be clearly described in the consent form, include the pro-rated amounts that will be received at certain project milestones as well as the total amount to be received.

      Credit for payment is to accrue as the study progresses (pro-rated amounts) and not be contingent only upon the participant completing the study. Any amount paid as a bonus for completion should be reasonable and not so large as to unduly induce participants to stay in the study when they would have

otherwise withdrawn.

g. Payments for involvement of young minors (<16 years of age) in research should not be made directly to the minor. Depending on scientific rationale and justification, minors can be offered and age-appropriate item through their parents for their participation. With appropriate rationale and justification, 16- through 18-year-olds may be compensated directly.

h. UMD IRB does not allow payment in exchange for referrals of prospective participants (finder's fees), nor does it allow payments to an organization or research staff tied to the rate or timing of enrollment (bonus payments).

4. **Use of Raffle**

The IRB will consider such plans for participation compensation on a case-by-case basis, with appropriate rationale and justification provided by the PI.

5. **Extra Credit**

Extra Credit may be offered to students as compensation. However, the credit should be reasonable and not so large as to unduly influence potential participants. In the case where a specific class is identified as the population and extra credit is offered as compensation, an alternative method to earn the extra credit must be offered to those in the class who do not wish to participate in the research.

1. **Purpose**

   The purpose of this SOP is to describe the IRB requirements for recruitment of participants through advertising.

2. **Policy**

   It is the policy of the IRB that all participant recruitment strategies including printed advertisements, bulletins, flyers, multimedia, radio, television, and online postings must be reviewed and approved before they can be used to recruit potential participants.

3. **Design**

   Advertisements should be limited to information a potential participant may need to determine if they are interested and eligible to participate in a study.

   a. Appropriate items to include in an advertisement are as follows:
      i. Name and address of investigator/laboratory and associated institution.
      ii. Purpose of the research.
      iii. Eligibility criteria (in shortened form)
      iv. Listing of direct benefits to participants (if any)
      v. Time or other commitments required from participants
      vi. Logistics (location, parking, contact person, contact info)
      vii. Compensation (if offered)
   b. The following are not permitted in advertisements:
      i. Statements or implications of certainty of a favorable outcome or other benefits beyond what is described in the consent document and IRB application.
      ii. Claims, implicit or explicit, that the research procedures are safe or effective for the purposes under investigation.
      iii. Inclusion of exculpatory language.
      iv. Overemphasis of compensation.
   c. Printed advertisements should use appropriate font size and bolding to ensure the prospective participant is not misled by having their attention inappropriately drawn to a particular section of the advertisement.
   d. In all cases, the investigator should ensure that the advertisement layout and font size approved by the IRB is reflected in the final published materials.

4. **Submission of Advertisements**

   Draft copies of all advertisements including audio scripts must be submitted to the IRB for review and approval. An advertisement may be reviewed by either the full IRB or by the expedited review process in accordance with Health and Human Services regulations at 45CFR46.110(b)(1) and (2).

1. **Purpose**

   The purpose of this SOP is to describe the process for determining whether a research proposal is eligible for an exempt determination.

2. **Policy**

   It is the policy of the IRB that all proposed exempt research is reviewed by the IRB staff to determine that the research meets at least one of the categories of exemption from federal regulations for protection of human research participants in accordance with Health and Human Services regulations at 45CFR46.104.

   The UMD IRB does not use limited IRB review or broad consent. Exempt review categories 45CFR46.104(d)7 & 8 will not be used to make exempt determinations.

3. **Research Not Eligible for Exempt Review**
   a. Sensitive survey research that is identifiable where the disclosure of the participant responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability or reputation.
   b. The research involves survey, interview, or participation observation activities involving children.
   c. Research involving prisoners, persons who have decisional or psychological impairment, who are economically or educationally disadvantaged and other participant populations determined to be vulnerable upon review.

4. **Ethical Considerations**

   Although exempt research is not covered by federal regulations, this research is not exempt from the ethical guidelines of the Belmont Report. The individual making the exempt determination may require additional protections for participants in keeping with the guidelines of the Belmont Report.

5. **Exempt Review Process**
   a. The PI must submit an IRB application through the electronic submission system.
   b. HRPO staff will determine whether an exempt determination should be made after completing a review of the proposed exempt determination.
   c. All exempt research involving human participants must maintain an ethically appropriate standard, which serves to protect the rights and welfare of the participants. This may require a consent process and appropriate measures to protect confidentiality.
   d. If the HRPO determines that the research qualifies for an exempt determination, the investigator will be notified through the electronic submission system as soon as the review is completed.
   e. Projects receiving an exempt determination do not require continuing review.
   f. All modifications to exempt projects must be submitted to the IRB for review via an Amendment application. If the proposed modifications required alteration of the exempt determination to expedited or

full board review, the reviewing HRPO staff member will consult with an IRB Chair, Director of the HRPP, or their designee.

g. The HRPO reserves the right to refer applications for an exempt determination to either the expedited review process or the full IRB review process as necessary.

1. **Purpose**

   The purpose of this SOP is to describe the expedited review process for initial and continuing review.

2. **Policy**

   It is the policy of the IRB that expedited review will be conducted in accordance with Health and Human Services (HHS) regulations at 45CFR46.110. Projects reviewed and approved by the expedited process must: 1) present no greater than minimal risk; 2) involve procedures described in one more of the categories specified in the Office of Human Research Protections guidance on Expedited Review Categories; and meet all the criteria specified in HHS regulation 45CFR46.111. Expedited review may be used to conduct continuing review in accordance with HRPP Policy 11.001.

   a. In general, expedited review will not be used for research involving prisoners. However, in certain cases, a prisoner representative may review a new project or transaction involving changes to a currently approved project involving prisoners or prisoner data. This decision will be made based on the risk – benefit ratio of the project and/or the impact the changes may have on the project.

      The prisoner representative will provide feedback and the transaction will be sent to the IRB Chair or designated IRB member reviewer for final determination. The Chair or designated IRB member reviewer may determine to approve the transaction, required modifications, or forward to the full board for review, discussion, and vote.

   b. Three (3) applicable criteria must be met for initial or continuing review using the expedited review process:
      i. The current and future research activities present no greater than minimal risk to participants [Not required for category (8)(b)].
      ii. The identification of participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to privacy and confidentiality are no greater than minimal [Not required for category (8)(b)].
      iii. The research is not classified.

3. **Expedited Review Process**

   a. The IRB staff will conduct a pre-review of each IRB application to determine if the research meets at least one of the Expedited review categories specified in the Office of Human Research Protections guidance on Expedited Review Categories. The IRB staff will generate modifications and request revision of applicable documents from the PI, if necessary.

   b. Once pre-review is completed, the IRB staff will review the PI responses and assign the project to an IRB Chair or IRB designated reviewer for final review and approval.

c. The IRB Chair, Director – HRPP, or designated IRB member reviewer retain the right to refer any project transaction to the full board for reviewer. However, these reviewers may not disapprove exempt or expedited project transactions. A project transaction may only be disapproved by the full board.
d. The expedited reviewer(s) will apply the criteria for approval specified in HRPP Policy 3.004 and 45CFR46.111. The expedited reviewer will complete a reviewer checklist for the expedited transaction to document their review and include it with their final determination.
e. After a project transaction is approved by the expedited process, the full IRB will be notified through listing the expedited and exempt determinations on the next board meeting agenda and documenting this report in the IRB meeting minutes.
f. All IRB members can access expedited transaction documents via the electronic submission system and may make comments that can be presented at the full board meeting. Even if a project transaction has been approved through the expedited process, the full IRB reserves the right to require modification to the project documents if warranted. Additionally, the full IRB can suspend or terminate the project or halt accrual if necessary.

4. **Expedited Continuing Review**

If required during the initial expedited determination, the PI will submit a Continuing Review application through the electronic submission system prior to the expiration date of the project. The IRB staff will conduct a pre-review of the continuing review application, send any required modifications to the PI, review the response from the PI and assign the continuing review to the IRB Chair or designated IRB member reviewer for final determination.

5. **Expedited Review Actions**

a. Approval

No modifications required. All of the criteria for IRB approval outlined in 45CFR46.111 have been satisfied. The PI will be notified of approval through the electronic submission system and authorized to begin the project.

b. Approval with Specific Changes/Modifications

The investigator will be notified of the required modifications through the electronic submission system. Once the modifications have been addressed and reviewed by the IRB staff, the project will be assigned to the IRB Chair or designee for final approval.

c. Full Board Review

The transaction is referred to the full IRB for review.

1. **Purpose**

   The purpose of this SOP is to describe the additional protections required for including vulnerable populations in human subject research.

2. **Policy**

   It is the policy of the IRB that the vulnerability of a potential participant population will be evaluated to ensure that appropriate protections are in place for any participant who may be vulnerable in accordance with Health and Human Services regulations 45CFR46.111(a)(3).

   HHS regulations at 45CFR46 provide special protections for pregnant women and neonates (Subpart B), prisoners (Subpart C), and children (Subpart D). 45CFR46 does not include specific requirements for the protection of other vulnerable participant populations, such as decisionally impaired persons, terminally ill, economically or educationally disadvantaged persons, etc. It is the responsibility of the PI to outline appropriate measures in the IRB application to protect any vulnerable populations that are targeted for enrollment. The IRB may discuss these measures with the PI if they are not adequately outlined in the IRB application.

3. **Definition – Vulnerable Population**

   Vulnerable population is defined as an individual or group of individuals with limited autonomy (e.g., lacks independence in decision-making for a variety of reasons) or is otherwise at increased risk compared to non-vulnerable individuals. Within any population of vulnerable participants, individuals will have different levels of vulnerability based on the level of capacity, circumstance, or condition affecting independent decision-making.

4. **Categories - Vulnerable Populations**

   Vulnerable Populations may be categorized according to the following groups (not exhaustive):

   a. Pregnant women & neonates (45CFR46 - Subpart B) (HRPP Policy 5.002)
   b. Prisoners (45CFR46 - Subpart C) (HRPP Policy 5.003)
   c. Children (45CFR46 – Subpart D) (HRPP Policy 5.004)
   d. Decisionally impaired (HRPP Policy 5.005)
   e. Employees and students (HRPP Policy 5.005)
   f. Comatose
   g. Terminally ill
   h. Economically disadvantaged
   i. Educationally disadvantaged
   j. Socially disadvantaged
   k. Others as determined by the IRB and investigator

5. **Factors Determining Vulnerability**
    a. The nature of the research.
    b. The risks of the research.
    c. An increased probability of risk occurrence in the population.
    d. Degree of autonomy, or limited autonomy, present in the population.
    e. The clinical status of the population.
    f. The educational status of the population.
    g. The economic status of the population.
    h. The presence of a support system (e.g. family and friends) for the population.
    i. Cultural or social factors associated with the proposed population.
    j. Other factors as applicable

6. **Additional Protections for Vulnerable Populations**

Upon determining the vulnerability of an individual or population, the IRB and investigator will provide special protections against risk. These additional protections will include those specified by HRPP policies for research involving pregnant women, prisoners, children, and/or decisionally impaired participants.

Examples of other additional protections may include:

a. The use of an extended consent process.
b. The use of a consent monitor/observer.
c. Appointment of a participant advocate.
d. Involvement of the participant's family and/or friends.
e. Exclusion from research participation.
f. Increased safeguards for privacy and confidentiality.
g. Increased monitoring by the IRB or external individual or board.
h. Longer study follow up.

1. **Purpose**

   The purpose of this SOP is to describe the IRB requirements for research involving pregnant women, fetuses, and neonates.

2. **Policy**

   It is the policy of the IRB that additional protections for pregnant women, fetuses, and neonates involved in research are applied. Research which is funded by DHHS must satisfy the additional protections described in 45CFR46 – Subpart B. The IRB will apply Subpart B to all research involving pregnant women, fetuses, and neonates regardless of funding.

3. **Definitions**

   a. Pregnancy

   Period from confirmation of implantation of a fertilized egg within the uterus until the fetus has been delivered. Implantation is confirmed through a presumptive sign of pregnancy (e.g. missed periods or a positive pregnancy test). While confirmation may be in error, investigators presume that a living fetus is present until evidence is presented to the contrary.

   b. Fetus

   The product of conception from implantation until delivery.

   c. Viable Neonate

   A neonate, after delivery that can survive to the point of independently maintaining heartbeat and respiration. (A viable neonate is covered by HHS regulations at 45CFR46 – Subparts A & D.)

   d. Nonviable Neonate

   A neonate after delivery that, although living, is not viable.

4. **IRB Review**

   In addition to review of research under HHS regulations at 45CFR46 – Subpart A, the IRB must provide apply the regulations at 45CFR46 - Subpart B to all behavioral/social science research where pregnant women, fetuses and/or neonates are involved.

5. **Non-pregnant participants who become pregnant during research**

   If a participant becomes pregnant while actively participating in a research project, the investigator must:

   a. Determine if it is in the best interest of the pregnant participant to continue participating in the study or terminate participation in the study by completing the report on unanticipated problems or adverse events involving risks to research participants or others, as described in HRPP Policy 13.001.
   b. If it is in the best interest of the pregnant participant to remain in the study, adequate justification must be provided to receive IRB Chair approval for the participant to continue. If it is not in the best interest of the participant to continue, their participation must be terminated.
   c. The study must be re-reviewed by the full IRB, as soon as possible, in consideration of this policy and the

regulations at 45CFR46 – Subpart B.

6. **Documentation of IRB findings under Subpart B**

The IRB will fully document compliance with Subpart B in the minutes of the IRB meeting by documenting the required determinations and project-specific findings justifying those determinations. The IRB Approval Letter will also reflect compliance with Subpart B if applicable.

1. **Purpose**

   The purpose of this SOP is to describe the IRB requirements for research involving prisoners.

2. **Policy**

   It is the policy of the IRB that additional protections for prisoners involved in research are applied. Research which is funded by DHHS must satisfy the additional protections described in 45CFR46 – Subpart C. These protections include individuals who are prisoners at the time of enrollment in the study, as well as participants that become incarcerated after enrollment in a study. The IRB will apply Subpart C to all research involving prisoners regardless of funding.

3. **Definitions**

   a. **Prisoner**

      As defined in HHS regulations, a prisoner is any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures, which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals pending arraignment, trial, or sentencing.

   b. **Minimal Risk in Prisoner Research**

      Defined in the HHS regulations as "the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

4. **Permitted Research involving Prisoners**

   Social/behavioral and biomedical research may involve prisoners as participants only if

   a. The IRB has reviewed, approved and determined that the research falls within one of the categories listed in 45CFR46.306. In the case of DHHS-funded research, the IRB must also certify the approval to OHRP as described in 45CFR46.305(c).

5. **Special Circumstances**

   a. When a **previously enrolled participant becomes a prisoner and the research was not reviewed by the IRB** in accordance with 45CFR46 Subpart C, the PI must report the situation to the IRB immediately. Upon notification that a previously enrolled research participant has become a prisoner and the PI wishes the prisoner to continue in the research the IRB will promptly re-review the project in accordance with the requirements of Subpart C (as applicable).

      All research activities for the now-incarcerated prisoner-participant must stop until the Subpart C requirements are met, except where the PI can justify that it is in the best interest of the participant to remain in the HHS-funded project while incarcerated. The IRB Chair may determine that the participant may

continue to participate until all requirements of Subpart C are satisfied.

b. If a **potential participant is an adolescent in a juvenile detention facility**, the individual is both a child and a prisoner. In such a case, HHS regulations at 45CFR46 Subpart C and Subpart D apply. In loco parentis will apply and the warden of the facility may sign the equivalent parental consent.

c. **Population has high risk of incarceration during course of the study (but are not prisoners)**. In this case, the IRB may choose to review the project under HHS 45CFR46 Subpart C. However, it should be noted that predetermination of a participant's potential for incarceration carries additional risks of violating the rights of justice and respect for persons.

6. **Expedited Review of Prisoner Research**

HHS regulations allow expedited review; however, OHRP recommends that the convened IRB review all research involving prisoners. Therefore, when the IRB employs expedited review of prisoner research, an IRB prisoner representative will be assigned as a designated IRB Member reviewer for the research application.

a. **Minor modifications to research**

i. If the changes impact prisoner research activities, the same procedure used for initial review must be used. This includes the IRB prisoner representative reviewing the changes as a designated IRB Member reviewer.

ii. If the changes are administrative in nature, the modifications may be reviewed by an IRB Chair or any designated IRB Member reviewer.

b. **Modifications involving more than a minor change reviewed by the convened IRB**

i. The same procedure used for initial review must be used. This includes the IRB prisoner representative reviewing the changes at the fully convened IRB Meeting.

c. **Continuing Review**

The same procedure used for initial review must be used. This includes the IRB prisoner representative reviewing the Continuing Review at the fully convened IRB Meeting if the project presents greater than minimal risk or acting as the Designated IRB Member reviewer if the project presents no greater than minimal risk.

i. If no participants have been enrolled in a project presenting greater than minimal risk, the project may be reviewed by the expedited review path in accordance with the appropriate expedited category (HRPP Policy 4.002).

d. **Existing Data/Record Review**

Research that does not involve interaction with prisoners (e.g. existing data, record review) may be reviewed by the expedited review path, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.

i. Review by a prisoner representative is not required.
ii. The prisoner representative may review the research as a reviewer or consultant if designated by an IRB Chair.

e. **Temporary Incarceration**
If the temporary incarceration has no effect on the study, keep the participant enrolled. If it does have an effect on the study, handle according to guidance in Section 5(a) & 5(c).

7. **Exempt Determinations**
The exempt review path shall not be used for research involving prisoners regardless of HHS funding or not.

8. **IRB Membership Requirements**
In addition to federal requirements regarding any research involving human subjects, the IRB will satisfy the following additional requirements when the research involves prisoners, regardless of funding source:
   a. The majority of the members of the IRB will not have an association with the prison(s) involved in the study.
   b. At least one member of the IRB present at the IRB meeting and involved in the review will be a prisoner or prisoner representative. The prisoner representative will have a close working knowledge, understanding, and appreciation of prison conditions from the perspective of the prisoner.
      i. The prisoner representative must be a voting member of the IRB. The prisoner representative may be listed as an alternate member who becomes a voting member when needed.
      ii. The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections. The prisoner representative will receive all review materials pertaining to the project (as will the rest of the IRB).
      iii. The prisoner representative must be present at a convened meeting when the project involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.
      iv. The prisoner representative must present their review either orally or in writing at the convened IRB meeting. The prisoner representative may attend the meeting in person, by phone, or videoconference.
   c. The IRB is aware that the special composition requirement for research involving prisoners involves not only the initial review of the project, but also continuing review, amendments, review of unanticipated problem reports involving risks to participants, and all other IRB matters pertaining to the project.

9. **IRB Findings**
The IRB will follow all pertinent federal regulations pertaining to human subject research as well as make seven additional findings for research involving prisoners regardless of funding source:
   a. The research represents one of the categories permissible under HHS regulations pertaining to research involving prisoners.

b. Any possible benefits to the prisoner through their participation in the research, when compared to general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that their ability to weigh the risks of the research against the value of such advantages in the limited-choice environment of the prison is impaired.
c. Risk involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
d. Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the PI provides justification to the IRB in writing for following other procedures, control participants will be selected randomly from the group of available prisoners who meet the eligibility criteria for that project.
e. Information is presented in language which is understandable to the participant population.
f. Adequate assurances exist that parole boards will not take into account a prisoner's participation in research in making decisions regarding parole. Each prisoner is clearly informed in advance that participation in the research will have no effect on their parole.

10. **Follow Up Exam or Care**

If the IRB finds there is a need for follow-up examination or care of participants after the end of participation, adequate provisions should be made for such examination or care, taking into account the varying lengths of individual prisoner's sentences and for informing participants of this fact. For the purposes of Subpart C, the IRB activities include making the specific findings required under HHS regulations along with protocol-specific findings justifying those determinations.

11. **Health and Human Services Funded Research - Notification to OHRP**

The IRB is responsible for providing certification to OHRP that the IRB has made the seven findings applicable to HHS funded research involving prisoners. The IRB will send a prisoner research certification letter to the OHRP Prisoner Research contact in OHRP to this effect, which includes:

a. The name and address of the institution.
b. Identification of the research project and relevant HHSR grant application.
c. A copy of paperwork necessary for IRB review.
d. Verification of a prisoner representative during review of the project.
e. Verification of the seven required findings at 45CFR46.305.
f. Determination that the research meets one of the categories of research permissible under 45CFR46.306.

12. **Department of Defense regulated research involving prisoners**

a. Research involving prisoners of war is prohibited
b. The IRB must be aware of the definition of "prisoner of war" for the Department of Defense component granting the addendum.

13. **Documentation of IRB Findings under Subpart C**

The IRB will fully document compliance with Subpart C in the minutes of the IRB meeting by documenting the required determinations and protocol-specific findings justifying those determinations. The IRB Approval document will also reflect compliance with Subpart C if applicable.

1. **Purpose**

   The purpose of this SOP is to describe the procedures for research involving children.

2. **Policy**

   It is the policy of the IRB that the board will review all exempt and non-exempt research projects involving participation of children in accordance with Health and Human Services regulations at 45CFR46 – Subpart D and applicable state law. The IRB will classify the research in accordance with Subpart D and document how and why the project meets the requirements.

3. **Definitions**

   a. **Age of Majority**: Defined according to the Annotated Code of Maryland, Article 1, Section 24(a). It states that "…a person eighteen years of age or more is an adult for all purposes whatsoever and has the same legal capacity, rights, powers, privileges, duties, liabilities, and responsibilities…and the 'age of majority' is hereby declared to be eighteen years."

      HRPP staff, in consultation with an IRB Chair or Designated IRB Member reviewer, will determine which individuals meet the DHHS definition of "children" in the case that the research is conducted outside of the state of Maryland.

      The exceptions to this rule are the following individuals who are able to consent to treatments or procedures involved in the research, so that they do not meet the DHHS definition of "children" and the additional protections if Subpart D are not required:

      i. Emancipated minors.
      ii. Individuals of any age where the research procedures are limited to: use of contraceptives; treatment for venereal disease; treatment for drug abuse.

      NOTE: For research conducted in jurisdictions other than Maryland, the research must comply with the laws regarding the legal age of consent in all relevant jurisdictions. The General Counsel for the University's Office will provide assistance with regard to the laws in other jurisdictions.

   b. **Assent**: A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

   c. **Children**: Persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted.

d. **Informed Consent:** Shall mean consent to a procedure based on information which would ordinarily be provided to the patient under like circumstances by health care providers engaged in a similar practice in the locality or similar localities. Failure to obtain informed consent shall include failure to obtain any express or implied consent for any operation, treatment, or procedure in a case in which a reasonably prudent health care provided in the community or similar communities would have obtained an express or implied consent for such operation, treatment, or procedure under similar circumstances.

e. **Commensurate:** The requirement that children and/or their parent/guardians are familiar with procedures that are reasonably similar in nature and risk proportionally to those the child has experienced, or is expected to experience, and not restricted to specific situations the child has experienced or will likely experience in the future.

f. **Disorder or condition:** A specific (or set of specific) physical, psychological, neurodevelopmental, or social characteristic(s) that an established body of scientific evidence or clinical knowledge has shown to negatively affect children's health and wellbeing or to increase their risk of developing a health problem in the future.

g. **Dissent:** A child's decision to decline participation in research.

h. **Emancipated Minor:** A legal status conferred upon persons who have not yet attained the age of legal competency as defined by Maryland state law, but who are entitled to treatment as if they had. Some minors do not meet the DHHS definition of "children", such as in Maryland individuals under 18 years of age who are legally emancipated or who are otherwise able to consent to the procedures involved in the research. Federal regulations require that to take part in research the legally effective consent must be obtained from such individuals or their legally authorized representative.

   Emancipated minor shall mean a person under eighteen years of age who is married or in the military, and it shall also mean a person under eighteen years of age who resides apart from his or her parents; is not under the care, custody, control, or supervision of his or her parents; and who receives no financial support or services from his or her parents and is responsible for securing his or her own support. The emancipation of a child is a question of fact, to be determined by the peculiar facts and circumstances of each case, and may be proved by circumstantial evidence, by an express agreement, or implied from the conduct of the parties. Emancipation may be terminated by a change of circumstances.

i. **Guardian**: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care [45CFR46.402(e)].

   NOTE: For research conducted in jurisdictions other than Maryland, the research must comply with the

laws regarding legally authorized representative in all relevant jurisdictions. The UMD Office of General Counsel will provide assistance to the investigator with regard to the laws in other jurisdictions.

j. **Legally Authorized Representative**: An individual or judicial body authorized under applicable law to give informed consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research [21CFR50.3(m)]. IRBs and clinical investigators should familiarize themselves with applicable local statutes and regulations pertaining to the definition of a legally authorized representative.

Parents and Guardians must meet the DHHS, FDA (if applicable), and Maryland definitions of a legally authorized representative. For persons with a "Power of Attorney", whether the power of attorney in each case will convey the authority to consent to participation on behalf of the principal in research depends on the specific language used in the durable power of attorney document.

The term "legally authorized representative" is not defined in the Maryland statutes. Under Maryland law there are essentially two different circumstances under which a person can act as a guardian or "legally authorized representative" for another adult. The investigator makes the decision about whether a person is a legally authorized representative, i.e., falls under the above. In general, researchers at UMD conducting research in Maryland and enrolling adults unable to consent can get permission for those individuals to participate in research from:

i. an individual's court appointed guardian which includes de facto health care Power of Attorney; or
ii. a person having "Power of Attorney" for another person.

NOTE: For research conducted in jurisdictions other than Maryland, the research must comply with the laws regarding legally authorized representative in all relevant jurisdictions. The UMD Office of General Counsel will provide assistance to the investigator with regard to the laws in other jurisdictions.

k. **Minimal risk:** The risks that normal, average, healthy children encounter while living in safe environments or the risks associated with routine physical or psychological examinations or tests. The determination of minimal risk should take into account that: 1) children face differing risks at different ages, 2) risks associated with repetitive tests may increase, and 3) special/unique characteristics may make a certain population more vulnerable than average children (e.g. hemophelia). The risk associated with routine examinations or tests are equivalent to a routine well-child examination.

l. **Minor increase over minimal risk:** The determination of whether the research procedures or interventions present a minor increase over minimal risk. In making this determination, the IRB will consider the following five criteria: magnitude, probability, duration, cumulative characteristics, and irreversibility of risk to the child.

m. **Parent**: A child's biological or adoptive parent. The father and mother are the nature guardians of their

minor children and are duly entitled to their custody and to direct their education, being themselves competent to transact their own business and not otherwise unsuitable. If either dies or is disqualified for action, or has abandoned his or her family, the guardianship devolves upon the other.

Therefore, in Maryland a father or mother of a child under the age of eighteen can act as a "legally authorized representative" of that child so long as their rights have not been terminated by law and so long as their minor child is not married or in the armed forces. For research conducted in jurisdictions other that Maryland, the research must comply with the laws regarding the legal age of consent in all relevant jurisdictions. The UMD Office of General Counsel will provide assistance with regard to the laws in other jurisdictions.

n. **Permission**: The agreement of the parent(s) or guardian(s) to the participation of his or her (their) child or ward in research.

o. **Vital importance**: The research is essential for the scientific understanding or evaluation of the procedures to alleviate the disorder or condition and perceived as essential to the understanding or amelioration of the child's disorder by practitioners and family stakeholders.

4. **Categories of Research**

Health and Human Services regulations specify that research involving children must be approvable under one or more of the following four (4) categories:

a. **Research not involving greater than minimal risk (e.g. most educational studies, studies in which behavior is not manipulated) (45CFR46.404)**
   i. The potential risks must be outweighed, or balanced, by the potential benefits to the participants and/or society.
   ii. Adequate provisions must be made for soliciting assent of the children and permission of the parent(s) or guardian(s).

b. **Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual participants (45CFR46.405)**
   i. The risk is justified by the anticipated benefit to the participants.
   ii. The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
   iii. Adequate provisions are made for soliciting the assent of the children and permission of their parent(s) or guardian(s).

c. **Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition (45CFR46.406).**
   i. The risk represents a minor increase over minimal risk.
   ii. The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.
   iii. The intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition, which is of vital importance for the understanding or amelioration of disorder, or condition.
   iv. Adequate provisions are made for soliciting assent of the children and permission of their parent(s) or guardian(s).

d. **Research, not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45CFR46.407).**
   i. The IRB will submit this category of research to Health and Human Services for approval, if the research is funded by Health and Human Services. If the research is not Health and Human Services-funded, the IRB will, at the board's discretion, convene an equivalent expert review panel.

5. **Process of Consent/Assent**

In accordance with 45CFR46.408(b) the IRB must determine that adequate provisions have been made for soliciting the permission of each child's parent or guardian.

In general, if an individual is not a parent, they can permit a child to take part in research only if that individual is legally authorized to make health care decisions for the child. Under federal law this is the case even for social and behavioral research. Before obtaining permission from an individual who is not a parent, make sure that the person is legally authorized to make health care decisions for the child. If needed, ask for written documentation of the individual's authority to make health care decisions on behalf of the child. If the person has such authorization, the individual can permit the child to take part in the research. If the person does not have such authorization, the individual cannot permit the child to take part in the research.

Parents or guardians must be provided with the basic elements of consent as stated in 45CFR46.116(a)(1-8) and any additional elements the IRB deems necessary.

The IRB may find that the permission of one parent is sufficient for research to be conducted under 45CFR46.404 or 45CFR46.405. The IRB's determination of whether consent must be obtained from one or both parents will be documented in the consent checklist when a project receives expedited review, and in meeting minutes when reviewed by the convened committee.

Consent from both parents is required for research to be conducted under 45CFR46.406 and 45CFR46.407 unless:

a. One parent is deceased, unknown, incompetent, or not reasonably available; or
b. When only one parent has legal responsibility for the care and custody of the child.

6. **Consent of a Mature Minor**

A minor may, with IRB approval, legally consent on his/her own behalf when he/she does not meet the DHHS definition of "child". In Maryland, if a participant under the age of 18 is legally declared emancipated, he/she may consent to participate in research because the individual no longer meets the DHHS definition of a child and therefore, Subpart D does not apply.

7. **Assent of Children**

In addition to obtaining parental/legal guardian consent (permission), the investigator must also solicit assent of minor participants age 7 years or older, unless the participant displays intellectual or emotional development below that of the average 7-year- old child. Obtaining assent shows respect for a child's developing autonomy. In most circumstances (non-therapeutic research), a child's deliberate objection should be regarded as a veto to his/her involvement in the research. Guidance on assent for different age ranges can be found on the UMD IRB website.

8. **Dissent of Children**

Dissent from participation or withdrawal from research is always to be honored unless the project affords access to a therapeutic intervention that is not otherwise available. In that case, parental consent for therapeutic intervention may override a child's dissent. However, that information must be provided to the child prior to the intervention procedure.

9. **Waiver of Assent**

Parents or guardians may, with IRB approval, override a young child's objections to interventions that hold the prospect of direct benefit to the child in accordance with 45CFR46.408(a). Assent may also be waived by the IRB under 45CFR46.116(d).

10. **Situations where Minors are Not Children**

Under the following circumstances, minors are not considered "children" and can consent for themselves:

a. If the research only involves a treatment for, which a minor's consent is permissible under applicable law (e.g., use of contraceptives, treatment for venereal disease or substance use).

b. If a participant under the age of 18 is legally declared emancipated, he/she may consent to participate in research.

11. **Waiver of Parental Permission**

Situations may be encountered where, with appropriate scientific rationale and justification, the IRB may approve a waiver of the requirements for parental consent. The research meets the criteria for waiver of informed consent in 45CFR46.116(d):

a. The research involves no more than minimal risk to the subjects;
b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
c. The research could not practicably be carried out without the waiver or alternation; and
d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

12. **Wards**

Health and Human Services regulations at 45CFR46.408 set specific requirements for children who have been declared wards of the state or any other agency, institution, or entity. Wards can participate in research approved under 45CFR46.406 or 45CFR46.407 if:

a. The research is related to their status as a ward.
b. The research is conducted in schools, camps, hospitals, institutions, or similar settings where the majority of children involved in research are not wards.
c. The IRB will require appointment of an advocate for each child who is a ward:
    i. The advocate serves in addition to any other individual acting on behalf of the child as a guardian or in the absence of the parent(s).
    ii. The advocate may represent more than one child.
    iii. The advocate must have the background and experience to act in the best interest of the child for the duration of the child's participation in research.
    iv. The advocate must not be associated in any way with the research, the investigator(s), or the guardian organization. The federal regulations do not specifically exclude IRB members from serving as a child advocate if the other conditions are met.

13. **Consent and Assent Documents**

a. **Parent/Guardian Consent Form**

If the participant is under the age of 7 years, only a Parental/Guardian Consent Form is required. The Parental/Guardian Consent Form should include all relevant elements of informed consent as outlined previously and be written in a proxy consent style that indicates it is the parent, or legal representative, who is consenting to allow the minor to participate in the study. The standard statements must be modified for the Parent Consent form (e.g., all references to "you" must be changed to "your child").

b. **Youth Assent Form**

If the participant is 13-17 years of age, a Youth Assent Form is required. The Youth Assent Form is based on the adult consent form but should be revised to meet the cognitive and educational level of an average youth. The assent form must contain simple language written at the appropriate educational level of the

youngest prospective participant in the youth age range. In some research projects, it may be necessary to utilize two assent forms written to accommodate participants at either end of the age range. The Youth Assent Form must contain all of the required elements of consent previously outlined in the IRB Guidelines except instructions about emergency care and rights of research participants and should follow the general format of the adult consent form.

c. **Child Assent Form**

If the participant is **under the age of 7 years**, only a Parental/Guardian Consent Form is required. However, verbal assent should be obtained as appropriate.

If the participant is **7 through 12 years of age**, a Child Assent Form is required. The Child Assent Form must be brief, without subheadings, and contain simple language arranged in brief paragraphs. The assent form must contain the following elements: title of the research study; opportunity to ask questions; basis for participant selection; purpose of the study; explanation of procedures; potential risks/discomforts; potential benefits; statement concerning consultation with parents; freedom to withdraw; and confidentiality statement.

14. **Documentation of IRB Findings**

Per federal regulations, the IRB will prepare and maintain adequate documentation of IRB activities. For the purposes of Subpart D, the IRB activities including making the specific findings required under Health and Human Services regulations along with project specific findings justifying those determinations. OHRP accepts documentation of project specific information justifying the IRB finding under Health and Human Services regulations at 45CFR46.404, 405, or 406. IRB actions will be documented in the approval letter. The IRB will fully document compliance with Subpart D in the IRB meeting minutes by noting the determinations and project specific findings justifying those determinations. The IRB Approval letter will also reflect compliance with Subpart D if applicable.

1. **Purpose**

   The purpose of this SOP is to describe the additional protections for participants with decisional impairment.

2. **Policy**

   It is the policy of the IRB that research involving participants with decisional impairment who cannot provide voluntary informed consent must include appropriate additional protections in accordance with the requirements of Health and Human Services regulations at 45CFR46.111(b).

3. **Definitions**
   a. **Participant with Decisional Impairment:** A person that lacks the ability to reason, exhibit sound judgment and provide voluntary consent to participate in research. The impairment may fluctuate (e.g., mental disorders), decline with time (e.g., Alzheimer's), or result from health conditions (e.g., coma or other infirmity).
   b. **Legally Authorized Representative (LAR):** The term "legally authorized representative" is not defined in the Maryland statutes. Under Maryland law there are essentially two different circumstances under which a person can act as a guardian or "legally authorized representative" for another adult. The investigator makes the decision about whether a person is a legally authorized representative, i.e., falls under the above. In general, researchers at UMD conducting research in Maryland and enrolling adults unable to consent can get permission for those individuals to participate in research from: an individual's court appointed guardian which includes de facto health care Power of Attorney; or a person having "Power of Attorney" for another person.
   c. **Institutionally Authorized Surrogate:** In the absence of a legally authorized representative as described in 3(b), no one can provide legally effective consent on behalf of a potential research participant. Under federal regulations Institutionally Authorized Surrogates who do not meet the DHHS definition of Legally Authorized Representatives may not provide consent on behalf of another individual unless the IRB has waived the requirement for informed consent.
   d. **Other Jurisdictions:** For research conducted in jurisdictions other than Maryland, the research must comply with the laws regarding legally authorized representatives in all relevant jurisdictions. The UMD Office of General Counsel will provide assistance to the investigator with regard to the laws in other jurisdictions.

4. **Acceptable Research**
   a. A participant with decisional impairment may participate in research involving great than minimal risk only of the research potentially offers an acceptable level of direct therapeutic benefit to that participant.
   b. A participant with decisional impairment may participate in research involving minimal or slightly above minimal risk without the prospect of direct benefit if a LAR is available and provides proxy consent.

5. **Use of Proxy Consent**
    a. If a potential participant has decisional impairment, the participant's LAR must provide written proxy consent.
    b. If a potential participant has decisional impairment but can execute a Durable Power of Attorney, the participant may grant authority to the holder of the Durable Power of Attorney to give written informed consent to participate in research on their behalf. The Durable Power of Attorney in this in this case is a Legally Authorized Representative (LAR). **Durable Power of Attorney Notes:**
        i. The Durable Power of Attorney may already be in effect, or one may be appointed to grant proxy consent for research participation.
        ii. The Durable Power of Attorney is to be used only with prior approval of the IRB.
        iii. The Durable Power of Attorney cannot be used if the prospective participant has a Legally Authorized Representative.
        iv. The prospective participant must understand the meaning of a Durable Power of Attorney and appoint someone of their choice.
        v. The person appointed as a Durable Power of Attorney must be willing to do so and understand the responsibilities involved.
        vi. Employees of UMD are not eligible for appointment as holder of a Durable Power of Attorney for a prospective participant unless they are the spouse, adult child, parent, or relative of the prospective participant.
        vii. A nursing home (e.g., owner, part-owner, manager, administrator, or employee, as well as spouses of these individuals) providing residential care to a participant or a community-based program is not eligible for appointment as holder of a Durable Power of Attorney for prospective participants.
        viii. Signed copies of the Durable Power of Attorney form should be maintained by the investigator.
        ix. The UMD HRPO must be contacted prior to appointing a Durable Power of Attorney.

    c. If a potential participant does not have a Legally Authorized Representative and is judged by the investigator to both lack the capacity to give consent and execute a Durable Power of Attorney, the research may only be conducted if the IRB waives the requirement for consent.

6. **Proxy Consent Form**
    The Proxy Consent Form must include all required elements of informed consent and be written in the proxy style that indicates that the Legally Authorized Representative (LAR) is providing permission to allow participants with decisional impairment to participate in the study.

7. **Adult Assent Form**
    The Adult Assent Form is based on the adult consent form but should be written in simple language aimed at the appropriate cognitive level of the participant with decisional impairment to be enrolled in the study. The Adult Assent Form must contain all required elements of informed consent.

8. **Application of Laws**

The IRB and/or investigators must apply State and local laws that reach beyond federal laws relevant to research involving human subjects. Examples of such laws are reporting of child abuse and educational privacy laws. The UMD Office of General Counsel (OGC) is available for advice in all cases as needed and requested. UMD HRPO staff and/or members of the IRB always have access to the UMD OGC for assistance in applying laws other than federal law to research involving human subjects.

1. **Purpose**

   Students are in a subordinate position to faculty members and instructors; therefore, a potential for coercion or undue influence exists when course credit is awarded for research participation. For this reason, recruitment of students in the laboratory or classroom requires additional participant protections.

2. **Policy**

   It is the policy of the UMD IRB that research involving the use of Extra Credit as Compensation must include additional protections for students, so they do not experience undue influence and are not compelled to participate. The following must be included in the IRB application submitted to the UMD IRB:

3. **Class Syllabus**
   a. Description of the proposed research activity along with the points allowed for extra credit must be included with the IRB application. It is recommended that the extra credit offered for research participation be worth no more than 2% of the course grade.
   b. Personal identifiers, such as names, initials, social security numbers, or institutional ID numbers (i.e. UID) should not be included in the research records to earn credit. If any of this information is required for distribution of extra credit, it must be collected separately from the research responses.
   c. Description of the alternative non-research activities to earn credit.
      i. The alternative activity should be equivalent in time, energy, and effort to participating in the research activity. For example, if the research requires half an hour to participate, the alternative activity should take the same amount of time to complete.
      ii. Alternatives activities should not be graded. If the research participant receives the credit for participating regardless of the quality of their participation, the alternative should be assessed on a similar participated/did not participate differentiation.
      iii. Alternate activities may include, but are not limited to:
         1. Attend a specific presentation on campus,
         2. Write an article/video review,
         3. Participation in alternative research studies

4. **Recruitment Procedures Requirements**
   a. The nature of the supervisory relationship between the investigator and the prospective participants must be described. This includes students in a class being taught by an investigator.
      i. If participants are recruited from an investigator's laboratory or class, the procedures used to avoid potential coercion must be described in the IRB Application. For example, use of a general bulletin board posting and no engagement in one-on-one solicitation; use of an individual to obtain consent that has no supervisory or instructional role relative to the prospective participant(s).
   b. Reference to approved department subject pool projects, if applicable, must be included in the IRB Application.

5. **Exclusions and Considerations**
   a. Students cannot earn extra credit for research activities completed by another person.
   b. Students who are required to perform research worker activities (i.e. recruiting subjects, conducting interviews) to obtain extra credit, must complete the required human subject research training prior to engaging in the research activities.

1. **Purpose**

   The purpose of this SOP is to describe the process of certification of review to funding agencies.

2. **Policy**

   It is the policy of the UMD IRB that certification of review will be sent to funding agencies in full accordance with regulations at Health and Human Services 45CFR46.

3. **Grant Application with Human Subject Research**

   When an investigator submits a proposal involving human subjects to the UMD Office of Research Administration (ORA), they will indicate that HSR will take place as part of the overall project. Upon receipt of the award notification ORA will contact the UMD IRB to confirm IRB Approval has been granted prior to releasing any funds. If the title on the IRB application on file does not match the title of the project listed on the proposal, the investigator should submit to the IRB an Amendment with either of the following:

   a. Addition of a second title (title on proposal) to the IRB application, or
   b. Substitution of a new title.

   Alternatively, if the differences in title are justified by the investigator as necessary, the PI may request a memo from the UMD IRB that confirms the title in the IRB application materials is related to the overall proposal title.

4. **Commercially Sponsored Contracts**

   It is preferable that titles match between all documents (i.e., contract, consent documents, and IRB application). The sponsor's protocol number may be included in the project title; however, the UMD IRB discourages inclusion of sponsor names in project titles.

1. **Purpose**

   The purpose of this SOP is to describe the Quality Assurance Program.

2. **Policy**

   It is the policy of the IRB to have a Quality Assurance Program to ensure compliance with applicable federal and state laws, the regulations at Health and Human Services 45CFR46, and all University policies designed to protect the health, safety, and welfare of human research participants.

3. **Quality Assurance Program**

   The Quality Assurance Program has been developed to reflect the vision, purpose, and mission of the Institution and the HRPP. The purpose of the program is to conduct activities designed to enhance the research process; assess compliance; educate researchers about ethical and regulatory responsibilities; and improve the overall quality, effectiveness, and efficiency of the UMD HRPP. The program is meant to be educational and collaborative rather than punitive in its approach. The Quality Assurance Program conducts routine monitoring activities, which include the following:

4. **Quality Assurance Reviews**

   a. **Purpose of Quality Assurance Reviews**

      i. To demonstrate the commitment of the HRPP to the safety, rights, and welfare of human research participants by verifying the implementation of approved research projects.

      ii. To conduct reviews that are designed to assist researchers and their staff by:
         1. Verifying compliance with the approved research project;
         2. Identifying areas in their research operations where there could be unrecognized potential for non-compliance with regulatory standards;
         3. Recommending best practices to minimize risks for study participants.

      iii. To identify standards of excellence and potential areas of improvement to enhance the quality of human research protections at the University of Maryland, College Park.

      iv. To design training materials, resources, and programs that identify and promote best practices; and to distribute these items to the UMD research community.

   b. **Selection of Projects for Quality Assurance Reviews**

      The Quality Assurance Program will select at least 12 Quality Assurance Reviews annually. Protocols will be selected for a Quality Assurance Review on a routine and for-cause basis. Investigators may also request to voluntarily undergo a Quality Assurance Review.

      i. **Routine Quality Assurance Reviews – Basis for Selection**
         1. The level of risk presented by the research activities (i.e. projects presenting greater than minimal risk to participants will be selected over projects presenting minimal risk);
         2. The inclusion of vulnerable populations; and
         3. The magnitude of IRB applications from the Campus Department and/or College (i.e. – A campus

department where researchers submit several IRB applications per year will result in the researchers from this Department having a higher likelihood of being selected for a Quality Assurance Review based on the HRPP algorithm used for selection of protocols).

Investigators who have a positive compliance review in the prior year will be removed from the sampling frame for the following year.

ii. **For-Cause Quality Assurance Reviews – Basis for Selection**

1. The request of the IRB, an IRB Chair, or the Institutional Official;
2. A concern, complaint, or allegation made by a participant, a researcher, or a member of the research team;
3. A project with continuing non-compliance;
4. A deviation, adverse event, or unanticipated problem report resulting in the need for follow-up or continuous monitoring.

c. **Elements of Quality Assurance Reviews**

i. **Review of project records**

1. Inclusion of appropriate regulatory citations on published approval letters;
2. Assessment of determined review path and category;
3. Inclusion and documentation of regulatory subparts;
4. Verification of project personnel;
5. Confirmation of valid human subject research training for all key personnel;
6. Documentation of additional approvals, if needed. This may include items such as school district approval letters, reliance agreements, or other letters of support;
7. Confirmation of compliance with IRB requirements for amendments, continuing reviews, and reportable events.

ii. **Onsite or Virtual Visits**

1. Onsite visits maybe requested for:
    a. Routine and for-cause quality assurance reviews;
    b. Lab studies and/or research projects requiring subjects to visit a research site;
    c. Research projects with hardcopy documentation such as signed consent forms;
    d. Projects presenting greater than minimal risk to participants;
    e. Other research projects as deemed appropriate by the QA Program Manager.

2. Onsite visits will be requested using the following procedures:
    a. Prior notification of the visit;
    b. Scheduling the visit time with the investigator;

c. Informing the investigator of the specific records (e.g. consent forms) or procedures (e.g. data storage and security) that could be reviewed during the visit.
d. Informing the investigator of topics or questions that may be discussed with members of the research staff during the visit.

3. Onsite visits will be conducted using the following procedures:
   a. The QA Program Manager will interview members of the research team. Topics may include:
      i. Recruitment processes.
      ii. Consent procedures.
      iii. Enrollment numbers.
      iv. Storage of research documents and data.
      v. Personnel with access to data.
      vi. Any unexpected and/or adverse events.
      vii. Any feedback regarding the IRB.
4. The QA Program Manager will review a sample of the most recently collected consent forms.
5. The QA Program Manager will ask the researchers to show them around the laboratory, highlighting areas where participants complete tasks as part of the approved research project.

iii. **Virtual Visits:**

1. Virtual visits may be requested for:
   a. Routine and for-cause Quality Assurance Reviews.
   b. Instances where researchers are remote and/or availability is limited.
   c. Research projects with electronic study documentation, (e.g. digitally signed consent forms).
   d. Research projects presenting no greater than minimal risk to participants.
   e. Other research projects as deemed appropriate by the QA Program Manager.

iv. **Virtual visits will be requested using the following procedures:**

1. Prior notification of the visit.
2. Scheduling the visit time with the investigator.
3. Informing the investigator of the specific records (e.g. consent forms) to provide via a secure storage system to the QA Program Manager prior to the visit.
4. Informing the investigator of topics or questions that may be discussed with members of the research staff during the visit.

v. **Virtual visits will be conducted using the following procedures:**

1. The QA Program Manager will interview members of the research team. Topics may include:
   a. Recruitment processes.
   b. Consent procedures.
   c. Enrollment numbers.

d. Storage of research documents and data.
e. Personnel with access to data.
f. Any unexpected and/or adverse events.
g. Any feedback regarding the IRB and/or QA review process.

2. The QA Program Manager will review a sample of the most recently collected consent forms via a secure storage system. This will typically occur prior to the virtual visit so that the QA Program Manager can ask questions, if needed.

d. **Quality Assurance Report**

At the conclusion of the Quality Assurance Review, the QA Program Manager will issue a report. The report will be emailed to the key personnel listed on the project and a copy of the report will be sent to the to the HRPP Director. The report will include a summary of the discussion that took place during the visit, as well as any recommended and/or required corrective actions.

i. Recommended actions are intended to provide the research team with best practices or suggestions to consider in the future.
ii. Required actions are items that the investigators must address within a two-week period. These actions may require the submission of a corrective action plan depending on the nature of the non-compliance included in the report.

Investigators will be asked to review and sign the report within two weeks. A copy of the final report will be presented to the IRB at the next full board meeting.

5. **Routine Quality Assurance Monitoring**

Routine Quality Assurance monitoring activities are designed to maintain compliance and assist in improving the overall quality, effectiveness, and efficiency of the HRPP. These activities include:

a. **Checklist monitoring:** The QA Program Manager reviews a random sample of IRB Member reviewer checklists, subpart checklists, and full board reviewer worksheets on a quarterly basis. During the QA review, the QA Program Manager ensures that the checklists are complete and in compliance with the information provided in the IRB application.
b. **Approval Letter monitoring:** The QA Program Manager reviews a random sample of published IRB approval letters each quarter. The sample includes expedited and full board approval letters. During the QA review, the QA Program Manager ensures that the approval letters list the correct regulatory citations, review categories, and feedback from the IRB Chair or IRB.
c. **Reliance Agreement monitoring:** A random sample of Reliance Agreements are reviewed by the QA Program Manager each quarter. The sample includes agreements in which UMD is both the reviewing and relying IRB. Agreements are monitored to ensure compliance with AAHRPP Standards, SMART IRB Standard Operating Procedures, and the Common Rule.

d. **IRB Minutes monitoring:** Each month the QA Program Manager reviews the IRB Meeting minutes to ensure accuracy and adherence to federal regulations. The QA Program Manager ensures that minutes include each of the following:
   i. Attendance at the meeting.
   ii. Actions taken by the IRB.
   iii. The vote on actions.
   iv. The basis for requiring changes in or disapproving a project.
   v. A summary of the IRB discussion regarding the reviewed projects.
   vi. A summary of the IRB discussion regarding regulatory requirements for applicable subparts.
   vii. Documentation of scientific merit.
   viii. Suspension of enrollment, if necessary.

e. **Quality Assurance Tag monitoring:** Once a quarter, the QA Program Manager will check for projects labeled with a QA tag in the electronic submission system. The QA tag is placed on projects that require follow-up with the research team. The QA Program Manager will assess the QA details and follow-up with the research team as needed.

f. **Reporting of Quality Assurance Monitoring Outcomes:**
Findings resulting from routine Quality Assurance monitoring activities are reported to the HRPP Director each quarter. Results are also reported to the Institutional Official on an annual basis. Improvements, changes or need for additional education as a result of QA findings is implemented, as needed, on a continuous basis.

6. **Quality Improvement / Assessment of the HRPP**
   a. **Purpose of the Quality Improvement**
      i. To conduct ongoing assessments of the HRPP in terms of quality, effectiveness, and efficiency.
      ii. To identify strengths and weaknesses of the existing HRPP and to highlight areas needing improvement.
      iii. To provide recommendations for improvement through the development of Quality Improvement Plans.
      iv. To document improvements made by the HRPP in areas of compliance, quality, effectiveness, and efficiency.

   b. **Quality Improvement Assessment Activities**
   Several activities and methods will be used to review the HRPP in terms of quality, effectiveness, and efficiency. The items listed below represent a few of the routine activities used to assess the HRPP. Please Note – this is not an exhaustive list.
      i. **Annual IRB Survey:** This is distributed to the UMD research community via the IRB listserv to collect feedback on the HRPP. The questions included in the survey may change from year to year to accommodate changes in the research environment, the HRPP, and identified areas of

interest/improvement. Results from the survey will help the HRPP identify, strengths, weaknesses, and areas of improvement. Additionally, survey results will be presented to the fully convened IRB for t transparency and discussion.

ii. **IRB Member Evaluation Survey:** IRB Members will be asked to complete an annual IB Member Self Evaluation Survey. The IRB Member Self Evaluation Survey will include questions asking members to assess the HRPP. This will provide IRB Members with the opportunity to provide feedback to the HRPP anonymously. Results from the survey will help the HRPP to identify strengths, weaknesses, and areas of improvement. Additionally, survey results will be presented to the fully convened IRB for transparency and discussion.

iii. **Annual Reports:** The Quality Assurance Program compiles an Annual IRB Report which is reviewed by the HRPP Director, the IRB Chairs, and the Institutional Official. The report highlights a variety of metrics. A few of which include: IRB review turnaround times, funding information, comparisons to AAHRPP member institutions, Post Approval Monitoring goals and activities, and IRB feedback received from the UMD research community.

iv. **Quality Assurance Reviews:** When conducting Quality Assurance Reviews, the Quality Assurance Program Manager asks researchers about their experience working with the IRB. Feedback from these interviews are documented in an excel spreadsheet and communicated to the HRPP Director.

v. **Community Outreach Assessments:** The HRPP Director, Quality Assurance Program Manager, IRB Specialists for Education and Improvement, and IRB Chair(s) conduct periodic assessments of the HRPP outreach activities. These assessments are done on a quarterly basis and occur more frequently if necessary. (HRPP Policy 17.001)

vi. **HRPP Emergency Preparedness Evaluation:** The Quality Assurance Program Manager is responsible for a periodic evaluation of the HRPP Emergency Preparedness Guidance to ensure that it adequately addresses the standards set forth by AAHRPP Element I.1.H. The QA Program Manager meets with the HRPP Director at least once a year to discuss any proposed changes and/or improvements to the existing HRPP emergency guidance. (HRPP Policy 18.001)

c. **Quality Improvement Log**

The Quality Assurance Program documents the improvements made to the HRPP each year in a spreadsheet. The spreadsheet categorizes the improvements made by the HRPP in terms of compliance, quality, effectiveness, and efficiency. It lists: the improvement item, the objective(s) of the item, and the method for evaluating the item moving forward.

The spreadsheet is reviewed with the HRPP Director on a quarterly basis, and more frequently, if needed.

d. **Quality Improvement Plans**

The HRPP Director and Quality Assurance Program Manager meet monthly to discuss the strengths and weaknesses of the existing HRPP. The Quality Assurance Program Manager uses the assessments listed above to highlight areas of the HRPP that require improvement. Recommendations for improvement are established through the development of Quality Improvement Plans.

Quality Improvement Plans aid in defining goals and measurable objectives to make improvements to the HRPP. Improvement actions are documented in the Quality Assurance Plan and a method for continuous assessment and monitoring is provided.

e. **Results of Quality Improvement Assessments**

Results of Quality Improvement Assessments are reported to the HRPP Director monthly. Results are reported to the Institutional Official on an annual basis.

Improvements, changes, or the need for additional education is implemented as needed.

1. **Purpose**
   The purpose of this SOP is to describe the requirements for research conducted by UMD students.

2. **Policy**
   It is the policy of the UMD IRB that research conducted by UMD students will adhere to the regulations set forth in 45CFR46 as well as the ethical standards contained in the Belmont Report.

3. **Research, Clinical Practica, and Class Projects**
   Research, clinical practica (usually in the form of course-related research or evaluation projects and/or directed studies) and class projects are designed to provide students an opportunity to practice various research methods such as interview, observation and survey techniques, measurement of behavior (e.g., reaction time, speech, problem solving) as well as data analysis. Typically, such projects are quite limited in scope, are not considered systematic investigations designed to develop or contribute to generalizable knowledge, and are not undertaken with that goal in mind.

   Such projects should not put the participants at more than minimal risk, and the data must be recorded anonymously by the students (e.g., with no names, social security numbers, or any other codes that can be linked to a list of names). These projects are considered "classroom exercises", are not systematic investigations designed to develop or contribute to generalizable knowledge and are not subject to review by the IRB. They do not require review unless the student researcher is conducting research involving human participants (the activity is a systematic investigation designed to develop or contribute to generalizable knowledge) and the student is interacting or intervening with living individuals to obtain information about those individuals or collecting private identifiable information about living individuals. If the student anticipates publishing the results or presenting at a professional meeting, consultation with the IRB is encouraged determine the appropriate review path.

4. **Research Projects (Directed or Independent)**
   Any research conducted by students that does not fall under the definition of a research or clinical practicum, which involves human subjects and, which is a systematic investigation designed to develop or contribute to generalizable knowledge, must be reviewed and approved by the IRB. This includes, but is not limited to, all independent undergraduate research projects and honors theses, masters' theses and dissertations that meet the definition of human subject research.

   Recognizing the time constraints imposed on projects that must begin and be completed within a single semester, the IRB will make every effort to work with instructors to process IRB applications promptly. However, instructors must plan for and allow adequate time for the review process (roughly 2-4 weeks, depending on the need for expedited or full board review). Instructors and/or students should submit IRB Applications within the first three weeks of the semester for projects that must be completed during the current semester.

5. **Faculty Advisor Responsibilities**

Faculty advisors must be included on any IRB application where a student is listed as Principal Investigator. Faculty advisors must complete the required human subject research training (Biomedical Research Investigators or Social & Behavioral Investigators) course for the IRB review process for a student project to begin.

It is the responsibility of faculty advisors to guide and oversee the IRB application submission process when an undergraduate or graduate student is the Principal Investigator. For example, faculty advisors have the responsibility to assist students in preparing review materials for the IRB and to ensure that the research is conducted in accordance with the UMD Federal wide Assurance with the federal government and with applicable UMD policy.

6. **Potential Practicum Problems**

Students engaged in the process of learning research techniques understandably want to focus on compelling or real-life issues. In the process of reviewing student research, however, the IRB has found topics and subjects that raise concerns for the well-being of the participants and students themselves. Projects collecting data about illegal activities, those which could cause emotional distress in the participants, those which would place the students at risk if confidentiality were breached, and those with children as participants, need to be constructed with special care.

While practica are not under the purview of the IRB, the staff of the IRB is available for consultation with students and for class presentations regarding issues of the protection of the rights and welfare of human participants. It is important to note that data collected as practica cannot later be used for presentation at conferences, publications, or doctoral dissertations. However, if a retrospective data review would be conducted on this data intended for contribution to generalizable knowledge, an IRB Application must be submitted to the IRB for review and approval.

7. **Activities Requiring IRB Review**

"All research involving human subjects must be reviewed and approved by the IRB" (HRPP Policy 3.001). This directive includes research conducted by students.

To determine if the activity meets the definition of research, the investigation must "be a systematic investigation designed to develop or contribute to generalizable knowledge". If the results of the investigation will be, or has the potential to be, published or presented through oral presentations, abstracts, or posters outside of UMD, the definition of research is likely met. Accordingly, if the research involves human subjects, it is subject to IRB review.

However, if the results of the investigation will be limited to publications, oral presentations, posters, or abstracts solely on the UMD campus, and relatedly are not systematic investigations designed to develop or contribute to generalizable knowledge, IRB review would not be required.

To determine if a project meets the definition of human subject research, a Human Subject Research Determination Form can be completed and submitted through the IRB electronic submission system. The IRB Office will provide an

official memo to the PI if the project does not qualify as human subject research. If the project does qualify as human subject research, the PI will be instructed to complete and submit the necessary IRB application documents.

8. **IRB Application and Review**

There is not a separate IRB review process for student research. The student researcher is expected to follow all current IRB policies and procedures for IRB initial approval, continuing review, change requests, and other project matters. All deadlines and time frames will remain the same as for other researchers falling under the jurisdiction of the IRB.

Key personnel for research conducted by students must include:

a. The student as PI. It is the student's responsibility to carry out all obligations of a project PI.
b. The student's faculty advisor as the supervising investigator. It is the responsibility of the faculty advisor to supervise the student's research project and provide necessary advice concerning IRB requirements and applicable federal regulations. Faculty who assign or supervise research conducted by students or staff have an obligation to consider carefully whether those individuals are qualified to adequately safeguard the rights and welfare of subjects and have been properly trained in human subject research protections.
c. Other supervising investigators and/or participating personnel as applicable.

9. **Training – Human Subject Research Protections**

The IRB requires that all study personnel engaged in human subject research be certified by completion of a web-based training program (CITI). All students conducting human subject research must complete CITI training prior to IRB approval of the research. This includes exempt research. (HRPP Policy 3.010)

Students participating in classroom projects that do not require IRB review are not required to complete CITI training. However, some colleges, departments, and sections may adopt internal requirements for all students to complete CITI training.

1. **Purpose**

   The purpose of this SOP is to describe the guidelines required when conducting epidemiological research.

2. **Policy**

   It is the policy of the IRB that all epidemiological research will be performed in accordance with the regulations set forth in 45CFR46.

3. **Definition**

   Epidemiological research is defined as the collection and analysis of medically relevant data about individuals or groups to determine the causes, distribution, and control of diseases in populations.

   Some epidemiological research requires access to sources of Protected Health Information (e.g., medical records, databases, disease registries, and hospital discharge records). As a result the greatest risk associated with this research is breach of confidentiality and privacy. While the HIPAA Privacy Rule is not intended to obstruct epidemiological research, the investigator must understand and follow specific rules in order to meet the HIPAA Privacy Rule regulations, if applicable, as well as minimize the risks.

4. **Project Development**

   During the development of an epidemiological research protocol, the investigator must consider several questions and be prepared to justify the responses in the IRB Application. Consideration of these questions will aid the investigator in meeting the requirements of the Privacy Rule, Health and Human Services regulations at 45CFR46, as well as all applicable IRB requirements:

   a. What is the purpose of the research and what data is required to achieve the purpose of the research?
   b. Will retrospective (already existing) or prospective (collected in the future) data be used in the study?
   c. Where will the data come from (e.g. medical record review, databases, registries, or clinical interaction with subjects)?
   d. Will the research involve banking of data for future use or for purposes that are not integral to the current research?
   e. Does, or will, the collected data contain Protected Health Information (PHI) or other information that can be directly, or indirectly, linked to a participant? If yes, why will the link be required and how long will identifiers be retained?
   f. Does the investigator have ethical access to the data (e.g. through a treatment relationship with the potential participants or through control of an existent database?
   g. Does the investigator have the potential to collect data on the participant (e.g. proband) and other related individuals (e.g. family members) identified by the participant or through other means (e.g. surveys and/or questionnaires)?

5. **Protected Health information**

Identifiers

The Privacy Rule states that only the minimum Protected Health Information necessary to achieve the research objective can be used. Where it has been determined that participant identifiers are crucial to the research, the investigator must list the identifiers to be used and provide justification for their use (HRPP Policy 10.001 for a list of identifiers).

Limited Data Set

In cases where the investigator provides justification for a need to maintain subject links to the data, the use of a Limited Data Set should be considered (HRPP Policy 10.002).

To obtain a Limited Data Set the investigator must complete a Data Use Agreement. This will identify the investigator as the recipient of the Limited Data Set, how the data may be used and disclosed by the investigator and provide assurances that the data will be protected.

During consideration of the application, the IRB will determine if the use of the limited data set meets the HIPAA, if applicable, and Health and Human Services requirements for waiver of informed consent.

De-identified Data Set

If the data has been de-identified, the IRB will consider one of the following review options:

a. The IRB may determine that the project qualifies for exempt review under Health and Human Services regulations at 45CFR46.101(d).
b. The research is not considered human subject research and would not be subject to Health and Human Services regulations at 45CFR46.

6. **Informed Consent**

Informed consent must be obtained from the participant, unless the IRB approves a waiver or alteration.

7. **Waiver or Alteration of Informed Consent**

While protection of patient privacy and confidentiality is the primary goal of the HIPAA regulations, it is understood that situations may arise where obtaining informed consent may not be practicable (e.g. research conducted on existing databases or repositories where no contact information is available). In these cases, HIPAA and Health and Human Services regulations have provided criteria required to justify granting a waiver or alteration of informed consent, if approved by the IRB. The following criteria must be met (HRPP Policy 9.006):

a. The use or disclosure of Protected Health Information (PHI) involves not more than minimal risk.
b. An adequate plan to protect identifiable health information from improper use and disclosure must be presented to the IRB (e.g. data is coded or linked and the codes are stored separately).

c. Using the "reasonable person standard", the alteration of waiver of informed consent will not adversely affect the rights and welfare of the individuals.
d. The research cannot practicably be conducted without the waiver or alteration of informed consent and justification is provided.
e. The research cannot be conducted without access to and use of the PHI. The objectives and validity of the study must provide justification for the use of specific PHI.

8. **Participant Recruitment**

All participant recruitment activities must be approved by the IRB (HRPP Policy 3.011).

IRB approval of the recruitment plan is particularly important in situations where the investigator requests that a participant identify family members (or other individuals) that might qualify for the study. It is important to note that the investigator has ethical access only to the enrolled participant, not those individuals identified by the participant. The investigator, or specialist, may not directly contact the family members (or others) without permission of those individuals.

The IRB recommends where possible the following recruitment plan be utilized:
The participant may be asked if they have family members that might qualify for the study. Rather than request the names and contact information, the investigator should ask the participant to speak with family members about the project. The participant may be provided an IRB-approved informational brochure or letter to give to the family member. The brochure/letter should provide information on whom to contact for further information. Alternately, it would be appropriate to provide self-addressed stamped postcards to the participant to hand out to family members. Interested family members (or others) could indicate their interest by returning the card with names and contact numbers filled in. In both cases, contact would be initiated by individuals expressing an interest in the study.

9. **Registries**

Recruitment registries generally require IRB approval, both for the creation and maintenance of the registry itself, as well as for future projects that wish to use a registry as a recruitment method. The UMD IRB considers each project on a case-by-case basis and will apply the appropriate human subject research protection regulations and HIPAA regulations, as applicable. Some projects may not be considered human subject research but may still be subject to HIPAA privacy regulations. Examples of registries:

a. Building and maintaining a registry or database for current/active research purposes – requires IRB approval.
b. Building and maintaining a registry or database for future research purposes - requires IRB approval.
c. Creating and maintaining a registry or database for quality improvement purposes – does not required IRB approval. However, if this registry or database will be accessed for research purposes, IRB approval is required.

Registry Development

There are two separate activities to consider in the development of a registry or database. Each is considered a separate research activity under the HIPAA regulations and will require IRB-approved participant authorization, unless the IRB grants a waiver or alteration to the informed consent requirement:

a. The use or disclosure of Protected Health Information for creating a research database or repository.
b. The use or disclosure of Protected Health Information in the database for a future research purpose.

IRB Considerations

During review of an IRB application to create a registry or database, the IRB must consider:

a. Will the registry or database maintain PHI? If yes, what is the justification?
b. Will written HIPAA authorization be required, or does the registry or database meet the qualifications for a waiver or alteration of informed consent? In most cases, if the registry or database involves collection of data through direct intervention or interaction with the participant, the IRB will require written HIPAA authorization.
c. Has the investigator provided sufficient assurance that the PHI in the registry or database will not be used or disclosed for future research without IRB approval prior to use?

1. **Purpose**

   The purpose of this SOP is to describe the guidelines required when conducting studies that include exercise activities.

2. **Policy**

   It is the policy of the IRB that all exercise studies will be conducted in accordance with regulations at Health and Human Services 45CFR46.

3. **Definition**

   The American College of Sports Medicine has published guidelines for studies involving exercise testing which are recognized as national standards. The guidelines are largely based on the following criteria:

   a. Intensity of exercise.
   b. Age of participant.
   c. Apparent health status of participant.
   d. Apparent fitness/activity level of participant.

   These criteria determine health screening, monitoring, physician oversight and the IRB review path of the project. The IRB reserves the right to rule in exception to the exercise guidelines if necessary.

4. **Health Screening**

   Appropriate participant health screening is required prior to the initiation of any maximal or sub-maximal intensity exercise test or program. Physician approval is required for those who may be placed at greater risk by participating. A questionnaire may be administered by qualified study personnel to participants that are at lower risk. This questionnaire and any required physician approval forms must be included with the IRB Application.

5. **Maximal Exercise Activities**

   a. **Cardiovascular Endurance**

      Cardiovascular endurance exercise procedures that are higher in intensity than 90% of maximal heart rate or 85% of maximal oxygen uptake or heart rate reserve maximum are regarded as maximal exercise and requires review by the full IRB.

   b. **Muscular Strength/Endurance**

      Muscular strength/endurance exercise procedures using maximal (e.g., one-to-five) repetitions require full IRB approval regardless of participant health, activity level, and/or age. Isokinetic exercise testing programs (e.g., Biodex) at slow movement speeds are included in this category.

      Scientific justification will be required to support the use of exercises that are considered high risk. These exercises include, but are not limited to

      i. Squat.

ii. Dead lift.
iii. Clean and jerk.
iv. Overhead press.
v. Any equivalent of the above.

6. **Other Exercise Activities**

Investigators intending to use exercise procedures not addressed in these guidelines should compare the proposed exercise to the most closely related category and classification. Attention should be given to the intensity of the exercise, the age of the participant, the apparent health status of the participant, and the apparent fitness/activity level of the participant. Finally, the appropriateness of the exercise should be considered in relation to these factors.

1. **Purpose**

   The purpose of this SOP is to describe the guidelines for research conducted in foreign countries.

2. **Policy**

   It is the policy of the IRB that all research in foreign countries will be conducted in accordance with the regulations at Health and Human Services 45CFR46. The IRB will review all human subject research being conducted in foreign countries regardless of the foreign institution's IRB or Ethics Committee approval system.

   For research conducted in jurisdictions other than Maryland, the research must comply with the laws regarding legally authorized representative in all relevant jurisdictions. The UMD Office of General Counsel will provide assistance to the investigator with regard to the laws in other jurisdictions.

3. **Non-Federally Funded Research**

   Non-federally funded research that is conducted in a foreign country is subject to all IRB requirements except that certain IRB requirements can be waived in consideration of the culture and local customs of the country in which the research is conducted. Investigators who seek a waiver of any IRB requirements must provide appropriate justification to the IRB.

   a. Any justifications for waivers of IRB requirements based on claims of local practices or customs will be independently verified with the foreign institution and/or appropriate governmental agency.

4. **Federally Funded Research**

   Federally funded research that is conducted in a foreign country is subject to all of the IRB requirements with exceptions granted in accordance with the federal (model) policy and OHRP guidance.

   According to the model policy for the protection of human participants and OHRP requirements, when federally funded research takes place in foreign countries, a FWA must be filed. However, procedures normally followed in the foreign countries to protect human participants may differ from those set forth in the model policy. In these circumstances, a department, or agency head, must determine that the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in the model policy. If the procedures meet these criteria, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in the model policy.

5. **IRB Requirements**

   Research that includes collaboration with an international institution must provide assurance to the IRB that all of its activities related to human participant research, regardless of funding source, will be guided by the ethical principles in one of the following documents:

   a. Declaration of Helsinki

b. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
c. Other appropriate international ethical standards recognized by federal departments and agencies that have adopted the US Federal Policy for the Protection of Human Subjects. A copy of these standards must be provided by the institution.

In addition, the IRB requires confirmation of IRB approval (or equivalent) from the foreign site, a copy of the protocol, and a copy of the informed consent document.

6. **Verification of International Research Standards**

The IRB will maintain links to information resources that provide information on foreign country regulations on human subject research. The DHHS Office for Human Research Protection (OHRP) maintains the International Compilation of Human Research Protections. The Compilation lists the laws, regulations, and guidelines for over 50 foreign countries.

This Compilation is maintained in electronic format, with direct web links to each country's regulatory organizations, laws, and other resources that establish local standards. OHRP provides this Compilation to assist researchers and IRBs in verifying that research studies are complying with local laws and customs. The Compilation can be accessed on the OHRP website: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html

7. **Knowledge of Local Laws**

For research involving and international study site, the IRB will ensure appropriate knowledge of cultural context through:

a. Reliance upon the local context review of an IRB or Ethics Committee (EC) in the country or region where the research will take place.
b. Utilizing a consultant with expertise in the country or region where the research will take place.

The IRB will confirm the qualifications of the researchers and research staff for conducting research in that country through:

c. Requiring of human subject research training.
d. Requiring a description of the researchers' knowledge of the foreign site, experience with conducting research in the international location, and understanding of the local culture.
e. Ensuring adequate resources exist within the country that researchers plan to conduct their study (i.e. local collaborators, local institutional affiliation).

The IRB will conduct initial reviews, continuing reviews, and reviews of modifications to previously approved projects for all research, ensuring that all requirements for conducting research in a foreign country are met throughout the totality of the study.

The consent process and documentation will be reviewed during the initial review, continuing reviews, and any modifications involving changes to these processes or documents. All consent documents that will be provided in languages other than English must be reviewed and approved by the IRB office before use by the research team. For studies that are greater than minimal risk, outside consultants may be utilized to confirm the appropriate translation and delivery of consent documents.

8. **Post Approval Monitoring**

The Quality Assurance Program Manager and/or Director – HRPP will handle reports of complaints, non-compliance, and unanticipated problems involving risk to participants or others. If determined by the IRB, a for-cause review (audit) of the project will take place in accordance with HRPP Policy 7.001.

1. **Purpose**

   The purpose of this SOP is to describe the guidelines for community-based research projects.

2. **Policy**

   It is the policy of the IRB that all community-based research projects will be conducted in accordance with the regulations at Health and Human Services 45CFR46.

3. **Definition of Community Based Research**

   Community-based research (CBR) is a research paradigm that attempts to make research a more inclusive and democratic process by fostering the development of partnerships between communities and academics to address community- relevant research priorities. The CBR paradigm emerged from research with autonomous indigenous communities, particularly American Indian tribes, but has expanded to a broader scope. Broadly, communities in this research domain represent population groups with social structures, common customs, and acknowledged leadership. These communities may include nations, cultural groups, small indigenous communities and some neighborhood groups.

   Some of the unique elements of CBR include: **1)** active engagement and shared decision-making of community members and academic researchers, **2)** involvement of community approval and representation in the research approval, design, and implementation, **3)** integration of community social action, social change, priorities with the scientific objectives of the academic researchers, and **4)** consideration and respect for the rights of the community in all aspects of the research.

4. **Special Considerations**

   In CBR human protections are not just about individuals but the respect, beneficence, and justice for the community. As such, the IRB review process requires documentation of access and approval to conduct research in communities.

   Most communities do not have the equivalent of an IRB, and even those with some formal ethics review process typically do not have an established FWA. As such, the UMCP IRB cannot use a formal collaboration agreement to address the dual processing of human subjects' protections at the community and university levels. Rather, we have established the following additional review guidelines for CBR:

   a. IRB review of CBR adds the principle of "respect for communities" or "respect for cultures" as a criterion for assessing the proposed research.
   b. IRB review of CBR will request the inclusion of additional, pertinent information from researchers concerning community-based research and any special considerations that are required to meet specific community needs. For example, the IRB may request information on how results from the study will be disseminated to the communities to ensure fair and appropriate access and distribution of potential benefits from knowledge obtained through the study.

c. Written consent or acknowledgement must be obtained from a community leader or group of community leaders prior to starting IRB approved research activities.
d. If the study is not approved by the community, individual informed consent may not be used as an alternative to gaining community approval.
e. For CBR projects that require full IRB review, the IRB review will include IRB members or consultants with expertise in community-based research.

5. **Community Based Research Resources**

There are several resources available to guide and aid university investigators in the design and implementation of CBR.

Investigator Resources

a. Community Campus Partnerships for Health for the Robert Wood Johnson: www.ccphealth.org.
b. Agency for Health Care Research and Quality literature review on CBR approaches: https://archive.ahrq.gov/clinic/epcsums/cbprsum.htm
c. UMD Center for Community Engagement: https://oce.umd.edu/

IRB Resources

a. The IRB has access to member of the UMD research community who have expertise CBR and can be called upon to provide expertise for IRB review of CBR.
b. Continuing education of IRB members in community-based research will be provided to ensure that members remain informed of best practices and ethical considerations for this type of research. Continued education may be accomplished through scholarly articles discussed at each convened IRB meeting, webinars provided by the Division of Research, and/or special guest speakers invited to speak at IRB meetings.

1. **Purpose**

   The purpose of this SOP is to describe the required elements for informed consent.

2. **Policy**

   It is the policy of the IRB that informed consent is documented in accordance with and to the extent required by 45CFR46.116 unless justification for a full waiver is met according to 45CFR46.116 or justification for a waiver of documentation is met according to 45CFR46.117. The UMD IRB does not utilize short form consent documentation or broad consent.

3. **Investigator Responsibilities**

   The investigator has a legal and ethical obligation to ensure that the prospective research participant has sufficient knowledge and comprehension of the elements of informed consent, meaning that the prospective research participant must be able to make an informed decision whether to participate in research. Obtaining informed consent should be seen as a communication process and not as an act of signing a form. As part of the process of obtaining informed consent, each element of consent should be explained clearly to the prospective participant. In addition, the investigator should periodically assess the prospective participant's comprehension by asking appropriate questions. Ultimately, the investigator bears responsibility for obtaining valid informed consent from the participant.

   Investigators should be sensitive to the possible needs of an interpreter or translator for participants who do not speak English as a first language or who are hearing or visually impaired.

4. **Required Elements of Informed Consent**

   Informed consent shall include the elements of consent outlined in 45CFR46.116 as applicable to the study and study population. UMD IRB specific guidance for informed consent will be located on the UMD IRB website and will be updated as needed. Additional informed consent requirements include:

   a. Approval by the IRB and include the elements of informed consent required by 45CFR46.116 and 46.116(b)(1);
   b. Participant or legally authorized representative signature [45CFR46.117(a)]; unless the IRB has waived the requirement for document of the consent process in, which case a cover letter may be used as an informed consent document; and
   c. Providing a copy of the consent document to the participant or legally authorized representative [45CFR46.117(a)]

   The agreement, written or oral, may not include language through which the participant is made to waive, or to appear to waive, any legal rights, or to release the investigator, the sponsor, UMD, or its agents from liability for negligence. Informed consent should be appropriate to the research and participant population being studied.

5. **Documentation of the Informed Consent Process**

   Unless a waiver or alteration has been approved by the IRB, the consent process must be appropriately documented in accordance with Health and Human Services regulations at 45CFR46.117 (HRPP Policy 9.002).

   a. The participant must provide their printed name, signature, and date at the end of the consent document.
   b. The investigator's name and contact information must be listed at the end of the consent form.

6. **Observation of the Consent Process**

   a. The IRB can observe the consent process where it determines that such observation will meaningfully contribute to the reduction of risk to the research participant.
   b. If the IRB decides that the consent process should be observed, the investigator will be notified before the observation. The PI will be contacted so that appropriate arrangements can be made for the observation to take place in a manner that is as unobtrusive as possible. HRPP staff and/or the Quality Assurance Program Manager will conduct the observation.

7. **Posting Clinical Trial Consent Form**

   If a clinical trial is conducted or supported by a Federal department or agency, one IRB-approved consent form must be posted on a website specified by the US Federal government.

   a. The Principal Investigator of the clinical trial is responsible for posting the consent form.
   b. The consent form must be posted on the website after the clinical trial is closed to recruitment, but no later than 60 days after the last study visit by any participant, as required by the protocol.
   c. An exception to this policy may be requested through clinicaltrials.gov or OHRP. The Federal department or agency conducting or supporting this protocol may determine whether information about the protocol should not be made public due to privacy or confidentiality concerns. Alternatively, the consent form may be published, but with redactions due to privacy or confidentiality concerns.

1. **Purpose**

   The purpose of this SOP is to describe development of the informed consent document.

2. **Policy**

   It is the policy of the UMD IRB that the informed consent document(s) will be developed in accordance with regulations at 45CFR46.

3. **Format according to Review Path**

   a. **Exempt:** If the research is exempt, but requires written informed consent, a narrative consent document may be used. In the narrative consent document, all necessary elements of consent should be present, but the elements do not require subheading identification.

   b. **Minimal Risk or Greater than Minimal Risk:** If the research involves procedures which are minimal risk or greater, the consent document must follow the IRB provided template. The IRB provided template is designed include all required elements of informed consent in order to minimize the effort needed for investigators designing a consent document. The template and completion guidelines can be found on the UMD IRB website.

   c. **Waiver of Written Consent Documentation:** If consent will be waived and the PI intends to provide a consent document to participants, an Information Sheet may be used. Typically, this document is reflective of the IRB provided consent template with the signature lines removed. Using the template will allow the PI to present the required elements of informed consent to the participant.

4. **Formatting Guidelines**

   All consent/assent documents should be suitable for reproduction and easy readability by participants.

   a. **Second Person:** The informed consent form should be written in the second person throughout (e.g., you are invited to participate; you will be assigned, etc.). When combined with conditional language and the invitation to participate, utilization of the second person communicates that the investigator believes there is a choice to be made by the prospective participant. Utilization of the first person may be interpreted as presumption of participant consent before consent has been legally obtained.

   b. **Readability**: The consent form must be written in simple enough language so that it is readily understood by the least educated of the participants to be involved. Generally, the level of language in the adult consent document should be an eighth-grade standard. Youth and child assent documents should be written in an age-appropriate style.

      Medical and scientific terms should be avoided where possible. If medical jargon is used the lay terms should be used first and then the medical term included in parentheses.

      Common units of measure should be used appropriate to the procedure or content.

It is recommended that the language consist of short, concise sentences arranged in relatively short simple paragraphs. Headers should be used to separate sections of the document for easier reading, particularly when describing what will happen during the study. Generally, abbreviations should not be used in the consent document that is, all words should be spelled out. The IRB may approve limited use of abbreviations where appropriate, if the acronym is spelled out the first time it is used.

c. **Length**: There are no restrictions on the length of the informed consent/assent documents. The informed consent form should be lengthy enough to explain the elements of consent adequately, but not so lengthy or detailed as to lose the attention of the participant or to cause confusion.

d. **Exculpatory Language:** The consent document must not contain any exculpatory language through which the participant or the participant's representative is made to waive, or appear to waive, any of the participant's legal rights. Additionally, the consent document must not release, or appear to release, the research investigator, the sponsor, the Institution, or its agents from liability for negligence.

e. **Identification of Study Personnel:** The PIs and Co-PIs, if any, listed in the IRB application must be listed on the last page of the informed consent/assent document along with contact information in accordance with Health and Human Services regulations at 45CFR46.111(a)(4) and 45CFR46.116(b)(7).

f. **Signatures:** Lines requiring the participant, witness, LAR, or PI signatures should not be placed on a separate page without the presence of any of the preceding language required in that section of the informed consent document.

g. **Consent/Assent Identification**

To easily identify the type of consent/assent document, one of the following labels should be placed at the top of the first page:

i. **Adult:** Utilized when enrolling competent adults in a research project. Defined in the State of Maryland as individuals 18 years of age or older and individuals under 18 years of age who are legally emancipated or who are otherwise able to consent to the research activities.

ii. **Parent/Guardian:** Utilized when enrolling minors in a research project. Defined in the State of Maryland as individuals under 18 years of age except those who are legally emancipated or who are otherwise able to consent to research activities.

iii. **Proxy, Legally Authorized Representative (LAR) or Durable Power of Attorney Consent:** Utilized when enrolling adults with decisional impairment. If possible, the enrolled adult should sign an **Adult Assent** document written in language understandable to them.

iv. **Youth Assent:** Written assent to be used for children aged 13-17 years. A separate consent form should be used to obtain youth consent. However, in certain circumstances, it may be combined the Adult Consent with added signature lines for the minor's signature.

v. **Child Assent:** Verbal assent to be used for children aged 7-12 years.

vi. **Young Child:** Under age 7, reasonable conversation should occur with the child and researcher about the research activities and their right to not participate. Researchers should be aware of signs of dissent from the young child and stop research activities in this case.

h. **Screening Consent:** Use to obtain participant consent to allow study-related screening tests for potential enrollment in a study. Full study consent will follow if eligibility criteria is met.

i. **Addendum Consent:** Commonly used to obtain additional consent from participants for auxiliary studies (e.g. tissue banking). Also, may be used to inform currently enrolled participants of new information pertaining to the research.

1. **Purpose**

   The purpose of this SOP is to describe the guidelines for designing and obtaining verbal informed consent.

2. **Policy**

   It is the policy of the UMD IRB that verbal informed consent will be obtained in accordance with the regulations at Health and Human Services 45CFR46.

3. **Consent Process**

   Whenever possible consent should be obtained in person by a member of the research team. However, the IRB recognizes that an alternative informed consent process may be designed to minimize risk to the participants. Therefore, the IRB may approve an informed consent process via verbal consent. IRB approval of a verbal consent process for nonexempt research requires a justification for a waiver of the requirement for written consent documentation.

4. **IRB Requirements – Verbal Consent**

   The principal investigator must provide adequate justification for waiving the requirement to obtain written informed consent. To do so, the PI must indicate the applicability of the one of the following criteria found in 45CFR46.117:

   a. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
   b. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
   c. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

5. **Verbal Re-Consent for Changes or Additional Risks**

   If the PI provides appropriate rationale and justification, the IRB may approve a verbal consent process to allow participants to be notified of new changes or risks. The following describes IRB requirements for the use of verbal consent for re-consent for changes or disclosure of additional risks.

   a. The updated consent document must be provided to the participant for review prior to the verbal re-consent process. No research interventions can be conducted until a signed copy (wet or digital signature) of the updated consent form has been received by the investigator. An extra copy must be provided for the participant to keep for their records.

b. A meeting is scheduled with the participant (phone, online, etc.). The minimum required participants in the consent process must include the participant and a member of the research team trained in the consent process.
c. Any element of the consent document that contains updated information must be explained to the participant. The participant's comprehension of the changes should be confirmed by the trained researcher. The participant must be given the opportunity to ask questions. It may be necessary to extend the process over several days and include other individuals such as the participant's family members. If the study involves in-person research site visits, the participant must be re-consented in the presence of the investigator during the next scheduled in-person visit.
d. The verbal re-consent process should be documented in the research record by indicating the need for this re-consent process and the date it occurred.
e. If a waiver of consent documentation was granted previously, the investigator may present the new information verbally to the participant and make a note of the conversation in the research record.

6. **Required Amendment**
   a. In parallel to re-consenting participants, the PI must submit an Amendment to the IRB to provide the modified consent documents. The updates to the consent document must be fully explained and justified in the Amendment.
   b. The IRB will review the proposed method of consent based upon the nature of the study, the risk level, participant population needs and/or significance of the treatment related change.
   c. Once approved, the research team will use the updated consent documents moving forward.

1. **Purpose**

   The purpose of this SOP is to describe the process of re-consent/re-assent of research participants if necessary during the course of the research project.

2. **Policy**

   It is the policy of the UMD IRB that the process of re-consent/re-assent of research participants will be conducted in accordance with the regulations at Health and Human Services 45CFR46.

3. **Process**

   Informed consent/assent is an ongoing process. It is not a one-time review and signature process during participants enrollment. To validate the voluntary nature of research participation and exhibit respect for the individual, participants must be provided new information which may affect their willingness to continue to participate in the research. Health and Human Services regulations at 45CFR46.116(b)(5) require investigators to inform participants of any new information that is germane to the participant's willingness to continue study participation.

4. **Amendment**

   The initial informed consent/assent document(s) signed by the research participant at the time of enrollment remains in effect for the duration of participation in the study or until the IRB approves a requested change in the consent/assent document(s). If the changes affect currently enrolled participants, a re-consent/re-assent process must be described in the Amendment application. If the changes do not affect currently enrolled participants, the Amendment must clearly state the updated consent/assent documents will only be presented to newly enrolled participants.

   a. **Minor Changes**

      Minor changes (e.g., changes in personnel or administrative changes in the consent document) are often provided to participants through verbal exchanges between the investigator and participant without undergoing a formal re-consent procedure. Minor changes are unlikely to affect a participant's willingness to continue participation in a study. However, significant new information, which requires re-consent/re-assent of participants must occur through use of IRB-approved, revised consent/assent document(s) or an Amendment to the consent/assent form. For example, significant new information may include:

      i. Changes in the duration of the study
      ii. Changes to study methods
      iii. Addition of study measures
      iv. Addition of compensation
      v. Description of new risks

5. **Continuing Review**

During the continuing review process for full board or expedited (if required) projects original consent/assent document(s) are submitted for review. If the project remains open to enrollment and the continuing review is approved, the consent/assent documents are approved for use from that date until the expiration date or until an amendment to the consent/assent documents is submitted for approval. The IRB does not require re-consent/re-assent of previously enrolled participants at the time of continuing review unless a change which requires re-consent/re-assent of the participants is discovered during the continuing review.

1. **Purpose**

   The purpose of this SOP is to describe the guidelines governing re-consent and use of data in the absence of valid informed consent.

2. **Policy**

   It is the policy of the IRB that, in the absence of valid informed consent, re-consent and the use of data will adhere to the regulations at Health and Human Services 45CFR46.

3. **Investigator Responsibilities**

   The investigator has a legal and an ethical obligation to ensure that the prospective participant has sufficient knowledge and comprehension of the elements of informed consent prior to enrollment and during participation in research. This is accomplished through the initial and on-going process of informed consent.

4. **Lack of Valid Informed Consent**

   If a participant enrolls and begins participation in a study without the presence of a valid informed consent document (e.g., the participant signed a wrong or outdated consent form), participant comprehension of the elements of informed consent and true informed decision making is called into question. The ethical principal of respect for persons demands that participants enter research voluntarily and with adequate information.

5. **IRB Notification**

   If a participant enrolls in a study without providing valid informed consent, the principal investigator must immediately notify the UMD IRB Office and explain the situation. After consultation with the UMD IRB Office, the PI should request that the participant re-consent to participate. If the participant agrees and a valid informed consent process is completed, including signatures on the consent document and documentation of consent in the research record, data obtained during the period of invalid consent may be used with approval of the IRB.

6. **Participant Refusal**

   If the participant refuses to consent during enrollment or during an attempt to correct an invalid consent process, participation in the study must be halted immediately and the collected data cannot be used.

1. **Purpose**

   The purpose of this SOP is to describe the situations in which the IRB may waive or alter the informed consent process and/or waiver consent documentation.

2. **Policy**

   It is the policy of the UMD IRB that all requests for a waiver or alteration of the consent process or consent documentation must undergo appropriate IRB review. Waivers and/or alterations will be granted in accordance with the relevant Health and Human Services regulations at 45CFR46.111, 45CFR46.116, and 45CFR46.117.

3. **Waiver of Consent Documentation**

   In accordance with 45CFR46.117(c), an IRB may waive the requirement for the investigator to obtain a signed informed consent document from some or all human subjects if it finds any of the following:

   a. The only record linking subject and the research would be the informed consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
   b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
   c. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing the forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

   In cases which the documentation is waived, the IRB may require the investigator to provide subjects a written statement describing the research. If a written statement is required, the IRB must review the documentation that will be provided to the participants.

4. **Waiver of Consent – Screening**

   In accordance with 45CFR46.116(g), an IRB may approve a research project in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subject without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

   a. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative.
   b. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

5. **Waiver or Alteration of Consent**

In accordance with 45CFR46.116(f)(3), an IRB may waive or alter the requirement for the investigator to obtain fully informed consent from some or all human subject if it finds all the following items are met:

a. The research involves no more than minimal risk to the subjects;
b. The research could not be practicably conducted without the requested waiver or alteration;
c. If the research involves using identifiable private information or identifiable biospecimens, the research could not be practicably carried out without using such information or biospecimens in an identifiable format.
d. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
e. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

6. **Use of Deception**

Deception is intentionally providing inaccurate or false information to participants. Deception is considered an alteration of consent according to 45CFR46.116(f) and includes omitting some or altering some or all of the basic elements of informed consent. To decide whether deception is used in the research, the IRB must determine whether all elements of informed consent at 45CFR46.116 are met. If they are met, it is not deception.

In accordance with 45CFR46.116(f)(3), an IRB may alter the requirement for the investigator to obtain fully informed consent from some or all human subject if deception is included in the research project, if the following documentation is included in the submission:

a. An appropriate debriefing script.
b. An opportunity for the participant to withdraw their data from the study.
c. An apology from the researcher for the deceiving the participant.

1. **Purpose**

   The purpose of this SOP is to define and describe Protected Health identifiers.

2. **Policy**

   It is the policy of the IRB that the use of Protected Health Information will be in accordance with regulations at 45CFR46, 45CFR164.512, and other applicable federal, state and local laws.

3. **Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule**

   HIPAA was issued August 13, 2002, with a compliance data of April 14, 2003. The purpose of this rule is to provide additional protections of the privacy rights of participants involved in research. The HIPAA Privacy Rule contains requirements designed to ensure that the Protected Health Information (PHI) of research participants is appropriately used and/or disclosed during the conduct of research.

   a. The Privacy Rule applies to health plans, health care clearinghouses, and to any health care provider who transmits health information in electronic form in connection with transactions for which the Secretary of HHS has adopted standards under HIPAA (the "covered entities").
   b. The UMD Health Center and the Hearing and Speech Pathology clinic are "covered entities" and comply with HIPAA (Privacy Rule).

4. **Protected Health Information (PHI)**

   The Privacy Rule protects all "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper or oral. The Privacy Rule calls this information "protected health information (PHI)".

   a. Individually Identifiable Health Information - Information including demographic data that relates to:
      i. the individual's past, present, or future physical or mental health or condition,
      ii. the provision of health care to the individual, or
      iii. the past, present, or future payment for the provision of health care to the individual,

      and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.
   b. 18 Identifiers – if any of the 18 identifiers listed below are associated with individual health information, then the information is considered "protected".
      i. Names
      ii. Postal address information: street address, city, county, precinct, ZIP code.
      iii. All elements of dates, except year, related to an individual (e.g. birth, admission, discharge). For participants over 89 years of age, all elements of dates, including year.
      iv. Telephone numbers.
      v. Fax numbers.
      vi. Electronic mail addresses.
      vii. Social Security numbers.

viii. Medical Record numbers.
ix. Health Plan beneficiary numbers.
x. Account numbers.
xi. Certificate/license numbers.
xii. Vehicle identifiers and serial numbers, including license plate numbers.
xiii. Device identifiers and serial numbers.
xiv. Web Universal Resource Locators (url)
xv. Internet protocols (ip) address numbers.
xvi. Biometric identifiers, including finger and voiceprints.
xvii. Full face photographic images.
xviii. Any other unique identifying number, characteristic, or code.

5. **De-identification of Protection Health Information requires either:**
   a. Removal of all 18 identifiers, or
   b. Documentation by an expert statistician as to how they determined the risk of participant identification using a subset of identifiers is minimal.

1. **Purpose**

   The purpose of this SOP is to describe the use of Limited Data Sets.

2. **Policy**

   It is the policy of the UMD IRB that the use of Limited Data Sets will be in full accordance with regulations at Health and Human Services 45CFR46.

3. **Limited Data Sets**

   A researcher with IRB approval and a Data Use Agreement between the researcher and the covered entity can use and disclose Protected Health Information that contains a Limited Data Set without HIPAA Authorization or a HIPAA waiver granted by the IRB (HIPAA Privacy Board).

   The limited data set must have all identifiers removed, except the following:

   1. A unique identifying number, characteristic or code (e.g., a registry or study number)
   2. Elements of dates (e.g., birth).
   3. Town, city, state, and ZIP code.

1. **Purpose**

   The purpose of this SOP is to describe research utilizing medical records.

2. **Policy**

   It is the policy of the UMD IRB that the use and disclosure Protected Health Information will be in full accordance with the HIPAA Privacy Rule requirements and federal regulations at Health and Human Services 45CFR46.

3. **Definitions**

   a. **Protected Health Information (PHI):** Individually identifiable health information. Health information means any information, whether oral or record in any medium that:
      i. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

   b. **De-Identified PHI:** Removal of all 18 identifiers from the health information (HRPP Policy 10.001)

   c. **Designated Record Set:** The medical records and billing records about individuals and records used to make decisions about individuals.

   d. **Authorized Investigators:** Any faculty member, student or staff member who is working with a person having ethical/legal access to PHI materials in a non-research context and who will assume responsibility for maintaining confidentiality safeguards as certified in writing.

   e. **Non-Authorized Investigators:** Person(s) that do not fall within the definition of an authorized investigator shall be deemed a non-authorized investigator.

   f. **Existing Medical Records:** "Existing" medical records is defined as medical records existing at the time of initial submission of the IRB application and not when the IRB grants final approval of the project.

4. **Access to Medical Records**

   Only authorized investigators listed by name in the IRB application shall have access to confidential records to be used for research purposes where participant identifiers are present.

   Non-authorized investigators shall have access to confidential records to be used for research purposes with IRB and covered entity approval only when the following conditions are met:

   a. Approval is obtained to use the records from the covered entity (e.g., medical records department) OR
   b. The investigator has obtained informed consent/HIPAA Authorization from the participant, OR
   c. All PHI has been de-identified in accordance with the requirements of HIPAA.

   In all cases, the non-authorized investigator shall have completed huma subject research training especially as it pertains to confidentiality and privacy.

5. **Exempt Research**

   Research involving medical records can be marked exempt provided the records utilized in the research are existing and the data are recorded in such a manner that participants cannot be identified.

6. **Expedited Research**

   Research involving the study of medical records is not exempt if the investigator records the data in such a manner that participants can be identified either directly or through identifiers linked to the participant or if the study involves prospective collection of records.

   If participant identifiers must be temporarily maintained in order to permit the investigator to identify additional records for inclusion in the study, informed consent/authorization is required unless the IRB grants a waiver of informed consent in accordance with the specific requirements of 45CFR164.512 [HIPAA] and 45CFR46.116(d):

   a. Only the minimum amount of participant identifier data is recorded.
   b. The use or disclosure of Protected Health Information or data, which is not Protected Health Information, involves no more than minimal risk.
   c. The alteration or waiver of informed consent will not adversely affect the rights and welfare of the participants.
   d. The research cannot practicably be carried out without the alteration or waiver.
   e. There must be an adequate plan to protect participant identifiers from improper use and disclosure.
   f. There must be an adequate plan to destroy the identifiers associated with Protected Health Information at the earliest opportunity unless there is a health or research justification for retaining the identifiers or retention is required by law.
   g. Whenever appropriate, the participants will be provided with additional pertinent information after participation.
   h. If identifiers are recorded for the purpose of selecting a prospective participant population and the investigator intends to subsequently solicit informed consent to participate in a prospective study, specific guidelines must be followed regarding initial contact with potential participants. Contact with potential participants should originate with an individual who has the appropriate professional relationship with the potential participant (e.g., primary care physician, counselor, teacher, etc.). If an investigator does not have such a relationship, they should obtain assistance from someone who does. Once the appropriate professional has originated the contact, negotiation for informed consent can begin as with any other research protocol.
   i. Additional details can be located on the HIPAA section of the Department of Health and Human Services website.

1. **Purpose**

   The purpose of this SOP is to describe the process of reviewing Protected Health Information (PHI) in preparation for research.

2. **Policy**

   It is the policy of the UMD IRB that the review of PHI in preparation for research (preparatory to research) will be conducted in full accordance with regulations at Health and Human Services 45CFR46 and 45CFR164.

3. **Preparatory to Research**

   HIPAA permits and investigator to review medical records containing PHI in preparation for a research project without obtaining an authorization or waiver of consent from the IRB. To meet this requirement, the investigator, or other study personnel, must have ethical-professional access to the PHI in the medical setting.

   The investigator must file a request for access with the pertinent institution (UMD Health Center, Hearing and Speech Clinic, local hospital or clinic). If the PHI is not contained within the medical record, the request should be filed with the IRB. The investigator must certify:

   1. Review of PHI will be conducted solely to determine the feasibility of a research project or for similar purposes in preparation for research.
   2. PHI may not be recorded, copied, or removed from the records repository in the course of review.
   3. PHI that is accessed is solely for research purposes.

   If an investigator intends to record PHI for the express purpose of contacting prospective research participants, the appropriate IRB application and associated informed consent documents must be submitted and approved by the IRB prior to the review of the medical records.

1. **Purpose**

   The purpose of this SOP is to describe the IRB's process for conducting continuing review.

2. **Policy**

   It is the policy of the UMD IRB that continuing review will be conducted in accordance with Health and Human Services regulations at 45CFR46 and OHRP guidance on continuing review (July 11, 2010).

   If a continuing review is required for a project review via the expedited or full board pathway, it will be approved for up to one year (365 days) and must be renewed annually if the project will remain active (open recruitment, analyzing identifiable information, etc.). This will be done by submitting a continuing review application to the IRB prior to the approval expiration date.

3. **Expedited Review Path**

   Continuing review applications are no longer required for projects approved through the Expedited review path according to (45CFR46.109(f)(1)(i)) unless the IRB determines there is a need for a Continuing Review at the time of Initial Approval or after an Amendment that has modified the initial project. If continuing review is to be required for an Expedited project, the IRB Chair or IRB Member reviewer must provide justification during the initial or amendment application review as to why the continuing review is required. The requirement for a continuing review may be removed if the justification is no longer adequate (e.g. enrollment is closed).

4. **Maintaining Oversight**

   The UMD IRB utilizes the Quality Assurance Program to maintain oversight over the research initially reviewed using the expedited procedure. The QA Program Manager conducts several routine monitoring activities as described in HRPP Policy 7.001 and also performs routine follow-up with approved projects that have not had an electronic submission in the last two years. When performing the routine follow-up, the QA Program Manager will administratively close projects that are no longer active.

5. **Full Board Review Path**

   Continuing Review must occur as long as the research remains active for long-term follow-up of subjects, even when the research is permanently closed to the enrollment of new participants and all participants have completed all research-related interventions. Continuing review of research must occur when the remaining activities are limited to collection or analysis of private identifiable information.

6. **Expiration**

   If an investigator does not provide continuing review information to the IRB, or the IRB has not approved the protocol by the expiration date, the investigator must cease all human subject research activities, including recruitment, enrollment, interventions, and interactions, and collection of private identifiable data with current

participants, unless the IRB finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating.

To maintain compliance with OHRP guidance for federally funded research, continuing review applications submitted 30 days or more prior to expiration will have the review begin within the 30 days period prior to expiration. The UMD IRB has adopted these OHRP guidelines for all human subject research projects that are required to submit a continuing review.

New enrollment of participants is not allowed after the expiration of IRB approval until the continuing review has been reviewed and approved by the UMD IRB provided it was submitted prior to the expiration date.

7. **Risk Determination**

All human participant studies are subject to continuing review based on the risk determination by the IRB. Research approved previously by expedited review is considered eligible for expedited review at the time of its regular continuing review, if, during the previous approval period, the risks of the study have not increased. Projects that were initially reviewed by the full board continue to receive full board review unless the IRB has determined at a full board meeting that the study meets the criteria for expedited review.

8. **Continuing Review Application Requirements**

It is the responsibility of the PI to submit the Continuing Review Application, which must include informed consent/assent forms if enrollment remains open, in sufficient time to allow the IRB to complete a substantive and meaningful review of the research, as well as provide the PI with a timely response prior to the expiration date indicated on the IRB approval letter.

a. The PI will receive four (4) email reminders that the project is due to expire. The reminders will be sent at 60, 45, 30, and 15 days prior to the project expiration date. If the continuing review is not approved by the expiration date, an email will be sent to the PI notifying them of the project expiration.
b. If the IRB determines that a project requires review more often than once every 365 days, the PI will be notified at the time of initial review and/or at the time of continuing review. Factors which determine the frequency of continuing review are described in HRPP Policy 3.010.

9. **Pre-Review**

The HRPO staff is responsible for conducting pre-review of continuing review applications. At any time, an HRPO staff member may consult with an IRB Chair, IRB member, Director – HRPP, and/or another HRPO staff member for guidance during this process.

a. The project file is accessed via the IRB electronic submission system. The title and study personnel listing are checked for accuracy and training for personnel is verified. The current application for continuing review will be compared with the previous year's application, as well as other documents found in the project record as necessary. When assigned to review a continuing review application, the IRB Chair or IRB member reviewer(s)

will have access to all records for that particular project. Additional information since the last IRB review that should be included in the Continuing Review:

i. Number of participants accrued to date.
ii. Adverse events and adverse outcomes experienced by participants.
iii. Unanticipated problems involving risks to participants or others.
iv. Participant withdrawals.
v. The reasons for withdrawals.
vi. Complaints about the research.
vii. Amendments or modifications.
viii. Any relevant recent literature.
ix. Any interim findings.
x. Any relevant multi-center trial reports.
xi. The researcher's current risk-potential benefit assessment based on study results.

b. The consent form(s) to be used during the next IRB approval period will be compared with the version last approved by the IRB to determine if the correct version of the consent form(s) has (have) been provided and if any changes have been made to the consent document.

c. Discrepancies or omissions in the continuing review application will result in a message to the PI requesting clarification and/or correction to appropriate forms. If the number of problems in the application are of such magnitude that IRB review is not possible, the full application and supporting documents will be sent back to the PI for revision and resubmission of the revised application and/or consent document(s).

d. In situations of possible non-compliance, the Quality Assurance Program Manager and Director – HRPP will be notified. A complete review of the IRB study record will be performed by the Quality Assurance Program Manager to determine what further action should be taken in accordance with HRPP Policy 14.001.

e. For full board continuing reviews, copies of all correspondence during the pre-review process will be available to all IRB members via the IRB electronic submission system. In addition, the IRB staff will contact the assigned reviewers to inform them of any unresolved problems or concerns.

10. **Expedited Continuing Review**
    a. Expedited continuing review will be conducted by an IRB Chair or IRB member reviewer. They will complete the expedited reviewer checklist to document the review.
    b. The expedited reviewer will determine if continuing review is required for the project and will provide adequate justification if it is.
    c. IRB approval periods cannot exceed one year. IRB approval expires one year after approval of the initial application. The expiration date will change only to update the year. The month and date of expiration will not

change. If a continuing review is not submitted by midnight of the expiration date, the PI and research team must cease all human subject research activity, and the project will be closed by the IRB.

11. **Expedited Review Actions**
    a. **Approval**
    No modifications or clarifications are required. All of the criteria for IRB approval specified in Health and Human Services regulations at 45CFR46.111 are satisfied. The investigator will be notified of the approval or acknowledgement electronically and is authorized to continue the study.

    b. **Approval with Specific Changes**
    Minor clarification(s) or information concerning the project is necessary for completion of the record. This action is only taken when the modifications are proscriptive and the IRB member reviewer knows what they are approving. The PI will be notified of the modifications, asked to make the changes and return the updated materials before final approval will be granted.

    Failure to respond to the IRB continuing review modification letter may result in the full IRB revoking approval of the study. In such a case, all research related activities must immediately cease, unless an extension is granted by the IRB Chair in consideration of a written request from the PI. The IRB will be notified of all extensions granted by the IRB Chair.

    c. **Referred for Full IRB Review**
    IRB members assigned to perform an expedited review can refer the project for review by the full IRB.

12. **Full IRB Review Procedure**
    a. **Approval**
    No modifications or clarifications are required. All of the criteria for IRB approval specified in Health and Human Services regulations at 45CFR46.111 are satisfied. The investigator will be notified of the approval or acknowledgement electronically and is authorized to continue the study.

    b. **Approval with Specific Changes**
    Minor clarification(s) or information concerning the project is necessary for completion of the record. This action is only taken when the modifications are proscriptive and the IRB member reviewer knows what they are approving. The PI will be notified of the modifications, asked to make the changes and return the updated materials before final approval will be granted.

    Failure to respond to the IRB continuing review modification letter may result in the full IRB revoking approval of the study. In such a case, all research related activities must immediately cease, unless an extension is granted

by the IRB Chair in consideration of a written request from the PI. The IRB will be notified of all extensions granted by the IRB Chair.

c. **Tabled**

Only the fully convened IRB may table a project or continuing review.

The PI will be notified in writing as to the nature of the required modifications. This action is only taken when the modifications are clarifications or explanations, and the IRB does not have enough information to approve the continuing review. During the remaining IRB approval period, the investigator is authorized to continue the research until the expiration date or until the tabled transaction is reviewed and approved. The investigator response will be reviewed by the IRB. If all modifications have been adequately addressed, the continuing review and response will be assigned to the next available IRB agenda for review.

If the PI fails to respond to the IRB's continuing review determination letter within the remaining IRB approval period, the protocol has, or will be, classified as administratively closed. If IRB approval expires, all research-related activities must immediately cease.

d. **Disapproved**

The IRB has a serious concern regarding participant safety and/or compliance. The project will be suspended or possibly terminated. If federally funded, a report will be submitted to the Office of Human Research Protections (OHRP) in accordance with HRPP Policy 14.002. No new participants may be enrolled. All research-related activities must cease and the full IRB will make a determination if currently enrolled participants may continue participation in the study. The Institutional Official and the PI's department chair and/or dean will be notified.

13. **IRB Approval Notification**

Once a project has been approved by the IRB, a letter of approval will be sent to the PI and maintained in the IRB electronic submission system. The letter provides a summary of investigator responsibilities and reminds investigators that changes in research activity may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to participants.

The currently approved consent/assent forms should be kept on file as the master copies and all outdated consent/assent forms must be destroyed as they are no longer valid.

Initial and amended informed consent documents signed by the participant remain in effect for the duration of the participant's participation in the study. Therefore, previously enrolled participants are not required to be reconsented each year following continuing review, unless the IRB approves a change during the continuing review process which requires reconsent of participants (e.g., participant notification of new risks or changes in protocol.)

14. **IRB Approval Termination**

    If the PI fails to submit the continuing review application prior to the expiration date, the project will be administratively closed and all human subject research activity must cease. If the PI does not respond to the IRB modifications letter in sufficient time to allow the IRB to complete its review prior to the expiration date, all human subject research activities must cease until the modifications have been addressed by the PI and reviewed by the IRB or IRB member reviewer.

    If the PI does not respond to the required modifications within 90 days, the project will be administratively closed.

15. **Final Progress Reports**

    When a project is terminated or completed by the PI, the PI is responsible for notifying the IRB by submitting a Closure Report in the electronic submission system. The IRB Office will review the closure report, request any needed clarifications, and close the project.

1. **Purpose**

   The purpose of this SOP is to describe the conditions under which suspension and termination apply and the process involved.

2. **Policy**

   Suspension of IRB approval is a directive of the convened IRB. However, if the situation is urgent and requires immediate suspension, the IRB Chair, Director – HRPP, or Institutional Official may either temporarily or permanently stop some or all previously approved research activities. Suspended protocols remain open and require continuing review but may not proceed with any human subject research activities. Termination of IRB approval is a directive of the convened IRB to permanently stop all activities in a previously approved research protocol. Terminated protocols are considered closed. The Institutional Official may terminate an IRB approval if the situation is urgent.

   a. The IRB, IRB Chair, or Director – HRPP (if delegated by and IRB Chair) may suspend research to ensure protection of the rights and welfare of participants if the following has occurred:
      1. The project is not being conducted in accordance with IRB requirements.
      2. The project has been or currently is associated with unexpected serious harm to participants.

      Suspension directives made by the IRB Chair or Director – HRPP must be reported to and reviewed by the convened IRB. Research may only be terminated by the convened IRB or the IO if it is an urgent matter. Terminations of projects approved under expedited review must be made by the convened IRB or the IO if it is an urgent matter.

   b. When study approval is suspended or terminated by the convened IRB or an authorized individual, in addition to stopping all research activities, the convened IRB or individual ordering the suspension or termination will notify any subjects currently participating that the study has been suspended or terminated. The convened IRB or individual ordering the suspension or termination will consider whether procedures for withdrawal of enrolled subjects are necessary to protect the rights and welfare of participants, such as: transferring participants to another investigator; making arrangements for care or follow-up outside the research; allowing continuation of some research activities under the supervision of an independent monitor; or requiring or permitting follow-up of participants for safety reasons.

   c. If follow-up of participants for safety reasons is permitted/required by the convened IRB or individual ordering the suspension or termination, the convened IRB or individual ordering the suspension or termination will require the participants should be so informed and that any adverse events/outcomes be reported to the IRB and the sponsor/funding agency.

   d. It is the policy of the UMD IRB that the following incidents will be promptly reported to the Office of Human Research Protections and Department or Agency heads if the project is federally funded in accordance with

Health and Human Services regulations at 45CFR46.103(b) or to other federal agencies when the research is overseen by those agencies:

1. Any unanticipated problem involving risk to participants or others,
2. Any serious noncompliance,
3. Any continuing noncompliance,
4. Any suspension or termination of IRB approval
5. Any internal or external holds place on IRB approved projects (HRPP Policy 14.002).

1. **Purpose**

   The purpose of this SOP is to describe the process for requesting changes to an approved project.

2. **Policy**

   It is the policy of the UMD IRB that review of all requests to approved projects will be conducted in full accordance with regulations at Health and Human Services 45CFR46.

3. **Application Requirements**

   Any proposed change in a project which affects the human subjects enrolled or to be enrolled must be reviewed and approved by the IRB prior to implementation except when an immediate change is necessary to eliminate a hazard to the participants, or to provide participants with new information on adverse events or research results considered essential to a participant's decision whether to continue participating.

   Investigators must submit:

   a. Amendment application through electronic submission system.
   b. Complete description of the changes requested.
   c. Revised project (as appropriate).
   d. Revised consent/assent document(s) (as appropriate).
   e. Revised supporting documents (as appropriate).

4. **IRB Review**

   When an Amendment application is received by the HRPO, the IRB staff will conduct an administrative review and provide a recommendation as to whether the changes are minor and present no greater than minimal risk or are major and present greater than minimal risk.

   a. The change is **minor** in nature and the risk to the participant is minimal. Minor changes include the addition of procedures found on the expedited review list (e.g., minor change in eligibility requirements, deletion of an intervention, and change in follow-up schedules). Minor changes are approvable under expedited review (or exempt if applicable). It must be documented that it is a minor change. If reconsent of current participants utilizing the revised IRB-approved consent document is required, the PI must provide a plan for notification of current participants. Other changes such as changes in contact information, addition or deletion of staff, providing external approval documents, and other administrative updates will be processed administratively by IRB Office staff and will receive a determination of Acknowledged.

      When conducting review using the expedited procedure, the reviewer has access and reviews all submitted information including the complete project history. The reviewer(s) refer to the Criteria for Approval guidance to determine whether the modifications meet the criteria allowing review using the expedited procedure, and if so, whether the research with the proposed modifications meets the regulatory criteria for approval. (HRPP Policy 2.009)

b. The change is **major** but does not require immediate implementation to reduce a hazard to participants. Examples of major changes include changing the treatment, revising eligibility requirements additional of a new population, etc. The changes cannot be implemented until reviewed by the full IRB for projects presenting greater than minimal risk. If reconsent of current participants utilizing the revised IRB-approved consent document is required, the PI must provide a plan for notification of current participants.

   All IRB members have access to all submitted materials for the review of modifications to previously approved research by the convened IRB. Primary and secondary reviewers (if assigned) will perform an in-depth review of all pertinent documentation and present an overview of the proposed modifications along with noting whether the changes meet the regulatory criteria for approval. All other IRB members will review all materials provided in enough depth to discuss the information at the convened meeting. (HRPP Policy 2.009)

c. The change is **significant and requires immediate implementation** to decrease risk to participants and requires full disclosure to the participants immediately. These changes may include the addition of a major risk resulting from a reported adverse event or other major changes enacted to reduce risk to participants. Reconsent of current participants utilizing the revised IRB-approved consent document or a consent addendum is required. A witness may be required during the reconsent process if appropriate.

5. **Change to Eliminate Immediate Risk prior to IRB Approval**
   If a change is initiated without any IRB approval to eliminate immediate hazards to the participants or to provide essential information to the participants, the IRB must be notified as soon as possible, but no later than two (2) business days from the time the change was initiated. If the change was initiated for all participants, an Amendment application must be submitted to the IRB as soon as possible.

1. **Purpose**

   The purpose of this SOP is to describe the procedure to ensure prompt reporting of reportable events to the UMD IRB.

2. **Policy**

   It is the policy of the UMD IRB to comply with the Health and Human Services regulations at 45CFR46.108(4)(i-ii), which states that the IRB will establish and follow written procedures for ensuring prompt reporting of all reportable events to the IRB; appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency.

3. **Definitions**

   a. **Protocol Deviation:** Any difference in study conduct from the criteria or activities prescribed in the IRB approved protocol, which may or may not affect the participants' rights, safety, welfare, and/or the integrity of the study.

   b. **Non-Compliance:** A failure to follow the regulations, Maryland state law, institutional policy, or the requirements or determinations of the IRB. Non-compliance may range from minor to serious; be unintentional or willful; and may occur once, sporadically, or continuously. The degree of non-compliance is evaluated on a case-by-case basis.

   c. **Continuing Non-Compliance:** Multiple or repeated instances of non-compliance, particularly after written notice from the IRB that the investigator must take action to correct the non-compliance, or from the Institutional Official (IO) that the IRB or individuals within UMD must take action to correct non-compliance. Continuing non-compliance may occur on one or more than one study and may occur over a period of time.

   d. **Serious Non-Compliance:** Non-compliance such that the failure to follow federal regulations, state laws or institutional policies relevant to human participants research or any determinations of the reviewing IRB and involves one or more the following: substantive harm or genuine risk of substantive harm to the safety, rights and welfare of research participants or others, decreases potential benefits, or compromises the integrity of the human research protection program.

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   e. **Adverse Event:** An event that occurs during a research protocol that either causes physical, social, economic, or psychological harm, or increases the risk of physical, social, economic, or psychological harm, or results in loss of privacy and/or confidentiality to a research participant or others (i.e. family members). Adverse events include expected and unexpected harmful effects and unexpected harms of an interaction or an intervention.

f. **Serious Adverse Event:** An adverse event that (1) results in death, (2) is life-threatening, (3) requires inpatient hospitalization or prolongation of existing hospitalization, (4) results in persistent or significant disability/incapacity, (5) results in a congenital anomaly/birth defect, or (6) is an important medical event that jeopardizes the subject or requires medical intervention to prevent one of outcomes listed above.

g. **Unexpected Adverse Event:** An adverse event that is not consistent in nature, frequency, or severity with either: 1.) the known foreseeable risk of adverse events associated with the procedures involved in the research as described in the protocol-related documents and other relevant sources of information (such as product labeling, etc.); and 2.) the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

h. **Unanticipated Problem:** Unanticipated problems are defined as any incident, experience or outcome that meets all of the following criteria: (1) Unexpected (unforeseen by the researcher or the research participant) in terms of nature, severity, or frequency, given the research procedures and the subject population being studied; (2) Related or probably related to participation in the research, or if the event or problem probably or definitely affects the safety, rights and welfare of current participants; (3) Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

4. **Reporting Adverse Events & Unanticipated Problems**

The following reportable events must be reported to the IRB within 72 hours from the date of discovery by using the Adverse Event/Unanticipated Problem Report:

a. **Adverse Events (AE)**

An adverse event occurs during a research project and either causes physical social, economic, or psychological harm, or increase the risk of physical, social, economic, or psychological harm, or result in loss of privacy and/or confidentiality to a research participant or others (i.e. family members). Adverse events include expected and unexpected harmful effects and unexpected harms of an interaction or an intervention.

i. Harm is "unexpected" when its specificity and severity are not accurately reflected in the consent document.
ii. Harm is "related to the research procedures" if in the opinion of the principal investigator, it is more likely than not to be caused by the research procedures or if it is more likely than not the event affects the rights and welfare of current participants.
iii. Examples of Adverse Events may include: A breach of confidentiality, participant complaints, incarceration of a participant in a protocol not approved to enroll prisoners, injury and/or death of a research participant that is unrelated to participation in the research.

b. **Unexpected Adverse Events**

Unexpected AEs are not consistent in nature, frequency, or severity with either: 1.) the known foreseeable risk of adverse events associated with the procedures involved in the research as described in the protocol-related documents and other relevant sources of information (such as product labeling, etc.); and 2.) the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

c. **Serious Adverse Events**

Serious AEs that (1) result in death, (2) are life-threatening, (3) require inpatient hospitalization or prolongation of existing hospitalization, (4) result in persistent or significant disability/incapacity, (5) result in a congenital anomaly/birth defect, or (6) are an important medical event that jeopardizes the subject or requires medical intervention to prevent one of outcomes listed above.

d. **Unanticipated Problems (UP)**

Unanticipated Problems are defined as any incident, experience or outcome that meets all of the following criteria: (1) Unexpected (unforeseen by the researcher or the research participant) in terms of nature, severity, or frequency, given the research procedures and the subject population being studied; (2) Related or probably related to participation in the research, or if the event or problem probably or definitely affects the safety, rights and welfare of current participants; (3) Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

e. **Cases of Continuing or Serious Non-Compliance**

i. **Continuing Non-Compliance** is defined as multiple or repeated instances of non-compliance, particularly after written notice from the IRB that the investigator must take action to correct the non-compliance, or from the Institutional Official (IO) that the IRB or individuals within UMD must take action to correct non-compliance. Continuing non-compliance may occur on one or more than one study and may occur over a period of time.

ii. **Serious Non-Compliance** is defined as the failure to follow federal regulations, state laws or institutional policies relevant to human participants research or any determinations of the reviewing IRB and involves one or more the following: substantive harm or genuine risk of substantive harm to the safety, rights and welfare of research participants or others, decreases potential benefits, or compromises the integrity of the human research protection program.

f. **Suspension or Termination**

i. This includes suspension or termination of IRB approval from external sites or study sponsors.

5. **Reporting Deviations**

The following reportable events should be reported to the IRB within 72 hours of the Principal Investigator learning of the event by using the Reportable Event Report.

a. **Deviations**

Deviations are defined by any difference in study conduct from the criteria or activities prescribed in the IRB approved protocol, which may or may not affect the participants' rights, safety, welfare, and/or the integrity of the study.

i. Examples: enrolling more than the approved number of participants for a research study, changes to study procedures without prior IRB approval, addition/implementation of new study materials without prior IRB approval.

6. **Review of Reportable Events**

a. The Quality Assurance Program Manager reviews all reportable event reports and determines whether the event describes new and/or added risks to participants. During the evaluation, the QA Program Manager will determine whether the event should be classified as an unanticipated problem, a serious adverse event, or continuing/serious noncompliance.

b. If the event does NOT classify as an unanticipated problem, a serious adverse event, or continuing/serious noncompliance, the Quality Assurance Program Manager will ensure that the research team has provided an effective corrective action plan, and the report will be acknowledged.

c. If the Quality Assurance Program Manager determines that the event DOES classify as an unanticipated problem, a serious adverse event, or continuing/serious noncompliance, the Quality Assurance Program Manager will consult with the IRB Chair or Co-Chair and request that the report be reviewed by the full committee at the next convened IRB meeting.

d. The IRB will review all reported unanticipated problems, serious adverse events, or cases of continuing/serious noncompliance at a convened meeting.

e. The IRB will discuss and vote on whether the reportable event represents an unanticipated problem involving risks to participants or others as defined above.

i. If the IRB determines by majority vote that the event or problem represented an unanticipated problem involving risks to participants or others, the SOP on Reporting to Regulatory Agencies and Institutional Officials will be followed (HRPP Policy 14.001 and 14.002).

ii. If the IRB determines that the problem is not an unanticipated problem involving risks to participants or others, the IRB will ensure that the research team has provided an effective corrective action plan, and the report will be acknowledged.

iii. All decisions made by the IRB will be documented in the IRB meeting minutes.

f. The IRB will consider the following actions when reviewing reportable events:

i. No action (i.e. – Acknowledgement of the reportable event and the proposed corrective action plan).

ii. Modification of the research protocol.

iii. Modification of the informed consent process.

iv. Additional information provided to past participants.
v. Notification of current participants (required when such information may relate to participants' willingness to continue to take part in the research).
vi. Requirement that current participants reconsent to continue participation.
vii. Requirement of a continuing review and/or modification to the existing continuing review schedule.
viii. Additional Quality Assurance monitoring of the research and/or consent process.
ix. Suspension of the research.
x. Termination of the research.
xi. Referral to other organizational entities (e.g., legal counsel, risk management).

1. **Purpose**

   The purpose of this SOP is to define the categories of noncompliance and describe the procedures for reporting noncompliance to the IRB.

2. **Policy**

   All members of the University community involved in human participant research are expected to comply with the ethical standards of professional conduct in accordance with federal and state regulations as well as UMD and IRB policies governing the conduct of research involving human participants. It is the policy of the IRB that investigators and research staff report any allegations or incidents of noncompliance to the HRPO. The IRB recommends that cases of non-compliance be reported as soon as possible, but no longer than 72 hours upon discovery of the incident.

   All allegations or incidents of noncompliance will be promptly investigated to ensure ongoing adequate protection of the rights and welfare of research participants. Confidentiality will be preserved, and due process utilized.

   Cases of serious or continuing non-compliance will be promptly reported the appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency in accordance with the Health and Human Services regulations at 45CFR46.108(a)(4)(i-ii) and HRPP Policy 14.002.

3. **Definitions**

   a. **Noncompliance:** is a failure to follow the regulations, Maryland state law, institutional policy, or the requirements or determinations of the IRB. Noncompliance may range from minor to serious; be unintentional or willful; and may occur once, sporadically, or continuously. The degree of noncompliance is evaluated on a case-by-case basis.

   b. Continuing Noncompliance: Multiple or repeated instances of non-compliance, particularly after written notice from the IRB that the investigator must take action to correct the non-compliance, or from the Institutional Official (IO) that the IRB or individuals within UMD must take action to correct non-compliance. Continuing non-compliance may occur on one or more than one study and may occur over a period of time.

   c. Serious Noncompliance: Non-compliance such that the failure to follow federal regulations, state laws or institutional policies relevant to human participants research or any determinations of the reviewing IRB and involves one or more the following: substantive harm or genuine risk of substantive harm to the safety, rights and welfare of research participants or others, decreases potential benefits, or compromises the integrity of the human research protection program.

   d. Allegation: An assertion made by a party that must be proved or supported with evidence.

e. Confirmed Report: Alleged noncompliance which in the judgment of the IRB administrator or IRB Chair is factual.

f. Research Misconduct: Any fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or reporting research results. This definition derives from federal regulation and is reflected in the University of Maryland Policy and Procedures Concerning Scholarly Misconduct, which governs the review of allegations of research misconduct at the institution. Instances meeting the definition of research misconduct will be reported to the Executive Director in the Office of Integrity and Responsible Conduct by the Director – HRPP or an IRB Chair.

4. **Procedures for Addressing Allegations of Noncompliance**

Allegations of noncompliance are investigated by HRPO staff (most likely Director – HRPP or QA Program Manager).

a. HRPO staff will document a receipt of the allegation of noncompliance.
b. HRPO staff will conduct a pre-inquiry review for the preliminary informal checking of the facts to determine if there is a reasonable basis for the allegation and if the allegation can be supported by the evidence. If the HRPO staff is unable to conduct the investigation on their own, others may be required to assist. Confidentiality will be maintained at all times.
    i. If the allegation of noncompliance is determined to not be a credible confirmed report of noncompliance, the inquiry stops, and no further action is taken.
    ii. If the allegation of noncompliance is determined to be a credible confirmed report of noncompliance, the inquiry proceeds as outlined in this policy. The allegation of noncompliance is considered a confirmed report of noncompliance.

5. **Procedures for Addressing Confirmed Reports of Noncompliance**

HRPO staff (most likely the Director – HRPP or the QA Program Manager) will review all reports of noncompliance.

a. HRPO staff will determine whether a confirmed report of noncompliance represents serious or continuing noncompliance as defined in this policy. If it is determined that the confirmed report of noncompliance is neither serious nor continuing noncompliance, as defined by this policy, the following actions may be taken:
    i. Acknowledgement of the problems, requiring no sanctions but instructions regarding the necessity to establish procedures and policies to avoid further infractions.
    ii. Require additional human research protections education and training for the investigator and/or research team.
    iii. Request a corrective action plan from the investigator.
    iv. Acknowledgement of the submitted corrective action plan.
    v. No further action.

b. If the HRPO staff determines that a confirmed report of noncompliance might represent either serious or continuing noncompliance the HRPO staff will refer the confirmed report of noncompliance to an IRB Chair for review and comment.
   i. If an IRB Chair determines that more information is needed because the inquiry discloses a reasonable basis for concern that significant infractions have occurred, further investigation will be conducted by the QA Program Manager. The research team will be notified in writing of the IRB Chair's determination to investigate.
   ii. An IRB Chair will determine whether the confirmed report of noncompliance represents serious or continuing noncompliance.
   iii. If it is determined that the confirmed report of noncompliance is neither serious nor continuing noncompliance, an IRB Chair will recommend one of the actions listed above [HRPP Policy 14.001, Section 5(a)(i)].
   iv. If an IRB Chair determines that the confirmed report of noncompliance might represent serious noncompliance and/or continuing noncompliance, the IRB Chair refers the confirmed report of noncompliance to the convened IRB with their determination.

c. When issues of noncompliance are reviewed by the convened IRB, the IRB staff prepares the documents listed below, if applicable, and makes them available to all members of the convened IRB for review prior to the meeting. All members are expected review the information and be prepared to discuss it at the meeting:
   i. The approved IRB application.
   ii. The informed consent documents.
   iii. The confirmed report of noncompliance.
   iv. The quality assurance report (investigation report) including a list of witnesses and documents reviewed.
   v. Previous reports of noncompliance and the past record of the researcher and their team.
   vi. All documents related to the allegation.

d. The IRB Chair will present their findings in conjunction with the QA Program Manager. The IRB Chair will lead the discussion during the convened IRB meeting.

e. The convened IRB votes on whether the confirmed report of noncompliance represents serious noncompliance and/or continuing noncompliance. IRB staff will record the discussion, including the rationale for any action and vote in the minutes.

f. If the convened IRB determines that the confirmed report of noncompliance is neither serious noncompliance nor continuing noncompliance, the IRB will consider but is not limited to the actions listed above.

g. If the convened IRB determines the confirmed report of non-compliance represents serious noncompliance and/or continuing noncompliance, the SOP on Reporting to Regulatory Agencies and Institutional Officials will be followed (HRPP Policy 14.002). The IRB will also consider, but is not limited to, the following actions:

i. Increased study monitoring by the Quality Assurance Program Manager.
ii. Required interim reports from the Principal Investigator.
iii. Reported internal audits be conducted by the PI and/or study personnel.
iv. Monitoring of the consent process by the Quality Assurance Program Manager.
v. Modify the frequency of the continuing review cycle.
vi. Notify current subjects, if the information about the non-compliance might affect their willingness to continue participation.
vii. Required additional training of the principal investigator and or/study personnel in the protection if human participants.
viii. Suspend IRB approval of the respective study pending a written plan for the correction and /or prevention of the non-compliance.
ix. Termination of the study.
x. Suspension of all principal investigator's studies pending the completion of an audit.
xi. Recommendation of the IO that a letter of reprimand is placed in the principal investigator's personnel file or the file of other study personnel.

6. **Reporting Non-compliance to Federal Agencies**

All noncompliance determined by the IRB Chair and Director – HRPP to be serious or continuing noncompliance will be reported to OHRP, AAHRPP (as applicable), and Federal Department or Agency Heads in accordance with HRPP Policy 14.002.

1. **Purpose**

   The purpose of this SOP is to describe the procedure to ensure prompt reporting to OHRP or Department or Agency Heads: 1) unanticipated problems involving risk to the participants or others, 2) serious or continuing noncompliance, and 3) suspensions or terminations of approved research by the IRB.

2. **Policy**

   It is the policy of the IRB that the following incidents will be promptly reported to OHRP and Department or Agency heads in accordance with Health and Human Services regulations at 45CFR46.103(b) or to other federal agencies when the research is overseen by or receives funding from those agencies: 1) any unanticipated problem involving risk to the participant or others, 2) any serious noncompliance, 3) any continuing noncompliance, 4) any suspension or termination of IRB approval, and 5) any internal or external holds placed on IRB approved protocols.

3. **Definitions**

   a. **Unanticipated problems involving risks to participants or others** are defined as any problem that (1) was unforeseen and (2) indicates that the research procedures caused harm to participants or others or indicates that participants or others are at increased risk of harm.

   b. **Serious noncompliance** is defined as failure to comply with any Health and Human Services regulations, and/or IRB requirements that places human participants at unacceptable risk or results in non-disclosure of pertinent information to all participants thereby compromising informed consent.

   c. **Continuing noncompliance** is defined as: 1) multiple incidents of serious or non-serious noncompliance in a twelve (12) month period, which occurs in any one research protocol, or 2) multiple incidents of serious or non-serious noncompliance in a twelve (12) month period carried out by the same individual in multiple research protocols. The incidents of continuing noncompliance may involve one specific issue or different issues.

   d. **Suspension or termination of IRB approval of research** is defined as a mandatory directive to the investigator in writing to suspend or terminate some or all research activities conducted under an IRB-approved protocol. Such directives may be issued because of decisions made by either the full IRB at a convened meeting or by the IRB Chair to eliminate apparent immediate hazards to the participants or others.

   e. **Internal Study Hold** is defined as a mandatory directive by the IRB to the investigator in writing to suspend further participant accrual on an IRB approved protocol. Such directives may be issued when the IRB has a concern about unresolved adverse event or serious problem reports, or other issues, which impact participant safety.

   f. **External Study Hold** is defined as a mandatory directive by the sponsor or cooperative group, to the investigator in writing to suspend further participant accrual on an IRB approved protocol. Such directives are usually issued for planned study holds to evaluate reported problematic therapeutic techniques.

4. **Reporting**
    a. The IO is responsible for the prompt submission of all required written reports to OHRP, and/or Department or Agency Heads.
    b. The IO may notify OHRP verbally in advance of a written report when the incident is particularly serious.
    c. All required reports will be submitted no later than five (5) business days from the time the convened IRB makes a final determination concerning the incident(s).
    d. If the study is conducted or funded by any Federal Agency other than DHHS that is subject to the Common Rule, the report is sent to OHRP or the agency head as required by the agency.

5. **Notification of Institutional Officials**
Copies of the letter sent to OHRP any supporting documents must be provided to:
    a. The individual(s) directly responsible for the incident(s) of noncompliance.
    b. The Principal Investigator.
    c. The IRB members through the IRB Chair(s).
    d. Department Chair of the PI.
    e. The Federal sponsor.
    f. Other institutional officials as determined by the IRB.

6. **Office of Human Research Protections (OHRP)**
Within five (5) business days of the decision from the convened IRB, the IO will send a formal letter to the OHRP Division of Compliance Oversight. The letter must include the following:
    a. Identification of the IRB application.
    b. Funding of the application (federal, non-federal, commercial, etc.)
    c. Timeline and description of the incident(s) of noncompliance.
    d. Copy of the IRB application and applicable consent documents.
    e. Reports from IRB consultants, if applicable.
    f. Other documentation pertaining to the incident(s).
    g. Corrective action plan approved by the convened IRB.

7. **Association for the Accreditation of Human Research Protection Programs (AAHRPP)**
The UMD HRPP will report to AAHRPP as soon as possible but generally within 48 hours after UMD or any researcher (if the researcher is notified rather than the organization) becomes aware of:
    a. Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.

b. Any litigation, arbitration, or settlements initiated related to human research protections. Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP.

1. **Purpose**

   The purpose of this SOP is to describe audits by outside agencies.

2. **Policy**

   It is the policy of the IRB that the HRPP will cooperate with audits by outside agencies in full accordance with regulations at Health and Human Services 45CFR46.

3. **FDA, OHRP, Department of Defense, or National Institutes of Health Cooperative Group – Audit or Inspection**

   When an IRB staff member is contacted by a representative from a federal agency or a NIH cooperative group for an audit of the IRB, the following actions must be taken:

   a. Ask for the reason for the visit if this has not already been provided.

   b. Inquire what documents and information they will require during the investigation.

   c. Immediately contact the Director – HRPP and an IRB Chair.

   d. An email confirming the visit will be sent to the Director, an IRB Chair, IRB staff, and the IO.

   e. When the auditor(s) arrives, ask to see the auditors' identification and business card for name and agency affiliation. Additionally, if the investigation is being conducted by a federal agency, the auditor may provide a copy of the memo from headquarters detailing the reason for the visit.

   f. During the visit, the Director and IRB Chair should be available to the auditor. A written record of the study files that are reviewed and documents photocopied must be kept.

   g. During the closing interview it is preferable that an IRB Chair, the Director and the Quality Assurance Program Manager be present. The Director and QA Program Manager will note all issues identified by the investigation and the action proposed by the auditor (if applicable).

   h. If the Director is unable to attend the exit interview, the QA Program Manager will provide a summary of the results of the interview and required actions resulting from the investigation. If necessary, all individuals involved in the investigation will meet with the Director for debriefing.

   i. Following the discussion with the Director, the QA Program Manager will immediately send an email to the individuals named in Item (d) above providing a synopsis of the investigation and the preliminary results presented at the closing interview. Special emphasis will be placed on those areas where deficiencies were found that require attention.

j. The IRB Chair(s), the Director, and the IRB staff will meet within five (5) days following the investigation to propose a corrective action plan to address deficiencies found during the investigation. The IRB members will be notified of the investigation and action plan. The IRB members may offer suggestions to modify the plan as necessary.

k. The Director will notify all principal investigators whose study files were examined during the investigation. Results from the audit that are pertinent to the specific study will be discussed. Following receipt of the official letter from the regulatory agency, the Principal Investigator will also be notified of areas of concern related to their study.

l. The IRB will normally receive a report of the results of an audit. Where there are identified areas of concern or sanctions placed, the IRB Chair(s), Director and other appropriate UMD officials will respond to the agency.

4. **OHRP For-Cause Investigation of Noncompliance and Not-For-Cause Compliance Oversight Evaluation**
If the IO receives notification from OHRP that they have initiated a for-cause investigation of noncompliance or a not-for-cause compliance oversight investigation, the IO, in collaboration with the IRB Chair(s), Director – HRPP, and other appropriate institutional officials will respond immediately and appropriately with an action plan to address the matter.

5. **Audits of Investigator's Records by Outside Agencies**
When a PI is contacted by a representative from any federal agency, sponsor, or other entity for an investigation or audit of a research project, the IRB must be notified of the visit. If the visit is pre-planned, an email may be sent to the Director – HRPP. If it is a no-notice investigation or audit, the Director – HRPP should be notified as soon as possible. The following information must be provided to the IRB:
    a. The IRB project number and title.
    b. The name of the governmental agency, sponsor, or other funding entity.
    c. Name of the PI.
    d. The dates of the visit.
    e. The type of visit:
        i. Routine surveillance/monitoring visit.
        ii. For-cause investigation.
        iii. Other

6. **Audit/Investigation Follow-up**
Following the investigation or audit, the IRB must be notified by the Principal Investigator of any compliance issues identified during the exit interview. If the investigation or audit revealed conditions or practices that are of significant departure from the federal regulations with potential for sanctions, the IRB Chair must be immediately

notified by telephone. If the IRB Chair is not available, the Director should be informed. This information will be relayed to the Director and other appropriate UMCP officials as soon as possible and HRPP Policy 14.003 will be implemented as necessary.

A copy of the official letter detailing the results of the investigation must be provided to the IRB. If the investigation or audit revealed areas of concern, the Principal Investigator must provide the IRB with a copy of the response with particular emphasis on the corrective action plan.

The full IRB will be given all information and will determine what action is necessary, including reporting noncompliance to OHRP and Food and Drug Administration.

1. **Purpose**

   The purpose of this policy is to outline ethical standards and practices of the Human Research Protection Program (HRPP) in accordance with Department of Education regulations.

2. **Policy**

   It is the policy of the HRPP to comply with all Department of Education Policies and procedures and with the Family Educational Rights and Privacy Act (FERPA). The University of Maryland will comply with all processes and guidelines when conducting any research funded by the Department of Education.

3. **Definitions**

   a. **Research or experimentation program or project** means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.

   b. **Children** are persons enrolled in research not above the elementary or secondary education level, who have not reached the age of majority as determined under state law.

4. **Procedures**

   a. FERPA applies when researchers obtain student records or personal education information from an education program as defined as any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, post-secondary education, special education, job training, career and technical education, and adult education.

   b. The IRB will follow these guidelines when processing parental/student consent for the release or non-release of any student records for research. This responsibility may be delegated to the IRB or another individual or component of the University of Maryland, College Park (e.g., a FERPA committee).

   c. An educational agency or institution may disclose personally identifiable information from an education record of a student without consent if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to:

      i. Develop, validate, or administer predictive tests.
      ii. Administer student aid programs.
      iii. Improve instruction.

   d. A school district or postsecondary institution that uses this exception is required to enter into a written agreement with the university or investigator conducting the research that specifies:

      i. The determination of the exception.
      ii. The purpose, scope, and duration of the study.
      iii. The information to be disclosed.

iv. That information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in U.S. Department of Education regulations on redisclosure and destruction of information.
v. That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the university with legitimate interests.
vi. That the university is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.
vii. The time period during which the university must either destroy or return the information.

e. Education records may be released without consent under FERPA if all personally identifiable information has been removed including:
   i. Student's name and other direct personal identifiers, such as the student's social security number or student identification number.
   ii. Indirect identifiers, such as the name of the student's parent or other family members; the student's or family's address, and personal characteristics or other information that would make the student's identity easily traceable; date and place of birth and mother's maiden name.
   iii. Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.
   iv. Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

f. The UMD IRB will follow these guidelines when conducting research that will comply with the Protection of Pupil Rights Amendment.
   i. No student shall be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:
      1. Political affiliations or beliefs of the student or the student's parent.
      2. Mental or psychological problems of the student or the student's family.
      3. Sex behavior or attitudes.
      4. Illegal, anti-social, self-incriminating, or demeaning behavior.
      5. Critical appraisals of other individuals with whom respondents have close family relationships.
      6. Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers.
      7. Religious practices, affiliations, or beliefs of the student or student's parent.
      8. Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program).

g. The IRB will follow these guidelines when reviewing any IRB application when prior consent is used. Prior consent means:
   i. Prior consent of the student if the student is an adult or emancipated minor; or
   ii. Prior written consent of the parent or guardian if the student is not an emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any Department of Education-funded survey, analysis, or evaluation.

h. Policies and procedures include that for research funded by the National Institute on Disability and Rehabilitation Research, when IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research participants, the IRB must include at least one person primarily concerned with the welfare of these research participants.

i. For research not funded by the US Department of Education but being conducted in conjunction with the University of Maryland, the IRB will follow these guidelines:
   i. The IRB must verify compliance with U.S. Department of Education regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:
      1. The right of parents to inspect, upon request, a survey created by a third party before the survey is administered or distributed by a school to students.
         a. Any applicable procedures for granting a request for reasonable access to such survey within a reasonable period of time after the request is received.
      2. Arrangements to protect student privacy that are provided by the agency in the event of the administration or distribution of a survey to a student containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items):
         a. Political affiliations or beliefs of the student or the student's parent.
         b. Mental or psychological problems of the student or the student's family.
         c. Sex behavior or attitudes.
         d. Illegal, anti-social, self-incriminating, or demeaning behavior.
         e. Critical appraisals of other individuals with whom respondents have close family relationships.
         f. Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.
         g. Religious practices, affiliations, or beliefs of the student or the student's parent.
         h. Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such a program).
      3. The right of a parent to inspect, upon request of the parent, any instructional material used as part of the educational curriculum for the student.

4. Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.
5. The administration of physical examinations or screenings that the school or agency may administer to a student.
6. The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.
7. The right of a parent of a student to inspect, upon the request of the parent, any instrument used in the collection of personal information before the instrument is administered or distributed to a student.
8. Any applicable procedures for granting a request by a parent for reasonable access to such an instrument within a reasonable period after the request is received.

1. **Purpose**
   The purpose of this policy is to outline ethical standards and practices of the Human Research Protection Program (HRPP) in accordance with the Environmental Protection Agency regulations.

2. **Policy**
   It is the policy of the HRPP to comply with all Environmental Protection Agency regulations when conducting research in conjunction with the protection of human health and the environment within 40CFR26.

3. **Pregnant Women**
   The IRB will follow the following policies and procedures when research supported by the EPA includes pregnant women and children:
   a. EPA prohibits research involving the intentional exposure of pregnant women, nursing women, or children to any substance.
   b. EPA requires application of 40CFR26 Subparts C and D to provide additional protections to pregnant women and children as participants in observational research, i.e., research that does not involve intentional exposure to any substance.
   c. EPA requires submission of IRB determinations and approval to the EPA human subjects research review official for final review and approval before the research can begin.

4. **Human Research Regulations**
   For research not conducted or supported by any federal agency that has regulations for protecting human research participants and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research participants apply, including:
   a. EPA extends the provisions of the 45CFR26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to substances.
   b. EPA prohibits the intentional exposure of pregnant women, nursing women, or children to any substance.

5. **Observational Behavior**
   The IRB will follow these guidelines when conducting research with observational behavior:
   a. The IRB will review all observational research involving pregnant women and fetuses using 40CFR26 and 45CFR46 - Subpart B.
   b. The IRB will review and approve observational research involving children that does not involve greater than minimal risk only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 40CFR26.406.
   c. The IRB will review and approve observational research involving children that involves greater than minimal risk but presenting the prospect of direct benefit to the individual participants if the IRB find and documents that:
      i. The intervention or procedure holds out the prospect of direct benefit to the individual participant or is likely to contribute to the participant's well-being.
      ii. The risk is justified by the anticipated benefit to the participants.
      iii. The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
      iv. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 40CFR26.406.

1. **Purpose**

   The purpose of this SOP is to outline the ethical standards and practices of the Human Research Protection Program (HRPP) in accordance with Department of Justice regulations.

2. **Policy**

   It is the policy of the UMD HRPP to comply with all Department of Justice regulations when conducting research within the Bureau of Prisons and/or when conducting National Institute of Justice-funded research.

   a. The UMD IRB, investigators, and research staff will follow the requirements outlined in 28CFR512 when conducting research within the Bureau of Prisons. **Please Note:** Implementation of programmatic or operational initiatives within the Bureau of Prisons made through pilot projects will not be considered research.

3. **Requirements**

   a. In all research projects the rights, health, and human dignity of individuals involved must be respected.
   b. The project must have an adequate research design and contribute to the advancement of knowledge about corrections.
   c. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
   d. The project must minimize risk to subjects; risks to subjects must be reasonable in relation to anticipated benefits. The selection of subjects within any one institution must be equitable. When applicable, informed consent must be sought and documented.
   e. Incentives may not be offered to help persuade inmate subjects to participate. However, soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both:
      i. No longer in Bureau of Prisons custody, and
      ii. Participating in authorized research being conducted by Bureau employees or contractors.
   f. The researcher must have academic preparation or experience in the area of study of the proposed research.
   g. The researcher must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the researcher.
   h. Except as noted in the informed consent statement to the subject, the researcher must not provide research information which identifies a subject to any person without that subject's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertains.
   i. The researcher must adhere to applicable provisions of the Privacy Act of 1974 and regulations pursuant to this Act.
   j. The research design must be compatible with both the operation of prison facilities and protection of human subjects. The researcher must observe the rules of the institution or office in which the research is conducted.
   k. Any researcher who is a non-employee of the Bureau must sign a statement in which the researcher agrees to adhere to the provisions of this subpart.
   l. Except for computerized data records maintained at an official Department of Justice site, records which contain non disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.
   m. If the researcher is conducting a study of special interest to the Office of Research and Evaluation (ORE), but the study is not a joint project involving ORE, the researcher may be asked to provide ORE with the computerized

research data, not identifiable to individual subjects, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

n. The researcher must submit planned methodological changes in a research project to the IRB for approval and may be required to revise study procedures in accordance with the new methodology.

o. All research receiving National Institute of Justice (NIJ) funding must:
   i. Have a privacy approved by the NIJ Human Subjects Protection Officer.
      (1) Under a privacy certificate, researchers and research staff do not have to report child abuse unless the participant signs another consent document to allow child abuse reporting.
   ii. Have Employee Confidentiality Statements signed by all investigators and research staff. These Statements must be maintained by the Principal Investigator (PI).
   iii. Have a confidentiality statement on the consent form stating that confidentiality can only be broken if the participant reports immediate harm to participants or others.
   iv. Have the name of the funding agency included in the informed consent document.
   v. For National Institute of Justice-funded research, a copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.

4. **Research Proposals**

All research proposals will be reviewed by the Bureau Research Review Board. When submitting a research proposal, the applicant shall provide the following information:

a. A summary statement which includes
   i. Name(s) and current affiliation(s) of the researcher(s);
   ii. Title of the study.
   iii. Purpose of the project.
   iv. Location of the project.
   v. Methods to be employed.
   vi. Anticipated results.
   vii. Duration of the study.
   viii. Number of subjects (staff/inmates) required and amount of time required from each.
   ix. Indication of risk or discomfort involved as a result of participation.

b. A comprehensive statement which includes:
   i. Review of related literature;
   ii. Detailed description of the research method;
   iii. Significance of anticipated results and their contribution to the advancement of knowledge;
   iv. Specific resources required from the Bureau;
   v. Description of all possible risks, discomforts, and benefits to individual subjects or a class of subjects, and a discussion of the likelihood that the risks and discomforts will actually occur;
   vi. Description of steps taken to minimize any risks described in (b)(5) of this section.
   vii. Description of physical and/or administrative procedures to be followed to:
      (1) Ensure the security of any individually identifiable data that are being collected for the project, and
      (2) Destroy any research records or remove individual identifiers from those records when the research has been completed.

viii. Description of any anticipated side effects of the research project on institutional programs and operations; and

ix. Relevant research materials such as vitae, endorsements, sample informed consent statements, questionnaires, and interview schedules.

c. A statement regarding assurances and certification required by 28CFR46, if applicable.

5. **Informed Consent**

a. Before commencing a research project requiring participation by staff or inmates, the researcher shall give each participant a written informed consent statement containing the following information:

i. Identification of the principal investigator(s).

ii. Objectives of the research project.

iii. Procedures to be followed in the conduct of research.

iv. Purpose of each procedure.

v. Anticipated uses of the results of the research.

vi. A statement of benefits reasonably to be expected.

vii. A declaration concerning discomfort and risk, including a description of anticipated discomfort and risk.

viii. A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).

ix. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the subject indicates an intent to commit future criminal conduct or harm himself/herself or someone else, or if the subject is an inmate, indicates an intent to leave the facility without authorization.

x. A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility.

xi. An offer to answer questions about the research project; and

xii. Appropriate additional information as needed to describe adequately the nature and risks of the research.

b. A researcher who is an employee of the Bureau shall include in the informed consent statement a declaration of the authority under which the research is conducted.

c. A researcher who is an employee of the Bureau, in addition to presenting the statement of informed consent to the subject, shall also obtain the subject's signature on the statement of informed consent, when:

i. The subject's activity requires something other than responses to a questionnaire or interview; or

ii. The Chief, ORE, determines the research project or data collection instrument is of a sensitive nature.

d. A researcher who is a non-employee of the Bureau, in addition to presenting the statement of informed consent to the subject, shall also obtain the subject's signature on the statement of informed consent prior to initiating the research activity. The researcher may not be required to obtain the signature if the researcher can demonstrate that the only link to the subject's identity is the signed statement of informed consent or that there is significantly more risk to the subject if the statement is signed. The signed statement shall be submitted to the chairperson of the appropriate local research review board.

6. **Reports**

The researcher shall prepare reports of progress on the research and at least one report of findings

a. At least once a year, the researcher shall provide the Chief of the Office of Research and Evaluation, with a report on the progress of the research.

b. At least twelve (12) working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board (BRRB), the regional director, ad the warden of each institution that provided data or assistance. The researcher shall include an abstract in the report of findings.

7. **Monitoring**

The BRRB shall monitor all research projects for compliance with Bureau policies. At a minimum, yearly reviews will be conducted.

8. **Publication**

A researcher may publish in book form and professional journals the results of any research project conducted under this subpart.

a. In any publication of results, the research shall acknowledge the Bureau's participation in the research project.
b. The researcher shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
c. Prior to submitting for publication the results of a research project conducted under this subpart, the researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation (ORE), Central Office, Bureau of Prisons.

1. **Purpose**
   The purpose of this policy is to outline ethical standards and practices of the HRPP in accordance with Department of Defense (DoD) regulations.

2. **Policy**
   It is the policy of the HRPP to comply with all federal regulations when conducting, reviewing, approving, overseeing, supporting, or managing Department of Defense sponsored human subject research. To ensure compliance with these regulations, the HRPP staff will review the current Department of Defense Addendum and requirements at the time of initial and continuing protocol review.

3. **Not Human Subject Research**
   The following activities are not considered research involving human subjects:
   a. Public or internal information collections of facts or opinions, obtained initially or in follow-up requests, from individuals (including individuals in control groups) under treatment or clinical examination in connection with research on, or prophylaxis to prevent, a clinical disorder;
   b. Direct treatment of that disorder; or
   c. The interpretation of biological analyses of body fluids, tissues, or other specimens; or the identification or classification of such specimens.

4. **Definition of Minimal Risk**
   The definition of minimal risk in 32CFR219 does not include the inherent occupational risks that certain participants face in their everyday life, such as those:
   a. Encountered by Service members, law enforcement, or first responders while on duty.
   b. Resulting from or associated with high-risk behaviors or pursuits.
   c. Experienced by individuals whose medical conditions involve frequent tests or constant pain.

5. **Surveys on DoD Personnel**
   UMD may conduct research involving DoD personnel. Surveys performed on DoD personnel must be submitted, reviewed, and approved by the DoD Information Management Control Officer (IMCO) after the research protocol is reviewed and approved by the IRB. When a survey crosses DoD components, additional review is required. More details regarding review and approval can be found in Appendix A titled, "Internal Process & Standard Operating Procedure – Human Subject Research (HSR) Application Approval at UMD and DOD/USG."
   a. Communicating DoD specific requirements:
      i) If the DoD sends a contract with specific requirements, the Office of Research Administration (ORA) will review the contract.
      ii) ORA then communicates these requirements to both the HRPP and the investigators.
      iii) ORA, HRPO, and the investigators work together to make sure the requirements are met.

6. **DoD Component-Level Review**
   Individual Department of Defense (DoD) sponsored research components may require additional specific requirements. Researchers should contact their DoD project coordinator to ensure adherence to any unique requirements. DoD component-level administrative review (CLAR) must be conducted prior to research starting when:

a. Human subject research is conducted in a foreign country, unless conducted by a DoD overseas institution, or only involves DoD-affiliated personnel who are US citizens.
b. The involvement of DoD personnel in the conduct of the research is secondary to that of the non-DoD institution
c. The research requires a waiver of informed consent pursuant to 10 USC 980, Subsection (b).
d. The research is fetal research, as described in 42 USC 289g-289g-2.
e. Large scale genomic data (LSGD) is collected from DoD-affiliated personnel. LSDG includes data derived from genome-wide association studies; single nucleotide polymorphisms arrays; genome sequencing; transcriptomic, metagenomic, epigenomic analyses; and gene expression data; etc.
f. The research constitutes classified research involving human participants.
g. The research is required to be approved by the DOHRP (in addition to the COHRP) in accordance with DoDI 3216.02.
h. Component review includes review of reliance agreements.

7. **Scientific Review of Research**
When an IRB or EC at a non-DoD institution reviews DoD-supported research, the IRB or EC must consider the scientific merit of the research.
a. The IRB or EC may rely on outside experts to provide an evaluation of the scientific merit.
b. Substantive amendments to approved research must undergo scientific review prior to IRB review (HRPP Policy 3.006).
c. If a continuing review is required for approved research, it must also undergo a scientific review prior to IRB review (HRPP Policy 3.006).

8. **Research with Vulnerable Populations**
Research involving pregnant women, prisoners, and children are subject to the DHHS Subparts B, C, and D, except where modified by DoDI 3216.02. For purposes of applying Subpart B, the phrase “biomedical knowledge” is replaced with “generalizable knowledge”.
a. The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and included interventions or invasive procedures to the woman or fetus or involving fetuses or neonates as participants.
b. Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.
    i) Research or experimentation may not be conducted, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not be ascertained unless the research or experimentation:
        (1) May enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or
        (2) Will pose no added risk of suffering, injury or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.
    ii) The risk standard must be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.
c. For human subject research that would not otherwise be approved but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, written approval from the DOHRP must be obtained through the COHPR prior to research starting.

d. In addition to the categories of permissible human participant research involving prisoners identified in DHHS regulations Subpart C, two additional categories are permissible:
   i) Epidemiological research is permitted under the following conditions:
      (1) Where the sole purpose of the research is to describe the prevalence or incidence of a disease by identifying all cases, or study potential risk factor associations for a disease
      (2) The research presents no more than minimal risk.
      (3) The research presents no more than an inconvenience to the subject.
      (4) Prisoners are not a particular focus of the research.
   ii) Human subject research involving prisoners that would otherwise meet exemption criteria may be conducted, but must first be approved by an IRB and meet the requirements of Subpart C and DoDI 3216.02.
e. DoD organizations conducting research involving prisoners must demonstrate to the senior designated official that the IRB has fulfilled its duties in accordance with Subpart C.
f. When a previously enrolled human subject becomes a prisoner, and the protocol has not been reviewed and approved by the IRB in accordance with Subpart C, the researcher must promptly notify the IRB.
   i) For DoD-conducted research, the human protections director must notify the COHRP.
   ii) For DoD-supported research, the non-DoD organization must notify the DOHRPO and other federal agencies.
   iii) The DOHRP must concur with the IRB before the participant can continue to participate while a prisoner.
g. Research involving a detainee or a prisoner of war as a human subject is prohibited.
   i) This prohibition does not apply to activities covered by investigational new drug or investigational device provisions of FDA regulations, when the purpose is for diagnosis or treatment of a medical condition in a patient.
   ii) Such treatment may be offered to detainees or prisoners of war with their informed consent when the medical products are subject to FDA regulations, and only when the same product may be available to DoD-affiliated personnel consistent with established medical practices.
h. Service members and DoD-affiliated personnel are considered to be vulnerable to coercion and undue influence by the DoD due to the nature of the command structure of the organization. Therefore, additional protections for DoD-affiliated personnel are required, as follows (DoDI 3216.02 section 3.9 (f)):
   i) If the research involves DoD-affiliated personnel as participants and if the research includes any risks to their fitness for duty (e.g., health, availability to perform job, data breach), the informed consent document must inform DoD-affiliated personnel about these risks and that they should seek command or component guidance before participating.
   ii) If the research involves DoD-affiliated personnel, the researcher must receive command or component approval to execute the research.
   iii) Military and civilian supervisors, officers, and others in the chain of command are prohibited from influencing their subordinates to participate in research.
   iv) Military and civilian supervisors, officers, and others in the chain of command must not be present at any participant recruitment sessions or during the consent process for DoD-affiliated personnel. Excluded supervisors or those in the chain of command may participate in separate recruitment sessions, if applicable.
   v) Service members and all Reserve component and National Guard members in a federal duty status are considered to be adults. If a Service member, Reserve component or National Guard member in federal duty status, student at a Service Academy, or trainee is under 18 years of age, the IRB must carefully consider the HSR recruitment process and the necessity of including such member as a human participant.

vi) In order to approve research involving DoD-affiliated personnel, the IRB or component HRPO must determine whether the following requirements have been satisfied:
   (1) The consent documentation must include if applicable, potential risks for revocation of clearance, credentials, or other privileged access or duty.
   (2) For research involving recruitment of DoD-affiliated personnel in research determined to be greater than minimal risk, and when recruitment occurs in a group setting, the IRB must appoint an ombudsperson. The ombudsperson:
      (a) Must not have a conflict of interest with the research or a be a part of the research team.
      (b) Must be present during the recruitment, monitoring that the recruitment and informed consent explain that participation is voluntary and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided materials.
      (c) Should be available to address DoD-affiliated personnel's concerns about participation.

i. Compensation to DoD-affiliated personnel for participation in research while on duty is prohibited in accordance with 5 USC, with particular reference to Subparts G and H, with some exceptions for purposes consistent with 24 USC 30.

9. **Research involving large-scale genomic data from DoD-affiliated personnel is subject to additional requirements (DoDI 3216.02 section 3.10):**
   a. The disclosure of DoD-affiliated personnel's genomic data may pose a risk to national security; accordingly, written materials must describe administrative, technical, and physical safeguards commensurate with risk, including the secondary use or sharing of de-identified data or specimens.
   b. All research involving large-scale genomic data collected from DoD-affiliated personnel must have a certificate of confidentiality from DHHS (Title 42, U.S.C., and Public Law 114-255).
   c. Research involving large-scale genomic data collected from DoD-affiliated personnel is subject to DoD component security review to ensure the adequacy of the proposed administrative, technical, and physical safeguards, including the secondary use or sharing of de-identified data or specimens.

   DoD organizations must demonstrate to the senior designated official that the IRB has fulfilled its duties in accordance with DHHS Subpart D, 45CFR46.407 and 21CFR50.24.

10. **Compensation to DoD-affiliated Personnel**
   When research involves U.S. military personnel, policies and procedures require limitations on dual compensation:
   a. Prohibit an individual from receiving pay of compensation for research during duty hours.
   b. U.S. military personnel may be compensated for research if the participant is involved in the research when not on duty
   c. Federal employees while on duty and non-federal persons may be compensated for blood draws for research up to $50 for each blood draw.
   d. Non-federal persons may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.

11. **Consent Requirements**
   Consent documents must include the following DoD elements of disclosure:
   a. A statement that the DoD or a DoD organization is funding the study.
   b. A statement that representatives of the DoD are authorized to review research records.

If the research involves DoD-affiliated personnel as participants, in addition to the basic and required consent disclosures, consent documents must include:

a. If the research involves risks to their fitness for duty (e.g., health, availability to perform job, data breach), the informed consent document (ICD) must inform DoD affiliated personnel about these risks and that they should seek command or Component guidance before participating.
b. If applicable, a statement of potential risks for the revocation of clearance, credentials, or other privileged access or duty.

For greater than minimal risk research consent documents must include the disclosure that participants may, for the duration of the study, be eligible for health care services for research-related injuries at a military treatment facility, and this eligibility for health care services extends beyond participants' participation in the study to such time after the study has ended.

a) DoD-supported research not conducted by the DoD must comply with the Common Rule requirements for medical care for research related injury; for greater than minimal risk research, the consent form must inform subjects of what, if any care is available in the event of an injury and who is responsible for costs related to this care.

For greater than minimal risk research involving DoD-personnel, when recruitment and consent occur in a group setting, the IRB must appoint an ombudsperson. The ombudsperson:

a. Must not have a conflict of interest with the research or be a part of the research team.
b. Must be present during the HSR recruitment, monitoring that the recruitment and informed consent explain that participation is voluntary and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided materials.
c. Should be available to address DoD-affiliated personnel's concerns about participation.

If non-exempt research is supported by DoD-appropriated funds and involves experimental subjects as defined in DODI 3216.02, consent must be obtained in advance, in accordance with 10 USC 980.

a. An IRB may waive or alter some elements of informed consent for research involving human beings as experimental subjects, so long as it preserves the informed consent of the participant (i.e., the consent indicates that participation in the research is voluntary and the participant/representative is informed of research risks).
b. The DOHRP may waive the requirements for prospective consent for research involving human beings as "experimental subjects" when all of the following are met:
   i) The research is necessary to advance the development of a medical product for the Military Services.
   ii) The research may directly benefit the individual experimental subject.
   iii) The research is conducted in compliance with all other applicable laws and regulations.
c. Waivers of consent are prohibited for DoD classified research.
d. If consent is to be obtained from the legal representative of the experimental subjects as defined in DODI 3216.02, the research must intend to benefit each participant enrolled in the study.
e. For research conducted by a non-DoD organization, consent forms cannot contain language indicating that the DoD will pay for care for research-related injury.

12. **Research in Foreign Countries**

Investigators conducting research in foreign countries must:

a. Obtain DoD component-level administrative approval (CLAR) prior to research starting.
b. Have permission to conduct research in that country by certification or through a local ethics review; and
c. Follow all laws, regulations, customs, and practices.

13. **Research Involving an Experimental Subject:**
UMD may conduct research with experimental subjects. However, a full waiver of consent may not be utilized in DOD funded research.

Research involving an "experimental subject" is an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving "experimental subjects" is a subset of research involving human participants. This definition relates only to the application of Section 980 of Title 10, U.S.C.; it does not affect the application of 32CFR219.

14. **Research with Chemical or Biological Agents:**
UMD does not conduct human subject research involving the testing of chemical or biological agents.

Human subject research involving the testing of chemical or biological agents is prohibited, pursuant to Section 1520a of Title 50, United States Code (U.S.C.). Some exceptions for research for prophylactic, protective, or other peaceful purposes apply. Before any excepted testing of chemical or biological agents involving human participant research can begin, the DoD component seeking to conduct such research must obtain explicit written approval from the DoD Office for Human Research Protections (DOHRP).

15. **Classified Research**
Classified research is defined in DoDI3216.02 section 3.13.
a. The UMD HRPO has the ability to establish a classified IRB if review of classified material is needed. This IRB will consist of members with appropriate levels of security clearance. More details regarding review and approval can be found in Appendix A titled, Internal Process & Standard Operating Procedure – Human Subject Research (HSR) Application Approval at UMD and DOD/USG.
b. Non-exempt classified research must be conducted following the requirements of Instruction 3216.020.13.

16. **Clinical Research**
In conducting or supporting clinical research, the Secretary of Defense shall ensure that:
a. Women who are members of the Armed Forces are included as participants in each project of such research; and
b. Members of minority groups who are members of the Armed Forces are included as participants of such research.
c. The Secretary of Defense may waive these requirements regarding women and members of minority groups with respect to a project of clinical research if the Secretary determines that the inclusion, as participants in the project, of women and members of minority groups, respectively:
    i) is inappropriate with respect to the health of the participants,
    ii) is inappropriate with respect to the purpose of the research, or
    iii) is inappropriate under such other circumstances as the Secretary of Defense may designate.

17. **Data and Safety Monitoring**
    For research involving greater than minimal risk (as defined in 32CFR219.102(j), reference (c)) an independent medical monitor shall oversee a Data and Safety Monitoring Plan. In some instances, the IRB may require the development of a Data and Safety Monitoring Plan for research involving no more than minimal risk (HRPP Policy 3.010).
    a. The independent medical monitor shall be appointed by name.
    b. The research monitor has the authority to:
        i) Stop a study in progress
        ii) Remove individuals from the study
        iii) Take any steps to protect the safety and well-being of participants until the IRB can assess the situation.

18. **Reliance and/or Multi-site Research**
    When conducting multi-site research, policies and procedures indicate that a formal agreement between organizations is required to specify the roles and responsibilities of each party.
    a. DoD institutions collaborating with non-DoD institutions may rely on a collaborating non-DoD institution's IRB if the following conditions are met:
        i) Each institution engaged in non-exempt human participant research must have a current federal assurance of compliance.
        ii) The non-DoD institution's IRB is registered in accordance with Subpart E of 45CFR46.
        iii) The DoD institution reviews the protocol to ensure all applicable local and DoD requirements are addressed in the protocol.
        iv) The DoD institution, non-DoD institution, and the non-DoD institution's IRB have a written agreement defining the responsibilities and authorities of each institution in complying with all legal requirements. This agreement must specify that the non-DoD IRB will apply the DoD requirements specified in DoDI 3216.02, including but not limited to non-DoD institutional responsibilities defined under DoDI 3216.02 section 3.6(b).
        v) If the research constitutes classified human participant research, the COHRP must approve the agreement to rely on the non-DoD institution's IRB.

19. **Record Keeping**
    a. The IRB shall maintain a complete set of materials relevant to the review of the research protocol for a period sufficient to comply with legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures.
        i) Contingent on the terms and conditions of the DoD award, the IRB may submit a copy of these materials to the DoD for archiving.
    b. Records maintained that document compliance or noncompliance with DoD requirements shall be made accessible for inspection and copying by representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD component. Records must be maintained for at least three years.

20. **IRB Training**
    IRB members and HRPP staff regularly receive training that provides information necessary to facilitate the performance of assigned responsibilities. In addition, all personnel involved in conducting human participation research are required to complete training in the protection of human participants prior to engaging in human research activities (HRPP Policy 2.004 and 3.009).

21. **Reporting**

For DoD-supported research reviewed via exempt, expedited, or full board review paths, the UMD PI is responsible for reporting project changes to the COHRP and the UMD Institutional Official (IO) or their Designee is responsible for reporting investigations to the COHRP. The following must be promptly reported to the Component Office of Human Research Protections (COHRP):

a. When significant changes to the research protocol are approved by the IRB or EC:
   i) Changes to key investigators or institutions.
   ii) Decreased benefit or increased risk to participants in greater than minimal risk research.
   iii) Addition of vulnerable populations as participants.
   iv) Addition of DoD-affiliated personnel as participants.
   v) Change of reviewing IRB.

b. When the organization is notified by any federal body, state agency, official governing body of a Native American or Alaskan native tribe, other entity, or foreign government that any part of an HRPP is under investigation for cause involving a DoD-supported research protocol.

c. Any problems involving risks to participants or others, suspension or termination of IRB approval, or any serious or continuing noncompliance pertaining to DoD-supported human participant research.
   i) Unanticipated problems involving risks to participants or others and any subsequent actions taken based on the findings.
   ii) Incidents of noncompliance will be reported according to HRPP Policy 14.002.
   iii) All allegations of serious or continuing noncompliance related to research involving human participants that are substantiated by investigation will be reported to OHRP and the DoD
   iv) Within five (5) business days of the full board decision, the IO will send a formal letter to the OHRP Director for Compliance Oversight and DoD. The letter must include the following
      (1) Identification of the protocol.
      (2) Funding of the protocol (federally or non-federally funded, commercially sponsored).
      (3) Timeline and description of non-compliance.
      (4) Copy of the IRB application and applicable consent documents.
      (5) Applicable reports from IRB consultants.
      (6) Other documentation pertaining to the event.
      (7) Corrective action plan approved by the convened IRB.

d. The results of the IRB's continuing review, if required.

e. The results of for-cause audits, reviews, or assessments.

f. Change in status when a previously enrolled participant becomes pregnant, or when the researcher learns that a previously enrolled participant is pregnant, and the protocol was not reviewed and approved by the IRB in accordance with 45CFR46, Subpart B.

g. Change in status when a previously enrolled participant becomes a prisoner, and the protocol was not reviewed and approved by the IRB in accordance with 32CFR219, Subpart C.

h. Substantiated allegations related to classified HSR must be reported immediately.

i. Closure of a DoD-supported study.

1. **Purpose**
   The purpose of this policy is to outline ethical standards and practices of the Human Research Protection Program (HRPP) in accordance with the Department of Energy principles for the protection of human subjects involved in Department of Energy research.

2. **Policy**
   It is the policy of the HRPP to comply with all Department of Energy (DOE) regulations when conducting research in the physical sciences in conjunction with human subjects.

3. **Requirements**
   DOE requirements apply to all research conducted with DOE funding, at DOE institutions (regardless of funding source), or by DOE or DOE contractor personnel (regardless of funding source or location conducted), whether done domestically or in an international environment, including classified and proprietary research.

   a. When research involves contractors, DOE "Contractor Requirements Document" describing contractor responsibilities for protecting human research participants must be included in the contracts.

4. **Human Subject Research**
   No human subject research conducted with DOE funding, at DOE institutions, regardless of funding source), or by DOE contractor personnel (regardless of funding source or location conducted), and whether done domestically or in an international environment, including classified and proprietary research, may be initiated without both a Federalwide Assurance (FWA) or comparable assurance (e.g., Department of Defense assurance) and approval by the cognizant IRB in accordance with 10CFR745.103.

   a. Research involving human participants involving multiple DOE sites (e.g., members of the research team from more than one DOE site and/or data or human subjects from more than one DOE site) must be reviewed and approved by one of the Central DOE IRBs prior to initiation, unless review by another appropriate IRB of record is authorized by the DOE and/or NNSA HSP Program Manager.

   b. If authorized by the DOE and/or NNSA HSP Program Manager, research may be reviewed by other appropriate IRB of record. In all cases, an IRB Authorization Agreement (IAA) or Memorandum of Understanding (MOU) must be in place between the organization(s) conducting the HSR and the organization responsible for IRB review.

   c. The Human Subjects Protection (HSP) Program Manager (and when an NNSA element is involved, the NNSA HSP Program Manager) must be notified in writing prior to initiation of the HSR portion of a new project, even if it meets the regulatory definition of exempt HSR as outlined in 10CFR745.104, that involves:
      i. An institution without an established IRB.
      ii. A foreign country.
      iii. A potential for significant controversy (e.g. negative press or reaction from stakeholder or oversight groups).
      iv. Research subjects in a protected class (prisoners, children, individuals with impaired decision making, or DOE/NNSA federal or DOE/NNSA contractor employees as human subjects, who may be

more vulnerable to coercion and undue influence to participate) that is outside of the reviewing IRB's typical range/scope.

v. The generation or use of classified information.

d. In addition to traditional biomedical and clinical studies, such Department of Energy human subject research includes but is not limited to the following:
   i. Research using humans to examine devices, products, or materials with the express purpose of investigating human-machine interfaces or evaluating environmental alterations when humans are the subjects being tested;
   ii. Research using personally identifiable bodily materials such as cells, blood, tissues, urine, or hair, even if the materials were collected previously for a purpose other than the current research;
   iii. Research that collects and uses personally identifiable information such as genetic information or medical and exposure records, even if the information was collected previously for a purpose other than the current research;
   iv. Research that collects personally identifiable data, surveys, or questionnaires through direct intervention or interaction with individuals; and
   v. Research that searches for generalizable knowledge about categories or classes of subjects (e.g., linking job conditions of worker populations to hazardous or adverse health outcomes).

e. Department of Energy human subject research does not include the following:
   i. Research that hopes to improve the safety or execution of procedures that apply to routine occupational activities;
   ii. Research for occupational health surveillance of DOE Federal and contractor employees to determine apparent departures from typical health status and not for the purpose of obtaining generalizable knowledge; and
   iii. Research that involves employee surveys used as management tools to improve worker or contractor performance as long as the identity of the participant is protected.

f. Research that uses social media data must be submitted to the appropriate IRB for human subject research review and determination.

g. Classified and unclassified human subject research that is funded through the Strategic Intelligence Partnership Program (SIPP) must be reviewed and approved by the Central DOE IRB-Classified.

h. When conducting or reviewing classified research, the use of expedited review procedure is prohibited. The fact that research meets a particular expedited category may be noted, but review by a convened IRB is required.

i. Human Terrain Mapping (HTM) is managed as research involving human subjects.

j. Personally identifiable information collected and/or used during human subject research projects must be protected in accordance with the requirements of DOE Order 206.1, Department of Energy Privacy Program. Any breach involving Personally Identifiable Information must be reported:

i. Immediately upon a finding of a suspected or confirmed data breach involving Personally Identifiable Information (PII) in printed or electronic form, the incident must be reported to the DOE-Cyber Incident Response Capability in accordance with the requirements of DOE O 206.1.
ii. Within 48 hours the DOE or NNSA HSP Program Manager must also be notified of any corrective actions taken and consulted regarding the plan for any remaining corrective actions.

k. DOE and DOE site employees are considered vulnerable subjects when participating in research and additional care must be taken to ensure their participation is truly voluntary (e.g., by ensuring they do not report to members of the research team) and that data collected about them is kept confidential.

l. Consent documents must include additional DOE elements of disclosure:
i. The identity of the sponsoring agency, unless the sponsor requests it not be done. The only acceptable reason for non-disclosure is that disclosure could compromise intelligence sources or methods. Additionally, the research must be no more than minimal risk to participants; and the IRB must determine that by not disclosing the identity the researchers will not adversely affect the participants.
ii. A statement indicating the project is classified, what it means for the purposes of the research project, and what part of the research that applies to.
iii. The IRB must determine if participants need access to classified information to make a valid consent decision.

m. Informed consent may only be waived for classified research if the work meets the definition of minimal risk at 10CFR745.102 and meets the waiver criteria outlined at 10CFR745.116.

n. The HRP Program Manager at DOE or NNSA must be notified:
i. Immediately upon learning of a serious adverse event. The HSP Program Manager(s) shall also be informed of any corrective actions taken and consulted regarding the plan for any remaining corrective actions.
ii. Within 48 hours, including a description of corrective actions taken, of:
1. Unanticipated problems.
2. Significant adverse events.
3. Complaints about the research.
4. Potential incidents of non-compliance.
5. Suspensions of IRB approval.
6. Terminations of IRB approval.

o. Prior to the approval of any DOE funded research involving human subjects research, the IRB will review the DOE Requirements Checklist to verify compliance with the following:
i. Protection of human subjects in compliance with the protection of personally identifiable information (PII).
ii. Protection of human subjects in compliance with 45CFR46 subparts A, B, and C.

1. **Purposes**

   The purpose of this SOP is to describe the process to identify and manage conflicts of interest, financial or otherwise, related to the Human Research Protection Program (HRPP) of university covered persons as defined in University of Maryland Board of Regents Policy [3.10(A), (B), (C), & (E)].

2. **Policy**

   It is the policy of the HRPP to prevent conflicts of interest the interfere with human research taking place at UMD in compliance with University of Maryland Board of Regents Policy [3.10(A), (B), (C) & (E)].

   a. The HRPO will review disclosures that describe outside activities and interests made by researchers, as well as the responses to the conflict-of-interest questions for all researchers that pertain to each active IRB protocol.

   b. Should there be any investigators or project personnel with a conflict of interest, the Chair of the President's Advisory Committee on Conflict of Interest ("COI Committee") along with the Chair of the Institutional Review Board will be notified. A management plan will be developed to manage, reduce or eliminate the perceived, potential or real conflict of interest by the COI Committee in accordance with the UMD Conflict of Interest in Research Policy. The researcher and the Chair of the Institutional Review Board will attend this meeting to provide input in the development of this plan regarding human subject protections. In addition, the Chair of the COI Committee will attend the IRB meeting where the project is reviewed in order to explain the background of the individual conflict of interest, provide greater detail regarding the management plan, and to address any concerns. The IRB then will vote to determine whether the management plan ensures independence of the conduct of human subject research from the interests of the researchers. If the vote is negative, the plan will be referred back to the COI Committee for further modification, until a management plan that is acceptable to the COI Committee and IRB is developed.

1. **Purpose**
   The purpose of this SOP is to describe the management of institutional conflicts of interest related to the HRPP of university covered persons as defined in the University of Maryland Board of Regents Policy [X-14.00(A)].

2. **Policy**
   It is the policy of the HRPP to prevent institutional conflicts of interest that interfere with human research taking place at the University of Maryland, College Park (UMCP) in compliance with University of Maryland Board of Regents Policy [X-14.00(A)].

   a. This policy governs institutional conflicts of interest at the University and applies to University Officials. This policy does not govern situations in which individuals who are not University Officials (i.e., faculty, staff, and students) might realize financial gain from the conduct of research or performance of other responsibilities at the University; the University's Conflict of Interest Committee, using existing policies and procedures, adequately identifies such situations and independently manages their associated risks to scientific objectivity and proper treatment of human and animal subjects.

   b. It is critical to the mission and reputation of the University to maintain the public's trust. Because of numerous and complex relationships with public and private entities, the University must be aware of any relationships involving financial gain that may compromise or appear to compromise its integrity. The University shall establish and maintain an oversight process to manage, reduce, or eliminate institutional conflicts of interest.

3. **ICOI Committee Review**
   The ICOI Committee is responsible for reviewing the University's investment structure, policies and procedures annually and determining whether they adequately address the identification, disclosure, and management of institutional conflicts of interest. If the ICOI Committee determines that changes are required, the ICOI Committee makes appropriate recommendations to the Vice President for Research who then consults with the President.
   a. The report of the ICOI Committee will be sent to the VPR who will review the report and recommendations of the ICOI Committee and forward them to the President to determine a course of action. In instances where the President has an Institutional Conflict of Interest, he or she must recuse himself or herself and defer to the Chancellor of the University System of Maryland who will review, create and approve management plans in consultation with the Vice President for Research.
   b. Should there be any investigators or project personnel with an ICOI impacting human subject research, the Chair of the ICOI Committee along with the Chair of the Institutional Review Board will be notified. A management plan will be developed to manage, reduce or eliminate the perceived, potential or real conflict of interest in accordance with the UMD Policy on Institutional Conflicts of Interest. The researcher and the Chair of the Institutional Review Board will attend this ICOI Committee meeting to provide input in the development of this plan regarding human subject protections. In addition, the Chair of the ICOI Committee will attend the IRB meeting where the project is reviewed in order to explain the background of the ICOI, provide greater detail regarding the management plan, and to address any concerns. The IRB then will vote to determine whether the management plan ensures independence of the conduct of human subject research from the interests of the researchers. If the vote is negative, the plan will be referred back to the ICOI Committee for further modification, until a management plan that is acceptable to the ICOI Committee and IRB is developed.

1. **Purpose**

   The purpose of this SOP is to describe the management of organizational conflicts of interest related to the HRPP of university covered persons as defined in the University of Maryland Board of Regents Policy [II-3.10(F)].

2. **Policy**

   It is the policy of the HRPP to prevent organizational conflicts of interest that interfere with human research taking place at the University of Maryland, College Park (UMCP) in compliance with University of Maryland Board of Regents Policy [II-3.10(F)].

   a. This policy is to provide guidance that will enable members of the University community to engage in activities outside the University while avoiding situations that harm the individual and/or the University through real or perceived ethical, legal, or financial conflicts. Although such conflicts arise most often when University Members engage in activities outside the University, this policy and associated procedures apply to all activities of University Members.

   b. It is critical to the mission and reputation of the University to maintain the public's trust. Because of numerous and complex relationships with public and private entities, the University must be aware of any relationships that may impact an individual's ability to render impartial assistance or advice to the Government, the individual's objectivity in performing the contract work, and/or an individual has an unfair competitive advantage. The University shall establish and maintain an oversight process to manage, reduce, or eliminate organizational conflicts of interest.

3. **OCI Committee Review**

   The OCI Committee is charged with reviewing any disclosed OCIs to determine whether the conflicts can be mitigated, reduced, or managed and make recommendations to the Vice President for Research (VPR), including any required conditions or circumstances designed to mitigate these conflicts. Following a review by the VPR, the applicable management measures will be outlined in the OCI Mitigation Plan that is provided to the sponsor for final approval.

   a. Should there be any investigators or project personnel with an OCI impacting human subject research, the Chair of the OCI Committee along with the Chair of the Institutional Review Board will be notified. A management plan will be developed to manage, reduce or eliminate the perceived, potential or real conflict of interest in accordance with the UMD Policy on Organizational Conflicts of Interest. The researcher and the Chair of the Institutional Review Board will attend this OCI Committee meeting to provide input in the development of this plan regarding human subject protections. In addition, the Chair of the OCI Committee will attend the IRB meeting where the project is reviewed in order to explain the background of the OCI, provide greater detail regarding the management plan, and to address any concerns. The IRB then will vote to determine whether the management plan ensures independence of the conduct of human subject research from the interests of the researchers. If the vote is negative, the plan will be referred back to the OCI Committee for further modification, until a management plan that is acceptable to the OCI Committee and IRB is developed.

1. **Purpose**
   The purpose of this SOP is to describe the procedure for enhancing the understanding of human research with participants, potential participants, and their communities and conducting outreach activities for increased involvement with human research participants and their communities.

2. **Policy**
   It is the policy that the IRB will provide information to the research community regarding the rights of a research participant as a volunteer. The IRB encourages and promotes community outreach efforts through the IRB Website, listservs, feedback materials, and presentations on campus whenever possible.

3. **Maintaining Community Outreach Efforts**
   The UMD IRB provides resources for research participants, prospective participants, researchers, and the community.
   a. The UMD IRB maintains a section of the IRB website entitled “For Research Participants”, which includes, but is not limited to the following:
      i. Information about an individual’s rights as a research participant.
      ii. Information about an individual's responsibilities as a research participant.
      iii. Participant Education Resources:
         1. Participant Brochure
         2. Informational videos for participants
         3. Information about AAHRPP accreditation
         4. Participant Outreach Flyer
      iv. Contact information for the IRB for questions, complaints, concerns or additional information concerning rights as a research participant.
   b. The IRB website includes links to websites that provide additional information regarding the rights of research participants such as:
      i. Office for Human Research Protections
      ii. National Institutes of Health
      iii. Belmont Report
   c. The IRB distributes an IRB Evaluation Survey to the research community to solicit feedback annually.
   d. HRPO staff conduct training or give presentations upon request that are designed to enhance the understanding of research involving participants and their community.
   e. HRPO staff reach out to departmental IRB Liaisons quarterly to enhance the understanding of research involving participants and their community. IRB Liaisons are also encouraged to set virtual appointments with HRPO staff.

4. **Responding to Participant Concerns or Requests**
   Current, former, or prospective research participants are encouraged to contact the IRB Office with questions, concerns, or complaints about the research. The Director of the HRPO responds to all participant concerns or requests within 48 hours. Depending on the nature and severity of the concern or request, the Director may contact the principal investigator for additional information, if necessary.

5. **Improving Community Outreach Efforts**

   The Director of the HRPO, the Quality Assurance Program Manager, the IRB Specialist for Education and Improvement, and the IRB Chair(s) evaluate, make changes, and implement changes to the outreach program as needed. These individuals may consult with the Vice President for Research or the Associate Vice President for Research to consider any complaints, concerns, suggestions, and other input from participants or others within the research community and consider other departmental outreach efforts on University campus.

   a. Periodic assessments of outreach efforts and the outreach program are done on a quarterly basis, and more frequently, if needed, as determined by the Director of the HRPO, the Quality Assurance Program Manager, the IRB Specialist for Education and Improvement, and the IRB Chair(s).

1. **Purpose**

   This Human Research Protection Program (HRPP) Emergency Preparedness and Response Plan ("Plan") establishes written procedures for initiating a response to an emergency impacting UMD research activities involving human subjects or HRPP operations.

   The UMD HRPP defines an emergency as an unforeseen combination of circumstances that may require immediate action. An emergency may include, but is not limited to, natural disasters, weather events, man-made disasters, and public health emergencies.

2. **Policy**

   It is the policy of the HRPP to provide HRPP-specific emergency planning. This policy is intended to supplement, not replace, emergency response planning by Institutional leadership and/or Institution-wide response measures. HRPP-specific emergency response planning and measures are limited only to those functions of the HRPP not otherwise covered by institution-level plans.

3. **HRPP Emergency Personnel**

   a. **Director – HRPP:** The Director of the HRPP is responsible for assessing the nature of an emergency in relation to the HRPP. If the Director believes that the emergency directly impacts UMD research activities involving human subjects or HRPP operations, the Institutional Official will be consulted to initiate an Emergency Response Plan.

   b. **Institutional Official (IO):** If deemed necessary, the IO will develop an HRPP Emergency Preparedness Team to assist in developing an Emergency Response Plan. The IO will serve as the leader of the Team. The Associate Vice President for Research can make decisions on behalf of the IO if the IO is unavailable at the time of the emergency.

   c. **HRPP Emergency Preparedness Team:** The HRPP Emergency Preparedness Team will further assess the nature and impact of the emergency in relation to the HRPP. The team will develop guidance in the form of an Emergency Response Plan. This guidance will be distributed to the UMD research community through the appropriate channels.

      The Team will include at least the following individuals: the Vice President for Research (IO), the Associate Vice President for Research, the Director - HRPP, and the IRB Chair(s), or their designees. Additional individuals may be included on the team, or consulted, based upon the nature of the event and the individual's area of expertise.

   d. **Additional HRPP Emergency Personnel:** A list of additional HRPP Emergency Preparedness Personnel is included in the HRPP Emergency Preparedness Guide.

4. **Education and Training**

The HRPO provides education and information regarding HRPP emergency preparedness planning to IRB members, HRPO staff, and the UMD research community. The HRPP Emergency Preparedness Guide (Appendix B) is posted on the UMD IRB website. IRB members, HRPO staff, and UMD researchers can access and review the guidance documents at any time. The HRPO notifies the UMD research community if changes are made to the existing HRPP Emergency Preparedness Guide or the UMD IRB SOPs. Changes are communicated to the research community via IRB listserv.

a. **IRB Members:** IRB Members are briefed on guidance related to HRPP emergency preparedness during New IRB Member on-boarding. The HRPO also reviews and discusses HRPP emergency preparedness guidance at least once annually, at a convened IRB Meeting. The HRPO will conduct additional training for IRB Members before, during, or after an emergency, if necessary

b. **HRPO Staff:** HRPO staff members are trained upon hire regarding their role during an emergency. All components of the emergency plan are reviewed including those to contact in the event of an emergency. The HRPO collectively reviews and discusses HRPP emergency preparedness guidance, at least annually. Additional training for HRPO staff may be required and will take place either before, during, or after an emergency, if necessary.

c. **Researchers:** All researchers have access to information regarding emergency preparedness via the IRB Website. Updates will be relayed to the UMD research community via the IRB Listserv. Principal Investigators will be responsible for ensuring that all members of their research teams are informed of any emergency preparedness plans. The HRPO will conduct additional training for UMD researchers either before, during or after an emergency, as deemed necessary.

5. **HRPP Emergency Procedures**

The Director – HRPP will use the HRPP Emergency Preparedness Checklist (Appendix C) to assess the nature of the emergency, implications to research activities at UMD, and disruptions in routine HRPP operations. The checklist will assist the Director in assigning an appropriate impact level to the emergency.

Levels of Impact

a. No Impact: the nature of the event has no impact on research activities related to human subjects or on the day-to-day operations of the HRPP

b. Low Impact: (1) The nature of the event is not likely to affect the health and safety of human subjects engaged in research at UMD, or the event only affects a small portion of research activities related to human subject research at UMD; and/or (2) the nature of the event has a limited impact on the day-to-day operations of the HRPP and will not result in a prolonged disruption of HRPP operations

c. Direct Impact: The nature of the event has the potential to affect the health and safety of human subjects engaged in research at UMD, or the nature of the event has a significant impact on the day-to-day operations of the HRPP resulting in an extended disruption to routine research activities.

Assessment of Impact

a. **No Impact or Low Impact:** When the Director determines that the nature of the event has either no impact and/or a low impact on HRPP research activities, the Director will respond to the event without the development of an Emergency Response Plan. The Director will consult with outside individuals (i.e. – the IRB Chairs, the Institutional Official, etc.) if additional input is needed. The Director will communicate all relevant information to HRPO staff and the UMD research community, as required. Education and training will be provided to the appropriate individuals, if necessary.

b. **Direct Impact:** If the Director determines that the nature of the emergency has a direct effect on the health and safety of human subjects engaging in research activities at UMD, or that the event has a direct impact on the daily operations of the HRPP, the Director will consult the Institutional Official. If the Institutional Official deems it necessary, an HRPP Emergency Preparedness Team will be called to action. The HRPP Emergency Preparedness Team will assist the Director in developing an Emergency Response Plan.

6. **Development - HRPP Emergency Response Plan**

The development of an HRPP Emergency Response Plan will establish guidance for HRPP-specific emergency planning. It is intended to supplement, not replace, emergency response guidance set forth by UMD and the State of Maryland.

a. **Activation of HRPP Emergency Response Team:** The Institutional Official will call an HRPP Emergency Preparedness Team to action. The HRPP Emergency Preparedness Team will assist the Director in further assessing the impact of the emergency on research activities related to human subjects and the impact on the daily operations of the HRPP.

b. **Assessment of Impact on Research Activities**

To evaluate the impact of the event on research activities involving human subjects at UMD, the Team will consider the following:

i. The safety and wellbeing of UMD researchers.
ii. The safety and wellbeing of UMD research participants.
iii. The ability to safely access the UMD campus.
iv. Whether the emergency impacts some or all investigators' ability to conduct human subject research.
v. Researchers' ability to effectively communicate with participants throughout the event.
vi. The need to temporarily pause some or all research activities at UMD, taking into consideration state, local, and institutional guidance.

c. **Assessment of Impact to Operations of HRPP**

To evaluate the impact of the event on routine operations of the HRPP, the Team will consider the following:

i. The safety and wellbeing of HRPO staff.
ii. Accessibility to the HRPO.
iii. Accessibility to the HRPO electronic submission system (for IRB applications).
iv. Ability to process IRB determinations.
v. Ability to hold IRB meetings.
vi. Ability to conduct other HRPO functions.
vii. Access to the HRPO Share Drive.
viii. Ability to communicate with HRPO staff.
ix. Ability to communicate with the UMD research community.

d. **Emergency Response Plan Development**

The Team will develop guidance in the form of an Emergency Response Plan to address any risks and/or impacts resulting from the emergency. Items included in the Plan will supplement, and incorporate any previously set state, local, and UMD guidance regarding the event. Emergency actions to be considered when drafting the Plan will include, but are not limited to, the following:

i. **Research Activities**
    1. Temporarily pausing some, or all research involving human subjects at UMD.
    2. Triaging and prioritizing IRB reviews.
    3. Allowing research activities that provide a direct benefit to participants to continue once researchers submit a protocol incorporating updated guidance.
    4. Imposing flexibility in IRB review processes.
    5. Allowing the continuation of research activities via alternate mechanisms.
    6. Relying on an external IRB if the impact on local research operations is extensive.

ii. **HRPP Operations**
    1. Allowing HRPO staff to work remotely.
    2. Conducting IRB meetings virtually.
    3. Proposing alternate means of communication (i.e. phone, email, video-conferencing, etc.) if traditional means are unavailable.
    4. Proposing an alternate means for submission and processing (i.e. – submission and processing via email) if the electronic submission system is unavailable. Providing a plan to transition alternate submissions to the HRPO's electronic system once its available.

7. **Communication – Emergency Response Plan**

After finalizing the details of the Emergency Response Plan, the Emergency Preparedness Team will work with the Director to develop and disseminate targeted communications to the UMD community. Targeted communications may include individualized messages for: IRB members, HRPO staff, UMD researchers, UMD research participants, and institutional leadership.

a. **Communication Channels:** Standard communication channels will be utilized to distribute information regarding the Plan to the research community. This includes the usage of platforms such as the IRB Website and Listserv. Additional communication channels may be utilized, if deemed necessary.

b. **Education and Training:** The HRPO will notify the research community of the need for any protocol specific, or risk mitigation planning. Education and training will be provided to the research community, as outlined by the Plan.

c. **Communication of Changes**: Changes made to an existing Plan will be communicated to the research community via standard communication channels. Updated guidance will be posted on the IRB Website.

d. **Resumption of Normal Activities:** When the Emergency Preparedness Team determines that the emergency no longer presents a limitation to human research activities, the research community will be notified that normal business operations may resume. This information will be communicated via standard channels and an announcement will be posted on the IRB Website.

8. **Evaluation – HRPP Emergency Preparedness Guidance**

The HRPP will periodically review its emergency preparedness policy, procedures, and guidance to ensure effectiveness and compliance. HRPP emergency preparedness planning will be assessed at least annually by HRPP leadership, HRPO staff, and IRB Members and the guidance will be updated, as deemed necessary.

a. **HRPO Staff**

The Quality Assurance Program Manager will be responsible for conducting a periodic evaluation of the HRPP's Emergency Preparedness Guidance to ensure that it adequately addresses the needs of the institution. (HRPP Policy #7.001)

The QA Program Manager will meet with the Director, at least once a year, to discuss any proposed changes and/or improvements to the existing HRPP emergency guidance. The guidance will be updated by the QA Program Manager, as deemed necessary.

b. **IRB Members**

IRB Members will be asked to review the HRPP's emergency preparedness guidance on an annual basis. A discussion among IRB Members will take place at a convened IRB Meeting. IRB Members will also provide feedback on the HRPP's emergency preparedness during their Annual IRB Member Evaluation.

c. **HRPP Leadership**
Links to HRPP Emergency Preparedness guidance will be included in the HRPO's Annual IRB Report, which is provided to the Vice President for Research's Office each year.

d. **Additional Evaluation**
The HRPP will consult with the University's Office of Emergency Management and Business Continuity, for assistance in assessing guidance in relations to emergency preparedness, if deemed necessary.

9. **Evaluation - Emergency Response Plans**
HRPP Emergency Response Plans will be periodically reviewed throughout an emergency, by the Emergency Preparedness Team or the appropriate individual(s) (Director- HRPP, Institutional Official, IRB Chairs, etc.), to ensure that the Plan adequately addresses the evolving nature of the emergency.

Emergency Response Plans will also be evaluated at the conclusion of an emergency (i.e. – resumption of normal business operations), to determine whether the HRPP could make improvements and/or changes to the Plan if a similar event was to occur in the future. Emergency Response Plans will be assessed by the Quality Assurance Program Manager and the Director - HRPP. Findings will be reported to the appropriate HRPP leadership.

APPLIED RESEARCH LABORATORY FOR INTELLIGENCE AND SECURITY

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Internal Process & Standard Operating Procedure

Human Subject Research (HSR) Application Approval at UMD and DoD/USG

Background

This Standard Operating Procedure (SOP) pertains to University of Maryland College Park's requirement to comply with the U.S. Health and Human Services (HHS) regulations for the protection of human subjects in research, Title 45CFR46. Additionally, U.S. Government-sponsored work that takes place at UMD must also be reviewed by a U.S. Government (USG) Human Research Protections Office (HRPO).

Purpose

The purpose of this SOP is to provide information regarding the human subject research (HSR) process at the University of Maryland College Park (UMD) and when, if needed, a USG HRPO provides a review for concurrence after initial UMD IRB review.

While all HSR requests at UMD must go through the UMD Institutional Review Board (IRB), some may need a secondary review by a USG HRPO. Both committees, IRB and USG HRPO, perform the ethical review of proposed research to help assure the protection of the rights and welfare of human participants.

Audience

This SOP applies to all ARLIS/ University of Maryland College Park employees.

Procedures

UMD IRB Review: The following information should be used as a guide to become familiar with HSR procedures at UMD and ARLIS.

1. Pre-Award and Release of Funds: Researchers must indicate in the Kuali Research Proposal Questionnaire whether the research is expected to include using Human Subjects.
    a. Upon Award: For sponsored research that is expected to include using Human Subjects and there is not already an approved IRB with the UMD IRB to cover the effort, the PI must submit a completed "Prior to IRB Account Authorization Form" to UMD ORA in order for funds to be released (i.e., for a KFS account to be created for the effort).

2. All new IRB applications must receive approval or determination from the UMD IRB. See **Appendix A** for a decision aid on whether to submit materials to the UMD IRB.
    a. The ARLIS IRB Liaison is the Director of the Human Research Protection Program (HRPP) at UMD. All IRB applications must be shared with the Director - HRPP (and alternate IRB liaisons, when applicable) for their signature in the IRB electronic submission system prior to initial submission.
    b. To support tracking of HSR at ARLIS, researchers must additionally send to the ARLIS IRB liaisons the information specified in **Appendix C**.

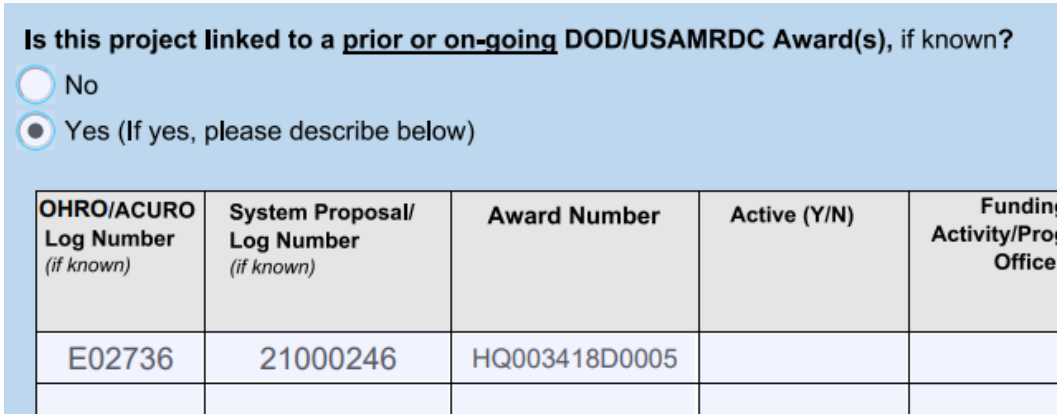
USG HRPO Review:

3. For federally sponsored work, the sponsor must designate a reviewing USG HRPO to review the protocol. See **Appendix B** for a decision aid on whether to submit materials to a USG HRPO.
    a. Principal Investigators (PIs) will coordinate with the USG Contracting Officer's Technical Representative (COTR) for information on which USG HRPO will provide the USG HRPO review.
    b. In the event that the USG COTR cannot provide this information, PIs will coordinate with UMD Office of Research Administration (ORA) staff to request this information from the USG Contracting Officer (KO).

U.S. Army Medical Research and Development Command (USAMRDC) HRPO Review:

4. This section of the SOP will cover the process when USAMRDC is the designated USG HRPO.
5. The request for USAMRDC concurrence will be sent to USAMRDC Office of Human Research Oversight (OHRO) for review and to OUSD (I&S):
    a. For Task Orders under the OUSD(I&S) Indefinite Delivery, Indefinite Quantity (IDIQ) contract and funded directly by OUSD(I&S), submit materials to the IDIQ Contracting Officer's Representative (COR).
    b. For Task Orders under the OUSD(I&S) IDIQ and NOT funded directly by OUSD(I&S), coordinate with the Task Order COR for submission instructions.
    c. For Task Orders funded outside of the OUSD(I&S) IDIQ, coordinate with the Task Order COR for submission instructions.

6. Additional information on requesting USAMRDC OHRO review for work funded by Task Orders under the OUSD(I&S) IDIQ **and funded directly by OUSD(I&S)**: Complete and send the following to the OUSD(I&S) IDIQ COR:
    a. USAMRDC proposal submission form
        i. For field 'PMO Contact': List the OUSD(I&S) IDIQ COR, unless otherwise discussed.
        ii. In Section II: Proposal Information, for "Is this project linked to a prior or on-going DOD/USAMRDC Award(s), if known?", select "Yes".
            1. For Task Orders under the "HQ003418D0005" IDIQ[1], complete the table fields below with: "OHRO/ACURO Log Number" as "E02736"; System Proposal/Log Number" as "21000246"; and Award Number" as "HQ003418D0005", as shown in this example:



Is this project linked to a prior or on-going DOD/USAMRDC Award(s), if known?

No

Yes (If yes, please describe below)

OHRO/ACURO Log Number *(if known)*	System Proposal/ Log Number *(if known)*	Award Number	Active (Y/N)	Funding Activity/Prog Office
E02736	21000246	HQ003418D0005		

    b. Attach a copy of the Statement of Work (SOW) funding the effort.
    c. Include a short description of the protocol (e.g., copied from the "Abstract" section of the UMD IRB submission).
    d. Statement of Scientific Merit: Include as an attachment the UMD IRB Approval letter; note in your submission that, as stated in the UMD IRB Approval letter, the protocol has undergone Scientific Merit review as part of the UMD IRB Approval process.

[1] For Task Orders under renewed or new IDIQs, coordinate with the ARLIS HSR liaison on whether there is an existing Log Number to input. This SOP will be updated with that information when available.

e. Indicate any timeline/schedule expectations or dependencies (e.g., if research will be supported by interns who are available per a fixed appointment of time, such that delays in OHRO review will impact their ability to contribute to the research effort).
f. All documents should be sanitized to an unclassified level. If this is not possible, the PI should contact the OUSD(I&S) COR via ARLIS leadership.
g. ARLIS PIs will coordinate directly with USAMRDC OHRO for next steps in the review.

7. **Approval:** Once USG HRPO review is completed, the HSR may begin.

8. **Monitoring:**

Amendment Submission (UMD): If changes are to be made to the approved IRB protocol, an Amendment outlining the changes must be submitted and approved before the changes can be implemented. Refer to **Appendix D** for additional information.

Amendment Submission (USG HRPO): Follow guidance received from the reviewing USG HRPO on the submission of amendments. Generally, it is expected that amendments (changed/new materials, amendment application forms, and UMD IRB approval or acknowledgement letters) will be submitted to the USG HRPO and must receive approval before implementation of the changes. Some USG HRPOs may only require substantive changes to be approved prior to implementation: refer to your USG HRPO approval memo or your USG HRPO point of contact for information on their requirements. Refer to **Appendix D** for additional information.

Continuing Review (UMD): A protocol approved by the Full Board will have an expiration date and be required to submit a Continuing Review application prior to the expiration date in order to maintain IRB Approval. This also applies to protocols approved through the Expedited process where the IRB has determined a Continuing Review is justified. Protocols approved through the Exempt process do not require a Continuing Review.

Continuing Review (USG HRPO): Follow guidance received from the reviewing USG HRPO on the requirement for Continuing Review. Generally, it is expected that Continuing Reviews (application and UMD IRB approval letter), if required by UMD IRB, will be submitted to the USG

HRPO. Refer to your USG HRPO approval memo or your USG HRPO point of contact for information on their requirements. Refer to **Appendix D** for additional information.

Tracking Database (Internal): ARLIS and UMD IRB collaboratively maintain a tracking database to monitor approvals of IRB and USG HRPO approvals. Refer to **Appendix C** for additional information.

9. **Early Termination:**
    a. UMD IRB will notify PI if Quality Assurance Program review determines that protocol should be terminated due to serious and/or continuing noncompliance, increased risk to participants, or other concerning findings.
    b. UMD HRPP will notify UMD Institutional Official (Vice President for Research), funding agency, and USG HRPO of early termination for cause.

10. **Closeout of protocol**
    a. PI will submit a closure report to UMD IRB when all research activities are complete and all data has been de-identified.
    b. PI will submit a closure report and UMD IRB closure letter to USG HRPO contact. Refer to **Appendix D** for additional information.

11. **Continuous Improvement:** The UMD IRB review process is periodically reviewed for continuous improvement, incorporating feedback from stakeholders involved in the process. This SOP provides a structured framework for the initiation, review, and closure/ termination of HSR Approvals within ARLIS at UMD, promoting transparency, accountability, and compliance with relevant policies.

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12. Responsibilities & Actions:

Duty	PI	ARLIS Pre-Award	ARLIS Post-Award	ARLIS Leadership	IRB
Initiation	x	x		x	
Approvals				x	x
Monitoring	x		x		x
Amendments/ Modifications	x	x		x	x
Early Termination	x	x	x	x	x
Close out	x				x

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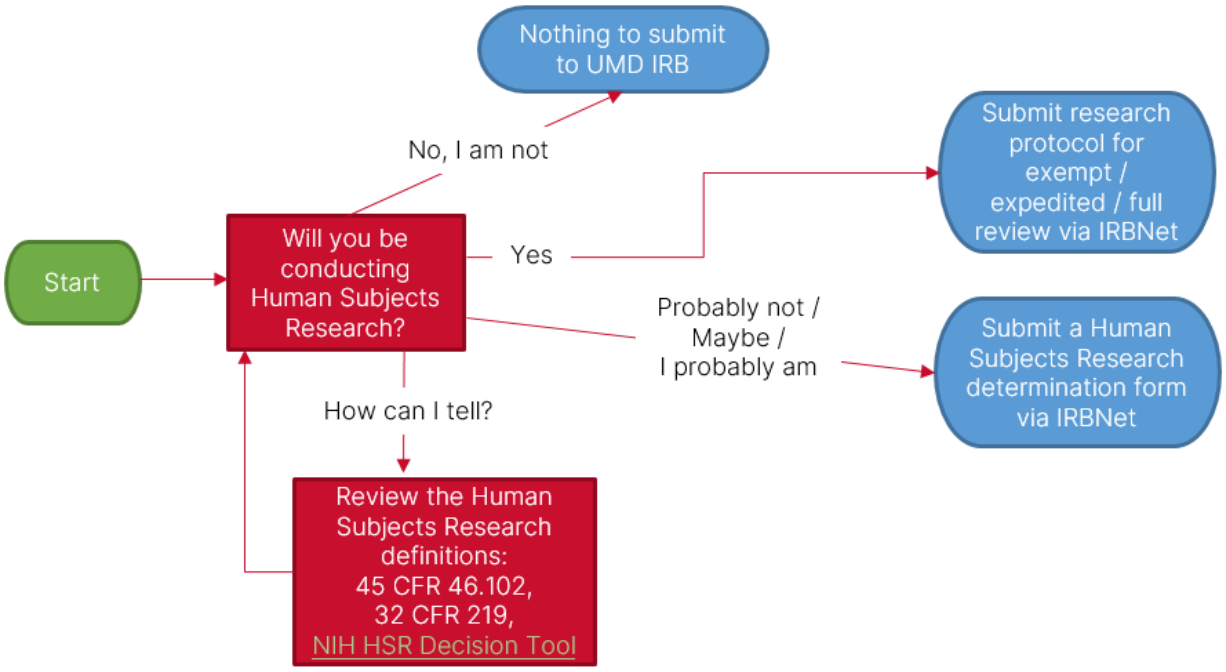
Appendices

Appendix A

Do you need to submit anything to the UMD IRB?



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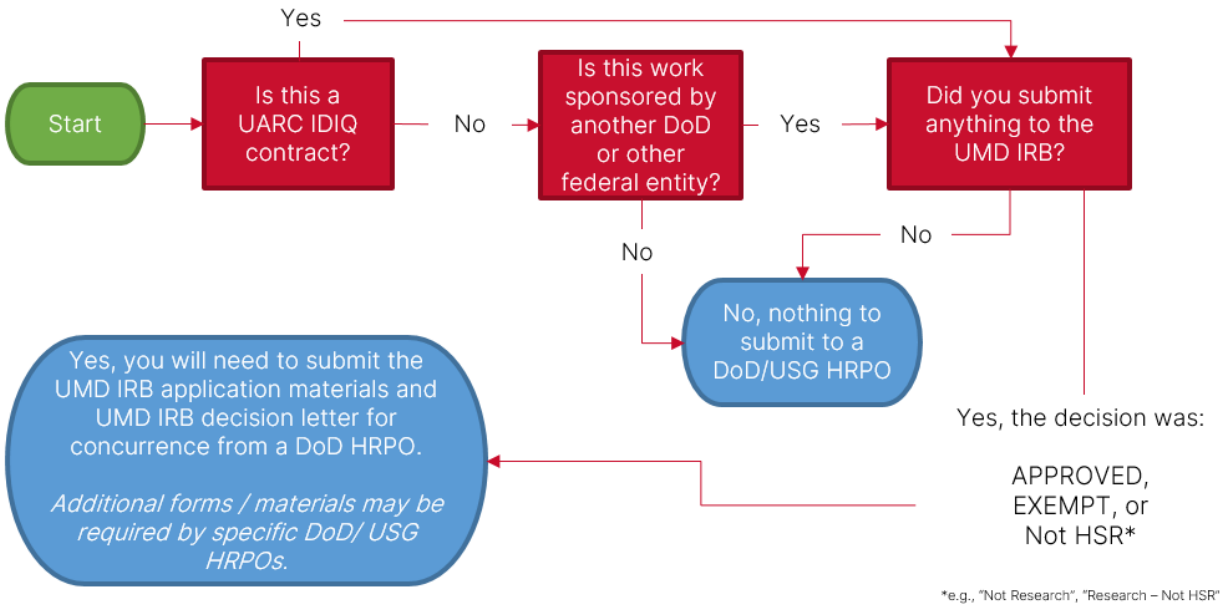
Appendix B

Do you need to submit anything to a DoD/USG HRPO?



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Appendix C

HSR Tracking Requirements

Researchers

- For all UMD IRB submissions (including Human Subjects Research Determinations forms): Share with ARLIS Liaison via IRBNet
    - Note: As a matter of course, UMD IRB requires IRB liaison signature for initial HSR submissions; **ARLIS further requires researchers to share HSRD forms with IRB liaison for departmental tracking**
- For all UMD IRB submissions, send the IRB liaison the following information:
    - UMD IRBNet Project Number:
    - UMD IRBNet Project Title:
    - Task Order / Contract Title:
    - Task Order / Contract number:
    - IDIQ number (if applicable):
    - Sponsor:
    - Contract period of performance:
- For all USG concurrence reviews, cc ARLIS liaison.
    - CC on all submissions
    - Request that the USG HRPO cc's ARLIS liaison on memos/correspondence
    - Check for ARLIS liaison on To-/CC-lines for critical correspondence with HRPO (approvals, closures, etc.); cc or forward the ARLIS liaison if they did not receive the correspondence.

Liaison tracking

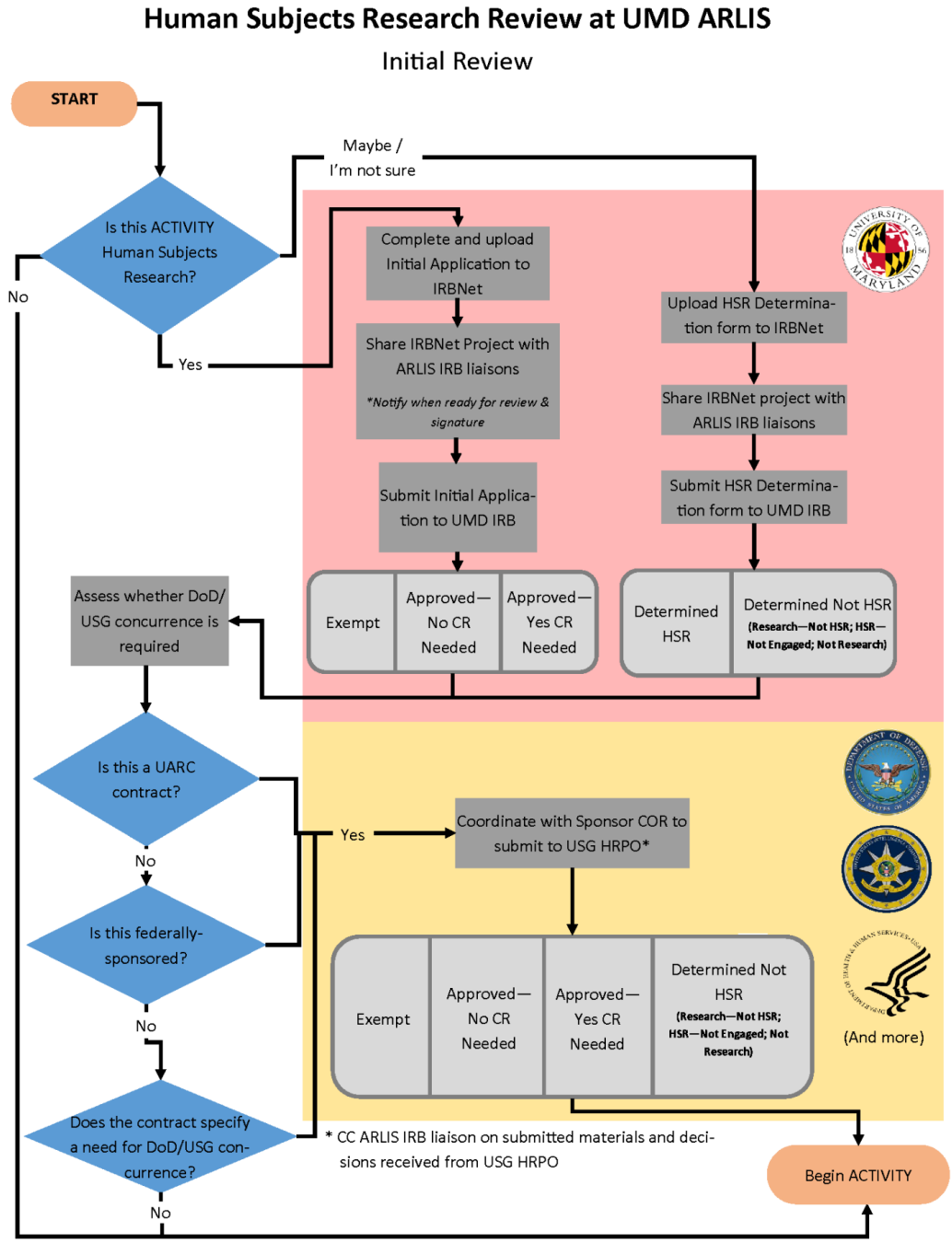
- Track UMD IRB submissions
- Determine whether USG HRPO review will be required; help identify cognizant HRPO if needed
- Tracking fields:
    - IRBNet Identifiers
        - IRBNet Number
        - IRBNet Project title
        - Protocol PI
    - Contract identifiers:
        - Task Order / Contract number
        - Task Order / Contract Title
        - Contract PI
        - DIQ number (if applicable)
        - Sponsor
        - Contract Period of Performance Start Date
        - Contract Period of Performance End Date
    - UMD IRB reviews
        - Reviewing IRB (typically UMD IRB, unless a Reliance Agreement with another board is in place)

- Initial Submission date
- Initial Determination date (date of approval or HSR determination)
- Initial Determination (Not HSR / EXEMPT / APPROVED)
- Expiration date (if applicable)
- Current status (Open / Closed / Not HSR)

- USG HRPO reviews
  - Cognizant HRPO
  - HRPO Log Number (if applicable)
  - Initial submission date
  - Initial determination date (date of approval or HSR determination)
  - Initial determination (Not HSR / EXEMPT / APPROVED)
  - Expiration date (if applicable)
  - Current status (Open / Closed / Not HSR)

Appendix D
HSR Process Flow Diagrams

Initial Review



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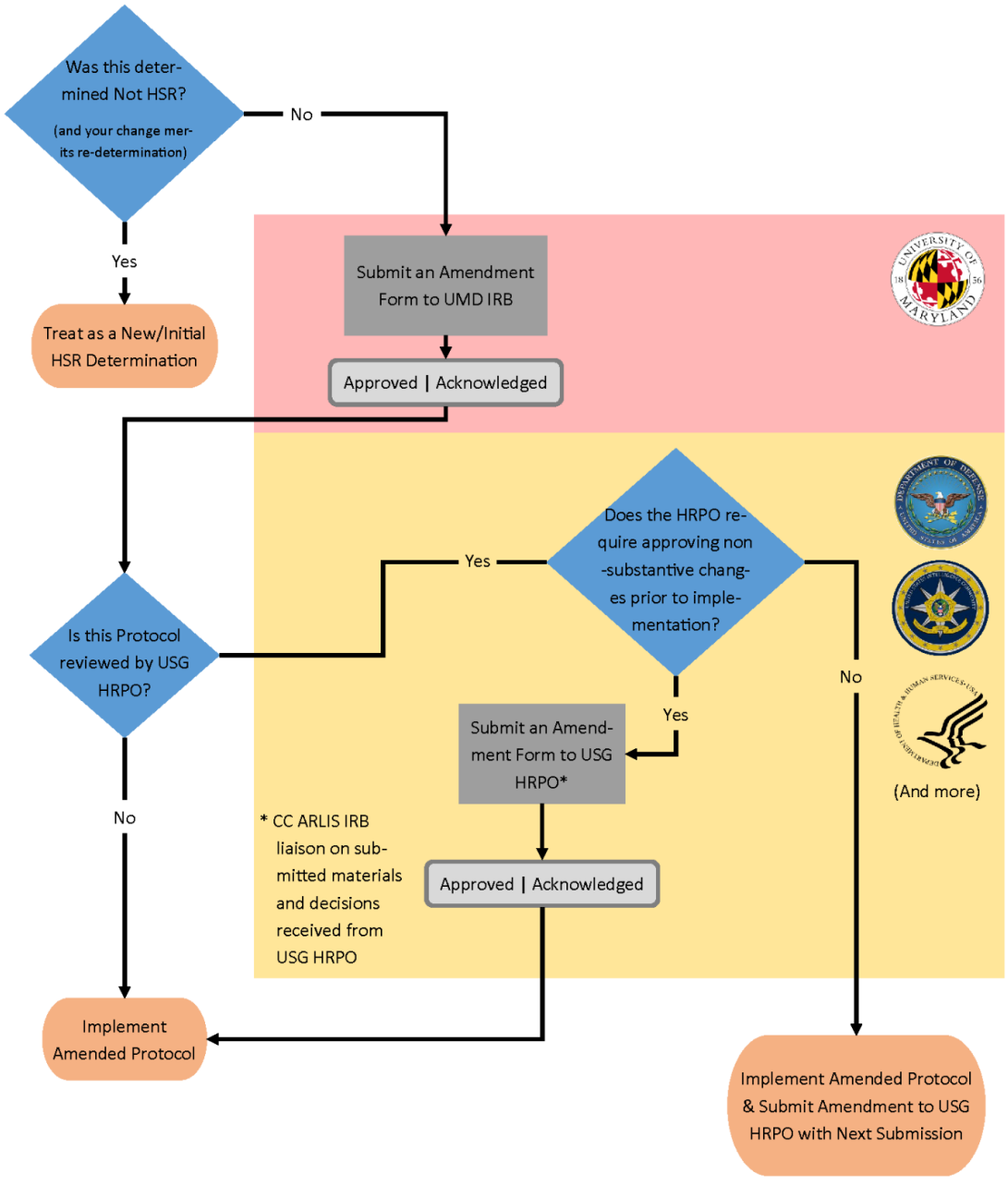
Amendments

Human Subjects Research Review at UMD ARLIS

Amendments



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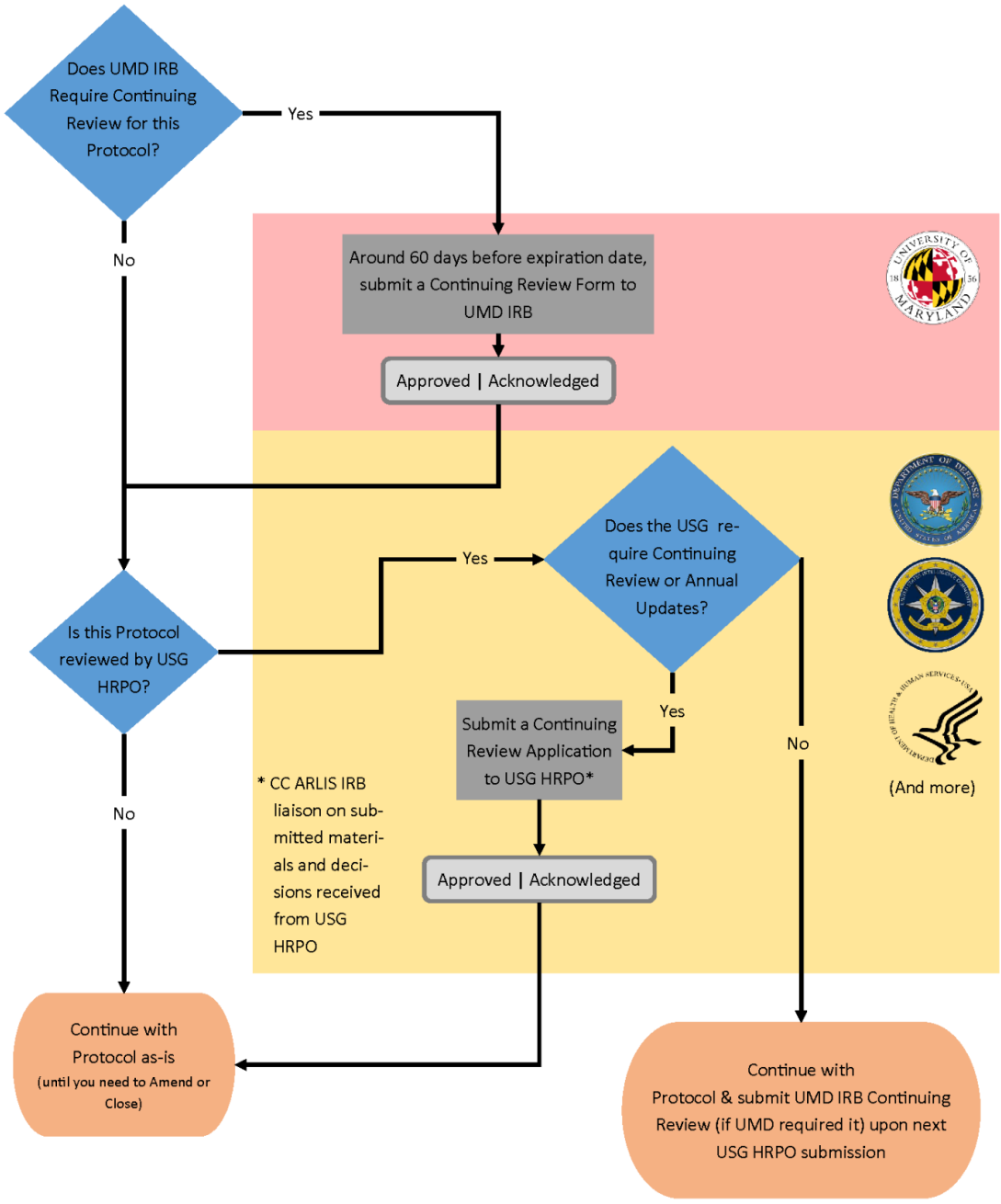
Continuing Review

Human Subjects Research Review at UMD ARLIS

Continuing Review



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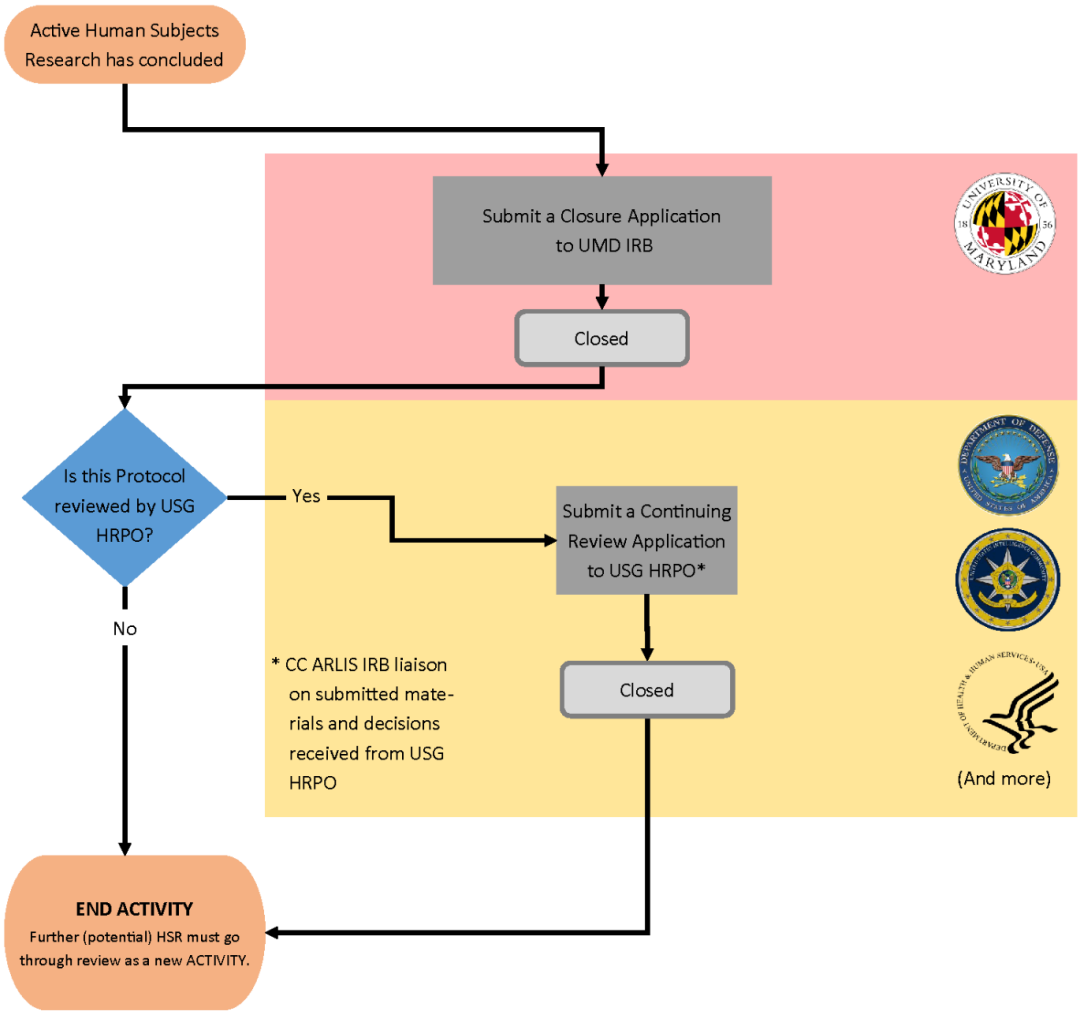
Project Closure

Human Subjects Research Review at UMD ARLIS

Project Closure



HRPP EMERGENCY PREPAREDNESS GUIDE

The Human Research Protections Program (HRPP) Emergency Preparedness Guide is intended to ensure the sustainability of the HRPP and continuing protection of research participants during emergencies. In the event of an emergency, employees, research participants, and their well-being are of the highest priority. Overall, research personnel will prioritize the health and safety of human subjects when deciding how to move forward with research activities.

The HRPP Emergency Preparedness Guide establishes guidance for HRPP-specific emergency planning and is intended to supplement, not replace, emergency response planning by Institutional leadership and/or Institution-wide response measures.

Potential HRPP Emergencies:

The UMD HRPP defines an emergency as an unforeseen combination of circumstances that may require immediate action.

For the sake of this guide, the UMD HRPP has identified four categories of emergencies:

1.) Public health emergencies,
2.) Weather-related emergencies,
3.) Natural disasters, and
4.) Man-made emergencies.

Each of these categories are described in more detail below:

Public Health Emergencies: A public health emergency is an adverse event that compromises the health of the population and has the potential to cause illness. A public health emergency may be widespread, such as a pandemic, or localized to the UMD community or the surrounding area.

Weather-related Events: A weather-related emergency occurs when severe weather causes damaging or hazardous conditions, resulting in a disruption to routine services and activities (i.e. – campus closure; building closure; campus power outage, etc.). Examples of weather-related emergencies may include: a severe thunderstorm, tornado, hurricane, or blizzard.

Natural Disasters: A natural disaster is a sudden event that is caused by environmental factors such as floods, fire, or a power outage. These events have the potential to cause damaging or hazardous conditions, resulting in a disruption to routine services and activities.

Man-made Emergencies: A man-made emergency is an event that was caused by human interaction, either intentionally or unintentionally, which results in a threat to safety, or causes a disruption to routine services and activities. Examples of man-made emergencies may include campus construction, a cyber-attack, an active shooter on campus, a bomb threat, a terrorist attack, or an IT system failure.

HRPP Emergency Preparedness Personnel:

HRPP Emergency Preparedness Team:

Whenever necessary, an HRPP Emergency Preparedness Team will be developed to formally assess the nature and severity of an emergency. At minimum, the team will consist of the Director of the Human Research Protections Program (HRPP), the Vice President for Research (Institutional Official), the Associate Vice President for Research, and the IRB Chair(s). Additional HRPP personnel may be asked to participate on the Emergency Preparedness Team depending on the nature or severity of the emergency and their area of expertise.

For instance, if a public health emergency was to arise, the HRPP Emergency Preparedness Team would consult the Director of the UMD Health Center to ensure that the HRPP's Emergency Response Plan adheres to, and incorporates any existing guidance set forth by the UMD Health Center.

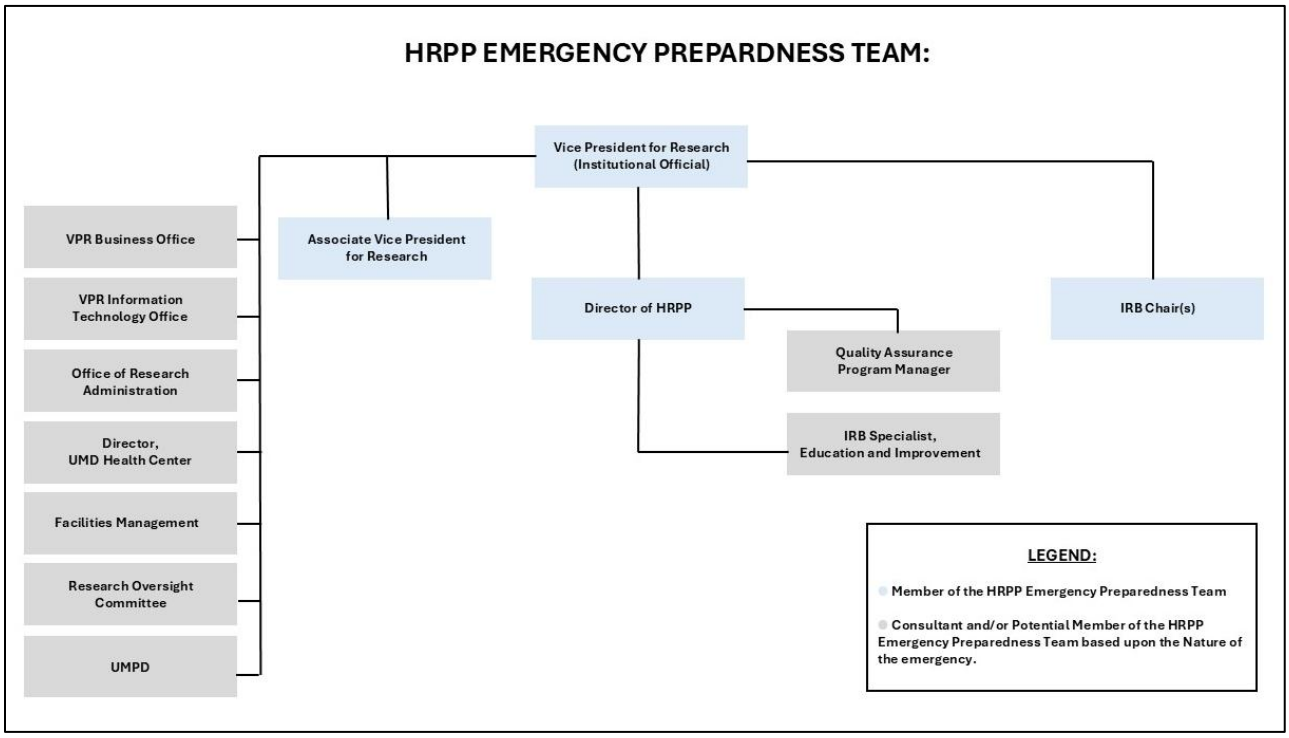


Figure A: This chart represents the HRPP Emergency Preparedness Team. Individuals in blue will participate in all HRPP Emergency Preparedness Teams. Individuals in gray will be consulted based on the nature of the event and their area of expertise.

Roles and Responsibilities:

<u>Director - HRPP:</u>

Prior to the implementation of an Emergency Response Team, the Director - HRPP will identify and assess potential emergencies and determine whether the emergency will have any impact on the HRPP. When the Director believes that an impact on the HRPP is unlikely, or relatively low, the

Director will respond to the event without the support of an Emergency Response Team. When the Director determines that an emergency poses a direct impact to the HRPP, the Institutional Official will be contacted, and an Emergency Preparedness Team will be called to action.

The Director - HRPP will serve as a member of the HRPP Emergency Preparedness Team. The Director will assist in assessing the level of risk posed by the event and the impact on HRPP operations. The Director will suggest actions to be taken in response to the event. If required, the Director - HRPP will implement and monitor Emergency Response Plans for IRB review of research during the emergency. The Director will enact a pause in research, if deemed necessary by the HRPP Emergency Preparedness Team.

The Director - HRPP will be responsible for communicating the details of the Emergency Response Plan to the UMD research community and for educating the community on their role(s) throughout the emergency. The Director will also update the UMD community regarding any changes to the Plan.

Vice President for Research/Institutional Official:

When the Vice President for Research believes an emergency has a direct effect on the health and safety of human subjects engaging in research activities at UMD, or that the event has a direct impact on the daily operations of the HRPP, an HRPP Emergency Preparedness Team will be called to action. The Vice President for Research (Institutional Official) will serve as the leader of the HRPP Emergency Preparedness Team and will appoint members to the Team, as they see fit. As the leader of the Team, the Vice President will ensure that team members communicate effectively; the Vice President will delegate responsibilities to members based upon their areas of expertise; and, the Vice President will ensure that an Emergency Response Plan, addressing the demands of the emergency, is developed in a timely manner.

Associate Vice President for Research:

The Associate Vice President for Research will serve as a member on the HRPP Emergency Preparedness Team. The Associate Vice President will assist in assessing the level of risk posed by the event and its impact on HRPP operations. The Associate Vice President will act as a designee for the Vice President if the Vice President is unavailable. This means that the Associate Vice President will have the authority to make decisions on behalf of the Vice President. The Associate Vice President will communicate regularly with the Director - HRPP, and relay updates from the Vice President as the emergency unfolds. The Associate Vice President will also have the authority to recommend individuals to add to the HRPP Emergency Preparedness Team.

IRB Chair(s):

The IRB Chair(s) will serve as members of the HRPP Emergency Preparedness Team. The IRB Chair(s) will assist the Vice President for Research, the Associate Vice President, and the Director - HRPP in assessing the level of risk posed by the event and its impact on HRPP operations. The IRB Chair(s) will support the Director in implementing and monitoring Emergency Response Plans for IRB review of research, should it be required, and the IRB Chair(s) will enforce a pause in research, if deemed necessary by the HRPP Emergency Preparedness Team. The IRB Chair(s) will routinely communicate with the Human Research Protection Office (HRPO) throughout the emergency and

the IRB Chair(s) will be responsible for communicating the Emergency Response Plan to IRB Members. The IRB Chair(s) will also update IRB Members regarding any changes to the Plan throughout the event.

Quality Assurance Program Manager:

The Quality Assurance Program Manager may be asked to join the Emergency Preparedness Team, if deemed appropriate by the Director - HRPP. The QA Program Manager will support the Director – HRPP in implementing and monitoring any Emergency Response Plans for IRB review of research through the duration of the emergency. The QA Program Manager will also support the Director in communicating the Emergency Response Plan to the UMD research community on behalf of the HRPP. The QA Program Manager will act as a designee for the Director if the Director is unavailable. This means that the QA Program Manager will have the authority to make decisions on behalf of the Director.

IRB Specialist for Education and Improvement:

The IRB Specialist for Education and Improvement may be asked to join the Emergency Preparedness Team, if deemed appropriate by the Director - HRPP. The IRB Specialist will assist the Director and the QA Program Manager in educating the UMD community about the Emergency Response Plan. The IRB Specialist will develop tailored training for key HRPP audiences. Audiences may include researchers, research participants, IRB Members, HRPO Staff, and Institutional leadership. The IRB Specialist will assist in developing guidance throughout the emergency and will provide updates on the IRB Website.

Vice President for Research - Business Office:

An individual from the Vice President for Research's Business Office may be consulted, or asked to join the Emergency Preparedness Team, if deemed appropriate by the Institutional Official. The Business Office ensures the safety of HRPP staff by overseeing the HRPP Office space. It also safeguards the financial stability of HRPP staff and research activities throughout an emergency. The Emergency Preparedness Team will confirm that the Emergency Response Plan encompasses any guidance set forth by the VPR's Business Office.

Vice President for Research -Information Technology Office:

An individual from the Vice President for Research's Information Technology Office may be consulted, or asked to join the Emergency Preparedness Team, if deemed appropriate by the Institutional Official. The VPR's IT Office helps to ensure continuity for UMD networks and accessibility to necessary computer systems. The VPR's IT Office will work to establish alternate network/computer system access, if required, during an emergency. The Emergency Preparedness Team will confirm that the Emergency Response Plan incorporates any guidance set forth by the VPR's IT Office.

Office of Research Administration:

An individual from the Office of Research Administration (ORA) may be consulted, or asked to join the Emergency Preparedness Team, if deemed appropriate by the Institutional Official. ORA will

work to ensure continuity with current grants and contracts throughout the emergency and will develop an emergency plan for any new grants and contracts, if necessary. The Emergency Preparedness Team will confirm that the Emergency Response Plan includes any guidance set forth by the ORA.

Director - UMD Health Center:

The Director of the UMD Health Center may be consulted by the Emergency Preparedness Team, if deemed appropriate based upon the nature and severity of the emergency. The Emergency Preparedness Team will guarantee that the Emergency Response Plan contains any guidance set forth by the Director and the UMD Health Center.

Facilities Management:

The UMD Facilities Management Department may be consulted by the Emergency Preparedness Team, if deemed appropriate based upon the nature and severity of the emergency. The Emergency Preparedness Team will guarantee that the Emergency Response Plan includes any guidance set forth by the Department of Facilities Management.

University of Maryland Police Department (UMPD):

The UMPD may be consulted by the Emergency Preparedness Team, if deemed appropriate based upon the nature and severity of the emergency. The Emergency Preparedness Team will incorporate any guidance set forth by the UMPD into the Emergency Response Plan.

Research Support Oversight Committee (RSOC):

The Research Support Oversight Committee (RSOC) may be consulted by the Emergency Preparedness Team, if requested by the Institutional Official. The RSOC serves as an advisory group to the Senior Vice President and Provost, the Vice President for Research, and the Vice President for Administration for research related safety, compliance, and reputational risks. Any guidance set forth by the RSOC will be incorporated into the Emergency Response Plan.

Emergency Preparedness Training:

The HRPO provides information, education, and training on HRPP emergency preparedness to IRB Members, HRPO staff, the UMD research community, and other members of the HRPP.

Training Methods:

An email was sent to the UMD research community in April 2025, via the IRB Listserv, to announce the HRPP's development of guidance on Emergency Preparedness.

The IRB's Standard Operating Procedures (SOPs) and the HRPP's Emergency Preparedness Guide are both included on the IRB Website. IRB Members, HRPO staff, and UMD researchers can access the documents from anywhere, at any time.

The HRPO will notify the UMD research community if/when revisions are made to the HRPP's existing emergency guidance. Changes will be communicated via the IRB Listserv.

Additional training mechanisms such as in-person meetings, webinars, and project-specific training will be dependent upon the ongoing and changing needs of the Institution.

IRB Members:

IRB Members will be briefed on guidance related to HRPP emergency preparedness during New IRB Member on-boarding.

The HRPO will also review and discuss HRPP emergency preparedness guidance at least once annually, at a convened IRB Meeting.

The HRPO may conduct additional training for IRB Members before, during, or after an emergency if it is deemed necessary.

HRPO Staff:

HRPO staff will be trained upon hire regarding their role during an emergency. All components of the HRPP's emergency guidance document will be reviewed, including who to contact in the event of an emergency.

HRPO staff will collectively review and discuss the HRPP's Emergency Preparedness Guide and SOP, at least annually. This discussion will ideally take place around the same time as the IRB Member's review of the HRPP's emergency guidance.

Additional training for HRPO staff may be required before, during, or after an emergency affecting the HRPP. This training will be provided on a case-by-case basis, based upon the nature of the event.

Researchers:

UMD researchers will have access to information regarding HRPP emergency planning via the IRB Website. The HRPO will notify the UMD research community if changes are made to any existing HRPP Emergency Guidance or the IRB's SOPs. Changes will be communicated via the IRB Listserv.

Principal Investigators will be responsible for ensuring that all members of their research team are informed of any emergency preparedness plans.

The HRPO may conduct additional training for UMD researchers either before, during or after an emergency, as deemed necessary.

HRPP Emergency Procedures:

Assess the Nature of the Risk and Potential Impact to the HRPP:

The Director - HRPP will use the HRPP Emergency Preparedness Checklist to assess the nature of the emergency, implications to research activities at UMD, and disruptions in routine HRPP operations. The checklist will assist the Director in assigning an appropriate impact level to the emergency. Impact levels are as follows:

1. **No Impact:** The nature of the event has no impact on research activities related to human subjects or on the day-to-day operations of the HRPP.

   EXAMPLE: No Impact Event

   Event: A tornado unexpectedly touched down at UMD over the weekend. There were no injuries. However, several buildings temporarily lost power due to fallen trees and downed power lines. The UMD campus re-opened shortly after the storm, but staff were asked to avoid areas of storm damage including buildings that were affected by the storm.

   Assessment: Campus remained accessible following the tornado. HRPO staff were able to access the Office as their building was not affected by the storm. Operations were able to continue as normal. The storm had no effect on the health or safety of human subjects engaged in research at UMD. Thus, this represents a no impact event.

2. **Low Impact:** 1.) The nature of the event is not likely to affect the health and safety of human subjects engaged in research at UMD, or the event only affects a small portion of research activities related to human subject research at UMD; and/or 2.) The nature of the event has a small impact on the day-to-day operations of the HRPP. But the impact on operations can be bypassed (i.e. – staff working remotely, changing modes of communication, etc.). Therefore, the event will not result in a prolonged disruption of HRPP operations.

   EXAMPLE: Low Impact Event

   Event: The HRPO's electronic submission system goes down for 24 hours.

   Assessment: The HRPO's electronic system going down for 24 hours presents a low impact situation for the HRPP. When the electronic system is down, IRB submissions cannot be submitted, processed, or approved. However, HRPO staff are still able to perform other duties during this time (such as working on projects, updating guidance documents, etc.). In addition to this, the HRPO's electronic system going down does not affect staff's ability to communicate with UMD researchers. The HRPO staff can continue to communicate electronically via email, Zoom, g-chat, and over the phone. Thus, while the electronic system being down somewhat hinders the operations of the HRPO, it does not halt operations entirely. It also does not affect the risk of conducting human subject research at UMD.

EXAMPLE: Low Impact Event

Event: There is a time sensitive IRB application being reviewed at the next Full Board Meeting, but the University has unexpectedly closed for snow on the date of the meeting.

Assessment: The University closing on the date of the Full Board Meeting presents a low impact event. Although it means that an in-person IRB Meeting cannot take place, the HRPO can still hold the meeting virtually to ensure that the time sensitive IRB application is reviewed by the Committee. Moving the meeting online presents a change in the routine operations of the HRPO. However, the virtual nature of the meeting does not affect the risk of conducting human subject research at UMD.

3. **Direct Impact:** The nature of the event has the potential to affect the health and safety of human subjects engaged in research at UMD, or the nature of the event has a significant impact on the day-to-day operations of the HRPP resulting in an extended disruption to routine research activities.

EXAMPLE: Direct Impact Event

Event: A global pandemic has caused the University to close campus for an extended period. The UMD Health Center has posted guidance requiring staff, students, and faculty to limit face-to-face exposure, wear masks when engaging with other individuals, and to temporarily work remotely to reduce exposure to the virus.

Assessment: A global pandemic represents a direct impact event. It directly affects the health and safety of human subjects engaged in research at UMD, as face-to-face interactions during a global pandemic put individuals at risk of spreading and/or catching the virus. As a result, in-person human subject research will need to be temporarily postponed to adhere to State and UMD guidance. The HRPO can continue to operate remotely. However, some procedures may need to be adjusted to accommodate the remote environment.

An Emergency Preparedness Team should be formed to develop an Emergency Response Plan to address the demands of this event.

No Impact / Low Impact Assessment:

If the Director determines that the nature of the event has no impact on research activities at UMD, that it will not likely affect the health or safety of human subjects, and that the event does not permanently disrupt the day-to-day operations of the HRPP, the Director may respond to the event without the development of an Emergency Response Plan. The Director - HRPP will consult with individuals such as the VPR's Business Office, the IRB Chairs, and the Institutional Official if additional input is needed. The Director will communicate all relevant information to HRPO staff and the UMD research community, as required. Education and training will be provided to the appropriate individuals, as deemed necessary.

Direct Impact Assessment:

When the Director - HRPP believes that the nature of the emergency has a direct effect on the health and safety of human subjects engaging in research activities at UMD, or that the event has a direct impact on the daily operations of the HRPP, the Director will consult the Institutional Official. If the Institutional Official deems it necessary, an HRPP Emergency Preparedness Team will be called to action. The HRPP Emergency Preparedness Team will assist the Director in developing an Emergency Response Plan.

Development of an HRPP Emergency Response Plan:

The development of an HRPP Emergency Preparedness Plan will establish guidance for HRPP-specific emergency planning. It is intended to supplement, not replace, any emergency response guidance set forth by UMD and the State of Maryland.

Activation of HRPP Emergency Preparedness Team:

The Institutional Official will call an HRPP Emergency Preparedness Team to action. The Team will include at least the following individuals: the Vice President for Research, the Associate Vice President for Research, the Director - HRPPO, and the IRB Chairs. Additional individuals may be included on the team, or consulted, based upon the nature of the event and the individual's area of expertise.

The HRPP Emergency Preparedness Team will assist the Director in further assessing the impact of the event on research activities related to human subjects and the impact of the event on the daily operations of the HRPP.

Assessment of Impact on Research Activities:

When evaluating the impact of the event on research activities involving human subjects at UMD, the Team will consider items, such as:

- The safety and wellbeing of UMD researchers.
- The safety and wellbeing of UMD research participants.
- The ability to safely access the UMD campus.
- Whether the emergency impacts some or all investigators' ability to conduct human subject research.
- Researchers' ability to effectively communicate with participants throughout the event.
- The need to temporarily pause some or all research activities at UMD, taking into consideration state, local, and Institutional guidance.

Assessment of Impact to Operations of HRPP:

When evaluating the impact of the event on routine operations of the HRPP, the Team will consider items, such as the following:

- The safety and wellbeing of HRPO staff.

- Accessibility to the HRPO office.
- Accessibility to the HRPO's electronic submission system (for IRB submissions).
- Ability to process IRB determinations.
- Ability to hold IRB Meetings.
- Ability to conduct other HRPO functions.
- Access to the HRPO Share Drive.
- Ability to communicate with HRPO staff.
- Ability to communicate with the UMD research community.

Development of an Emergency Response Actions:

After assessing the impact of the emergency, the Team will develop guidance, in the form of an Emergency Response Plan, to address any risks and/or impacts resulting from the emergency. Items included in the Plan will supplement and incorporate any previously set state, local, and UMD guidance regarding the event. Potential emergency actions to be considered when drafting the Emergency Response Plan may include, but are not limited to, the following:

Operations of the HRPP:

- Allowing HRPO staff to work remotely if access to campus and/or the Office is not possible or deemed unsafe.
- Conducing virtual IRB Meetings if in-person meetings are not possible or unsafe.
- Proposing alternate means of communication (i.e. – phone, email, Zoom, Microsoft Teams, etc.) if traditional methods are unavailable.
- Proposing a temporary, alternate means for protocol submission and processing (i.e. – submission and processing via email) if the electronic submission system is unavailable; Providing a plan to transition alternate submissions to the HRPO's electronic system once its available.

Research Activities:

- Temporarily pausing some, or all research involving human subjects at UMD, if research activities are deemed unsafe, or access to campus is not possible.
  - Please Note: The plan will outline which types of research projects should be postponed, which should have recruitment or enrollment halted, and which may continue via alternate means, such as by remote procedures.
- Prioritizing IRB reviews, as appropriate, based upon the nature of the emergency.
- Allowing research activities that provide a direct benefit to continue once researchers submit a protocol incorporating updated guidance (i.e. – social distancing requirements, mask, gloves, etc.).
- Imposing flexibility in IRB review processes (i.e. – allow research activities previously conducted in-person to transition to remote procedures without the submission of an amendment).
- Allowing the continuation of research activities via alternate mechanisms, such as implementing online or remote strategies for recruitment, consent, data collection, debriefing, and follow-up, or altering the timing of in-person visits and procedures.
- Relying on an external IRB if the impact on local research operations is extensive or long lasting.

    - Please Note: The plan will list all the IRBs that have existing broad user agreements with UMD. These institutions will be prioritized when relying on external IRBs. When/if a broad user agreement is utilized, the Plan will describe how any research that was transferred to the external IRB will return to UMD at the conclusion of the emergency.
- When studies have an external sponsor, contact the Office of Research Administration to implement sponsor mitigation plans.

Communication of HRPP Emergency Response Plan:

Once the HRPP Emergency Response Plan has been finalized, the Emergency Preparedness Team will work with the Director to develop and disseminate targeted communications to the UMD community. Targeted communications may include individualized messages for: IRB members, HRPO staff, UMD researchers, UMD research participants, and institutional leadership. The IRB Specialist for Education and Improvement will be called upon to assist in developing guidance materials for the targeted populations, if needed. Guidance materials will be posted on the IRB Website.

Standard University communication channels will be utilized to distribute important information about the Emergency Response Plan to the research community. This includes the usage of platforms such as the IRB Website, the Division of Research's Website, IRB Email Listservs, and the Division of Research's Email Listservs.

The HRPO will notify the research community of the need for any protocol specific, or risk mitigation planning. Education and training will be provided to the UMD research community, as outlined in the Emergency Response Plan, and deemed necessary by the HRPO and the Division of Research. The IRB Specialist for Education and Improvement will assist in developing any required education and training materials throughout the emergency. Methods of training may include materials posted to the IRB Website, informational Zoom sessions, or in-person training.

Researchers are expected to follow guidance, adjust research appropriately, and inform their research teams about the plan.

Revisions to the HRPP Emergency Response Plan:

If the Emergency Preparedness Team deems that revisions must be made to the existing Emergency Response Plan due to the evolving nature of the event, the Emergency Response Plan will be updated appropriately. Any changes made to the Emergency Response Plan will be communicated to the UMD research community via standard University channels. Updated guidance will be posted on the IRB Website.

Resumption of Normal Operations:

When the Emergency Preparedness Team determines that the emergency no longer presents a limitation to human research activities, the UMD research community will be notified that normal business operations may resume. This information will be communicated via standard University channels and an announcement will be posted on the IRB Website.

Evaluation of HRPP Emergency Response:

Periodic Evaluation of the HRPP Emergency Preparedness Guidance:

The HRPP will periodically review the emergency preparedness policy and procedures. Supporting guidance documents such as: the HRPP's Emergency Preparedness Guide, the IRB's Standard Operating Procedures, and the HRPP's Emergency Preparedness Checklist will be assessed during this evaluation. Additional guidance documents will be reviewed, if necessary. Guidance documents will be updated to reflect changes, as needed.

HRPO Staff:

The Quality Assurance Program Manager will be responsible for conducting a periodic evaluation of the HRPP's Emergency Preparedness Guidance to ensure that it adequately addresses the standards set forth by AAHRPP Element I.1.H.

The QA Program Manager will review the guidance documents in support of HRPP emergency preparedness and will suggest revisions or improvements, as necessary. The QA Program Manager will meet with the Director - HRPP on an annual basis to discuss any suggested improvements and to review the HRPP's existing emergency preparedness policy, procedures, and guidance. Documents will be updated by the QA Program Manager, as deemed necessary.

IRB Members:

IRB Members will be asked to review the HRPP's emergency preparedness guidance on an annual basis. A discussion among IRB Members will take place at a convened IRB Meeting. IRB Members will also provide feedback on the HRPP's emergency preparedness during their Annual IRB Member Evaluation.

HRPP Leadership:

A link to the HRPP's Emergency Preparedness Guide and the IRB SOPs will be included in the HRPO's Annual IRB Report. The Annual IRB Report is provided to HRPP leadership on an annual basis and is reviewed in a meeting amongst the Vice President for Research (Institutional Official), the Associate Vice President for Research, the Director - HRPP, and the IRB Chair(s). During this meeting, the Director - HRPP will briefly discuss any updates to the guidance in support of emergency planning for the HRPP. The Vice President and Associate Vice President for Research can suggest improvements and/or revisions to the existing guidance as they see fit.

Additional Evaluation:

The HRPP will contact the University's Office of Emergency Management and Business Continuity, for assistance in assessing guidance in relations to emergency preparedness, if deemed necessary.

Evaluation of HRPP Emergency Response Plans:

Any HRPP Emergency Response Plans will be periodically reviewed throughout duration of the emergency, by the Emergency Preparedness Team or the appropriate individual(s) (Director of the

HRPO, Institutional Official, IRB Chairs, etc.), to ensure that the Plan adequately addresses the evolving nature of the emergency.

Emergency Response Plans will also be evaluated at the conclusion of an emergency (i.e. – resumption of normal business operations), to determine whether the HRPP could make improvements and/or changes to the Plan if a similar event was to occur in the future. All Emergency Response Plans will be assessed by the Quality Assurance Program Manager and the Director - HRPO. Findings will be reported to the Vice President and Associate Vice President for Research, the IRB Chairs, the IRB Committee, and HRPO staff, as deemed appropriate.

HRPP EMERGENCY PREPARDNESS CHECKLIST:

The UMD HRPP defines an emergency as an unforeseen combination of circumstances that may require immediate action.

TYPE OF EMERGENCY:

☐	**Public Health Emergency**	A public health emergency is any adverse event that compromises the health of the population and has the potential to cause illness. A public health emergency may be widespread, such as a pandemic, or localized to the UMD community or the surrounding area.
☐	**Weather Emergency**	A weather-related emergency occurs when severe weather causes damaging or hazardous conditions, resulting in a disruption to routine services and activities (i.e. – campus closure; building closure; campus power outage, etc.). Examples of weather-related emergencies may include: a tornado, a hurricane, or a blizzard.
☐	**Natural Disaster**	A natural disaster is a sudden event that is caused by environmental factors such as floods, fire, or a power outage. These events have the potential to cause damaging or hazardous conditions resulting in a disruption to routine services and activities.
☐	**Man-made Emergency**	A man-made emergency is an event that was caused by human interaction, either intentionally or unintentionally, which results in a threat to safety, or causes a disruption to routine services and activities. Examples of man-made emergencies may include campus construction, a cyber-attack, an active shooter on campus, a bomb threat, a terrorist attack, or an IT system failure.
☐	**Other**	Click or tap here to enter text.

IMPACT ON RESEARCH ACTIVITIES:

☐ The event may affect the safety and wellbeing of UMD researchers.

☐ The event may impact some or all UMD researchers' ability to conduct human subject research.

☐ The event may affect the safety and wellbeing of some or all UMD research participants.

☐ Researchers' ability to access the UMD campus may be affected by the event.

☐ Researchers may not be able to effectively communicate with research participants as a result of the event.

☐ Research activities may need to be temporarily paused as a result of the event.

☐ Federal, state, local, and university guidance have been considered when assessing the risks posed by the event.

IMPACT ON HRPP OPERATIONS:

☐ The event may affect the safety and wellbeing of HRPO staff.

☐ HRPO staff's ability to access the HRPO Office may be affected by the event.

☐ HRPO staff's ability to access the electronic submission system may be affected by the event.

☐ The event may affect the HRPO's ability to process IRB determinations.

☐ The event may affect the HRPO's ability to hold IRB Meetings.

☐ The event may affect the HRPO's ability to conduct other routine functions.

☐ The event may affect HRPO staff's ability to access the Share Drive.

☐ The event may affect HRPO staff's ability to communicate with one another and/or the research community.

LEVEL OF IMPACT:

☐	**NO IMPACT**	The nature of the event has no impact on research activities related to human subjects or on the day-to-day operations of the HRPP.
☐	**LOW IMPACT**	1.) The nature of the event is not likely to affect the health and safety of human subjects engaged in research at UMD, or the event only affects a small portion of research activities related to human subject research at UMD; and/or 2.) The event may have a small impact on the day-to-day operations of the HRPP. But the nature of the event can be bypassed and therefore, will not result in a continued disruption of HRPP operations.
☐	***DIRECT IMPACT**	The nature of the event has the potential to affect the health and safety of human subjects engaged in research at UMD, or the nature of the event has a significant impact on the day-to-day operations of the HRPP resulting in a disruption to routine research activities.

***PLEAE NOTE:** When the nature of the emergency will have a **DIRECT IMPACT** on the health and safety of human subjects engaged in research at UMD, or the event will have a **DIRECT IMPACT** on the operations of the HRPP, the Institutional Official should be notified to determine whether an HRPP Emergency Preparedness Team is needed to construct an Emergency Response Plan.

Institutional Official: Dr. Patrick O'Shea, poshea@umd.edu

HRPP EMERGENCY PREPARDNESS TEAM CONTACTS:

PRIMARY MEMBERS:

Name:	Title:	Email:	Phone:
Joseph Smith	Director, HRPP	jsmith54@umd.edu	301-405-0678
Dr. Patrick O'Shea	VP for Research & Institutional Official	poshea@umd.edu	301-405-5020
Denise Clark	Associate VP for Research	djclark@umd.edu	301-405-4282
Jim Hagberg	IRB Chair	hagberg@umd.edu	301-405-2487
Yasmeen Faroqi Shah	IRB Vice Chair	yfshah@umd.edu	301-405-4229

ADDITIONAL CONSULTANTS:

Name:	Title:	Email:	Phone:
Jenn Blackburn	QA Program Manager	jdesi@umd.edu	301-405-3488
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SMART IRB

Reliance Agreement
Version 3.0

Standard Operating Procedures

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Version Date: March 17, 2025

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Introduction

The SMART IRB Standard Operating Procedures (SOPs) are the default SOPs for SMART IRB reliance arrangements, unless other SOPs are specifically documented. The SMART IRB SOPs are not intended to overlap with or replace existing institutional-level SOPs that have already been implemented internally at institutions participating in the SMART IRB Agreement. These SOPs serve as a mechanism for highlighting the unique features associated with participating in the SMART IRB Agreement, and serve as guidelines for establishing reliant review of multi-site human research conducted using the SMART IRB Agreement.

The implementation of these SOPs helps assure that institutions using the SMART IRB Agreement follow the responsibilities documented within the SMART IRB Agreement, and provides a reference and guideline for internal stakeholders and external sponsors as to how multi-site research is undertaken using the SMART IRB Agreement. Furthermore, these SOPs provide an additional training source for investigators and administrators participating in the SMART IRB Agreement.

Glossary of Terms

Agreement: SMART IRB Reliance Agreement.

Assurance: An assurance of compliance with the Federal Policy that is maintained with a federal department or agency.

Ceded Review: The transfer of authority to, and reliance on, a Reviewing IRB for IRB review and oversight of research.

Confidential Information: Any non-public, confidential and/or proprietary information, including but not limited to the scientific content of Research proposals and information provided by the Overall PI, Site Investigator(s), or other Personnel not generally known or available to the public. Information is not Confidential Information hereunder if such information (a) is or becomes known to the receiving party independently of disclosure by the disclosing party, directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing party; (b) becomes publicly known or otherwise ceases to be confidential, except through a breach of this Agreement by the receiving party; or (c) is independently developed by or on behalf of the receiving party. For clarity, as used in this Agreement, the term Confidential Information has no relation to the classification level of information/documents within a federal department or agency.

Covered Activity/Covered Activities: Ceded Review of Research and Exemption Determinations, individually or collectively.

DHHS: U.S. Department of Health and Human Services.

Effective Date of the Agreement: With respect to any Participating Institution, the Effective Date of its Joinder Agreement.

Effective Date of the Indemnification Addendum: With respect to any Indemnification Participating Institution, the date on which the Indemnification Participating Institution's Institutional Official/Signatory executes the Indemnification Addendum Joinder Agreement.

Effective Date of a Joinder Agreement: The date on which the Participating Institution's Institutional Official/Signatory executes the Joinder Agreement.

Executive Committee: Composed of SMART IRB Team leadership and representatives from NCATS.

Exemption Determinations: A determination by a Reviewing IRB or Reviewing IRB Institution whether Research is exempt from some or all of the requirements of the Federal Policy.

FDA: U.S. Food and Drug Administration.

FDA Clinical Investigation Regulations: 21 CFR Parts 50, 56, 312, and 812.

Federal Institution: An Institution/Participating Institution that is a department or agency of federal government.

Federal Policy: The Federal Policy for the Protection of Human Subjects set forth in the DHHS regulations at 45 CFR Part 46, Subpart A and corresponding regulations of other federal departments and agencies adopting such Policy.

Force Majeure Event: An unforeseeable natural, political, or similar event beyond the control of a Participating Institution, including, without limitation, fire, flood, pandemics, epidemics, riots, war, acts of terrorism, or governmental actions or decrees in response to same, except as provided in Section 8.13 hereof.

FWA: The OHRP-approved Federalwide Assurance in which a research institution commits to DHHS that it will comply with the Federal Policy.

HIPAA: Collectively, the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act of 2009, and their implementing privacy and security regulations, including but not limited to the implementing privacy regulations at 45 CFR Part 160 and 45 CFR Part 164, Subparts A and E.

HIPAA Covered Entity: A health care provider, health plan, or health care clearinghouse subject to HIPAA as further defined and provided in 45 CFR 160.103.

Human Research Protection Program or HRPP: An Institution's policies, procedures, and oversight mechanisms for addressing human research protections.

Indemnification Addendum: The SMART IRB Indemnification Addendum attached to the Agreement at Exhibit C.

Indemnification Addendum Joinder Agreement: The SMART IRB Indemnification Addendum Joinder Agreement available at www.smartirb.org, which will be in substantially the same form as in Exhibit C.

Indemnification Participating Institution: A Participating Institution that joins the Indemnification Addendum.

Indemnification Terminating Institution: An Indemnification Participating Institution that terminates its participation in the Indemnification Addendum or whose participation in the Indemnification Addendum is terminated pursuant to Sections 7.2.2.2 or 7.2.2.3 hereof, respectively, or whose participation in the Indemnification Addendum ends as a result of the termination of the Indemnification Addendum in its entirety pursuant to Section 7.2.2.1.

Indemnified Party(ies): An Indemnification Participating Institution and its trustees, directors, officers, Personnel, and IRB members eligible to be held harmless, indemnified, and defended by an Indemnifying Party under the Indemnification Addendum.

Indemnifying Party: An Indemnification Participating Institution that is a Private Institution and is agreeing in the Indemnification Addendum to hold harmless, indemnify, and defend the Indemnified Parties.

Independent IRB Organization: An independent IRB organization that provides IRB review services.

Institutional Official/Signatory: The person who has the authority on behalf of an Institution to bind such Institution to the terms and conditions of the Agreement and, if applicable, the Indemnification Addendum.

IRB: Institutional Review Board(s).

Joinder Agreement: The SMART IRB Joinder Agreement available at www.smartirb.org, which will be in substantially the same form as attached to the Agreement at Exhibit B.

Limited IRB Review: The IRB review required pursuant to 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(C), (d)(7), or (d)(8) or the corresponding provisions in the regulations of any federal department or agency adopting the Federal Policy in order for Research to be considered exempt under one of those provisions.

Local Considerations: Requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local ancillary reviews.

Losses: Any and all damages, judgments, liabilities, costs, expenses (including, without limitation, reasonable attorney's fees and expenses of litigation), or other losses incurred by or imposed upon any Indemnified Party(ies) or Other Party(ies) as a result of third-party claims, suits, demands, actions, or causes of action.

Mandated Policy/Policies: Federal department- or agency-mandated policies and procedures governing the conduct of a reliance relationship once it is established.

Mandated Processes: Federal department or agency processes for initiating reliance and for determination of the Reviewing IRB/Reviewing IRB Institution.

NCATS: National Center for Advancing Translational Sciences at NIH.

NIH: National Institutes of Health.

OHRP: The Office for Human Research Protections of DHHS.

Other Considerations: The requirements of any applicable federal laws or regulations or of relevant federal departments or agencies that are not readily apparent from the IRB submission for the Research or that are specific to the Relying Institution. For purposes of this Agreement, HIPAA and its requirements are not considered Other Considerations.

Other Party(ies): An Indemnification Participating Institution and its trustees, directors, officers, Personnel, and IRB members to whom a Responsible Party is responsible and who are eligible to be reimbursed by a Responsible Party Under the Indemnification Addendum.

Other Policies: Policies and procedures for the conduct of a reliance relationship that are not Mandated Policies but that Participating Institutions agree among themselves to apply to a reliance relationship under the Agreement.

Overall PI: The lead multi-site principal investigator with ultimate responsibility for the conduct and integrity of Research (generally, the initiating principal investigator or funding principal investigator, as applicable).

Party/Parties: A Participating Institution or, collectively, the Participating Institutions.

Participating Institution: An Institution (including an Independent IRB Organization) that meets the eligibility requirements set forth in the Agreement and accepts the terms and conditions of the Agreement through the execution of a SMART IRB Joinder Agreement.

Personnel: Members of a Participating Institution's team (including the Overall PI (if any) and Site Investigator(s)) involved in conducting an instance of Research. These individuals may include, as applicable, physicians, nurses, coordinators, data managers, lab technicians, postdoctoral fellows, students, volunteers and/or other personnel.

POC: Contact person or point of contact responsible for communicating on behalf of the Institution/Participating Institution with respect to matters concerning the initial and ongoing implementation of the Agreement.

Private Institution: An Institution/Participating Institution that is not a department, agency or instrumentality of federal, state, local, or other government.

Protected Health Information or PHI: Protected Health Information as defined in 45 CFR 160.103.

Public Institution: An Institution/Participating Institution that is a department, agency, or instrumentality of U.S. federal, state, local, or other domestic government.

Reliance Request: A request for Ceded Review or for an Exemption Determination, as applicable, with respect to an instance or multiple instances of Research.

Relying Institution: A Participating Institution that will obtain IRB review from a Reviewing IRB and/or determinations of exemption from IRB review from a Reviewing IRB or Reviewing IRB Institution under the Agreement.

Report: A report required under applicable federal human subjects protection regulations or under the terms of a Relying Institution's Assurance to a federal human subjects research regulatory agency (e.g., OHRP, FDA) regarding any unanticipated problems involving risks to human subjects or others; serious and/or continuing noncompliance with the Federal Policy, other applicable federal human subjects protection regulations or policies, or the FDA Clinical Investigation Regulations, as applicable, or with the requirements or determinations of the Reviewing IRB; and/or any suspensions or terminations of IRB approval.

Research: Any human subjects research within the meaning of the Federal Policy or within the meaning of any other federal human subjects protection regulations or policies; any investigation/ clinical investigation within the meaning of the FDA Clinical Investigation Regulations; and any other research for which any Participating Institution seeks or is required to rely on a Reviewing IRB. Research may reference a specific study or protocol (an instance of Research) or collectively any or all of the studies or protocols eligible under the Agreement.

Responsible Party: An Indemnification Participating Institution that is a Public Institution and is agreeing in the Indemnification Addendum to be responsible to and to reimburse the Other Parties.

Reviewing IRB: The IRB of a Participating Institution that will provide IRB review and/or determinations of exemption from IRB review for a Relying Institution under the Agreement.

Reviewing IRB Institution: The Participating Institution whose IRB will become the Reviewing IRB for a Relying Institution under the Agreement and/or that will provide determinations of exemption from IRB review for a Relying Institution under this Agreement.

Site Investigator(s): An investigator(s) responsible for the conduct of the Research at their Participating Institution.

SMART IRB SOPs: The SMART IRB Standard Operating Procedures developed in support of the Agreement.

SMART IRB Team, including SMART IRB Administrators, Administration, and/or Administrative personnel: collectively, these terms include leadership, staff, and SMART IRB Ambassadors supporting the development, implementation, and operations of SMART IRB and its systems and programming.

Terminating Institution: A Participating Institution that terminates its participation in the Agreement or whose participation in the Agreement is terminated pursuant to Sections 7.2.1.2 or 7.2.1.3 hereof, respectively, or whose participation in the Agreement ends as a result of the termination of the Agreement in its entirety pursuant to Section 7.2.1

Responsibilities: PIs and Study Teams

Overall PI and Lead Study Team

The Overall PI is responsible for identifying a Lead Study Team and providing the Lead Study Team/ Coordinating Center contact information to the Site Investigators. The Overall PI and Lead Study Team (or their designees) are responsible for providing the information or performing the activities described below related to the reliance review process and once IRB review has been ceded:

- Work in collaboration with the Reviewing IRB and POC to determine and document specific roles and responsibilities for communicating and coordinating key information to Relying Institutions and the Reviewing IRB as described throughout these SOPs and summarized in the Appendix: Communication Plan.
- Promptly responding to questions or requests for information from Site Investigators, study teams, and/or IRB/HRPPs at Relying Institutions.
- Providing the Site Investigators with the IRB policies of the Reviewing Institution. This will include but is not limited to providing the Site Investigators with the IRB policies applicable to the study for reporting unanticipated problems, noncompliance, and subject complaints.
- Obtaining and collating information from Relying Site Study Teams and/or Relying Site Points of Contacts (depending on who is designated to provide that information at the Relying Institution) regarding local variations in study conduct, such as recruitment materials and process, consent process and language, and subject identification processes.
- Participating in meetings regarding a study as requested by the Reviewing IRB, Relying Site Study Team, or home institution.
- Providing participating Relying Site Study Teams with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials).
- Assisting Relying Site Study Teams and/or POCs at the Relying Institution(s) (depending on who is designated to provide that information) in ensuring consent documents follow the Reviewing IRB's template form and include applicable site-specific required language from each Relying Institution.
- When agreed upon in coordination with the Reviewing IRB, promptly reporting to the Site Investigator (or designee on the Relying Site Study Team) any unanticipated problems involving risks to subjects or others research-related subject injuries, or significant subject complaints that are related to or may affect subjects participating in the Research (i.e., the specific study or studies ceded to the Reviewing IRB) at the Relying Institution.
- Ensuring Site Investigators are notified of all Reviewing IRB determinations and communications, including those for initial review, continuing review, amendments, and reportable events, as applicable.

- If a Relying Site Study Team does not provide the Lead Study Team (or designee) with the required information before the continuing review application is submitted to the Reviewing IRB, reporting the absence of this information as part of the continuing review and notifying affected Relying Site Study Team of lapse in approval for their site and any applicable corrective action plans.
- Providing access, upon request, to study records for audit by the Relying Institution, the Reviewing IRB, and other regulatory or monitoring entities.
- Following all ceded review requirements of the Relying Institution, such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a Relying Institution.

Relying Site Study Teams

The Relying Site Study Teams, which include Site Investigators, are responsible for providing the information or performing the activities described below related to the reliance review process and once IRB review has been ceded:

- Following all requirements of their home institution regarding ceded review, such as ensuring other reviews or sign-offs required by the institution have been completed before a study is activated.
- Promptly responding to questions or requests for information from the Lead Study Team (or designee) as well as from the Reviewing IRB through the communication mechanism(s).
- Participating in meetings regarding a study as requested by the Lead Study Team, Reviewing IRB, or home institution.
- Working with the Lead Study Team and the POC from their home institution or the Reviewing IRB, as applicable, to incorporate site-specific required language into the consent template to be used at their institution.
- Providing the applicable office (e.g. grants/contracts) at their institution with documentation that IRB oversight for a study has been ceded to and approved by an IRB external to their home institution.
- Providing the POC from their home institution with information regarding local Site Investigator or other Relying Site Study Team personnel changes.
- Reporting to their home institution POC any changes in conflict of interest (COI) disclosures and resulting changes in COI management plans related to the Research (i.e., the specific study or studies ceded to the Reviewing IRB).
- Promptly reporting to the Lead Study Team (or designee) any applicable information for continuing review progress reports in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions.

- Reporting to the Lead Study Team (or designee) any changes (including funding changes and personnel changes), reportable events, and continuing review progress reports, for submission to the Reviewing IRB in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions.
- Promptly reporting to the Overall PI via the Lead Study Team (or designee) any unanticipated problems involving risks to subjects or others, subject injuries related to the research, or significant complaints that could impact the conduct of the Research (i.e., the specific study or studies ceded to the Reviewing IRB) in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions. Significant complaints are defined as those that cannot be resolved by the study team and a) suggest an increased or unexpected new risk or harm or b) change the risk/benefit ratio of the Research. Other complaints should be reported in accordance with the Reviewing IRB's policies and procedures.
- Promptly reporting to the Overall PI via the Lead Study Team (or designee) any potential noncompliance that occurs in relation to the Research (i.e., the specific study or studies ceded to the Reviewing IRB) in accordance with the Reviewing IRB's policies and procedures for timing of submission and content of such submissions.
- Providing, upon request, access to study records for audit by the local institution, the Reviewing IRB's institution, and other regulatory or monitoring entities.

Responsibilities: Reviewing IRBs and Relying Institutions

This section of the SOPs provides an overview of the key responsibilities of Reviewing IRBs and Relying Institutions. The responsibilities of the POC, who plays a critical role in ensuring that many of these Reviewing IRB and Relying Institution responsibilities are met, are addressed in detail in the next section.

Reviewing IRBs

The Reviewing IRB is responsible for reviewing and overseeing any studies ceded to it for the life of the study, unless the research is withdrawn from Ceded Review, Institution ends its participation in the SMART IRB Agreement or a specific study section below. In addition, the Reviewing IRB (or designee) is responsible for the following activities related to the initial reliance review process and subsequent management of the study:

- Working in collaboration with the POC and Lead Study Team (or designee) to determine and document specific roles and responsibilities for communicating key information to Relying Institutions and the Reviewing IRB as described throughout these SOPs, and as summarized in the Appendix: Communication Plan.
- Providing POCs and Relying Site Study Teams with template informed consent form(s), which indicate areas where the Relying Institutions must add information (e.g., local contacts)[1].
- Sending written notification to the Overall PI and Lead Study Team of: (i) its decision to approve or disapprove any Research (i.e., the specific study or studies ceded to the Reviewing IRB), (ii) any modifications required to secure approval of the Research, and (iii) the date by which renewal of an approval is required.
- Upon reasonable request, providing to the Relying Institution with access to relevant records related to the IRB review.
- Promptly notifying the Overall PI and relevant POCs from a Relying Institution of its findings and actions with respect to any unanticipated problems involving risks to subjects or others or any research-related subject injuries or significant subject complaints that occurred at the Relying Institution—or that occurred at another Relying Institution if such events or actions relate to or may affect the conduct of the Research or the safety, rights, or welfare of subjects participating in the Research at the Relying Institution.
- In the event a continuing review is submitted after IRB approval for the study expires or the study expires before the Reviewing IRB can reapprove the study, notifying the POCs and Relying Site Study Teams from affected sites, in addition to the Overall PI and Lead Study Team, of the lapse in IRB approval and any applicable corrective action plans.

1 Alternatively, a member of the Lead Study Team may assume responsibility for notifying Relying Site POCs and Study Team members as described in this section, if agreed upon by the POC for the Reviewing IRB.

- Promptly notifying relevant POCs and Relying Site Study Teams, in addition to the Overall PI and Lead Study Team, of any finding of serious and or/continuing noncompliance that may affect the conduct of the Research or the safety, rights, or welfare of human subjects participating in the Research at the Relying Institution(s). If the finding of serious and/or continuing noncompliance has a study-wide impact, all Relying Institutions must be notified.
- Promptly notifying the Overall PI, Lead Study Team, relevant POCs, and relevant Relying Site Study Teams of any suspension or termination of IRB approval for that portion of the Research taking place at those Relying Institutions. If the suspension or termination is study-wide, all Relying Institutions must be notified.
- Unless an alternate reporting arrangement has been previously agreed upon between the Relying Institutions and Reviewing IRB, reporting to regulatory agencies and/or sponsors any findings of unanticipated problems involving risks to subjects or others, determinations of serious and/or continuing noncompliance, and/or any suspensions or terminations of IRB approval on behalf of all applicable institutions covered by this Agreement. The Reviewing IRB will also provide the involved Relying Institutions the opportunity to review and comment on the report before it is sent to federal authorities, such as OHRP, the FDA, or others.
- If the Reviewing IRB ends its participation in the SMART IRB Agreement or a specific study, informing all Relying Institutions of this change, as described in the “Ending Site Participation in the SMART IRB Agreement or Specific Studies” section below.

Relying Institutions

Relying Institutions are responsible for the following activities related to the initial reliance review process and subsequent management of the study; these will generally occur through the Overall PI and Lead Study Team:

- Communicating local considerations to the Reviewing IRB, including requirements of applicable state or local laws, regulations, institutional policies and standards, and other local factors including ancillary review processes as are relevant to the Research (i.e., the specific study or studies ceded to the Reviewing IRB). Generally, this will occur through the POC (see sections below).
- Communicating other considerations including the requirements of any applicable federal laws or regulations of relevant federal departments or agencies that may not be apparent from the research submission or that are specific to the relying institution that would affect the conduct by or approval of the research.
- Providing information about local restrictions, stipulations, or requested substitutions to informed consent documents for approval by the Reviewing IRB, Generally, this will occur through the POC (see sections below).
- Ensuring there is a mechanism for which significant complaints about the research may be received locally.

- Notifying the Reviewing IRB of the following:
  - Any unanticipated problems or potential noncompliance that occurred
  - Findings of serious and/or continuing noncompliance that occurred on research that has not been ceded under this Agreement but that may have relevance to ceded Research
  - Any significant research participant complaints
  - Any suspension or restriction of a Relying Site's Study Team member(s) ability to conduct human subjects research.
- Maintaining policies regarding the disclosure and management of personnel conflicts of interest related to the research submitted for ceded review and sharing those policies with Reviewing IRB, as requested.
- Disclosing any COI related to Research conducted under this Agreement and providing applicable management plans to the Reviewing IRB; this may occur through the Lead Study Team or the Relying Institution POC.
- If the Reviewing IRB requests an audit, the Relying Institution will cooperate, and report audit findings to the Reviewing IRB within a reasonable timeframe.
- Report to federal funding agencies, sponsors, and/or other federal authorities and that are required related to the ceded research but not made by the Reviewing IRB (e.g., report of a determination of serious noncompliance to a study sponsor).
- Notifying the Reviewing IRB(s) of communications regarding Research covered by this Agreement to/from the Relying Institution and FDA, OHRP, and/or other regulatory agencies (e.g., re. unanticipated problems or serious and/or continuing noncompliance), as applicable.
- Informing the Reviewing IRB if the Relying Institution ends its participation in the SMART IRB Agreement or a specific study.

Responsibilities: SMART IRB Points of Contact (POCs)

This section of the SOPs provides an overview of the key responsibilities of SMART IRB POCs during the reliance review process and after IRB review is ceded.

Each Participating Institution must designate a primary POC and an (optional) alternate POC. Generally, the POC is associated with the Participating Institution's IRB. However, some Participating Institutions will not have IRBs or will appoint an individual outside of the local IRB office to serve as a POC.

All Participating Institutions are responsible for designating an individual (a SMART IRB POC) to carry out the following activities; Participating Institutions may designate some of these activities to personnel other than the designated SMART IRB POC (e.g., Research Integrity Officers, legal counsels, Institutional Officials, or post-approval monitoring programs):

- Communicating to other SMART IRB POCs, the Lead Study Team, and to their Site Investigator the institution's decisions to serve as the Reviewing IRB, cede review to the proposed Reviewing IRB, or retain local IRB review of Research.
- Promptly reviewing reliance requests and any supporting materials to determine whether ceding IRB review or serving as the Reviewing IRB is appropriate, in accordance with that institution's policies and procedures.
- On a study-by-study basis, communicating with SMART IRB POCs at other institutions identified as potential study sites to identify a single Reviewing IRB and determine which institutions choose to rely on the identified Reviewing IRB.
- Consulting, as needed, with individuals and resources (e.g., other IRB staff, legal counsel) at the institution regarding ceding IRB review or accepting IRB oversight for Research under the SMART IRB Agreement.
- Addressing any questions from the Site PI and/or potential Relying Site Study Team regarding the SMART IRB Agreement reliance review process and status of the reliance request.
- Notifying Relying Institutions of any legal action related to Research that had been ceded to the institution's IRB under the SMART IRB Agreement.
- Notifying the Reviewing IRB regarding the outcome of any internal audit findings related to Research ceded under the SMART IRB Agreement that represent reportable information per the Reviewing IRB's policies and procedures (e.g. unanticipated problems, serious or continuing noncompliance, or other reportable information).
- As appropriate, notifying other SMART IRB POCs regarding the outcome of any other audit findings not addressed above and related to Research that had been ceded under the SMART IRB Agreement.
- Promptly communicating to the SMART IRB Team, and to SMART IRB POCs at Participating Institutions with which the institution is engaged, any changes in the institution's designated SMART IRB POC(s).

- In regard to the institution's FWA or other Federal Assurance, notifying POCs at other Participating Institutions of:
  - A suspension or restriction to the institution's FWA or other assurance
  - A modification to the scope of research to which the FWA or other assurance applies
  - Invalidation of the institution's FWA or other assurance for any reason (e.g., termination or expiration)
  - Filing of a new or updated Federal Assurance (e.g. FWA or other assurance)
- Notifying the SMART IRB Team of changes in the components of the institution that are covered under the FWA or other assurance.
- When the POC's institution serves as the Reviewing IRB:
  - Working in collaboration with the Reviewing IRB and Lead Study Team to determine and document specific roles and responsibilities for communicating key information to Relying Institutions and the Reviewing IRB as described throughout these SOPs and as summarized in the Appendix: Communication Plan.
  - Verifying that any changes in Site PIs or Relying Site Study Team personnel have been signed-off on by the Relying Institution POC for submission to the Reviewing IRB.
  - Communicating lapses in IRB approval to affected Relying Institutions as addressed in the "Continuing Review Submission and Review Process" section below.
  - Communicating information related to reportable events to affected Relying Institutions as addressed in "Reportable Event Submission and Review Process" below.
- When a POC's institution is a Relying Institution:
  - Communicating to the Reviewing IRB POC any questions or concerns about the Research and local considerations (e.g., State law and any outstanding institutional requirements that must be met), in coordination with the Relying Site Study Team.
  - Verifying, in coordination with the Reviewing IRB POC, that Site Investigator or Relying Site Study Team personnel meet the institutional requirements for the Relying Institution, including education, training, and qualifications to perform the Research and safeguard the rights and welfare of research participants. This verification includes, but is not limited to, having any local institutionally required professional staff appointments, credentialing, insurance or other liability coverage (if required), and training in human subjects protections, and background checks for their assigned role in the Research.
  - For any proposed changes in Site PI or Relying Site Study Team personnel, verifying, in coordination with the Reviewing IRB POC, that any institutional requirements for investigators and study team members are met, including education, training, qualifications, and resources to perform the Research and safeguard the rights and welfare of research subjects. This verification includes, but is not limited to, having any local institutionally required professional staff appointments, credentialing, insurance or other liability coverage (if required), training in human subjects protections, and background checks for their assigned role in the Research.

- Notifying the Reviewing IRB's POC regarding events that occur at the Relying Institution that may alter the Reviewing IRB's decision to accept IRB oversight for the Relying Institution or the Relying Institution's decision to cede review, such as suspension of research privileges of a Site Investigator at a Relying Institution. NOTE: This notification would be limited to events that might not otherwise be reported to the Reviewing IRB by the Lead Study Team (e.g., noncompliance concerns identified by the Relying Institution on a study not ceded to the Reviewing IRB).
- Responding promptly to any requests for assistance or information from the Reviewing IRB's POC (e.g., gathering information on behalf of the Reviewing IRB regarding reportable events occurring at the Relying Institution)

Establishing the Reviewing IRB

This section describes the process for establishing a Reviewing IRB for any studies conducted under the SMART IRB Agreement. The process begins when a proposed human research study has been identified and an “Overall PI” has been established.

The default prioritization scheme used for identifying potential Reviewing IRBs will be as follows:

1. Reviewing IRB that has been pre-determined by study sponsor or grant or established by prior arrangement (e.g., network central IRB).
2. Overall PI’s Home Institution (HI) IRB. (NOTE: the HI is where the Overall PI is primarily employed or is affiliated.)
3. Another Participating Institution IRB, when Overall PI HI does not have an IRB or Reviewing IRB(s) is selected based on type of procedures to be performed, subject population, or other criteria; more than one Reviewing IRB may be appropriate if these will significantly vary among participating sites.

Note: For research that is subject to federal regulations or funding policies mandating reliance on a single IRB, specific federal department or agency processes for initiating reliance and for determination of the Reviewing IRB/Reviewing IRB Institution will apply and should be used to establish the Reviewing IRB/Reviewing IRB Institution.

Each Participating Institution will determine whether the responsibility for submitting reliance request is assigned to the Overall PI, Lead Study Team, or the IRB POC. The Overall PI or designee submits a request and supporting documents via the mechanism established by the HI IRB and identifies a proposed Reviewing IRB, which may be the IRB at the HI or an external IRB. If the Overall PI HI does not have an IRB, the Overall PI will follow the institution’s policies for requesting the use of an external IRB.

The SMART IRB POC at the Overall PI’s HI reviews the request and supporting documents and determines, in consultation with other Participating Institutions as necessary, if the institution’s IRB will serve as the Reviewing IRB for the Overall PI and other sites. If the SMART IRB POC determines that the HI IRB agrees serve as the Reviewing IRB, the POC will notify the Overall PI of the decision, and proceed to the section below on “Establishing the Relying Institutions.”

If the HI has an IRB and declines to serve as the Reviewing IRB for all Participating Institutions, the HI SMART IRB POC will then determine whether the HI is willing to cede review to another IRB to serve as the Reviewing IRB for the Overall PI. If the HI is willing to cede review to another institution, the HI SMART IRB POC contacts the POC(s) for potential alternate Reviewing IRB(s) identified by the Overall PI. The Overall PI may participate in this process where necessary. Once the Reviewing IRB has been established, the SMART IRB POC (on behalf of the Reviewing IRB) will notify the Overall PI of the decision, and proceed to the section below on “Establishing the Relying Institutions.” If the HI is unwilling to cede review to another institution, the HI IRB proceeds to conduct a review of the study for its own study team. The other Site Investigators are referred to new potential Reviewing IRBs identified by the Overall PI or by the HI POC.

The Overall PI, SMART IRB POC, and representative(s) from the Reviewing IRB will establish and document the party who will assume responsibility for the reliance-related communication and administrative functions described within these SOPs for which flexibility exists (e.g., whether the Reviewing IRB will review waivers and alterations of authorization on behalf of Relying Institutions. A sample “Communication Plan” matrix is attached to these SOPs.

NOTE: There may be situations where the Overall PI does not seek Ceded Review but a sub-group of POCs determine Ceded Review is appropriate for the Research. If the Overall PI and/or the POC for the Overall PI’s HI do not object, Participating Institutions may still participate in Ceded Review for the Research. In this case, a Site Investigator may make a request for Ceded Review to their HI IRB.

2 For example, it may be appropriate to identify more than one Reviewing IRB for a single study if a study involves both pediatric and adult populations and separate reviewing IRBs are established to oversee each population.

Establishing the Relying Institutions – Prior to IRB Approval

Once the proposed Reviewing IRB has been established, the SMART IRB POC from the Reviewing IRB Institution contacts the SMART IRB POCs at the other known Participating Institutions engaged in the proposed research, providing these sites access to the available materials provided by the Overall PI. These potential Relying Institutions should complete the following steps within 14 calendar days:

1. Review the materials provided by the Overall PI.
2. Render a determination about ceding IRB review to the proposed Reviewing IRB.

If a potential Relying Institution agrees to cede review to the proposed Reviewing IRB, the Relying Institution SMART IRB POC provides the following information to the Reviewing IRB POC, Overall PI, and local Site Investigator:

1. The decision to cede review.
2. Any outstanding concerns or requirements that must be addressed before the Reviewing IRB approves the Research for that Relying Institution.
3. Any local considerations or other considerations related to the Research that the Reviewing IRB must consider.

NOTE: Once informed consent document (ICD) templates are available for site-specific customization, Relying Institutions will provide institution-specific language for a limited number of areas as described in the "Customization, Submission, and Review of Informed Consent Documents" section below.

If a potential Relying Institution declines to cede review to the proposed Reviewing IRB, the SMART IRB POC for the institution communicates this determination to the proposed Reviewing IRB POC, Overall PI, and local Site Investigator. If the institution still plans to conduct the research, the institution will do so by maintaining local IRB oversight, ceding to a different Participating Institution IRB or ceding to an IRB that is not part of the SMART IRB Agreement. On the rare occasion that more than one Reviewing IRB becomes involved in overseeing a multi-site study[2], it is the Overall PI's responsibility to ensure coordination among the reviewing IRBs.

2 For example, it may be appropriate to identify more than one Reviewing IRB for a single study if a study involves both pediatric and adult populations and separate reviewing IRBs are established to oversee each population.

Adding New Relying Institutions – Post-IRB Approval

This section describes the process for adding a new Relying Institution for Research already reviewed and approved by a Reviewing IRB under the SMART IRB Agreement.

This process begins when the Overall PI/Lead Study Team provides the new proposed Relying Institution Site Investigator and SMART IRB POC with available study materials. The POC completes the following:

1. Reviews the materials provided by the Overall PI (or designee).
2. Renders a determination about ceding IRB review to the proposed Reviewing IRB.

If the potential new Relying Institution agrees to cede review to the Reviewing IRB, the Relying Institution SMART IRB POC provides the following information to the Reviewing IRB POC, Overall PI, and local Site Investigator:

1. The decision to cede review.
2. Any outstanding concerns or requirements that must be addressed before the Reviewing IRB approves the Research for that Relying Institution.
3. Any local considerations or other considerations related to the Research that the Reviewing IRB must consider.

The Overall PI (or designee) then completes and submits a protocol amendment to add the proposed new Relying Institution to the study in accordance with the SOP section on “Protocol Amendment Submission and Review Process.”

Coordination of IRB Review when a Single Central IRB is Not Identified

Under some circumstances, more than one Reviewing IRB may be established for a particular study. In these cases, it is the responsibility of the Overall PI to coordinate and communicate to each Reviewing IRB the necessary information related to the conduct of the study across all institutions throughout the life of the Research, not just information related to the sites overseen by each Reviewing IRB. Such information must be communicated in accordance with each Reviewing IRB's applicable policies and procedures.

Initial Review: Submission and Review Process

This section describes the IRB review process and responsibilities of the Reviewing IRB, Relying Institutions, Overall PI and Lead Study Team, Site Investigators and Relying Site Study Teams, and SMART IRB POCs.

Once the determination has been made regarding which institution will provide IRB oversight (i.e., act as the Reviewing IRB), as described in the "Identifying the Reviewing IRB" section above, the Lead Study Team submits an application for initial review to the designated Reviewing IRB following the processes and policies and using the forms established by the Reviewing IRB. The initial review application must contain sufficient information to allow the Reviewing IRB to identify a) all known institutions engaged in human subjects research that intend to cede review to the Reviewing IRB (Relying Institutions), b) the activities performed at each institution, and c) the Overall PI and Lead Study Team for the study.

The Reviewing IRB will review initial applications for new Research in accordance with the human subject protection requirements of each Relying Institution's FWA or other federal assurance, the federal regulations and ethical principles referenced therein, any other applicable federal human subjects research regulations or policies, and any local considerations communicated to the Reviewing IRB (e.g., state law). The processes and procedures for review will be in accord with the Reviewing IRB's own policies and procedures. As part of its responsibilities for conducting the initial review, the Reviewing IRB must:

- Take into consideration the local considerations and other considerations provided to it by the SMART IRB POCs from the Relying Institutions as part of their decision to cede review, including institution-specific information for any informed consent documents. This information will be provided to the Reviewing IRB as described in the section above on "Establishing the Relying Institutions."
- If agreed upon by both institutions, review and make any applicable determinations regarding requests for waivers or alterations of authorization under the HIPAA Privacy Rule, per the SOP section below titled 'HIPAA Privacy Rule'.

Unless an issue is discovered during the course of review that requires input from the Relying Institution, the Reviewing IRB generally will not provide any direct communication to the Relying Institution regarding the initial review of the application other than notifications about the Research review.

The Reviewing IRB will notify the Lead Study Team when it has approved the Research through its established processes. The Reviewing IRB may rely on the Lead Study Team to notify the Overall PI and Relying Site Study Teams of the IRB approval or notify the Relying Site Study Team directly.

If the Reviewing IRB disapproves the Research or disapproves a Relying Institution's participation in the Research, the Reviewing IRB POC will inform the Overall PI and Lead Study Team. The Lead Study Team is responsible for notifying relevant institutions of the IRB's determination to disapprove the study or the proposed Relying Institution's participation in the Research. If the Research is disapproved by a Reviewing IRB, and the Overall PI chooses to seek approval from a different IRB rather than substantively revise the protocol materials to address the concerns of the IRB that disapproved the study, the study cannot be subsequently submitted to another Participating Institution for review without disclosing the nature of the previous Reviewing IRB's disapproval.

Customization, Submission, and Review of Informed Consent Documents (ICD)

This section describes how consent documents will be handled and certain language from Relying Institutions incorporated into them.

When informed consent documents (ICDs) are required for a study reviewed under the SMART IRB Agreement, the ICD template(s) of the Reviewing IRB will be used by all Relying Institutions for that Research, except for key areas where regulatory or institutional areas have been identified as requiring site-specific changes to the ICD. If the Reviewing IRB uses a stamp to indicate approval of ICDs, the stamp of the Reviewing IRB will be used. However, Reviewing IRBs are not obligated to stamp approved ICDs, unless required by their own institutional policy or other regulatory requirement.

The Reviewing IRB will determine the content of ICDs except for sections for which Relying Institutions may provide their institution-specific language, as applicable. The institution-specific language in the ICD to be provided by Relying Institutions is generally limited to:

- Compensation for injury
- Availability of treatment for injury
- Payment or reimbursement of research costs incurred by subjects
- Local study team contact(s) for questions about the study
- Changes to address legal or regulatory issues, federal department or agency-specific requirements, or institutional requirements

HIPAA waiver and authorization language is addressed separately in the “Waivers and Alterations of Authorization” section of these SOPs.

Relying Institutions will customize these sections of the ICD by one of two mechanisms, as determined through coordination between the SMART IRB POC and Relying Site Study Team:

1. The Relying Institution POC requests the local Relying Site Study Team incorporate the information into the appropriate section(s) of the ICD(s). Once this has been finalized, the Relying Institution POC provides the local language to the Reviewing IRB POC for reference. The Relying Site Study Team is responsible for forwarding the ICD(s) to the Lead Study Team for submission to the Reviewing IRB through the Reviewing IRB’s established processes.

OR

2. The Relying Institution POC takes responsibility for incorporating the information into the local ICD(s). Once finalized, the Relying Institution POC forwards the ICD(s) to the Lead Study Team for communication to the Reviewing IRB in accordance with the Reviewing IRB’s established processes.

The Reviewing IRB will ensure a copy of the approved ICD(s) is sent to the Relying Institution POC, Overall PI, Lead Study Team, and Site Investigators. The Reviewing IRB may rely on the Lead Study Team to distribute the IRB-approved ICD(s). If a Relying Site Study Team or Relying Institution requires changes to its local language after the Reviewing IRB has approved the ICD(s) for that site, an amendment must be submitted to and approved by the Reviewing IRB before revised ICDs can be used at that institution.

Continuing Review: Submission and Review Process

This section describes the key components for continuing review and responsibilities of the Reviewing IRB, Relying Institutions, Lead Study Team, Relying Site Study Team, and SMART IRB POCs during this process.

The Lead Study Team will submit a continuing review progress report to the Reviewing IRB in accordance with the Reviewing IRB's policies and procedures (e.g., when the report is due and the mechanism through which it is submitted to the IRB). The Lead Study Team (or designee) is responsible for obtaining information from each Relying Site Study Team, regardless of whether the institution is under the purview of the Reviewing IRB, so that the Reviewing IRB can assess a comprehensive report regarding study progress, new information, and problems that have occurred. If a Relying Site Study Team does not provide the Lead Study Team with required information before the continuing review application is submitted to the Reviewing IRB, the Lead Study Team must report the absence of this information as part of the continuing review submission.

The Reviewing IRB is responsible for reviewing all relevant information for the Lead Study Team's and Relying Study Team's sites until the Research is closed. The Reviewing IRB will conduct continuing reviews in accordance with the human subject protection requirements of each Relying Institution's FWA or other federal assurance, the federal regulations and ethical principles referenced therein, any other applicable federal human subjects research regulations or policies, and any local requirements communicated to the Reviewing IRB (e.g., state law). The processes and procedures for review will be in accord with the Reviewing IRB's own policies and procedures.

Unless a Reportable Event is discovered in the course of the continuing review, the Reviewing IRB generally will not provide any direct communication to the Relying Institution regarding the review. The Reviewing IRB will notify the Lead Study Team when it has reapproved the Research through its established processes. The Reviewing IRB may rely on the Lead Study Team to notify Relying Site Study Teams of the IRB reapproval (or disapproval) of the Research or notify the Relying Site Study Team directly. If Research is disapproved by a Reviewing IRB at continuing review, and the Overall PI chooses to seek approval from a different IRB rather than substantively revise the study materials to address the concerns of the IRB that disapproved the Research, the Research cannot be subsequently submitted to another Participating Institution for review without disclosing the nature of the previous IRB's disapproval.

In the event a continuing review is submitted after IRB approval for the study expires or the study expires before the Reviewing IRB can reapprove the study, the Reviewing IRB will notify all participating site SMART IRB POCs, Overall PI, Lead Study Team, and Relying Site Investigators of the expiration of IRB approval. The Reviewing IRB will notify the Lead Study Team and applicable Relying Institution POCs of any applicable corrective action plans required.

Relying Site Study Teams may be required by their home institutions to provide study updates to local officials (e.g., local IRB offices) and are responsible for meeting these requirements.

Protocol Amendment: Submission and Review Process

This section describes the process for reviewing study amendments (i.e., changes to the study or supporting documents) and associated responsibilities of the Reviewing IRB, Relying Institution, Lead Study Team, Relying Site Study Team, and SMART IRB POCs during this process.

The Lead Study Team is responsible for submitting amendments (studywide or local amendments for Relying Sites) to the Reviewing IRB for review in accordance with the Reviewing IRB's policies and procedures (e.g., timing and mechanism of submission).

The Reviewing IRB will conduct reviews of changes in research in accordance with the human subject protection requirements of each Relying Institution's FWA(s) or other federal assurance(s), the federal regulations and ethical principles referenced therein, any other applicable federal human subjects research regulations or policies, and any local considerations communicated to the Reviewing IRB (e.g., state law). The processes and procedures for review will be in accord with the Reviewing IRB's own policies and procedures. A Relying Institution POC must authorize their Relying Site Study Team's submissions of the following types of changes to the Lead Study Team for consideration by the Reviewing IRB POC:

- Changes to a Site Investigator or other Relying Site Study Team personnel, in order to ensure these personnel meet the institutional requirements for the Relying Institution;
- Changes that appear to affect any state law or local considerations or other considerations a Relying Institution noted as part of its agreement to cede review; or
- Changes that indicate a newly identified COI.

Relying Site Study Teams will report changes in COI to their local Relying Institution in accordance with the local procedures and policies for COI reporting and management already established at each site. Relying Institution POCs will coordinate with local COI administrators and the local Relying Site Study Team in order to communicate this information to the Reviewing IRB. Reporting new or updated COI information, as well as personnel changes, to local SMART IRB POCs will occur in accord with the Relying Institution's processes.

The Reviewing IRB will notify the Lead Study Team when it has approved an amendment/change in research through its established processes. The Reviewing IRB may rely on the Lead Study Team to notify applicable Relying Institutions of the IRB approval. In advance, determine and document specific roles and responsibilities for communicating and coordinating key information to Relying Institutions and the Reviewing IRB. In the case of local amendments (e.g. local recruitment materials, site-specific changes to consent documents) that do not affect all Relying Institutions, only the sites affected by the approved amendment must be notified of the IRB approval.

Record Keeping and Document Retention

This section describes the process for maintaining and storing SMART IRB administrative records and the responsibilities of SMART IRB Administration, Reviewing IRBs, and Relying Institutions for the maintenance of these records, covering SMART IRB administrative records and study-specific IRB records related to reliance, but not the investigators' Research files.

SMART IRB Administrators, Reviewing IRBs, and Relying Institutions will maintain the following records in the locations specified in the table below:

SMART IRB Records

RECORD TYPE	RESPONSIBLE PARTY	STORAGE LOCATION
Current SMART IRB policies and procedures including: SOPs, forms, templates, etc.	SMART IRB Administrators	SMARTIRB.org
Current executed SMART IRB Reliance Agreements and Joinder Agreements, as well as any amendments	SMART IRB Administrators and Participating Institutions	SMARTIRB.org and at Participating Institutions
Study-specific reliance requests including: identification of Reviewing IRB(s) and Relying Institutions, and Study Team information	Participating Institutions	Local storage at Participating Institutions
Minutes from IRB meetings at which Research ceded under the SMART IRB Agreement was reviewed; portions of the minutes that are relevant to a Relying Institution available upon request to designated officials of the Relying Institution.	Reviewing IRB	Local storage; available to Relying Institution(s) upon request
Records of any applicable COI management plans provided by the Relying Institution and received by the Reviewing Institution	Reviewing IRB and Relying Institution	Local storage
Records of events reported by Relying Institution and received by the Reviewing Institutions	Reviewing IRB and Relying Institution	Local storage; available to Relying Institutions upon request
Study-specific review and approval notifications	Reviewing IRB and Relying Institutions	Reviewing IRB and Lead Study Team
Other general correspondence between the Relying Institution and the Reviewing IRB	Reviewing IRB and Relying Institution	Reviewing IRB and Lead Study Team; available to Relying Institutions upon request
Study-specific determinations related to ceding review to a Reviewing IRB (e.g., forms documenting decision to cede review; any outstanding concerns or requirements that must be addressed by the Reviewing IRB, and any institutional requirements related to the ceded study that the Reviewing IRB must take into consideration.)	Relying Institution and Reviewing Institution	Local storage

Document Retention

The records described in the table above will be retained by the respective responsible parties for a minimum of seven years after the closure or termination of the study by the Reviewing IRB. Participating Institutions, including Lead Study Teams and Relying Site Study Teams, are advised to refer to their local institutional policies, as they may require a longer period of retention.

Access to Locally Stored Records and Reliance-Related Documents

The SMART IRB Team and Participating Institution personnel, including POCs, Study Team members, and Reviewing IRBs will have access, where relevant and appropriate, to records listed in the table above for all studies for which they serve either as a Reviewing IRB or as a Relying Institution.

All other reasonable requests for access to records not listed above, or records stored locally, will be granted upon request by the applicable SMART IRB Team member, Reviewing IRB POC, or Relying Site POC, within a reasonable timeframe, and in accordance with the policies of the institution storing the records and applicable state and federal laws or regulations.

Supplemental Study Protocol Content

This section describes the additional content (beyond that which is typically included in a human research protocol) that should be provided to the Reviewing IRB. This additional information addresses coordinating the conduct of the research across multiple sites and establishing roles and responsibilities that supplement the high-level information already included in these SOPs.

Recommendations for information that should be collected at key points during the reliant review process are outlined below.

When requests to cede IRB review are made the following should be identified:

- The Overall PI and Lead Study Team, which retains overall responsibility for the Research.
- Any applicable Coordinating Center, which is responsible for coordinating activities at all other sites, receiving and analyzing data, and developing and updating the study protocol as needed. The Coordinating Center may be the same as the Lead Study Team.

The following should be collected about potential Relying Institutions:

- All Institutions that will be involved in the conduct of the Research
- Types of activities that will occur at each site (e.g., subject recruitment, laboratory analyses, and/or data analyses)
- Nature of the site(s) at which various research activities will occur (e.g., hospital, academic medical center, research clinic, medical office).
- If the study involves sample banking, identification of all institutions at which samples will be stored, what samples will be stored at which site(s).
- Description of any differences among performance sites in study procedures, subject remuneration, or subject populations.

On a study-by-study basis, the following additional information may need to be provided to the Reviewing IRB using forms/format specific to the Reviewing IRB:

- Description of how potential subjects are identified and the recruitment methods used at each recruiting site.
- Description of how informed consent is obtained at each site and who conducts the consent and/or assent process, including any special processes for subjects, such as those who may be non-English speaking, illiterate, have impaired decision-making capacity, or who may be children.
- Description of data storage, including all sites at which data will be stored, what data will be stored at what site(s), data security measures employed, who will have access to identifiable data at a site, when data will be anonymized or destroyed, or if data will be transferred to a central site for storage.
- If the Research involves sample banking, additional information regarding how sample confidentiality will be protected, who will have access to identifiable samples, will whether an honest broker system will be used (and if so, who the honest broker is), when samples will be anonymized or destroyed, and what types of analyses may be conducted on the banked samples.

In addition to the information above, Lead Study Teams (or designee, such as a Coordinating Center) will need to establish processes to address the following issues:

- How they will ensure all Relying Site Study Teams have the most current version of the protocol, consent documents, and other supporting materials.
- How they will ensure that all Relying Site Study Teams use the same version of the protocol, including a description of the procedures that must be followed in order to amend the protocol.
- How they will communicate with, collect information from, and disseminate information to other sites, regarding:
  - Local ICD requirements
  - Study updates (e.g., recruitment holds for interim analyses, closure to enrollment) or other changes to the study
  - Continuing reviews
  - Local changes of protocol (e.g., personnel updates, COI updates)
  - Reportable events
  - Study closure
  - The plan for collection and management of data from all sites

Federal Grant Congruency Review

The Lead Study Team is responsible for submitting any federal grant award or proposal that supports a proposed or approved study to the Reviewing IRB at the time of initial review or as an amendment (change of protocol) if the funds are awarded after initial IRB approval. If the federal grant is not held by a member of the Lead Study Team but by a Relying Site Study Team instead, the Relying Site Study Team must provide a copy of the federal grant to the Lead Study Team for submission to the Reviewing IRB. The Reviewing IRB is expected to review a copy of the entire proposal in order to understand the scope of a project.

The Participating Institution, rather than the Reviewing IRB, that holds the grant is responsible for providing documentation of congruency (when required) for certification to its local sponsored programs office per local policies and procedures. Relying Institutions retain responsibility for making relevant certifications to a Federal Department or Agency for awards their Institution receives.

HIPAA Privacy Rule

This section describes how determinations related to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) will be handled under the SMART IRB Agreement.

Under the SMART IRB Agreement Protected Health Information (PHI) will not be used or disclosed among collaborating institutions unless there is: (1) appropriate authorization to use and disclose such information for the purposes of research; (2) an appropriate waiver or alteration of such authorization has been granted by the Reviewing IRB in accordance with the HIPAA Privacy Rule, or; (3) the information constitutes a Limited Data Set and is shared pursuant to a Data Use Agreement as those terms are defined in HIPAA.

Waivers and Alterations of Authorization

Relying Institutions who are covered entities under HIPAA are responsible for making determinations regarding waivers or alterations of authorization under the HIPAA Privacy Rule for their institution, and will follow their institutional policies and procedures as well as federal regulations for the review and approval of waivers or alterations of authorization.

If agreed by both the Reviewing IRB and the Relying Institution, the Reviewing IRB may make determinations regarding waivers or alterations of authorization under the HIPAA Privacy Rule for Relying Institutions that are Covered Entities. When considering waivers or alterations of authorization, Reviewing IRBs will not approve waivers for the release of directly identifiable data outside the Covered Entity without consulting with Relying Institution POCs to determine whether the policies of the Relying Institutions would allow such a disclosure.

If the Reviewing IRB approves a waiver of authorization for use and disclosure of PHI, a Relying Institution may rely on the Reviewing IRB's determination to the extent that it comports with institutional requirements.

If the Relying Institution has a concern about a waiver, partial waiver, or alteration of authorization the Reviewing IRB has granted, then the Relying Institution should discuss alternative approaches with the Reviewing IRB. Until an alternative approach is agreed upon between the Reviewing IRB and the Relying Institution, the Relying Site Study Team cannot perform the activity covered by the waiver, partial waiver, or alteration of authorization.

If a research subject revokes permission to use his or her PHI, the affected investigator will determine whether the revocation occurred due to circumstances that require reporting to the Reviewing IRB in accordance with the Reviewing IRB's policies and procedures.

HIPAA Authorization Language

The language required under the HIPAA Privacy Rule to obtain authorization for the use and/or disclosure of PHI will be provided by the Relying Institution, and may be incorporated into the (ICD) or as a separate HIPAA authorization form. The Relying Institution will provide any relevant local considerations information that require a HIPAA authorization form or language to be separate from the consent document(s). If the Relying Institution does not provide a separate HIPAA authorization form or section to be incorporated into the ICD, the Reviewing IRB will provide the Relying Institution with the proposed HIPAA authorization form/section, ensure that certain elements of authorization are sufficiently broad to cover the Relying Institutions (e.g., the sources of the PHI, who may use the PHI, and to whom the covered entity may disclose the PHI), and consider any institution-specific requirements for HIPAA authorization language that a Relying Institution wishes to be incorporated into combined consent/authorization documents. A Relying Institution can delegate this responsibility for communicating Institution-specific HIPAA authorization language to the Relying Site Study Team or Relying Institution POC.

Potential Breaches of PHI

Participating Institutions are responsible for investigating and reporting to appropriate authorities, including Privacy Officers at affected institutions, breaches of PHI in accordance with institutional policies.

In the event that a potential privacy breach is discovered, Relying Site Study Teams must promptly notify their local Privacy Officer. The local Privacy Officer must then determine if a breach occurred. If it is determined that a breach occurred, the Relying Site POC (or designee) should ensure that the Lead Study Team and Reviewing IRB are notified of the breach, and should be involved in any subsequent investigation of the breach as well as any notifications individuals or offices required by local institutional policy (e.g., their local Institutional Official for the Protection of Human Subjects).

The Reviewing IRB may review the reported breach as a potential unanticipated problem in accordance with the Reviewing IRB’s policies and procedures for unanticipated problems.

Financial and Other Conflicts of Interest

This section describes key components of the process for communicating and evaluating financial conflicts of interest (henceforth COIs) for Research under the SMART IRB Agreement, and responsibilities of the Federal and non-federal Relying Institutions, Reviewing IRB, Lead Study Team, Relying Site Study Teams, and POCs.

Unless the Reviewing IRB and a non-federal relying institution agrees to an alternative approach, the non-federal Relying Institutions are responsible for review and management of any COIs related to Research ceded to an external Reviewing IRB under the SMART IRB Agreement. Non-federal Relying Institution POCs will take into consideration COIs and applicable management plans when determining whether Research will be ceded to the proposed Reviewing IRB or continue to be ceded to the Reviewing IRB (if the potential or new COI is identified after the study has been approved). If a study will be ceded to the proposed Reviewing IRB, the non-federal Relying Institution POC will coordinate with the appropriate COI administrator at their institution to ensure any COIs and applicable management plans are communicated to the Reviewing IRB. The non-federal Relying Institution POC may communicate this COI information directly to the POC for the Reviewing IRB or delegate this responsibility to the local Relying Site Study Team for submission to Lead Study Team, who will provide this information to the Reviewing IRB. If the non-federal Relying Institution's policies require IRB review of institutional COI, the Reviewing IRB will review such conflicts upon request.

Relying Site Study Teams must disclose any COI and applicable management plans to their SMART IRB POCs and the Lead Study Team at the time a reliance request is submitted and when the initial review application is submitted to the Reviewing IRB. Any new COIs identified for any Study Team member or updates to management plans must be reported to the Reviewing IRB. In these cases, non-federal Relying Site Study Teams provide information about new COIs or updated management plans to their local SMART IRB POC through the process established at their institution. The non-federal Relying Institution POC will coordinate with the appropriate COI administrator at their institution to determine whether any additional action is required by their institution regarding the new COI and/or updated management plan.

Relying Site Study Teams are also responsible for disclosing to the Lead Study Team any new COIs or updated management plans issued by the non-federal Relying Institution after the study is ceded. The Relying Site Study Teams must inform their SMART IRB POCs of these updates and obtain confirmation from their POCs that this new information does not affect the decision to cede IRB review and ensure no additional actions must be taken (e.g., potential removal of a study team member or restriction of some personnel's activities). The Lead Study Team is responsible for submitting information about new COIs or updated management plans to the Reviewing IRB in accordance with the Reviewing IRB's policies and procedures (e.g., timing and mechanism for submission).

If a Relying Institution is a Federal Institution, the Federal Institution provides assurances to the Reviewing IRB that it has completed conflict of interest analyses under existing relevant federal policies and that the participation of federal department or agency Personnel is permissible and consistent with federal law.

The Reviewing IRB is responsible for the consideration of any Federal Institution assurances or non-federal Relying Institution COIs and applicable management plan(s) for Study Teams participating in Research that has been ceded to them under the SMART IRB Agreement. The Reviewing IRB will ensure that any management plan is incorporated into its deliberations and that any mandated disclosures to subjects are included in the approved informed consent documents, as the Reviewing IRB deems applicable. The Reviewing IRB may not modify any management plan or mandated disclosure to subjects without discussion and acceptance by the Relying Institution, and retains the authority to impose additional prohibitions or conflict management requirements that are more stringent or restrictive than those included in the Relying Institution's management plan. In the extraordinary circumstance that the Reviewing IRB is unable to rely upon Federal Assurances or implement or approve a non-federal Relying Institution's prohibitions or management plans, the Reviewing IRB will so inform the Relying Institution and withdraw the Ceded Review with respect to that Relying Institution.

If a proposed Reviewing IRB knows of any institutional COI involving its institution, that IRB should decline to serve as the Reviewing IRB, following the procedures in "Establishing the Reviewing IRB".

Reportable Event Submission and Review Process

This section describes the key components of the process for review of reportable events after reliance decisions have been finalized and a study has been approved by the Reviewing IRB, as well as the responsibilities of the Reviewing IRB, Relying Institutions, Lead Study Team, Relying Site Study Teams, and POCs during this process.

All study teams under the purview of the Reviewing IRB will follow the Reviewing IRB's policies and procedures for reportable events (e.g., what requires reporting, reporting timeframes, and mechanism for reporting). The Reviewing IRB will conduct reviews of reportable events in accordance with the SMART IRB Agreement and SOPs as well as its own policies and procedures. Relying Site Study Teams may be required by their local institutions to provide additional reports to local officials (e.g., local IRB offices) and are responsible for meeting these requirements.

Noncompliance and Unanticipated Problems

Reports of potential or actual noncompliance and potential or actual unanticipated problems will be submitted to the Reviewing IRB by the Lead Study Team, unless otherwise delegated. These submissions will be reviewed by the Reviewing IRB in accordance with its own policies and procedures. Upon becoming aware of such a report, the Reviewing IRB will notify and work with any Relying Institution(s) involved in or affected by the report as follows:

- Reviewing IRB POCs will promptly inform any Relying Institution POCs not already aware of reports of noncompliance and unanticipated problems occurring at or involving that institution, even if the Reviewing IRB Institution's information gathering regarding the report is ongoing.
- As needed, the Reviewing IRB Institution may request assistance from Relying Institution POCs in gathering information about the reported event.
- The Reviewing IRB POC will notify the Relying Institution POC(s) and Site PIs from the affected Relying Institutions, as well as, in some circumstances, those from unaffected Relying Institutions, of the Reviewing IRB's determination regarding the reportable event.
- In the event that reporting to a regulatory agency(ies), sponsor, funding agency(ies), and/or other oversight authority(ies) is required under federal regulations or under the terms of a Relying Institution's FWA or other federal assurance, the Reviewing Institution will provide the Relying Institutions with opportunity to review and provide input on such reports (no fewer than 5 business days) before they are sent to the applicable entity(ies).
- If the Reviewing Institution agreed to cede the obligation to report to federal authorities to the Relying Institution, the Relying Institution will provide the Reviewing Institution with the opportunity to review and comment on the report (no fewer than 5 business days) before it is sent to the applicable entity(ies). The Reviewing Institution will promptly provide any comments on the report to the Relying Institution.

Relying Institutions remain responsible for ensuring that any additional actions regarding the reportable event are taken as required by that Institution's policies and procedures.

Serious Adverse Events, Deviations, Subject Complaints, and Other Types of Reportable Events

Reports of serious adverse events, deviations, significant subject complaints and other events specifically requiring reporting to the Reviewing IRB in accordance with Reviewing IRB policies and procedures will be submitted to and reviewed by the Reviewing IRB. If such a report is found to constitute serious or continuing noncompliance or an unanticipated problem, the Reviewing IRB will notify and work with any Relying Institutions involved in or affected by the report as described in the section above on “Noncompliance and Unanticipated Problems.”

Suspensions and Terminations of Reviewing IRB Approval

The Reviewing IRB will suspend or terminate the approval of studies in accordance its own policies and procedures. If the Research as a whole is suspended or terminated, the Reviewing IRB POC will promptly notify in writing all Relying Institution POC(s), Overall PI, Lead Study Team, and Site Investigator(s) of the suspension or termination. If a Relying Institution(s) is suspended or terminated, the Reviewing IRB POC will promptly notify the Relying Institution POC(s), Overall PI, Lead Study Team, and Site Investigator(s) from affected Relying Institution(s) (and in some circumstances other sites) in writing of the decision to suspend or terminate the site(s). In the event of a suspension, the Reviewing IRB will determine whether it can continue to accept IRB oversight for the Relying Institution(s) or determine that it will end its oversight or participation in the specific Research.

Research Misconduct

Both the Reviewing Institution and Relying Institutions are responsible for notifying each other regarding potential research misconduct.

Any individual at a Reviewing or Relying Institution who becomes aware of a potential instance of research misconduct must notify their local Research Integrity Officer (RIO) in accordance with local policies and procedures for handling cases of potential research misconduct. When the research involves a study ceded under SMART IRB, the local RIO will notify and confer with the RIOs at other affected institutions, including the Reviewing IRB’s institution.

If a Reviewing IRB discovers or receives information regarding potential or actual research misconduct, the Reviewing IRB will handle the report as a potential unanticipated problem with further notifications to Relying Institutions as outlined under that section of these SOPs.

Other Reporting Requirements

This section describes other events that may occur that require reporting to the Reviewing IRB Institution and/or Relying Institutions.

CHANGES IN FEDERAL ASSURANCE, IRB REGISTRATION, OR ACCREDITATION STATUS

Reviewing IRB Institution and Relying Institutions are responsible for notifications regarding changes to FWA or accreditation status (also described in the Responsibilities section of this SOP):

- A Reviewing IRB Institution will promptly notify in writing all Participating Institutions and SMART IRB Administration:
  - If its Federal Assurance is suspended or restricted, lapses, or changes in scope.
  - Of any loss or change in its accreditation status.
  - Of any expiration of or change to its IRB registration status.
- Relying Sites will promptly notify:
  - All Participating Institutions and SMART IRB Administration if their FWA is suspended or restricted or if its Federal Assurance lapses or changes in scope.
  - SMART IRB Administration of any loss or change in its accreditation status.

Reviewing IRB Institutions and Relying Institutions are responsible for designating a point person for these types of communications, which may be the SMART IRB POC.

FEDERAL AUDITS AND LEGAL ACTIONS

The Reviewing IRB and Relying Institutions are responsible for notifying each other regarding audit findings related to studies ceded under the SMART IRB Agreement that represent reportable information per the Reviewing IRB's policies and procedures (e.g., unanticipated problems, serious or continuing noncompliance, or other reportable information) as well as legal actions related to any studies for which the Reviewing IRB provides IRB oversight. Participating Institutions will assist as appropriate in investigating and responding to such issues. The Reviewing Institutions and Relying Institutions are responsible for designating a point person for these types of communications, which may be the SMART IRB POC.

Suspension or Restriction of Relying Site Investigator or Relying Site Study Team Member

Relying Institution POCs are responsible for promptly notifying the Reviewing IRB of any suspension or restriction of Site PI or Relying Site Study Team member status to conduct research at the institution.

Withdrawal from Ceded Review

If a Relying Institution determines that it must withdraw the Research from Ceded Review, it will notify the Reviewing IRB of this determination. Participating Institutions are responsible for designating a point person for these types of communications, which may be the SMART IRB POC.

When a change in acceptance of reliance occurs, the Reviewing IRB and Relying Institution(s) will work together to facilitate the transfer of IRB oversight with the goal of limiting the potential disruption to the Research and continuing human subjects protections. Until oversight is transferred, the Reviewing IRB will continue to assume oversight responsibility.

If a Reviewing IRB determines based on significant cause as described in the SMART IRB Agreement that it must withdraw from providing review and oversight of the Research for a Relying Institution, the Reviewing IRB will provide sixty (60) business days' prior written notice to the Relying Institution explaining the significant cause for the Reviewing IRB's withdrawal.

Standard Operating Procedure (SOP) Development, Adoption, Modification, and Maintenance

This section describes the process to create and update SMART IRB SOPs and associated materials.

The Executive Committee (or designee) is responsible for determining whether new SOPs must be created or whether revisions to existing SOPs are necessary. Once a determination has been made that SMART IRB SOPs or associated materials (templates, forms, etc.) must be developed or revised, the Executive Committee (or designee) will designate an individual or group to draft or revise those document(s).

During the drafting process, the individual(s) drafting the new/revised SOPs and associated materials will seek input from the individuals or committees identified by the Executive Committee (or designee). Materials will be revised based on the review and feedback from these individuals/committees.

New or revised SOPs will be approved for finalization by the Executive Committee (or designee).

Once the necessary feedback and revisions have been incorporated into the draft SOPs and/or associated materials, SMART IRB Administrative personnel will finalize the documents by:

- Updating the “version date,” “approved by,” and “approval date” sections of the SMART IRB SOPs.
- Posting the updated SOP Manual and associated materials on the SMARTIRB.org website.
- Archiving the previous version of the materials.
- Notifying all affected Participating Institutions in writing of any material changes.

Purpose of the form: This form should be used to document key communication roles/responsibilities for specific studies. Reviewing IRB/HRPPs may use this form to document general expectations of study teams and relying site IRB/HRPPs, or less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team. The SMART IRB recommends this form be kept up to date with all key information throughout the life of a study.

Communication Plan Template

Definitions:

+ **REVIEWING IRB – Point of Contact (POC):** Main person responsible for addressing questions related to the Reviewing IRB's policies and procedures and review status for a ceded study
+ **LEAD STUDY TEAM – Representative:** Main person responsible for communication with the Reviewing IRB and facilitating communication between relying site study teams and the Reviewing IRB regarding the ceded study
+ **RELYING SITE – POC:** Main person responsible for communication with the Reviewing IRB and local study team regarding the ceded study (e.g., personnel in the local IRB office or local human research protection program personnel)
+ **RELYING SITE STUDY TEAM – Representative:** Main person responsible for communication with the Lead Study Team regarding the ceded study

ROLE	NAME, TITLE, INSTITUTION	CONTACT INFORMATION
Reviewing IRB POC		
Lead Study Team Representative		
Relying Site POC		
Relying Site Study Team Representative		
Study Name		
Overall PI (Lead PI)		
Site Investigator (Local PI)		

Purpose of the form: This form should be used to document key communication roles/responsibilities for specific studies. Reviewing IRB/HRPPs may use this form to document general expectations of study teams and relying site IRB/HRPPs, or less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team. The SMART IRB recommends this form be kept up to date with all key information throughout the life of a study.

AREA OF COMMUNICATION RESPONSIBILITY	RESPONSIBLE PARTY (*TYPICAL PARTY IDENTIFIED)	NOTES
Conflict of Interest: Providing applicable Relying Site Conflict of Interest management plans to the Reviewing IRB	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Study Team Training & Qualifications: Providing confirmation to the Reviewing IRB that relying site study teams have completed relevant training and are qualified to conduct the proposed research	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Local Considerations: Collecting local information related to Relying Institution's local and state laws; federalwide assurance applicability (e.g. "checking the box"); institutional requirements; unique cultural, language, geography, or socioeconomic factors; or standard of care	☐ Relying Site Study Team* ☐ Relying Site POC* ☐ Lead Study Team ☐ Other, specify:	
Local Considerations: Providing completed local context information to the Reviewing IRB throughout the study	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
IRB Application – Studywide: Preparing and submitting the initial studywide application and studywide amendments to the Reviewing IRB	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
IRB Application – Site-Specific: Preparing and submitting the site-specific applications to the Reviewing IRB	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	

Purpose of the form: This form should be used to document key communication roles/responsibilities for specific studies. Reviewing IRB/HRPPs may use this form to document general expectations of study teams and relying site IRB/HRPPs, or less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team. The SMART IRB recommends this form be kept up to date with all key information throughout the life of a study.

AREA OF COMMUNICATION RESPONSIBILITY	RESPONSIBLE PARTY (*TYPICAL PARTY IDENTIFIED)	NOTES
IRB Determinations: Providing documentation of IRB determinations to relying site study teams	☐ Reviewing IRB POC ☐ Lead Study Team* ☐ Relying Site POC ☐ Other, specify:	
IRB-Approved Documents: Providing copies of IRB-approved materials to the lead study team	☐ Reviewing IRB POC* ☐ Relying Site POC ☐ Relying Site Study Team ☐ Other, specify:	
IRB-Approved Documents – Relying Sites: Providing copies of the most current versions of IRB-approved materials to relying site study teams	☐ Reviewing IRB POC ☐ Lead Study Team* ☐ Relying Site POC ☐ Other, specify:	
Consent Form Template: Providing the consent form template to relying site study teams	☐ Reviewing IRB POC ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Consent Form Language: Incorporating site-specific language into consent form(s) and providing these consent form(s) to the Reviewing IRB	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Reviewing IRB Policies (Lead Study Team): Providing relevant Reviewing IRB policies to the Lead Study Team	☐ Reviewing IRB POC* ☐ Relying Site POC ☐ Relying Site Study Team ☐ Other, specify:	

Purpose of the form: This form should be used to document key communication roles/responsibilities for specific studies. Reviewing IRB/HRPPs may use this form to document general expectations of study teams and relying site IRB/HRPPs, or less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team. The SMART IRB recommends this form be kept up to date with all key information throughout the life of a study.

AREA OF COMMUNICATION RESPONSIBILITY	RESPONSIBLE PARTY (*TYPICAL PARTY IDENTIFIED)	NOTES
Reviewing IRB Policies (Relying Sites): Providing relevant Reviewing IRB policies to Relying Site study teams	☐ Reviewing IRB POC ☐ Lead Study Team* ☐ Relying Site POC ☐ Other, specify:	
Continuing Review Information: Obtaining and collating studywide information for continuing review to the Reviewing IRB	☐ Relying Site Study Team* ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Continuing Review Submission: Submitting continuing review progress report to the Reviewing IRB	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Reportable Events: Providing reportable events to the Reviewing IRB (e.g., unanticipated problems, noncompliance, significant subject complaints)	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	
Closure Reports: Providing the Reviewing IRB with required information when all research activities are completed at a Relying Site	☐ Relying Site Study Team ☐ Relying Site POC ☐ Lead Study Team* ☐ Other, specify:	