AAHRPP Site Visit 2020:  
Interview Guide for IRB Members & Staff

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 protections program (HRPP). Long regarded as the gold standard, AAHRPP accreditation is becoming the norm for quality research programs; this will be WMed’s first visit for accreditation.

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 IRB member or staff, 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: IRB Review
- Section 5: Minimizing Risks and Protecting Participants’ Rights and Welfare

Western Michigan University Homer Stryker M.D. School of Medicine (WMed)
AAHRPP Accreditation, 2020

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Section 6: Compliance with IRB

Section 7: Obtaining and Documenting Informed Consent and Waiver of Informed Consent

Section 8: Conflict of Interest Disclosure

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Section 1: General Tips

WMed HRPP accreditation depends largely on these interviews. You will be expected to:

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

Possible General Questions

### Role of the IRB

- What does the IRB do?
- What are your responsibilities as an IRB member?
- What is the IRB’s reputation at WMed?
- Is the IRB workload fair?
- Why does WMed value AAHRPP accreditation?
- What do you think of it?

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 mission of WMed 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 WMed?
• What are the components of the WMed HRPP?
• What is your role in the WMed HRPP?

Section 3: Ethical Conduct of Research and Federal Regulations

WMed 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 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**

### Possible Questions About the Ethical Conduct of Research and Federal Regulations

- What are the three fundamental ethical principles of the Belmont Report?
- When was the first time you heard of the Belmont Report?
- What is the Common Rule (45 CFR 46)?
- What is the Office for Human Research Protections (OHRP)?
- What types of research are regulated by the FDA?
- What is HIPAA and what is its relevance to human research?
- Are there additional requirements for studies sponsored by the DoD, DOE?

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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 iMedRIS 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 WMed 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** if the research:

- Involves activities or data subject to other rules or regulations (i.e. HIPPA, FERPA, etc.), the review ensures compliance with these external regulations or rules.
- Is not regulated, the Chair/Designee may issue a “non-human research” determination through iMedRis when the Principal Investigator submits a non-regulated application.
- Is exempt, an IRB staff member assigns the IRB Chair / Designee the request for an exempt determination.
Note that WMed may conduct FDA regulated Investigational New Drug (IND) research. If WMed does conduct FDA regulated IND research, the WMed IRB will ensure appropriate expertise in the Board is present to review the research. If the WMed IRB does not have appropriate expertise to review the FDA IND regulated research, it will not conduct the review.

Possible Questions About the Ethical Conduct of Research and Federal Regulations

- What is your process for reviewing a study? Do you utilize guidance or written checklists?
- What is the process for scientific review of research at WMed?
- Do you consider the scientific validity of studies that you review?
- What are the expedited and exempt review categories? When are they used?
- What is the difference between human research that is exempt from IRB oversight and research determined to be not-human-subjects research?
- What is a continuing review?
- Do you know what is not part of an IRB review? Can you give examples?
- Are IRB community members recognized as contributing board members?

Section 5: 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:
  - Privacy – Relates to an individual having control over the extent, timing, and circumstances regarding the sharing of information about themselves with others.
  - 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, mentally disabled persons, etc.).
Section 6: 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.

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

- Research must be conducted as specified in the IRB-approved protocol.

- Materials must be submitted to the IRB in a timely fashion (e.g., requests for changes, continuing review applications, etc.).

- 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.

- 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?
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 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 (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 practically carried out without the waiver; 4) Whenever appropriate, the participants will be provided with additional pertinent information after participation.
Possible Questions About Informed Consent

- What is the process of consent?
- How can a participant obtain information about human research protections at WMed?
- When reviewing a consent form, what do you look for?
- Describe the informed consent process.
- Describe the waiver of informed consent process.

Section 7: Conflict of Interest Disclosure

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.

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

- What is a conflict of interest?
- How does WMed assess and manage conflicts of interest?
- What should be disclosed regarding a financial conflict of interest?
- Does the IRB review and approve COI management plans for human research?
- What do you do if you have a conflict of interest related to a protocol you are reviewing?

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;
- 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; and,
- Creating and maintaining accurate records.

The PI is ultimately 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 Maureen Owens, Director, HRPP, or Amy Shipley, Assistant Director for Research Compliance, with additional questions, express concerns, or share suggestions regarding the HRPP.

Possible Questions About Accountability and Additional Administrative Requirements

- Do you think you have adequate resources to perform your duties related to human research?
- What sort of support do you receive from WMed’s administration?
- To whom do you go for help on issues, be they regulatory or ethical?
- How is communication facilitated throughout the HRPP? Is this an effective system?
- Is the IRB workload reasonable?

Section 9: Education

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. Each member receives the book: Institutional Review Board Member Handbook by Robert Amdur and Elizabeth A. Bankert. Also a 90 minute appointment with the Chair and the HRPP Director is scheduled with any new IRB Member or Alternate to complete training.

Possible Questions About Education

- Describe the training you’ve had to be qualified to review human research projects.
- What sort of continuing education do you receive related to research ethics and human research?
- What ongoing professional meetings/trainings are offered or have you attended?
- How does the medical school 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