AAHRPP Site Visit 2016:
Interview Guide for Administrators

Accreditation

AAHRPP, or the **Association for the Accreditation of Human Research Protection Programs**, will conduct a reaccreditation site visit at U-M from **March 30, 2016 – April 1, 2016**. AAHRPP is an international, independent nonprofit organization that reviews and accredits an institution's human research protections program (HRPP). U-M has been accredited by AAHRPP since 2008.

AAHRPP has been provided with a written description of U-M's 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 have been implemented effectively and are being adhered to throughout the university.

As a research administrator, you are an integral part of the U-M HRPP. During the site visit, AAHRPP will select nearly 100 individuals to be interviewed. Anyone who has a role in human subjects research may be selected for an interview. A number of administrators will be interviewed. 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.

We anticipate each session will take between 20-40 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 your impressions of the HRPP and IRBs at U-M. 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.

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, it is important that you 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

U-M's HRPP re-accreditation largely depends on these interviews. You will be expected to:

- Understand the U-M HRPP structure
- Clearly describe your role in the U-M HRPP
- Know the U-M HRPP policies
- Understand the AAHRPP accreditation process
- Understand and describe the ethical aspects, the purpose, and the value of your work
- Know the process for noncompliance reporting at U-M
- Know human subjects training requirements and resources at U-M
- Know IRB application (eResearch) terminology
- Understand what constitutes conflict of interest at all levels (i.e. staff, IRB, institution)
- Understand how a conflict of interest is managed at U-M

Possible General Questions

Role of the IRB

- What does the IRB do?
- What is the IRB's reputation on campus?
- What do you think about the IRB and their efforts to protect human subjects?
- Why does U-M value AAHRPP accreditation? What do you think of it?

Section 2: HRPP Policies and Procedures

The following section summarizes key elements of U-M policies and procedures that you should be familiar with for your interview. The source of this information is the **HRPP Operations Manual**.

Jack Hu, the Vice President for Research (VPR), serves as the **Institutional Official (IO)** for the U-M HRPP, and he is responsible for the conduct of research at the University of Michigan. The VPR established the HRPP at U-M. The HRPP is supported by:

- The U-M Office of Research (UMOR) and its central operating units, including UMOR's HRPP staff, the Office of Research and Sponsored Projects (ORSP), the Office of Human Research Compliance Review (OHRCR), and coordinating committees, such as the IRB Council;
- Academic units, including schools, colleges, and other academic units to which faculty, staff, and trainees engaged in human research are appointed;
- The IRBs (i.e., IRBMED, IRB-HSBS, IRB-Dearborn, and IRB-Flint);
- Other research review and support units and committees, such as the Michigan Institute for Clinical & Health Research (MICHR), the conflict of interest committees (UMOR COI and MEDCOI); and
- Key executive and administrative offices, including the Provost's Office, the Executive Vice President for Medical Affairs, the Chancellors at Flint and Dearborn, and the General Counsel.

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

Generally, the Health Sciences and Behavioral Sciences IRB (IRB-HSBS) has oversight for human subject research conducted by the schools, colleges, and units of the University that comprise the Ann Arbor campus, but that are not part of the Medical School. IRBMED, on the other hand, oversees research conducted at the Medical School and the U-M Health System; while IRB-Dearborn and IRB-Flint oversee research at their respective campuses.

Possible Questions About HRPP Policies and Procedures
▪ Who is the institutional official responsible for research at U-M? ▪ What is the U-M HRPP? ▪ What is your role in the U-M HRPP? What research is under your purview? ▪ What is the guiding philosophy of the HRPP at U-M? ▪ What does your administration do to support human subjects activities?

Section 3: Ethical Conduct of Research and Federal Regulations

U-M 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 U-M. All members of the U-M community involved in human subject research are expected to comply with the highest standards of ethical and professional conduct in accordance with federal and state regulations and institutional and IRB policies governing research involving human subjects.

The review and conduct of research at U-M 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 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)** 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) data through interaction or intervention, or (2) identifiable private information.
- **21 CFR 50** and **21 CFR 56** serve as the regulatory framework for research regulated by the FDA (i.e., research involving drugs, devices, 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. **DoD**, **DOE**, **ED**, **EPA**).
- Institutional policies and procedures.

Possible Questions About the Ethical Conduct of Research and Federal Regulations

- What is ethical research?
- How do you communicate University values and ethical messages to your associates and institution?
- 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 are OHRP, FDA, and HIPAA?
- Are there additional requirements for studies sponsored by the DoD, EPA, DOE, or ED?

Section 4: Minimizing Risks to Subjects and Protecting Subjects' Rights and Welfare

Minimizing risks to subjects and ensuring subjects' rights and welfare are key components of human subjects 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 subjects.
- 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 subjects to identify adverse events and to review data collected to ensure subject safety, when appropriate.
- Develop plans for protecting subject privacy and the confidentiality of data. In human subjects research, these terms are defined as follows:
    - *Subject privacy* – Relates to *individual's* having control over the extent, timing, and circumstances regarding the sharing of information about themselves with others.
    - *Confidentiality* – Relates to the protection of subject *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 subjects vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, mentally disabled persons, etc.).

For further guidance on study risk levels, refer to the **Guidelines for Using Magnitude of Harm in Categorizing Risk Level**.

Section 5: Compliance with IRB and Other Review Unit Requirements

Research at U-M 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, amendments, 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 subjects.
- Materials must be submitted to the IRB in a timely fashion (e.g., requests for changes, contingencies, continuing review applications, etc.).
- Unanticipated problems involving risks to subjects or others (UaPs or sometimes called UPIRSOs) and adverse events (AEs) must be reported to the IRB in a timely manner. These terms are defined as follows:
    - *Unanticipated Problem (UaP)* – An event that is not expected in terms of its nature, severity, or frequency and for which there is a reasonable possibility that the event may have been caused by or linked to the research. The event suggests that the research places subjects or others at *greater risk of harm* than previously known or recognized.
    - *Adverse Event* - Events that involve physiological, social, economic, or psychological harm to subjects. This can also indicate risks of harm to others. AEs include expected and unexpected harmful effects, and unexpected harms of an interaction or intervention.
- Potential noncompliance with laws, regulations, or IRB requirements by the research team or others must be reported, even if this noncompliance was unintentional or discovered during the course of quality assurance activities. Subjects being exposed to unnecessary risk may also be reported as potential noncompliance.
- Protocol deviations, subject complaints, or loss of research data must be reported to the IRB via an Other Reportable Information or Occurrence (ORIO) report.

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?

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 and the participant's role in that research, understanding of that role by the potential participant, and the participant's voluntary choice to join the study.

- 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 subjects 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 the 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 subject obtain information about human subjects protections at U-M?

Section 7: Conflict of Interest Disclosure

A **potential conflict of interest (COI)** exists whenever personal, professional, commercial, or financial interests or activities outside of the university have the possibility (either in actuality or in appearance) of (1) compromising a faculty or staff member's judgment; (2) biasing the nature or direction of scholarly research; (3) influencing a faculty or staff member's decision or behavior with respect to teaching and student affairs, appointments and promotions, uses of University resources, interactions with human subjects, or other matters of interest to the University; or (4) resulting in a personal or family member's gain or advancement at the expense of the University. Family members include spouse, domestic partners and dependents. With respect to research, COIs must be managed to ensure they do not improperly affect, or give the appearance of affecting, the conduct of the research.

Potential financial COIs are identified through annual disclosure requirements and questions in the eResearch IRB and proposal management systems, and are reviewed by the **UMOR COI** or Medical School COI **(MEDCOI)** Committees.

The Standard Practice Guide **(SPG) 201.65-1** represents the overarching university policy on conflicts of interest and conflict of commitment. In addition, the University established operational policies to guide employees in disclosing and managing outside conflicts of interest and commitment and to ensure that clinical trials conducted at U-M are conducted without untoward influence resulting from the University's equity holdings in any start-up company supporting the clinical trials. Please take some time to review the full policies, using the links below (or find them on the COI website):

- **Policy for Identification and Management of Financial Conflicts of Interest**
- **Policy on Institutional Conflict of Interest in Clinical Trials of Drugs, Devices, or Biologics Supported by University Start-up Companies**

Possible Questions About Conflict of Interest Disclosure

- Do you understand the U-M individual COI policy and how this issue may influence the protection of human research participants?
- Do you understand the U-M institutional COI policy and how this issue 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 must perform or delegate to qualified research staff all necessary tasks to carry out research, including specifically, 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 and fulfillment of related obligations.

Researchers may contact the Institutional Official (**Jack Hu, VPR**), the Deputy Institutional Official (**James Ashton-Miller, Associate VPR**), the HRPP Director (**Lois Brako, Assistant VPR**) or the **Office of General Counsel** to obtain answers to questions, express concerns, or share suggestions regarding the HRPP. An anonymous **compliance hotline** is also available for reporting concerns at: **compliancehotline@umich.edu**.

Possible Questions About Accountability and Additional Administrative Requirements

- Do have access to adequate resources to perform your duties related to human research subjects?
- 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 Program for the Education and Evaluation in Responsible Research and Scholarship (PEERRS) is a web-based curriculum that serves as the minimum level of human subjects protection education required for all investigators and key personnel involved in conducting research with human subjects at U-M. Please take a moment to visit the **PEERRS website** and verify your certification status for the required PEERRS courses for your role.

IRB-HSBS and IRBMED also offer in-person educational seminars and consultations for researchers, students, and staff, host courses, and distribute newsletters and educational materials in order to keep the research community apprised of developments related to human subjects research regulation. Online educational resources are **available on the HRPP and IRB websites**.

Possible Questions About Education

- What education must an investigator complete to be qualified to participate in a human subjects project?
- Were you trained in human subjects research/ethics/carrying out research duties, etc.?
- How do you train your staff?
- How do you verify PEERRS certification status?
- How do university officials keep you informed of new developments in human subjects regulation?

Remember! Protecting research participants is a shared responsibility.
HRPP 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: **aahrppvisit@umich.edu**.

Section 10: Additional Resources

- **U-M AAHRPP Re-Accreditation Webpage**
  http://research-compliance.umich.edu/human-subjects/aahrpp-re-accreditation
- **U-M HRPP Webpage (includes links to IRB websites)**
  http://research-compliance.umich.edu/human-subjects
- **U-M HRPP Operations Manual**
  http://research-compliance.umich.edu/operations-manual-contents-page
- **PEERRS**
  http://my.research.umich.edu/peerrs
- **AAHRPP**
  http://www.aahrpp.org/
- **Office of Human Research Protections**
  http://www.hhs.gov/ohrp/