AAHRPP Site Visit 2020: Interview Guide for Administrators

Accreditation
AAHRPP, or the Association for the Accreditation of Human Research Protection Programs, will conduct an accreditation site visit at WMed on March 17, 2020 and March 18, 2020. AAHRPP is an international, independent nonprofit organization that reviews and accredits an institution’s human research protection program (HRPP).

AAHRPP has been provided with a written description of our WMed’s Human Research Protection Program (HRPP) and Institutional Review Board (IRB) Policy Manual, 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 our policies have been implemented effectively and are being adhered to throughout the medical school.

As a WMed administrator, you are an integral part of the WMed HRPP. During the site visit, AAHRPP has selected 40 individuals to be interviewed. Each session will take between 20-45 minutes. Sessions will be in the form of individual or group interviews. We expect questions to be focused on regulatory and ethical issues related to research with human participants, but questions may also relate to your impressions of the HRPP and IRB at WMed. We recommend that you respond directly to the question asked. If a question seems unrelated to the type of work you do, please let the interviewers know.

Common Rule Implementation
In preparation for the updated Common Rule, which went into effect on January 21, 2019, the WMed HRPP implemented the burden-reducing provisions which included the elimination of continuing review for non-exempt, non-FDA or DOD minimal risk studies, and clarification of the activities that do not meet the definition of human research. The IRB Office also made relevant updates to the protocol templates, as well as consent form templates.

The most significant change for the WMed HRPP is the broadening of the type of secondary research that can be done under exemption category 4. This has impacted the WMed HRPP because:

- The requirement that all study data be existing at the time of IRB submission has been eliminated. Data under this exemption may be both retrospective and prospective.
- Creating a de-identified dataset for analysis is still an approvable option and continues to be the most straightforward approach.

If investigators need to retain data that contains any HIPAA elements or need to retain a linking list, then appropriate HIPAA protections could make the project approvable. Depending on the circumstances of the data, the HIPAA protections might include a waiver of HIPAA authorization.

The WMed HRPP did not implement Broad Consent (consent process for use only for the storage, maintenance and secondary use of indefinable private information or identifiable bio specimens for future, yet-to-be-specified research) because it was optional and the regulatory agencies have not distributed formal guidance.

Preparing for the Site Visit
Early preparation is key and this document is intended to help you prepare. You may be familiar with the information included however, this guide is provided so that you can refresh your understanding. 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: Ethical Conduct of Research and Federal Regulations**
- **Section 4: Minimizing Risks and Protecting Participants’ Rights and Welfare**
- **Section 5: Compliance with IRB and Other Review Unit Requirements**
Section 1: General Tips
WMed HRPP accreditation depends largely on these interviews. You will be expected to:

- Understand the WMed HRPP structure
- Clearly describe your role in the WMed HRPP
- Be familiar with the WMed IRB and HRPP Policy Manual, January 2020
- Understand the AAHRPP accreditation process
- Understand and describe the ethical aspects, the purpose, and the value of your work
- Know the process for non-compliance reporting at WMed
- Know human research training requirements and resources at WMed
- Know IRB application (iMedRIS) terminology
- Understand what constitutes conflict of interest at all levels (i.e. staff, IRB, institution)
- Understand how a conflict of interest is managed at WMed

Possible General Questions

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<th>Role of the IRB</th>
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<td>What does the IRB do?</td>
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<td>What is the IRB’s reputation at WMed?</td>
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<td>What do you think about the IRB and their efforts to protect human subjects?</td>
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<tr>
<td>Why does WMed value AAHRPP accreditation?</td>
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<td>What do you think of it?</td>
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Section 2: HRPP Policies and Procedures
The following section summarizes key elements of WMed IRB’s policies and procedures with which you should be familiar for your interview. The source of this information is Organizational Policy Human Research Protection Program (HRP01).

Hal B. Jenson, M.D, the dean of the medical school, serves as the Institutional Official (IO) for WMed and is responsible for the overall conduct of research at the Institution. The duties of the Institutional Official include:

- Fostering, supporting, and maintaining an organizational culture that promotes and facilitates the ethical conduct of all research involving human subjects and the adherence to regulations and organizational policies;
- Ensuring that the IRB functions independently by, among other mechanisms, being directly accessible to the IRB Chair(s) and member if they experience undue influence or if they have concerns about the function of the IRB;
- Oversight of the IRB;
- Oversight of the conduct of research conducted by all WMed investigators;
- Ensuring the IRB members are appropriately knowledgeable to review research in accordance with ethical standards and applicable regulations;
• Ensuring that all investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and applicable regulations;
• Oversight of the development and implementation of an educational plan for IRB members, staff and investigators;
• Serving as the signatory authority and ensuring compliance with the terms of the Federal wide Assurance to the Office of Human Research Protections; and
• Providing support to the HRPP by ensuring that the HRPP has sufficient staff and resources to fulfill its role and obligations.

The HRPP is supported by:

- Research compliance which includes the Institutional Review Board (IRB), Sponsored Program Administration (SPA), Institutional Biosafety Committee (including radiation) and the Research Integrity Officer (RIO) who oversees the conflict of interest program.
- WMed departments in which faculty, staff, medical students, and residents are engaged in human research.
- The IRB and IRB Committee members.
- Key executive and administrative offices including the Office of Technology Development and ancillary departments (e.g. IT, Epi/Bio).

The mission of WMed Human Research Protection Program plan is to protect the rights and welfare of participants involved in human research that is overseen by this Institution.

Possible Questions About HRPP Policies and Procedures

- Who is the institutional official responsible for research at WMed?
- Who is the institutional official/organizational official responsible for the WMed HRPP?
- What is the WMed HRPP?
- What is your role in the WMed HRPP?
- What is the guiding philosophy of the HRPP at WMed University?
- What does administration do to support human research activities?

Section 3: Ethical Conduct of Research and Federal Regulations

WMed fosters a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of WMed. All members of the WMed community involved in human research are expected to comply with the highest standards of ethical and professional conduct in accordance with federal and state regulations as well as institutional and IRB policies governing research involving humans.

The review and conduct of research at WMed is guided by principles set forth in the Belmont Report and performed in accordance with Department of Health and Human Services (DHHS) regulations (45 CFR 46 or the “Common Rule”), and Food and Drug Administration (FDA) regulations (21 CFR 50, 21 CFR 56), as well as all other applicable federal, state, and local laws and regulations.

- The Belmont Report identifies and summarizes three main ethical principles that should govern human research:
  o Respect for persons (autonomy/voluntary participation/adequate information)
  o Beneficence (risks of research are reasonable in relation to the benefits the research may provide to subjects or science)
  o Justice (selection of subjects is equitable and is representative)
The Common Rule (45 CFR 46) is the federal regulatory framework that governs federally funded 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) information or bio specimens through interaction or intervention with the individual, and uses, studies or analyzes the information or bio specimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable bio specimens.

21 CFR 50 and 21 CFR 56 serve as the regulatory framework for research regulated by the FDA (i.e., research involving drugs, devices, and biologics). This set of regulations is derived from the Common Rule, but there are some notable differences in their content.

Other federal and state laws and regulations that apply to research (i.e. Family Educational Rights and Privacy Act [FERPA], Health Insurance Portability and Accountability Act [HIPAA], 21st Century Cures Act, General Data Protection Regulation [GDPR], and National Institutes of Health Policy on the Use of a Single Institutional Review Board for Multi-Site Research).

WMed HRPP/IRB Policy Manual

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<th>Possible Questions About the Ethical Conduct of Research and Federal Regulations</th>
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<tr>
<td>What is ethical research?</td>
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<td>How do you communicate University values and ethical messages to your associates and institution?</td>
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<tr>
<td>What are the three fundamental ethical principles of the Belmont Report?</td>
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<td>When was the first time you heard of the Belmont Report?</td>
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<tr>
<td>What is the Common Rule (45 CFR 46)?</td>
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<td>What are OHRP, FDA, and HIPAA?</td>
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Section 4: Minimizing Risks and Protecting Participants’ Rights and Welfare

Minimizing risks to participants and ensuring participants rights and welfare are key components of human research protections. Below are some strategies through which these goals can be accomplished.

- Design and implement protocols that comply with applicable regulatory and institutional policies, as well as the principles of the Belmont Report.

- Verify procedures are consistent with sound research design by ensuring that the research is reasonably expected to answer the proposed question and that the resulting knowledge is expected to be sufficiently important to justify the research.

- Ensure that recruitment procedures foster the equitable selection of participants.

- Utilize procedures already being performed for diagnostic or treatment purposes, when possible.

- Ensure that appropriate resources are available to conduct the research (e.g., personnel, facilities, equipment, etc.).

- Establish adequate provisions for monitoring participants to identify adverse events and to review data collected to ensure participant safety, when appropriate.
• Develop plans for protecting participant privacy and the confidentiality of data. In human research, these terms are defined as follows:
  o Privacy – Relates to an individual having control over the extent, timing, and circumstances regarding the sharing of information about themselves with others.
  o Confidentiality – Relates to the protection of a participant’s data that has been shared with the researcher with the expectation that it will be protected and not disclosed.

• Put in place enhanced protection for participants vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, cognitively impaired individuals, etc.).

Possible Questions About Minimizing Risks & Protecting Participants’ 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?

Section 5: Compliance with IRB and Other Review Unit Requirements
Research at WMed must be conducted in compliance with IRB, as well as other institutional and regulatory requirements. Below are some requirements that you should be aware of related to this responsibility.

• All research with human subjects must obtain IRB review and approval or a determination of exemption before work can begin.

• IRB disapproval decisions may be appealed to the IRB, but cannot be overruled by any other institutional official or organization.

• The requirements of the IRB (i.e., initial review, continuing review, modifications, and reporting of adverse events and unanticipated problems) must be met and 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.).

• Reportable New Information, including unanticipated problems involving risks to subjects or others (UAP’s) must be reported to the IRB within 7 business days of after the investigator first learns of the event.
  o UAP – Any information, including any incident, experience, or outcome that meets ALL of the following conditions:
    1. is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied;
    2. is related or possibly related to participation in the research ("possibly related" means...
there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. indicates that human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

- 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 or discovered during the course of quality assurance activities. Participants being exposed to unnecessary risk may also be reported as potential non-compliance.

The goal of the HRPP/IRB is to enhance the caliber of research and increase the effectiveness of the institution’s Human Research Protection Program (HRPP) through education and compliance initiatives. Post-approval monitoring and/or for-cause audits are performed to ensure the research complies with the federal regulations, guidelines and institutional policies that govern research. Post approval monitoring and directed review activities aims to ensure the rights participants are protected; researchers and staff have educational resources that enables them to fulfill their roles as investigator and study staff; and the research community has access to study support tools and other compliance related resources.

**Possible Questions About Compliance with IRB and Other Review Unit Requirements**

- What does the IRB do?
- In a dispute between IRB and a researcher, can an administrator overrule IRB’s decision?
- How do you handle complaints regarding the IRB system?

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**Section 6: Obtaining and Documenting Informed Consent**

Informed consent is the voluntary choice of an individual to participate in research based on a complete and accurate understanding of the study. Informed consent is not a single event or document but rather an ongoing process involving the investigator (or designees) and the research participant. Informed consent requires full disclosure of the nature of the research, the participant’s role in that research, an understanding of that role by the potential participant, and the participant’s voluntary choice to join the study. For more information on obtaining and documenting informed consent, please review HRPP/IRB Policy Manual, Section 11: Obtaining Informed Consent from Research Subjects

- Investigators are responsible for obtaining and documenting informed consent before the research begins unless the IRB waives this requirement.
- Informed consent must be conveyed in language that is understandable to participants or their legally authorized representative.
- Consent must be sought under circumstances that minimize potential for coercion or undue influence.
- Time for questioning between the initial request for participation and the final decision as recorded in the consent document should be allowed.
- It must be made clear to participants that their participation is voluntary and that they may withdraw at any time with no penalty.
- Consent is documented by use of a consent form approved by an IRB unless a waiver of informed consent or a waiver of documentation of informed consent is granted.
The Common Rule (45 CFR 46.116 (a)) outlines the **required elements of informed consent**.

- 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.

**Possible Questions About Informed Consent**

- What is the process of consent?
- How can a participant obtain information about human research protections at WMED?

**Section 7: Conflict of Interest Disclosure**

**Conflict of Interest** is a situation in which an individual’s financial, professional or other personal considerations may directly or indirectly affect, or have the appearance of affecting, his or her professional judgment in exercising any University duty or responsibility. A conflict of interest in research is a significant financial interest that relates to and could directly and significantly affect the design, conduct or reporting of the funded research, or present the appearance thereof.

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 WMED or affiliates in compliance with the HRPP / IRB Policy Manual.

Potential COI’s are identified through completed disclosures for the investigator, and study team member(s) at the time of new study submission, continuing review, with the addition of a new researcher, and whenever a researcher updates their disclosure indicating a new or changed interest related to the research. The Research Integrity Officer (RIO) reviews positive disclosures made by researchers and notifies the researcher(s) and the HRPP / IRB staff that either no researcher conflict was identified and/or that one or more researchers has an interest that requires further review. In the event a conflict that requires management is identified, the Research Integrity Officer provides to the IRB in writing a summary of the conflict, and also the conflict management plan approved by the associate dean for research and the Research Integrity Officer. If the associate dean for research, associate dean for finance administration, and the Research Integrity Officer have not completed the review, the IRB defers the research study review or prohibits participation by the researcher with a potential conflict until the review process is completed and the results are made available to the IRB. As part of the review process, the IRB makes a final determination as to whether any conflict of interest or commitment is adequately addressed and protects the human subjects in the research.

**Possible Questions About Conflict of Interest Disclosure**

- Do you understand the WMED COI policies and how COIs may influence the protection of human research participants?
- What is your role in managing conflicts of interest and institutional conflict of interest?
Section 8: Accountability and Additional Administrative Requirements
Principal Investigators (PI’s) must perform, or delegate, to qualified research staff all necessary tasks to carry out research. This includes: obtaining IRB approval before research begins; securing informed consent of participants prior to study enrollment; conducting continuing review in a timely manner; informing the IRB of any disapprovals, suspensions or terminations by other review units; and the creation and maintenance of accurate records. The PI is ultimately responsible for proper conduct of the study.

Researchers may contact Maureen Owens, Director, HRPP, or Amy Shipley, Assistant Director for Research Compliance, with additional questions, express concerns, or share suggestions regarding the HRPP. Please take some time to review:
Organizational Policy Human Research Protection Program (HRP01)
HRPP/IRB Policy Manual, Section 1: Human Research Protection Program

Possible Questions About Accountability and Additional Administrative Requirements
- Do have access to adequate resources to perform your duties related to human research?
- Does the organization provide support for review and negotiation of contracts?
- To whom do you go for help on issues, be they regulatory or ethical?

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 WMed HRPP/IRB also offers in-person educational sessions for researchers, students, and staff. Online educational resources are available on the WMed HRPP/IRB Website.

Possible Questions About Education
- What education must an investigator complete to be qualified to participate in human research?
- Were you trained in human research/ethics/carrying out research duties, etc.?
- How do you verify CITI certification status?
- How do university officials keep you informed of new developments in human research regulations?

Remember! Protecting research participants is a shared responsibility.
WMed HRPP Director is available to answer your questions and to help you have a successful interview.

Section 10: Additional Resources
- WMed AAHRPP Accreditation Webpage
- WMed Website
- Institutional Policy Human Subject Protection Program (HRP-01)
- AAHRPP
- Office of Human Research Protections