**Application for Modification Approval**

**Complete this form for all revisions/modifications.**

1. **Go into your PACS study, click the Create Modification/CR Button.**
2. **Under Modification Scope, please select BOTH "Study team member information" and "Other parts of the study".**
3. **Upload your completed Modification application for Approval under #8 Attach the Protocol.**
4. **Attach other revised documents as necessary (informed consent, revised surveys, recruitment emails, etc.)**
5. **Once this is done, please be sure to click the Submit button.**
6. **Once the HREB Coordinator does a pre-review, it will then be assigned to the HREB Chair for review.**

**Principal Investigator Name:**

**Project Title:**

**Protocol Number:**

**DESCRIPTION OF MODIFICATION**

**Response:**

**A. Changes to Study Personnel/Researchers:**

Are you changing the Principal Investigator or the Faculty Advisor?

YES  NO

Please provide a brief rationale.

**Response:**

**If you are changing faculty advisor or changing a student Principal Investigator to another student Principal investigator, a revised Faculty Advisor Assurances Addendum must be submitted.**

Are you making any other changes to the personnel working on your study?

YES  NO

If yes, please indicate the name, role, responsibilities, and status (faculty, graduate, undergraduate, staff) of the individual(s) you are adding to your study or removing from your study. For each individual you are adding, indicate whether they have completed CITI training or not.

**Response:**

**B. Participant Sample Changes**

Are you making any changes to the participant sample from which you plan to collect your data?

YES  NO

If yes, please describe the change.

**Response:**

Does this change pose any increased risk to the participants?

YES  NO

**If Yes, explain:**

Does this change involve adding participant samples that would include individuals under the age of 18?  YES  NO

**If Yes, explain:**

If yes, please be aware that parental consent and participant assent are required for most studies involving individuals under the age of 18.

Does this change involve adding an international sample?  YES  NO

**If Yes, explain:**

If yes, please be aware that you will need to submit an International Research Addendum. You will need to provide the name and contact information for a cultural consultant, as well as translations and back translations of all materials (if appropriate).

**C. Procedures:**

Are you making any changes to the study's procedures including changes to your questionnaire or interview protocol? YES  NO

If yes, describe in detail the changes you plan to make.

**Response:**

State the rationale for the changes.

**Response:**

Do you anticipate that these changes will alter the risks to the participants?

YES  NO

If yes, how so?

**Response:**

Will these changes lead to the collection and/or storage of identified data?

YES  NO

If yes, answer the following:

**Response:**

1. What is the justification for needing identifiers in order to conduct the research?
2. What is the sensitivity of the data being collected?
3. What is the likely retention period for identifiable data?
4. What security controls do you have in place for the identifiable data (i.e., physical safeguards for paper records or recordings, technical safeguards for electronic records, Secure sharing or transfer of data outside the institution, if applicable)?
5. What is the potential risk for harm that would occur if the security of the data was compromised?

Do you plan to change your questionnaire or interview protocol?

YES  NO

**If Yes Explain:**

**If you are making changes to your questionnaire or interview protocol, attach copies of the original and revised versions.**

**D. Informed Consent**

Will your planned changes require revision of your informed consent form?  YES  NO

If yes, please describe the change and attach both the original consent form and a revised version of the consent form.

**Response:**

**E. Health Information and Biospecimens**

YES  NO

Do your changes involve the collection of health information or biospecimens?

If yes, do you plan to obtain Broad Consent?

YES  NO

If yes, have you satisfied HIPAA requirements?

YES  N

**F. Other Changes**

Do you plan any other changes to your study?

YES  NO

**If Yes, explain:**