Amendment: Amendment Title

Section 1: Amendment Type

1.1) Type of Amendment (check all that apply)

- ☐ Administrative Changes: Changing study personnel, Correcting typos and grammar, Changing document formatting, Changing study locations and participating sites, Adding approvals from other sites, Translation of approved documents
- ☐ Changes to study design elements: Changing study purpose and objectives, Changing study design type (retrospective, prospective, clinical trial, observational, etc.), Changing inclusion/exclusion criteria or participant cohorts (including vulnerable populations), Changing the number of participants (enrollment goal), Changing data or safety monitoring plans
- ☐ Changes to study procedures: Changing the recruitment process and/or materials, Changing the consent process or waivers of consent, Changing the study interventions, Changing data collection procedures, Changing data analysis procedures, Changing data sharing procedures, Changing compensation for participants
- ☐ Changes to consent, parental permission, or assent documents
- ☐ Changes to the risk/benefit profile and/or participant safety parameters
- ☐ Addition of radiation exposure or biological material collection
- ☐ Sponsor Protocol Revisions
- ☐ Investigational Brochure changes
- ☐ Other changes

1.2) Current status of the study

- ○ Open for Enrollment
- ○ Closed to Enrollment
- ○ Enrollment on Hold

1.3) Total Number of Participants Enrolled To Date (provide specific numbers if possible)

1.3.1) Participants UIUC researchers enrolled and/or are responsible for

1.3.2) All Centers – for multi-site research all participants UIUC researchers are not responsible for

- If this is a single-center project, you can list the same enrollment number as 1.3.1 or enter N/A.
- If this is a multi-center project, an estimate should be included.
- If UIUC is acting as the IRB for external sites, the PI is expected to include an accurate enrollment number for all centers UIUC is responsible for.

Section 2: Amendment Description

Please address all changes categorically in the text boxes below. See examples for more details.

2.1) What changes are being made? List and number change, grouping similar changes together.

Example:

1. Administrative changes: This includes adding a new sub-investigator and fixing typos in the consent form.
2. Changes to study design and procedures:
    1. We would like to add a new participant cohort, recruited from community centers
    2. We are also adding a questionnaire component to the study.

This is an open text box that allows for you to list out the changes that are being made. Do not just list the "type" of change, describe the changes. For example, list the specific research team members who are being added or removed.

2.2) Describe the reason for each of the changes described above. List and number the reasons according to the list above.

Example:

1. Administrative changes are needed to add personnel to the study team and correct past errors.
2. Changes to study design and procedures:
    1. The new cohort is being added in order to improve enrollment such that enrollment goals can be achieved in a timely manner.
    2. The new questionnaire is being added to collect information about each participant's daily activities, to improve the analysis required for Aim 2.

This is an open text box that allows for you to list out the reason for each change. For a more efficient review, make sure that you are listing out your reasons in this box to match, in order, the changes listed in 2.1 above.

2.3) How does each change described above affect participants? List and number the effects according to the above list.

Example:

1. Administrative changes will have no effect on participants.
2. Changes to study design and procedures
    1. The addition of a new cohort will not affect currently enrolled participants.
    2. The addition of a questionnaire will require extra time from participants. Currently enrolled participants will need to be re-contacted in order to complete the new questionnaire. The questionnaire is of little risk.

This is an open text box that allows for you to list out how each change impacts participants. For a more efficient review, make sure that you are listing out your reasons in this box to match, in order the changes listed in 2.1 and 2.2 above.

2.4) Will the modification(s), in the opinion of the local PI, increase or decrease the risk to participants?

- ○ Increase (If the risk increases, a report may need to be submitted, according to the IRB Reporting Policy for Unanticipated Problems)
- ○ Decrease
- ○ Neither

2.6) How will enrolled participants (current and past) be notified of this change?

- ☐ N/A – No participants have been enrolled in this study

Note: N/A means no participants have EVER been enrolled. If participants were enrolled, but are now finished participating, do NOT select this response.

- ☐ Participants will not be notified
- ☐ Re-consent participants
- ☐ Letter from investigator or sponsor
- ☐ Other

You may need to select two responses if past participants will not be notified, but current participants will be re-consented.

2.7) Which approved documents are affected by these changes?

- ☐ Consent, Parental Permission, or Assent Documents
- ☐ Surveys, Questionnaires, Interview Scripts, etc.
- ☐ Full Protocol (Company protocol, sponsor protocol, etc.)
- ☐ Investigational Brochure
- ☐ Recruitment Materials, Advertisements, etc.
- ☐ Other Documents

2.8) Which sections of the study form that is being updated are affected by these changes?

The current form on this screen is a copy of your approved project form and changes should be made directly on this form.

List the questions/sections that are being changed with this amendment.

2.9) Is UIUC acting as the IRB for any external sites/individuals?

- ○ Yes
- ○ No

Section 3: Report Forms

3.1) Is this amendment related to information that meets the IRB reporting policy for unanticipated problems and non-compliance?

- ○ Yes
- ○ No