Reviewer Checklist for Unanticipated Serious Adverse Events, Unanticipated Adverse Device Effects and/or Unanticipated Problems Involving Risks to Participants or Others

VA Central IRB
VA Institutional Review Board for Multisite Studies

Note: A determination as to whether any actions are warranted to eliminate apparent immediate hazards to subjects must be made within 5 working days of receipt of the report by the VA Central IRB Administration Office. If a determination cannot be made within 5 working days, the report and this checklist must be immediately forwarded to a VA Central IRB Co-Chair.

Date Received by VA Central IRB: **Report Number:** 1

Date by Which a Preliminary Determination Must be Made:

I. Project Information (*To be completed by VA Central IRB Manager)*

VA Central IRB Study Number	
Title of Project	
Reporting Site (Include City)	
Reviewer	**If the assigned reviewer has a Conflict of Interest, do not proceed. Go to Section III and check the applicable box.**

II. Preliminary Report Evaluation

The reviewer must answer each of the following questions.	**YES**	**NO**
1. Is the reported event or problem serious?	☐	☐
2. Is the reported event or problem unanticipated?	☐	☐
3. Is the reported event or problem related or probably related to participation in the research?	☐	☐
Note: Related means the event or problem may reasonably be regarded as caused by, or probably caused by the research. If a determination that it is related or probably related cannot be made at this time without additional information check the box below: ☐ Additional information required for the convened IRB to make a determination *Specify the additional information required to make a determination in the Comment section below.*		

4. a. Does the reported event or problem place participants or others at a substantially greater risk of harm (including physical, psychological, economic, social, or legal harm) than was previously known or recognized?	☐	☐
b. Were actions taken in response to the reported event or problem?	☐	☐
Answer one of the following as applicable:		
If yes, were the actions appropriate?	☐	☐
If no, are any actions warranted to eliminate apparent immediate hazards to subjects? If yes, note actions in comment section.	☐	☐
5. Does this project continue to meet criteria for IRB approval?	☐	☐

III. Reviewer Recommendations

The reviewer must make one or more of the following recommendations; If all of the first three boxes in Section II of this form and/or if the report was submitted as "Related" by the study team, this report must be reviewed at the next meeting of the convened IRB. (Check all that apply)

☐ No further action is required.

☐ The protocol needs to be modified per the comments indicated in the comment section below.

☐ Modify the information disclosed during the consent process. <u>If this box is checked, also check</u> one of the boxes below:

- ☐ Previously enrolled participants <u>do not require notification</u>.
- ☐ Previously enrolled participants <u>must be notified</u>. If this box is checked, please specify:
  - a. Method of notification (e.g., re-consent with modified informed consent, information letter):
  - b. Timeline for notification (enter suggested notification timeline: e.g., contact participant by phone and send information letter within 30 days):
  - c. Method for documentation of notification (e.g., copy of informed consent documents to IRB at continuing review, letter from PI/SC or LSI following completion of notification)?

☐ Provide additional information to current participants. <u>If this box is checked, also check method of notification</u>:

- ☐ Reconsent with modified informed consent document.
- ☐ Information letter.
- ☐ Other:

☐ Modify the continuing review schedule as specified below.

☐ Monitor the research. *Provide comments below on how this should be done, i.e., request an RCO audit).*

☐ Monitor the consent process. *Provide comments below on how this should be done, i.e., request the local RCO monitor a sample of consent processes).*

☐ Refer to other organization entities as specified below.

☐ Require additional training of the PI/SC, LSI, or other members of the study team.

☐ Suspend VA Central IRB approval of the research.
If there is an immediate safety issue, inform one of the VA Central IRB Co-Chairs immediately.

☐ Terminate VA Central IRB approval of the research.

☐ Noncompliance may be involved as specified below.

☐ Other actions:

☐ I have a conflict of interest and am returning this checklist without review.

_____ Date: _____
Signature of Reviewer

Comments: