Continuation Review (CR) Primary Reviewer Checklist

The research meets the criteria for IRB approval
(Refer to this Criteria for IRB Approval Checklist as needed)
○ Yes ○ No

The risk/benefit ratio or review category has changed since the last approved protocol?
Refer to ORI's Risk Assessment guidance
○ Yes ○ No

If YES to the risk/benefit ratio or review category changing, select the single option below that describes the protocol now:

- ○ Expedited Category 8: The IRB agreed that this research, previously reviewed by the convened IRB, meets the Expedited criteria set forth in 45 CFR 46.110(a)(8); therefore an Expedited review was conducted.
- ○ Expedited Category 9: Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
- ○ Risk Level 1: Not greater than minimal risk
- ○ Risk Level 2: Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects
- ○ Risk Level 3: Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition;
- ○ Risk Level 4: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

Please describe in the space below why the risk/benefit ratio or review category has changed:

Significant new findings that might relate to the subject's willingness to continue participation need to be relayed to the subject.
(e.g. from scientific literature; a procedural change; PI disclosure of financial interest; privacy/ confidentiality issues, etc...)
○ Yes ○ No

If YES to significant new findings, describe what should be relayed to the subjects and how the subjects should be informed:
(e.g., revise consent document and re-consent subjects; send letter to subjects):

The consent documents are complete and accurately describe the research.
[The consent form(s) include the required elements of informed consent (see Required Elements of Informed Consent) which applies to, for example, consent form, cover letter and/or phone script when used alone or in combination with a debriefing and permission to use data form when applicable.]
○ Yes ○ No ○ N/A

If NO, provide related comments:

Recommended interval for Continuation Review:

○ 12 months

○ Other - specify below

If recommended interval for Continuation Review or AAR is other than 12 months, please describe the other recommendation:

Some of the following may or may not apply to the research. You only need to provide in the text boxes provided for the applicable topic your comments, requests, and/or recommendations for items deemed to involve controverted issues.
[MINOR concerns include, but are not limited to: typographical errors, grammar, pagination, headers/footers, template language, signatures;
MAJOR concerns include, but are not limited to: risk/benefit ratio, ethical concerns, cognitive ability, failure to obtain consent, waiver of consent, etc.]

For Minor concerns regarding the consent document submitted for approval, you may write the corrections on your copy of the consent document(s) and return it to the ORI staff person OR provide comments in E-IRB. For other minor or major concerns about the consent document(s)/ process, please describe in the space below, providing specific page numbers:
Consent Document(s) / Process

☐ Human subjects training for each new or existing study personnel has NOT been completed.

If there are other issues related to study personnel (expertise not appropriate, etc.), please describe below:

Unanticipated problem(s)/Adverse Event(s) or other New Safety Information (e.g. data and safety monitoring report, new relative literature, etc.):

Subject withdrawals:

Deviations/Exceptions/Violations:

Other (e.g. unanswered questions, form missing, etc.):

Determinations Page for "Long" Continuation Review Form

IRB Review*

Protocol Review

Review Details | CR Primary Reviewer | Finish

--> Refer to this **Criteria for IRB Approval Checklist** as needed.
--> Refer to this **Elements of Informed Consent Checklist** as needed.
--> Refer to this **Reviewer Determinations Guidance** document for info about what each determination means.

Select Your Determination

- ○ Approve
- ○ Minor Revision
- ○ Approved CR - Eligible for Expedited Process
- ○ Full Review Required
- ○ Major Revision and ask ORI to invite PI to meeting
- ○ Disapproved
- ○ Withdrawn

☐ Serious/Continuing Non-compliance or Suspension/Termination.

Comments / Requested Revisions

☐ I am not aware of any *conflict of interest* that would prohibit me from reviewing and/or making a determination about the IRB application materials.

Save | Complete Review