Application Checklist for Expedited or Full-Board Review of Research

Project Title:

Principal Investigator: _____

☐ **Training was completed for all researchers:** All Co-Investigators, Student Researchers and/or Staff Members must complete the CITI course for Human Subjects Research also and indicate the date of completion.

Attachments uploaded with this application:

☐ Appendix A – Level of Review Request – ***Required for all applications***
☐ Appendix B – Conflict of Interest - ***Required only for applicants who have declared a conflict of interest***
☐ Copies of all research instruments are attached. (Surveys, interview questions, focus group questions, screen shots of web based research, etc.)
☐ Copies of recruitment materials are attached. (Advertisements, flyers, emails, letters, phone scripts, web pages, etc.)
☐ Letters of permission and/or IRB approval from other organizations involved in the project are attached.
☐ Consent materials are attached. (Consent forms, assent forms, copy of oral script, etc)
Sample consent forms can be found at http://www.potsdam.edu/faculty/research/rspo/irb

SUNY Potsdam Application for Permission to Involve Human Subjects in Research
☐ Full Board Review ☐ Expedited Review

☐ I have read ***Appendix D Conflict of Interest guidelines*** and the ***SUNY Potsdam Conflict of Interest Policy*** and declare that I do not have a potential conflict of interest associated with this project.

☐ I have read Article 24-A as amended to the New York State Public Health Law (available on the SUNY Potsdam IRB website) and agree to comply with SUNY Potsdam policy and state and federal regulations regarding the use of human subjects in research. I further agree to execute this project as described in this proposal; request approval from the IRB for changes; submit applications for continuation of approval as required; submit a final report at the conclusion of the study; and am responsible for the supervision and work of my staff and/or students.

_____ _____
Electronic Signature of Principal Investigator Date

1. Description of the project

Describe the purpose of the research, including research question(s), hypotheses, background information, etc…:
Describe the methodology the research will use in detail (e.g. experimental design, ethnographic design, survey or interview, etc…:
Describe the tasks the participants will be asked to perform in detail:
Describe where subjects will be engaging in the tasks:
What is the expected length of the study:

2. Confidentiality

1. Describe any information that will be collected from the subjects that could directly identify them (e.g., names, social security numbers, addresses, telephone numbers, email addresses, etc.). Explain why it is necessary to collect this information:
2. Describe any codes that will be used to identify subjects:
3. Will there be a link between codes and direct identifiers after the data collection is complete? If so, explain why it is necessary and state how long this link will exist:
4. Explain the precautions taken to protect participants' identities:
5. Where, how long and in what format (such as paper, digital or electronic media, video, audio or photographic) will data be kept?
6. Describe the security measures that will be taken to protect the data (locks, password protects, encryption, etc.):
7. What is going to be done with the data when the study is complete?

3. Risks and Benefits:

1. Which of the following risks or harms might subjects experience in this study? Select **ALL** that apply:

☐ Use of deception

☐ Use of private medical records

☐ Manipulation of psychological or social Variables such as sensory deprivation, social

☐ Probing for personal or sensitive information in surveys or interviewsIsolation, psychological stresses, etc…

☐ Presentation of materials subjects might Consider sensitive, offensive, threatening or Degrading

☐ Possible invasion of privacy of subject or family

☐ Social risk (risk of stigma, risk to reputation)

☐ Emotional or psychological risk

☐ Economic risk

☐ Physical risk

☐ Other risks – list ALL other risks:

2. Describe the nature and degree of risk or harm selected above and of any other moral/ethical objections that might be raised by others. (Note that all risk/harms must be disclosed in the consent form).

3. Describe the steps taken to minimize each risk or harm selected above and to protect subjects' welfare generally.

4. Describe the anticipated benefits of this research:
For subjects (identify which subjects will be likely to experience these benefits):

For society:

5. Explain how the benefits of this study outweigh the risks:

4. Participants and Recruitment

1. Describe the subjects for this study. Include subjects' age, gender, race/ethnicity and other relevant characteristics in the description and note any specific groups that will be explicitly included or excluded from the study:
2. Describe the process by which potential participants will be identified. If contact information will be obtained from another organization, explain how potential subjects will give consent for this information to be shared with the investigator.
3. How many participants will be recruited?
4. Describe the process by which participants will be recruited.
5. Who will approach potential participants? (Note that initial contact of potential subjects identified through records search must be made by the official holder of the record, i.e., primary physician, therapist, public school official, etc.):

5. Informed Consent and Voluntary Participation

1. Will participants in this study be voluntary? ☐ No, please explain:	☐ Yes
2. Will participants be able to end their participation and/or skip parts of the study without experiencing any negative consequences? ☐ No, please explain:	☐ Yes
3. Please describe any compensation that will be offered to potential participants and explain how it will be offered to them. This may include money, services, gifts, extra credit, etc.	
4. If the participants are a captive audience (e.g. students in a classroom, one's own employee's, patients in a hospital, etc.), what steps will be taken to ensure that there is no element of duress and that the consent to participate is clearly voluntary?	
5. Describe in detail what will be said to potential subjects to introduce the research prior to distributing consent forms. Where appropriate attach a script.	
6. In relation to the actual data gathering, when and how will consent be discussed and documentation obtained? (e.g. Mailing out materials, delivery of consent form, meeting, etc.) Be specific.	
7. Will the investigator(s) be securing all of the informed consent? ☐ Yes ☐ No. Please list all team members on the "Study Team Members" smartform of the online application. Please note that each person involved in the project must complete the modules of CITI training required by SUNY Potsdam.	
8. Will all potential subjects be competent to consent to participate in the study? Please note that individuals under the age of 18 cannot give consent. ☐ Yes ☐ No. If not please answer all of the following:	
a. How will the competence (or age) of the potential participants be established?	
b. From whom will consent be sought for potential participants who are not competent (or of age) to consent and how will that consent be obtained?	

c. How will assent be obtained from the potential participants who are not competent (or of age) to consent?

d. Where and for how long will consent documents be stored? (Please note that consent documents must be retained for a minimum of three years).

e. What security measures will be used to protect the consent documents?

9. Under specific conditions, when justifiable, procedures for obtaining and documenting informed consent can be waived or altered. These limited conditions are described in Part II – D4 and Part II E4 of the SUNY Potsdam Policy on the Use of Human Subjects in Research.

a. To request to waive or use altered consent procedures, please explain what you will do and why:

b. Is a waiver of *documentation* of consent requested for distinct cultural groups or communities in which signing forms is not the norm? Yes ☐ No ☐