

IRB AMENDMENT REQUEST

Section A: General Information

IRB Approval Number:

Project Title:

Principal Investigator(s):

Co-Principal Investigator(s):

Category of Review: Full Board Expedited Exempt

Section B: Amendment Description

1. Check appropriate box(s):

- Amendment to recruitment materials
- Amendment to debriefing forms
- Amendment to data collection tools
- Amendment to currently approved procedures on applications (i.e., general information section, data collection methods, confidentiality, recruitment, risk and benefits, etc.).
- Other (describe below):

2. List and describe the proposed changes to each document or sections on the application:

3. State the reason for the proposed changes:

4. Potential risks to the participants (as a result of this amendment: check all that apply)

- No Change
- Not Applicable
- Invasion of privacy to the subject of family
- Breach of confidentiality
- Physical harm or discomfort
- Psychological/ emotional discomfort or distress
- Psychological effect that is more than discomfort or distress

- Social stigmatization
- Economic (e.g., employment, insurability)
- Legal
- Any study related activity which subjects might consider sensitive, offensive, threatening, or degrading?
- Withholding standard care and procedures
- Significant time of inconvenience
- Other (describe)

5. Indicate which of the categories listed below accurately described the overall potential risk level on items in question 4 of this amendment form.

- No Changes
- Not Applicable
- Not greater than minimal risk
- Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects
- Greater than minimal risk, not prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

6. How will you minimize these potential risks in order to protect participants rights and welfare (e.g., compensation, counseling, etc.)?

- Not Applicable
- Applicable Details (describe):

7. Is it possible that you will discover a participants previously unknown physical or psychological condition as a result of your revised procedure?

- YES
- NO
- Not Applicable

8. Is there a change in benefits as a result of this amendment?

- YES
- NO
- Not Applicable

If YES, describe the expected benefits of this amendment (either to individual or society).

9. Do the benefits of this amendment outweigh the increased risks to the participants (e.g., risk/benefit ration)

- YES
- NO

Not Applicable

If YES, explain:

10. Did you attach amended material, as applicable?

YES

Section C: Signatures

By signing this form, the principal investigator or Co-IP/ faculty advisor attests that he/she has read the information provided and attached the needed documents.

Principal Investigator (PRINT)

Signature

Date

Co- PI/ Faculty Advisor (PRINT)

Signature

Date