Research Involving Human Subjects
Application for Approval Form

ADMINISTRATIVE INFORMATION:

- **Title of Project:** (if applicable, use the exact title listed in the grant/contract application)

- **Type of Application:**
  - [ ] New,
  - [ ] Addendum/Modification,
  - [ ] Other (explain)

- **Funding Source:** (identify all source(s) of funding for the project)

  Principal Investigator:
  (student or faculty)
  Title:
  Date:

  Co-Principal Investigator: (must be a FSC faculty member)
  Name:
  Department:
  Campus Address:
  E-mail
  Degree/Title:
  Campus Phone:
  Fax #:

- **Contact Name/Email/Phone for Questions/Problems/Emergencies:**

- **Does this project involve any collaborators not part of the student/faculty/staff at FSC?** (projects with non-FSC collaborators may require additional coordination and approvals):
  - [ ] No
  - [ ] Yes

- **Project Classification** (Is this project part of one of the following?):
  - [ ] Thesis
  - [ ] Class Project
  - [ ] Faculty Research
  - [ ] Other:

- **Please attach a copy of the Consent Form:**
  - [ ] Copy attached
  - [ ] Consent form not used

- **Please attach a copy of the sponsor’s grant application or contract as submitted to the funding agency:**
  - [ ] Copy attached
  - [ ] Not applicable

- **Based upon criteria found in 45 CFR 46 – and the overview of projects that may qualify for exemption, I believe that my project using human subjects should be determined by the IRB to be exempt from IRB review:**
  - [ ] No
  - [ ] Yes (If yes, please complete Section X. C. ‘Exempt Projects’; remember that only the IRB has the authority to determine that a project is exempt from IRB review)

If you have questions, please contact the chairman of the Institutional Review Board.
Human Subjects Research Protocol Application Form

The FSC IRB is required by law to ensure that all research involving human subjects is adequately reviewed for specific information and is approved prior to inception of any proposed activity. Consequently, it is important that you answer all questions accurately. Please provide the requested information in the shaded text boxes. The shaded text boxes are designed to accommodate responses within the body of the application. As you type your answers, the text boxes will expand as needed. After completion, print the form and send the original to the Institutional Testing & Research Committee.

I. **BACKGROUND** (concise narrative review of the literature and basis for the study):

II. **PROJECT/STUDY DESCRIPTION** (please provide a concise narrative description of the proposed activity in terms that will allow the IRB or other interested parties to clearly understand what it is that you propose to do that involves human subjects. This description must be in enough detail so that IRB members can make an informed decision about proposal):

III. **OBJECTIVE** (briefly state the objective – what you hope to learn from the study):

IV. **DESIGN AND PROCEDURES** (succinctly outline formal plan for study):
   A. Location of study:
   B. Variables to be studied:
   C. Data collection methods: (surveys, instruments, etc – please attach)
   D. Factors that would lead to halting study due to emotional or physical stress:
   E. Biological samples taken: (if any)
   F. Debriefing procedures for participants:

V. **RESEARCH SUBJECTS**:
   A. Source:
   B. Number:
   C. Characteristics: (any unique qualifiers for participation)
   D. Recruitment procedures: (attach any fliers, posters, etc. used in recruitment)

VI. **RISK – PROTECTION – BENEFITS**: The answers for the three questions below are central to human subjects research. You must demonstrate a reasonable balance between anticipated risks to research participants, protection strategies, and anticipated benefits to participants or others.
   A. **Risks for Subjects**: (Identify any reasonably foreseeable physical, psychological, or social risks for participants. State that there are “no known risks” if appropriate.)
   B. **Minimizing Risk**: (Describe specific measures used to minimize or protect subjects from anticipated risks.)
   C. **Benefits**: (Describe any reasonably expected benefits for research participants, a class of participants, or to society as a whole.)

In your opinion, does the research involve more than **minimal risk** to subjects? (“Minimal risk” means that “the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered...
in daily life or during the performance of routine physical or psychological examinations or tests.”

☐ Yes  ☐ No

VII. CONFIDENTIALITY: Confidentiality is the formal treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure. (Explain how you are going to protect confidentiality of research subjects and/or records. Include plans for maintaining records after completion – it is a federal requirement to maintain consent forms for 3 years after the study completion.)

VIII. INFORMED CONSENT: You must provide potential participants with information that informs them of their rights as subjects, i.e. explanation that the project is research and the purpose of the research, length of study, study procedures, debriefing issues to include anticipated benefits, study and administrative contact information, confidentiality strategy, and the fact that participation is entirely voluntary and can be terminated at any time without penalty, etc. Even if your potential subjects are completely anonymous, you must provide them with this information.

☐ Yes  ☐ No  Answer the following questions about the informed consent procedures.

☐ ☐ a. Are you using a written informed consent form? (If “yes” include a copy with this application. If “no” see next paragraph.)

☐ ☐ b. In accordance with guidance in Title 45 Code of Federal Regulations Part 46, I am requesting a waiver or alteration of informed consent elements (See Section VII above). If “yes,” provide a basis and/or justification for your request.

☐ ☐ c. Does your Informed Consent document have all the minimum required elements of informed consent found in the Consent Form Template? (Please explain)

☐ ☐ d. Do you preserve the anonymity of subjects? (An anonymous subject is one whose identity is unknown, even to the researcher.) If “no” explain why and describe how you will protect the identity of subjects.

☐ ☐ e. Are subjects debriefed about the purposes, consequences, and benefits of the research? Debriefing refers to a mechanism for informing the research subjects of the results or conclusions, after the data is collected and analyzed, and the study is over. (If “no” explain why.)

* It is a requirement that you maintain all signed copies of informed consent documents for at least 3 years following the completion of your study. These documents must be available for examination and review by federal compliance officials.

IX. PROJECT INFORMATION: (If you answer yes to any of the questions below, you should explain them on an attached page.)

☐ Yes  ☐ No  Does the project involve any of the following?

☐ ☐ a. Deception of subjects

☐ ☐ b. Shock or other forms of punishment

☐ ☐ c. Sexually explicit materials or questions about sexual orientation, sexual experience or sexual abuse

☐ ☐ d. Handling of money or other valuable commodities

☐ ☐ e. Extraction or use of blood, other bodily fluids, or tissues

☐ ☐ f. Questions about any kind of illegal or illicit activity

☐ ☐ g. Purposeful creation of anxiety

☐ ☐ h. Any procedure that might be viewed as invasion of privacy

☐ ☐ i. Physical exercise or stress

☐ ☐ j. Administration of substances (food, drugs, etc.) to subjects

☐ ☐ k. Any procedure that might place subjects at risk

☐ ☐ l. Any form of potential abuse; i.e., psychological, physical, sexual

X. SUBJECT INFORMATION: (If you answer yes to any of the questions below, you should explain them in one of the
Does the research involve subjects from any of the following categories?

- [ ] Yes  [ ] No
  a. Under 18 years of age
  b. Physically or mentally disabled
  c. Pregnant females as target population
  d. Subjects in institutions (e.g., prisons, nursing homes, halfway houses)
  e. Economically or educationally disadvantaged
  f. Unable to provide their own legal informed consent

**XI. PROJECT COLLABORATORS:**

**A. FSC Collaborators – anyone who is collecting or analyzing data:** (list all collaborators on the project, including undergraduate and graduate students)

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<th>Name</th>
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**B. Non-FSC Collaborators:** It is critical that you identify non-FSC collaborators, and initiate any coordination and/or approval process early, to minimize delays caused by administrative requirements.

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Does your non-FSC collaborator’s organization have an Assurance with OHRP? (for Federalwide Assurance and Multiple Project Assurance (MPA) listings of other institutions, please reference the OHRP website under Assurance Information at: http://ohrp.osophs.dhhs.gov/polasur.htm).

- [ ] No  [ ] Yes  If yes, Collaborator’s MPA #

Is your non-FSC collaborator’s IRB reviewing this proposal?

- [ ] No  [ ] Yes  If yes, IRB approval #

**C. Exempt Projects:** 45 CFR 46 identifies six categories of research involving human subjects that may be exempt from IRB review. If you believe that your project qualifies for exemption, please indicate which exemption category applies (1-6). Please remember that only the IRB can make the final determination whether a project is exempt from IRB review, or not.

Exemption Category: ____________________________
INVESTIGATOR ASSURANCE FOR RESEARCH INVOLVING HUMAN SUBJECTS
(Print this page separately because it requires a signature by the PI.)

P.I. or Co- P.I. Name: 

Title of Project: 

XII. ASSURANCES: As the Principal Investigator on this protocol, I provide assurances for the following:

A. Research Involving Human Subjects: This project will be performed in the manner described in this proposal, and in accordance with Title 45 Code of Federal Regulation Part 46 available at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm, applicable laws, regulations, and guidelines. Any proposed deviation or modification from the procedures detailed herein must be submitted to the IRB, and be approved by the Committee prior to implementation.

B. Training: I assure that all personnel working with human subjects described in this protocol are technically competent and have completed training in the treatment of human subjects.

C. Extramural Funding: If funded by an extramural source, I assure that this application accurately reflects all procedures involving human subjects as described in the grant/contract proposal to the funding agency. I also assure that I will notify the IRB, and the funding/contract entity if there are modifications or changes made to the protocol after the initial submission to the funding agency.

A. Study Duration: I also understand that as continuing reviews are conducted, it is my responsibility to provide timely and accurate review or update information when requested, to include notification of the ITRC when my study is changed or completed.

(Principal Investigator Signature) (date)