FLORIDA TECH

RESEARCH INVOLVING HUMAN PARTICIPANTS
EXEMPT APPLICATION

This form shall be used if there is minimal risk to human subjects. One of the categories on the next page applies to the research; if there is more than minimal risk associated with the research (none of the conditions apply) or if the research utilizes a special population (children, prisoners, institutionalized individuals, etc.), please use the expedited/full application form found on the IRB website.

You should consult the university's document Principles, Policy, and Applicability for Research Involving Human Subjects and instructions on the IRB website prior to completion of this form.
floridatech.edu/research/compliance--regulations/institutional-review-board

Submit via email to FIT_IRB@fit.edu.

IRB Contact Information:
Dr. Jignya Patel
IRB Chairperson
FIT_IRB@fit.edu
321-674-7391

INVESTIGATOR INFORMATION

Title of project _____

Date of submission _____

Expected project start date _____ Expected project duration _____

Principal investigator _____

Title _____

Academic unit _____

Phone _____ Email _____

List all co-investigator(s). Please include name, title, academic unit/affiliation and email.

CATEGORIES OF EXEMPT RESEARCH

Must choose one:

❑ 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:

a. Research on regular and special education instruction strategies, or
b. Research on the effectiveness of or the comparison among instruction techniques, curricula or classroom management methods.

❑ 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:

a. 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; or
b. 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; or
c. 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 IRB can determine if there are adequate provisions in place to protect the privacy of the subjects and confidentiality of the data.

Note: Subcategories A and B can include research with children if the research only includes educational tests or public observation and investigator does not take part in activities being observed; subcategory C does NOT apply to research involving children.

❑ 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 and at least one of the following criteria is met:

a. 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; or
b. 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; or
c. 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 IRB can determine if there are adequate provisions in place to protect the privacy of the subjects and confidentiality of the data.

Note: Benign behavioral interventions are 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. This exemption is not applicable to research with children and to research involving deception unless the subject authorizes deception.

❑ Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable bio specimens, if at least one of the following criteria is met:

a. The identifiable private information or identifiable bio specimens are publicly available;
b. Information, which may include information about bio specimens, 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;
c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated by HIPAA as health care operations, research, or public health activities and purposes; or
d. Analysis of data on behalf of a federal agency or department—as opposed to an investigator-initiated analysis of federally supplied data—if the requirements of certain federal laws are met. These sources are publicly available OR if the information is recorded in such a manner that subjects cannot be identified, directly or indirectly, through identifiers linked to the participants.

❑ Research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads, and 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. Examples of such projects include, but are not limited to, internal studies by federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants.

❑ Taste and food quality evaluation and consumer acceptance studies if:

a. Wholesome foods without additives are consumed, or
b. Food is consumed that contains food ingredients 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.

❑ Storage or maintenance for secondary research (prior to secondary analyses) for which broad consent is required:

a. Storage or maintenance of identifiable private information or identifiable bio specimens for potential secondary research use if an IRB can determine adequate provisions in place to protect the privacy of the subjects and confidentiality of the data (e.g., storing student data collected from previously conducted surveys).

Note: Visit floridatech.edu/broad-consent-form for instructions on creating broad consent.

❑ Secondary research for which broad consent is required: Research involving the secondary analysis of existing private identifiable data and identifiable bio specimens if the following criteria are met:

a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable bio specimens was obtained, and
b. Documentation of informed consent or waiver of informed consent was obtained, and
c. The IRB determines that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data, and
d. The investigator does not include returning individual research results to subjects as part of the study plan.

Note: Visit floridatech.edu/broad-consent-form for instructions on creating broad consent.

RESEARCH FUNDING

If any part of this study will be funded by an external funding source, you must note the funding source and award/solicitation number below:

ANSWER THE FOLLOWING QUESTIONS AS THOROUGHLY AS POSSIBLE.

1. List the objectives of the proposed project.

2. Describe the research project design/methodology. Discuss how you will conduct your study and what measurement instruments you are using. Attach all research materials to this application. Please describe your study in enough detail so the IRB can identify what you are doing and why.

3. Describe the characteristics of the participant population, including number, age, sex and recruitment strategy (attach actual recruitment email text, recruitment flyers, etc).

4. Describe any potential risks to the participants (physical, psychological, social, legal, etc.) and assess their likelihood and seriousness. Describe steps that will be taken to mitigate each risk.

5. Describe the procedures you will use to maintain the confidentiality and privacy of your research participants and project data. If video or audio recordings will be made, you must review the video/audio recording policy found on the IRB website and address precautions you will take in this section.

6. Describe your plan for informed consent (attach proposed form).

7. Discuss the importance of the knowledge that will result from your study (benefits to the field and to society) and what benefits will accrue to your participants (if any). Include information about participant compensation if appropriate.

8. Explain how your proposed study meets criteria for exemption from Institutional Review Board review (as outlined on page 2 of this form).

SIGNATURE ASSURANCES

I understand Florida Institute of Technology's policy concerning research involving human participants, and I agree:

1. To accept responsibility for the scientific and ethical conduct of this research study.
2. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent form.
3. To immediately report to the IRB any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study.
4. To complete, on request by the IRB, a Continuation Review form if the study exceeds its estimated duration.

Principal investigator's signature _____ Date _____

Principal investigator's name (print) _____

ADVISOR ASSURANCES
(If primary investigator is a student)

This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of the study, the necessity for the use of human subjects in the study to the student's academic program and the competency of the student to conduct the project.

Major advisor's signature _____ Date _____

Major advisor's name (print) _____

ACADEMIC UNIT HEAD
(It is the PI's responsibility to obtain this signature.)

This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the study.

Academic unit head's signature _____ Date _____

Academic unit head's name (print) _____

FOR IRB USE ONLY

IRB approval _____ Date _____

IRB # _____