Institutional Review Board

Checklist: Criteria For Approval

Amendment & Continuing Review: 2018 Common Rule Regulations, with an IC

NUMBER | HRP-228

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 – (complete Section 5, Consent Process) ☐ Waiver of informed consent & HIPAA (Also complete HRP 410 or 411, and HRP 441)

☐ The Informed Consent (IC) documentation meets one of these:
☐ There is an IC – (complete Section 6, Documentation of IC) ☐ Waiver of Informed Consent & HIPAA (Also complete HRP 410 or 411, and HRP 441)

3. Only Complete Section 3 for Continuing Review.

A. Continuing Review will Not Be Required if the following is true. (Reminder, this Only applies to studies that are subject to the *NEW 2018 Rule* Requirements, and not regulated by the FDA.)

☐ 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: Other, specify length of review period (i.e., 6 months) _____

4. This part is only applicable for Amendments. For Amendments Only ~ One of the following is true:

- ☐ The change DOES NOT require the consent form to be revised.

Or

- ☐ The change DOES require the consent form to be revised, and:

One of the following is true:

- ☐ (a) Changes to the informed consent document will ***not*** require re-consenting of previously enrolled subjects.
- ☐ (b) Changes to the research activities ***will*** require changes to the informed consent document that ***will*** require re-consenting of currently enrolled participants (example: change in risk *to the subject*, additional tests or procedures being added to the study).
- ☐ (c) Changes to the research activities ***will*** require changes to the informed consent document that ***will*** require re-consenting of currently enrolled participants and/or notification of participants who have completed the research. *The notification must be approved by the IRB before it is sent to the participants and may not qualify for expedited review.* (Major change that impacts risk to the subjects)

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:	
☐	*** Consent should begin with a concise and focused presentation of the "Key Information" that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
☐	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. The purpose 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. Whom to contact for answers to questions about the research, and research subjects' rights.

☐	10. Whom to contact in the event of a research- related injury to the subject.
☐	11. 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.
☐	12. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
Required Elements under New 2018 Common Rule	
☐	The prospective subject (or the LAR) must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
☐	Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the subject's or LAR's understanding of the reasons why one might or might not want to participate.
☐	When research collects identifiable private information OR biospecimens, One of these statements must be included: ☐ Identifiers might be removed and the information / biospecimens might be shared for future research or distributed to another investigator without additional informed consent. *OR* ☐ Even if identifiers are removed, the information / biospecimens will not be used or distributed for future research studies.
☐	When research involves the use of biospecimens, a statement indicating whether biospecimens may be used for commercial profit, and the subject will share in the profit.
☐	When research involves the use of biospecimens, a statement indicating that the research will or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.)
☐	A statement indicating whether the clinically relevant research results (including individual research results) will be returned to the subject, and if so under what conditions.
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:

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(Name) (Signature) (Date)