

## Huston-Tillotson University Research Standards Committee and Institutional Review Board Research Proposal

To ensure an effective review by the Institutional Review Board, a full description of the planned research must be submitted with the application for initial review. A research protocol provides the reader with background information of the problem under study, including the study rationale, a detailed plan for conducting the research involving human research participants, and a discussion of the potential importance of the research. Every application submitted for review and approval shall have attached to it a page organized in numerical brief paragraph form as outlined below.

- 1. Title [Insert study title]
- Principal Investigator
   [List the name, HT ID, Department]
   [Complete and upload the Research Personnel Form for co-investigators and research personnel]
- 3. Purpose

[Provide a brief overview (1-3 paragraphs) of your study written for a general audience explaining the purpose of the research and theories and/or hypotheses to be tested. DO NOT copy/paste a lengthy literature review in this section. Do not overuse academic jargon.]

4. Procedures

[Briefly describe your research methodology and study design. Outline step-by-step what will happen to participants in this study. You must include information that allows the HT RSC&IRB to conduct an analysis of the risks and the potential benefits]

a. Location

[Describe where data collection and all other study activities will occur. Indicate the names of all sites or agencies (e.g., school districts, day care centers, etc.) involved in the research.

For a multi-site study in which the University is the lead or coordinating institution, provide the following:

- i. The name(s) of each participating institution that will be engaged in human subject research.
- ii. Confirmation of whether participating institution has an FWA.
- iii. The contact name and information for the PI at each institution.
- iv. The contact name and information for the RSC&IRB of record at each institution.

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v. The method of multilateral communication between institutions/IRBs of any unanticipated problems involving risks to subjects or others and other study related information.

For international site research you will need to provide additional information in Number 6.f and 9.]

b. Resources

[Describe whether internal/external funds, personal funds, other resources will be used to support this research.]

c. Study Timeline

[Describe how long the project will take from data collection to dissemination of results.]

5. Measures

[Describe all study measures. For surveys, focus groups, or interviews – clarify whether question items and measures are standardized, published, or designed specifically for this project. Attach interview guides, survey documents, etc.]

- 6. Participants
  - a. Target Population

[Briefly describe the study population (e.g., students, patients, etc.) and your anticipated sample size (N) of participants, and/or societal benefits.]

b. Inclusion/Exclusion

[If applicable, list criteria that will be used to include or exclude participants from the study (e.g., age restrictions, health restrictions, etc.).]

c. Benefits

[List any potential benefits that participants may expect from the study, such as, health information, and/or other intrinsic value stemming from study participation.]

d. Risks

[Discuss any possible risks that participants may incur by participating in the study. Explain what will be done to minimize those risks (if applicable). Describe procedures regarding notification of the IRB and treatment of participant in the event that a participant is harmed during the study.]

e. Recruitment

[Discuss how potential participants will be recruited to participate. Submit all recruitment materials (e.g., flyers, scripts, letters, e-mails, etc.) that will be used.]

f. Obtaining Informed Consent

[Explain all informed consent procedures. If consent forms will be used, submit a copy. If applying for a waiver of signed consent, specifically state this and explain why. If the study involves deception, describe the procedures for debriefing the participants. For international research you must include how the informed consent could be affected by

local customs, cultural context, laws and regulations. You must also describe how you will address these issues.]

7. Privacy and Confidentiality

[Describe how you will protect the identity of study participants (privacy).

Confidentiality of the Data or Samples

- a. Describe how data or samples (i.e., blood, salvia, tissue, etc.) will be collected.
- b. Describe how the data or samples will be securely stored and how you will achieve this.
- c. Provide the length of time the data or samples will be kept.
- d. Describe whether data or samples will be kept confidential (i.e., data can potentially be linked to participants) or anonymous (i.e., impossible to link data and participants). You must include if the data or samples will be shared by other researchers for research purposes not detailed in this study.
- e. If the data or samples will be destroyed, describe when and how the destruction will occur.]
- 8. Compensation

[Clarify if participants will be compensated for participation and specify how participants will receive compensation (e.g., required course credit, extra course credit, cash, a gift card, etc.). Compensation should not unduly influence potential participants and upload corresponding debriefing documents.]

- International Research (Eliminate this section if it does not pertain to your study.) [Participant protections need not to be the same as provided in the US but should be equal in function and effect.
  - a. Provide the name of each country in which the research will be conducted.
  - b. Describe how you are aware or will become aware, i.e., local collaborator, of the local customs, cultural context, laws, and regulations of the site where the research will be conducted.
  - c. Clarify if your research requires local ethics committee review and approval and/or permission/certification by a local, provincial or national government entity.]
- 10. In addition to this protocol/proposal outline, you are required to submit all relevant documentation for review. This may include, but is not necessarily limited to:
  - a. Recruiting documents (e.g., flyers, letter, e-mails, brochures, etc.).
  - b. A consent form.
  - c. An assent form.

- d. Letters of approval from relevant organization(s).
- e. Surveys/instruments/questionnaires.
- f. A list of questions that the researcher may ask (e.g., focus groups questions, questions for qualitative studies, etc.).

All documents in translated versions.

Principal Investigator's Printed Name

Date Submitted

Principal Investigator's Signature