Suffolk University
Office of Research and Sponsored Programs

INSTITUTIONAL REVIEW BOARD
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HUMAN SUBJECTS RESEARCH APPLICATION

Instructions: Please complete this form and submit a copy of the **study protocol** and all supporting documentation, to include verification of CITI or equivalent training for key personnel for all new human subject research. All questions must be answered completely in order to provide the Institutional Review Board with the necessary information to review your proposed research study. IRB approval without conditions **must** be obtained prior to beginning any human subject research. **The application should be written in layman's terms such that it can be understood by a non-scientist. Appendix I specifies the Office of Human Research Protections (OHRP) criteria for IRB Approval and Appendix II specifies the required elements of informed consent.**

1. GENERAL INFORMATION:	
Protocol Title:	
Date:	
2. PRINCIPAL INVESTIGATOR:	
Name:	**CITI Certified:** ☐ **Yes** **Date:**
School/Department:	
Campus Mailing Address:	**Telephone Number:** ( ) -
E-mail Address:	☐ **Faculty** ☐ **Staff**
3. CO-INVESTIGATOR: If additional space is needed, please add on a separate page.	
Name:	**CITI Certified:** ☐ **Yes** **Date:**
School/Department:	
Campus Mailing Address:	**Telephone Number:** ( ) -
E-mail Address:	☐ **Faculty** ☐ **Staff** ☐ **Student**
Name:	**CITI Certified:** ☐ **Yes** **Date:**
School/Department:	
Campus Mailing Address:	**Telephone Number:** ( ) -
E-mail Address:	☐ **Faculty** ☐ **Staff** ☐ **Student**

4. RESEARCH STAFF: If additional space is needed, please add on a separate page. All research staff must be CITI certified in the protection of human research subjects.

Name	**CITI Certified**
	☐ **Yes** **Date:**
	☐ **Yes** **Date:**
	☐ **Yes** **Date:**
	☐ **Yes** **Date:**
	☐ **Yes** **Date:**

5. COLLABORATORS FROM OTHER INSTITUTIONS: If you will be conducting this study in collaboration with non-Suffolk investigators or in non-Suffolk facilities, please complete the section below. If the IRB from a collaborating institution has approved their participation in this research study, attach a copy of the IRB approval letter. ☐ **N/A**

Name	**Affiliated Institution**	**IRB Approval**	**CITI Certified**
		☐ **Yes** ☐ **No** ☐ **Pending**	☐ **Yes**
		☐ **Yes** ☐ **No** ☐ **Pending**	☐ **Yes**
		☐ **Yes** ☐ **No** ☐ **Pending**	☐ **Yes**

Do the collaborating institutions hold a Federalwide Assurance (FWA)? ☐ **Yes** ☐ No
If yes, specify which institutions hold an FWA:

Does the involvement of Suffolk University include the receipt of a sub-award from a collaborating institution? ☐ **Yes** ☐ **No**

Does any part of this research involve collaboration with an independent investigator? ☐ **Yes** ☐ No
If yes, please identify investigator:

Is the involvement of a Suffolk University investigator limited to the evaluation of de-identified data? ☐ **Yes** ☐ No

6. FUNDING SOURCES: If the study is funded, please provide a copy of the full grant, proposal and/or award ☐ **N/A**

☐ External Federal-Fund	Agency:
☐ External Non-Federal Fund	Source:

7. PURPOSE AND SCOPE: Please provide a brief summary of any relevant background information, study aims and its hypothesis.

Duration: From: **To:**

Study Site(s):

8. DECEPTION

Does this study involve the use of deception? ☐ Yes ☐ No If yes, describe in detail how deception is to be used, include a plan for debriefing participants, and attach any debriefing scripts that will be used.

9 . DESCRIPTION OF STUDY POPULATION

Maximum Number of Subjects:	**Age Range**:
Characteristics of Study Population: Please check any that may apply.	
☐ Elderly	☐ Children
☐ Suffolk Students/Staff	☐ Educationally-Disadvantaged Persons
☐ Prisoners	☐ Economically Disadvantaged Persons
☐ Non-English Speaking	☐ Other:
☐ Cognitively Impaired	

10. SELECTION OF SUBJECTS: Describe the **inclusion/exclusion criteria** and explain rationale for such. Explain rationale for using special populations such as children, pregnant women, prisoners, minorities or any vulnerable individuals and describe the additional safeguards that are in place to protect their rights and welfare. Provide rationale for concluding that the risks and benefits are fairly distributed among the population that stands to benefit from the research. If Suffolk University students are involved in research as subjects appropriate measures must be in place to ensure the age requirement for informed consent (age 18 or older) is met. If not,

11. RECRUITMENT TOOLS: Please provide copies for all marked.

☐	**Flyers, Posters, Brochures**
☐	**Study Advertisement** (*e.g., radio, television, online (Facebook, craigslist, private or public websites), newspaper, student newsletters, etc.)*
☐	**Word of Mouth** *(e.g., participants referring other individuals to study)*
☐	**In Person Recruitment** *(e.g., public events, meetings, open houses, school events, etc.)*
☐	**Referrals (***e.g., psychologist refer patients to study, teachers refer students to study, etc.)*
☐	**Scripts** *(e.g., phone scripts, e-mail scripts, screening scripts, presentations, etc)*

12. RECRUITMENT PROCESS: Describe in detail how subjects will be identified, method of initial contact and rationale for such method. If the recruitment process involves the recruitment of children who are being accessed through school or places where children participate in extracurricular activities, a letter of authorization must be obtained from the school principal, district superintendent, or administrative director or CEO of all applicable sites and included with the application.

13. INFORMED CONSENT/ASSENT/PARENTAL PERMISSION PROCEDURES: Informed consent is an essential process protecting the rights and well-being of participants. As per the Office for Human Research Protections (OHRP), the informed consent process involves three key features: (1) disclosing to potential research subjects information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research. The standard is an informed consent process that includes all necessary elements of informed consent (See Appendix II below) stated in a written informed consent form with informed consent documented by having participants signing the consent document. The nature of the informed consent process can vary as a function of the risk involved in the study with some of the elements of the consent process waived. <u>Please choose the option below (1-4) that best describes the nature of the informed consent process</u>. IF YOU CHOOSE ANY OPTION OTHER THAN THE FIRST (1), PLEASE SUBMIT A "Waiver of Some or All Requirements of Informed Consent" FORM WITH YOUR APPLICATION.

☐	1) **Informed consent will be obtained and include all of the necessary components (see Appendix II) and consent will be documented by participants signing a consent form.**
☐	**2) Informed consent will be obtained and include all of the necessary elements (See Appendix II). However, documentation of consent will not be obtained. If this option is chosen, please include a Waiver of Some or All Requirements of Informed Consent form with your application form** Please note to waive this requirement at least one of the criterion must be met**.**
	☐ The only record linking the subject to the research would be the consent document and the principal risk of the research would be a potential harm resulting from a breach of confidentiality. If this criterion is met, each subject must still be asked whether the subject wants to document consent and the subject's wishes must govern.
	☐ The research presents no more than minimal risk of harm to subjects and involved no procedures for which written consent is normally required outside of the research context (e.g. diagnostic tests).
☐	

☐	**3) Waiver of some of the elements of informed consent per §46.116(d)** Please submit a **Waiver of Some or All Requirements of Informed Consent form on which you describe the elements of informed consent that you would like to waive.**
☐	**4) Waiver of informed consent per §46.116(d)** If requesting a waiver of a required element of informed consent or the informed consent process altogether, please provide a rationale for each of the following criterion. Please note that a waiver can only be granted if all of the following criteria are met. Please submit a Waiver of Some or All Requirements of Informed Consent form to provide a detailed rationale for waiving informed consent
	☐ The research involves no more than minimal risk to subjects.
	Rationale:
	☐ The waiver of alteration will not adversely affect the rights and welfare of the subjects.
	Rationale:
	☐ The research could not be practicably be carried out without the waiver or alteration.
	Rationale:
	☐ Whenever appropriate, the subject will be provided with additional pertinent information after participation
	Rationale:
☐	**Participants will be audio or video-taped** *(Please complete appropriate consent document)*

14. INFORMED CONSENT OR ASSENT AND PARENTAL PERMISSION PROCESS: Describe consent/assent and/or parental permission procedures, including the circumstances under which consent/assent and/or parental permission will be sought and obtained, the nature of information to be provided to prospective subjects, and method of documentation**. Indicate that you have checked the Flesch-Kincaid Grade level test and document the score of the document (for adults and children 14-17 years old, aim for a score between 7.0 and 8.0). For children 7-13 years old ensure the grade level is age-appropriate. N/A** ☐

15. PROTECTED HEALTH INFORMATION: If collecting protected health information (PHI), describe the PHI being collected, the purpose for which it will be used, the entity from which the PHI will be collected and whether or not the entity is a HIPAA covered entity. If not applicable, insert NA below and skip item 16.

16. METHOD OF COLLECTING PROTECTED HEALTH INFORMATION AND AUTHORIZATION: *Check all that apply.*

☐ **Prospective Chart Review** ☐ **Retrospective Chart Review** ☐ **Other:**

☐ **Authorization to be obtained** ☐ **Request Authorization Waiver** *(Please complete appropriate form)*

17. RESEARCH TOOLS: *Please provide copies for all marked.*

☐	**Surveys or Questionnaires (e.g. online surveys, mailed surveys, personal or medical history)**	
☐	**Measurement Instruments (e.g. psychological tests, IQ tests, diagnostic tools)**	
☐	**Interviews ☐ In Person ☐ Phone ☐ Other:**	**Recorded: ☐ Audio ☐ Video**
☐	**Focus Groups ☐ In Person ☐ Phone ☐ Other:**	**Recorded: ☐ Audio ☐ Video**
☐	**Record Review (e.g. chart review, public school records, medical records, agency records)**	
☐	**Other:**	

18. RESEARCH PROCEDURES: Describe the study procedures that a research participant should expect during the protocol. Define the type, frequency, duration of participation (e.g., what is done and when). When applicable, describe which procedures are experimental and which are routine.

19. COMPENSATION METHOD: If participants will not be compensated check this box ☐ N/A; skip to section 20.

Amount/value of total compensation?	Type: ☐ Gift Card ☐ Cash ☐ Drawing ☐ Other:

If students are participating in research will they receive course credit? ☐ Yes ☐ No

If yes, describe criteria for awarding credit, i.e. amount of credit awarded and alternatives for receiving equivalent credit in lieu of participating in a study as a research subject. If credit is awarded in accordance with departmental policy, include the policy with your submission.

Is compensation pro-rated? ☐ Yes ☐ No; If yes, describe how it will be pro-rated:

20. RISKS/DISCOMFORTS: Describe any known or potential risks and/or discomforts (physical, psychological, social, legal or other) and assess their likelihood, seriousness and potential reversibility. Describe procedures for protecting against these risks and assess their likely effectiveness. Describe any alternative procedures that may be available to subjects including the choice not to participate.

21. BENEFITS: Describe any potential benefits to the individual subjects and/or to society in general that may be expected from the research. Describe the importance of knowledge that may reasonably be expected to result from the study. If no direct benefits are anticipated, please state so.

22. RISK/BENEFIT ANALYSIS: Discuss why risks are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

23. RESEARCH DATA

Will personally identifiable or protected health information be recorded? ☐ Yes ☐ No

If so, please check all that apply:

☐ Names (First and Last)	☐ Date of Birth	☐ Telephone/Fax Number
☐ Email Address	☐ Social Security Number	☐ Student ID
☐ Street address, city, five digit zip code, county	☐ Internet IP Address	☐ Other:

Will you be sharing any research data with any other investigator outside of Suffolk? ☐ Yes ☐ No
If yes, with whom and for what purpose?

Will the research data be coded? ☐ Yes ☐ No
If yes, will a link between code and person's identifiable information be retained? ☐ Yes ☐ No
If yes, for how long?

24. PRIVACY AND CONFIDENTIALITY: Describe procedures for protecting privacy and maintaining confidentiality including procedures for collection, storage, and future use of data. Describe whether codes will substitute names and/or identifiable records, who will have access to study data, whether database will be password-protected or encrypted for online data collection. Describe how long written records, tapes, or recordings will be maintained and in what manner they will be kept or destroyed (the retention period for IRB records not containing protected health information is a minimum of three years; the retention period for protected health information is six years). **Please note**: when applicable, the IRB may request that a Data Safety Monitoring Plan is attached.

25. FINANCIAL AND OTHER CONFLICTS OF INTEREST DISCLOSURE

☐ The investigator and key study team personnel have no financial or other conflicts of interest related to this study.

☐ The investigator or other key study team personnel have conflicts of interest or potential conflicts of interest related to this study. *(Identify specifically who on the study team has a conflict of interest. Identify the precise nature of the conflict(s) of interest to include financial conflicts of interest or other and how these conflicts will be managed.* ***Conflicts of interest must be disclosed to research participants in informed consent documents****).*

☐ This project includes an investigator or key personnel from another institution who will comply with his or her own institution's COI policies.

☐ This project involves an investigator or key personnel from another institution who will comply with Suffolk University COI policies (completed Suffolk University COI disclosure form attached).

26. *PRINCIPAL INVESTIGATOR'S CERTIFICATION (E-SIGNATURE)

I certify that the information contained in this application is true. I understand that IRB approval of this application must be received prior to beginning any subject recruitment. I also understand that the IRB must be notified in writing of any modifications made to the study subsequent to approval of this application. I acknowledge and accept my responsibility for protecting the rights and welfare of human research participants as discussed in the Common Rule (45 CFR 46) and Belmont Report. I certify that I will comply with all applicable regulations and directions of the Institutional Review Board, which may include:

1. Conducting this research study as approved by the IRB.
2. Complying with the requirements for the continuing review of research.
3. Submitting any changes to the protocol to the IRB for review and approval prior to implementation.
4. Monitoring and supervising investigators and research staff in the conduct of the research.
5. Maintaining accurate, current and complete records of all study materials including all IRB correspondence.
6. Complying with all state and federal laws as well as Suffolk University's institutional policies regarding the conduct of research with human subjects.
7. Promptly reporting adverse and unanticipated events related to the study to the IRB.
8. When applicable, filing a final report with the IRB upon completion of the study.

*E-SIGNATURES ARE ***REQUIRED PRIOR TO SUBMISSION*** from the following:

Department Chair or Dean
Principle Investigator
Co-Investigator(s)
Faculty Advisor (for students only if different from PI)

Please contact the Office of Research and Sponsored Programs if you need assistance with setting up an account on www.irbnet.org.

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Appendix I OHRP Criteria for IRB Approval

(1) Risks to subjects are minimized
(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
(3) Selection of subjects is equitable
(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative
(5) Informed consent will be appropriately documented
(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Vulnerable populations:

§46.111(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

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Appendix II Required Elements of Informed Consent

The goal of the informed consent (IC) process is to provide individuals with sufficient information for making an informed decision before participating in a research study. By providing a summary of the research procedures, risk and benefits and describing the individual's rights as a research participant the IC document serves as a starting point for the necessary exchange of information between the investigator and research subjects. It is important to note that the IC document is only one part of the entire process of informed consent.

The regulations require that the following information must be conveyed to each subject during the informed consent process:

- A statement that the study involves research
- An explanation of the purposes of the research
- Expected duration of the subject's participation, a
- Description of the procedures to be followed
- Identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.