Reviewer Checklist for Continuing Review

☐ **Full Board Review** ☐ **Expedited Review**

Reviewer:	**Principal Investigator:**
Protocol #:	**Submission ID:**
Category # at last review: (Expedited only)	**Study Status:**

Reviewer Presentation Guidance

From OHRP's Guidance on IRB Continuing Review of Research:
"When conducting continuing review, the IRB should start with the working presumption that the research, as previously approved, does satisfy all [criteria for approval]. The IRB should focus on whether there is any new information provided by the investigator, or otherwise available to the IRB, that would alter the IRB's prior determinations, particularly with respect to the IRB's prior evaluation of the potential benefits or risks to the subjects. The IRB also should assess whether there is any new information that would necessitate revision of the protocol and/or the informed consent document."

For Full Board Presentations for Continuing Reviews:

- **Primary reviewer should provide a brief (< 2 minutes) synopsis of the research, e.g., study aims/hypotheses, general design, subject population, significant study procedures,**
- **State the study status, e.g., Open, Closed to Accrual (research interventions continuing or limited to long-term follow-up,**
- **Use checklist below to guide remainder of presentation, and**
- **Make a recommendation, e.g., approval, minor modifications, etc.**

SUMMARY OF FINDINGS AND RECOMMENDATIONS

	YES	NO	Comment or N/A
1. Have any unanticipated problems, protocol violations, or noncompliance occurred since the last Continuing Review? ► If yes, has the IRB been properly informed?	☐ ☐	☐ ☐	
2. If the study has a DSMB, has the charter been submitted? ► If no, request minor modifications.	☐	☐	
3. Have any interim findings, Medwatch reports, DSMB reports, safety officer or medical officer reports recommended changes to the protocol and/or consent? ► If so, have appropriate changes been made?	☐ ☐	☐ ☐	
4. Have all previously approved study amendments been appropriately incorporated into the protocol and/or application form?	☐	☐	
5. Since the last IRB review, is there new information that might affect a subject's willingness to continue to participate in the research?	☐	☐	
6. Is the number of subjects enrolled consistent with the IRB approved number?	☐	☐	
7. If there are any external sites under COMIRB's oversight, does the submission include a summary of enrollment numbers at those sites (including withdrawals and screen failures)?	☐	☐	☐ **N/A**

8. If there are any external sites under COMIRB's oversight, have the relying site details form and all site-specific consent forms been submitted with the continuing review? (N/A if study is closed to enrollment of new subjects)	☐	☐	☐ **N/A**
9. If there are any external sites under COMIRB's oversight, has the IRB approved a Single IRB (sIRB) oversight plan?	☐	☐	☐ **N/A**
10. Do the subject withdrawals indicate a problem with the protocol that needs correction?	☐	☐	
11. Does the IRB need to request verification from other sources that no material changes have occurred since the previous IRB review (i.e. if there is a history of investigator non-compliance or current indications that material changes have occurred without IRB approval or unusual types or levels of risk to subjects exist in the study)?	☐	☐	
12. **If the research is funded or conducted by DoD:** Does the submission include a copy of the DoD component's HRPO approval letter? ► If not, request documentation from study team	☐	☐	☐ **N/A**

CRITERIA FOR APPROVAL			
If necessary, refer to Primary Reviewer Checklist			
	YES	**NO**	**Comment or N/A**
Criteria for Approval: 1. Does the research continue to satisfy all criteria under 45 CFR 46.111? (1) Risks to participants are minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes. (2) Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. (3) 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 §46.116. (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117. (6) When appropriate, 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	☐	☐	

Vulnerable Populations: 1. Does the inclusion of vulnerable populations continue to be acceptable, and satisfy the additional requirements for IRB approval under HHS regulations at subpart B, C, or D, respectively, of 45 CFR 46? *If the study is approved to include vulnerable populations, reference applicable checklist(s).*	☐	☐	
Informed consent: 1. Does the informed consent process continue to be satisfactory? 2. Does the consent form continue to meet criteria at 45 CFR 46.116? 3. Does documentation of consent continue to meet the criteria of 45 CFR 46.117?	☐ ☐ ☐	☐ ☐ ☐	☐ **N/A (study is closed to enrollment of new subjects)**
Risk Assessment: ☐ Minimal Risk ☐ More than Minimal Risk (requires full board review) *Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*			
If review is occurring at Full Board, can future reviews be Expedited? The research must be minimal risk.	☐	☐	☐ **N/A**
Expedited review category(ies):			

Continuing Review:

Continuing Review is required at least annually for any research that:

- Requires ongoing Full Board review
- Is currently approved under Pre-2018 Requirements (do not transition to 2018 Requirements)
- Is under FDA oversight (i.e., reviewed under 21 CFR 50 and 56)
- Is under DOJ oversight (i.e., reviewed under 28 CFR 46), or
- (COMIRB Requirement) At least one other site is relying on COMIRB as IRB of record, and interactions with subjects will take place at that site.

Continuing Review is not required by federal regulation for any research that:

- Is currently approved under the 2018 Requirements, and
- Is eligible for Expedited Review, or
- If greater than minimal risk and currently approved under the 2018 Requirements, has progressed to the point that it involves only data analysis and/or collecting follow-up data from clinical (i.e., not research) procedures

After reviewing the criteria above, please select a review interval:

☐ **12 months**

If approved under the 2018 Requirements, the reviewer may still determine that annual review is necessary if they provide a specific rationale (select from the list below):

☐ COMIRB requirement: At least one other site is relying on COMIRB as IRB of record, and interactions with subjects will take place at that site.
☐ FDA oversight

- ☐ DOJ oversight
- ☐ PI is a mentee (e.g., student, resident, fellow, trainee)
- ☐ Study involves greater than minimal risk and has a status of "Not Yet Started," "Enrollment Continues," "Research-related Interventions," or "Data Analysis" (expedited category 8).
- ☐ Other (please specify):

☐ **Less than 12 months:** months

If less than 12 months, Provide a rationale for your recommended review cycle:

- ☐ Significant risk to research subjects (e.g. death, permanent or long lasting disability or morbidity, severe toxicity) without the possibility of direct benefit to the subjects.
- ☐ The probability and magnitude of anticipated risks to the subjects.
- ☐ The nature and frequency of adverse events observed in similar research at this and other institutions.
- ☐ The novelty of the research making unanticipated adverse events more likely.
- ☐ The likely medical condition of the proposed subjects.
- ☐ The involvement of especially vulnerable populations likely to be subject to coercion (e.g. institutionalized psychiatric patients, incarcerated minors).
- ☐ A history or continuing non-compliance on the part of the PI

☐ **No continuing review. Study reviewed under 2018 Requirements.**

► Reviewer Recommendation

☐ Approved

☐ Approved with Administrative Changes

☐ Minor Modifications Required

☐ Deferred

Comments (if needed): ☐ See Electronic/Typed Comments

