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FOR THE NATIONAL CANCER INSTITUTE

NCI Choose 1
REVIEWER WORKSHEET

Initial Review

Attachment_B15_Adult_IR

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 180 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:

Documents reviewed (check all that apply):

- ☐ CIRB Initial Review Application
- ☐ Study Protocol
- ☐ Model Informed Consent Form(s)
- ☐ Investigator's Brochure
- ☐ Study instruments to be completed by participants
- ☐ Recruitment materials
- ☐ Other (specify _____)

I. CRITERIA FOR CIRB APPROVAL

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A. Risks and Benefits

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

   ☐ Yes.

   ☐ No.

   ☐ Unsure.

   If 'No' or 'Unsure,' use the space below to describe why the requirement isn't met or why you are unsure. You may also use the space to describe how the requirement is met.

2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the CIRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The CIRB 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.

   ☐ Yes.

   ☐ No.

   ☐ Unsure.

   If 'No' or 'Unsure,' use the space below to describe why the requirement isn't met or why you are unsure. You may also use the space to describe how the requirement is met.

3. Risk Determination:

   ☐ **Minimal Risk:** the probability and magnitude of harm or discomfort anticipated in the research <u>are not greater</u> than those risks ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

   Support your assessment with protocol-specific references:

   ☐ **Greater than Minimal Risk:** the probability and magnitude of harm or discomfort anticipated in the research <u>are greater</u> than those risks ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

   Support your assessment with protocol-specific references:

If there are different study groups (e.g. control group and intervention group) and the risks differ between the groups, describe the risks and benefits to each group below:

B. Selection of Participants

1. Selection of participants is equitable.
   You may wish to consider whether the inclusion/exclusion criteria are clearly specified and appropriate and whether there is sufficient justification to target or exclude particular populations.

   ☐ Yes.

   ☐ No.

   ☐ Unsure.

   If 'No' or 'Unsure,' use the space below to describe why the requirement isn't met or why you are unsure. You may also use the space to describe how the requirement is met.

***NOTE:** Vulnerable populations eligible to participate in the study are included in the application for initial review. Additional regulatory or CIRB SOP criteria may apply to specific vulnerable populations noted above. CIRB Operations Office will provide additional detail in CIRB Staff Summary.*

2. Are the safeguards for vulnerable population(s), as indicated in the submitted CIRB Application, sufficient for the study population(s)?

   ☐ Not applicable

   ☐ Yes.

   ☐ No.

   ☐ Unsure.

   If 'No' or 'Unsure,' use the space below to describe why the requirement isn't met or why you are unsure. You may also use the space to describe how the requirement is met.

C. Informed Consent

1. Informed consent will be sought from each prospective participant or the participant's legally authorized representative, and will be appropriately documented using a written consent document that includes the elements listed in the checklist below.

   ☐ Yes.

☐ No.

☐ Unsure.

If 'No' or 'Unsure,' use the space below to describe why the requirement isn't met or why you are unsure. You may also use the space to describe how the requirement is met.

2. Checklist of Informed Consent Elements

***Note: List any stipulations for the consent form in Section III below under "Proposed Stipulations".**

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

☐ A statement that the study involves research

☐ An explanation of the purposes of the research,

☐ A description of the expected duration of the subject's participation,

☐ A description of the procedures to be followed,

☐ Identification of any procedures which are experimental;

☐ A description of any reasonably foreseeable risks or discomforts to the subject;

☐ A description of any benefits to the subject or to others which may reasonably be expected from the research;

☐ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

☐ A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

☐ 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;

☐ 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.

☐ 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

☐ 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)*

☐ 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)

☐ 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*)

☐ 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

☐ 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)*

☐ 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 the subject;

☐ 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;

☐ The approximate number of subjects involved in the study.

3. Is there a request for waiver of consent, exclusion or alteration of required elements, or waiver of documentation of consent? **

☐ No.

☐ Yes.

Describe why the request is appropriate:

***Note:** Additional regulatory criteria apply to determine if requested consent waiver, exclusion, or alteration is appropriate. CIRB Operations Office will provide additional detail in CIRB Staff Summary.*

4. Is the use of a short form consent reasonable for this study, given the study population and complexity of the study?

☐ No.

☐ Yes.

Support your determination:

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D. Data Monitoring, Privacy, and Confidentiality

1. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

   ☐ Yes.

   ☐ No.

   ☐ Unsure.

   If 'No' or 'Unsure,' use the space below to describe why the requirement isn't met or why you are unsure. You may also use the space to describe how the requirement is met.

2. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

   ☐ Yes.

   ☐ No.

   ☐ Unsure.

   If 'No' or 'Unsure,' use the space below to describe why the requirement isn't met or why you are unsure. You may also use the space to describe how the requirement is met.

II. ADDITIONAL DETERMINATIONS

A. Investigational New Drug

1. ☐ The study does not use drugs.

2. ☐ The drugs are approved for the indications for which they will be used in the study and are used according to their approved labels.

3. ☐ An IND has been obtained for each drug that does not have FDA approval or that is not being used according to its approved labeling or for approved indications.

4. ☐ An IND application has been submitted for each drug that does not have FDA approval or that is not being used according to its approved labeling or for approved indications.

5. ☐ The Study Chair claims exemption from IND requirements for a drug used in the study and each of the following conditions are met: (1) The drug product is lawfully marketed in the United States; (2) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication

for use nor intended to be used to support any other significant change in the labeling for the drug; (3) The investigation is not intended to support a significant change in the advertising for the product; (4) The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product; (5)The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50; and (6)The investigation is conducted in compliance with the requirements of 312.7.

Support your determination:

B. Investigational Device Exemption

1. ☐ The study does not involve the use of a medical device (diagnostic or otherwise).

2. ☐ The study involves the use of an FDA-approved device according to its approved label.

3. ☐ The study involves the use of an investigational device and the Study Chair has obtained an Investigational Device Exemption (IDE) from the FDA

   ☐ The study involves the use of an investigational device and the Study Chair/Sponsor has determined and the reviewer agrees that the device is a Non-Significant Risk device. The CIRB may move forward with review and approval of the study.

4. ☐ The study involves the use of an investigational device and the Study Chair has not obtained an Investigational Device Exemption (IDE) from the FDA, and the reviewer believes the device to be a Significant Risk device. The Study Chair must obtain an IDE before the CIRB can approve the study.

   Support your determination:

   ***Note:** Additional regulatory or CIRB SOP criteria may apply to determine if IDE requirements are met. CIRB Operations Office will provide additional detail in CIRB Staff Summary.*

C. Study Team Conflicts of Interest

1. ☐ No conflicts of interest are reported for the Study Chair or others involved in oversight of the study.

2. ☐ A conflict of interest is reported and the management plan provided is sufficient.

3. ☐ A conflict of interest is reported and no management plan is provided.

4. ☐ A conflict of interest is reported and the management plan requires changes. Indicate the required changes below:

III. RECOMMENDATIONS FOR THE CIRB MEETING

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A. Review Summary

All CIRB members are asked to use this Review Summary worksheet to summarize questions for the Study Team, Topics for the CIRB to discuss, required changes (stipulations) for approval, and any recommended changes.

1. **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.

2. **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).

3. **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.

4. **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.

B. 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: