AAHRPP Site Visit 2021:
Interview Guide for UMD Researchers & Research Staff

The Association for the Accreditation of Human Research Protection Programs, Inc. (AHHRP) will conduct an accreditation site visit at The University of Maryland, College Park campus from **July 28, 2021 – July 29, 2021**. AAHRPP is an international, independent nonprofit organization that reviews and accredits an institution's human research protections program (HRPP). Long regarded as the gold standard, AAHRPP accreditation is becoming the norm for quality research programs; this will be UMD's first visit for accreditation.

The UMD IRB Office has provided AAHRPP with a written description of our HRPP policies, procedures, and resources, as well as with a list of all active IRB protocols. During the site visit, representatives from AAHRPP will conduct interviews and review records to ensure that those policies and procedures are being adhered to.

AAHRPP will provide a list of individuals selected for interviews approximately three weeks prior to the site visit. If selected for an interview by AAHRPP, you will be notified closer to the visit date and provided with additional information. Anyone who has a role in human research may be selected for an interview.

We anticipate that each interview session will take between 20-40 minutes. Sessions will be in the form of individual or group interviews. We expect most questions to be focused on regulatory and ethical issues related to general research with human participants, but questions may also relate to the conduct of your research and your impressions of the UMD HRPP.

Preparing for the Site Visit
This document is intended to help you prepare for a potential interview. Each section of this document is followed by a list of questions that you may be asked. This document includes sections on the following topics:

- **Section 1: General Tips**
- **Section 2: HRPP Policies and Procedures**
- **Section 3: Roles and Responsibilities of Investigators and Research Staff**
- **Section 4: Minimizing Risks to Participants and Protecting Participants' Rights and Welfare**
- **Section 5: Compliance with IRB and Other Review Unit Requirements**
- **Section 6: Obtaining and Documenting Informed Consent and Waiver of Informed Consent**
- **Section 7: Conflict of Interest Disclosure**
- **Section 8: Accountability and Additional Administrative Requirements**
- **Section 9: Education**
- **Section 10: Additional Resources**

Section 1: General Tips

Accreditation largely depends on the interviews conducted by AHHRPP with members from the UMD research community. You will be expected to:

- Understand the UMD HRPP structure
- Know your role in the UMD HRPP
- Be familiar with the UMD HRPP policies and/or where to access them
- Know how to report non-compliance and adverse events
- Understand and describe the ethical aspects, the purpose, and the value of your work
- Know the regulatory standards that apply to your research
- Know IRBNet terminology, and describe your IRB submissions
- Understand what constitutes conflict of interest
- Know how a potential conflict of interest is disclosed and reviewed at UMD
- Describe the human research training that you had: (e.g. CITI Training)
- Know how to recruit participants ethically and in an equitable manner while adhering to inclusion/exclusion criteria

We suggest that you respond directly to the question asked if AAHRPP chooses to interview you. If a question seems unrelated to your work, please let the interviewer(s) know. Below are examples of the type of general questions you may receive:

About Your Own Project(s)
▪ *Describe your study. What are the procedures? How do you recruit? What is the consent process?* ▪ *What kinds of risks exist in your study? How do you minimize those risks?* ▪ *Do you communicate results with your participants after the completion of your research?* ▪ *How did you interact with the IRB on this study?*
About Your Relationship with the IRB
▪ *What is AAHRPP accreditation and why is it important to UMD?* ▪ *What is the IRB's reputation on campus?* ▪ *What are typical turnaround times?* ▪ *How did the IRB prepare you to conduct your research?* ▪ *How do you feel about the IRB?* ▪ *Do you think IRB reviews are fair?* ▪ *What do you think about the IRB and their efforts to protect human research participants?* ▪ *Do you know how often the convened (full board) IRB meets?*

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Section 2: UMD HRPP Policies and Procedures

The following provides a summary of important components of the UMD IRB's policies and procedures that you should familiarize yourself with. The source of this information is the **HRPP Standard Operating Procedures** and **The Investigator Handbook**.

Laurie E. Locascio, PhD (the Vice President of Research) serves as the **Institutional Official (IO)** for the UMD HRPP and is responsible for the conduct of research at The University of Maryland, College Park. The HRPP is supported by:

- The University of Maryland, College Park HRPP and its key components, including the Institutional Review Board (IRB) Office, The Conflict of Interest Committee (COI), The Office of Research Administration (ORA), The Human Subject Working Group, and the Research Support Oversight Committee;
- Academic units, including schools, colleges, and other campus facilities to which faculty, staff, and trainees engaged in human research are appointed;
- The IRB Committee;
- Key executive and administrative offices, including the Office of General Counsel.

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

Possible Questions About HRPP Policies and Procedures
▪ *Who is the institutional official responsible for research at UMD?* ▪ *What are the components of the UM HRPP?* ▪ *Where would you go for help on regulatory or ethical issues?*

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Section 3: Roles and Responsibilities of Investigators and Research Staff

UMD Investigators have primary responsibility for protecting the rights and welfare of humans participating in their research, which should be the primary goal of any research endeavor. It is the policy of the IRB that all research which is reviewed, approved, and conducted under the IRB Board's jurisdiction will generally conform to the following guidance documents: **1) The Nuremberg Code** and **2) The Belmont Report**. The Health and Human Services regulations **45 CFR §46** reflect the basic ethical principles for the conduct of human participant research found in these documents.

- **The Nuremberg Code**, which contains 10 basic ethical principles that are presented in abbreviated form below:
    - Obtain voluntary consent of the participant.
    - Design the study to yield results for the good of society, otherwise unobtainable through other means.
    - Base studies involving humans on animal experiments.
    - Avoid physical and mental suffering and injury to the participant or others.
    - Do not conduct the study if death or disabling injury is an expected result.

  - The degree of risk should never exceed the humanitarian importance of the problem to be solved by the research.
  - Protect the participant from injury, disability, or death.
  - Be scientifically qualified to conduct the study.
  - Allow the participant to voluntarily withdraw at any time.
  - Be prepared to stop the study when continuation is likely to result in injury, disability, or death to the participant.

- **The Belmont Report**, which identifies and summarizes three main ethical principles that should govern research with human subjects:
  - Respect for persons (autonomy/voluntary participation/adequate information)
  - Beneficence (risks of research are reasonable in relation to the benefits the research may provide to subjects or science)
  - Justice (selection of subjects is equitable and is representative)

- **The Common Rule (45 CFR 46)**, which is the federal regulatory framework that governs research with human subjects and codifies the ethical principles of the Belmont Report. Under the Common Rule, research with human subjects is defined as follows:
  - *Research* – A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
  - *Human subject* – A living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through interaction or intervention, or (2) identifiable private information.

- **21 CFR 50** and **21 CFR 56**, which serve as the regulatory framework for research regulated by the Food and Drug Administration (i.e., research involving drugs, devices, biologics). Please note that there are **differences between FDA and HHS regulations**.

- Other federal and state laws and regulations that apply to research (i.e. Mental Health and Developmental Disabilities Confidentiality Act (**MHDDCA**), Family Educational Rights and Privacy Act (**FERPA**), Health Insurance Portability and Accountability Act (**HIPAA**).

- Requirements for studies sponsored by federal departments and agencies such as the DoD, EPA, etc.

- UMD Institutional policies and procedures

Possible Questions About Roles/Responsibilities of Investigators and Research Staff
▪ *What is the PI's primary responsibility in conducting the research?* ▪ *What is the Nuremberg Code?* ▪ *What are the Belmont Principles and when did you first hear of them?* ▪ *What is the Common Rule?* ▪ *Are there additional requirements for studies sponsored by the DoD, EPA, DOE, or ED?*

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Section 4: Minimizing Risks to Participants and Protecting Their Rights and Welfare

Investigators and research staff have a responsibility for minimizing risks to participants and for ensuring their rights and welfare. This can be accomplished by:

- Designing and implementing protocols that comply with applicable regulatory and institutional policies, as well as the principles of the Belmont Report.
- Verifying procedures are consistent with sound research design and that resulting knowledge is expected to be sufficiently important to justify the research.
- Ensuring equitable selection of participants.
- Establishing provisions for monitoring participants and their data to identify and report any adverse events that may compromise participant safety.
- Developing plans for protecting participant privacy and the confidentiality of data. In human research, these terms are defined as follows:
    - *Privacy* – Relates to *individuals* having control over the extent, timing, and circumstances regarding the sharing of information about themselves with others.
    - *Confidentiality* – Relates to the protection of participant *data* that have been shared with the researcher with the expectation that it will be protected and not disclosed.
- Putting in place enhanced protection for vulnerable participant populations (e.g., children, prisoners, pregnant women, mentally disabled persons, etc.).

Possible Questions About Minimizing Risks and Protecting Participant's Rights and Welfare
▪ *What is the process of scientific review for your research?* ▪ *Do you know the difference between minimal and more-than-minimal risk?* ▪ *What is the difference between privacy and confidentiality?* ▪ *How do you protect participant privacy and confidentiality of data?* ▪ *How/who do you recruit for your research?* ▪ *How do you ensure that only participants meeting the inclusion criteria are enrolled?* ▪ *What additional mechanisms do you have in place to protect your research participants?*

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Section 5: Compliance with IRB and Other Review Unit Requirements

Investigators and research staff have a responsibility for ensuring research is conducted in compliance with the IRB, as well as other institutional and regulatory requirements. Below are examples of some of these requirements:

- 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**.
- The requirements of the IRB (i.e., initial review, continuing review, modifications, and reporting of adverse events and unanticipated problems) must be met.
- Research must be conducted as specified in the IRB-approved protocol.

- All proposed changes to the research, no matter how minor, must be approved by the IRB prior to implementation unless necessary to eliminate immediate hazard to participants.
- PI's are responsible for the content of all submissions to the IRB.
- Materials must be submitted to the IRB in a timely fashion (e.g., requests for changes, continuing review applications, etc.).
- Unanticipated problems involving risks to participants or others must be reported to the IRB in a timely manner.
- Potential non-compliance with laws, regulations, or IRB requirements by the research team or others must be reported, even if this non-compliance was unintentional.
- Protocol deviations, participant complaints, or loss of research data must be reported to the IRB.

Possible Questions About Compliance with IRB and Other Review Unit Requirements
▪ *How do you notify the IRB about proposed changes to your research?* ▪ *What would you do if you lost your research data and who would you tell?* ▪ *Do you know how to report a participant complaint or a problem with your study?* ▪ *What is an adverse event? Have you ever had one on a study? How would you report it?* ▪ *Do you know what non-compliance is and when and how to report it?*

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Section 6: Obtaining and Documenting Informed Consent or a Waiver of Informed Consent

The informed consent process emphasizes that the participant is competent to understand the purpose and requirement of the research, is volunteering to participate in the research study, and has the ability to withdraw from the study at any time without any adverse effect. The process starts with the exchange of information about the study. The setting and the tone of the study must be non-coercive. A thorough explanation of the study along with all risks, benefits, and alternatives to participation is essential. The individual must be given an opportunity to ask questions and have those questions satisfactorily answered. The participant must be fully informed in order for consent to be truly voluntary.

Informed Consent

Investigators are responsible for obtaining and documenting informed consent before the research begins unless the IRB waives this requirement; informed consent should include the following:

- 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 discomfort 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 signature line with a statement that the participant is fully informed and agrees to participate on a purely voluntary basis.

The participant (or their legally authorized representative) must be provided with a copy of the consent document at the time of consent unless this requirement is waived by the IRB.

Investigators are responsible for retaining signed consent documents for at least three years after completion of the research (seven years if protected health information will be used or disclosed in connection with the study) or longer if required by the institution or research sponsor.

Waiver of Informed Consent
The IRB may waive the requirement for the Investigator to obtain signed consent for some or all participants [45 CFR 46.117(c)] if it finds that:

- The only record linking the participant to the research would be the consent document, and the principal risk to the participant is the potential harm resulting from a breach of confidentiality. In that event, each participant should be asked if he/she wishes to have documentation linking the participant with the research. The participant's wishes will govern.
- The research presents no more than a minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context (e.g., drawing a blood sample, or asking shoppers in a mall about the ambient lighting or temperature). In cases where the requirement of documentation is waived, the IRB may require that the Investigator provide the participant with a written statement regarding the research.
- The Investigator may request the IRB's ruling on waived consent at the time the Project is submitted.

In order to grant a waiver, the IRB (Full Committee or Chair/Designee) must document that it believes the request meets the following criteria: **1)** The research involves no more than minimal risk to the participants; **2)** The waiver will not adversely affect the rights and welfare of the participants; **3)** The research could not be practicably carried out without the waiver; **4)** Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Possible Questions About the Consent Process
▪ *What are the required elements of informed consent?* ▪ *Describe your consenting process. Does the participant get a copy? If yes, when do they get it?* ▪ *What is the process for obtaining consent? Who does it? Where are participants approached? Do participants have time to think about it before they agree to participate?* ▪ *What would you do if you recruited a non-English speaking participant? How would you consent?* ▪ *How do you know if the participant understands the consent document?* ▪ *Who answers questions about the research?* ▪ *What is a waiver of informed consent?*

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Section 7: Conflict of Interest Disclosure

A conflict of interest in research is an interest that relates to and could significantly affect the design, conduct, or reporting of the funded research.

The following relationships are examples of situations that may raise questions regarding an apparent or actual conflict of interest in research:

a) An investigator has a consulting or other relationship with a company sponsoring a research project, or a company that manufactures or markets a product under evaluation in the research

b) An investigator has intellectual property interests in a product or method under evaluation in the research

c) An investigator is a founder and has equity interests in a start-up company that owns intellectual property under evaluation in the research

It is the policy of the HRPP to prevent financial conflicts of interest that interfere with human research taking place at the University of Maryland, College Park (UMCP) in compliance with **University of Maryland Board of Regents Policy [3.10(A), (B), & (C)]**

Potential COI's are identified through annual and continual disclosure requirements for investigators. The IRB will review disclosures that describe outside activities and interests made by researchers, as well as the responses to the conflict of interest questions for all researchers that pertain to each active IRB protocol.

Should there be any investigators or project personnel with a conflict of interest, the Chair of the Conflict of Interest in Research Committee (CIRC) along with the Chair of the Institutional Review Board will be notified. A management plan will be developed to manage, reduce or eliminate the perceived, potential or real conflict of interest by the CIRC in accordance with the UMCP Conflict of Interest in Research Policy. The researcher and the Chair of the Institutional Review Board will attend this meeting to provide input in the development of this plan regarding human subject protections. In addition, the Chair of the CIRC will attend the IRB meeting where the protocol is reviewed in order to explain the background of the individual conflict of interest, provide greater detail regarding the management plan, and to address any concerns. The IRB then will vote to determine whether the management plan ensures independence of the conduct of human participant research from the interests of the researchers. If the vote is negative, the plan will be referred back to the Conflict of Interest in Research Committee for further modification, until a management plan that is acceptable to the CIRC and IRB is developed.

Possible Questions About Conflict of Interest Disclosure
▪ *What do you know about conflict of interest?* ▪ *What do you disclose to participants regarding a financial conflict of interest?*

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Section 8: Accountability and Additional Administrative Requirements

Principal investigators must perform or delegate to authorized research staff all necessary research tasks, including specifically:

- Obtaining IRB approval before research begins;
- Obtaining informed consent of participants prior to study enrollment;
- Conducting continuing review in a timely manner;
- Informing the IRB of any disapprovals, suspensions, or terminations to active research studies; and
- Creating and maintaining accurate records.

The PI is responsible for proper conduct of the study and fulfillment of related obligations, including specifically:

- Appropriate training for all study team members on protocol and safety issues;
- Cooperating with investigations/inspections by authorized internal oversight activities as well as external reviews; and
- Supporting student researchers and the protection of human participants in the students' research, if applicable.

Researchers may contact the Institutional Official, **Laurie Locascio**, Vice President of Research, or **Joseph Smith**, Director of the HRPP, to obtain answers to questions, express concerns, or share suggestions regarding the HRPP.

Possible Questions About Accountability and Additional Administrative Requirements
▪ *Who prepares the IRB application and who submits the application?* ▪ *Who communicates with the IRB?* ▪ *What are the qualifications of your study team?* ▪ *How does your study team work together (delineation of roles)?* ▪ *How do you communicate within your team?* ▪ *How are you trained in the details of the study protocol?* ▪ *How do you ensure that study protocols are followed?* ▪ *Do you maintain a regulatory file for the study? Where is it?* ▪ *Where are your research records maintained?* ▪ *What kind of workload do you have?* ▪ *Do you have the appropriate resources to conduct the research properly?* ▪ *Do you work on any other studies?*

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Section 9: Education

The **Collaborative Institutional Training Initiative (CITI) Program** provides research ethics education to the research community. The CITI program offers both initial and refresher courses covering human research protections and HIPAA requirements.

The UMD IRB also offers in-person educational sessions for researchers, students, and staff. Online educational resources are **available on the UMD IRB Website**.

Possible Questions About Education
▪ *What kind of training did you receive?* ▪ *What training do you require/provide for your research team?* ▪ *Were you trained in human research, ethics, and carrying out your research duties?* ▪ *How do you verify CITI certification status for yourself and other study team members?*

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Section 10: Additional Resources

- **UMD AAHRPP Accreditation Webpage**
  - **https://research.umd.edu/accreditation**
- **UMD Research Compliance Webpage (includes links to the IRB website)**
  - **https://research.umd.edu/RCO/**
- **AAHRPP**
  - **http://www.aahrpp.org/**
- **Office of Human Research Protections**
  - **http://www.hhs.gov/ohrp/**

Remember! Protecting research participants is a shared responsibility.
UMD IRB staff are available to answer your questions and to help you have a successful interview. If you have any questions, don't hesitate to contact us at: **irb@umd.edu.**

*Document adapted from Northwestern University's *Resources for AAHRPP Accreditation**