IRB MED

CONTINUING REVIEW

FORM

Continuing Review Form:

1. **Participant Enrollment.**

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.

a.

b. Number of males, # of females.

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

d. Number of children (less then 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. Indicate whether adverse events experienced by participants are different from those originally 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 in the study, or any finding of noncompliance concerning a member of the research team? If yes, please explain.

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. O Yes O No. Is the study open to enrollment?
b. O Yes O No Is the study permanently closed to enrollment of new participants?
c. O Yes O No Have all participants completed all research-related interventions?
d. O Yes O No Are you still engaged in research-related intervention(s)? If yes, please describe.

e. O Yes O No Do you wish to renew this study only for long term follow-up?
(Protocols must be renewed to follow participants.)

f. O Yes O No 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.

O Yes O 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 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.

a. Summarize all of the proposed changes to the protocol application including consent form changes..

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.

- **O** Increase
- **O** No Change
- **O** Decrease

c. **Approval Includes**

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

e. **Describe any other changes.**