Institutional Review Board

Checklist: Criteria For Approval

Amendment and Continuing Review: 2018 Common Rule, Without IC

NUMBER | HRP-229

IRB Number	
Abbrev. Protocol Name	
Investigator	

☐	The Convened IRB (or Designated Reviewer) has, or has obtained through consultation, adequate expertise. *Contact IRB Manager if you feel someone with additional expertise needs to review the study also.*
Criteria for Approval of Research:	(Check if "Yes" or "N/A". All must be checked).
☐	Risks to subjects are minimized by using procedures, which are consistent with sound research design and which do not unnecessarily expose subjects to risk. N/A: ☐
☐	Risks to subjects are minimized by using procedures already being performed on the subjects for other purposes. N/A: ☐
☐	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. N/A: ☐
☐	Selection of subjects is equitable (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures). N/A: ☐
☐	The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. N/A: ☐
☐	There are adequate provisions to protect the privacy of subjects, AND maintain the confidentiality of data. N/A: ☐
☐	*Vulnerable Subjects*: Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence. (examples: children, pregnant women, prisoners, LARs, neonates of uncertain viability, etc) OR, N/A if there are no vulnerable subjects for this study: ☐
☐	The Informed Consent (IC) process meets one of these: ☐ Permanently closed to enrollment ☐ Waiver of IC & HIPAA ☐ There is an IC, but this submission does not include IC edits.
☐	The Informed Consent (IC) documentation meets one of these: ☐ Permanently closed to enrollment ☐ Waiver of IC & HIPAA ☐ There is an IC, but this submission does not include IC edits.

3. Only Complete Section 3 for Continuing Reviews.

A. Continuing Review will Not Be Required if the following is true.

☐ Research involves no more than minimal risk. And

☐ Research is eligible for expedited review.

B. However, the IRB May require continuing review for research eligible for expedited review under the 2018 Rule requirements whereas it is normally not required. The following are circumstances that may justify the requirement of continuing review for these studies. Check if any are appropriate. If checked, continuing review may be required.

☐ Previous serious or continuing non-compliance determinations. Please ask IRB for additional information if unsure.

☐ Studies with additional regulatory oversight (e.g. conflicts of interest)

☐ Studies with new findings that require additional oversight.

C. For research requiring continuing review, review is adequate to take place:

☐ Annually OR ☐ Research should occur more often: specify length of review period (i.e., 6 months) _____

4. Only Complete Section 4 for Amendments. IF this study has a current Informed Consent, or if this study has No IC, the following is true:

☐ The change DOES NOT require the consent form to be revised (if there is one).

NOTE: If the study does have an IC and a change to the IC is needed for this amendment, STOP this form and instead complete #228.

At this time I recommend the research be: (Please check one, and sign/date)

☐ APPROVED.

☐ Approved with Conditions, Minor Clarifications and/or Modifications back to the IRB Office. *Note conditions below*

☐ Approved with Conditions, Major Clarifications and/or Modifications back to the Full IRB Meeting. *Note conditions below*

☐ Do Not Recommend approval at this time. List Reasons.

(Convened board must agree by a vote if study is not approved.)

Comments Section:

_____

(Name) (Signature) (Date)