Preparing for the 2021 AAHRPP Site Visit: *What Should I Know?*

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Site Visit Tips

AHHRPP will conduct interviews with UMD Human Research Protections Program (**HRPP**) stakeholders. This presentation acts as a refresher for key concepts regarding our HRPP that you - as a member of the UMD research community – should know. Following this presentation, you will:

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

UMD HRPP Overview - Structure

- **Mission:**
  - Ensure the protection of human participants who choose to participate in research conducted by investigators at and affiliates with UMD.

- **Laurie E. Locascio, PhD** (the Vice President of Research) serves as the **Institutional Official (IO)** for the UMD HRPP

- **Joseph M. Smith, MA** serves as the Director for the UMD HRPP.

UMD HRPP Overview - Structure

- **The UMD HRPP is supported by:**

  - 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.

UMD HRPP Overview - Policies

- **The primary sources of information on the UMD IRB's policies and procedures can be found in:**
  - The HRPP Standard Operating Procedures
  - The Investigator Handbook
  - The UMD IRB's Website: https://research.umd.edu/irbprocess

Ethical Conduct

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

Contains 10 basic ethical principles for human research:

1. Obtain voluntary consent of the participant.

2. Design the study to yield results for the good of society, otherwise unobtainable through other means.

3. Base studies involving humans on animal experiments.

4. Avoid physical and mental suffering and injury to the participant or others.

5. Do not conduct the study if death or disabling injury is an expected result.

6. The degree of risk should never exceed the humanitarian importance of the problem to be solved by the research.

7. Protect the participant from injury, disability, or death.

8. Be scientifically qualified to conduct the study.

9. Allow the participant to voluntarily withdraw at any time.

10. Be prepared to stop the study when continuation is likely to result in injury, disability, or death to the participant.

The Belmont Report

Identifies and summarizes three main ethical principles that should govern research with human subjects:

1. Respect for persons (autonomy/voluntary participation/adequate information)

2. Beneficence (risks of research are reasonable in relation to the benefits the research may provide to subjects or science)

3. Justice (selection of subjects is equitable and is representative)

The Common Rule (45 CFR 46)

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.

IRB Review

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?

For more information on the UMD IRB Review Process, please see:
https://research.umd.edu/irbprocess#Review

Participant Risks, 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 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.

☐ Enhancing protection for vulnerable participant populations.

Obtaining Informed Consent

Investigators are responsible for obtaining and documenting informed consent before the research begins. 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.

- 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 study-specific or general participant rights questions.

- A clear confirmation of consent from the participant (written, verbally, online selection, etc.).

Researcher Compliance

Investigators and their staff must ensure research is in compliance with the IRB and other institutional and regulatory requirements:

- All Investigators must apply for IRB approval **before soliciting and working with human subjects**.

- 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.

- Unanticipated problems involving risks 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.

Researcher Conflict of Interest

A conflict of interest (COI) in research is an interest that relates to and could significantly affect the design, conduct, or reporting of the funded research. Potential COI's are identified through <u>annual and continual disclosure requirements for investigators</u>.

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

- 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

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

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

Researcher Accountability

- **PI's must:**
  - Obtain IRB approval before research begins;
  - Obtain informed consent prior to enrollment;
  - Inform the IRB about any study changes/problems;
  - Ensure appropriate HSR training for all team members;
  - Create and maintain accurate records including data management

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.

Researcher Education

- **Collaborative Institutional Training Initiative (CITI) Program**
  - Provides research ethics education to the research community
  - Courses required for UMD IRB Approval:
    - Biomedical and/or Social and Behavior Research
  - www.citiprogram.org
- For additional training opportunities, see:
  - https://research.umd.edu/irbtraining

Additional Resources

- **UMD AAHRPP Accreditation webpage:**
  - https://research.umd.edu/accreditation
- **UMD Research Compliance Webpage:**
  - https://research.umd.edu/RCO/
- **AAHRPP:**
  - http://www.aahrpp.org/
- **Office of Human Research Protections (Federal):**
  - 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.**