Reviewer Checklist for Continuing Review (PI/SC Application)

VA Central IRB
VA Institutional Review Board for Multisite Studies

Project and Reviewer Identification (*To be completed by VA Central IRB Manager*)

VA Central IRB Number	
Title of Project	
Type of Review	☐ **Expedited** ☐ **Convened Board**
Study compliance to which Common Rule:	☐ **Pre-2018 Requirements** ☐ **2018 Requirements**
Check all that apply	☐ **FDA-regulated** ☐ **DoD-funded** ☐ **Pre-2018 Study Eligible for Transition per VA Central IRB Policy**
Current Expiration Date	
Current Risk Level	☐ **No more than minimal risk** ☐ **Greater than minimal risk**
Reviewer	
Review Assignment	☐ **Primary** ☐ **Secondary** ☐ **Ad Hoc** **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: Principal Investigator/Study Chair General Information

	YES	NO	N/A
1. Has there been any change in the status of the Principal Investigator/Study Chair or PI/SC study team (e.g., additions or removal) since the most recent approval of the project?	☐	☐	
2. Has new information been received since the most recent IRB approval of the project that changes the Principal Investigator/Study Chair's expertise to conduct or complete the project?	☐	☐	
3. Are there any potential conflicts of interest that have been identified and submitted with this Continuing Review application by the PI/SC? *Note: If potential conflicts of interest have been submitted with the Continuing Review application, a copy of the determinations made by the local facility must also be included.*	☐	☐	
Comments:			

Section 3: Continuing Review Issues

	YES	NO	N/A
1. Has participant enrollment exceeded the number of participants approved for this project?	☐	☐	☐
2. Have any participant recruitment issues or complaints been submitted by the PI/SC that require additional action by the VA Central IRB?	☐	☐	
3. Have there been any DMC/DSMB reports submitted with this Continuing Review application or since the last approval of this project?	☐	☐	☐
If yes, are there issues within the DMC/DSMB reports that require additional action by the VA Central IRB?	☐	☐	
4. Have there been SAEs, unanticipated problems, or adverse events submitted since the last approval of this project?	☐	☐	
If yes, are there issues within these reports that require additional action by the VA Central IRB?	☐	☐	
5. Has any new information been received since the last approval of this project requiring additional action by the VA Central IRB that impacts the potential risks or benefits associated with this study or the willingness of participants to enroll or continue in the research?	☐	☐	
Comments:			

Section 4: Evaluation of Additional Information Submitted by PI/SC

	YES	NO	N/A
1. Upon review of the abstract did the PI/SC report any preliminary observations, interim findings not included in a DSMB report, literature, or other information about presentations or publications applicable to the approved project requiring action by the VA Central IRB?	☐	☐	
2. Is there any other supplemental material in the PI/SC's continuing review application (e.g., audits, correspondence from sponsor) not previously referenced requiring action by the VA Central IRB?	☐	☐	
Comments:			

Section 5: Summary of Issues After Review of Local Site Investigator Applications

	YES	NO	N/A
1. Following review of the Local Site Investigator Continuing Review Applications, are there trends or commonalities in the reasons participants withdrew from the approved project requiring action by the VA Central IRB?	☐	☐	☐
2. Following review of the Local Site Investigator Continuing Review Applications, are there trends or commonalities in reported protocol deviations or violations requiring action by the VA Central IRB?	☐	☐	☐
3. Following review of the Local Site Investigator Continuing Review Applications, are there trends or commonalities in reported unanticipated problems involving risks to subjects or others or adverse events requiring action by the VA Central IRB?	☐	☐	☐

4. Is there new information reported in a Local Site Investigator Continuing Review Application (e.g., RCO audits) that requires action by the VA Central IRB for the PI/SC and/or all participating site investigators and coordinating centers?	☐	☐	☐
5. Do you recommend independent verification (e.g., audit) of this project to ensure that no material changes have occurred? If so, indicate why in the comments section below.	☐	☐	
Comments:			

Section 6: IRB Approval Criteria

The following are the IRB Approval Criteria. Please check whether each criterion is still met for continued approval.	**YES**	**NO**	**N/A**
1. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) by using procedures already being performed on the subjects for diagnostic or treatment purposes whenever appropriate.	☐	☐	
2. 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. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.	☐	☐	
3. Selection of subjects is equitable.	☐	☐	
4. Informed consent is being sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 38 CFR 116, the informed consent form contains all applicable elements to include appropriate blocks for signatures and dates, and the informed consent form is consistent with the protocol and, if applicable, the HIPAA Authorization. *Note: Or an IRB-approved waivers can be in place.*	☐	☐	
5. Informed consent is appropriately documented, in accordance with, and to the extent required by 38 CFR 116 and VHA Handbook 1200.05. *Note: Or an IRB-approved waiver can be in place.*	☐	☐	
6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.	☐	☐	
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.	☐	☐	
8. 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.	☐	☐	
9. 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 and students, or any others whom may be at increased susceptibility to harm, additional safeguards have been included in the study to protect the rights and welfare of these subjects.	☐	☐	☐

10. The investigators are qualified to perform the research, all required training is up-to-date, and there have been no new conflicts of interest identified.	☐	☐	

Comments:

Section 7: Determining if Continued Review is Required for Next Cycle

Check and complete ONLY ONE of the two sections below depending on whether the study is subject to the 2018 or the Pre-2018 Common Rule requirements:
**** DOES NOT APPLY TO FDA and DoD REGULATED STUDIES - SKIP TO SECTION 9**

☐ ***For Studies Subject to the 2018 Requirements:***

1. Was the study eligible for expedited review when it was initially approved?

   ☐ Yes ☐ No (***skip to question 2***)

   If yes, does the study need to undergo continuing review next cycle?

   ☐ Yes ☐ No, the study no longer requires continuing review.

   If yes, provide justification as to why this study requires continuing review approval:

   Justification:

2. For studies reviewed by the convened IRB, has the study progressed so that it involves: 1) only data analysis, inclusive of analysis of identifiable private information or specimens, **and/or** 2) access to follow-up clinical data obtained from procedures that subjects undergo as part of clinical care?

   ☐ No, the study still requires continuing review approval.

   ☐ Yes, the study does not require continuing review approval for the next cycle.

   ☐ Yes, but the study still requires continuing review approval. ***(Complete below justification)***

   Justification:

☐ ***For Studies Subject to the Pre- 2018 requirements:***

Does the study meet one of the following criteria established by the VA Central IRB to consider for transitioning to the 2018 requirements for elimination of continuing review: 1) Is the study a data use only study for which there are no consent forms or participant interventions or 2) is the study in data analysis only and all participant interventions and follow-up actions have been completed?

☐ No, the study still requires continuing review approval. ***(Go to Section 9)***

☐ Yes, the study does not require further continuing review approval. ***(Go to Section 8)***

☐ Yes, but the study still requires continuing review approval.

Justification:

Section 8: Transition Approval for Pre-2018 Studies *(Skip to next session if not applicable)*

Please complete the following only for Pre-2018 Common Rule studies that are being transitioned to the 2018 requirements based on the evaluation in Section 7.

This study is being transitioned to the 2018 Common Rule requirements and will no longer require continuing review approval for future cycles as it meets the criteria established by the VA Central IRB for such conversion.

☐ Approved ☐ Not Approved *(If not approved provide justification below)*

Justification:

If approved, does this study have an informed consent waiver that requires re-approval under the revised 2018 criteria?

☐ Yes (*See below for re-review and approval of waiver)*

☐ No *(Go to Section 9)*

Note: Projects in data analysis only that had an informed consent waiver for recruitment only can be answered NO since recruitment is closed and no further information is being collected.

Projects that are still actively collecting and accessing data under an informed consent waiver and/or projects that are still analyzing identifiable data and/or specimens under the current informed consent waiver (there is no consent form or waiver of documentation of consent) must have the waiver re-reviewed using the current 2018 informed consent waiver approval criteria.
The current approved informed consent waiver was reviewed as part of this review utilizing the revised 2018 informed consent waiver approval criteria as indicated below:

This waiver request meets the below checked regulatory criteria for approval:
(*Check applicable box)*

☐	**Public Service and Benefits Programs** The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to evaluate or otherwise examine: • Public benefit or service programs; • Procedures for obtaining benefits or services under those programs; • Possible changes in or alternatives to those programs or procedures; **or** • Possible changes in methods or levels of payment for benefits or services under those programs; **and** • The research could not practicably be carried out without the waiver or alteration.
☐	**General Waiver or Alteration** • The research involves no more than minimal risk to the subjects; • The research could not practicably be carried out without the requested waiver or alteration; • For studies subject to the 2018 Requirements, if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; • The waiver or alteration will not adversely affect the rights and welfare of the participants; **and** • Whenever appropriate, the participants will be provided with additional pertinent information after participation

The action taken regarding this waiver request is indicated by the box checked below:

☐	The waiver of the informed consent requirement for all aspects of the study as described in the original waiver request is approved in accordance with the above criteria. No changes need to be made in the original waiver.
☐	The original waiver cannot be approved under the revised 2018 criteria and will require modification by the study team and re-submission before approval can be granted. Comments on changes required are indicated below.
☐	The request for waiver or alteration of the informed consent requirement is not approved. The reasons for the disapproval are indicated in the comments below.

Comments/Required Modifications:

Section 9: Reviewer Recommendation (Convened) or Approval Decision (Expedited)

Please check a box under applicable heading as indicated and make one selection under that category to indicated continuing approval recommendation or decison.

Please indicate one of the following:

☐ **FOR PROJECTS TO BE REVIEWED AT A CONVENED BOARD MEETING*:***

- ☐ Continued approval recommended to the convened IRB with no modifications.
- ☐ Continued approval pending minor modifications recommended prior to final approval. Required minor modifications are indicated below. *Note: These will be forwarded to study team when received from reviewer to get them resolved prior to the meeting.*
- ☐ Table. Major modifications are required as described below requiring additional review of responses by the convened IRB.
- ☐ Suspend or Terminate for reasons indicated below.

☐ **FOR PROJECTS UNDERGOING EXPEDITED REVIEW**

- ☐ Approved. No modifications required. The study continues to meet the criteria for expedited review.
- ☐ Modifications required for approval. See below.
- ☐ Sent to Co-Chair for possible Suspension for reasons indicated below.
- ☐ Project submitted for expedited review, but defer for continuing review by the convened IRB for reasons detailed below.

Required Modifications or Reasons for Deferral/Suspension/or Termination (please list below):

These sections are only completed for projects still requiring continuing review:

The Continuing Review Frequency (check one):

☐ 12 months ☐ 6 months ☐ Other:

Level of Risk (check one):

☐ Minimal Risk ☐ Greater than Minimal Risk

_____ _____

Reviewer Signature Date