Investigator and Study Team Interview Questions

As an Investigator/Researcher, you are an integral part of the Human Research Protection Program (HRPP) at UT Health San Antonio. UTHSA is preparing for re-accreditation of its HRPP. Achieving accreditation publicly affirms UTHSA as a top-tier academic institution in its ethical and regulatory conduct of human subjects research.

What are the components of the UTHSA Human Subjects Protection Program (HSPP)?

UTHSA Human Subjects Protection Program (HRPP) is a team effort that includes:
- OIRB staff, IRB directors, IRB chairs, IRB vice chairs, IRB members
- VPR Office, Institutional Official (IO)
- HRPP Steering Committee, Community Outreach Programs
- Office of Clinical Research (OCR), Office of Regulatory Affairs & Compliance (ORAC), Clinical Trials Office (CTO), Office of Sponsored Programs (OSP), Conflict of Interest (COI), Technology Transfer and Commercialization
- Legal office, affiliate research offices
- Investigators, study team members.

What are your research topics?

This is researcher-specific. Know the regulatory standards that pertain to your research (e.g. OHRP, FDA, regulations for experimental drugs or devices). They will ask about interaction with IRB, about the study listed (e.g. how did you get it through the IRB, how do you protect vulnerable populations, what do you do if subjects complain or get ill, how do you communicate with the research staff and the IRB, how and when to report problems, and what do you do if IRB approval lapses?

What methods do you use to protect human subjects in your research?

This is researcher-specific, should include confidentiality, consent, etc. Know your role(s) in the Human Research Protection Program (HRPP) and the roles of the HRPP offices (e.g. IRBs, OSP, Office of Compliance)

What education have you taken to be qualified to complete a human subjects project?

The answer is person-specific but can include CITI Human Subjects Protection course, Good Clinical Practices, Responsible Conduct of Research, and HIPAA training if applicable. All individuals involved in or supervising human subjects research projects at UTHSA must be licensed, certified, or possess a degree appropriate for their field.
Who should you contact for help with regulatory or ethical issues?

The first point of contact is normally the Office of the IRB and/or the IRB Director, and human subjects policies and procedures available on the IRB website [http://research.uthscsa.edu/irb](http://research.uthscsa.edu/irb). Additional follow-up may be necessary with the IRB Chairs, Office of Compliance, General Counsel, the FDA, or the Health and Human Services Office for Human Research Protections (OHRP).

**What is ethical research?**

- Research must have sound design and not unnecessarily expose subjects to risk (45 CFR 46.111)
- It is unethical to put subjects at risk or even to inconvenience them in a flawed study.
- Research should advance scientific understanding and promote human welfare.

**What does the IRB do?**

There are three Institutional Review Boards at UTHSA that meet on a regular basis and one IRB that can meet on an ad hoc basis. The main mission of the Institutional Review Boards is to protect the rights, safety and welfare of research subjects. The IRBs review and approve research in accordance with Department of Health and Human Services (HHS) regulations in [45 CFR 46](http://research.uthscsa.edu/irb). For studies involving products regulated by the Food and Drug Administration (FDA), the IRBs review research according to the requirements in [21 CFR 50](http://research.uthscsa.edu/irb), [21 CFR 56](http://research.uthscsa.edu/irb), [21 CFR 312](http://research.uthscsa.edu/irb), [21 CFR 812](http://research.uthscsa.edu/irb). The IRBs also comply with HIPAA and the regulations in [45 CFR 160](http://research.uthscsa.edu/irb) and [164](http://research.uthscsa.edu/irb).

Know that the IRB must include an unaffiliated member, a nonscientific member, and a scientific member.

**What are expedited and exempted categories? When are they used?**

Know why your study is full board, expedited or exempt.

The categories of exempt and expedited are mutually exclusive. If the study is minimal risk, the designated reviewer considers whether the research falls into an exempt category. If the research does not meet criteria for one of the exempt categories, then the expedited review categories are considered.

**Exempt Review**

Only the IRB may determine which activities qualify for an exempt review. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt.
Research may be granted exempt status by the IRB if all research activities involve procedures listed in one or more of the specific categories under 45 CFR 46.101(b).

**Expedited Review**
Federal regulations allow the IRB to review certain applications on an expedited basis if they meet specified criteria (45 CFR 46.110, 21 CFR 56.110 and 38 CFR 16.110). Expedited review categories applies to research that involves no more than minimal risk. All expedited protocols are reviewed by the IRB at least once per year.

**What is the difference between exempt human subjects research and not-human- subjects research?**

Certain activities have characteristics of research but do not meet the regulatory definition of human subjects research. Some studies fall in gray areas and it is difficult to determine if in fact they are human subjects research and require IRB review. To be considered research, a study must involve human subjects and be research. Below are the federal definitions of each.

**Does the study involve Human Subjects?**
To involve human subjects, the study must involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual OR the study must involve a living individual about whom an investigator conducting research obtains identifiable private information.

**Is the activity Research?**
To be Research, the activity must be a systematic investigation including research, development, testing and evaluation AND the activity must be designed to develop or contribute to generalizable knowledge.

If a study does not meet both definitions, it is “not-human-subjects research” and does not require IRB review. However, this is different from exempt human subjects research.

**What is the “process” of consent? Do you know how to properly obtain consent?**

Obtaining informed consent is a basic ethical obligation for researchers. The process of consent should ensure that potential subjects are provided with information about the study in a way that is understandable to them (communicated and written in “lay language” and in the subject’s language) allowing them to make an informed and voluntary decision about participation. The consent process should be an ongoing educational interaction between the investigator and the research subject that is ongoing throughout the study.
The amount of information and the manner of presentation (verbal or written) can vary depending on the complexity and risk involved in the study. The consent form serves to document that the subject agreed to participate in the study and also serves for the subject’s future reference. Subjects should sign the consent form after the investigator has verbally explained the purpose and procedures involved in the study, answered questions, and provided information that permits the subject to make an informed decision. The consent form must be signed before any study data collection procedures begin.

Only legally competent adults can give legally effective informed consent. Minors and those individuals who are not competent to provide consent should be given the opportunity to assent to participate in the research project. Assent is an affirmative, knowledgeable agreement to participate in the project. Adequate provisions should be made for soliciting the independent, non-coerced assent from minors or cognitively-impaired persons who are capable of a knowledgeable agreement.

**What is a waiver of consent? What is a waiver of documentation of consent? What justifies each? How do they differ?**

**Waiver of Documentation of Consent**

In some situations, the IRB may waive the requirement for obtaining a signed informed consent document (45 CFR 46.117(c)). Waiver of signed consent is allowed if:

- The only record linking the subject and the research would be the consent document and potential harm may result from a breach of confidentiality (the subjects would be placed at risk by documents linking them with an illegal or stigmatizing characteristic or behavior). For example, survey or interview studies that contain highly sensitive (e.g., criminal behavior, sexual behavior) questions.

- The research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context. For example, online surveys about topics that could not reasonably damage a participant’s reputation or employability or be otherwise stigmatizing.

In cases where the documentation requirement is waived the IRB may require the investigator to provide subjects with a written statement regarding the research (the documentation may also be referred to as an info, fact sheet or similar title).

**Waiver of consent or elements of consent**

Some research projects would not be possible if informed consent were required. The IRB may approve a consent procedure that does not include, or which alters, some or all of the
elements of informed consent, or may waive the requirements to obtain informed consent (45 CFR 46.116(d)). The regulations state that informed consent may be waived in full or in part if the IRB determines that:

- the research involves no more than minimal risk to the subjects; and
- the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- the research could not practicably be carried out without the waiver or alteration; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Examples of types of studies in which all of the elements of consent have been waived include retrospective chart reviews. If the study can be classified as minimal risk and adequate provisions for protecting data confidentiality are in place, the IRB expedited reviewer generally finds that obtaining consent is not impracticable (not possible).

If the investigator seeks a waiver of any or all of the elements of consent, the IRB application should justify the request by showing the research could not be conducted without the waiver.

**What is the difference between privacy and confidentiality?**

- **Privacy is related to setting;** it relates to control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

- **Confidentiality is related to information/data;** it pertains to the steps taken to protect an individual’s personal information (limited access, password-protection) including the assurances made to a subject in the consent form that his/her information will not be divulged to unauthorized personnel without their permission.

- The IRB must decide on a case-by-case (e.g. study by study) basis whether there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. The IRB must take into account the degree of sensitivity of the information that may be obtained in the research and the protections offered the study and study population. As with other aspects of IRB review, these determinations will be dependent on the circumstances of the study and subjects.

**What is the UTHSA policy regarding Conflict of Interest (COI)?**

Know who creates and approves the management plan (COI Committee). The UTHSA IRB has the final authority regarding the management plan when human subjects research is involved. The IRB may add additional protections/requirements to the management plan.
Know who is required to annually disclose financial interests and who is required to report COIs.

What is the UTHSA policy regarding Reportable Events?

A serious adverse event (SAE) is an adverse event (untoward or unfavorable event that occurs during a study, whether or not it is related to participation in the study) that involves one of the following:

- Inpatient hospitalization or prolongation of hospitalization
- Life-threatening reactions
- Persistent or significant disability/incapacity or permanent harm or disability (either physical or psychological)
- A congenital anomaly/birth defect in the offspring of the subject
- Jeopardizes the subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition
- A breach of confidentiality that may have a negative consequence
- Results in death or places subject in immediate risk of death

Not all serious adverse events are unanticipated problems involving risks to subjects or others. Serious adverse events that are unexpected, related or possibly related meet the criteria for an UPIRSO and must be reported to the IRB promptly.

An unanticipated problem involving risk to subjects or others (UPIRSO) is an incident, experience or outcome that was unexpected (e.g., not described in the protocol, study or consent document), related or possibly related to participation in the research and suggests that research places subjects or others at a greater risk of harm than was previously known or recognized. UPIRSOs must be reported to the IRB as soon as possible but no later than 7 days for an internal event or 14 for an external event from the time the investigator becomes aware of the event.

Special shortened reporting timeframe: All UPIRSOs based on internal information that are either life threatening or fatal events must be reported within 48 hours

Unanticipated adverse device effects (UADEs) must be reported to the IRB within 10 days for an internal event or 14 days for an external event. Special shortened reporting timeframe of UADEs involving “an unreasonable risk to subjects requiring termination by the sponsor of all investigations or parts of investigation presenting that risk” must be reported within 5 days after notification from the sponsor to terminate some or all of the research.

Adverse events that do not meet criteria for UPIRSOs are summarized and reviewed as part of the progress report.

Investigators and research staff are responsible for promptly reporting possible noncompliance to the IRB. Protocol deviations that do not constitute noncompliance are summarized and reviewed as part of the progress report.
What is the UTHSA policy regarding amendments?
Investigators may not initiate any minor or major changes in research protocol, procedures or consent form(s) without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject. This includes single subject exceptions.

Other questions to consider:

- Know how to maintain compliant research records and documentation, and be able to explain your research submission and rationale

- How do you and your team stay abreast of and comply with FDA regulations for drugs/devices/biological? Have you had direct interaction with FDA?

- Know how to recruit subjects ethically and justly while adhering to inclusion/exclusion criteria. How are subjects recruited for your studies? How is equitable subject selection addressed? Are there extra protections for vulnerable populations?

- How do you handle subject complaints? How do staff inform the PI about subject complaints?

- How do you communicate with research staff? Are there regular meetings?

- How would you describe the general oversight of research? Who trains? Who oversees? How do new research members learn about study procedures?

- How are drugs/devices/biological stored? Who has access to these? What happens to these after study completion?

- Is your study multi-site? If so, how do sites communicate? Is your site the coordinating center? Know your relationship with sponsor, monitor, other sites