IRB Annual Administrative Review Primary Reviewer Checklist

Primary Reviewer: _____ IRB # _____ PI: _____

Title of Project: _____

Level of risk as currently approved: 1 ◯ 2 ◯ 3 ◯ 4 ◯

Please check the applicable boxes:

REQUIRED DETERMINATIONS

◯ **Yes** ◯ **No**	1. The research meets the criteria for IRB approval (refer to Criteria for IRB Approval checklist if necessary).
◯ **Yes** ◯ **No**	2. **The risk/benefit ratio has changed.** If "Yes" to the risk/benefit ratio changing, select the category that describes what the risk/benefit ratio has changed to and describe in the space below why it has changed: ☐ **Category 1** Not greater than minimal risk; ☐ 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. ☐ **Category 2** Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects; ☐ **Category 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; ☐ **Category 4** Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects. ========== **Why the risk/benefit ratio has changed:**
◯ **Yes** ◯ **No**	3. Significant new findings (*e.g., from scientific literature; a procedural change; PI disclosure of financial interest; privacy/confidentiality issues, etc…*) that might relate to the subject's willingness to continue participation need to be relayed to the subject. ***If "yes"*, describe** what should be relayed to the subjects and how the subjects should be informed (e.g., revise consent/assent document & re-consent subjects; send letter to subjects):
◯ **Yes** ◯ **No**	◯ **N/A** 4. The consent/assent document(s) are complete and accurately describe the research [The consent/assent form(s) include the required elements of informed consent (see guidance document "Federally Required Elements of Informed Consent")]. *If "No"*, provide related comments in space provided on page 2.

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Reviewer's Recommendations **Review Date:**

- ◯ Approve
- ◯ Approve pending minor revisions/additional information (you review)
- ◯ Investigator submit Continuation Review (CR) (you review): Provide specific justification for recommending PI submit CR

Justification for recommending CR:

Recommended period of Approval: ◯ **12 months** ◯ **Other - specify period:**

If recommended period of Approval is other than 12 months, provide justification:

Some of the following may or may not apply to the research. You only need to provide comments/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.]

Area to Address	Page	Specific Requests/Questions
Consent/Assent Document(s)/ Process For Minor concerns regarding the consent/assent document submitted for approval, you may write the corrections on your copy of the consent/ assent document(s) and return it to ORI staff. For other minor or major concerns about the consent/assent document(s)/process, please describe in the space to the right.		
Study Personnel Changes:		☐ Human subject protections training for each new (or existing) study personnel (SP) has **not** been completed.
		☐ Other (e.g., expertise not appropriate). **Please describe**:
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 question,form missing):		