**Application for Ethical Review of Research on Human Subjects**

**Project Title:**

**Section A: Project Personnel**

For each principal investigator (PI), co-principle investigator (Co-PI), faculty sponsor, student investigator and research assistant, provide the requested information and submit evidence of completion of CITI or NIH training (a screenshot suffices). CITI or NIH certification for all project personnel must be less than 3 years old, and electronic copies of certificates must be submitted with each application for IRB approval.

Principal Investigator:

Name: Phone:

Faculty Rank: Email:

School/Department:

CITI/NIH Completion Code: Expiration Date:

Co-Principal Investigators (Co-PIs) or Faculty Sponsor:

Name: Phone:

Faculty Rank: Email:

School/Department:

CITI/NIH Completion Code: Expiration Date:

Student Investigators:

Name: Phone:

Email:

School/Department: Graduate or Undergraduate:

CITI/NIH Completion Code: Expiration Date:

Research Assistants:

Name: Phone:

Email:

School/Department: Graduate or Undergraduate:

CITI/NIH Completion Code: Expiration Date:

*Insert additional entries for the various categories as needed.*

**Section B: Conflict of Interest**

1. Do any of the project personnel have a relationship with any entities related to the proposed research project that would constitute or appear to constitute a conflict of interest?

Yes No

If yes, identify each individual with a conflict, the nature of each conflict, and describe the plan for mitigating each conflict.

**Section C: Project Summary**

1. State both the general purpose(s) of your research and the specific research question(s) to be explored.
2. If an intervention or treatment is to be conducted or given, describe it, who will conduct or provide it, as well as how and when it will be conducted or provided. If the project does not include a treatment or intervention, then proceed to the next item.
3. Describe all data collection procedures. Be sure to address what data will be collected, when it will be collected, how it will be collected, where it will be collected, and by whom it will be collected. If observations are to be used, indicate whether they will be participatory or non-participatory observations. If surveys, focus groups or interviews are to be used, attach questions and/or scripts to be used. *Please attach copies of all data collection instruments. If a copyrighted instrument is to be used, provide evidence of authorization of each such instrument’s use. If any research materials to be provided to participants are to be written in a language other than English, please submit both original and translated copies of the materials along with this proposal*.

**Section D: Research Context**

1. Describe the context (school, classroom, clinic, hospital, home, park, etc.) in which the research will be conducted.
2. Will the research be conducted at a non-SXU site?

Yes No

If the answer to the preceding question was yes, then include with this application a letter of approval to conduct the off-site research from the local representative. If it is not possible to garner such authorization for the project prior to seeking IRB approval, the PI should submit a written explanation of why an exception to this requirement is necessary and appropriate. Similarly, if documentation of site approval would jeopardize the participants, then again, the PI should submit a written explanation of why an exception to this requirement is necessary and appropriate.

1. Anticipated Start Date: Anticipated End Date:

**Section E: Research Participants & Participant Protection**

1. How will participants be selected? If potential participants may be excluded from participation, state the criteria for exclusion.
2. Will your research involve the use of vulnerable human subject populations such as pregnant women, minors (provide age range), and people who are the researcher’s students, elderly, economically disadvantaged, homeless, imprisoned, physically or cognitively impaired, etc.?

Yes No

If yes, identify the relevant population, and describe the methods you will employ to safeguard such participants’ rights and well-being to the fullest extent possible.

1. Describe how the anonymity of subjects and confidentiality of personally identifiable data will be protected.
2. Describe any potential physical, emotional, psychological, social, economic, or any other known potential dangers or risks to participants, and explain what will be done to minimize or mitigate such dangers or risks.
3. Describe any potential direct or indirect benefits, including incentives, to participants. *If students are offered extra credit for participation, be sure to provide students who opt not to participate an opportunity to earn an equivalent amount of extra credit.*
4. Describe any benefits to the field of research.
5. Will the study involve some form of deception (hiding purpose of research, false feedback, placebo use, etc.) of human subjects?

Yes No

If yes, explain why use of deception is justified in this study?

**Section F: Informed Consent (See page 12 for a list of elements of informed consent)**

1. If you are requesting a waiver or alteration to the requirement to garner informed consent from all participants, indicate whether you are requesting a waiver or an alteration to the informed consent process. If you are not seeking a waiver or alteration to the informed consent process, go to item 2 on page 9.

\_\_\_ I am seeking a waiver for the requirement to secure written documentation of informed consent, i.e., to secure signed written consent. Go to G.1.A.

\_\_\_ I am seeking to have waived or to alter the elements of informed consent. Go to G.1.B.

G.1.A. Indicate which of the following situations best fits your research study.

\_\_\_ The only record linking the participant(s) and the research would be the consent document, and the primary risk to the participant(s) would be breach of confidentiality.

Explain how your study meets this criterion.

\_\_\_ The research presents only minimal risk to the participant(s) and involves no procedures for which written consent is normally required outside the research context.

Explain how your study meets this criterion.

If completing G.1.A., i.e., if seeking a waiver of the requirement to secure written documentation of informed consent, provide a script for verbally garnering the informed consent of participants, which addresses all required components of informed consent. Then go to item 2 on page 9.

G. 1.B. Indicate whether you are requesting a waiver of the entire process of garnering informed consent (written and verbal) or alteration to the required components of the informed consent process.

 I am requesting that the informed consent process be waived. If so, indicate that and go to justification section at the bottom of the page.

 I am requesting that the informed consent process be altered.

For an alteration, identify which of the elements of the consent process you wish to alter, and how you wish to alter those elements of the process. Then, go to the justification section at the bottom of the page.

Elements to be altered:

Nature of alteration:

Justifications for requests to waive or alter the informed consent process (requests falling into category G.1.B.) must be grounded in the four criteria established in 45 CFR 46.116 (d). Provide a justification for each of the four criteria.

1. The research involves no more than minimal risk to the subjects;

Justification:

1. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

Justification:

1. The research could not practicably be carried out without the waiver or alteration; and

Justification:

1. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Justification:

1. Describe the methods for attaining informed consent of subjects.
2. Please attach a copy of all informed consent letters/forms (e.g., adults, students, minors, research site administrator’s consent). Unless a waiver for some or all aspects of informed consent is granted, all elements of informed consent (see page 12) must be evident in the content of the related documents and verbal process. Be sure to include IRB Chair contact information for issues related to participant rights or injury. Keep in mind that all documents and discourse related to informed consent must be in language the participants can understand. *If any research materials related to informed consent or explanation of the study are to be provided to participants in a language other than English, please submit both original and translated copies of the materials along with this proposal*.

Identify the requested category of review: exempt, expedited or full

\_\_\_\_\_ Full \_\_\_\_\_ Expedited \_\_\_\_\_ Exempt

Criteria for exempt status: Per Section 46.101(b) of 45 Code of Federal Regulations (CFR) 46 (Department of Health and Human Services (DHHS), 2009, p. 3), unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that 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.

Criteria for expedited processing: As stated in Section 46.110(b) of 45 CFR 46 (DHHS, 2009, p. 6), an IRB may use the expedited review procedure to review either or both of the following:

1. some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,
2. minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

*The IRB recommends that applicants garner feedback from an experienced human subjects researcher, possibly a department chair, prior to submission of the application to the IRB.*

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| I certify that the above information is correct**(all investigators must sign)**: | I have read and approved of the protocol: |
|  |  |
| Principal Investigator (sign *and* print) | Date | Faculty Sponsor (if appropriate - sign) | Date |
|  | **IRB USE ONLY:** |
| Approve exemption:  | [ ]  |
| Co-Investigator (sign) | Date | Recommend full review:  | [ ]  |
|  |  |
| Co-Investigator (sign) | Date | Reviewer signature | Date |
|  |  |
| Co-Investigator (sign) | Date |
|  |
| Co-Investigator (sign) | Date | Tracking/approval number  |

**Elements of Informed Consent**

Unless the IRB approves a waiver or alteration to the informed consent process and content, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

The above lists are taken from Sections 46.116(a-b) of 45 CFR 46 (DHHS, 2009, pp. 7-8), which is available at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.