AAHRPP Virtual Site Visit 2023: Interview Guide for Investigators

Accreditation

AAHRPP (*pronounced A-HARP*), or the Association for the Accreditation of Human Research Protection Programs, will conduct a virtual accreditation site visit on **Tuesday, February 14 and Wednesday, February 15, 2023**. AAHRPP uses a voluntary, peer-driven and educational model to ensure that a Human Research Protections Program (HRPP) meets rigorous standards for quality and protection. The goals of accreditation are to improve the systems that protect the rights and welfare of individuals who participate in research, and to communicate to the public the strength of an organizations commitment to the protection of human research participants.

Accreditation largely depends on how well TAMU's policies and procedures address the AAHRPP standards. AAHRPP will check our practices by going through our records, first. Then they will check how well we understand and follow the policies and procedures through the interviews.

TAMU was first AAHRPP accredited in June of 2015. The most recent accreditation was awarded in June of 2018.

Interview

You have been selected by AAHRPP to be interviewed during Texas A&M University's reaccreditation site visit. This guidance is intended to help you prepare for your interview, and contains common information that may be touched on by the interviewers. 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 TAMU. 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.

You will present to Blocker Building Room 228 on your designated date. Please arrive at least 15 minutes prior to your appointment to ensure that the site visit remains on schedule. The HRPP staff can assist you with any last minute details or questions you may have.

If you are unable to attend your interview session in person due to being outside the College Station area, you will be emailed a Zoom link with additional instructions a few days before your interview. Please test your equipment and internet connections prior to the interview to ensure you have no technical issues.

AAHRPP representatives will attend the meeting remotely via Zoom. Only the pre-determined individuals on the AAHRPP interview list are allowed to participate. No HRPP staff will be present in the interview room. The interview will not be recorded.

Due to the strict requirements set for the site visit, the HRPP staff will manage meeting sessions and assist key personnel with meeting attendance. Parking is available on the Northside Garage (NGS), upon request. If you do not have a business pass or a NSG parking permit, please contact Shelia Douglas (sedouglas@tamu.edu) **as soon as possible** with your name and address to secure a temporary parking

pass. The temporary parking pass will be mailed to you at the address provided. Please allow at least a week for the temporary parking pass to arrive to your mailbox.

If you are on or near the College Station campus and for some reason unable to come to Blocker Building Room 228 for your interview, you must notify the individuals below as soon as possible.

If you would like additional assistance preparing for your interview, please contact Aliese Seawright (a.seawright@tamu.edu) or Denise Puga (denisepuga@tamu.edu).

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

TAMU HRPP reaccreditation depends largely on these interviews. You will be expected to:

- Know where to find HRPP policies: **HRPP Toolkit**
- Know how to report noncompliance and adverse events
- Understand which activities are overseen by the HRPP and what must be submitted to the IRB
- Know the regulatory standards that apply to your research
- Know IRB application questions, and describe your IRB submissions
- Understand what constitutes conflict of interest
- Know how a potential conflict of interest is disclosed and reviewed at TAMU
- 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
- Understand the concept of respect for persons and the obligation to obtain the consent of participants or their legally authorized representatives
- Know your role and your responsibilities that go along with conducting human subjects research
- Be familiar with the response plan for emergencies and disasters impacting the HRPP and human research.
- Know how to contact your IRB Coordinator for additional assistance or guidance: **My IRB Contact**

Stay current. The AAHRPP site visitors are not interested in old history. They want to know what is going now and your recent experiences.

If interviewed, we recommend that you respond directly to the question asked. Providing information that is not requested is not always helpful.

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 completion of your research?
- How did you interact with the IRB on this study?

Relationship with the IRB

- Why has AAHRPP selected you to be interviewed?
- What are typical turnaround times?
- Are you familiar with the general IRB review process?
- What are typical stipulations/modifications requested by the IRB?
- How did the IRB prepare you to conduct your research?
- How do you feel about the IRB?
- What do you think about the IRB and their efforts to protect human subjects?
- Do you know how often the convened (full) IRB meets? **TAMU Full Meeting Schedule**

Section 2: Introduction to the HRPP

The Human Research Protection Program (HRPP) is composed of all the units and people at Texas A&M that work together to protect the participants that volunteer for research. This is explained in more detail in the next section. The TAMU HRPP has oversight and the responsibility to protect the rights and welfare of participants in research conducted or reviewed by Texas A&M University, including Texas A&M Health and all of its locations, the School of Law, and branch campuses in Galveston and Qatar. Additionally, the TAMU HRPP has agreements with several system agencies for oversight of research conducted by their agents.

Toolkit – Division of Research | **HRP-101 HUMAN RESEARCH PROTECTION PROGRAM PLAN**

Dr. Jack Baldauf, the Vice President for Research, serves as the **Institutional Official (IO)** for Texas A&M University and is responsible for ensuring that the HRPP has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research.

The HRPP consists of many integrated components tasked with protecting the rights and welfare of research participants. The IRB is only one component of the HRPP but has a large responsibility in helping

protect participants in research. Both the HRPP and the IRB communicate with, and rely on, other components of TAMU's integrated program to ensure the rights of research participants are upheld.

The HRPP is supported by the following components:

- Research compliance which includes Biosafety Program (IBC), Animal Welfare Program (IACUC), Export Controls Office, Conflict of Interest, Sponsored Research Services, Radiation Safety Program, Environmental Health and Safety, Office of the Registrar, Privacy Officer, the Chief Information Security Officer and the Office of Compliance and Risk Management.
- TAMU departments in which faculty, staff, and students are engaged in human research (investigators)
- The IRB and IRB Committee members

Possible Questions about HRPP Policies and Procedures

- Who is the official (IO) responsible for research at TAMU?
- Who supports the HRPP?
- Where would you go for help on regulatory or ethical issues?

Section 3: Research requiring IRB review

First, what does an IRB do?

The main mission of the Institutional Review Board is to protect the rights, safety and welfare of research subjects. The IRB is formally designated by the institution and given authority through federal regulations to:

- approve, modify or disapprove research,
- conduct continuing review of already approved research,
- suspend or terminate approval of research,
- to observe or have a third part party observe the consent process and the research.

The IRB reviews and approves research in accordance with the rules and regulations described in section 4 of this document.

Determining whether or not a project requires IRB review can be challenging. For that reason, the HRPP has **HRP 310 Worksheet Human Research** to assist investigators in determining whether or not a research project meets the definition of human subjects research, and **HRP 093 SOP Activities that Require IRB Review** provides a list of activities that may or may not require IRB as a general guide.

Any investigator who is unsure of whether a proposal constitutes "human subjects research" must submit a human subjects research determination (HSRD) request to the IRB via the electronic system. If a HSRD request form does not qualify as human subjects research, the HRPP will issue correspondence stating that the project does not require further IRB review or approval. If the project is determined to meet the regulatory definition of human subjects research, the researcher will be prompted to complete a new project application for IRB review. The HRPP/IRB office makes the final determination on whether or not your project requires IRB review.

The Institutional Review Board (IRB) must review all research involving human subjects conducted by Texas A&M University faculty, staff, and students prior to implementation. IRB approval is required regardless of funding source (or lack thereof) and/or location at which the research will be conducted. Also, any research reviewed by an external IRB must also be submitted to the TAMU HRPP office via an IRB application prior to the involvement of any TAMU agents.

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 (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

The federal regulations (45 CFR 46.102) further define:

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g. venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes
Interaction includes communication or interpersonal contact between investigator and subject.
Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g. medical record)
Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
Identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Possible Questions about Research Requiring IRB review

- How do you determine if your project requires IRB review?
- How do you submit to the HRPP for a Human Subjects Research (HSR) determination?
- Do you have any guidance tools to assist you in identifying if your project requires IRB review?
- What authority does the IRB have?

Section 4: Roles and Responsibilities of Investigators and Research Staff

Although, the IRB looks for procedures that minimize the risks to subjects, it is the investigators that have the 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 ethical guidelines when conducting any type of research regardless of the level of risk or review category (exempt, expedited, full board):

- The **Belmont Report** identifies and summarizes three main ethical principles that govern human research:
  - **Respects 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 part 46**) is the federal regulatory framework that governs federally funded research with human subjects and codifies the ethical principles of the Belmont Report. The TAMU IRB uses the Common Rule as a guide for approving all research regardless of federal support.

  - **Pre-2018 Requirements**: The Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991 and includes four subparts: subpart A, also known as the Federal Policy or the "Common Rule"; subpart B, additional protections for pregnant women, human fetuses, and neonates; subpart C, additional protections for prisoners; and subpart D, additional protections for children. The Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance. TAMU studies approved prior to January 2019 are subject to the pre-2018 Common Rule.

  - **Revised Common Rule:** The Common Rule was revised in January 2019 to strengthen protections for people who volunteer to participate in research, while ensuring that the oversight system does not add inappropriate administrative burdens, particularly to low-risk research by no longer requiring continuing review for non-exempt minimal risk research. Furthermore, the consent document was amended to include a concise introductory explanation of **key information** that would be most important to individuals contemplating participation in a study. Revisions to the Common Rule took effect on January 21, 2019, and all research approved after this date are subject to the Revised Common Rule.

- The **Office for Human Research Protections (OHRP)** oversees operation of the IRB and provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP is the office to which any serious/continuing noncompliance or unanticipated problems are reported.

- The **Food and Drug Administration (FDA)** is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. When submissions include FDA regulated drugs, devices or biologics, TAMU follows the FDA regulations for research, 21 CFR Parts 50 and 56. Specific FDA regulations (Parts 312 and 812) are used as when investigators are conducting research with investigational drugs or devices.

- **TAMU Policies and Procedures:** These include TAMU specific policies as well as federal regulations. Standard Operating Procedures for the Human Research Protection Program are available here: **University Rules and SAPs - Texas A&M University**

- The **Human Research Protection Program (HRPP)** is entrusted to provide support, guidance, and education to the TAMU campuses and its affiliated agencies in support of the mission to protect the rights and welfare of research volunteers. The HRPP has an expansive **plan** to ensure that the rights and welfare of participants in Human Research are protected.

- 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**], General Data Protection Regulation [**GDPR**] .

Possible Questions about the Ethical Conduct of Research and Federal Regulations

- What are your primary responsibilities when conducting human subjects research?
- What is the Common Rule?
- What are the three fundamental ethical principles of the Belmont Report?
- What are OHRP, FDA?
- Do you work with the Privacy Officer to determine how to manage identifiable information?

Section 5: Minimizing Risks and Protecting Participants' Rights and Welfare

A risk is a potential harm or injury associated with the research that a reasonable person in the subject's position would likely consider injurious. Risks can be categorized as physical, psychological, sociological, economic, and legal. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects; and to the importance of knowledge that may reasonably be expected to result from the research.

> **Minimal Risk**: the risks of harm anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. These are risks that reflect background risks that are familiar and part of the routine experience of life for an average person in the general population.
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> **Greater than Minimal Risk**: The probability and magnitude of harm or discomfort anticipated in the research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Research that is greater than minimal risk is reviewed at full board meetings.

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 the proposed research has scientific merit.
- Ensure that recruitment procedures foster the equitable selection of participants and is not just based on convenience. The chosen study population should be justified by the purpose/nature of the research, the research setting and the potential benefits to that population. In addition, the recruitment process should be free of coercion or present no undue influence. Special attention should be given to populations that are more susceptible to coercion or undue influence, such as children, prisoners, cognitively disabled individuals, students, economically or educationally disadvantaged participants. Extra measures of protection should be included in the study protocol when vulnerable populations are included in the research (additional information may be found in Section 6: Enhanced Protections for Vulnerable Populations).
    - **HRP 094 SOP Subject Selection, Recruitment, and Payments**

  - **HRP 315 Worksheet Advertisements**
  - **HRP 316 Worksheet Payments**
- When applicable, utilize procedures already being performed for diagnostic or treatment purposes.
- Ensure that you have the appropriate resources available to conduct the research (e.g., qualified personnel, facilities, equipment, funding, etc.).
- Establish adequate provisions for monitoring participants to identify adverse events or trends that need to be examined. Review the 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.
  - You may access the **Data Classification Tool | IT.tamu.edu** for additional guidance on how to manage research data.
- 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 and Protecting Participants

- What is the process of scientific review for your research?
- 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 6: Enhanced Protections for Vulnerable Populations

Some populations are inherently vulnerable to coercion or undue influence due to a lack of autonomy or ability to understand research procedures. Federal regulations outline specific requirements for conducting human research with children, prisoners, pregnant women, and cognitively impaired adults. Pregnant women need special protections in that research participation may affect their unborn child. Additional groups of participants may also be susceptible to coercion and undue influence such as students, economically or educationally disadvantaged participants. It is important to remember that inability to consent does not limit participation in a study but instead requires that additional safeguards and consent procedures are followed. In certain cases, it may be necessary to consult with experts in specialized areas on protecting vulnerable populations.

Investigators must consider whether subjects to be enrolled in their research might be vulnerable, and if so, what additional measures might be appropriate to provide additional protections. In making the latter determination, investigators should consider:

- Is inclusion of the vulnerable person or population necessary? That is, could the aims of the research be accomplished by enrolling persons or a population that is not (or less) vulnerable?
- Do prospective subjects have difficulty providing voluntary, informed consent? Are condition for informed consent satisfied? (Is information presented in an understandable manner? Do subjects comprehend the details of the research and their rights as research subjects? Is the process of consent conducive to true voluntariness?)

- The extent to which proposed participants are already burdened by poverty, illness, poor education, or chronic disabilities.
- Inconvenience to participants (i.e., the time required, travel involved, restrictions on diet, or other activities), and any discomfort, or potential embarrassment in addition to the risks associated with the research procedures.
- Whether the convenience of the researcher, or possible improvement in the quality of the research, justifies the involvement of participants who may be susceptible to pressure or who are already burdened.
- Whether it is possible to reduce pressure on certain groups of participants to participate in research (such as by consulting with a representative of the group beforehand)
- Whether the selection process overprotects vulnerable participants, such that they would be denied opportunities to participate in research.
- Whether recruitment materials and consent documents are appropriate for the population, and do not include exculpatory language

Additional resources include:

- **HRP 412 Checklist Pregnant Women**
- **HRP 415 Checklist Prisoners**
- **HRP 416 Checklist Children**
- **HRP 417 Checklist Cognitively Impaired Adults**
- **HRP 013 SOP LARs, Children, and Guardians**

Possible Questions about Vulnerable Populations

- Who is considered a vulnerable subject?
- Can you include vulnerable populations in your research?

Section 7: Compliance with HRPP policies

The protection of human subjects participating in research is a shared responsibility between the research community and the institution. The policies and standard operating procedures (SOPs) of the HRPP ensure that TAMU acts responsibly, ethically, and in compliance with federal, state, and local regulations. 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 (typically, research may be granted exempt status by the HRPP if all research activities involve procedures listed in one or more of the specific categories under 45 CFR 46.101(b): **Exemptions (2018 Requirements) | HHS.gov**). Investigator may not make their own exemption determinations.
- IRB disapproval decisions may be appealed to the IRB but cannot be overruled by any other institutional official or organization. There is an appeal process when an investigator disagrees with an IRB decision. See **HRP 052 SOP Post Review**
- The requirements of the IRB (i.e., initial review, continuing review, modifications, and reporting of serious adverse events and unanticipated problems) must be followed and the investigator must follow the protocol approved by the IRB.

- The TAMU HRPP asks all investigators to submit an annual administrative check-in report on all non-exempt research that does not require continuing review.
- 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.).
- Report New Information to the IRB within 5 working days (this topic will be discussed in greater detail in Section 7: Reporting to the IRB)
- Maintain research records in review-ready state at all times for HRPP Post Approval Monitoring and Quality Assurance: **HRP 005 SOP Human Research Protection Program Post Approval Monitoring and Quality Assurance**

Possible Questions about compliance with HRPP policies

- How do you notify the IRB about proposed changes to your research?
- Do you always get IRB approval prior to implementing any changes to an approved IRB protocol?
- Do you follow the approved IRB protocol?
- What changes can be made to a protocol without prior IRB approval?
- Do you ever modify your approved study documents without consulting the IRB first?
- Do you ever allow your IRB approval to expire while still conducting research?

Section 8: Reporting to the IRB

Investigators are required to report certain events that occur during the conduct of a study to the IRB. These events are referred to as Reportable New Information. Report any of the events listed below to the IRB within five (5) working days of the research staff having knowledge of the event. Reportable New Information must be submitted via the electronic system.

If you are unsure whether an event needs to be reported to the IRB or not, please contact your **IRB coordinator** for a consultation.

1. **Harm**: Any harm experienced by a subject or other individual, which in the opinion of the investigator is unexpected and probably related to the research procedures. Example: Serious adverse event or **unanticipated problem**
2. **Risk**: Information that indicates a new or increased risk or a new safety issue. For example: safety monitoring report, drug or device changes, interim analysis, or investigator finding.
3. **Non-compliance:** Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
4. **Audit**: Audit, inspection, or inquiry by a federal agency or government agency.
5. **Report**: Written reports of study monitors or DSMB Reports.
6. **Deviation (researcher error):** Failure to follow the protocol due to the action or inaction of the investigator or research staff.
7. **Confidentiality:** Breach of confidentiality.
8. **Unreviewed change:** Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
9. **Incarceration:** Incarceration of a subject in a study not approved by the IRB to involve prisoners.
10. **Complaint:** Complaint of a subject that cannot be resolved by the research team.

11. **Suspension:** Premature suspension or termination of the research by the sponsor, investigator, or institution.
12. **Unanticipated adverse device effect:** Any serious adverse effect on health or safety or any life-threatening problem or death caused by or associated with a device.

Unanticipated Problems (UAPs): Unanticipated problems, in general, include any incident, experience, or outcome that meets all three of the following criteria:

1. **unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; (b) the characteristics of the subject population being studied; and
2. **is related or possibly related** to the research (this means that it is more likely than not, the incident, experience, or outcome was caused by the procedures involved in the research); and
3. suggests that the research **places subjects or others at a greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

UAPs are "unanticipated" and therefore are generally not previously identified in the consent document. Anticipated problems occurring at a greater severity or frequency than previously expected may qualify as unanticipated problems reportable to the IRB. There are other types of incidents, experiences, and outcomes that occur during the conduct of human subjects research that represent unanticipated problems but are not considered **adverse events**. For example, some unanticipated problems involve social or economic harm instead of the physical or psychological harm associated with adverse events. In other cases, unanticipated problems place subjects or others at increased risk of harm, but no harm occurs.

Adverse events (AE): Any unfavorable and unintended event, including an abnormal laboratory finding, symptom, or disease associated with the research or the use of a medical investigational test article. It does not necessarily have to have a causal relationship with the research.

Use the flowchart in **HRP 029 SOP Reportable New Information** to determine when an adverse event needs to be reported as an unanticipated problem to the IRB. It is important to understand that while adverse events that do not rise to the level of an unanticipated problem do not need to be reported to the IRB, it is still the responsibility of the investigator to keep documentation of any adverse events encountered during the course of research.

HRP 024 SOP New Information Process | **HRP 029 SOP Reportable New Information**

Possible Questions about Reporting to the IRB

- What would you do if you lost your research data and who would you tell?
- What action would you take if a subject complaint cannot be resolved?
- 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 an unanticipated problem in your research?
- Do you need to report all adverse events to the IRB?

- Do you know what noncompliance is and when/how to report it?

Section 9: Obtaining and Documenting Informed Consent

Informed consent is one of the primary ethical requirements underpinning research involving humans; it reflects the basic principle of respect for persons. It should always be remembered that informed consent is **not simply providing a document** to a potential participant. Informed consent is an **ongoing process, not a single event**, designed to provide potential research subjects with all of the relevant information they need to make a fully informed, autonomous decision as to whether they wish to participate in a research study. 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. In general, informed consent is to be documented by the use of a written consent document, approved by the IRB, and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A copy of the consent form should be given to the person signing the informed consent document. For more information on obtaining and documenting informed consent, please review **Informed Consent FAQs | HHS.gov**

- 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 of the participant 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 the informed consent document 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;
    - 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 (six years if an authorization to use or disclose protected health information is involved) 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?
- What is informed consent and when, why, and how must it be obtained?
- Describe your consenting process. Does the subject get a copy? If yes, when do they get it?
- How do you know if the subject understands the consent document?
- Who answers questions about the research?
- What is a waiver of informed consent?
- Is obtaining informed consent an ongoing process?

Section 10: Conflict of Interest Disclosure

A **conflict of interest (COI)** occurs when an individual's private interests compete with his/her professional obligations to the system to a degree that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. Investigators have a responsibility to identify and manage, reduce or eliminate conflicts of interest that may arise due to financial or other personal interests. TAMU requires investigators to disclose **financial conflict of interest (FCOI)** that could directly and significantly affect the design, conduct or reporting of research or research activities.

Each investigator must submit or update a Financial Disclosure Statement to the COI Official on a yearly basis, or within 30 days after acquiring a new significant financial interest (SFI) requiring disclosure, online via Huron. Additionally, investigators are prompted to disclose all interests that may be perceived as conflicting with the best interest of the participants engaged in human subjects research at the time of initial IRB submission. If a COI is identified, the HRPP refers individual financial interests to the COI Official to assists with the development of a COI management plan. Once the COI Official approves the management plan, it is shared with the IRB. The IRB has the authority to decide whether a financial interest and its management allows the research to meet the criteria for approval.

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate an investigator's FCOI include, but are not limited to:

a) For research projects involving human subjects, disclosure of the FCOI to the participants;
b) Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of research against bias resulting from the FCOI;
c) Modification of the research plan or research activities;
d) Requiring a change in personnel and/or responsibilities for all or a portion of the research activities;
e) Disqualification of personnel from participation in that portion of the research activities that would be affected by the FCOI;
f) Reduction or elimination of the financial interest (e.g., sale of an equity interest); and
g) Severance of relationships that create an FCOI.

HRP 055 SOP Financial Conflict of Interests | **Texas A&M University System Regulation 15.01.03 Financial Conflicts of Interest in Sponsored Research** | **University Rule 15.01.03.M1 Financial Conflicts of Interest in Sponsored Research**

Possible Questions about Conflict of Interest Disclosure

- How do you disclose a FCOI?
- To whom do you disclose a FCOI?
- How do you disclose a COI related to your research (financial or otherwise)?
- Could you be prompted to disclose a FCOI to study participants as part of a FCOI management plan?

Section 11: Principal Investigator Responsibilities

The Principal Investigator (PI) plays a crucial role in protecting the rights and welfare of human subjects and are responsible for carrying out sound ethical research consistent with research plans approved by an IRB. The PI has the ultimate responsibility for the conduct of the research study. This includes following the study protocol, keeping the study up-to-date with modifications and continuing reviews and ensuring that the research team has adequate training and resources to conduct the study safely and properly. The PI also holds the responsibility for the following aspects:

- Obtain IRB approval prior to initiating Human Research activities.
- Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
- Ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
- The Principal Investigator is always held accountable for the actions of the study staff. This responsibility cannot be delegated or explained away. The PI must personally conduct or supervise the Human Research.
    a. Conduct the Human Research in accordance with the relevant current protocol as approved by the IRB, and in accordance with applicable federal regulations and local laws.
    b. When required by the IRB ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
    c. Do not deviate or modify the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
    d. Protect the rights, safety, and welfare of subjects involved in the research.
    e. Submit to the IRB:
        - Submit all **Report of New Information (RNI)** to the IRB within five (5) working days of the research staff having knowledge of the event being reported.
        - Submit an updated disclosure of financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

        For a list of additional investigator obligations, please visit the **Investigator Manual**.

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?
- Do you keep all your correspondence from the IRB?
- Where are your research records maintained?
- Do you have the appropriate resources to conduct the research properly?

Section 12: Education

All members of the research team involved in the design, conduct or reporting of the research must complete training. At a minimum, all researchers and staff must complete courses from the Collaborative Institutional Training Institute (CITI), a web-based ethics training program for those conducting or reviewing research with human subjects. Other courses may be required depending on the type of research being conducted. For instance, investigators using FDA regulated test articles are required to complete Good Clinical Practice, and if accessing, recording or disclosing Protected Health Information (PHI), additional HIPAA training is required. Please refer to the **Investigator Manual** for a summary of all courses that need to be completed prior to receiving IRB approval. Members of the research team who have not completed human research protections training may not take part in research that involves human subjects.

The TAMU HRPP also offers in-person educational sessions for researchers, students, and staff. Investigators may request an individual or group meeting, or schedule a class lecture, to receive additional education and training in research ethics and issues related to human research protections.

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?

Section 13: Single IRB for Multi-Site or Cooperative Research

The Revised Common Rule requires that all sites located in the United States participating in cooperative research conducted or supported by a Federal department or agency must rely upon approval by a **single IRB** for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research, or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

The following research is not subject to this provision:

a) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
b) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.
c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

Consultation with the TAMU HRPP is required prior to entering into any arrangement with a collaborating institution(s) or any external IRB.

Possible Questions single IRB

- When is single IRB required?
- Have you ever used single IRB?

Section 14: FDA Regulated Research

The Food and Drug Administration (FDA) regulates research that involves food, dietary supplements, drugs, medical devices as well as electronic products to ensure that the data collected from these investigations was done so in an ethical, compliant, and sound manner before any product developed from the research is marketed and readily available to anyone.

The FDA uses the term “Clinical Investigation” instead of “research”. This is different than the standard human subject regulations, also known as the Common Rule. A Clinical Investigation involves any experiment that involves a test article and one or more human subjects.

- The FDA defines a **tests article** as any drug, food and color additive, biological product, electronic product, and medical device intended for human use.
- The FDA defines a human subject as “an individual who is or becomes a participant in research, either as a recipient of a test article or control. A subject may be either a healthy human or a patient.” Notice that there is no mention of intervention or interaction or identifiable data, for that matter. That is because the FDA definition of a human subject is much broader than that found in the Common Rule. For example, if you are using non-identifiable human blood to test a new diagnostic assay or test, that is a human subject according to the FDA.

When an investigator is intending to develop a test article (such as a drug, device, or biologic) to cure, treat, mitigate, diagnose, or prevent disease in humans, it is important that the investigator reach out to the HRPP to obtain additional guidance and instructions on how proceed.

- The FDA defines a **drug**, in part, as “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and any “substance (other than food) intended to affect the structure or any function of the body of man or other animals.”
- The FDA defines a **medical device,** in part**,** as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part

or accessory" "or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Know that additional regulations apply to FDA regulated research involving drugs and devices such as:

- **Investigational New Drug Application (21 CFR Part 312)**
- **Investigational Device Exemptions (21 CFR Part 812)**

The **Investigator Manual** is also a useful resource for obtaining information to assist in the early stages of research development for sponsor-investigator initiated protocols that require FDA oversight.

Possible Questions FDA regulated research

- What are some differences between the FDA regulations and the Common Rule?
- Have you ever submitted to the FDA?

Section 15: Response Plan for Emergencies-Disaster Impacting the HRPP

The HRPP has an emergency preparedness and response plan that addresses how continuity of operations will be maintained to ensure human participant protections during an emergency. The plan is enacted when an emergency or disaster situation impacting the HRPP has occurred, or in preparation for scenarios where a potential emergency situation is imminent (e.g., natural disaster, man-made disaster, infectious disease pandemic, etc.) and HRPP operations and/or the ability of investigators to conduct Human Research is, or is likely to be, adversely impacted. In such instances, the HRPP leadership will defer to designated institutional leadership and institution-wide disaster and emergency response planning, and limit HRPP-specific disaster and emergency response planning only to those areas of operations or human research protections not otherwise covered by institution-level plans. Investigators will be notified by the HRPP of any additional measures the IRB will take to maximize regulatory flexibility during the emergency/disaster, and issue guidance on developing study-specific plans to modify research during an emergency/disaster situation impacting the investigator's ability ensure the ongoing safety of research subjects.

HRP 065 SOP Response Plan for Emergencies-Disasters Impacting the HRPP | **HRP 351 Worksheet Protocol Specific Emergency Disaster Risk Mitigation Planning** | **HRP 352 Worksheet Additional Emergency-Disaster Review Considerations**

Possible Questions about Response Plan for Emergencies-Disaster Impacting the HRPP

- Does TAMU HRPP have an Emergency Preparedness Plan?
- What is the purpose of the Emergency Preparedness Plan?
- How was your research impacted by COVID-19?