**Hardin-Simmons University Institutional Review Board**

**Full Review Application**

Instructions: Complete the Application and send as an email attachment to IRB@hsutx.edu. Include all appendix materials, including but not limited to consent forms, surveys, documentation of training, solicitation materials, and Vulnerable Populations Consideration Form (if applicable), and the *signed* Investigator Assurance form.

**Section I- Project and Researcher Information**

Title of Proposed Project:

Principal Investigator Name:

Role: [ ] HSU Faculty

 [ ] Non-HSU Faculty

 [ ] HSU graduate student (Faculty Advisor MUST be identified)

 [ ] HSU undergraduate student (Faculty Advisor MUST be identified)

Phone:       Email:

Institution (if not HSU):       Department:

Faculty Advisor (if applicable):       Department:

Phone:       Email:

|  |  |  |
| --- | --- | --- |
| Co-Investigators | Department/Affiliation | Date Completed Ethics Training |
| 1.
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This project will be conducted [ ] On Campus [ ] Off Campus

If off campus, please indicate where:

Do you have permission to conduct the study at this site? [ ]  Yes [ ] No

Person of Contact at Off-campus site:       Phone:

Will this site require their own IRB approval or will they accept approval from the HSU IRB?

[ ] Yes [ ]  No

Is this project being funded by an outside agency? [ ] Yes [ ] No

If yes, please indicate which agency:

**Section II- Research Proposal**

Please answer the following with sufficient detail so that reviewers will be able to determine the exemption that applies.

1. State the specific purpose of your research study.
2. Describe the need for your research study.
3. Describe how subjects will be recruited for your study.
	1. Will your research include any of the following special populations that require additional considerations? (Check those that apply)

[ ] Children

[ ] Pregnant Women or Fetuses *(Research in this category is aimed at pregnancy or fetuses, not the use of benign surveys).*

[ ] Neonates

[ ] Decisionally Impaired

[ ] Prisoners

[ ] Students

If checked, then complete the Vulnerable Populations Considerations form.

* 1. Will participants be compensated? [ ]  Yes [ ] No

If yes, please describe the compensation:

* 1. Will participants be screened prior to consent? [ ]  Yes [ ] No

If yes, please describe the screening criteria, any information that will be recorded, and how the information will be managed if the prospective subject declines participation or withdraws.

* 1. Do you expect to enroll anyone whose first language is not English or who is not fluent in English? [ ]  Yes [ ]  No

If yes, then please note that a translated informed consent form may be required depending on your target population.

1. Explain your experimental methods in a step-bey-step manner. Provide as appendices examples of surveys, photos, illustrations, etc. that will aid the IRB members.
	1. Will you be using private information that is protected by HIPAA or FERPA?

[ ] Yes [ ] No

If yes, then please attach the HIPAA/ FERPA form.

1. Describe the alternative treatment the experimental or control groups may receive.
2. Describe how the data will be analyzed. If qualitative data are collected, describe the analysis method.
	1. How will the date be coded?
	2. Where will the data be stored?
	3. When will the data be destroyed:
	4. What is your estimated sample size?
3. Will data be shared with anyone outside of the research team (ex. statistician, consultant)?

 [ ]  Yes [ ] No

If yes, please describe which data will be shared, whether it is identifiable or de-identified, or a limited data set. Describe how the data will be transferred.

**Section III – Risk Assessment**

1. List the potential physical risks associated with participation in this study and check the estimated likelihood

|  |  |  |  |
| --- | --- | --- | --- |
| Potential Physical Risk |  |  |  |
| 1.
 | [ ] Likely | [ ] Less likely | [ ] Rare |
| 1.
 | [ ] Likely | [ ] Less likely | [ ] Rare |
| 1.
 | [ ] Likely | [ ] Less likely | [ ] Rare |
| 1.
 | [ ] Likely | [ ] Less likely | [ ] Rare |
| 1.
 | [ ] Likely | [ ] Less likely | [ ] Rare |

1. Describe how these potential physical risks will be minimized.
2. List the potential psychological risks associated with participation in this study and check the estimated likelihood

|  |  |  |  |
| --- | --- | --- | --- |
| Potential Psychological Risk |  |  |  |
| 1.
 | [ ] Likely | [ ] Less likely | [ ] Rare |
| 1.
 | [ ] Likely | [ ] Less likely | [ ] Rare |
| 1.
 | [ ] Likely | [ ] Less likely | [ ] Rare |
| 1.
 | [ ] Likely | [ ] Less likely | [ ] Rare |
| 1.
 | [ ] Likely | [ ] Less likely | [ ] Rare |

1. Describe how these potentialpsychological risks will be minimized.
2. What are the benefits of the study:
	1. To the participants:
	2. To broader knowledge and society:

**Section IV- Conflicts of Interest**

Does anyone associated with the research team have a conflict of interest? [ ]  Yes [ ]  No

If yes, please identify the team member, the conflict, and plans to manage the conflict?

**APPENDICES**

Attach all necessary Forms/documents in support of your application.

[ ] *Signed* Investigator Assurance Form (required)

[ ] Research training Form for ALL research team members (required)

[ ] Vulnerable Populations Considerations Form

[ ] Informed Consent Form

[ ] HIPAA/FERPA Form

[ ] Surveys

[ ] Other (please specify):