Institutional Review Board

Checklist: Criteria For Approval

Amendment and Continuing Review: FDA Regulated Study, Without IC

NUMBER | HRP-221

IRB Number	
Abbrev. Protocol Name	
Investigator	

1 General Considerations	
☐	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.*
2 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: ☐ There is an IC, but this submission does not include IC edits. ☐ Waiver of IC & HIPAA ☐ Permanently closed to enrollment
☐	The Informed Consent (IC) documentation meets one of these: ☐ There is an IC, but this submission does not include IC edits. ☐ Waiver of IC & HIPAA ☐ Permanently closed to enrollment

3. Only Complete Section 3 for Continuing Reviews. Continuing review is required for research regulated by the FDA.
Review for this study is adequate to take place:
☐ Annually OR ☐ Research should occur more often: Other, 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 #220.

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)