EMPIRE STATE UNIVERSITY

Institutional Review Board

Application for Approval of Research Using Human Subjects

This form serves as an application for approval in relation to research using human subjects. Research is defined as a systematic investigation designed to develop or contribute to generalizable knowledge. It includes, but is not limited to, the procedures listed in Section VII of this form. Human subjects are living people about or from whom information or data is collected. Please answer all questions in the space provided on this form.

SECTION I: INVESTIGATOR

Principal Investigator's Name:

Has the PI completed the CITI training?
Note: Your application will not be reviewed until CITI training is completed.

Date CITI training completed:

◯ Yes ◯ No

Address:

City: State: Zip Code:

Email Address: Telephone:

Faculty Sponsor (for students): Location:

Additional investigators' names, affiliations, and dates they completed the CITI training:

SECTION II: PROJECT / STUDY INFORMATION

Title:

Anticipated Start Date:

Anticipated End Date:

Is this project supported by any federal funds?

◯ Yes ◯ No

If yes, please state which federal agency is supporting this research:

Please include the name and contact information of the federal program manager:

Note: No work with subjects may begin prior to approval by the IRB.

SECTION III: PROJECT DESCRIPTION

1. Please describe the purpose / background of your research. Provide relevant background information and scientific justification for your study. You may provide citations as necessary. If you need additional space, you may add additional pages.

2. Please state your research question (one or two sentences).

SECTION IV: SUBJECTS

1. Who will your potential subjects be? Please check the subject population(s) that will be involved in the research project:

- ☐ Adults (competent to consent)
- ☐ Adults (not competent to consent)
- ☐ Minors
- ☐ Prisoners
- ☐ Disabled / Cognitively Impaired
- ☐ SUNY Empire faculty, staff, and/or students
- ☐ Non-English Speaking
- ☐ Other (vulnerable population)-specify:

2. Please describe their anticipated age range, sex, race/ethnicity (if applicable), institutional affiliation, and any other important characteristics.

3. Certain groups of people are considered particularly vulnerable to coercion or undue influence in research, including children, wards of the state, prisoners, persons who are mentally disabled or otherwise cognitively impaired, and economically or educationally disadvantaged persons. Explain the selection of special and / or vulnerable populations and, if there are alternatives, why they are not being used. Explain how the rights and welfare of these special populations will be protected.

4. Federal guidelines state that research cannot exclude any classes of subjects without scientific justification. Will your study purposely be excluding any classes of subjects (e.g., children 17 and under, by gender, class, race)? If so, please justify this.

5. If relevant, describe how permission has been obtained from participating institution(s) - schools, prisons, clinics, other organizations. For research within school districts, New York State law requires that the superintendent of schools (not a principal) must grant permission. For each institution, please attach a copy of the signed approval letter which clearly states the roles and responsibilities of each.

SECTION V: RECRUITMENT

1. Please describe your recruitment methods. How and where will subjects be recruited?

Note: Please attach any recruitment letters/flyers/emails/etc.

2. How many subjects are you planning to recruit?

3. Will subjects be compensated for their participation in the study? If so, please describe.

SECTION VI: INFORMED CONSENT

Note: Informed consent is a process, not a form.

1. Describe how you will explain the research to potential subjects to ensure they understand the research procedures.

2. Describe how you will obtain informed consent from subjects to participate in the study. If subjects are minors or otherwise not legally competent to consent, describe how assent is obtained from the subjects and from whom proxy consent is obtained. Indicate how subjects are informed that they can quit the study at any time.

3. A standard consent form should include the following items:

- The name of each primary investigator and where each person is from (i.e. institution).
- Contact information for the primary investigator(s).
- Description and purpose of the project / research, including procedures (during and after the study).
- What is expected of the subjects.
- Length of time their participation is required.
- Location of the study.
- A statement that participation is voluntary.
- A statement that the subject can withdraw at any time and that the subject does not have to answer any questions she/he does not want to.
- Compensation, if any (including the amount and how it will be paid).
- Referrals, if appropriate.
- A risk / discomfort / benefit statement (Note that risk to subjects can be physical, social, psychological, legal, or financial. If there are no anticipated risks, that should be stated)
- An explanation of how confidentiality or anonymity will be maintained.
- An explanation of what will happen to the collected data after the study is completed, including when.
- Recordings (if applicable) - provide a separate line to consent for recording, which should also include information on how the recordings will be used, stored and disposed.

If you have any questions concerning your rights as a subject, contact Robert Sanders,

Ed.D., Associate Provost for Faculty and Academic Excellence /IRB Compliance Officer,

Empire State University, 1 Union Avenue, Saratoga Springs, 12866; (518) 580-4862, ext.

2449.

Please include a copy of the consent form with this application.

SECTION VII: RESEARCH PROCEDURES

1. What specific data will you collect and how will the subjects you choose help you to answer your research question (check all that apply and provide any narrative descriptions necessary in item 3 below)?

- ☐ Questionnaires: submit a copy of all questionnaires, including any cover page or introductory material.
- ■ Interviews: Provide a copy of the complete interview script or protocol.
- ☐ Observation: Provide a description of who and what you plan to observe. Explain the planned interaction with the subjects. Attach permission letters from the observation site.
- ☐ Recording: Describe planned procedures and how you will use, store and dispose of recordings. Describe the consent process and attach the consent form or script.
- ☐ Records Review: Describe the medical or school records you will be reviewing and the data you will be extracting from those records. Attach permission letters from appropriate officials.
- ☐ Files: Define what information you will be extracting from files. Attach permission letters from appropriate officials.
- ☐ Secondary Data Analysis: Describe the source of information and explain if individuals are identifiable in the data, or if the information is identifiable through links, such as coded information or pseudonyms. Attach permission letters from appropriate officials.
- ☐ Tasks: Provide details of the activity(ies) that will be expected of the subjects, and what you expect to gain. Include the length of time the tasks will take. Describe any risks and how you intend to minimize them.
- ☐ Tests or Other Instruments: Explain the nature of the tests or other measurement instruments to be used. Describe what information obtained from the instrument will be shared with the subject and, when applicable, procedures for referral.
- ☐ Treatment/Intervention: Give full details on the treatment process and if there are any alternatives to be offered. Describe any risks and how you intend to minimize them.

2. Will deception be used? If so, you must provide a convincing justification for deception. Describe the nature of the deception and the significance to subjects. Describe any consequent risk and how you plan to minimize the risk. Discuss alternatives to the procedure and explain why you have not chosen one of these alternative methods. Describe the debriefing for the subjects, including when it will take place. The debriefing must clearly explain the deception, whit it was necessary, and that the subjects still have the opportunity to withdraw their participation/data at that time. Attach additional pages if necessary.

3. Please provide a narrative description of all of the activities (checked above) the subjects will be engaging in. If you need more space, please add pages as necessary.

SECTION VIII: CONFIDENTIALITY PROCEDURES

1. How will you ensure subjects' confidentiality (or anonymity)? Indicate when and how identifiers will be separated from the data and when the identifiers will be destroyed. If identifiers will be retained, explain why. Note: If you will be compensating subjects after their participation, please make it clear how you will link their names/contact information confidentially to their compensation.

SECTION IX: RISK / DISCOMFORT / BENEFIT ANALYSIS

1. What are the risks of harm (physical, psychological, legal, social, or financial) the subjects may encounter as participants in the study? Why are these risks necessary? Explain what you plan to do to minimize these risks. Do the expected benefits outweigh the risk(s)? Explain.

2. What are your plans for ensuring necessary intervention in the event of a distressed subject (physically, mentally, emotionally, etc)? What are your plans and sources for professional referral if there is a need for (immediate) psychological and/or physical treatment / assistance?

3. Explain how the study will benefit the subjects, the population, and/or society in general.

4. Explain how the benefits outweigh the risks. *If the benefits do not outweigh the risks, even minimal risks, the project will not be approved.*

SECTION X: CLOSING DOWN THE PROJECT

1. Will you be debriefing subjects or providing educational materials and outcomes after the study has been completed? If so, please describe this debriefing procedure and include any debriefing or educational materials.

2. Explain what will be done with the research data (written or otherwise recorded) at the end of the study. If not destroyed, describe where, in what format, and for how long the data will be stored. Explain what uses - research, educational, demonstration, archiving, etc. - the data might be used for in the future. Describe how subjects' permission for further use of their data will be obtained.

SECTION XI: EXPERIENCE AND CERTIFICATION

1. Cite your qualifications (training, experience, etc) for conducting this kind of research. List any other contributors to the research and cite their qualifications as well.

I certify that the information provided for this project is accurate, no other procedures will be used in this project, and any modifications in this project will be submitted for approval prior to use.

Applicant signature: _____ Date: _____

If the principal investigator is a student, the faculty sponsor (first reader) must also sign this form.

I have reviewed this completed application, and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of human subjects. I certify that this project is under my direct supervision and that I am responsible for ensuring that the investigator complies with all of the provisions of approval.

Faculty signature: _____ Date: _____