EMPIRE STATE UNIVERSITY

Institutional Review Board

Request for Modification for 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): Location:

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

SECTION II: PROJECT/STUDY INFORMATION

Title:

Original Approval Date:

Anticipated End Date:

Have you received approval for continuation of your study?

◯ Yes
◯ No

If Yes, please provide the continuation dates:

Note: This modification application is only applicable for the period of original or continued approval. 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: MODIFICATIONS

1. Please describe the change(s) you would like to make to your currently IRB approved protocol.

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

◯ Yes ◯ No

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

4. Is this modification the result of an unanticipated problem or adverse event?

◯ Yes ◯ No

5. If you responded 'Yes' to the question above, please explain below.

6. Is this modification likely to affect your participants' willingness to participate in the project?

◯ 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: _____