

OVERVIEW OF RESEARCH WITH HUMAN SUBJECTS

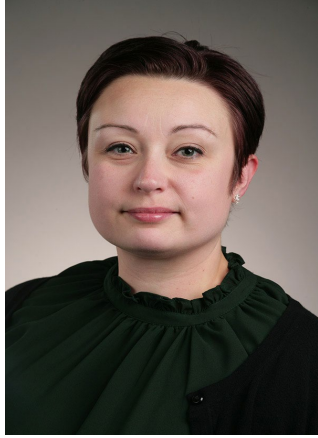


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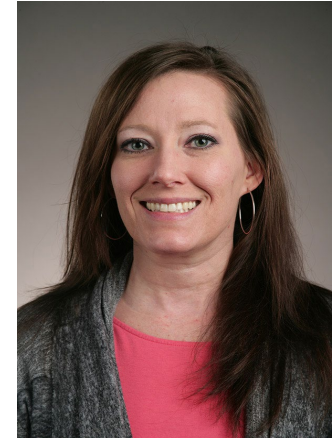
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UT INSTITUTIONAL REVIEW BOARDS

- Biomedical IRB
 - Research involving drugs, medical devices, diagnostic procedures, surgeries, protected health information (PHI), biospecimens, and more
- Cancer IRB
 - Specializes in the review of cancer research
- Social, Behavioral, and Educational (SBE) IRB
 - Research involving surveys, interviews, focus groups, behavioral interventions, observations, secondary data, and more



WHY DO WE NEED AN IRB?

- Past abuses demonstrate that researchers are not always ethical in conducting research with human subjects (Nuremberg's Doctors' Trials, Tuskegee syphilis study, Willowbrook hepatitis study, amongst many others)
- The [Declaration of Helsinki](#) (1964) requires that an independent committee must review human studies
- Federal law and regulations require such reviews ([45 CFR 46](#), [21 CFR 50](#), and [21 CFR 56](#))
- University policy requires IRB review (Protection of human subjects in research, [3364-70-05](#))

OTHER LAWS AND REGULATIONS THAT MAY BE APPLICABLE TO RESEARCH

- Health Insurance Portability and Accountability act (HIPAA): [45 CFR 160](#) and [45 CFR 164](#)
- Family and Educational Rights and Privacy Act (FERPA): [34 CFR 99](#)
- The Protection of Pupil Rights Amendment (PPRA): [20 U.S.C 1232h](#)
- Ohio Laws and Rules: [Ohio Revised Code](#)
- Other UT [policies](#) related to research

RISKS OF NONCOMPLIANCE

- May include
 - Cannot use the data
 - Publication restrictions
 - Suspension/termination of research
 - Limitations for conducting future research
 - Notifying journals
 - Impact student graduation
 - Pay back funding agency and additional fines
 - Institution loses ability to apply for external funding
 - Prison

WHAT DOES THE IRB REVIEW?

In general, any study that meets both the federal definitions of “human subject” AND “research

- **Human Subject:** Living individual about whom an investigator conducting research: [\[45 CFR 46.102\(e\)\]](#)
 - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; **OR**
 - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
 - Intervention: Manipulations of the subject or the subject’s environment that are performed for research purposes.
 - Interaction: Communication or interpersonal contact between investigator and subject.
 - Private information: Information in which an individual can reasonably expect will not be made public, and/or reasonably expect will not be observed or recorded.
 - Identifiable private information or biospecimens: information or biospecimens for which the identity of the subject is or may readily be ascertained

WHAT DOES THE IRB REVIEW? (CONT.)

- Research:** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. [[45 CFR 46.102\(l\)](#)]
- Systematic investigation: well-defined question(s) and organized data collection
- Generalizable knowledge: results can be applied to a wider or different range of circumstances; can infer a general conclusion. This is not always easy to ascertain.

CATEGORIES OF RESEARCH

- **Not human subjects research (NHSR):** Research that does not meet the federal definition of research or human subject [\[45 CFR 46.102\(l\) or \(e\)\]](#) as discussed on the previous slides. This is not always easy to ascertain and in most cases our brief NHSR application should be submitted and a formal determination should be made by HRPP staff or the IRB.
- **Exempt:** Research that is generally innocuous, posing little to no risks, and falls into one of the exemption categories per the federal regulations [\[45 CFR 46.104\(d\)\]](#). Exemption does NOT mean the research is exempt from the scope of the IRB nor does it mean that it is exempt from further oversight of the IRB once exemption is granted.
- **Expedited:** Research that is minimal risk but does not qualify for exemption and falls into one of OHRP's [expedited review categories](#).
- **Convened:** Research that is more than minimal risk, the research doesn't fit into another category, most research involving prisoners, some research involving children, when risks are unknown, or at the discretion of the IRB

INFORMED CONSENT

- **Signed consent:** Standard practice for research that is conducted in person. Elements of consent are required by the federal regulations [\[45 CFR 46.116\(b\)\(1-9\)\]](#).
- **Waiver of signed consent:** Often used for online, survey research or other research in which there will be no direct contact with the participant. The federal regulations [\[45 CFR 46.117\(c\)\(1\)\]](#) require one of three criteria to be justifiable and approved by the IRB.
- **Waiver of consent:** Often difficult to justify. The federal regulations [\[45 CFR 46.116\(f\)\(1\)\]](#) require that this must be justified by five criteria and approved by the IRB.
- **Alteration of consent:** Refers to when some of the required elements of consent are omitted or altered. Typically seen in research that involves deception. An alteration of consent is subject to the same five criteria as a waiver of consent.
- IRB approved templates must be used and can be found on the HRPP web page. The Biomedical [templates](#) must be used if you are submitting to the Biomedical or Cancer IRB and SBE [templates](#) must be used when submitting to the SBE IRB.

TRAININGS

- Collaborative Institutional Training Initiative ([CITI](#))
 - Social, Behavioral, and Educational Researchers and Students **OR** Biomedical Researchers and Students. [Instructions](#) are provided on the HRPP web page to ensure you are taking the correct training.
- Health Insurance Portability and Accountability Act ([HIPAA](#))
 - Required when the research involves accessing medical records, receiving PHI, OR if the researcher(s) is affiliated with the covered entity. [Instructions](#) are provided the HRPP web page to ensure you are taking the correct training.
- Social, Behavioral, and Educational IRB “New Application” training
 - Optional for researchers conducting SBE research. Refer to the SBE IRB [training](#) page for details



THE IRB APPLICATION

- Applications must be submitted in [IRB Manager](#). Your login information is your utad credentials.
- Students cannot be the principal investigator
- Ensure you attach all of the required, applicable documents (e.g. consent, assent, parental consent, data collection instruments, conflict of interest disclosure forms, recruitment materials, key code, permission letters, etc.)
- Ensure you answer all questions and only provide information that is relevant to the question
- Clear and concise is best
- When unsure, guidance can be found at the [HRPP web page](#) or reach out to your [IRB Administrator](#) for support



TIPS AND REMINDERS

- Some aspects FDA regulated research are subject to different or additional requirements ([21 CFR 50](#) and [21 CFR 56](#)) than those outlined in [45 CFR 46](#).
- The requirements imposed upon you for conducting research with human subjects are set by federal law and regulations. The HRPP and the IRB does not make these guidelines nor can they allow deviations from them.
- Your IRB approved application is binding, if you wish to modify any procedures, materials, study personnel, or any other aspect of the research, you must submit an amendment and receive IRB approval prior to implementing any changes.
- Your research may be subject to continuing review at a duration determined by the IRB. Ensure adequate time to submit a continuing review application and obtain IRB approval. Should your IRB approval expire, you must cease all research activities.
- If your research is not subject to continuing review, you are required to submit an annual progress report.
- When your research is complete, you must submit a final report to close out your research with the IRB.

TIPS AND REMINDERS (CONT.)

- The PI and the submitter of the application (if different from the PI) will receive emails from IRB Manager any time your application is received by the HRPP office, has been returned, and when it's approved.
- All of your application documents (consent, recruitment materials, etc.) will be stamped with UT IRB approval and are accessible from your study file in IRB Manager. You must use these stamped documents for your research. You can also access your IRB approval letter from your study file.
- Turnaround time from HRPP staff or a reviewer for exempt or expedited research can take up to two weeks or more depending on workload. For convened research, please refer to the [IRB meeting schedules](#) for meeting dates and submission deadlines. Often times applications go through several rounds of revisions. We generally suggest allowing yourself at least 6-8 weeks from initial submission to final approval.
- It is your responsibility as a researcher to know and abide by the regulations, policies, and procedures. Ensure that you are familiar with them to avoid non-compliance.

