Institutional Review Board

Checklist: Criteria For Approval

Original Review: otherwise "Unregulated Research" with no IC
[Meaning No Federal Dept. or agency support, and not FDA regulated]

NUMBER	HRP-217

IRB Number	
Abbrev. Protocol Name	
Investigator	

1 General Considerations	
☐	This study meets these requirements, which makes it otherwise "Unregulated Research": ☐ This study is NOT regulated by the FDA, and has no mention of the FDA in a consent or protocol. ☐ This study is NOT regulated by DHHS / OHRP. No Federal Department or agency supports or conducts this study.
☐	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. *NOTE: if Vulnerable Subjects are part of the research, an additional checklist needs to be completed by the IRB.* (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 & documentation meets this: ☐ Waiver of informed consent & HIPAA (Also Complete HRP 410 or 411, and HRP 441)
3. Continuing Review Determination. (All reviewers are to complete this section) 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. However, the IRB May require continuing review for research eligible for expedited review. B. As the reviewer of this research study, continuing review for this study is adequate to take place: ☐ As noted above, I agree that continuing review will not be required. (**most common*) ☐ Annually *(typically not required, unless PI has history of non-compliance or deviations)* ☐ Research should occur more often: Other, specify length of review period (i.e., 6 months) _____	
4 Additional Criteria for Initial Review (Check if "Yes")	
☐	The research has the resources necessary to protect subjects. (Time to conduct and complete the research; adequate facilities, subject pool, and medical/psychosocial resources; qualified investigators and research staff; appropriate qualifications for international research.)

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)