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FOR THE NATIONAL CANCER INSTITUTE

NCI Choose 1

REVIEWER WORKSHEET

Amendment to Study

Attachment_B19_Amend_Study OMB# 0925-0753, Expiration Date: 07/31/2021

The purpose of the information collection is to conduct reviews of clinical trial studies. NCI guidelines mandate the participation of institutions in the CIRB for Network group studies. You are being requested to complete this instrument so that we can conduct activities involved with the operations of the NCI CIRB Initiative. Although your participation in Network group research and completion of the forms is voluntary, if you wish to participate in the CIRB, you must complete all questions on the form. The information you provide will be combined for all participants and reported as summaries. It will be kept private to the extent provided by law.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 120 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0753). Do not return the completed form to this address.

STUDY ID:

STUDY TITLE:

NAME OF CIRB REVIEWER:

DATE COMPLETED:

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1. **I have reviewed the following documents (check all that apply):**
   - ☐ NCI CIRB Amendment Review Application
   - ☐ Summary of CIRB Application Revisions
   - ☐ Summary of Changes related to the Amendment
   - ☐ Study Protocol
   - ☐ Revised Model Informed Consent Form(s)
   - ☐ Other (specify):

2. **The amendment includes the following changes (check all that apply):**
   - ☐ Increase or decrease in accrual (impacts statistical design)
   - ☐ Addition or deletion of a treatment group/arm
   - ☐ Addition or deletion of a study drug
   - ☐ Change in treatment period/treatment design
   - ☐ Changes in the informed consent document(s)
   - ☐ Editorial and/or administrative changes
   - ☐ Other: _____

3. **Please provide a brief summary of the current approved protocol. (Note to reviewer: Not applicable for amendments containing solely editorial and/or administrative changes)**

_____

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4. **Please provide the rationale for the amendment. (Note to reviewer: Not applicable for amendments containing solely editorial and/or administrative changes)**

_____

5. **Do the changes in the amendment impact the regulatory criteria for IRB approval?**

☐ Yes
☐ No
☐ Uncertain

If 'Yes', describe the impact and whether the criteria remain satisfied in the space provided below. If 'Uncertain, please summarize your concerns in the space provided below:

Criteria for IRB Approval of Research

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

(2) 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. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility;

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons;

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116;

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117;

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;

(8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

6. **Do any of the changes in this amendment include significant new findings that might relate to the participant's willingness to continue participation in the research?**

   ☐ Yes
   ☐ No

   If 'Yes', describe what plans are included to notify/re-consent participants and indicate whether the plans are sufficient in the space provided below. If 'No', please summarize your concerns in the space provided below:

7. **Please provide your comments and/or concerns regarding the amendment.**

   _____

Informed Consent

8. **Does the amended consent form(s) accurately reflect information included in the protocol?**

   ☐ Yes
   ☐ No

   If 'No', use the space below to describe what information needs to be added.

   _____

9. **Does the amended consent form(s) include all the required basic informed consent elements, and, as appropriate, any FDA-regulated and additional informed consent elements?**

   ☐ Yes
   ☐ No

   If 'No', use the space below to indicate which required informed consent elements are not included:

   _____

   Basic Elements of Informed Consent - All basic elements are expected to be included unless the CIRB determines that the element can be waived.

   (1) A statement that the study involves research
   (2) An explanation of the purposes of the research,
   (3) A description of the expected duration of the subject's participation,
   (4) A description of the procedures to be followed,
   (5) Identification of any procedures which are experimental;
   (6) A description of any reasonably foreseeable risks or discomforts to the subject;
   (7) A description of any benefits to the subject or to others which may reasonably be expected from the research;
   (8) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
   (9) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
   (10) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(11) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
(12) The consent form does not include exculpatory language through which the subject or their representative is made to waive any of the subject's legal rights or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Additional Required Elements of Informed Consent for FDA-regulated research only

(1) For FDA regulated research, the following statement is included for trials activated after 03/12/12: "A description 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." (Not Applicable for non-FDA regulated studies)
(2) For FDA regulated research, a statement that notes the possibility that the FDA may inspect the records. (Not Applicable for non-FDA regulated studies)

Additional Elements of Informed Consent (to be included when appropriate):

(1) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; (Not Applicable for research involving minimal risk)
(2) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
(3) For FDA research that includes women of childbearing potential, an explanation of any measures to prevent pregnancy that should be taken while in the study. (Not Applicable if women are excluded from participation)
(4) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
(5) Any additional costs to the subject that may result from participation in the research;
(6) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
(7) A statement that 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;
(8) The approximate number of subjects involved in the study.

10. **Does the amendment include a new request for waiver of consent, exclusion or alteration of required elements, or waiver of documentation of consent?**

☐ No.
☐ Yes.

If 'Yes', describe why the request is appropriate in the space provided below:

Risk Determination

11. **Are there any changes in the study that alter the risk/benefit ratio and, therefore, would change the study's risk assessment?**

☐ No
☐ Yes

If 'Yes', please explain in the space provided below:

Review Summary

12. **Questions for the Study Team**
    Questions included below will be sent to the Study Team in advance of the CIRB meeting. Whenever possible, CIRB Operations Office staff will forward responses received prior to the meeting to the primary reviewers and post those responses in ePanel. In order to ensure questions are sent to the Study Chair, questions should be posted here in ePanel at least 36 hours prior to the CIRB meeting.

13. **Topics for CIRB Discussion**
    List below any topics requiring discussion among the CIRB members prior to a final assessment of the study (e.g. whether inclusion of individuals with impaired decision-making is appropriate).

14. **Proposed Stipulations**
    Changes or additional information that the CIRB requires before the study can be approved should be listed below. The changes or requested information must pertain to the regulatory criteria for approval or have a direct impact on the protection of study participants.

15. **Recommendations**
    List recommended changes below. Recommended changes do not relate to the regulatory criteria for approval nor do they relate to protection of study participants. The Study Chair may opt to address the recommendations, or may disregard them.

Recommended Actions for the CIRB

1. ☐ **Approve** (no changes are required and the research may be approved as submitted)
2. ☐ **Approve Pending Modification** (the criteria for CIRB approval are met but minor changes are required or the criteria can be met by way of minor changes)
3. ☐ **Table** (the CIRB requires additional information or significant revisions to the research in order to determine that the criteria for CIRB approval are met)
4. ☐ **Disapprove** (the criteria for CIRB approval are not and cannot be met)

Support your recommendation: