**Hardin-Simmons University Institutional Review Board**

**Exempt Research 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:** Click or tap here to enter text.

**Principal Investigator (PI):** Click or tap here to enter text.

**Role**: [ ]  HSU Faculty

 [ ]  non-HSU Faculty

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

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

 [ ]  HSU Staff (Faculty Advisor MUST be identified)

**Date PI Completed Ethics Training:** Click or tap here to enter text.

**Phone Number:** Click or tap here to enter text.

**Email Address:** Click or tap here to enter text.

**Department:** Click or tap here to enter text.

**Institution (if not HSU):** Click or tap here to enter text.

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| **Faculty Advisor Information** |
| **Name:** Click or tap here to enter text. | **Department:** Click or tap here to enter text. |
| **Phone:** Click or tap here to enter text. | **Email:** Click or tap here to enter text. |

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| **Co-Investigator’s Information** |
| **Investigator’s Name** | **Department / Affiliation** | **Date Completed Ethics Training** |
| 1. Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| 2. Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| 3. Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| 4. Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| 5. Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

**Where will the research project be conducted?**

 [ ]  On Campus

 [ ]  Off Campus

* Location: Click or tap here to enter text.
* Do you have permission to conduct the study at this site? [ ]  Yes [ ]  No
* Contact person who granted permission to conduct study at this site
	+ Name: Click or tap here to enter text.
	+ Phone number: Click or tap here to enter text.
	+ Email address: Click or tap here to enter text.
* Will this site require their own IRB approval? [ ]  Yes [ ]  No
* Will this site 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: Click or tap here to enter text.

**Section II – Exemptions**

Please select the exemption that would classify your research as exempt human research according to [45 CFR 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html). **ALL** human research activities in your project must fall under one or more of these exempt categories to be considered exempt. If your project includes exempt and non-exempt activities, then your project is NOT exempt (ex. a survey following physical manipulations of the body).

*Exempt research cannot involve prisoners unless incidentally from the broader population.*

*[ ]* **Exemption 1** *(Exemption 45 CFR 46.101(b)(1)* – Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

*[ ]*  **Exemption 2** *(Exemption 45 CFR 46.101(b)(2) -* Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met (please select those that apply):

[ ]  The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects. (If the participants are children, then ONLY educational tests or observation of public behavior when the investigator(s) do not participate can be considered exempt).

*[ ]*  Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. (If the participants are children, then ONLY educational tests or observation of public behavior when the investigator(s) do not participate can be considered exempt).

[ ]  The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7). (In a limited IRB review, the IRB must determine that protections are in place to maintain the privacy of the subjects and confidentiality of the data. Complete the Limited IRB review section of this form if checked. May not involve children)

[ ]  **Exemption 3** *(Exemption 45 CFR 46.101(b)(3)*- Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.

Benign behavioral interventions are defined as brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

Research also meets at least one of the following criteria (please select those that apply):

[ ]  The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects

[ ]  Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation

[ ]  The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7). (In a limited IRB review, the IRB must determine that protections are in place to maintain the privacy of the subjects and confidentiality of the data. Complete the Limited IRB review section of this form if checked.).

Will the subjects be deceived regarding the nature or purposes of the research?

[ ]  Yes [ ] No

If yes, this exemption is not applicable *unless* the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

[ ] **Exemption 4** *(Exemption 45 CFR 46.101(b)(4)*- Research involving collection or study of *existing* data, documents, records, or pathological or diagnostic specimens, if at least one of the following criteria is met (please select those that apply):

[ ] The identifiable private information or identifiable biospecimens are publicly available.

[ ] The information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects

[ ] The research involves only information collection (not biospecimens) and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA regulations for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b)

[ ] The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities.

[ ] **Exemption 5** *(Exemption 45 CFR 46.101(b)(5)*- Research and demonstration projects that are conducted or supported by a Federal department or agency that are that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants.

Note: For this exemption, the research or demonstration project must be publicly accessible on a Federal Web site or in a list of research that the Federal department or agency conducts or supports. See full regulations for more details.

[ ] **Exemption 6**- *(Exemption 45 CFR 46.101(b)(6)-* Taste and food quality evaluation and consumer acceptance studies if one of the following criteria are met (please select):

[ ] Wholesome foods without additives are consumed

[ ] The food consumed contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

[ ] **Exemption 7** - *(Exemption 45 CFR 46.101(b)(7)-* Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8). (In a limited IRB review, the IRB must determine that protections are in place to maintain the privacy of the subjects and confidentiality of the data, and that broad consent will be obtained. Complete the Limited IRB review section of this form if checked.)

Note: This request is for information or specimens collected for another purpose, not for establishing a repository for research purposes.

[ ] **Exemption 8** - *(Exemption 45 CFR 46.101(b)(8)-* Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met (please select):

[ ] Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with HHS regulations. (Note: An example of the previously signed broad consent must be submitted).

[ ] Documentation of informed consent or waiver of documentation of consent was obtained

[ ] The investigator does not include returning individual research results to subjects as part of the study plan.

[ ] An IRB conducts a limited IRB review. (In a limited IRB review, the IRB must determine that protections are in place to maintain the privacy of the subjects and confidentiality of the data, and that broad consent will be obtained. Complete the Limited IRB review section of this form if checked.)

**Section III – Research Proposal**

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

1. **Summary**: *Provide a one paragraph summary of the research that includes a brief description of the purpose, methods, potential risks, and risk management procedures in lay language.*

Click or tap here to enter text.

1. **State the specific purpose of your research study.** *Specify aims and what question(s) and/or hypotheses this research is designed to answer.*

Click or tap here to enter text.

1. **Describe the need for your research study.** *Cite references in the text to justify the need of the study and hypothesis(es). State the relevance of this research to and potential for contribution to the field of research.*

Click or tap here to enter text.

1. **Describe how subjects will be recruited for your study.** *Note: human subjects should be recruited fairly, informed adequately, and, if applicable, compensated appropriately.*
	1. **Where will subjects be recruited from?**  Click or tap here to enter text.
	2. **How will subjects be identified for recruitment?** This may include self-identification. Click or tap here to enter text.
		* Family Education Rights and Privacy Act (FERPA) protects the privacy of student education records. FERPA applies when student educational records are used for research. FERPA requires a signed permission when IDENTIFIABLE information from student records is released to anyone for research.
		* If subjects are identified from student records, provide documentation that authorizes your access to those records OR include permission in the consent document.
	3. **Materials**: List each item used in the recruitment of subjects (advertisements, flyers, contact letters or emails, telephone protocols/scripts, web site template, or other recruitment materials). Provide a copy of each material that will be used. Click or tap here to enter text.
	4. **Voluntary participation**: Describe measures that will be taken to ensure voluntary participation. Click or tap here to enter text.
	5. **Informed Consent Documents**: Indicate the informed consent document(s) used to document informed consent for each group. **Submit a copy of the informed consent document for review**.

[ ]  Consent to participate

[ ]  Parental permission for Minor/Child

[ ]  Assent to participate (under 18 if applicable)

[ ]  Oral script and short form consent for individuals with low literacy

* 1. **Vulnerable Populations**: Will your research include any of the following special populations that require additional considerations? (Check all that apply) **If any checked, complete the Vulnerable Populations Considerations form.**

[ ]  Children and Minors (under 18 years)

[ ]  Pregnant women or fetuses

[ ]  Neonates

[ ]  Impaired decision-making capacity

[ ]  Prisoners **[STOP!! Research with Prisoners CANNOT be exempted]**

[ ]  Economically or educationally disadvantaged persons

[ ]  Students

[ ]  Elderly

* 1. **Inclusion criteria:** What characteristics (e.g. age, conditions, diagnosis, work qualifications, etc.) must subjects have to be in this research? Answer for each group if there are multiple groups. Click or tap here to enter text.
	2. **Exclusion criteria:** What characteristics would exclude subjects from this research who are otherwise eligible. **Note: Exclusion criteria are not the opposite of inclusion criteria, but rather a further limit.** Answer for each subject group, if there are multiple groups. Click or tap here to enter text.
	3. **Will participants be compensated**? [ ]  Yes [ ]  No
	+ If yes, please describe the compensation: Click or tap here to enter text.
	1. **Do you expect to enroll anyone whose first language is not English or who is not fluent in English**? [ ]  Yes [ ]  No
		+ If yes, list the languages expected to be represented by the subjects. Click or tap here to enter text.
		+ Describe the mechanisms for identifying and providing certified interpreters. Click or tap here to enter text.
		+ Describe the mechanism for verifying the accuracy of print materials. (e.g. certified translator, back translation). Click or tap here to enter text.
	+ *Note: if yes, a translated informed consent form may be required depending on your target population.*
1. **Design & Methodology**: Describe the research design and methodology. Explain your experimental methods in a step-by-step (chronological) manner. Describe the procedures/activities that the participants must complete/undergo. Describe any special considerations associated with the subject tasks at the location (for example, if subjects are students identify whether class time is used or activities take place outside of classroom time; address nonparticipating students; supervision of non-participants, etc.) Provide as appendices examples of surveys, photos, illustrations, etc. that will aid the IRB members. Submit a flow sheet as a separate document if it will aid understanding. Click or tap here to enter text.
2. **Deception or Incomplete Disclosure**: Does the research involve any deception or withholding of complete information? [ ]  Yes [ ]  No
	1. Deception involves intentionally providing inaccurate or false information to subjects
	2. Incomplete disclosure involves withholding information about the study purpose and/or reason for procedures in order to prevent biasing the results.
	3. If yes, fully explain why this is necessary. Provide justification for AND possible alternatives to the use of deception or withholding information. Click or tap here to enter text.
3. **Risk & Benefits**:
	1. Risk and Risk Management: List and describe the risks related to confidentiality or psychosocial issues and how they will be managed. Click or tap here to enter text.
	2. Anticipated benefits for individual subjects: Describe the anticipated benefits of this research for individual subjects in each subject group.Click or tap here to enter text.
	3. Anticipated benefits for society: Describe the anticipated benefits for society and explain how the benefits outweigh the risk. Click or tap here to enter text.
4. **Data Collection & Protection**:

|  |  |
| --- | --- |
| Will you collect demographic data or direct subject identifiers? (Direct subject identifiers include names, SSN, email addresses, job titles, etc.). | [ ]  Yes [ ]  No If yes, explain why this is necessary. Click or tap here to enter text. |
| Describe how the data will be kept confidential during collection, analysis, and storage, including what coding system will be used. Click or tap here to enter text. |
| Describe how the data will be coded, stored, and transferred. | Click or tap here to enter text. |
| Code link after data collection: will a link between participants and any direct identifiers be retained **after** the data collection is complete? | [ ]  Yes [ ]  No If yes, explain why this is necessary and for how long you will keep this link. Click or tap here to enter text. |
| List all data collection instruments, surveys, questionnaires, etc. that will be used in this research.  | Click or tap here to enter text. |
| Will audio or visual recordings or photographs of subjects be made? | [ ]  Yes [ ]  No If yes, explain what type of recordings or photos you will make, how you will make the recordings or take photographs, how long you will keep them, and if anyone other than members of the research team will be able to see them. Click or tap here to enter text. |
| Will subjects’ medical, academic, or other personal records be accessed for screening purposes or during this research?  | [ ]  Yes [ ]  No  |
| Accidental disclosure: How will the data be protected against disclosure to the public, other researchers, or non-researchers? | Click or tap here to enter text. |
| Will protected health information (PHI) be received and/or used in the course of conducting this research? | [ ]  Yes [ ]  No If Yes, describe why and what information to be received and/or used is. Click or tap here to enter text. |
| If enrolling students, will you give extra course credit? | [ ]  N/A [ ]  Yes [ ]  No If yes, describe what alternative will be offered for students who choose not to participate. Click or tap here to enter text. |
| How will the data be stored? | Click or tap here to enter text. |
| When will the data be destroyed? | Click or tap here to enter text. |
| What is the estimated sample size? What are the factors used to support the proposed sample size (e.g. power) or how the number to complete the research was determined? | Click or tap here to enter text. |

1. **Data Analysis**: Describe how the data will be analyzed. If qualitative data is collected, describe the analysis method. Click or tap here to enter text.

**Section IV – Conflicts of Interest**

1. **Does anyone associated with the research team have a conflict of interest?**

[ ]  Yes [ ]  No

* 1. If yes, identify the team member, the conflict, and plans to manage the conflict. Click or tap here to enter text.

**Appendices**

Attach all necessary documents in support of your application.

[ ]  Signed Investigator Assurance form (required)

[ ]  Copy of research training for ALL research team members, including the PI and Faculty Advisor (required)

[ ]  Vulnerable Populations Considerations form (if applicable)

[ ]  Informed consent form (required)

[ ]  HIPAA/FERPA form (if applicable)

[ ]  Survey Instruments

[ ]  Other (please specify) Click or tap here to enter text.