

IRB NON-MED
CONTINUING REVIEW
FORM

Continuing Review Form

1. Select one of the following:

I will continue to enroll participants.

If so, go to question 2, and then complete the rest of the form.

I will not continue to enroll participants.

If so, select one of the following, and then complete the rest of the form. Remainder of the study:

I will continue to do research-related interventions with participants or continue to obtain/gather data.

I am renewing this study ONLY for long term follow-up.

I am ONLY doing data analysis. If all data have been de-identified, you may be eligible to close this protocol. Contact the IRB Associate .

2. Study Assessment

a. Briefly describe the progress of your study so far, including interim findings, if any.

b. Provide a narrative summary of benefits experienced by participants in the past year, if any.

c. Has the ratio of the risk to potential benefit changed? If yes, explain.

3. Participant Enrollment.

Include the total number of participants entered since the beginning of the study. If pertinent to the study, include the number of children (age 17 or younger), the number of males and females, the ethnicity or race of the participants, and/or the number of other potentially vulnerable subjects.

4. Study Problems/Complications

a. Include the number of withdrawals of participants and number of participants lost to follow-up, if any, since the beginning of the study; and

b. Summarize problems or complications, if any, encountered since the last renewal (e.g., noncompliance or unanticipated problems).

5. Potential Conflict of Interest

Update the Conflict of Interest (COI) section if any changes in COI have been made since the last protocol submission.

Yes No Is there a change in the conflicting interest status of this protocol?

If yes, explain the change in the potential conflict of interest in the box below.

6. Protocol Modification

Yes No Are you proposing to make changes to the protocol at this time? If yes:

a. Summarize all of the proposed changes to the protocol application and/or consent form in the box below. Proceed to the appropriate Protocol Information section(s) and make your changes.

Proceed to the appropriate section(s) and make your changes. Make necessary changes in Consent Form(s) when applicable.

b. Indicate Level of Risk

Increase

No Change

Decrease

If level of risk has changed, please update the answers to the Risks questions in the Protocol Information section.