INSTITUTIONAL REVIEW BOARD (IRB)

STATE UNIVERSITY OF NEW YORK (SUNY) AT ONEONTA HUMAN SUBJECTS RESEARCH REVIEW PROTOCOL FORM

This is a fillable form. Please type in or check as appropriate.
The space provided will expand to accommodate your narrative responses.

This form must be submitted via the PACS web application. PLEASE COMPLETE THE FOLLOWING FOR EACH INVESTIGATOR:

INVESTIGATOR 1)
NAME:
CAMPUS PHONE NUMBER:
EMAIL ADDRESS:
INVESTIGATOR STATUS:

☐ Faculty/Staff (including adjuncts)
☐ Graduate Student
☐ Undergraduate Student
☐ Other (explain):

INVESTIGATOR 2)
NAME:
CAMPUS PHONE NUMBER:
EMAIL ADDRESS:
INVESTIGATOR STATUS:

☐ Faculty/Staff (including adjuncts)
☐ Graduate Student
☐ Undergraduate Student
☐ Other (explain):

If any additional investigators, please list:

Students: Enter the name of your faculty supervisor:

DEPARTMENT OR UNIVERSITY UNIT:

RESEARCH STUDY INFORMATION

PROJECT TITLE:

PROJECT DATES: **Dates cannot be before IRB approval is issued.**

START DATE (allow 3 - 4 weeks from date of submission):

COMPLETION DATE (should be one year from the start date):

Note: Approvals for Research Studies are valid for one year only. After one year, researcher must file a continuation of the study via a Modification Request in the PACS system.

Is this project Action Research ? ☐ Yes ☐ No

*"Action Research" is a designation that applies specifically to teachers, defined as a systematic inquiry to address problems, and improve one's own teaching pedagogy and practice. At Oneonta, to qualify as action research, the teacher-researcher must confirm that: (a) the study will be completed in the teacher's **own classroom**; and (b) **all students** in the class will take part in the research activities (e.g., serve as participants), but only data from students who have granted assent/consent will be collected for use in analysis.*

1. **DATA COLLECTION METHOD****: Check all that apply:

☐ Questionnaire
☐ Observation
☐ Test
☐ Task
☐ Interviewing
☐ Audiotaping
☐ Videotaping
☐ Treatment
☐ Files
☐ Psychological Intervention
☐ Social Intervention
☐ Deception
☐ Research Journal/Field Notes

Other (please describe)

**** Your application must include a copy of your questionnaire, survey, or any instrument that you will use to collect data and information from your subjects.**

2. **PROJECT DESCRIPTION:** Using simplified terms, please provide a thorough and descriptive overview of the proposed research project. This MUST include:

- a statement of the problem,
- the purpose of the study,
- the research hypothesis/research question,
- information about the subjects,
- a detailed description of the methods that will be used to conduct the study (including the data collection instruments), and
- the processes used to obtain consent and assent (if assent is required).

Please fill in your Project Description below. This overview must be no longer than 500 words.:

4. SUBJECTS:

(ESTIMATED)NUMBER OF SUBJECTS:

If you cannot identify the number of subjects, please explain:

SUBJECT POPULATION: Check all that apply:

- ☐ Adult
- ☐ Minor
- ☐ Physically Disabled
- ☐ Intellectually Disabled
- ☐ Prisoner
- ☐ Economically Disadvantaged
- ☐ Physically Ill
- ☐ Pregnant
- ☐ Educationally Disadvantaged
- ☐ Other (please specify):

If any of the subjects are minors, physically disabled, intellectually disabled, prisoners, economically disadvantaged, educationally disadvantaged, or others who are vulnerable to coercion or undue influence, state the rationale for their involvement in this research study:

SUBJECTS RECRUITMENT AND SELECTION: Explain how subjects in this research study will be recruited and who will be recruiting them. Describe in detail how subjects will be selected for participation in this research study:

Will subjects to be drawn from a subject pool (e.g. SONA)? Yes ☐ No ☐

If you answered YES: A copy of the sign-up intention sheet must be submitted to the IRB along with this form as part of your Recruitment Materials.

Letter of Permission Requirement: If subjects are to be drawn from an institution that has the responsibility for the subjects (e.g., hospital, social services agency, prison, school), you must provide a letter of permission signed by an authorized official from that institution with the IRB application before final approval can be given. This letter must be on that agency's letterhead.

Subject compensation

Will subjects receive compensation for their participation in this tudy? Yes ☐ No ☐

If yes, provide details about the compensation:

Note: If this research study is funded by Research Foundation monies then a Participant Stipend Form for each subject must be completed.

5. CONFIDENTIALITY AND RECORD RETENTION:

Please provide specifics about each of the following:

1. The methods that will be used to guard the anonymity of subjects and to protect the confidentiality of their responses:

2. Indicate all personal identifying indicators that will be collected from subjects:

3. How long will the data from this study be kept by the investigators? (Data shall be kept a minimum of 3 years in accordance with Federal DHHS OHRP regulations for Human Subjects Research.)

4. If the data from the study will be kept indefinitely, then explain why:

5. How will data, including any and all personal information, ultimately be disposed of?

6. What procedures and methods will be used to secure and store the data including the format (hardcopy or electronic, de-identified or identified)?

7. List everyone who will have access to the data:

8. Will any personal identifying information be stored with data? If yes, explain why.

☐ Ye s ☐ No

Explain if yes:

Note: Data shall be kept a minimum of 3 years in accordance with Federal dDHHS OHRP regulations for Human Subjects Research.

6. CONSENT FORM

Most research involving adult human participants requires that written consent be obtained prior to data collection. Most research involving minor human participants requires that consent be obtained from the minor's legal guardian and that the minor assents to participating in the research. **Both consent and assent forms must communicate the following to participants and guardians:**

- ☐ a. A description of the research study including the purpose of the study and everything the subjects will be asked to do during the research study in language that can be understood by the subjects and guardians based on their education level and age.
- ☐ b. That subject participation is voluntary.
- ☐ c. That the subject may withdraw from the research, without consequence, at any time.
- ☐ d. That subject personal information and responses are confidential.
- ☐ e. The steps that will be taken to protect their anonymity.

Please check all that apply:

☐ This research requires written consent (for adults). **(Submit the Consent Form in PACS).**

☐ This research requires written assent (for minors). **(Submit the Assent Form in PACS.)**

Requests for Oral Informed Consent

☐ This research does NOT require oral informed consent. (Continue to the next section.)

There are specific reasons for using oral informed consent in place of written consent. Reasons for using an oral informed-consent process include:

1. The only documentation linking the subject to the research is the consent or assent document and the principle risk of harm to the subject would be harm resulting from a breach of confidentiality.
2. Signing the consent or assent form is culturally inappropriate in the context of the research study.
3. The research poses only minimal risk to the subjects.
4. The participants are unable to sign a consent form due to age or inability to write (i.e., children).

Please check all that apply: Oral informed consent is being requested in place of written informed consent for this research study for the following reasons:

☐ The only documentation linking the subjects to the research is the consent or assent document and the principle risk of harm to the subjects is harm resulting from a breach of confidentiality. Provide further explanation:

☐ Signing the consent or assent form is culturally inappropriate in the context of research study. Provide further explanation:

☐ The research poses only minimal risk to the subjects.

Note: If oral consent is being requested than a script of what is to be communicated during the oral informed consent process must be submitted to the IRB along with this application. Also, there must be a witness present for each oral informed consent.

7. SIGNATURES

Institutional/Agency Approval
Any research study being conducted at another institution requires documented approval from the institution. Hence, an informed consent form that contains the same details and information about the study as the other consent and assent forms must be signed by an institutional representative who is authorized to sign such forms before any research can begin at the institution.

SIGNATURES: All PIs and Co PIs need to submit a signature page. Typed names will be accepted as electronic signatures.

Principal Investigator (PI)

I hereby certify that:

- The information provided for this project is accurate.
- No other procedures will be used in this project.
- Any modifications in this project will be submitted for IRB approval prior to use.
- If this is determined to fall under human subjects regulations, I will complete the course in human subject protection (www.citiprogram.org) or will provide documentation of a current and comparable certification before beginning this study.

Name: **Date:**

Co-Principal Investigator (Co PI)

I hereby certify that:

- The information provided for this project is accurate.
- No other procedures will be used in this project.
- Any modifications in this project will be submitted for IRB approval prior to use.
- If this is determined to fall under human subjects regulations, I will complete the course in human subject protection (www.citiprogram.org) or will provide documentation of a current and comparable certification before beginning this study.

Name: **Date:**

Faculty Supervisor (if PI is a student.) I certify that:

- This project is under my direct supervision.
- I am responsible for insuring that all provisions of approval are complied with by the Investigator.
- The information provided about this research study is accurate.
- No other procedures will be used in the completion of this research study.
- Any modifications to this research study will be submitted for IRB approval prior to use.
- If this is determined to fall under human subjects regulations, I will complete the course in human protection (www.citiprogram.org) or will provide documentation of a current and comparable certification before beginning this study.

Name: **Date:**