

Classroom Projects Involving Human Subjects Research (Guidance for Faculty)

The purpose of this document is to provide guidance to faculty members about whether or not a classroom or student project will need to be reviewed by HT's Research Standards and Institutional Review Board. Projects that meet certain criteria will not need to be reviewed at all by the IRB, others will need to apply for exemption from IRB oversight, and others will need to submit a full proposal to the IRB for review.

Faculty are responsible for ensuring that classroom and student projects are conducted to the ethical standards of human subjects research. Faculty and students conducting human subjects' research at HT must complete the online CITI research ethics training, the Protecting Human Research Participants (PHRP) Online Training for human subjects research (https://phrptraining.com/#!/) or the Association of Clinical Research Professionals (ACRP) Ethics and Human Subject Protection web-based training (https://acrpnet.org/courses/ethics-human-subject-protection/) regardless of whether the particular project is deemed exempt or non-exempt. If the activity is not classified as human subjects research, then CITI or any other formal training is not required.

In accordance with federal regulations, the HT IRB must review all human subjects research before any participant recruitment or data collection may begin.

- **Human subjects research** is defined as a **systematic investigation** of living human participants on a research topic concerning the human experience that can contribute to **generalizable knowledge** about the human experience.
 - Systematic investigation is defined as the application of consistent protocols and procedures to test a
 hypothesis and/or permit conclusions to be drawn. Examples include surveys and questionnaires,
 scripted interviews, interventions, and manipulations designed to record individual responses to
 particular events or stimuli.
 - O Generalizable knowledge is defined as findings/results/conclusions that have the potential to increase understanding of a group of individuals larger than those sampled for the study. For example, conducting research about HT faculty stress before and after exam week could potentially apply to a larger population of faculty members beyond HT.

Important:

- Please note that for ethical and IRB purposes, generalizability of a study is determined by the study design/method, not the results from the sample achieved.
- Please note that a study can produce generalizable knowledge even if the results are not presented outside of the classroom. Please contact the IRB with any questions about generalizable knowledge.

STUDENT CLASSROOM PROJECT GUIDELINES

The following (A–E) are examples of classroom and/or student projects that *do not* require IRB oversight. Please carefully review the criteria in A–E and also review the information about MINIMAL RISK on the next page. If your class project meets the specific criteria in A, B, C, D, or E then you do not need to submit anything to the IRB.

- A. Capstone interviews, journalism interviews, interviews for art pieces. Please note that faculty and students are strongly encouraged to use informed consent and/or media consent forms for these projects, as appropriate.
- B. Research that does not collect any data from or about human participants.
- C. Demonstrations intended to teach research methods OR illustrate the use of laboratory equipment that do NOT ask students to engage in formal hypothesis generation.
- D. Marketing, environmental, or political research that does not collect any **personally identifying or sensitive information** from participants and **does NOT pose more than minimal risk** (defined as no more emotionally or physically distressing than an individual would expect to encounter in a typical day).
- E. Class projects about the human experience that meet the all of the following criteria:
- All students and faculty involved have completed the CITI or NIH research ethics training
- The project includes the process of informed consent for participants
- The project is limited to surveys, questionnaires, interviews, or observations of public behavior
- Human participants will only be students currently enrolled in that specific course (or public observations)
- Collected data is NOT presented beyond course-related activities for that specific course
- No **personally identifying information** is recorded to link a person with data that could reasonably harm the individual's reputation, employability, financial standing, or place them at risk for criminal or civil liability
- The project method and topic **do NOT pose more than minimal risk** (defined as no more emotionally or physically distressing than an individual would expect to encounter in a typical day).

The concept of **MINIMAL RISK** is a particularly important for human subjects research. Federal guidelines define minimal risk as no more emotionally or physically distressing than an individual would expect to encounter in a typical day.

- Please note that some survey/interview questions could pose more than minimal risk in terms of emotional distress (e.g. history of trauma, history of mental health diagnosis/treatment) and such questions should be avoided for class projects not reviewed by the IRB.
- To maintain less than minimal risk to participants, the IRB suggests that classroom research activities be no more emotionally upsetting than a normal workplace conversation and require no more physical exertion than walking to class across campus.
- If you have any uncertainty about whether a research project poses more than minimal risk to participants, please consult the IRB.

If your classroom and/or student project does NOT meet the specific criteria described in A, B, C, D, or E above, then you have two options:

- 1. **APPLY FOR AN EXEMPTION.** When a faculty member believes a class assignment qualifies for exemption from IRB oversight, but it does not meet the specific criteria above, then the faculty member can submit a *Request for IRB Exemption of Student Classroom Projects* that could be applied to multiple projects under the same classroom assignment exemption. The IRB processes applications for exemptions on a rolling basis, and makes every effort to review applications within 20 days of submission.
- 2. **SUBMIT A FULL IRB PROPOSAL FOR REVIEW.** When a faculty member believes that the class project does not qualify for exemption from IRB oversight, then the faculty member can serve as the

Principal Investigator or the Faculty Advisor for the project. The faculty member would then supervise the preparation and submission of an IRB proposal for review. Please see the IRB website for more information about the review process and timeline. The IRB reviews proposals for approval on a rolling basis if the project qualifies for EXPEDITED REVIEW (determined by the IRB). If a proposal requires FULL BOARD REVIEW (determined by the IRB), then it needs to be received by the IRB at least 5 days prior to the full board meeting date (see the IRB website for scheduled meetings). Please see the IRB website and/or contact the IRB for more information about whether your project would be assigned to EXPEDITED or FULL BOARD.

Huston-Tillotson University Faculty are strongly encouraged to contact the IRB with any questions about the IRB review process and requirements for student classroom projects.

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