

**HUSTON-TILLOTSON UNIVERSITY**

**IRB STUDY SYNOPSIS PROPOSAL TEMPLATE**

**How to Use this Document**

Fill in the information where text is in brackets and delete the descriptions provide in the template within the brackets. While all sections of this form must be completed, IF any sections are not applicable to your research study write “N/A” for not applicable.

The protocol should describe your research procedures and participant population in detail. Your consent documents, data collection instruments (surveys, questionnaires, interview guides, etc.), and recruitment materials need to be added to the proposal submission as outline in the IRB form.

**What to Include in the Submission?**

* The HT IRB Application.
* Cover letter (see example in the next page).
* A completed research/project proposal (using the template below).
* All necessary appended materials, including consent forms, measures planned to be used, recruitment materials (including flyers), ethical research training, and any other supportive document as necessary to support the proposal.

IRB forms can be accessed at the university’s IRB website at:

 <https://htu.edu/academics/institutional-review-board>

**Note to Investigators**

Based on the research/project proposal and materials submitted, the Huston-Tillotson University Research Standards and IRB Committee will decide whether the research should be categorized as “exempt” or whether it requires further review. If you believe your research satisfies the conditions of exempt review, please include the “HT IRB Request for Exemption Form” as part of your submission as well as discuss it in your cover letter.

Huston-Tillotson University does not have reciprocity agreement with other institutions. Therefore, even if your study has received IRB approval at another institution, you will still need to submit your research proposal to Huston-Tillotson University’s to receive IRB approval. Certainly, including your IRB approval from your host institution as part of your submission can help in expediting the review process.

**Cover Letter Example**

Institutional Review Board

Huston-Tillotson University

900 Chicon Street

Austin, Texas 78702

Dear IRB Chair & Board Members:

Attached is a research proposal that (name of PI and Co-PI) have developed as part of the submission process for the institutional review board. If approved, I/we intend to begin data collection [specify when **data collection** will begin, and **analysis** will commence on]. Therefore, the entire research study will be completed by [specify date].

Include one short paragraph describing the purpose of your research.

If the research involves human participants, include the following paragraph:

“We have complied with the U.S. Department of Health and Human Services policies and regulations on the protection of human subjects, as contained in Title 45, Part 46 of the Code of Federal Regulations, the amended Declaration of Helsinki, and all University of Evansville policies. I/we have completed an approved social and behavioral research ethical procedures course and/or certificate.”

Thank you for your consideration and assistance with this endeavor.

Sincerely,

List the names of all researchers [Including students and faculty sponsor(s), with signatures].

**RESEARCH/PROJECT PROPOSAL**

Estimated/Proposed Start Date: Completion Date: [Up to 1 year]

Title of the Study or Project:

Principal Investigator:

Other Investigators:

Institutional Affiliations:

Indicate and Describe Any Funding Source(s) [i.e., grants, departmental funds] to support research study].

Review Type: Exempt Preliminary Expedited Full Review

Confidentiality of Data: (Check all that apply)

------- Grant Research

\_\_\_\_ Dissertation

\_\_\_\_ Thesis

\_\_\_\_ Capstone project

\_\_\_\_ Undergraduate Honors Project

\_\_\_\_ Conference Presentation

\_\_\_\_ Publication for Journal Article

**ABSTRACT AND PURPOSE**

[Provide a thorough description and purpose for your research study]

**STUDY OBJECTIVE(S), SPECIFIC AIMS AND/OR HYPOTHESES**

[What are the objectives, aims and the if then statements, if applicable]

**DELIMINATIONS**

[Boundaries set by the researcher (s) for this study.]

**LIMITATIONS**

[Influences what the researcher (s) cannot control.]

**DEFINITIONS**

**BACKGROUND/LITERATURE REVIEW**

[Provide scientific and scholarly background, rationale, and significance for the proposed study]

**PARTICIPANTS**

[Provide a description of the target population, exclusionary criteria (e.g., specific age range, race/ethnicity, gender, gender identity) and how participants will be recruited].

**MATERIALS AND MEASURES**

[Describe the materials that will be used to conduct the study, how will be data collected, validity, reliability of data (e.g., surveys, and interviews) and included copies of surveys and interview questions in the appendix].

**RESEARCH METHODS AND PROCEDURES**

[Outline the exact protocol. What will happen to the participant (s)? How long will the process take? Provide detailed instructions in a handout. Location: Where will the data collected, analysis and storage occur?]

**ETHICAL CONSIDERATIONS**

* **RISK TO PARTICIPANTS.** [Is there more than minimal risk of harm? Discuss possible risk that participants may experience by participating in the research study, (e.g., physical, psychological, legal, or social.) What are the procedures to inform IRB and what will you do if a research participant is harmed or injured?
* **INCOMPLETE DISCLOSURE OR DECEPTION.** [Will the participants be deliberately deceived in any way? If so, please describe. Because deception and incomplete disclosure alter the information presented during the consent process, the debriefing process serves as the remedy by completing the consent process. If debriefing is appropriate, explain how you will conduct the debriefing process.]
* **BENEFITS TO PARTICIPANTS.** [Discuss any potential benefit that participants may expect, (e.g., health or educational related information.]
* **COMPENSATION.** [Explain whether research participants will be compensated for participation in the study.]
* **CONFIDENTIALITY.** [How will confidentiality and anonymity assure? When will individual identifiers be removed from data?
* **NON-ENGLISH-SPEAKING PARTICIPANTS**. [Explain which languages will be used by the individuals obtaining consent and which language(s) are understood by the potential participants. Describe the process to ensure that oral and written information provided to those not fluent in English. If you plan to use a translator, explain how you will identify an appropriate translator.
* **INDIVIDUALS WHO LACK THE ABILITY TO GIVE CONSENT AND CHILDREN.** [Parental permission must be obtained for children’s participation in research. Describe how parental permission will be obtained and the assent process for child participants. NOTE: Children generally cannot provide “consent” to participate in research – rather, children provide assent. Assent means a child's affirmative agreement to participate in research. M Describe how you will assess capacity to consent if your study will include individuals who may lack capacity to consent. If you will have more than one interaction with the participants, you must re-check capacity to consent at each interaction with the participant – some participants may lack capacity to consent at one point and have capacity to consent at other time points. When research involves adults unable to consent, permission to participate in research must be obtained from a Legally Authorized Representative (unless the IRB has granted a waiver of consent)]
* **WITHDRAWL FROM STUDY.** [Include a statement allowing for voluntary withdrawal from the study without prejudice.]
* **CONSENT PROCESS.** [Describe the process you will use to obtain informed consent (written, verbal, online, etc.) from the research participants, including where and when the consent process will occur. If consent will be obtained in different ways for different participant groups or study phases, describe the consent process that will be used for each participant group and/or study phase. Please keep in mind that consent is not JUST a document-it is a process in which the participant gains an understanding of the research procedures and the potential benefits and risk.]
* **RESEARCH DATA.** [How will the data be destroyed at the end of the study? If not, where will it be stored and kept secure? You must state whether the data will be kept confidential or anonymous. How will this be achieved? Will this data be used in the future? How will you obtain the participant’s permission?

**TIMELINE**

[Detailed Timeline]

**PLANS FOR DISSEMINATING THE FINDINGS**

**REFERENCES**

[APA or MLA style]

**APPENDICES**