AAHRPP Site Visit 2016:
Interview Guide for Researchers and Research Staff

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 researcher or research member, 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 researchers and research staff 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 the conduct of your research, as well as your impressions of the HRPP and IRBs at U-M. If you were selected for an interview based on a specific type of protocol (e.g., international, device, etc.), please review your procedures for conducting that kind of research.

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
- Know your role in the U-M HRPP
- Know where to find HRPP 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 (eResearch) terminology, and describe your IRB submissions
- Understand what constitutes conflict of interest
- Know how a potential conflict of interest is disclosed and reviewed at U-M
- Describe the human subjects training that you had: (e.g. PEERRS, HIPAA training, GCP)
- 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 Own 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 U-M?
- What is the IRB's reputation on campus?
- 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 U-M policies and procedures that you should be familiar with for your interview. The source of this information is the **HRPP Operations Manual**, in particular **Part 6: Roles and Responsibilities of Investigators and Research Staff**.

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

- What U-M official is responsible for research at U-M?
- What are the components of the U-M HRPP?
- Where would you go for help on regulatory or ethical issues?

Section 3: Roles and Responsibilities of Investigators and Research Staff

Investigators are 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), co-investigator (CO-I), and other members of the research team are expected to be knowledgeable about and adhere to:

- **The Belmont Report**, which 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)**, which is the federal regulatory framework that governs research with human subjects and codifies the ethical principles of the Belmont Report. Under the Common Rule, research with human subjects is defined as follows:
  - *Research* – A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

- *Human subject* – A living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through interaction or intervention, or (2) identifiable private information.

- **21 CFR 50** and **21 CFR 56**, which serve as the regulatory framework for research regulated by the Food and Drug Administration (i.e., research involving drugs, devices, biologics). There are some notable **differences between FDA and HHS regulations**.
- Other federal and state laws and regulations that apply to research (i.e. **DoD**, **DOE**, **ED**, **EPA**).
- Institutional policies and procedures.

Possible Questions About Roles/Responsibilities of Investigators and Research Staff

- What is the PI's primary responsibility in conducting the research?
- What is the Common Rule?
- What are the Belmont Principles and when did you first hear of them?
- 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

Investigators and research staff have a responsibility for minimizing risks to subjects and for ensuring subjects' rights and welfare. Below are some strategies through which this 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**.

Possible Questions About Minimizing Risks and Protecting Subjects' 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

Investigators and research staff have a responsibility for ensuring research is conducted in compliance with IRB, as well as other institutional and regulatory requirements. Below are some requirements that investigators and research staff 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, amendments, and reporting of adverse events and unanticipated problems) must be met.
- 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.
- PIs are responsible for the content of all submissions to the IRB (e.g., eResearch application, supporting documents, etc.).
- 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 additional subjects or 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 within eResearch.

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/UPIRSO)? 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 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)) requires that informed consent includes:
    - 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;
    - A description of any **benefits** to subjects or others;
    - Disclosure of appropriate **alternative treatments/procedures**, if the research involves clinical treatment;
    - A description of how the **confidentiality** of records will be maintained;
    - A description of procedures related to **compensation for injury,** if the research is more than minimal risk;
    - **Contact information** for the PI and IRB; and
    - 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 would you consent?
- 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 **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

- 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 must perform or delegate to qualified research staff all necessary tasks to carry out research, including specifically:

- 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 by other review units; and
- Creating and maintaining accurate records.

The PI is also ultimately responsible for proper conduct of the study and fulfillment of related obligations, including specifically:

- Appropriate training for staff 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 subjects in the students' research, if applicable.

Researchers may contact the Institutional Official (**Jack Hu, VPR**), the Deputy Institutional Official (**James Ashton-Miller, Associate VPR**), the HRPP Director (**Lois Brako, Assistant VP**R) or **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

- 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 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.

The IRBs also offer in-person educational seminars and consultations for researchers, students, and staff. Online educational resources are **available on the HRPP and IRB websites**.

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 PEERRS certification status for yourself and other study team members?

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/