FLORIDA TECH

RESEARCH INVOLVING HUMAN PARTICIPANTS
EXPEDITED/FULL APPLICATION

This information listed below should be submitted to Florida Tech's IRB if the proposed research has more than minimal risk (none of the exempt conditions apply) or if the research utilizes a special population (children, prisoners, institutionalized individuals, etc.). Please consult the IRB website for detailed information, or contact the IRB Chairperson.
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

PART 1: GENERAL 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.

PART 2: PROJECT SPONSORSHIP INFORMATION

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

PART 3: RESEARCH DESCRIPTION

1. In lay terms, please describe the GENERAL PURPOSE of the study and how human subjects will be involved. List the SPECIFIC AIMS and RESEARCH QUESTIONS or HYPOTHESES. Avoid the use of jargon when describing the purpose of the study.

2. Outline the INCLUSION CRITERIA for subjects, explaining the rationale for the involvement of any special groups, including children, prisoners, pregnant women or subjects with cognitive impairments. Describe the characteristics of the targeted subjects, including gender, age ranges, ethnic background and health/treatment status. If women or minorities are excluded, provide written justification. Give the number of subjects you anticipate including from each targeted group listed above.

3. Describe sources for potential participants, how subjects will be RECRUITED or the sampling procedures. Attach recruitment advertisement(s), if applicable.

4. Describe any COMPENSATION the subjects will receive, including course credit. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms of payment.

5. Explain how CONFIDENTIALITY and privacy of participant data (and anonymity if appropriate) will be maintained. If the research study involves collection of images or audio recordings of subjects, explain how the material will be used, who will see the images or hear the recordings and in what setting (refer to the audio/video recording policy).

6. Describe the study design/research/measurement PROCEDURE (e.g., control and experimental groups, etc.). Indicate whether or not the subjects will be randomized for this study. Discuss how you will conduct your study and what measurement instruments you are using. List the specific steps of your research protocol. Explain scientific jargon. Attach a copy of any questionnaires, measurement instruments, interview protocols or a description of topics or an approximate script that will be used. If not available at this time, explain. Please describe your study in enough detail so the IRB can identify what you are doing and why.

7. If the study will use deception, describe the nature of the deception, discuss why deception is necessary and fully indicate how participants will be debriefed. Deceptive techniques must be justified by the study's prospective scientific, educational or applied value, and the investigator should explore equally effective alternative procedures that do not use deception. A debrief form/process must be discussed here.

8. Describe all SITES where this research will take place and attach documentation of permission from the appropriate source if the study involves subjects from places other than common public spaces.

9. Describe any POTENTIAL RISKS (physical, psychological, social, legal or other) and the steps that will be taken to minimize risk. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects. Research involving children must carefully assess risks and describe the safeguards in place to minimize these risks.

10. Discuss the importance of the knowledge that will result from your study and what benefits will accrue to your subjects (if any). Discuss why the risks to subjects are reasonable in relation to the anticipated BENEFITS to subjects.

11. CONSENT. Informed consent can be in either written or oral format. If you request waiver of informed consent, documentation of informed consent or of written informed consent, please state your justifications. Attach consent form if applicable. If an oral consent is planned, attach a copy of the text of the statement. If the study will be conducted with minors, provide an assent script. If assent is deemed unnecessary or inappropriate, you must discuss why. The consent form should contain all eight elements listed in Part 4. Researchers are strongly encouraged to use the formal headers found in Part 4, Item 3 to structure the consent document.

PART 4: INSTRUCTIONS FOR DOCUMENTATION OF INFORMED CONSENT

Informed consent is one of the primary ethical requirements underlying human subjects research, reflecting the principle of respect for potential subjects. Informed consent assures that prospective human subjects understand the nature of the research and can decide knowledgeably and voluntarily whether or not to participate.

Informed consent refers to the voluntary choice of an individual to participate in research based on an accurate and complete understanding of, among other things, its purposes, procedures, risks, benefits, alternatives and any other factors that may affect a person's decision to participate.

The basic concepts of the consent process include:

- Full disclosure of the nature of the research and the subject's participation
- Adequate comprehension on the part of the potential subject
- Voluntary choice to participate

Informed consent must be documented by use of a written consent form approved by the IRB and signed by the participant or the participant's legally authorized representative. A copy should be given to the person signing the form. Even though the IRB has approved a consent procedure, it is the investigator's responsibility to ensure that each potential subject understands the information and to take the appropriate steps necessary to gain that comprehension.

Individuals may not be involved as research participants unless a) they understand the information that has been provided and informed consent has been obtained, or b) the IRB has approved a waiver for informed consent.

REMEMBER: if the participant is under the age of 18, parental consent is required. This includes college students under the age of 18.

If the research involves the participation of minors (under 18 years of age), read the description of requirements for research involving children. Additional requirements concerning parental consent forms and child assent are discussed.

Please follow the instructions for documentation carefully.

1. The consent form should be written in language that the participants can understand. Whenever possible, simple declarative sentences should be used. Ordinary language should explain technical terms.
2. Avoid the use of exculpatory language through which the subject or the representative is made to waive or appear to waive any of his/her legal rights or release the investigator, sponsor or institution or its agents from liability for negligence.
3. Important information that must be included on the consent form:
    a. Purpose of the research.
    b. Procedures to be followed (what will the participants be asked to do? Include physical requirements or experimental procedures if applicable.)
    c. Foreseeable risks or discomforts to the subjects. What are the risks associated with participating and what safeguards are in place? Include the following statement, where appropriate: "In the event of physical injury resulting from the research procedures, no form of compensation is available. Medical treatment may be provided at your expense or at the expense of your health care insurer (i.e., Medicare, Medicaid, private payer) which may or may not provide coverage. If you have questions it is your responsibility to contact your insurer."
    d. Benefits to the subject or others which may reasonably be expected to result.
    e. Alternative procedures or alternatives to participation, if any.
    f. Level of confidentiality of participant records. Is data anonymous? How will data be stored? If audio or visual records are obtained, how will they be maintained? Who will have access to the data?
    g. Primary investigator's contact information. Point of contact for questions or problems related to this study.

h. IRB contact. Also note the study was approved by Florida Institute of Technology's IRB, and list the current IRB chair and his/her contact information for questions about the rights of people who take part in research.

i. Voluntary participation, refusal and withdrawal. Include the following statement: "Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled."

j. Signatures, if appropriate. Provide a place for:

    I. Signature of the participant (or his/her legally authorized representative)

    II. Date of signature

WAIVER OF INFORMED CONSENT

The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent outlined above or waives the requirements to obtain informed consent, provided the IRB finds and documents that the following four conditions have been met:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be debriefed—provided with additional pertinent information—after they have participated in the study.

PART 5: SIGNATURE ASSURANCE SHEET

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 # _____