

AAHRPP Site Visit 2021: Interview Guide for HRPP Members & Staff

The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) 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: UMD HRPP Policies and Procedures**
- **Section 3: Ethical Conduct of Research and Federal Regulations**
- **Section 4: IRB Review**
- **Section 5: Minimizing Risks to Participants and Protecting Participants' Rights and Welfare**
- **Section 6: Compliance with IRB and Other Review Unit Requirements**
- **Section 7: Obtaining and Documenting Informed Consent and Waiver of Informed Consent**
- **Section 8: Conflict of Interest Disclosure**
- **Section 9: Accountability and Additional Administrative Requirements**
- **Section 10: Education**
- **Section 11: Additional Resources**

Section 1: General Tips

Accreditation largely depends on the interviews conducted by AAHRPP 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:

<i>Role of the IRB</i>
<ul style="list-style-type: none"> ▪ <i>What does the IRB do? What are your responsibilities as an IRB member?</i> ▪ <i>What is the IRB's reputation on campus?</i> ▪ <i>Is the IRB workload fair?</i> ▪ <i>Why does UMD value AAHRPP accreditation? What do you think of it?</i>

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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.

<i>Possible Questions About HRPP Policies and Procedures</i>
<ul style="list-style-type: none"> ▪ <i>Who is the institutional official responsible for research at UMD?</i> ▪ <i>What are the components of the UMD HRPP?</i> ▪ <i>What is your role in the UMD HRPP?</i>

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Section 3: Ethical Conduct of Research and Federal Regulations

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

<p><i>Possible Questions About the Ethical Conduct of Research and Federal Regulations</i></p> <ul style="list-style-type: none"> ▪ <i>What are the three fundamental ethical principles of the Belmont Report?</i> ▪ <i>When was the first time you heard of the Belmont Report?</i> ▪ <i>What is the Common Rule (45 CFR 46)?</i> ▪ <i>What is the Office for Human Research Protections (OHRP)?</i> ▪ <i>What types of research are regulated by the FDA?</i> ▪ <i>What is HIPAA and what is its relevance to human research?</i> ▪ <i>Are there additional requirements for studies sponsored by the DoD, EPA, DOE, or ED?</i>
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Section 4: IRB Review

The IRB must obtain sufficient information prior to review of applications for initial or continuing review so that it can apply and satisfy the requirements for approval of research.

The IRB considers the following with respect to each application for initial, continuing, or modification review:

1. Does the activity described in the IRBNet application meet the definition of human research as defined in the “Common Rule?”
2. Is the activity human research as defined in FDA regulations?
3. Is UMD engaged in the proposed research? Is the research exempt from IRB review?

These determinations informed by the guidance provided by the **US Department of Health and Human Services Human Subject Regulations Decision Charts** and in consultation with IRB administrators or chairs, as appropriate. If the research:|

- **Involves activities or data subject to other rules or regulations** (i.e. HIPPA, HITECH, FERPA, etc.), the review ensures compliance with these external regulations or rules.
- **Is not regulated**, a designated IRB staff member may issue a “non-human research” determination through IRBNet when the Principal Investigator submits a **Human Subjects Research Determination Form**.
- **Is exempt**, an IRB staff member ensures that the application indicates the request for an exempt determination.

Note that UMD may conduct FDA regulated Investigational New Drug(IND) research. If UMD does conduct FDA regulated IND research, the UMD IRB will ensure appropriate expertise in the Board is present to review the research. If the UMD IRB does not have appropriate expertise to review the FDA IND regulated research, it will not conduct the review.

Possible Questions About the IRB Review
<ul style="list-style-type: none"> ▪ <i>What is your process for reviewing a study? Do you utilize guidance or written checklists?</i> ▪ <i>What is the process for scientific review of research at UMD?</i> ▪ <i>Do you consider the scientific validity of studies that you review?</i> ▪ <i>What are the expedited and exempt review categories? When are they used?</i> ▪ <i>What is the difference between human research that is exempt from IRB oversight and research determined to be not-human-subjects research?</i> ▪ <i>What is a continuing review?</i> ▪ <i>Do you know what is not part of an IRB review? Can you give examples?</i> ▪ <i>Are IRB community members recognized as contributing board members?</i>

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Section 5: 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 difference between privacy and confidentiality?*
- *What additional mechanisms can be put in place to protect research participants?*
- *What are the different possible levels of risk associated with a study? How is risk level assigned?*
- *Can sensitive information affect the risk level?*
- *What are your primary concerns when reviewing a protocol?*

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Section 6: Compliance with IRB and Other Review Unit Requirements

Investigators, research staff, and the IRB Board 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 research with human participants must obtain IRB review and approval or a determination of exemption before work can begin.
- 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.
- 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

- *What is the process for continuing review?*
- *What is non-compliance? When is it considered serious and/or continuing?*
- *What is the difference between non-compliance and an adverse event?*

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Section 7: 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?*
- *How can a participant obtain information about human protections at UMD?*
- *When reviewing a consent form, what do you look for?*
- *Describe the informed consent process.*
- *Describe the waiver of informed consent process*

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Section 8: 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.

<i>Possible Questions About Conflict of Interest Disclosure</i>
<ul style="list-style-type: none"> ▪ <i>What is a conflict of interest?</i> ▪ <i>How does UMD assess and manage conflicts of interest?</i> ▪ <i>What should be disclosed to subjects regarding a financial conflict of interest?</i> ▪ <i>Does the IRB view and approve COI management plans for human research?</i> ▪ <i>What do you do if you have a conflict of interest related to a protocol you are reviewing?</i>

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Section 9: 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

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| <ul style="list-style-type: none"> ▪ <i>Do you think you have access to adequate resources to perform your duties related to the protection of humans in research?</i> ▪ <i>What sort of support do you receive from UMD's administration?</i> ▪ <i>To whom do you go for help on issues, be they regulatory or ethical?</i> ▪ <i>How is communication facilitated throughout the HRPP? Is this an effective system?</i> ▪ <i>Is the IRB workload reasonable?</i> |
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Section 10: Education

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

All new IRB members and HRPP staff must complete a two (2) hour new member orientation. The IRB Chair and/or the Director conduct the orientation. HRPP policies and procedures are reviewed and explained and OHRP training videos are shown.

The Orientation Packet includes the following materials:

1. IRB Membership Roster;
2. Code of Federal Regulations 45 CFR §46;
3. The Belmont Report;
4. Federal Wide Assurance (FWA 00005856);
5. HRPP Policies and Procedures;
6. All current UMCP IRB Forms;
7. Copy of the IRB Member Handbook by R. Amdur.

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

Possible Questions About Education

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| <ul style="list-style-type: none"> ▪ <i>Describe the training you've had to be qualified to review human research projects.</i> ▪ <i>What sort of continuing education do you receive related to research ethics and human research?</i> ▪ <i>What ongoing professional meetings/trainings are offered or have you attended?</i> ▪ <i>How do university officials keep you informed of new developments in human research regulations?</i> |
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Section 11: 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**.