**For IRB Use Only:** Proposal #:

**INSTITUTIONAL REVIEW BOARD (IRB)**

STATE UNIVERSITY OF NEW YORK (SUNY) COLLEGE AT ONEONTA

[HUMAN SUBJECTS](file:///C:\Documents%20and%20Settings\nicosima\Local%20Settings\Local%20Settings\Desktop\IRB%20Review%20Form%20HyperLinks.doc) RESEARCH REVIEW 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 should be submitted via web application here:** [**https://pacsprd2.rfsuny.org**](https://pacsprd2.rfsuny.org) **(signature page can be printed, signed and sent via campus mail to: Sponsored Programs, 27 Bacon Hall**

**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):

**Investigator 3)**

**Name**:

**Campus Phone Number:**

**Email Address**:

**Investigator Status:**

Faculty/Staff (including adjuncts)

Graduate Student

Undergraduate Student

Other (explain):

**NAME OF FACULTY SPONSOR, if applicable**:

**Department or University Unit**:

**RESEARCH STUDY INFORMATION**

**Project Title**:

**Source of Funding for Project** (select from drop-down list):

If External or Other, indicate source:

**Research Dates:**

**Expected Starting Date for Project**:

**Anticipated Completion Date**:

***Note****: Approvals for Research Studies are valid for one year only. After one year, a summary report must be submitted to the Chair of the IRB. Failure to comply with this requirement may jeopardize re-approval and/or approval of future proposals. Investigators must request a continuation of the research study annually if the research study lasts more than one year. No more than two continuations will be granted for any research study. If a research study lasts more than three years the research study must be resubmitted for IRB review at the end of the third year.*

**Project Description:** Using layman’s terms, provide a descriptive overview of the proposed research that includes a statement of the problem, the purpose of the study, the hypothesis, and the methods that will be used to complete the study including information about the subjects.

**DATA COLLECTION METHOD\*\***: Check all that apply:

Questionnaire  Observation  Test  Interviewing Audiotaping

Treatment  Files  Task  Other\* Videotaping

Psychological Intervention  Physiological Intervention Deception

Biomedical Procedures  Social Intervention

\*If Other, please provide a detailed explanation of any other data collection method that will be used during this research study:

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

**SUBJECTS:**

**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 considered vulnerable to coercion or undue influence, state the rationale and need 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:

Will subjects to be drawn from a subject pool?  Yes  No

*If* ***yes****, a copy of the sign-up intention sheet must be submitted to the IRB along with this form.*

If **no**, describe how subjects will be selected for participation in this research study:

***Note:*** *If subjects are to be drawn from an institution or organization that has the responsibility for the subjects (e.g., hospital, social services agency, prison, school), you must provide documentation of permission from that institution to the IRB before final approval can be given.*

**Subject compensation**

Will subjects receive compensation for their participation in the Research Study?  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.*

**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\*:
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 the data?:
7. What procedures and methods will be used to store the data including the format (hardcopy or electronic, de-identified or identified)?:
8. List everyone who will have access to the data: :
9. Will any personal identifying information be stored with data?  Yes  No

(If yes, explain why) :

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

**CONSENT**

Most research involving adult human subjects requires that written consent be obtained from adult participants. Most research involving minor human subjects requires that consent be obtained from the minor’s legal guardian and that the minor Assent to participating in the research. Consent and Assent forms must communicate the following to participants and guardians:

1. 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;
2. That subject participation is voluntary;
3. That the subject may withdraw from the research, without consequence, at any time;
4. That subject personal information and responses are confidential
5. The steps that will be taken to protect their anonymity.

**Please check all that apply:**

**This research requires written consent.** *(A copy of the Consent Form must be submitted to the IRB along with this application).*

**This research requires written assent** *(a copy of the Assent Form must be submitted to the IRB along with this application).*

**Requests for Oral Informed Consent**

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.

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 the 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.*

**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):**

***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](http://www.citiprogram.org) ) or will provide documentation of a current and comparable certification before beginning this study

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Signature of PI Date

\*For electronic signatures, insert here:

***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](http://www.citiprogram.org) ) or will provide documentation of a current and comparable certification before beginning this study.

**Name of Faculty Supervisor (Please print)**:

**Campus Address & Telephone**:

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Signature of Faculty Supervisor\* Date

\*For electronic signatures, insert here:

***Department Chair/Supervisor*** (If the Principal Investigator is a faculty/staff member)

My signature hereby indicates that I am aware of this proposal.

**Name of Department Chair/Supervisor**:

**Campus Address & Telephone**:

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Signature of Department Chair/Supervisor\* Date

\*For electronic signatures, insert here: