SUNY EMPIRE STATE COLLEGE

Institutional Review Board

Request for Continuation of Approved Research Using Human Subjects

This form serves as a request 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:

Address:

City: State: Zip Code:

Email Address: Telephone:

Faculty Sponsor (for students): Center:

Additional Investigators' Names, Affiliations, and Dates completed the CITI training:

SECTION II: PROJECT/STUDY INFORMATION

Title:

Original Approval Date:

Anticipated End Date:

Note: This continuation application is only applicable for one year. Further continuations must be submitted to the IRB before the end of the approved year for extension of approval.
Note: No work with subjects may begin/continue prior to approval by the IRB.

SECTION III: SUMMARY OF PROGRESS

1. Please give a summary of your project's progress to date.

2. Please briefly list modifications, if any, that were approved by the IRB during the last approval period.

3. Is there any other relevant information about your study that the IRB should be made aware of?

SECTION IV: HUMAN SUBJECTS PARTICIPATION

1. Have participants been enrolled during the last approval period?

◯ Yes ◯ No

If Yes, how many?

2. Do you anticipate enrolling new participants?

◯ Yes ◯ No

If Yes, how many?

3. If you have concluded human subject participation (i.e., the answer to number 2 above is 'No'), please explain the purpose for seeking continuation of IRB approval (e.g., data analysis, additional follow-up).

SECTION V: CHANGES TO PROTOCOL

1. Are you requesting any alterations to the protocol during the period of continuation?

◯ Yes ◯ No

2. If you are requesting alterations, please explain them below.

3. Have any new risks or benefits been identified since the last review?

◯ Yes ◯ No

4. If new risks and/or benefits have emerged since the last review, please explain them below.

5. Are you requesting any changes to the consent form(s)?

◯ Yes ◯ No

6. If 'Yes," please explain below *and provide a copy of the original and new consent form(s).*

SECTION VI: WITHDRAWALS, COMPLAINTS, AND ADVERSE EVENTS

1. During the last approval period, have any participants been withdrawn by the research team?

◯ Yes ◯ No

2. During the last approval period, have any participants withdrawn themselves from the study?

◯ Yes ◯ No

3. If you responded 'Yes' to either question above, please explain below.

4. During the last approval period, have there been any participant complaints?

◯ Yes ◯ No

5. If 'Yes,' please explain below.

6. During the last approval period, have there been any adverse events?

◯ Yes ◯ No

7. If 'Yes,' please explain below

SECTION VII: CERTIFICATION

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: _____