



FORT HAYS STATE UNIVERSITY

THE OFFICE OF RESEARCH

INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH

NEW IRB SUBMISSION

I. Project Title and Research Team Members

Project Title:

Principal Investigator Name:

Faculty Research Supervisor (If student is the PI):

Additional Team Members:

This form must be used to submit an application through the IRBNet system.
No other methods of submission will be accepted.

Access the system here: www.irbnet.org

Student and Adjunct Faculty researchers: Please note that Faculty Research Supervisor approval is required prior to submission to IRB. The Faculty Research Supervisor signature in IRBNet indicates approval and agreement with section XII. For faster processing, ensure all research team members have completed all required CITI training through <https://www.citiprogram.org/> prior to submitting this application.

II. Type of investigator and nature of the activity: (Check all appropriate categories.)

A. Faculty/Staff at FHSU:

- Submitted for extramural funding to:
- Submitted for intramural funding to:
- Project unfunded
- Quality improvement/program evaluation
- Quality assurance
- Other (Please explain)

- B. Student at FHSU:**
- | | | | |
|--------|---------------------------------|---------------------------------------|-------------------|
| Thesis | Graduate Specialist Field Study | Undergraduate Graduate Research Paper | Independent Study |
|--------|---------------------------------|---------------------------------------|-------------------|

C. Class Project (Course Number and Course Title), explain activity:

D. Other than faculty, staff, or student at FHSU (Unaffiliated with FHSU)
Please explain:

III. Human Subjects Research Ethics Training: The IRB will not review submissions without verification of appropriate CITI training. The Principal Investigator and all members of the research team must complete the appropriate CITI training modules. Faculty Research Advisors, when listed above, must also complete CITI training. If the PI is not affiliated with FHSU, documentation of CITI or other comparable training must be provided.

Date completed CITI training:

IV. Project Information

A. Expected study period from: _____ To: _____

B. Describe the purpose of the research. Explain what is intended to be discovered, including goals, aims, and objectives and/or state the hypothesis to be tested.

Background: provide a brief scientific or scholarly rationale for the research activities, and address gaps in current knowledge.

Investigators NOT currently affiliated with FHSU will collaborate on this project.

C. (If checked above) Identify any cooperating institutions by name.

D. This study is being/has been reviewed by another IRB. Yes No
If yes, please attach relevant documentation.

V. Subject Information

A. Number of subjects:

B. Subject Age (Check all that apply):

- 1-7
- 8-17
- 18-65
- 65+

C. Special Populations (Check all that apply):

- Minors
- Non-English speaking
- Prisoners
- Individuals with impaired decision-making capacity
- Individuals who are economically or educationally disadvantaged
- Individuals with Legally Authorized Representatives
- Individuals who are vulnerable to coercion or undue influence

D. Describe target demographic of proposed subjects; explain how you will ensure that selection is equitable and that all relevant ethnic groups, genders, and populations have access to the study.

E. Describe any specific populations targeted for inclusion or exclusion: Justify criteria based on age, gender, race, ethnicity, sexual orientation, or origin.

VI. Recruitment

A. Describe the recruitment process for the study. Explain in detail how you will gain access to and recruit participants for participation in this project. Upload scripts, emails, letters, advertising, and all marketing materials with your application. Provide a step-by-step description of how potential participants will be recruited.

B. Identify all applicable recruitment methods. (Please provide copies of materials).

- | | |
|---|--|
| Flyers | Internet |
| Purchased Sample List | Letter |
| Email | Personal or Professional Contacts |
| Telephone | Amazon MTurk |
| Newspaper | Social Media |
| Poster | SONA |
| Class Announcement | Snowball method (if used, must describe process in detail) |
| Departmental Communication | Other (describe) |
| Third Party (Professional or Charitable Organization) | |

C. Are you recruiting students from a class you teach or for which you have responsibility?

Yes

No

D. Are you recruiting employees who directly or indirectly report to you?

Yes

No

E. If yes to either VI C or D, please explain why this population is necessary and describe what precautions have been taken to minimize potential undue influence or coercion.

VII. Compensation

Participants will not receive compensation

Students will receive extra credit or course credit

Participants will receive monetary compensation

Participants' names will be entered into a drawing for a prize

Describe the compensation or credit, including amount, scheduling and method.
Explain what will happen if participants withdraw from the study.

VIII. Risks and Benefits

A. Describe the anticipated benefits of the research for individual subjects.

B. Describe the anticipated benefits of the research for society or the discipline. Explain how the benefits outweigh the risks.

C. Does this study involve any of the following? (Check all that apply.)

- | | |
|---|---|
| Deception | Information relating to sexual attitudes, orientation or practice |
| Omission | Private identifiable information |
| Misleading Information/false feedback | Personal or sensitive information |
| Physical or mental stress | Private records (academic or medical) |
| Collection of fluids or tissue | Social or economic burden to participants |
| Substances taken internally or applied externally | Mechanical or electrical device applied to subjects |
| Information pertaining to illegal activity | Information pertaining to substance use |
| DXA Scan, X-RAY, MRI | |
| Information that, if released, could damage an individual's financial standing, reputation, employability, or cause social stigmatization, discrimination, or embarrassment | |
| Other | |
- None of these**

D. Describe the nature and degree of the risk or harm checked above. If using deception, include a justification for the deception.

E. What steps will be taken to minimize risks or harm and to protect the subject's welfare (when risk is greater than minimal)?

IX. Emergencies

How will emergencies or unanticipated events related to the research be handled if they arise? (Please note that this refers to an emergency situation associated with the research activity not an emergency such as a fire alarm.)

X. Data Collection and Security

A. Procedures: Describe the setting and tasks subjects will be asked to perform. Describe the frequency and duration of procedures, tests, and experiments. Include a timeline or a step-by-step description.

B. Describe the steps that will be taken to secure the data during storage, use, and transmission. How and where will the data be stored, for how long will it be kept, when will it be destroyed, what safeguards are in place for data with identifying information? Include a description of physical and electronic security.

C. Identify any direct identifiers like name, unique identifier, address, email, etc. that will be kept with the records. Explain why it is necessary to record the identifiers and describe the coding system to be used.

D. If retaining a link between study code numbers and direct identifiers after data collection is complete, please explain why this is necessary, how long the link will be kept, how it will be stored, and when it will be destroyed.

E. Data collection methods (check all that apply)

Observation	Blood draw, saliva swab, or other biological sampling
Interviews	Audio recording (see section X. F)
Focus groups	Video Recording (see section X. F)
Surveys/Questionnaires	Previously collected data (no individual identifiers)
Psychological tests	Previously collected data (with individual identifiers)
Educational tests	Internet-based methods
	Other (describe)

F. If using audio or video recording, describe how the recordings will be used, how confidentiality will be maintained, who will have access, and how and when the recordings will be destroyed or completely deidentified.

- G. Protected data to be collected (check all that apply)
- Protected health Information (see Section X, Part H)
 - Unique ID number (e.g. employee ID, driver's license number, student ID number, etc.)
 - Academic records
 - Social security number
 - Other personally identifiable information

H. If the research involves protected health information, it must comply with the HIPAA Privacy Rule.

Select one:

The research does not involve protected health information

Do you plan to use or disclose identifiable health information outside FHSU?

Yes

No

If yes, the consent form must include a release of protected health information.

The IRB may make a waiver of authorization for disclosure if criteria are met under the HIPAA Privacy Rule. *If a waiver of authorization is being requested, the researcher must contact the IRB administrator prior to submitting this application.*

Will the protected health information to be used or disclosed be deidentified, or will a limited data set be used or disclosed? *Please describe:*

I. Sharing results with subjects (Indicate if results, like tests or incidental findings, will be shared with the subject or others, and if so, indicate how it will be shared.)

J. Withdrawal of subjects (Describe the procedures to be followed when subjects withdraw from research or under what circumstances subjects may be withdrawn without their consent.)

XI. Informed Consent

A. Specify the type of informed consent you will use with this research project.

Signed Consent

Consent forms included with this submission:

Adult	Assent Script/Procedures	Parent/Guardian
Foreign Language Version		Agency Consent

Oral Consent (Waiver of documentation of consent, include script with application)

Signed consent form would be the only record linking the subject to the research, and the principal risk of signing a consent form would be the potential harm resulting from a breach of confidentiality.

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

Information Statement (include with application)

Debriefing Statement (include with application)

B. Describe any potential concerns with obtaining informed consent (Foreign language, minimizing possibility of coercion, etc.)

C. Describe the process you will follow to obtain consent and/or assent. Include names of individuals on the research team who will obtain consent, where and when the process will take place, and how you will ensure the subject's understanding.

All materials related to this study must be uploaded into your [IRBNet](#) study workspace. Instructions for using IRBNet are located at [the FHSU IRB website](#). Required materials may include, but are not limited to:

- Completed application
- Copies of all recruiting materials, including scripts, emails, letters, posters, advertising, etc.
- Copies of all measurements, instruments, surveys, interview questions being used, etc.
- All consent forms and assent forms or scripts (for children).
- Debriefing materials, if used.

Please note that all materials and scripts to be used for this study need to be reviewed and approved by the IRB.

XII Certifications:

I am familiar with the policies and procedures of Fort Hays State University regarding human subjects in research. I subscribe to the university standards and applicable state and federal standards and will adhere to the policies and procedures of the Institutional Review Board for the Protection of Human Subjects. I will comply with all instructions from the IRB at the beginning and during the project or will stop the project.

AND

I am familiar with the published guidelines for the ethical treatment of human subjects associated with my particular field of study.

Statement of Agreement:

By electronically signing and submitting this application package, I certify that I am willing to conduct and /or supervise these activities in accordance with the guidelines for human subjects in research. Further, I certify that any changes in procedures from those outlined above or in the attached proposal will be cleared through the IRB.

If the Principal Investigator is a student, the electronic signature of the Faculty Advisor certifies:

1) Agreement to supervise the student research; and, 2) This application is ready for IRB review. The Student is the "Principal Investigator". The Faculty Research Advisor is the "Advisor". Designees may not sign the package. It is the student's responsibility to contact their Faculty Research Advisor when the study is ready for the Advisor's signature.

I certify the information provided in this application is complete and correct.
I understand that I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects and strict adherence to any stipulations imposed by the IRB.

I agree to comply with all FHSU policies, as well as all federal, state and local laws on the protection of human subjects in research, including:

- Ensuring all study personnel satisfactorily complete human subjects research training.
- Performing the study according to the approved protocol.
- Implementing no changes in the approved study without IRB approval.
- Obtaining informed consent from subjects using only the currently approved process and form.
- Protecting identifiable health information in accordance with HIPAA Privacy rule.
- Promptly reporting significant or untoward adverse effects or unanticipated problems to the IRB.