Continuing Review Form

1. Participant Enrollment.
   a. Number of participants entered (or number of specimens examined or charts reviewed) since the beginning of study. If this is a combined VA-Stanford study, in addition indicate how many of the participants (or number of VA specimens examined or VA charts reviewed) enrolled with a VA consent. If this is a multi-site study, in addition to the number of participants enrolled locally, include the number of participants enrolled study-wide.

   b. Number of males, # of females.

   c. Minority status of participants entered since beginning of study.

   d. Number of children (less than 18 years) entered since beginning of study.

   e. Number of other potentially vulnerable subjects (if applicable) entered since the beginning of study, including prisoners, pregnant women, economically and educationally disadvantaged, decisionally impaired and homeless people.

2. Study Problems/Complications
   a. Number of withdrawals of participants from the research (both participant and investigator initiated) since the beginning of the research study. Provide reasons for the withdrawals.

   b. Number of participants lost to follow-up since the beginning of the study.

   c. Provide a narrative summary of the adverse events since the last renewal indicating whether the adverse events were expected and/or related to the study, OR, state if all adverse events were expected and occurred at the same severity and frequency as anticipated.

   d. Provide a narrative summary (not a list) of the unanticipated problems involving risks to participants or others that have occurred in the research in the past year. Confirm that all events and information that require prompt reporting to the IRB (guidance GUI-P13) have been reported as required.

   e. Provide a narrative summary of all relevant reports received in the past year whether or not the report has been previously submitted to the IRB. Summarize adverse event reports, audit results, and any other reports. Include corrective actions taken as a result of any audits.

   f. Complaints about the research in the past year.
g. Noncompliance: Has there been any agency, institutional, or other inquiry into noncompliance related to the study, or concerning a member of the research team. If yes, provide an explanation of the noncompliance, indicate if the noncompliance has previously been reported to the IRB, and provide a corrective action plan that includes how you will ensure the noncompliance does not recur.

3. Study Assessment
   a. Provide a narrative summary of any interim findings from your data in the past year.
   
   b. Provide a narrative summary of any recent relevant literature.
   
   c. Attach Data Safety Monitoring Reports in section 16 received in the past year which have not previously been submitted to the IRB.
   
   d. Provide a narrative summary of benefits experienced by participants in the past year.
   
   e. Provide an assessment of whether the relationship of risks to potential benefits has changed.

4. Description of the remainder of project:
   a. Is the study open to enrollment?
   b. Is the study permanently closed to enrollment of new participants?
   c. Have all participants completed all research-related interventions?
   d. Are you still engaged in research-related intervention(s)? If yes, please describe.
   e. Do you wish to renew this study only for long term follow-up? (Protocols must be renewed to follow participants.)
   f. Are you only doing data analysis?

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.
   a. Is there a change in the conflicting interest status of this protocol?
   b. If yes, explain the change in the potential conflict of interest.

6. Protocol Changes
   Please note that if these changes involve changes to Radiation Safety or Biosafety, the IRB will hold its approval until Radiation Safety or Biosafety forwards its approval to the IRB. Use track changes if revising consent, assent or HIPAA.
   a. Summarize all of the proposed changes to the protocol application including consent form changes.
   b. Proceed to the appropriate section(s) and make your changes. Make necessary changes in Consent Form(s) and HIPAA, when applicable.
b. **Indicate Level of Risk**
   If level of risk has changed, please update the answers to the Risks questions in the Protocol Information section.
   - Increase
   - No Change
   - Decrease

c. **Approval Includes**

d. **List of Sections (and questions) that have been changed/modified**

e. **Describe any other changes.**
12. Potential Conflict of Interest

Investigators are required to disclose any financial interests that reasonably appear to be related to this protocol.

Financial Interest Tasks

<table>
<thead>
<tr>
<th>Investigators</th>
<th>Role</th>
<th>Has Financial Interest?</th>
<th>Date Financial Interest Answered</th>
<th>Date OPACS Disclosure Submitted</th>
<th>Date OPACS Review Completed</th>
</tr>
</thead>
</table>

INSTRUCTIONS FOR ADMIN CONTACT

- Please reload this page to see updated financial interest information.
- Issues submitting protocol? Hover over information icons.
- Incomplete tasks must be completed by the investigator. Forward instructions below.

To Disclose Financial Interests for this protocol:

1. Log on to your dashboard at https://OPACSprd.stanford.edu
2. Click the red “enter response” button for this protocol
3. If you enter “yes”, you will need to disclose related financial interests

Issues? Please submit an OPACS HelpSU ticket.
Obligations

The Protocol Director agrees to:

- Adhere to principles of sound scientific research designed to yield valid results
- Conduct the study according to the protocol approved by the IRB
- Be appropriately qualified to conduct the research and be trained in Human Research protection, ethical principles, regulations, policies and procedures
- Ensure all Stanford research personnel are adequately trained and supervised
- Ensure that the rights and welfare of participants are protected including privacy and confidentiality of data
- Ensure that when de-identified materials are obtained for research purposes, no attempt will be made to re-identify them.
- Disclose to the appropriate entities any potential conflict of interest
- Report promptly any new information, modification, or unanticipated problems that raise risks to participants or others
- Apply relevant professional standards.

Any change in the research protocol must be submitted to the IRB for review prior to the implementation of such change. Any complications in participants or evidence of increase in the original estimate of risk should be reported at once to the IRB before continuing with the project. Inasmuch as the Institutional Review Board (IRB) includes faculty, staff, legal counsel, public members, and students, protocols should be written in language that can be understood by all Panel members. The investigators must inform the participants of any significant new knowledge obtained during the course of the research.

IRB approval of any project is for a maximum period of one year. For continuing projects and activities, it is the responsibility of the investigator(s) to resubmit the project to the IRB for review and re-approval prior to the end of the approval period. A Notice to Renew Protocol is sent to the Protocol Director 7 weeks prior to the expiration date of the protocol.

Department Chair must approve faculty and staff research that is not part of a sponsored project. VA applicants must have Division Chief or Ward Supervisor approval. E-mail the Department Chair approval to IRBCoordinator@lists.stanford.edu.

All data including signed consent form documents must be retained for a minimum of three years past the completion of the research. Additional requirements may be imposed by your funding agency, your department, or other entities. [Policy on Retention of and Access to Research Data, Research Policy Handbook, http://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research-retention-and-access-research-data]

PLEASE NOTE: List all items (verbatim) that you want to be reflected in your approval letter (e.g., Amendment, Investigator’s Brochure, consent form(s), advertisement, etc.) in the box below. Include number and date when appropriate.

☐ By checking this box, I verify that I, as the Protocol Director (PD) responsible for this research protocol, have read and agree to abide by the above obligations, or that I have been delegated authority by the PD to certify that the PD has read and agrees to abide by the above obligations.