Eastern Florida STATE COLLEGE
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Human Subjects Application Form

for Full IRB and Expedited IRB Review

1. **Project Title and Identification**

As Principal Investigator of this study, I assure the IRB that the following statements are true:

- The information provided in this form is correct.
- I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc.
- I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study.
- I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participation.
- I will not begin my research until I have received written notification of final IRB approval.
- I will comply with all IRB requests to report on the status of the study.
- I will maintain records of this research according to IRB guidelines.
- The grant that I have submitted to my funding agency which is submitted with this IRB submission accurately and completely reflects what is contained in this application.
- If these conditions are not met, I understand that approval of this research could be suspended or terminated.

I Agree _____ (Initial)

Project Title (Project title must match grant title. If different, also provide grant title)

_____

Principal Investigator (PI) (Full Name and Contact Information)

First: _____ **Middle:** _____ **Last:** _____
Mailing Address or Campus Mail Address:

_____

Phone: _____ **Email:** _____

College/University Department: _____

Highest Education Level: _____

Occupational Position:
☐EFSC Faculty ☐ EFSC Staff ☐EFSC Student ☐Other _____

Indicate the training and education, if any, completed in the protection of human subjects or human subjects records:
☐ Investigator ☐ 101 ☐ NIH ☐ HIPAA ☐ Other ☐ None

Co-Investigators/Research Staff (Include any individual who will have responsibility for the consent process, direct data collection from subjects, or follow-up.)

Add Co-Investigators (or Research Staff).

First: _____ **Middle:** _____ **Last:** _____
Mailing Address or Campus Mail Address:
_____

Phone: _____ **Email:** _____

College/University Department: _____

Highest Education Level: _____
Occupational Position:
☐EFSC Faculty ☐ EFSC Staff ☐EFSC Student ☐Other _____
Indicate the training and education, if any, completed in the protection of human subjects or human subjects records:
☐ Investigator ☐ 101 ☐ NIH ☐ HIPAA ☐ Other ☐ None

First: _____ **Middle:** _____ **Last:** _____
Mailing Address or Campus Mail Address:
_____

Phone: _____ **Email:** _____

College/University Department: _____

Highest Education Level: _____
Occupational Position:
☐EFSC Faculty ☐ EFSC Staff ☐EFSC Student ☐Other: _____
Indicate the training and education, if any, completed in the protection of human subjects or human subjects records:
☐ Investigator ☐ 101 ☐ NIH ☐ HIPAA ☐ Other ☐ None

Faculty Advisor/Chair/Dean Information (If the PI is a student, the advisor's information is required. If PI is faculty or staff, the Department Head's information is required. If PI is also the Department Head, the Dean or Division Head's information is required.)

☐ Faculty Advisor ☐ Department Chair ☐ Director ☐ Dean ☐Other _____
First: _____ **Middle:** _____ **Last:** _____
Mailing Address or Campus Mail Address:
_____

Phone: _____ **Email:** _____

College/University Department/Unit: _____

Funding
Is this research funded by an internal (EFSC) or external agency? ☐Internal (EFSC) ☐External

Sponsored or Funded Projects
If you are applying for funding, please answer all of the following questions. If you are receiving funding from multiple sources, please fill out the form for each of your sources.

Funding Source #1:
This project has been/will be submitted to the following funding agency:

Name of Sponsor: _____
OMNI Number: _____
SRS/Researcher Foundation Contact Person: _____
The funding decision: ☐ is pending ☐ has been awarded
Type of funding source: _____

Funding Source #2:
This project has been/will be submitted to the following funding agency:

Name of Sponsor: _____
OMNI Number: _____
SRS/Researcher Foundation Contact Person: _____
The funding decision: ☐ is pending ☐ has been awarded
Type of funding source: _____

Non-funded Projects
If no, please explain how costs of research will be covered:

_____

Institutional Oversight

Is this research proposal being reviewed by any other institution or peer review committee?
☐ Yes ☐ No

Please select which other committee approvals are required for this research and provide documentation of their approval if it has been granted, or the application submitted if approval has not been granted (please attach the documentation at the end of the application):
☐ CRC
☐ Other IRB, please specify: _____
☐ Other, please specify: _____

Conflict of Interest

Federal guidelines encourage Institutions to assure there are no conflicts of interest in research projects that could adversely affect the rights and welfare of human subjects. If this proposed research study involves a potential conflict of interest, additional information will need to be provided to the IRB. Examples of potential conflicts of interest may include: any sort of compensation, in cash or other form, for services to an individual and his or her immediate family, the value of which exceeds $10,000 in a one-year period or an equity interest which exceeds $10,000 or which exceeds a five percent ownership interest.

Do any of the Investigators or personnel listed on this research have a potential conflict of interest associated with this study? ☐ Yes ☐ No

Identify the individual(s): _____
Has this potential conflict of interest been disclosed and managed? ☐ Yes ☐ No

If you are an Eastern Florida State College researcher, please disclose your potential conflict of interest in writing for review by IRB. Final IRB approval cannot be granted until all potential conflict matters are settled. The full IRB committee determines what disclosure language should be in the consent form.

Payment or Other Compensation for Research Subjects

Will you give subjects gifts, payments, compensation, reimbursement, services without charge or extra credit/class credit? ☐ Yes ☐ No

Please explain:

Protocol Description and Other Detail (Use lay language, do not refer to grant or abstract. All questions are required!)

Describe the objective(s) of the proposed research including purpose, research question, hypothesis, method, data analysis, research design and relevant background information etc.

For Evaluation of your project, please check the following which apply:

☐ Mentally or Physically Challenged Subjects
☐ Children or Minor Subjects (under 18 years old)
☐ Prisoners, Parolees, or Incarcerated Subjects
☐ Filming, Video or Audio recording of Subjects
☐ Questionnaires or Surveys to be administered
☐ Review of Existing Data, Archives, or Medical Records
☐ Subjects' major language is not English
☐ Involves Deception
☐ Exclusion of Women or Children Subjects (must explain why they are being excluded)
☐ Subjects studied at EFSC
☐ Subjects studied at non-EFSC location(s)
☐ Students as Subjects
☐ Employees as Subjects
☐ Pregnant Subjects
☐ Fetal, placental, or surgical pathology tissues(s)
☐ Involves blood Samples (finger pricks, venipuncture, etc.)

Survey Techniques: (check applicable category if the only involvement of human subjects will be in one or more of the following categories)

☐ Research on normal educational practices in commonly accepted educational settings
☐ Research involving educational tests (cognitive, diagnostic, aptitude, achievement)
☐ Research involving survey or interview procedures
☐ Research involving the collection or study of existing data, documents, records, archives, specimens

Which methods will this study include? (check all that apply or specify other)

☐ Descriptive Formative Phenomenological
☐ Ethnographic Longitudinal Qualitative
☐ Experimental/Control
☐ Design Oral history Quantitative
☐ Field work
☐ Other, specify: _____

Describe the tasks subjects will be asked to perform.

_____

Describe the frequency and duration of procedures, psychological tests, educational tests, and experiments; including screening, intervention, follow-up etc. (If you intend to pilot a process before recruiting for the main study please explain.)

_____

Attach surveys, instruments, interview questions, focus group questions etc.

How many months do you anticipate this research study will last from the time final approval is granted? _____

Participant (Subject) Population

Expected number of participants

Number of males: _____ **Number of females:** _____

Total: _____

Expected Age Range (Check all that apply)

☐ 0-7 (Attach parental permission form)
☐ 8-17 (Attach child's assent form and parental permission form)
☐ 18-65
☐ 65 and older

Inclusion/Exclusion of Children in this Research: ☐ Inclusion ☐ Exclusion

Other Protected Populations to be Included in this Research (Check all that apply)

☐ Protected by Federal Regulations
☐ Pregnant Woman/Fetuses/Neonates
☐ Prisoners
☐ Protected by Federal Guidelines (Refer to 45 CFR 46 subpart B and 45 CFR 46 subpart C on the populations protected by Federal Regulations)
☐ Mentally/Emotionally/Developmentally/Decisionally Impaired Persons
☐ Minority Group(s) and Non-English Speakers
☐ Elderly Subjects -- 65+
☐ Gender Imbalance - all or more of one gender

Inclusion and Exclusion of Subjects in this Research Study (Describe criteria for inclusion and exclusion of subjects in this study)

Inclusion Criteria: _____

Exclusion Criteria: _____

Location of subjects during research activity or location of records to be accessed for research (check all that apply and specify):

☐ Eastern Florida State College
☐ Other, specify: Hospitals, specify:
☐ Community Clinic, specify:
☐ Elementary/Secondary Schools, specify:
☐ Community Center, specify:
☐ University Campus (non-clinical), specify:
☐ Prisons/Halfway
☐ Houses, detention centers, specify: Nursing Home(s), specify:
☐ Subject's Home, specify:
☐ International Location, specify:
☐ Other Special Institutions, specify:

Describe the rationale for using each location checked above

_____

Attach copies of IRB approvals or letters of cooperation from other agencies or sites, if it has been granted or the application submitted if approval has not been granted.

Recruitment of Participants (Subjects)

Describe the recruitment process to be used for each group of subjects

_____

Attach a copy of any and all recruitment materials to be used e.g. advertisements, bulletin board notices, e-mails, letters, phone scripts, or URLs.

Explain who will approach potential subjects to take part in the research study and what will be done to protect individuals' privacy if required in this process

_____

Are subjects chosen from records? ☐ Yes ☐ No

Are records "private" medical or student records? ☐ Yes ☐ No

Who or what entity is the custodian of the records? _____

Who gave approval for use of the records? _____

EFSC policy prohibits researchers from accepting gifts for research activities.
Is the study sponsor offering any incentive connected with subject enrollment or completion of the research study (i.e. finder's fees, recruitment bonus, etc.) that would be paid directly to the research staff? ☐ Yes ☐ No

Risks and Benefits

Does the research involve any of these possible risks or harms to subjects? (check all that apply)

☐ Use of a deceptive technique
☐ Use of private records (educational or medical records)
☐ Manipulation of psychological or social variables such as sensory deprivation, social isolation, psychological stresses
☐ Any probing for personal or sensitive information in surveys, interviews or questionnaires
☐ Presentation of materials which subjects might consider sensitive, offensive, threatening, degrading or dangerous
☐ Possible invasion of privacy of subject or family
☐ Financial standing, employability, or reputation
☐ Criminal, civil, or legal liability
☐ Other risks, specify: _____

Does Research Involve Greater Than Minimal Risk to Human Subjects? ☐ Yes ☐ No

"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.

Describe the nature and degree of the risk or harm checked above (The described risks/harms must be disclosed in the consent form.)

_____

Explain what steps will be taken to minimize risks or harms and to protect subjects' welfare. If the research will include protected populations (see question 7.4) please identify each group and answer this question for each group

_____

Describe the anticipated benefits of this research for individual subjects in each subject group. If none, state "None"

_____

Describe the anticipated benefits of this research for society, and explain how the benefits outweigh the risks.

_____

Confidentiality of Data

Will you record any direct identifiers, names, social security numbers, addresses, telephone numbers, email addresses, cookies etc.? ☐ Yes ☐ No

Explain why it is necessary to record findings using these identifiers and describe the coding system you will use to protect against disclosure of these identifiers:

_____

Will you retain a link between study code numbers and direct identifiers after the data collection is complete? ☐ Yes ☐ No

Explain why this is necessary and state how long you will keep this link:

_____

Will you provide the link or identifier to anyone outside the co-investigators/research staff? ☐ Yes ☐ No

Explain why and to whom:

_____

Where, how long, and in what format (such as paper, digital or electronic media, video, audio, or photographic) **will data be kept?** In addition, **describe what security provisions will be taken to protect this data** (password protection, encryption, etc.)

_____

Will you place a copy of the consent form or other research study information in the subjects' record such as medical, personal or educational record? ☐ Yes ☐ No

Explain why this is necessary:

_____

If the data collected contains information about illegal behavior, please refer to the NIH Certificates of Confidentiality Kiosk for information about obtaining a Federal Certificate of Confidentiality.

Use of Protected Health Information (PHI): HIPAA Requirements

In the course of conducting research, researchers may desire to obtain, create, use, and/or disclose individually identifiable health information. Under the HIPAA Privacy Rule, covered entities (healthcare providers, health plans, employer or healthcare clearinghouses) are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule.

As part of this study, will you be accessing PHI from a covered entity for research purposes?

☐ Yes ☐ No

Please explain which of the following you will be utilizing to comply with the HIPAA regulations for use of PHI:

☐ Research Use/Disclosure Without Authorization
☐ Documented Institutional Review Board or Privacy Board Approval (alteration or waiver of research participants' authorization)
☐ Preparatory to Research
☐ Research on Protected health Information of Decedents
☐ Limited Data Sets with a Data Use Agreement
☐ Research Use/Disclosure With Individual Authorization

Rationale:

_____

Informed Consent Process

Recognizing that consent itself is a process of communication, **please expand on your responses to questions 8.1 and 8.2 and describe what will be said to the subjects to introduce the research.** Do not say "see consent form". **Write the explanation in lay language**. If you are using telephone surveys, telephone scripts are required.

_____

In relation to the actual data gathering, when will consent be discussed and documentation obtained? (e.g., mailing out materials, delivery of consent form, meetings) Be specific.

_____

Please name the specific individuals who will obtain informed consent and include their job title/credentials and a brief description of your plans to train these individuals to obtain informed consent and answer subject's questions:

_____

What questions will you ask to assess the subjects' understanding of the risks and benefits of participation? (Questions should be open-ended and go beyond requiring only a yes/no response.)

_____

Attach all supporting documents to the application such as consent forms, assent forms, cover letters, parental permission forms, guardianship permission form, reminder postcards, recruiting flyers, questionnaires, support letters for research sites, and other IRB approval letters.

- The following file extensions are acceptable formats: .doc, .pdf, .xls, .ppt, and .vsd. Name each file with the PI's last name and type of document it is. (e.g. Smithconsentform.doc)
- The size of attached file cannot be larger than 4MB.

Total Number of Files Attached: _____

Appendix A: Inclusion of Vulnerable Populations

The targeting or inclusion of potentially vulnerable populations (other than children, pregnant women/fetuses and prisoners) in research requires special considerations. Provide information on the following populations, if applicable, in this research. Note: 1-4 not all required but at least one must be filled out.

☐ 1. Mentally/Emotionally/Developmentally Disabled
Provide justification: _____
Explain how competency to provide consent will be determined and plan for obtaining surrogate consent: _____

☐ 2. Minority Group(s)/Non-English Speakers
Provide justification: _____

Provide plan for obtaining consent: _____

☐ 3. Elderly (65+) Provide justification:
If competency to provide consent may be an issue, describe how competency will be determined and plan for obtaining consent: _____

☐ 4. Gender Imbalance
If all or more of one gender are targeted, provide justification for this:

_____

Appendix B: Pregnant Women, Human Fetuses and Neonates involved in Research

Federal regulations define pregnancy as encompassing the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery. Fetus means the product of conception from implantation until delivery.

1. **Does your research involve a pregnant woman or her fetus?** ☐ Yes ☐ No
   If yes, please explain:

   _____

2. **Is there any risk involved in this research?** ☐ Yes ☐ No
   If yes, the risk must be the least possible for achieving the objectives of the research.
   Please explain how any risk has been minimized for subjects:

   _____

3. **Is there any direct benefit to the pregnant woman and/or the fetus?** ☐ Yes ☐ No
   If yes, please explain:

   _____

4. **Is the pregnant woman a minor (under age 18)?** ☐ Yes ☐ No
   If yes, how will you obtain assent and permission of the parent?

   _____

5. **Does this research involve a neonate? Neonate is defined in the federal regulations to mean a newborn**. ☐ Yes ☐ No
   If yes, please explain:

   _____

6. **Is the neonate of uncertain viability?** ☐ Yes ☐ No

7. **Does the research involve nonviable neonates? A nonviable neonate means a neonate after delivery that, although living, is not viable.** ☐ Yes ☐ No
   If yes, please explain:

   _____

Appendix C: Prisoners as Subjects in Research

Federal Regulations require that investigators comply with the additional protections as summarized below. Please respond to each factor below for consideration:

1. **Will this study examine the possible causes, effects, or processes of incarceration and/or criminal behavior?** ☐ Yes ☐ No
2. **Will this study examine prisons as institutional structures or prisoners as incarcerated persons?** ☐ Yes ☐ No
3. **Will this study examine a condition(s) particularly affecting prisoners as a class of people?** ☐ Yes ☐ No
4. **Will this study examine a procedure, innovative or accepted, that will have the intent or reasonable probability of improving the health or well-being of the subjects?** ☐ Yes ☐ No
5. **Will prisoners receive any incentives or advantages by agreeing to participate?** ☐ Yes ☐ No

Appendix D: Children Involved as Subjects in Research

Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (in Florida, the age of 18). Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. Permission means the agreement or parent(s) or guardian to the participation of their child or ward in research. Parent means a child's biological or adoptive parent. Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

1. **What is the age range of the children involved in the research?** _____
2. **What is the psychological and maturity state of the children involved in the research?**

   _____
3. **Are any of the children involved in the research wards of the State?** ☐ Yes ☐ No
4. **Is the research not involving greater than minimal risk?** ☐ Yes ☐ No
5. **Explain how assent of the children will be obtained in this research:**

   _____
6. **Explain how permission will be obtained from the parent(s) or guardian for the participation of their child or ward in this research:**

   _____

Appendix D: Use of Deception

Subjects must be told the purpose of the study, the reason for the deception and given an opportunity to withdraw their data from the project. (For guidance, see APA Ethical Standard 8.07)

1. **Explain the scientific rationale for deceiving the study subjects. Which aspects of study procedures will be withheld from subjects? Why?**

   _____
2. **Describe when the subjects will be told the true purpose of the study, the reason for the deception and explain how they will be informed and by whom. (Attach a copy of the material or script to be used)**

   _____
3. **Describe how and when subjects will be given an opportunity to withhold use of the data gathered under deceptive conditions.**

   _____
4. **Attach the full debriefing "protocol" or explanation that will be provided to subjects.**

   _____