Avera

Institutional Review Board

Checklist: Criteria For Approval

Original Review: FDA Regulated Study

NUMBER	HRP-210

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. *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 meets one of these: ☐ There is an IC – (complete Section 5, Consent Process) ☐ Waiver of informed consent & HIPAA
☐	The Informed Consent (IC) documentation meets one of these: ☐ There is an IC – (complete Section 6, Documentation of IC) ☐ Waiver of Informed Consent & HIPAA
3. 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 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 & research staff; appropriate qualifications.)
☐	When appropriate, IRB Manager or designee will complete these additional sections below. Reviewer does not need to complete. ☐ Study has investigational Drugs or Biologics (IRB Manager to complete #306) ☐ Study has a Medical Device (IRB Manager to complete #307)
5 Consent Process (Check if "Yes". All must be checked).	
☐	The investigator or delegated study staff will obtain informed consent of the subject or LAR.
☐	The circumstances of consent provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate.
☐	The circumstances of consent minimize the possibility of coercion or undue influence.
☐	Information to be given to the subject or LAR will be in language understandable to the subject or LAR.
☐	There is no exculpatory language through which the subject or LAR is made to waive or appear to waive the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence.
6 Documentation of Informed Consent (Check if "Yes" or "N/A". All must be checked).	
☐	The written consent document is accurate, complete and consistent with the protocol.
☐	The written consent document embodies the elements in Section 7: Elements of Consent Disclosure
☐	The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed.
☐	The subject or LAR will sign and date the consent document
☐	The person obtaining consent will sign and date the consent document.
☐	A copy of the signed and dated consent document will be given to the person signing the document.
☐	If there is a LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. "N/A" if no signature line needed for this study ☐

☐	When a subject or LAR is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent documentation and any other information provided was accurately explained to, and apparently understood by, the subject or LAR, and that consent was freely given. ("N/A" if all subjects are able to read) N/A: ☐
☐	There is HIPAA language in informed consent document

7 Required Elements of Consent for FDA-Regulated RESEARCH:	
☐	1. The study involves research.
☐	2. The study is voluntary. ☐ Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. ☐ The subject may discontinue participation at any time without the penalty or loss of benefits to which the subject is otherwise entitled.
☐	3. An explanation of the purposes of the research.
☐	4. The expected duration of the subject's participation.
☐	5. A description of the procedures to be followed and identification of any experimental procedures.
☐	6. A description of any reasonably foreseeable risks or discomforts to the subject.
☐	7. A description of any benefits to the subject or the others, which may reasonably be expected from the research
☐	8. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
☐	9. How to contact the research team for questions, concerns, or complaints about the research.
☐	10. How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information or to offer input.
☐	11. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and notes the possibility that the Food and Drug Administration may inspect the records.
☐	12. Whom to contact in the event of a research- related injury to the subject.
☐	13. The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
☐	14. The investigator will ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.
☐	15. For controlled drug/device trials (except Phase 1 drug trials) and pediatric device surveillance trials, this is in the ICF: *"A decription of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time."*

Required for More than Minimal Risk Research Or: "N/A" for this study ☐	
☐	Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.
☐	Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
☐	The probability for random assignment to each treatment
☐	The subject's responsibilities.
☐	When applicable, the reasonably foreseeable risks or inconveniences to an unborn child or nursing infant.
☐	The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject.
☐	When there is no intended clinical benefit to the subject, a statement to this effect.
☐	The monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access.
☐	If the results of the trial are published, the subject's identity will remain confidential.

Additional Elements of IC: (Include when applicable to study) Or: "N/A" for this study ☐	
☐	The particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.
☐	If the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the unborn child, which are currently unforeseeable.
☐	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
☐	Any additional costs to the subject that may result from participation in the research.
☐	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by subject
☐	Significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation will be provided to the subject.
☐	Approximate number of subjects involved in the study.

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)