Institutional Review Board

Investigator Handbook

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CHAPTER 1: INSTITUTIONAL REVIEW BOARD

WHAT IS THE HUMAN RESEARCH PROTECTION PROGRAM (HRPP)?

The University of Maryland College Park (UMD) HRPP is a collaborative effort between all who develop, conduct, review, approve and facilitate human research. It includes institutional leaders, the Institutional Review Board (IRB), the Office of Research Administration (ORA), the Office of General Counsel, the UMD Disclosure Office, researchers, faculty, staff, students and the community. The HRPP aims to protect the rights and welfare of research volunteers, by providing support, guidance, and education to facilitate research that is ethical and scientifically sound.

AAHRPP Accreditation:

The UMD HRPP is one of approximately 250 national and international organizations earning full accreditation status from the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). AAHRPP is a non-profit accrediting body that promotes ethical research through processes that help organizations to evaluate and strengthen their human research protection programs.

AAHRPP enhances research quality and protection by accrediting organizations using educational, peer-review processes conducted by independent experts. Accreditation standards are based on regulations and HRPP best practices. To earn accreditation, organizations must demonstrate (e.g., through policies, procedures, and practices) their commitment to ethical scientific and scholarly research and to continuous quality improvement.

UMD's HRPP was first awarded Full Accreditation by AAHRPP in December 2018.

WHAT IS THE IRB?

The UMD Institutional Review Board (IRB) is a committee that performs ethical review of proposed research to help assure the protection of the rights and welfare of human participants. The composition of the IRB consists of faculty, students, staff, and outside members.

The IRB approves the initiation of, and conducts periodic reviews of, research involving human participants. The UMD IRB has the authority to conduct the following:

- Approve, require modifications to secure approval, and disapprove all human research overseen and conducted by the organization. Officials of this organization may not approve human research that has not been approved by the IRB.

- Suspend or terminate approval of human research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

- Observe, or have a third party observe, the consent process and the conduct of the human research.

- Determine whether data may be used that was not collected in accordance with the IRB's requirements.

- Evaluate conflicts of interest of investigators and research staff and have the final authority to decide whether the conflict of interest and management plan, if any, allow the human research to be approved.

The IRB may work in conjunction with other university or institutional committees; however, it reviews research projects independently based upon the principle that human participants will be adequately protected.

Federalwide Assurance:

The UMD IRB operates under a Federalwide Assurance (FWA), which is a federal wide assurance program. This is an agreement between the UMD IRB and the Department of Health and Human Services (DHHS), which outlines the responsibilities of the UMD IRB for upholding the ethical principles regarding research involving human participants. These principles are outlined in the report of the National Commission for the Protection of Human Participants in Biomedical and Behavioral Research titled, Ethical Principles and Guidelines for the Protection of Human Participants of Research, known as the Belmont Report.

The IRB will agree to serve as the institutional review board of record for other institutions only if a member or appointee of UMD is involved as a Principal or Co-Investigator. [Please refer to Chapter 4 for more information on collaborative research studies.]

WHEN IS IRB REVIEW REQUIRED?

IRB review and approval is required for any project that meets the definition of human subject research [Chapter 2].

Examples of human subject research activities may include:

- Surveys
- Interviews
- Behavioral investigations
- Prospective or retrospective reviews

- Experiments with physiological fluids and tissue
- Demonstration or service programs

If a researcher is not sure whether their project meets the definition, the IRB recommends that they submit a Human Subject Research Determination Application. [Please refer to Chapter 2 for more information on research that does not meet the definition of human subjects research.]

IRB Submission Requirements:

Researchers are required to submit an initial IRB application through the UMD IRB electronic submission system. Step by step instructions on how to submit an initial application are located on the UMD IRB's website.

For additional assistance when submitting an IRB application, researchers can contact the IRB office at 301-405-4212 or irb@umd.edu.

No human subject research may be initiated prior to IRB approval.

CHAPTER 2: HUMAN SUBJECT RESEARCH

WHAT IS RESEARCH?

According to the United States Code of Federal Regulations (at 45 CFR 46.102(l)) research is defined as a systematic investigation, including research development, testing, and evaluation, that is designed to develop or contribute to generalizable knowledge.

A **systematic investigation** is the use of a methodological approach to an activity. This usually involves a hypothesis, a research question, and a plan to systematically collect and analyze data. Note that the absence of a hypothesis does not automatically mean an activity is not a systematic investigation.

Research develops or contributes to **generalizable knowledge** when it is designed with the intent of sharing the findings with others (e.g. via publication or presentation).

WHAT IS A HUMAN SUBJECT?

A human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains information **OR** biospecimens through intervention or interaction with the individual.

An **intervention** can include both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) as well as manipulations of the subject or the subject's environment that are performed for research purposes.

An **interaction** includes communication or interpersonal contact between the investigator and subject. The interaction may take place verbally, in writing, or electronically.

WHAT IS IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMENS?

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, as well as information that has been provided for specific purposes by an individual that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable biospecimens is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

CLASSIFICATIONS OF HUMAN SUBJECT RESEARCH:

Social Science, Behavioral and Education Research (SBER):

SBER includes all research performed with the 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)

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.

Research Involving Secondary Use of Data:

Projects that use data from human participants gathered in earlier projects require IRB review. If the data are gathered by someone who has legitimate access to the records and who gives the investigator only "blinded" or de-identified data (so that the investigator is unable to identify the participants), the project may qualify as exempt.

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.

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.

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 community settings (such as churches, historical sites, community centers, etc.)

Research in Foreign Countries:

Research conducted by UMD investigators in foreign countries remains under University purview and guidelines. While the University cannot impose its standards for written documentation of consent on other cultures, it does not relax its standards for ethical conduct or consent process.

The Office for Human Research Protections (OHRP), which provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (DHHS), can determine whether procedures described by a foreign institution afford protections that are at least equivalent to U.S. regulations [45CFR46.101(h)]. Under this provision, OHRP investigates the foreign country's guidelines for human participant research, and if the foreign guidelines are found to be equivalent to U.S. regulations, the investigator is permitted to substitute those foreign procedures. Researchers proposing international research should allow additional time for this review process.

WHAT IS NOT HUMAN SUBJECT RESEARCH?

There are specific types of activities that are deemed **NOT** to be human subject research:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship) that focus on information specifically about certain individuals.

2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.

3. 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.

4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

5. Quality improvement projects which include the collection and analysis of information intended to improve an existing process or program when there is no intent to contribute to generalizable knowledge.

6. Student projects that include the collection and analysis of information intended to complete coursework for a grade or presented within the academic confines of the institution but do not intend to contribute to generalizable knowledge. The student's instructor (or advisor) is responsible for providing appropriate oversight of the student project and should consult with the UMD HRPP as needed.

Examples of projects that MAY not be considered research:

Oral history projects where investigators intend to use the findings only to document or report on events or situations without the intent to form hypotheses, draw conclusions, or generalize findings outside the sample. These projects are not considered human subjects research and thus would not require IRB approval.

However, oral history projects that intend to develop generalized knowledge (e.g. using findings to describe human beliefs or behaviors in a specific cultural setting or draw conclusions to influence public policy or decisions) do require IRB approval. If they are human subject research, oral history projects generally are exempt. [For more information on exempt research, please refer to Chapter 3.]

Quality assurance/quality improvement projects where data are collected systematically but without the intention of sharing the information with others (contribute to generalizable knowledge).

However, if investigators intend to publish the results of a quality assurance/improvement project prior to the initiation of data collection, then the project should be submitted to the IRB via an Initial Application.

If a researcher is not sure whether their project meets the definition, the IRB recommends that they submit a Human Subject Research Determination Application.

Human Subject Research Determination:

Any activity that might meet the definition of human subject research should be submitted to the IRB for determination.

The Human Subject Research Determination (HSRD) is used by faculty, staff and students when they are unsure if their activity requires IRB review. The HSRD application isolates elements of the project that help the IRB Office make a quick and accurate determination as to whether the project constitutes human subject research.

All research activities, including those deemed not to be human subject research, must be carried out in an ethical and respectful fashion in compliance with the principles of the Belmont Report, all state and local laws, and institutional policies.

CHAPTER 3: IRB REVIEW PATHS

There are three IRB review paths for research involving human subjects:

1. Exempt
2. Expedited
3. Full Board Review

When a project is submitted to the IRB, the IRB Office (in consultation with the IRB Chair) will ensure that the project is reviewed by the appropriate review path under the appropriate review categories.

EXEMPT REVIEW:

To receive an exempt determination from the IRB, a project must fall into one or more of the eight (8) federally-defined exempt categories. The UMD IRB requires all human subject research meeting, or appearing to meet, one of the exempt review criteria to be submitted through their electronic system for review and determination. No investigator or department on campus shall have the authority to make this decision other than the IRB.

All research, including that in the exempt categories, must meet at a minimum the principles outlined in the Belmont Report. The IRB Office may require additional protections to meet these principles, including a level of informed consent appropriate to the research or review by an IRB Member.

The IRB shall be made aware of any changes in the study scope or design prior to implementation of the changes to ensure that the study continues to meet the exempt criteria. Any changes to the previously approved project should be submitted to the IRB via an amendment. [Please refer to Chapter 8 for more information on Amendments.]

No research involving, or potentially involving, prisoners as participants may be classified under exempt categories.

Some examples of exempt research include:

- Anonymous surveys or interviews,
- Passive observation of public behavior without the collection of identifiable information,
- Retrospective chart, record, or data reviews, and
- Analysis of discarded pathological specimens without identifiers.

EXPEDITED REVIEW:

To qualify for an expedited review, the research should fall into one or more of the nine (9) federally-defined expedited categories and present no greater than minimal risk to participants.

Expedited research typically does not necessitate review by the convened IRB. These types of projects may be approved by an IRB Member and reported to the convened IRB at its next meeting.

An expedited review consists of a review of research involving human subjects by an IRB Member. In reviewing the research, the reviewer may exercise all of the authorities of the full Committee except that the reviewer may not disapprove the research. Additionally, the reviewer may refer the application to the full Committee for a standard review as warranted.

In order to qualify for an expedited review, the research must meet the following qualifications:

1. The research must present no more than minimal risk to human subjects. **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2. The research may not involve the identification of the participants and/or responses which would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

The expedited review procedure may not be used for classified research involving human subjects.

Expedited Review Process:

Prior to granting approval, an IRB Chair or IRB Member reviewer will confirm that the materials included in the IRB application provide sufficient detail to determine that the study meets the criteria for approval. The IRB Chair or IRB Member will determine the expedited category into which the project fits and document the category on the reviewer checklist. If the study as designed does not meet any of the expedited categories, the IRB Chair or IRB Member will refer the study to the convened IRB for review.

FULL BOARD REVIEW:

Projects which do not meet either exempt or expedited review criteria will be added to the next available agenda for review at the fully convened IRB meeting. Research activities presenting greater than minimal risk or transactions increasing the potential risk, will

always be referred to the full convened IRB meeting for review. However, the IRB reserves the right to take any transaction to the full committee.

All committee members will have access to the IRB application forms, project summary, and informed consent documents. The primary reviewers will present the project and issues to the convened IRB for discussion before a vote for approval can be cast.

A quorum (51% of the specific committee's voting membership including the chair) of members, including at least one non-scientific member, must be present for voting purposes on each review. After the vote, the investigator will be notified in writing regarding the status of the application.

IRB Meeting Schedule and Submission Deadlines:

The convened IRB typically meets on the second Thursday of each month on the UMD campus or via online teleconference. The deadline for submission of projects for IRB review is two weeks prior to the scheduled meeting. Submissions that are not received by the IRB office prior to the two-week deadline will be held for consideration at the next month's meeting. Deadline adjustments can be made at the discretion of the IRB chair. In addition, official UMD holidays may sometimes require an adjustment to the meeting dates.

Risk Category and Frequency of Continuing Review:

All non-exempt initial applications are assigned categories of risk and frequency of continuing review. To approve the research, the IRB must determine the degree of risk.

DEFINITION OF RISK FOR ADULT PARTICIPANTS	
Minimal Risk:	**Greater than Minimal Risk:**
Activity where the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests.	The probability and magnitude of harm or discomfort anticipated in the research IS greater in and of themselves than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests.

DEFINITION OF RISK FOR MINOR PARTICIPANTS			
Minimal Risk:	**Greater than Minimal Risk – Direct Benefit:**	**Greater than Minimal Risk – No Direct Benefit:**	**Greater than Minimal Risk:**
Activity where the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than those	Greater than minimal risk but presenting the prospect of direct benefit to individual participants.	Greater than minimal risk and no prospect of direct benefit to individual participants but likely to yield important generalizable	Otherwise not approvable but presents an opportunity to understand serious health or welfare problems of children.

ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests.		knowledge about the participant's disorder or condition.	

New projects not eligible for expedited review will be reviewed by at least two IRB members chosen based on expertise with the subject matter of the study. These individuals will be responsible for presenting the project to the convened IRB for discussion.

The IRB must deliberate on all projects deemed greater than minimal risk for the purpose of assigning the frequency of continuing review. Greater than minimal risk projects reviewed by the convened IRB will be reviewed at intervals appropriate to the degree of risk, but not less than once per year. The IRB may decide to review greater than minimal risk studies more frequently than every twelve months.

Full Board Review Results:

The IRB will provide investigators with a written determination indicating that the IRB has approved the human research, requires modifications to secure approval, has tabled, or disapproved the human research.

If the IRB disapproves a study, it will notify the investigator of the reasons for the disapproval and allow the investigator an opportunity to respond. The investigator may submit a new application for the IRB to review, but no other authority may approve a study if the IRB disapproves it.

Convened IRB Review Actions:	
Approved	The project and its study tools, including the informed consent documents, are approved as submitted. Once the Investigator receives the IRB approval letter, the study may begin.
Approved with Conditions	The project requires specific revisions, which the IRB can list as part of the motion. The PI will be provided with comments explaining rationale for the decision and given an opportunity to respond. The revisions may be reviewed outside of a convened IRB meeting by the IRB Chair or any other individual designated by the IRB.
Tabled	The project has serious deficiencies in the materials submitted to the IRB. These must be addressed and re-reviewed by the convened IRB before the IRB can grant approval. The PI will be provided with comments explaining rationale for the decision and given an opportunity to respond. The response will be reviewed by the convened IRB. PIs should be aware that the IRB upon receiving the responses to a tabled motion may have additional requested revisions.
Disapproved	The project has serious deficiencies in submitted project affecting the safety and welfare of the projected participant population. These must be addressed in a new project and be reviewed by the convened IRB before the IRB can grant approval. The PI will be provided with comments explaining rationale for the decision and given an opportunity to respond. The response will be reviewed by the convened IRB.

Notification to Investigators Following Review:

The IRB Office notifies each investigator in writing regarding the Committee's review of their project. The notification is issued within 7 business days and outlines the IRB actions which must be addressed by the principal investigator. Upon receipt of that notification the principal investigator, or their designee, should make the required corrections, modifications, or resubmission of the project through the IRB's electronic submission system.

Notification of Institutional Officials:

The minutes of the IRB meetings reflect a summarized discussion of project issues and documentation of the vote on each IRB action. Upon request, a copy of the IRB minutes will be sent to the Vice President for Research.

CHAPTER 4: RESEARCH TEAM

Any research project that is conducted by or under the direction of an employee or agent of UMD, in connection with his or her institutional responsibilities, requires IRB approval.

PRINCIPAL INVESTIGATOR:

The UMD IRB defines the principal investigator (PI) as the individual overseeing, or leading, the research effort. PIs are responsible for protecting the rights and welfare of human subjects involved in their research and PIs are responsible for carrying out ethical research that is consistent with research plans approved by the IRB.

Because PI responsibilities involve direct interaction and supervision of the research team, the PI must be a current employee or student at the University who is operating within their University role to oversee the conduct of the study. PIs leaving the institution are responsible for notifying the IRB well in advance of their departure so that they can make arrangements to either close the study or name another appropriately qualified individual currently at the institution to serve as the PI.

Responsibilities of Principal Investigators:

As a general condition for the approval of a research study, the IRB holds the PI of the study responsible for ensuring that:

- Risks to research subjects are minimized by using procedures which are consistent with sound research design, and which do not unnecessarily expose the subjects to risk; and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

- Risks to human research subjects are reasonable in relation to the anticipated benefits (if any) to the individual, and the importance of the knowledge that may be expected to result.

- Selection of human subjects and/or patients for research participation is equitable.

- Individuals are adequately informed of the risks and benefits of research participation and the procedures that will be involved in the research, and that informed consent will be obtained from each prospective human research subject, or his/her legally authorized representative, in accordance with, and to the extent required, by University policies and federal regulations.

- Informed consent of human research subjects will be obtained in advance of research participation and appropriately documented in accordance with, and to the extent required, by University policies and federal regulations.

- Where appropriate, there is routine monitoring of the data collected to ensure the safety of human research subjects.

- The privacy of human research subjects is protected and the confidentiality of data is maintained.

- Appropriate additional safeguards are included in the study to protect the rights and welfare of human research subjects who are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons).

CO-INVESTIGATORS AND RESEARCH STAFF:

A co-investigator (Co-I) is defined as any individual engaged in human subject research.

Individuals are engaged in human subject research if:

1. The individuals will obtain or analyze data about the subjects of the research through intervention or interaction with them; or

2. The individuals will obtain or analyze identifiable private information about the subjects of the research; or

3. The individuals will obtain the informed consent of human subjects for the research.

Appropriately qualified co-investigators and research staff may perform tasks as delegated by the Principal Investigator, but they do not accept primary responsibility for the research study.

Responsibilities of Co-Investigators and Research Staff:

Responsibilities of co-investigators and research staff include:

- Completing required institutional and project specific training.

- Adhering to the federal regulations, state and local laws, institutional policies and procedures surrounding the safety and protection of human participants.

- Assuring participant privacy and confidentiality according to institutional regulations and IRB policies and procedures.

STUDENT RESEARCHERS:

Students may be listed as the principal investigator for independent class projects, senior theses, undergraduate research projects, master's and doctoral projects, partial fulfillment of fellowship requirements, and similar exercises utilizing human research.

During the design of a project, advisors and faculty members should instruct students on the ethical conduct of research and help them prepare applications for IRB approval.

Students should do the following:

- Include their faculty advisor on any IRB application they plan to submit.
- Understand the elements of informed consent.
- Develop a readable consent form written in the second person and at a level equivalent to an eighth-grade education.
- Plan appropriate recruitment strategies for identifying participants.
- Establish and maintain strict guidelines for protecting privacy and confidentiality.
- Allow sufficient time for IRB review and completion of the project during the student's matriculation.
- Complete CITI Training in either Biomedical Research or Social and Behavioral Research for Investigators.

FACULTY ADVISOR:

Advisors shoulder the responsibility for students engaged in independent research, and instructors are responsible for research that is conducted as part of a course.

After IRB approval, faculty members should take an active role in ensuring that projects are conducted in accordance with the IRB's requirements. One way to meet this responsibility is to meet periodically with students to review their progress and to assist in submitting any required amendments or continuing reviews.

RESEARCH CONDUCTED BY AFFILIATED FACULTY:

Research conducted by "affiliated faculty" – faculty members who hold clinical or adjunct appointments – conducting research as part of their role at UMD is covered by the University's guidelines for research on human participants and must be submitted for IRB review.

RESEARCH CONDUCTED AT OTHER ORGANIZATIONS:

If a UMD researcher wishes to conduct research at another site, it is the researcher's responsibility to contact the organization, or site, to obtain approval to carry out the research at the intended location.

Letters of Organizational Support:

If collaborating with an outside entity such as a nursing home, school, community center, or other organization to conduct the research, specifically if data collection will be done in-person at that location, researchers must provide documentation of support from the organization indicating that the organization is aware of and supports the research activities.

Letters of support should be provided on institutional letterhead, if possible.

Documentation of support can be provided via email. However, the documentation must originate from an official organization email address and include the approving individual's title within the organization. Personal email correspondence will not be accepted.

COLLABORATIVE RESEARCH STUDIES:

When UMD researchers are collaborating with researchers at another institution, UMD researchers should contact the IRB Office to determine whether a Reliance Agreement is required.

Reliance Agreement:

A Reliance Agreement is a formal, written document that provides a mechanism for an institution engaged in research to delegate institutional review board (IRB) review to an independent IRB or an IRB of another institution. Institutions that are engaged in human subject research, where one institution will rely on the other institution's IRB, must agree to the terms of the Reliance Agreement before research can begin.

SMART IRB:

The UMD IRB has adopted the Standard Operating Procedures of the SMART IRB initiative.

The “SMART IRB” master reliance agreement was created in 2016 to harmonize and streamline the IRB review process for multisite studies. It enables reliance on a study-by-study basis, clearly defines roles and responsibilities of relying institutions and reviewing IRBs, and eliminates the need to sign reliance agreements for each study [e.g., a non-SMART IRB agreement]. 500+ institutions have already signed onto this agreement and are actively using it as the basis of reliance for multisite projects.

SMART IRB Reliance Agreements will be utilized when engaging with institutions who also follow SMART IRB.

National Institutes of Health (NIH) Policy:

Effective January 25, 2018, the NIH requires use of a Single IRB [sIRB] for the review of NIH-funded multisite studies where each site will conduct the same project involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. This Policy applies to domestic sites only. Implementation of the NIH sIRB policy is expected to reduce unnecessary administrative burdens and systemic inefficiencies while maintaining appropriate human subject protections. Under the policy, “multi-site” is defined as two or more sites.

Revised Common Rule Requirements:

The Common Rule is a federal policy regarding Human Subjects Protection that applies to 17 Federal agencies and offices. Under the new Final Rule governing human subjects protections approved by the DHHS in January 2017, most U.S. government funded cooperative studies that meet the criteria for non-exempt “human subjects research”, and involve more than one site, will also require sIRB review. This requirement is in effect as of January 20, 2020.

If a researcher is not sure whether their research may require a Reliance Agreement, OR, they would like to request a Reliance Agreement, they should email RelianceAgreements@umd.edu.

Individual Investigator Agreement:

Individual Investigator Agreements are used 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).

The Individual Investigator will be required to review:

- The Belmont Report

- The U. S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45CFR46.

- The FWA and the applicable Terms of the FWA for UMD.

- The relevant institutional policies and procedures for the protection of human subjects.

- Documented completion of human subject research training. Please affiliate with UMD-College Park if taking CITI Training.

To request an Individual Investigator Agreement, a researcher should email RelianceAgreements@umd.edu.

CHAPTER 5: IRB TRAINING

All investigators desiring to engage in research using human participants must familiarize themselves with IRB policies and procedures related to federal regulations and apply for IRB approval before soliciting and working with human subjects. Moreover, investigators should then maintain an ongoing relationship with the IRB to gain assistance in following policies and procedures during the conduct of their studies. This will help assure that both investigators and the IRB remain in compliance with all state and federal regulations regarding research involving human participants. Please remember that the IRB does not in any way intend to discourage or obstruct research projects, but to work as collaboratively as possible with researchers ensure that their work meets ethical and legal standards.

HUMAN SUBJECT RESEARCH TRAINING:

CITI Training:

CITI (Collaborative Institutional Training Initiative) Training is the online human subject research training application utilized by the UMD IRB. Ongoing education and training in protection of human participants is a federal requirement. Enhanced oversight, new requirements, and recent guidance provided by the Office of Human Research Protections (OHRP) have required actions to strengthen human research protections programs.

The required training is titled Biomedical Research - Basic/Refresher or Social & Behavioral Research - Basic/Refresher. Both of these courses will provide you with the CITI Basic/Refresher course.

Who Should Complete CITI Training?

Principal investigators, faculty advisors (for students serving as PIs), co-investigators and research team members who will interact with human subjects and/or their identifiable data for the purposes of research must complete CITI Training before a project can be approved. During the administrative review of IRB transactions, the IRB Office will check to ensure that team members have up-to-date CITI training. All members of the research community are required to complete the CITI Training Refresher every three years.

How to Access CITI Training:

1. Go to www.citiprogram.org.

2. Sign In/Register.

3. At the top, right corner of the screen, hit the “Log In” button. This will give you three options: Log In, Log In Through My Institution, OR Register.

4. If you are affiliated with the University of Maryland you should choose the Log In Through My Institution option. This will allow you to register for CITI by using your University ID and password. To assist with having external investigators complete the CITI Training, please email the IRB Office at irb@umd.edu.

5. Choose the "University of Maryland, College Park" as your institution.

6. On the following screen, select "I don't have a CITI Program account and I need to create one."

7. Follow the prompts to set up your CITI account.

8. If you are not affiliated with the University, please log in through your institution or choose Register.

How to Add a CITI Course:

1. At the bottom of the page after logging in, under Learner Tools for the University of Maryland College Park, click Add a Course.

2. For Question 1, select one of the following Basic Courses depending on the scope of your research:

    (i) Biomedical Research - Basic/Refresher – 15 Required Modules, 2 Supplemental Modules

    (ii) Social and Behavioral Research - Basic/Refresher – 11 Required Modules

3. If you are only looking to take the course that is REQUIRED by the IRB, only make a selection for Questions 1 and 7 ONLY.

4. Complete the training. If you cannot complete the training in one sitting, you can save and finish at a later time. You can stop and start as many times as you need.

How to Find and View a CITI Certificate:

1. Your CITI certificate is available on the CITI website through your account. Go to www.citiprogram.org.

2. On the Main Menu, click University of Maryland, College Park Courses. This should give you a list of your completed CITI courses. Under the heading titled "Completion Record," there is an option to View/Print your certificate. Please be sure to save a

copy of your certificate to your computer. You should be able to save this certificate as a PDF.

3. You can also access your completed CITI Courses by clicking on My Records. This tab lists all of your completed courses. The View/Print option under Completion Record allows you to print and/or save your CITI certificate as a PDF.

COMMUNITY PARTNER TRAINING:

CIRTification: Community Involvement in Research Training is a human research protections training program designed especially for community partners. This is an appropriate training for community partners who will be involved in research and responsible for recruiting research participants, obtaining informed consent, or collecting data.

Please note: This training does NOT replace the required CITI training for UMD-affiliated investigators. This training is designed for non-academic personnel (for example, business associates, local government representatives, school system representatives) who may or may not be engaged in research requiring IRB approval in collaboration with UMD-affiliated investigators.

If you are interested in using CIRTification for training community partners, please see the UMD CIRTification Guidance Document.

HIPAA TRAINING FOR INVESTIGATORS:

HIPAA (Health Insurance Portability and Accountability Act of 1996) Training ensures that national health information privacy standards issued by the U.S. Department of Health and Human Services (DHHS) are upheld. Research organizations and researchers may or may not be covered by the HIPAA Privacy Rule. Covered entities may use and disclose protected health information (PHI) for research with authorization or without individual authorization under limited circumstances.

CHAPTER 6: INFORMED CONSENT

Consent for participation in research requires an informed consent process. This involves an on-going information exchange between the investigator and the potential research participant or the potential participant's legally authorized representative (LAR).

The informed consent process emphasizes that a participant is competent to understand the purpose and requirement of the research, is volunteering to participate in the research, and has the ability to withdraw from the research at any time without any adverse effect.

The consent process starts with the initial presentation of a research activity to a prospective subject (including advertisements and notices), continues with a discussion and information exchange between the researcher and the prospective subject, and requires documenting that consent was obtained.

The information that is given to the participant should be in language understandable to the participant. The setting and the tone of the communication must be non-coercive, and participants must be given an opportunity to ask questions and have those questions satisfactorily answered.

ELEMENTS OF INFORMED CONSENT:

An effective informed consent process involves each of the following elements:

- A clear and concise explanation of the research to be conducted and the procedures to be employed.
- Language appropriate for the targeted participant population (e.g., eighth grade reading level, English and foreign language versions for a multi-cultural study).
- Clear and precise language detailing all potential risks or discomforts and procedures to minimize such risks, duration of participation, and benefits of participation.
- A statement defining the right of the participant to withdraw at any time without any adverse effect.
- A statement describing alternatives to the proposed research activity, if any exist.
- A statement that the data/information will be kept confidential and how confidentiality will be maintained.

- A statement of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant.

- A statement that the participant is fully informed and agrees to participate on a purely voluntary basis.

OBTAINING INFORMED CONSENT:

When obtaining consent, the principal investigator must explain the research and assess the participant's comprehension. Informed consent from the participant and/or his or her legally authorized representative (LAR) must be obtained prior to initiating any research activities, including screening procedures.

Legally Authorized Representative (LAR):

In cases where participants may not be able to provide informed consent, such as in research projects working with participants with dementia, the investigators must explain whether there will be an evaluation for capacity to consent and how they will determine whether participants have the ability to consent/assent for themselves versus when a LAR would be needed. One method to evaluate capacity to consent is consent quizzes where participants are asked to answer several questions regarding the procedures, risks, and benefits after reviewing the consent form.

Translated Consent Materials:

The information that is given to the participant should be in a language that is understandable to the participant. If a study will be offered in languages other than English, the investigators must provide translated consent materials when submitting their IRB project or state that they will do so in an amendment. Translated materials should be developed and reviewed by a native speaker, translation service, or an individual with the appropriate credentials/familiarity of the language.

Privacy During Consent:

Investigators should conduct the consent process in a location that allows participants as much privacy as possible. This is more applicable to in-person studies where the consent procedure is being conducted in a location with the investigators. However, when conducting research online, investigators should state that participants should complete the consent process in a location in which they feel comfortable.

Ongoing Studies (for 1+ years):

It's best practice to have participants re-consent/review the consent form if there is no study activity for a year or longer. For example, if the study involves yearly surveys with no other activities in between.

DOCUMENTATION OF INFORMED CONSENT:

Documenting informed consent occurs after explaining the research and assessing participant comprehension. At minimum, it involves obtaining the signature of the participant (or the LAR/parent(s) of the participant), when approved.

Please Note: A written signature (wet) and a digital signature (including typing one's name into the consent form) are considered equivalent.

Investigators must retain the original signed consent form in the study file and offer a copy to the participant. The PI must retain copies of the completed consent forms for a period of at least seven years following the completion of the project.

For those participants that have a medical record, a copy of the participant's informed consent should be placed in the medical record. The original should be retained by the principal investigator.

WAIVER OF CONSENT DOCUMENTATION:

A waiver of consent documentation is a form of consent where participants do not sign (physically or digitally) their name on a consent document but provide consent through an alternative method.

Examples include verbally consenting, clicking a button or checking a box to indicate consent, or providing implied consent (e.g. "By proceeding to the survey, you consent to participate"). This is also applicable for opt-out parental consent, as the part of the consent process that is being modified is the signature (e.g. parents sign so their child does not participate).

The IRB may waive the requirement for the investigator to obtain a signed consent for some or all participants [45 CFR 46.117(c)] if it finds that **one** of the following statements is true:

- 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;

- 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; or

- 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

WAIVER OR ALTERATION OF INFORMED CONSENT:

The IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent, OR it may waive the requirement to obtain informed consent under the federal regulations [45CFR46.116(f)(3)] if it finds and documents **ALL** of the following:

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

PARENTAL CONSENT AND CHILD ASSENT:

Research with children requires additional considerations to ensure that the rights and welfare of children are upheld during the course of human subject research. By definition, children are unable to provide informed consent to participate in research, although they might be able to give their assent. The federal regulations also mandate that parents/guardians be notified of the research and provided the opportunity to consent to

their child's participation, unless a waiver if justified or the IRB finds that obtaining parent/guardian consent could put the child at additional risk (example, neglected or abused children).

Child Assent:

The federal regulations define **children** as persons who have not attained the legal age for consent to treatment or procedures involved in research, under the applicable law of the jurisdiction in which the research will take place [45CFR46.402(a)]. As stated above, children are unable to provide informed consent to participate in research, but they might be able to give their assent.

Assent is a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent [45 CFR 46.402(b)]. This means the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve.

Documentation of Assent:

The IRB has the discretion to determine the appropriate manner, if any, of documenting child assent. Based on such considerations as the child's age, maturity, and degree of literacy, the IRB will decide what form of documentation, if any, is most appropriate.

Children up to 7 years old:

In most cases, children under 7 will not be able to participate in the assent process, and only consent from the parents or legal guardians will be needed.

However, in certain cases, the PI may deem a child in this age range capable of being involved in the assent process. When this occurs, the child should be given a simple verbal explanation of what will happen to him or her and it should be documented on either the parental permission form or in the project records that verbal assent was obtained.

If a project includes minors under two, the principal investigator should explain how they will monitor for signs of dissent (e.g. passivity, lack of cooperation, fussiness, silence, crying, looking towards the door, lack of eye contact with Investigators, and multiple yawns) when submitting their project to the IRB.

Children 7 to 12 years old:

Often, children aged 7 to 12 years old will be able to participate in the assent process, using a simplified assent form. A separate, more detailed permission form will be needed for the parents or guardians.

The assent form should be brief and study specific, with subheadings or numerical paragraphs, and contain language that is both appropriate to the child's development and age. The assent form should have a simple format that is easy to read and when possible, limited to one page. The use of larger type, simple schema, and pictures will facilitate the child's understanding of the text.

Adolescents 13 to 17 years old:

In most cases, adolescents aged 13 to 17 should be fully informed about the research and given the opportunity to provide assent. A signed assent form, written in clear, straightforward language (eighth grade reading level) can be used for these participants. If using verbal assent for participants 13 to 17 years old, investigators must justify why this method is appropriate in their IRB submission.

Participants 13 to 17 may sign the same form as their parents since the information provided will be mostly the same, provided it makes sense within the project. The language should be directed at both individuals (e.g. you/your child).

Waiver of Child Assent:

The regulations at 45CFR46.408(a) identify three types of circumstances where the IRB may determine that waiver of children's assent is appropriate:

1. If the capability of some or all of the children is so limited that they cannot reasonably be consulted.

2. If the intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research.

3. If the research meets the same conditions as those for waiver or alteration of informed consent in research involving adults.

Parental Consent:

In general, parental or guardian consent should be sought before seeking the assent of a child, particularly in more than minimal risk research, unless the requirement for obtaining parental or guardian consent can be waived.

- **Parental Consent (or Permission)** is the agreement of parent(s) or guardian to the participation of their child or ward in research.

- **Parent** means a child's biological or adoptive parent.

- **Guardian** means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

In general, permission should be obtained from both parents before a child is enrolled in research. However, the IRB may find that the permission of one parent is sufficient for research to be conducted under 45CFR46.404 or 45CFR46.405. When research is to be conducted under 45CFR46.406 and 45CFR46.407 permission must be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

PERMISSIBLE RESEARCH WITH CHILDREN:		
Category:	**Requirements:**	**Parental Permission:**
Minimal risk	Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 45CFR46.408 and 21CFR50.55.	Permission from one parent may be sufficient
Greater than minimal risk, prospect of direct benefit	a. The risk is justified by the anticipated benefit to the subjects; b. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and c. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 45CFR46.408 and 21CFR50.55.	Permission from one parent may be sufficient
Greater than minimal risk, no direct benefit, prospect of yielding generalizable knowledge	a. The risk represents a minor increase over minimal risk; b. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations; c. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and d. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in 45CFR46.408 and 21CFR50.55.	Permission must be obtained from both parents
Research not otherwise approvable, presents an opportunity to understand, prevent, or	a. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and b. The Secretary of DHHS or Commissioner of Food and Drugs for the FDA, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has	Permission must be obtained from both parents

alleviate a serious problem affecting the health or welfare of children	determined either: 1. That the research in fact satisfies the conditions of 45CFR46.404 and 21CFR50.51, 45CFR46.405 and 21CFR50.52, or 45CFR46.406 and 21CFR50.53, as applicable, OR 2. The following: i. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and welfare of children; ii. The research will be conducted in accordance with sound ethical principles; iii. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in 45CFR46.408 and 21CFR50.55.	

PLEASE NOTE:

Minimal risk *means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45CFR46.102(j)]*

"The prospect of direct benefit" *means the intervention or procedure holds out the possibility of direct benefit to the individual subject, or the study involves a monitoring and diagnostic procedures that may contribute to the subject's care or well-being." [45CFR46.405 & 21CFR50.52]*

When research is to be conducted under 45CFR46.406 and 45CFR46.407 permission must be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

Waiver of Parental Consent Documentation:

For some research projects, the IRB may approve a request to waive the documentation of parental consent. This means that the researcher still provides the parents or legal guardian with the required consent information, but the researcher is not required to obtain the parents or legal guardian's signature on the informed consent document.

A **waiver of documentation of informed consent** is permissible when:

1. The signature on the informed consent document would be the only record linking the subject to the research and the principal risk of harm to the subject would be a breach of confidentiality. For example, for research on sensitive topics, such as domestic violence or illegal activities;

2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. For example, minimal risk research that involves surveys/interviews conducted via telephone or online; or

3. The participants are members of a cultural group in which signing forms is a not a normal/acceptable practice.

Waiver of Parental Consent:

The IRB may waive the requirement for obtaining parental or guardian consent if documents that:

1. The research involves no more than minimal risk to the subjects;

2. The research could not practicably be carried out without the requested waiver or alteration;

3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

In addition to the provisions for waiver contained in the federal regulations, if the IRB determines that a research project is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the parental permission requirements provided that an appropriate mechanism is in place to protect the children, and provided that the waiver is not inconsistent with federal, state, or local law [45CFR46.408(c)].

Passive or Implied Parental Consent:

The term "passive or opt-out consent" is sometimes used in research with children to describe situations in which the investigator can assume that a parent is permitting a child to participate. For example, researchers collecting survey and behavioral data from children at school provide parents with information regarding the study by mail and ask the parent(s) to return a form if they do NOT want their child to participate.

In these instances, the investigator must provide the parent(s) with a written document containing all the required elements of informed consent that gives parents the opportunity and sufficient time to opt-out of providing permission. The project should detail how the written document will be distributed to parents/guardians (e.g. the letter will be mailed/emailed by the school, the letter will be distributed at parent-teacher conferences, etc.) so that the IRB can determine whether the conditions for waiver of parental consent documentation can be met under 45CFR46.117(c).

Please Note: Some school districts require active parental consent regardless of whether IRB waiver of documentation of consent is appropriate, so the researcher must check with the participating school district(s) prior to the development of a passive consent process.

CHAPTER 7: DECEPTION IN RESEARCH

Please Note: The federal regulations do not explicitly define deception in research. The guidance provided below reflects UMD's interpretation of deception as it relates to human subject research.

What is deception?	What is NOT deception?
Deception: an alteration of consent [45CFR46.116(f)] and includes omitting some, or altering some or all of the basic elements of informed consent. **Deception includes:** providing a completely false purpose of the research and/or providing false information about the procedures to be followed. **Required:** debriefing script; opportunity to withdraw data; apology	Deception does NOT include withholding an element of the purpose and/or presenting false/manipulated information during participation. **Recommended:** debriefing script; PI contact information for additional information

To decide whether deception is being used, determine whether all of the elements of informed consent at 45CFR46.116(b) and (c) are met. If they are, it is not deception.

WHAT IS DECEPTION?

Deception is intentionally providing inaccurate or false information to participants. Deception is considered an alteration of consent [45CFR46.116(f)] and includes omitting some, or altering some or all of the basic elements of informed consent [45CFR46.116(b) and (c)], primarily the criteria at:

> 45CFR46.116(b)(1): A statement that the study involves research, **an explanation of the purposes of the research** and the expected duration of the subject's participation, **a description of the procedures to be followed**, and identification of any procedures that are experimental;

The majority of studies involving deception at UMD provide a completely inaccurate explanation of the purposes of the research.

Investigators often believe that deception is included in their research when they include an accurate description of the duration and the procedures of the study but omit information about the true purpose or provide false/manipulated information to participants. The UMD IRB has determined that these instances do not meet the definition of deception. [For more information, please see "What is NOT deception" listed below.]

WHEN IS DECEPTION ACCEPTABLE?

Deception should only be used when:

- The research is deemed minimal risk (per the IRB).
- There are no alternative methods that can yield scientifically valid results.
- The deception does not deprive participants the opportunity to protect their own interests.
- The missing information does not affect participants' ability to assess the risks related to participation
- The missing information would not have impacted a person's decision to participate if they had the information before they agreed to participate.

WHAT IS REQUIRED FOR DECEPTION TO BE APPROVED?

In order to waive or alter consent per 45CFR46.116(f)(3), the IRB must find and document that:

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

EXAMPLES OF DECEPTION:

False Purpose of the Research:

A false purpose is defined as the investigators providing participants with a completely different purpose from what the investigators are truly studying (i.e. - participants are fully

misled regarding the purpose of the research). Sometimes investigators provide a false purpose of the study to participants to avoid priming or biasing participants.

Providing participants with a false or completely inaccurate purpose of the study alters the informed consent criteria at 45CFR46.116(b)(1), which states that "participants will be provided with an explanation of the purposes of the research," since the purpose provided is false.

A false purpose differs from incomplete disclosure. Incomplete disclosure only withholds an element of the purpose or hypothesis from participants, but the purpose is still generally accurate. Incomplete disclosure, therefore, is not considered deception.

EXAMPLE:

Purpose Provided to Participants:	Purpose of Study:
The purpose of the study is to understand how age impacts pattern recognition.	The purpose of the study is to understand the impact of anxiety on ability to multitask.

False Information about Procedures:

Investigators may provide false information or withhold information about what will happen during the study through the informed consent process. **Please Note**: This is rare at UMD. However, this alters informed consent criteria at 45CFR46.116(b)(1) which states that "participants will be provided with a description of the procedures to be followed."

EXAMPLE:

Procedures Provided to Participants:	Procedures in the Study:
In a study on the impact of anxiety on ability to multitask, participants will be asked to switch between solving math problems and verbally providing phone numbers from a phone book, and informed that they may receive mild pain while in the process.	No painful procedures are administered in the study.

DEBRIEFING:

Participants should be debriefed immediately following a study that includes deception unless an immediate debriefing would compromise study results. In these instances, a delayed debriefing is acceptable, such as sending debriefing information to participants via email when the study has been completed.

Debriefing statements should generally include the following:

1. An acknowledgement that participants were deceived;
2. An apology for the deception;
3. An explanation of the reason for the deception;
4. An explanation of how the deception occurred (false purpose of the research, false information about procedures); and
5. The opportunity to withdraw their data from the research should participants choose to do so.

In circumstances where debriefing participants would present greater harm to the participant than the deception itself, debriefing should not occur. For example, if participants were selected for a study based on certain "negative" behaviors or characteristics, it may not be appropriate to include this component in the debriefing.

WHAT IS NOT DECEPTION?

Presenting False or Manipulated Materials:

Investigators may use materials they have manipulated or created in order to elicit certain responses from participants. This is not considered deception as long as the study includes all of the basic elements of informed consent, including informing participants through the consent form about the purpose of the research and the procedures to be followed, per 45CFR46.116(b)(1).

EXAMPLE:

Information given to participants:	What was false/manipulated:
In a study on the impact of anxiety on ability to multitask, participants are told that 95% of people are able to switch between the given tasks without making any errors	95% of people are not able to switch between the given tasks without making any errors

Please Note: A traditional debriefing is not required for studies presenting false or manipulated materials, but as a recommended way to mitigate risks, investigators should provide a post-participation information document that "corrects the record" stating that the true purpose of the research was not altered, describes what was created/altered by the researchers, and provides the PI's contact information for any further questions.

Incomplete Disclosure:

Sometimes investigators need to withhold an element of the study purpose or reason for the procedures in order to prevent biasing the results of the research. This is not considered deception as long as the study includes all of the basic elements of informed consent, including being informed about the purpose of the research, even if the purpose of the research is slightly altered (e.g. one element is withheld so investigators do not reveal their specific hypothesis). It is not considered deception as long as they have an accurate (albeit incomplete) description of the purpose.

EXAMPLE:

Purpose Provided to Participants:	Purpose of Study:
The purpose of the study is to understand how different conditions impact ability to multitask.	The purpose of the study is to understand the impact of anxiety on ability to multitask.

Please Note: A traditional debriefing is not required. Investigators may choose to inform participants or not inform them of the hypothesis after their participation.

Investigators may also use the strategies above in conjunction. These elements combined do not necessarily mean that the study includes deception, as long as the study includes all of the basic elements of informed consent at 45CFR46.116(b), including being informed about the purpose of the research and the procedures to be followed, per 45CFR 46.116(b)(1).

CHAPTER 8: AMENDMENTS, CONTINUING REVIEWS, AND CLOSURE REPORTS

AMENDMENTS:

During a research project, the investigator may decide that elements of the research require modification. When investigators need to make changes to a project that has been previously approved by the IRB, the investigator must submit an amendment to the IRB to request these changes.

Changes in the research may not occur until IRB approval of the amendment is received unless there is an immediate threat to the health of the participant. If such a situation were to occur, it would be the PI's responsibility to immediately report the event to the IRB as a project deviation and serve notice that an amendment to the project will be forthcoming.

This applies to exempt, expedited, and full board projects.

Please Note: If the proposed revisions modify the project a great deal, the IRB may request that a new project be submitted.

Examples of Changes that Warrant an Amendment:

- Adding or removing study personnel
- Adding or removing a research site
- Updating contact information on a flyer
- Changing wording on the previously approved consent form
- Revising the study procedures
- Revising the study title
- Changing the principal investigator
- Adding or removing a question in a survey or interview script
- Adding translated versions of study documents (recruitment materials, consent forms)
- Adding letters of support/approval from schools, research sites, or community partners

Please Note: This is not an exhaustive list. When/if investigators are unsure as to whether a change requires an amendment, they should contact the IRB Office at irb@umd.edu.

Procedures for Reviewing Amendments:

Amendments for projects presenting greater than minimal risk will be reviewed by the fully convened IRB, except as described below.

The IRB Chair/IRB Member Reviewer may review an amendment by an expedited procedure if the following criteria are met:

- The requested changes do not materially affect an assessment of the risks and benefits of the study.
- The requested changes do not substantially change the aims or design of the study.
- The requested changes are not directly relevant to the determinations required for approval.

Amendments may also be reviewed via an administrative procedure by IRB Office staff if the changes requested are minimal (e.g. – adding or removing study personnel, adding letters of support from research sites, etc.)

CONTINUING REVIEWS:

It is the responsibility of the PI to submit continuing reviews, if required. All continuing reviews must be submitted to the IRB 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, written response prior to the expiration date indicated on the current IRB approval letter.

A project's most up-to-date informed consent and assent forms should be included when submitting a Continuing Review if the project will remain open to enrollment.

If a project requiring continuing review expires, all interactions with participants and/or their data must cease. If a continuing review is not submitted within the 30 days following the project's expiration, the project will be administratively closed.

Exempt and Expedited Projects:

Many IRB projects no longer require the submission of a continuing review.

IRB projects that have received an exempt determination after 2022 do not require continuing review.

Continuing review applications are also 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 a project requires a continuing review, the investigators will be notified in writing. The approval letter will include an expiration date. If there is no expiration date included on a project's approval letter, a continuing review is not required.

Full Board Projects:

Projects initially reviewed by the convened IRB generally undergo a substantive continuing review by the IRB committee at least once a year. An annual continuing review is required for all research determined to present greater than minimal risk to participants or minimal risk that does not fit into an expedited category. The Committee may also determine that the degree of risk warrants a more frequent review in order to protect human participants from harm (i.e. – quarterly, semi-annually, etc.).

If the Committee determines that a project that was initially reviewed by the full IRB presents no greater than minimal risk and fits within an expedited review category, the application for continuing review can be assigned an expedited category and reviewed by the IRB Chair/IRB Member Reviewer through the expedited review path. Expedited review may also be used for continuing review if a full board study has been closed to accrual and intervention has been completed, but the investigator is still collecting follow-up data.

CLOSURE REPORTS:

Investigators should notify the IRB when a project is complete by submitting a closure report to formally close the project.

A project is eligible for closure if **ALL** of the following are true:

- Data collection is complete
- There is no more participant contact (including follow-up interviews, calls, surveys).
- The only research activity remaining is analysis of de-identified data.
    - Information is identifiable if participants can be identified directly or indirectly through identifiers linked to the participants. This includes any key linking participants to pseudonyms/study IDs.

CHAPTER 9: RESEARCH PARTICIPANTS

NUMBER OF ENROLLED PARTICIPANTS:

The number of enrolled participants is defined as the total number of participants who have consented to participate in the research, regardless of whether the participants complete the research in its entirety or provide invalid responses.

Initial requests for participant enrollment should be large enough to reflect accurate enrollment goals plus any screening failures or anticipated drop-out rates.

Exceeding the enrollment limits approved by the IRB is considered a deviation of the research. An amendment application should be submitted to formally request an increase in enrollment. [Please see Chapter 8 for more information about Amendments.]

If over enrollment occurs, the investigator must do the following:

- Submit a deviation report to document the over-enrollment, explaining when and why it occurred.
- In the deviation report, include a corrective action plan to implement moving forward to ensure that over enrollment does occur in the future.
- Add a statement requesting the ability to use the information of the over recruited participants in the data analysis and writing phase of the study.
- Provide a justification explaining why data from the over enrolled participants is deemed necessary for the scientific integrity of the study.

RECRUITMENT OF STUDY PARTICIPANTS:

The UMD IRB is responsible for ensuring the equitable selection of research participants with the proper safeguards in place to protect the rights and welfare of participants. Projects should be designed so that research benefits and burdens are fairly distributed. If an individual or group is denied access to a project that might be beneficial or if some people are singled out to bear the burden of risks associated with a study, the requirement for fairness is not met.

Women and Minorities in Study Populations:

Studies with the potential to address issues relevant to both sexes must recruit both genders, and minority populations should be included in a study population wherever feasible. Researchers must justify the exclusion of any group of individuals. The IRB may make exceptions if there is adequate scientific justification for exclusion, such as when a

disease predominates in one gender, or the focus of the research question is on a specific group.

Students as Research Participants:

When students are to be recruited for research, consent must state that students are allowed to refuse participation or withdraw early from a study without affecting their academic standing at UMD. An alternative way to protect against coercion is to require that faculty-investigators advertise for participants generally (e.g., through notices posted in the school or department) rather than recruit individual students directly. As with any research involving a potentially vulnerable participant population, the IRB will pay special attention to the potential for coercion or undue influence and consider ways in which the possibility of exploitation can be reduced or eliminated.

Confidentiality is a concern raised by the involvement of students as participants in research. The IRB will consider that research involving the collection of data on sensitive participants such as mental health, sexual activity, or the use of illicit drugs or alcohol presents risks to participants of which they should be made aware and from which they should be protected to the greatest extent possible.

Employees as Research Participants:

The issues with respect to employees as research participants are essentially identical to those involving students as research participants: coercion or undue influence, and confidentiality. Employee research programs raise the possibility that the decision will affect performance evaluations or job advancement. When employees are to be recruited for research, consent must state that employees are allowed to refuse participation or withdraw early from a study without affecting the conditions of their employment at the university.

Department of Defense Requirements:

Civilian researchers attempting to access military volunteers should seek collaboration with a military researcher familiar with service-specific requirements.

ADVERTISING FOR PARTICIPANT RECRUITMENT:

To further fulfill its responsibility to ensure proper safeguards are in place to protect the rights and welfare of participants, the UMD IRB will review the materials that investigators use to recruit participants.

Recruitment can be performed in a number of ways depending on the context of the research. Examples include posting flyers on bulletin boards, speaking to someone in

person or by telephone, sending someone an email, or posting online through social media platforms or online discussion boards.

For many recruitment methods, institutional permissions must be sought in advance. For example, investigators may need permission to post a notice on a bulletin board in an institution or organization, to post an online notice in a closed group or page in a social network platform, or via list serves. Documentation of this approval must be submitted and/or confirmed in your project.

Advertisements should not be coercive and should not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the project.

Generally, any advertisement (print, electronic, or other media) used to recruit participants should include:

- The name of the Principal Investigator and/or the research lab.
- The location of the research and the person to contact for further information.
- The purpose of the research and that it is in fact research.
- The eligibility criteria that will be used to admit participants to the study.
- A straightforward and truthful description of the benefits or burdens to the participant for participating in the study.
- The time or other commitment required from the participant.
- Accurate contact information. Email addresses must be @umd.edu.

Advertisements, regardless of form may not:

- Be misleading or coercive either in wording or visual effects.
- Promise a favorable outcome.
- Promise “free medical treatment” if the intent is simply that there is no charge to partake in the research project.
- Imply any benefits beyond what is outlined in the consent and project.

- Use terms such as “new treatment,” “new drug,” or “new medication” without explaining that the test article is investigational.

- Emphasize amount of payment for participation.

- Make claims, either explicitly or implicitly, that a drug or device is safe or effective for the purposes under investigation, or that the drug or device is in any way equivalent or superior to any other drug or device.

When following FDA Regulations, the IRB reviews advertising to ensure that advertisements do not:

- Allow compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

CHAPTER 10: VULNERABLE POPULATIONS

RESEARCH INVOLVING VULNERABLE POPULATIONS:

Certain groups of human participants are particularly vulnerable to coercion or undue influence in a research setting. These groups require special attention during the research process as outlined in 45CFR46.111(b) and 21CFR56.111(b).

The regulations specifically identify additional requirements for review and approval of research involving fetuses, pregnant women, and human in vitro fertilization under 45CFR46 Subpart B, prisoners under 45CFR46 Subpart C, and children under 45CFR46 Subpart D.

Other potentially vulnerable populations may include:

- Persons who are mentally disabled or otherwise cognitively impaired
- Minorities
- Economically or educationally disadvantaged participants
- Illiterate English-speaking participants
- Employees as participants
- Students as participants
- Non-English-speaking participants
- Terminally ill participants

In reviewing research projects involving all categories of vulnerable participants, the IRB must ascertain that their inclusion is adequately justified and that additional safeguards are implemented to minimize risks unique to each group.

RESEARCHING INVOLVING CHILDREN:

Special ethical and regulatory considerations apply when reviewing research involving children. **Children** are defined as "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." [45CFR46.402(a)]

In Maryland, children include all those who have not yet reached their 18th birthday and have not been legally emancipated. Emancipation may be obtained through judicial decree or based upon certain events such as marriage or military service. Marriage or military service does not automatically emancipate an individual, and investigators should seek guidance from the IRB Office, if the issue arises.

Categories of Research Involving Children:

45CFR46, Subpart D classifies research involving children into one of four categories depending upon the risks and benefits of the proposed study.

PERMISSIBLE RESEARCH WITH CHILDREN:		
Category:	**Requirements:**	**Parental Permission:**
Minimal risk	Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 45CFR46.408 and 21CFR50.55.	Permission from one parent may be sufficient
Greater than minimal risk, prospect of direct benefit	a. The risk is justified by the anticipated benefit to the subjects; b. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and c. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 45CFR46.408 and 21CFR50.55.	Permission from one parent may be sufficient
Greater than minimal risk, no direct benefit, prospect of yielding generalizable knowledge	a. The risk represents a minor increase over minimal risk; b. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations; c. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and d. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in 45CFR46.408 and 21CFR50.55.	Permission must be obtained from both parents
Research not otherwise approvable, presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children	a. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and b. The Secretary of DHHS or Commissioner of Food and Drugs for the FDA, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: 1. That the research in fact satisfies the conditions of 45CFR46.404 and 21CFR50.51, 45CFR46.405 and 21CFR50.52, or 45CFR46.406 and 21CFR50.53, as applicable, OR 2. The following: i. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and welfare of children; ii. The research will be conducted in accordance with sound ethical principles; iii. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in 45CFR46.408 and 21CFR50.55.	Permission must be obtained from both parents

PLEASE NOTE:

Minimal risk *means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45CFR46.102(j)]*

"The prospect of direct benefit" *means the intervention or procedure holds out the possibility of direct benefit to the individual subject, or the study involves a monitoring and diagnostic procedures that may contribute to the subject's care or well-being." [45CFR46.405 & 21CFR50.52]*

Child Assent and Parental Consent Requirements:

By definition, children are unable to provide informed consent to participate in research, although they might be able to give their assent. Federal regulations task IRBs with determining if the age, maturity and psychological state of the children allows for the children to assent to their participation in the research. If the children are found to be able to assent, adequate provisions must be put in place to solicit assent from the children prior to participating in research.

The federal regulations also mandate that parents/guardians be notified of the research and provided the opportunity to consent to their child's participation, unless a waiver is adequately justified or the IRB finds that obtaining parent/guardian permission could put the child at additional risk.

[For more information on Child Assent and Parental Consent requirements, please refer to Chapter 6.]

Child Abuse Reporting:

As per State law, all researchers must report all suspicions of current or past incidents of child abuse or neglect to the Chief of Police and submit a written report to Child Protective Services within 48 hours, as per University of Maryland, College Park's policy. Regardless of whether the participant is currently an adult, the researchers are responsible to report cases of suspected child abuse or neglect that are presently occurring or occurred in the past.

If a project involves interviewing children about topics that might lead to a suspicion or to knowledge on the part of the Investigator of child abuse or neglect, the child (and parent or guardian) must be informed of the reporting requirement as part of the informed consent process. The following sentence(s) should be integrated into the currently required Informed Consent Document among the statements about confidentiality and its limits:

"Possible exceptions to confidentiality include cases of suspected child abuse or neglect. If there is reason to believe that a child has been abused or neglected, we are required by law to report this suspicion to the proper authorities."

Wards of the State:

Children who are wards of the state or any other agency, institution, or entity can be included in IRB research approved under 45CFR46.406 or 45CFR46.407 only if the IRB finds and documents that such research is: (1) related to their status as wards; or (2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.

If the research is approved, the IRB must require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the Investigator(s), or the guardian organization.

Emancipated Minors:

In Maryland, children include all those who have not yet reached their 18th birthday and have not been legally emancipated. Emancipation may be obtained through judicial decree or based upon certain events such as marriage or military service. Marriage or military service does not automatically emancipate an individual and Investigators should seek guidance from the IRB office, if the issue arises. Consent is sought from an emancipated minor; not assent.

RESEARCHING INVOLVING PRISONERS:

The special vulnerability of prisoners makes consideration of involving them as research participants particularly important. Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate in research. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving prisoners. [45CFR46, Subpart C]

Please Note: Research that would otherwise be exempt from the requirement that it receive IRB approval is not exempt when the research involves prisoners.

Definition of Prisoner:

A **prisoner** is defined as 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 detained pending arraignment, trial, or sentencing. [45CFR46.303(c)]

For research involving prisoners, **minimal risk** is defined 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. [45CFR46.303(d)]

Categories of Research Involving Prisoners [45 CFR 46.306(a)]:

- Studies regarding the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants.

- Studies of prisons as institutions, or of prisoners as incarcerated persons, if those studies present no more than minimal risk or inconvenience to the participants.

- Research on conditions affecting prisoners as a class after DHHS publishes a notice in the federal register.

- Research on practices that are intended, and reasonably likely, to enhance the well-being of the participants; however, if some of the prisoners will be assigned to control groups which will not benefit from the research, then the study must first be approved by DHHS.

In addition to the general requirements for review, in reviewing prisoner research, IRBs are required by 45CFR46.305(a) to ensure that:

- The membership of the IRB reviewing the project includes a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity, and that the majority of the IRB is not associated with the penal institution involved. If no current member of the IRB meets the prisoner or prisoners' representative criteria, then the IRB Chair will identify and recruit a qualified individual to fulfill this requirement and advise the IRB. In addition, a majority of the IRB members at the meeting must not be associated with the prison.

- Any advantages that prisoners will realize as a result of participating in the research, when compared to the general living conditions within the prison, are not so great as to impair each prisoner's ability to weigh the risks and benefits of participation and freely choose whether to participate.

- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.

- Procedures for selecting participants are determined to be fair and free from arbitrary manipulation by prison authorities or prisoners.

- Control participants will be selected randomly from among the group of eligible volunteers, unless the PI justifies a different procedure.

- The information presented during the recruitment and consent procedures is in a language, and level of complexity, that is understandable to the participant population.

- The parole board will not take participation in the study into account, and that each prisoner will be informed that participation will have no effect on parole or release.

- Adequate provision will be made for follow-up care as necessary.

Please Note: A PI may not enroll a prisoner in an ongoing IRB-approved study without the approval of the IRB. If a participant becomes a prisoner during the course of a research study, the IRB must be notified.

RESEARCH INVOLVING PREGNANT WOMEN AND FETUSES:

Pregnant women and fetuses are provided additional protections in 45CFR46, Subpart B of the federal regulations. Generally, this designation applies to medical studies where the procedure has the potential to cause harm to the unborn child. As the fetus is unable to consent to risky procedures that may have a significant impact on their development, there are additional protections and requirements for conducting studies involving pregnant women.

Applicable Definitions:

- **Pregnancy** encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery. [45CFR46.202(f)]

- **Fetus** means the product of conception from implantation until delivery. [45CFR46.202(c)]

- **Viable** is a neonate that is able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. [45CFR46.202(h)]

- **Nonviable neonate** means a neonate after delivery that, although living, is not viable. [45CFR46.202(e)]

Please Note: Research with the potential to harm an unborn child is rare at UMD. In instances where the risk to pregnant participants is minimal, these individuals can be treated as any other participant.

Non-Pregnant Participants Who Become Pregnant During Research:

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

1. 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. [Please refer to Chapter 12 for more information on Adverse Events and Unanticipated Problems.]

2. Provide justification to the IRB Chair for approval if it is in the best interest of the pregnant participant to remain in the study. If it is not in the best interest of the participant to continue, their participation must be terminated.

3. The study must be re-reviewed by the full IRB, as soon as possible.

Conditions for Involving Pregnant Women or Fetuses in Research:

When pregnant women or fetuses are involved in research, the IRB must determine that all of the following conditions are met:

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risk to pregnant women and fetuses; and

2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means; and

3. Any risk is the least possible for achieving the objectives of the research; and

4. No inducements, monetary or otherwise, will be offered to terminate a pregnancy; and

5. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

6. Individuals engaged in the research will have no part in determining the viability of the neonate.

Consent Requirements for Research with Pregnant Women, Fetuses or Neonates:

When research involves pregnant women, fetuses or neonates, in addition to the requirements of the policy on informed consent, additional requirements policy must be met. Each individual providing consent must be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

When the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, consent from the pregnant woman must be obtained according to the policy on informed consent.

When the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with policy on research involving children, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

	Direct benefit to mother only	Direct benefit to mother and fetus	Direct benefit to fetus only	No direct benefit or societal benefits only
Risk is greater than minimal	Mother consent	Mother consent	Mother and father consent*	N/A - not permissible under 45CFR46.204
Risk is no more than minimal	Mother consent	Mother consent	Mother and father consent*	Mother consent

Except if father is unable to consent due to unavailability, incompetence, temporary incapacity, or the pregnancy resulted from rape or incest.

When research involves children who are pregnant, assent and consent are obtained according to policy on research involving children.

RESEARCH INVOLVING COGNITIVELY IMPAIRED INDIVIDUALS:

A cognitively impaired person is defined as having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia), or a developmental (e.g. mentally disabled) disorder that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished.

Cognitively impaired individuals could be vulnerable to coercion and may lack the capacity to provide consent. Capacity is defined as the "ability of an individual to understand the choices presented, to appreciate the implications of choosing one alternative or another, and to make and communicate a decision."

There must be specific evidence of individuals' incapacity to understand and to make a choice before they are deemed unable to consent. If cognitive impairment cannot be determined, then mental status testing should be included in the research design. The investigator must develop a plan to determine whether or not the prospective adult subject has the capacity to consent and if they do not, there must be a method to determine whether there is a designated LAR who can consent on the adult's behalf.

Legally Authorized Representative (LAR):

In Maryland, the following individuals may serve as legally authorized representative for another person for the purpose of providing consent for research prescribed or directed by a licensed physician:

1. Any parent, whether an adult or a minor, for his minor child or adult child of unsound mind. Child as used here includes biological, adopted, step, or foster children. The father of an illegitimate child, however, cannot consent for the child solely on the basis of parenthood;

2. Any person standing in loco parentis, whether formally serving or not;

3. Any guardian, conservator, or custodian, for his ward or other charge under disability;

4. Any adult for a minor sibling or adult sibling of unsound mind;

5. If an authorized parent is absent, any maternal grandparent and, if the father is an authorized parent, any paternal grandparent, for a minor grandchild or for an adult grandchild of unsound mind;

6. Any married person, for a spouse of unsound mind; or

7. Any adult child, for their mother or father of unsound mind.

Assent of Adults Not Capable of Consenting:

Whenever possible the investigators will obtain the assent of adults who are not capable of consenting for themselves. When assent is obtained, it will be documented in the consent form. To have the capacity to assent, the subject must be able to understand the general purpose of the research and the nature of the procedures and must be able to understand the concept of voluntariness. If the capability of some of the participants is limited so that they cannot reasonably be consulted, assent will not be obtained; the investigators will document it on the consent form.

OTHER POTENTIALLY VULNERABLE POPULATIONS:

Economically or Educationally Disadvantaged Participants:

For research involving economically disadvantaged participants, special care must be taken to assure that the financial inducements offered do not constitute the sole grounds for the participant's participation in the research project. Financial inducements should also not be used to assume risks that participants would not ordinarily incur.

The consent form for research involving educationally disadvantaged participants should be written with special attention to assure that terminology has been sufficiently simplified. The investigator should discuss orally every aspect of the study with the participants to ensure their understanding.

Illiterate English-Speaking Participants:

An investigator in an IRB approved project may enroll individuals who can speak and understand English but cannot read or write. The potential participant must be able to place a written mark on the consent form.

The participant must also be able to:

- Comprehend the concepts of the study and understand the risks and benefits of the study as it is explained verbally.

- Be able to indicate approval or disapproval for study enrollment.

If an investigator uses the above method to obtain consent, there must be documentation on the participant's consent form specifying what method was used to communicate the information and the specific means that the participant communicated agreement to study participation.

Non-English-Speaking Participants:

Non-English-Speaking participants may not be excluded from research on the basis of language use if there is a possibility that they might benefit by participating in the study.

If a research participant does not understand English, the informed consent document should be in the language readily understood by the participant to meet the requirements of 45CFR46.116(a)(3) and 21CFR50.20. If the principal investigator anticipates that consent interviews will be routinely conducted in a language other than English, the IRB requires a translated consent document be submitted with the original project for approval. It is the investigator's responsibility to ensure that the translation is accurate.

As required by 45CFR46.117(a) and 21CFR50.27, a copy of the consent document must be given to each participant. While a translator may be helpful in facilitating conversation with non-English- speaking participants, verbal translation of the consent document must not be substituted for a written translation.

Terminally Ill Participants:

Terminally ill patients are those who are deteriorating from a life-threatening disease or condition for which no effective standard treatment exists. It is generally considered unacceptable to ask such persons to participate in research for which alternative, not similarly burdened, populations of participants exist. Nevertheless, it may often be necessary to involve terminally ill patients in research concerning their disease and its treatment. Further, terminally ill persons should not be excluded from research in which they may want to participate simply because of their status. One can imagine that altruism and a desire to bring good from adversity may well motivate persons suffering from life-threatening illnesses to become involved in biomedical or behavioral research. Still, terminally ill individuals are a vulnerable population of research participants, and, therefore, require additional protection against coercion and undue influence.

Elderly Participants:

Aside from the regulatory requirement that IRBs provide additional protections for especially vulnerable persons, there are no specific regulations governing research with elderly participants. The elderly are, as a group, heterogeneous and not usually in need of special protections, except in two circumstances: cognitive impairment and institutionalization. Under those conditions, the same considerations are applicable as with any other, non-elderly participant in the same circumstances.

Institutionalization:

In the past, persons in nursing homes or other institutions have been selected as participants because of their easy accessibility. However, conditions in institutional

settings increase the chances for coercion and undue influence because of the lack of freedom inherent in such situations. Research in these settings should therefore be avoided, unless the involvement of the institutional population is necessary to the conduct of the research (e.g., the disease or condition is endemic to the institutional setting, persons who suffer from the disease or condition reside primarily in institutions, or the study focuses on the institutional setting itself).

When a research study is undertaken at a nursing home or similar institutions, all necessary parties are informed, and all documentation is maintained in a manner that meets all local, state, and federal research requirements.

CHAPTER 11: PARTICIPANT COMPENSATION

Compensation or payment to research participants for participation in research is not considered a benefit. Rather it is considered a recruitment incentive per the regulations at 46CFR46.116.

Compensation 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. Compensation should be equitable across participants who are asked to do the same activities. However, differences in compensation based on online platform requirements are allowed (like MTurk vs Prolific as they sometimes have different compensation requirements).

The amount and schedule of all payments should be presented to the IRB at the time of initial review. When/if investigators need to change the amount of compensation included in a previously approved project OR investigators would like to add compensation to a previously unfunded project, an amendment application should be submitted to formally request this change.

TIMING OF COMPENSATION:

Credit for payment should accrue as the research progresses and should not be contingent upon the participant completing the entire study. The participant should be paid in proportion to their time and inconvenience as a result of participating in the research project. Unless it creates undue inconvenience or a coercive practice, payment to participants who withdraw from the study may be paid at the time they would have completed the study (or completed a phase of the study) had they not withdrawn. For example, in a study lasting only a few days, an IRB may find it permissible to allow a single payment date at the end of the study, even to participants who had withdrawn before that date.

Advertisement of Compensation:

Advertisements may state that participants will be paid or compensated but should not emphasize the payment or the amount to be paid, by such means as larger or bold type.

DISCLOSURE OF COMPENSATION:

All information concerning payment, including the amount, method, and schedule of payment(s) should be set forth in the informed consent document.

Attention/Bot Checks:

Researchers may elect to use attention check questions to ensure that participants are putting forth reasonable effort to complete the survey, particularly for survey studies conducted on crowdsourcing sites such as MTurk or Prolific. If there will be attention/bot check questions in the survey materials, investigators should explain whether this will impact compensation.

Compensation Section of Consent Form:

The compensation section of the consent form should include the following information:

- A description of how participants can expect to receive compensation.
- The amount of compensation participants can expect to receive.
- A statement that if compensation is over $100, participants must provide SSN to receive compensation. [See text included below]
- Any stipulations/restrictions to compensation*

**This may include requiring participants to complete the entire study to receive compensation (as opposed to offering partial compensation) or using attention check questions to determine compensation.*

Below is a sample of the language that should be included in the Compensation Section of the Consent Form:

> *You will receive _____. You will be responsible for any taxes assessed on the compensation.*
>
> *If you will earn $100 or more as a research participant in this study, you must provide your name, address and SSN to receive compensation.*
>
> *If you do not earn over $100 only your name and address will be collected to receive compensation.*

METHODS OF COMPENSATION:

Cash or Gift Cards:

Investigators may offer participants compensation in the form of cash or a gift card. However, Tango is the University's preferred method of compensation for human subject

participants. Investigators are encouraged to contact their Department's Business Office to set up a purchase order for Tango gift cards.

Please Note: Venmo, PayPal, and Zelle are not approved methods for compensating participants.

Service as Compensation:

Sometimes investigators may not have the funds to compensate participants and will offer services as compensation. Services can include things like volunteering at a nonprofit organization that agrees to have the PI recruit their employees, volunteers, or beneficiaries. If opting for this type of compensation, investigators must ensure that the compensation is equitable across all participants and ensure they can clearly document the distribution of this form of compensation.

Course Credit:

When participants are being recruited from specific courses and can earn credit for completing a research activity, they should be offered an alternative non-research assignment that is commensurate in time and effort. This should be detailed in the both the IRB project and consent form. Offering a non-research alternative ensures that the research remains voluntary and that everyone who wishes to receive credit has both a research and non-research means to do so.

Gifts:

Investigators may offer participants gifts so long as the gift is not coercive. Examples of gifts may include snacks, a coffee, a book, a small toy, etc.

Transportation Reimbursement:

When transportation expenses are incurred by the participant due to their participation in the research, investigators may offer to reimburse participants for travel expenses.

International Compensation:

The recommended compensation method for international research participants is Tango. Investigators are encouraged to contact their Department's Business Office to set up a Purchase Order for Tango gift cards. For assistance with international participant payments, investigators may also email the Human Subject Payment Working Group at hswg-admin@umd.edu.

Referral Incentives:

When/if researchers would like to provide incentives to previously enrolled participants for providing the contact information for potential participants, the UMD IRB recommends the following:

- Researchers provide a rationale explaining why this process is appropriate for the project.
- Researchers should set a limit (or cap) on the number of potential referrals to be compensated.
- Incentives should not be so large as to unduly influence participants to refer and/or pressure others to participate in the research.
- Payment for referrals must be provided for the referral and cannot be based upon whether or not the referred individual participates in the research.

Please Note: The UMD IRB does not allow finder's fees, or payments to the organization or research staff designed to accelerate recruitment that were tied to the rate or timing of enrollment (bonus payments).

DOCUMENTATION OF COMPENSATION:

Reimbursement of Human Subject Participant Incentives Form:

The Reimbursement of Human Subject Participant Incentives Form may be used to assist in documenting reimbursement of allowable human subject participant incentives. It is designed to be supporting documentation included with itemized receipts for incentives purchased to acknowledge human subjects who participated in a research study as a group. Examples are groups of student participants in K-12 school classrooms.

This form should be completed before the research study visit occurs and must be acknowledged with an original signature by the school or organization. Please attach the completed form along with original itemized receipts for allowable items purchased to accounts payable. For meal purchases provided as incentives, a list of attendee names or class roster must also be attached.

Please remember that this form is to be used as supporting documentation to ORIGINAL itemized receipts as required by the State of Maryland.

Participant Receipt Forms:

Two receipt forms have been developed to allow investigators to document and report compensation while minimizing the potential risk of breach of confidentiality:

- Receipt Form - $100 or less
- Receipt Form – Greater than $100

In order to manage/mitigate potential risk, a limit of $100 has been set. $100 is the current IRS threshold for collection of Name, Address and Social Security Number (SSN) in order to generate IRS Form 1099. The following will be implemented:

- If participants will earn **more than $100** in **one study**, they must be told up front that name, address and SSN will be collected in order to receive compensation. Participants will be given the opportunity to participate without receiving payment if they do not wish to provide identifying information.
  [Use Receipt Form – Greater than $100]

- If participants will earn $100 or less in one study, they must be told up front that their name and address will be collected in order to receive compensation.
  [Use Receipt Form – $100 or less]

- If no compensation is given, the Compensation Section can be deleted from the Consent Form.

Please Note: Participants may refuse compensation and still participate.

CHAPTER 12: REPORTABLE EVENTS AND NON-COMPLIANCE

ADVERSE EVENTS:

Adverse events should be reported to the IRB within 72 hours of the research team learning of the event.

An **adverse event (AE)** is defined as event that occurs during the course of a research project 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.

Harm is "unexpected" when its specificity and severity are not accurately reflected in the consent document. 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.

Examples of adverse events include:

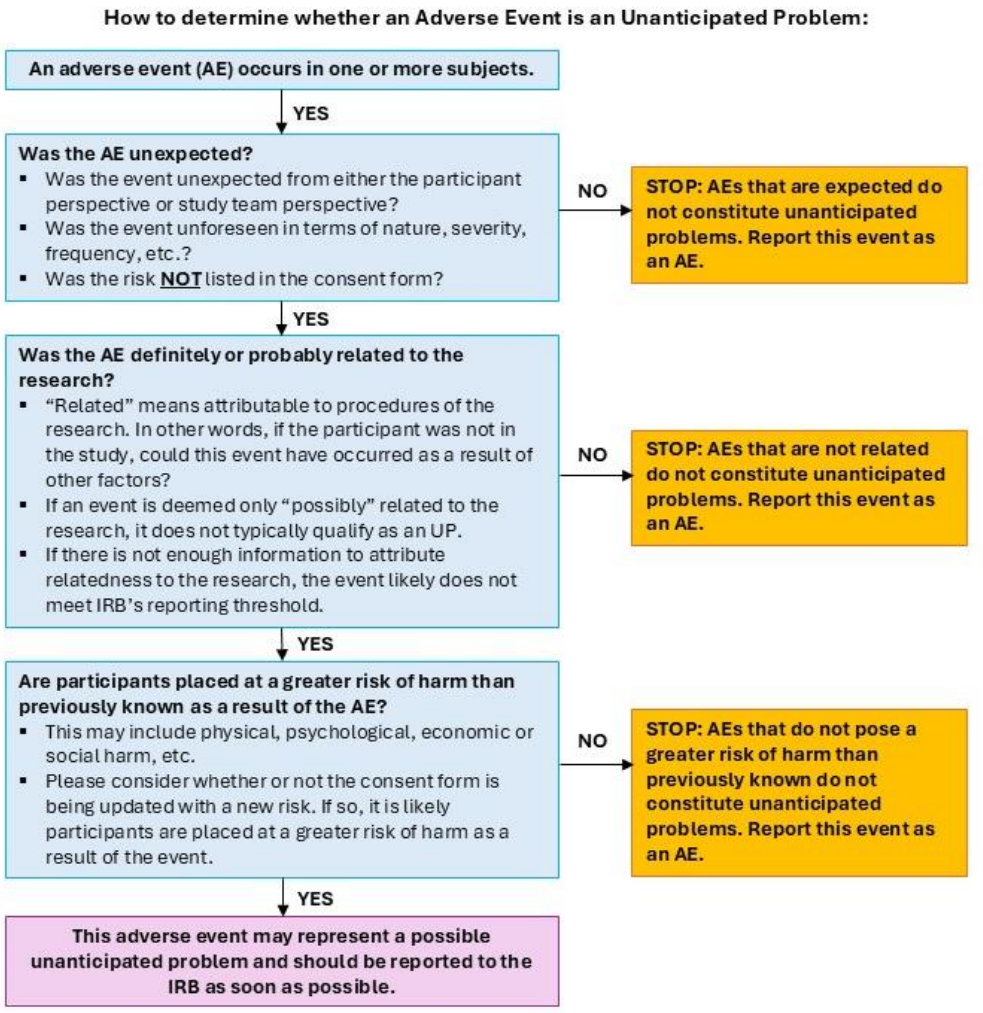
- a breach in participant confidentiality;
- participant complaints;
- incarceration of a participant in a project not approved to enroll prisoners;
- injury and/or death of a research participant that is unrelated to participation in the research.

Serious adverse events (SAE) are those 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.

UNANTICIPATED PROBLEMS:

Unanticipated Problems (UP) should be reported to the IRB within 72 hours of the research team learning of the event.

How to determine whether an Adverse Event is an 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; and

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.

DEVIATIONS:

Deviations should be reported to the IRB within 72 hours of the research team learning of the event,

A deviation is defined by any difference in study conduct from the criteria or activities prescribed in the IRB approved project, which may or may not affect the participants' rights, safety, welfare, and/or the integrity of the study.

Examples of deviations include:

- Enrolling more than the approved number of participants for a research study;
- Changes to study procedures without prior IRB approval;
- The addition/implementation of new study materials without prior IRB approval.

REVIEW OF REPORTABLE EVENTS:

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.

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.

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 Vice Chair and request that the report be reviewed by the full committee at the next convened IRB meeting.

The Committee will review all unanticipated problems, serious adverse events, or cases of continuing/serious noncompliance at a convened meeting. If the IRB determines by majority vote that the event or problem represents an unanticipated problem involving risks to participants or others, the IRB will report the incident to the appropriate Regulatory Agencies and Institutional Officials as applicable. If the IRB determines that the problem is not an unanticipated problem involving risks to participants or others, the Committee will

ensure that the research team has provided an effective corrective action plan, and the report will be acknowledged.

All decisions made by the Committee will be documented in the IRB meeting minutes.

The IRB will consider the following actions when reviewing reportable events:

- No action (i.e. – Acknowledgement of the reportable event and the proposed corrective action plan).
- Modification of the research project.
- Modification of the informed consent process.
- Additional information provided to past participants.
- Notification of current participants (required when such information may relate to participants' willingness to continue to take part in the research).
- Requirement that current participants re-consent to participation.
- Requirement of a continuing review and/or modification to the existing continuing review schedule.
- Additional Quality Assurance monitoring of the research and/or consent process.
- Suspension of the research.
- Termination of the research.
- Referral to other organizational entities (e.g., legal counsel, risk management).

REPORTING NON-COMPLIANCE:

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 non-compliance to the HRPP office. 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 non-compliance 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).

Definitions of Non-Compliance:

Non-Compliance is defined as 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.

Continuing Non-Compliance includes 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.

Serious Non-Compliance involves 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.

Research Misconduct is defined as 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 Research Integrity Officer (RIO) in the Office of Faculty Affairs (OFA) by the Director of the HRPP, the IRB Chair, or IRB Vice-Chair.

Procedures for Addressing Allegations of Non-Compliance:

Allegations of non-compliance are investigated and documented by IRB staff. IRB staff will conduct a pre-inquiry review for preliminary informal checking of the facts to determine if there is a reasonable basis for the allegation and if the allegation can be supported or

proved by the evidence. If the IRB staff is unable to conduct the investigation on their own, others may be requested to assist. Confidentiality will be maintained at all times.

If the allegation of non-compliance is determined not to be a credible confirmed report of non-compliance in fact by definition, the inquiry stops and no further action is taken.

If the allegation of non-compliance is determined to be a credible, confirmed report of non-compliance, the inquiry proceeds as outlined in this policy.

Procedures for Addressing Confirmed Reports of Non-Compliance:

IRB staff will review all reports of non-compliance to determine whether a confirmed report of non-compliance represents serious or continuing non-compliance.

If it is determined that the confirmed report of non-compliance is neither serious nor continuing non-compliance, the following actions may be taken:

- Acknowledgement of the problems, requiring no sanctions but instructions regarding the necessity to establish procedures and policies to avoid further infractions.

- Require additional education and training applicable to human research participant protections of the Investigator and/or staff.

- Request a corrective action plan from the Investigator.

- Acknowledgement of the submitted corrective action plan.

- No further action.

If IRB staff determine that a confirmed report of non-compliance might represent serious or continuing non-compliance, IRB staff will refer the confirmed report of non-compliance to the IRB Chair.

An IRB Chair may determine that more information is needed if significant infractions have occurred and request further investigation to be conducted by the QA Program Manager. The research team will be notified in writing of the directed investigation by the IRB Chair.

The IRB Chair may also request that the report of non-compliance be reviewed by the convened IRB. The IRB will consider, but is not limited to, the following actions:

- Increased study monitoring by the Quality Assurance Program Manager.

- Required interim reports from the Principal Investigator.
- Reported internal audits be conducted by the PI and/or study personnel.
- Monitoring of the consent process by the Quality Assurance Program Manager.
- Modify the frequency of the continuing review cycle.
- Notify current subjects, if the information about the non-compliance might affect their willingness to continue participation.
- Required additional training of the principal investigator and or/study personnel in the protection if human participants.
- Suspend IRB approval of the respective study pending a written plan for the correction and /or prevention of the non-compliance.
- Termination of the study.
- Suspension of all principal investigator's studies pending the completion of an audit.
- 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.

Reporting Non-Compliance to Federal Agencies:

All noncompliance determined by the Chair and Director to be serious or continuing noncompliance will be reported to the Institutional Official, OHRP, and Federal Department or Agency Heads if the project is federally funded. If not federally funded, serious or continuing non-compliance will be reported to the relevant UMD institutional officials.

REPORTING RESOURCES:

UMD Compliance Reporting System:

In situations in which individuals prefer to make a confidential or anonymous report, they are encouraged to use the UMD Compliance Reporting System. It is a safe way to report problems or raise concerns, and each report will be followed up appropriately.

To anonymously report a human subject research concern please visit the UMD online Ethics, Integrity and Compliance Reporting system.

University System of Maryland Reporting Resources:

Employees, students and other members of the University System of Maryland (USM) community are strongly encouraged to communicate suspected fraud or other financial irregularities to appropriate authorities.

At the Report Fraud, Waste, and Abuse website and via telephone "Hotline" (1-877-330-2320), members of the USM community may report such concerns. This user-friendly process is both anonymous and confidential. It is designed to deter and detect fraud, unethical business practices, and financial irregularities at USM institutions.

In addition to the portal and hotline, reports of fraud may be submitted to a fax number and mailing address. A full summary of contact information for all of these channels follows at the bottom.

USM encourages anyone familiar with any fraud, misuse or misappropriation of USM resources to use the Web portal, hotline and other channels to confidentially and anonymously report suspected fraud so that it may be appropriately investigated.

For more information visit the USM Communication Channels for Anonymous, Confidential Reporting of Fraud page.

CHAPTER 13: QUALITY ASSURANCE PROGRAM

OVERVIEW:

The Quality Assurance (QA) Program was established to promote and maintain ethical research conduct at UMD. The primary mission of the QA Program is to evaluate and improve human research protections through education, training, and monitoring. Quality Assurance staff work with investigators, research staff, and the IRB to ensure research is compliant with regulations, guidance, institutional policies, and best practices for human research protections.

QUALITY ASSURANCE ACTIVITIES:

The QA Program is responsible for reviewing activities associated with human research protections. These responsibilities include:

- Routine, on-site and virtual Quality Assurance Reviews
- Assistance with IRB projects, reporting, and recordkeeping
- Internal reviews of approved IRB projects
- IRB member evaluations
- Participant and community outreach initiatives
- Development of QA tools and training
- Random reviews of IRB meeting minutes and reviewer checklists
- Monitoring of Reliance Agreements and IRB approval letters
- Compliance follow-up of IRB projects

QUALITY ASSURANCE REVIEWS:

A **Routine (Not-for-Cause) QA Review** is an assessment or examination of a research-related practice or procedure with the possibility (or intention) of instituting change if necessary. Routine QA Reviews of study activities and study documentation are performed on-site as a service to investigators, with feedback provided regarding practices associated with the conduct of the study.

A **For-Cause (Directed) QA Review** is an assessment of research or investigators that is initiated at the request of the IRB or the Institutional Official to obtain (or verify) information necessary to ensure compliance with regulations and institutional requirements. A for-cause QA Review is generally based on a concern, complaint, or an allegation that was brought to the attention of the IRB and is used to inform decisions about the conduct of human subject research and/or human subjects protection.

Projects Selected for QA Review:

Projects are randomly identified for routine on-site QA Reviews from the list of all open studies in the IRB database. Any study involving human subjects may be selected for a routine QA Review. Exceptions to random selection include studies that have received QA Reviews or for-cause reviews within the same calendar year as well as studies closing prior to scheduled review.

Process for QA Review:

The research team (Principal Investigator, Co-investigators, and/or individuals listed in IRBNet) will receive an email notification from the QA staff indicating that a particular IRB project has been selected for a QA Review. The QA staff will arrange a mutually agreeable appointment for an on-site or virtual review, typically within 2-4 weeks of notification.

The QA Review will involve an internal records review, a brief interview with a few members of the research team, and a possible on-site visit. If selected for an on-site visit, it will consist of two parts: (1) An on-site records review of all project documentation and (2) a tour of the research facility.

QA staff will ask that specific IRB-related records are available for review. Examples include:

- IRB-approved documents, including initial, continuing, and amendment reviews
- IRB-related correspondence, including IRB approval letters
- Informed consent documents
- Screening/enrollment lists used to identify potential participants
- Sponsor correspondence
- Reports of unanticipated problems and adverse events
- Drug and device accountability records

The QA staff may ask questions regarding the research team, project procedures, recruitment, the consent process, record keeping, adverse events, or other questions specific to the project.

QA staff will provide the research team with a written report via email, no later than one week following the QA Review. The principal investigator is expected to review the report and return a signed copy within 10 business days.

The results of the QA Review will be shared with all members of the research team. The results will also be reviewed by the IRB chair and the IRB committee at the monthly full board meeting.

QUALITY IMPROVEMEMT ASSESSMENTS:

The QA program also evaluates UMD's HRPP as required by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Through routine Quality Improvement Assessments, the QA Program:

1. Conducts ongoing evaluations of the HRPP in terms of quality, effectiveness, and efficiency;

2. Identifies strengths and weaknesses of the existing HRPP and highlight areas needing improvement;

3. Provides recommendations for improvement through the development of Quality Improvement Plans (if necessary); and

4. Documents improvements made by the HRPP in areas of compliance, quality, effectiveness, and efficiency.

A number of methods are used to conduct the routine Quality Improvement Assessments. The items listed below represent a few activities designed to assess the overall quality, effectiveness, and efficiency of the HRPP.

Please Note: **This is not an exhaustive list.**

1. Annual IRB Evaluation Surveys

2. Annual IRB Member Evaluations

3. Annual IRB Reports (reviewed by the Vice President for Research)

4. Quarterly Community Outreach Assessments

5. HRPP Emergency Preparedness Evaluation

Results of Quality Improvement Assessments are reported to the Director of the HRPP and the Institutional Official. Improvements, changes, or the need for additional education is implemented, as needed.