Reviewer Checklist for Amendments

VA Central IRB
VA Institutional Review Board for Multisite Studies

Section 1: Project and Reviewer Information (*To be completed by VA Central IRB Manager)*

VA Central IRB Number	
Title of Project	
Type of Review	◉ **Expedited** ○ **Convened Board** ***If Expedited is checked, one of the following must also be checked:*** ☐ **The Research Project for which this modification was submitted was previously approved under the expedited review process. The Research continues to pose no more than minimal risk to human participants and the modifications do not involve any procedures that do not meet the expedited review categories 1 through 7. *(See Section 5 for expedited review categories)*** ☐ **The Research Project for which this modification was submitted was previously approved by the convened IRB. The modifications do not pose an increased risk to participants and the modifications constitute a minor change to previously approved research.**
PI/SC or LSI Amendment	◉ **PI/SC** ○ **LSI** **Site:**
Amendment Number	
Reviewer	

If the assigned reviewer has a Conflict of Interest, do not proceed. Check this box ☐ and return this form to the VA Central IRB Manager for this study.

Section 2: Issues to be Considered

All of the following questions must be answered.	**YES**	**NO**	**N/A**
1. Does the investigator give an adequate rationale for the changes requested in the proposed amendment?	☐	☐	
2. Have all applicable documents been submitted with the changes incorporated to maintain consistency between the protocol and any informed consent or HIPAA authorization documents?	☐	☐	☐
3. Does this amendment result in any change in the risk/benefit ratio for participants?	☐	☐	☐
4. Could these changes affect the willingness of participants to continue in the project?	☐	☐	☐
5. Is there an adequate plan for informing the participant of these changes and re-consenting of participants if required?	☐	☐	☐
6. Does this change require a more frequent continuing review interval than is currently established for this project?	☐	☐	☐
Comments:			

Section 3: IRB Approval Criteria

Check which, if any, of the below IRB approval criteria are affected by this amendment.	
1. The **risks** to the subjects have been minimized by:	
(1) Using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk	☐
(2) Using procedures already being performed on the subjects for diagnostic or treatment purposes whenever appropriate.	☐
2. The **risks** to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.	☐
3. The **selection of subjects** is equitable.	☐
4. **Informed consent** will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by 38 CFR 16.116?. *Note. This includes the submission of appropriate and adequately justified waiver requests which meet all approval criteria.*	☐
5. If applicable, the **informed consent** contains all applicable elements to include appropriate blocks for signatures and dates.	☐
6. The **informed consent** form is consistent with the **protocol** and if applicable, the **HIPAA authorization.**	☐
7. **Informed consent** will be appropriately documented, in accordance with and to the extent required by 38 CFR 16.117. *Note: this includes the submission of an appropriate and justified request for waiver of documentation of informed consent which meets all approval criteria.*	☐
8. When appropriate, the research plan makes adequate provision for **monitoring** the data collected to ensure the **safety** of subjects.	☐
9. When appropriate, there are adequate provisions to protect the **privacy** of subjects and to maintain the **confidentiality** of data.	☐
10. VHA and VA **information security** policies pertaining to research have been implemented and are continually monitored to ensure compliance as set forth in VA Directive 6500 and its Handbooks.	☐
11. When some or all of the subjects are likely to be **vulnerable** to coercion or undue influence, such as children, prisoners, pregnant women, individuals lacking decision making capacity, economically or educationally disadvantaged persons, VA employees or students, and any others who may be at increased susceptibility to harm, additional safeguards are included in the study to protect the rights and welfare of these subjects.	☐
12. All real or potential **conflicts of interest** been managed, reduced, or eliminated.	☐
13. The **investigators** listed on the PI Application meet all required educational requirements for the protection of human subjects and are they qualified to conduct the research.	☐

Indicate whether the amendment approval continue to be met by checking one of the below boxes or indicate that the amendment did not relate directly to any of the above criteria:

☐ **Criteria Still Met** ☐ **Criteria Not Met**. *If not met, indicate in Section 4 what modifications are required in order to meet the criteria and secure approval.*

☐ **Amendment did not pertain to or affect any of the above criteria**.

Section 4: Reviewer Recommendation (Convened Board) or Decision (Expedited Review)

Indicate Recommendations or Decisions below depending on whether the amendment is being reviewed using expedited review procedures or if will be reviewed at a convened meeting.

For amendments reviewed at a convened Board meeting check one of the following:

☐ **Approval with no modifications. All IRB approval criteria are still met or have been met.**

☐ **Approval after minor modifications as described below are approved. All IRB approval criteria are still met, or will have been met upon review and approval of required minor modifications.** *Specify required modifications in item 3 below.*

☐ **Defer. Major modifications are required as described below requiring additional review of responses by the convened IRB.** *Specify required modifications in item 3 below.*

☐ **Disapprove the amendment.** *Specify basis for disapproval in item 3 below.*

For amendments undergoing expedited review only:

Check one of the following three boxes:

☐ **I agree that this amendment is eligible for expedited review since this project was originally approved under the expedited review process, the research continues to pose no more than minimal risk to human participants and the modifications do not involve any procedures that do not meet expedited review categories 1 through 7.** *See Section V for expedited review categories.*

☐ **Although this project did not qualify for expedited review, the modifications proposed do not pose an increased risk to participants and the modifications constitute only a minor change to the previously approved research.**

☐ **This amendment is not eligible for expedited review and must be scheduled for review by the convened IRB.** *Please specify basis for referral to the convened IRB in next section below.*

If amendment is eligible for expedited review, please check one of the following for both PI/SC and LSI Amendments and sign and date below:

☐ **No modifications required. All IRB approval criteria are still met or have been met. The amendment is approved.**

☐ **Modifications required for approval.** *Specify required modifications in next section below.*

☐ **The amendment is eligible for expedited review, but defer for review by the convened IRB.** *Specify reasons for deferral and any required modifications in next section below.*

Modifications or Reasons for Disapproval and/or Deferral to Convened IRB Meeting:

_____ _____

Reviewer Signature Date

Section 5: Expedited Review Categories for Reference in Completing Section 1

Category 1: Clinical studies of drugs and medical devices only when one of the following conditions is met.

1a: An investigational new drug application (21 CFR Part 312) or investigational device exemption application (21 CFR Part 812) is not required.

1b: The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

2a: From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.

2b: From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Category 3: Prospective collection of biological specimens for research purposes by noninvasive means.

Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.

Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

Category 6: Collection from voice, video, digital or image recordings made for research purposes.

Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.