AAHRPP Site Visit 2020:
Interview Guide for Researchers & Research 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).

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 researcher or research 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 issues related to research with human subjects, but questions may also relate to the conduct of your research, as well as your impressions of the HRPP and IRB at WMed. If you were selected for an interview based on a specific type of protocol (e.g., drug, device, community research etc.), please review your procedures for conducting that kind of research.

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: Roles and Responsibilities of Investigators and Research Staff
- Section 4: Minimizing Risks and Protecting Participants’ Rights and Welfare
- Section 5: Compliance with IRB and Other Review Unit Requirements

Western Michigan University Homer Stryker M.D. School of Medicine (WMed)
AAHRPP Accreditation, 2020
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- Section 6: Obtaining and Documenting 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
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
- Know where to find WMed policies
- Know how to report noncompliance 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 IRB application (iMedRIS) terminology, and describe your IRB submissions
- Understand what constitutes conflict of interest
- Know how a potential conflict of interest is disclosed and reviewed at WMed
- Describe the human subjects training that you had: (e.g. CITI)
- Know how to recruit subjects ethically and in an equitable manner while adhering to inclusion/exclusion criteria

If interviewed, 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 interviewer(s) know. For example, if a question regarding Food and Drug Administration (FDA) regulations is asked, a social/behavioral researcher should let the interviewer(s) know that drugs or medical devices are not part of their research. Below are examples of the type of general questions you might be asked.

Possible General Questions

About your Project(s)

- Describe your study. What are the procedures? How do you recruit? What is the consent process?
- What kinds of harms can occur in your study? How do you minimize those harms?
- Do you communicate results with your subjects after the completion of your research?
- How did you interact with the IRB on this study?

Relationship with the IRB

- What is AAHRPP accreditation and why is it important to WMed?
- What is the IRB’s reputation?
- 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 subjects?
- Do you know how often the convened (full) IRB meets?
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 HRPP / IRB Policy Manual, Section 19.

Investigator Responsibilities

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 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 purpose of the HRPP is to protect the rights and welfare of human subjects participating in biomedical and behavioral research conducted at WMed or elsewhere by University faculty, staff, students, and residents; promote compliance with relevant legal requirements and ethical standards at all levels; and support investigators in their research activities.

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

Section 3: Roles & Responsibilities of Investigators and Research Staff
Investigators have primary responsibility for protecting the rights and welfare of human subjects. Safeguarding human subjects takes precedence over the goals and requirements of any research endeavor. The principal investigator (PI), and other members of the research team are expected to be knowledgeable about and adhere to:

- **The Belmont Report** identifies and summarizes three main ethical principles that should govern human research:
  - 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)** 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 primary responsibilities in conducting the research?
- What is the Common Rule?
- What are the three fundamental ethical principles of the Belmont Report?
- When was the first time you heard of the Belmont Report?
- What are OHRP, FDA, and HIPAA?

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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:

  - **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, cognitively impaired individuals, etc.).

### Possible Questions About Minimizing Risks & Protecting Participants’ Rights and Welfare

- What is the process of scientific review for your research?
- Do you know the difference between minimal and minor increase over minimal risk?
- What is the difference between privacy and confidentiality?
- How do you protect subject privacy and confidentiality of data?
- How/who do you recruit for your research?
- How do you ensure that only subjects meeting the inclusion criteria are enrolled?
- What additional mechanisms do you have in place to protect your research subjects?

### 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.

  - **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.

### 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 subject complaint or a problem with your study?
- What is an unanticipated problem regarding risks to subjects or others (UAP)?
- Have you ever had one on a study?
- How would you report an adverse event or a UAP?
- Do you know what noncompliance is and when and how to report it?

### 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)) requires that informed consent include:
- A statement that the study involves research;
- Information on the purpose of the research;
- The expected duration of subject participation;
- A description of the procedures (identification of experimental procedures);
- A description of reasonably foreseeable risks or harms;
o A description of any benefits to subjects or others;
o Disclosure of appropriate alternative treatments/procedures, if the research involves clinical treatment;
o A description of how the confidentiality of records will be maintained;
o A description of procedures related to compensation for injury, if the research is more than minimal risk;
o Contact information for the PI and IRB; and
o A statement that participation is voluntary and that the subject may withdraw at any time with no penalty or loss of benefits.

- 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.

### Possible Questions About Obtaining and Documenting Informed Consent

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

### Section 7: Conflict of Interest Disclosure

A 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

Conflicts of Interest and Commitment (GEN04), serves as the IRB research conflict of interest policy. The medical school IRB collaborates with the Research Integrity Officer (RIO) to ensure that conflicts of investigators and research staff are identified and managed before the IRB completes its review of any research application. Each study team member listed on the IRB application is required to complete a Project/Research Conflict of Interest Form in iMedRIS before the application can be submitted for IRB review. For research
involving human subjects for which a COI determination is made, management plan information is provided by the RIO to the WMed IRB and external IRB, if applicable, so that the IRB can assess whether or not the management strategies adequately protect the rights and welfare of human research participants.

For IRB purposes, review of completed disclosures for the investigator, and study team member(s) are required at the time of new study submission, continuing review, with the addition of a new researcher, and whenever a researcher updates their medical school IRB conflicts disclosure indicating a new or changed interest.

**Possible Questions About Conflict of Interest Disclosure**

- What do you know about conflict of interest?
- What do you disclose to subjects regarding a financial 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**

- 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?

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

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