C›I›R›B
FOR THE NATIONAL CANCER INSTITUTE

NCI CIRB
REVIEWER WORKSHEET

Expedited Initial Review

Attachment_B35_Exp_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 30 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:

PROTOCOL VERSION DATE:

NAME OF CIRB REVIEWER:

ROLE: ☐ Chair ☐ Vice Chair ☐ Designated Reviewer

DATE COMPLETED:

REVIEWER CONFLICT OF INTEREST:

☐ By checking this box, the reviewer confirms there are no conflicts of interest relative to this study per the Conflict of Interest Policy for CIRB Members.

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1. Indicate the documents reviewed (check all that apply):

☐ NCI CIRB Application for Initial Review
☐ Study Protocol
☐ Model Consent Form (☐ N/A; Waived)
☐ Other, please specify _____

CENTRAL IRB FOR THE NATIONAL CANCER INSTITUTE
NCI CIRB Operations Office › 401 N. Washington St. › Suite 700 › Rockville, MD 20850

2. Answer the following questions to determine if the proposed research is eligible for expedited review:

a. Does the study meet the definition of minimal risk?

Definition of "minimal risk": *A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the protocol research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.*

☐ **Yes,** this study meets the definition of minimal risk.
If Yes, explain why this study is not greater than minimal risk: _____

If Yes, is this is a study enrolling participants from the pediatric population?
☐ Yes (If Yes, proceed to Question 2b below)
☐ No (If No, proceed to Question 2c below)

☐ **No,** this study does not meet the definition of minimal risk. ***If No****, stop here. The study will be reviewed at the next convened CIRB meeting and may be assigned to another reviewer.*

b. For studies enrolling pediatric participants:

For a study enrolling participants from the pediatric population and meeting the definition of minimal risk, it means the study satisfies the requirements of Federal regulations ***45 CFR 46.404, and 21 CFR 50.52 (Subpart D –Additional Safeguards for Children in Clinical Investigations****) described as "research/clinical investigations not involving greater than minimal risk."*

In addition, the CIRB must determine that adequate provisions are made for soliciting the assent of the children when in the judgment of the IRB the children are capable of providing assent and the requirements for permission by parents or guardians ***(per Federal regulations 45 CFR 46.408, and 21 CFR 50.55, Subpart D –Additional Safeguards for Children in Clinical Investigations)****.*

The CIRB has determined the following assent and parental permission requirements:

☐ **Assent Requirement:** Choose 1 Enter other age
If assent is waived, provide a rationale for this determination: _____

☐ **Parental Permission Requirement:** Choose 1

c. Does the study only include research that is not classified?

☐ Yes
☐ No If No, stop here. The study will be reviewed at the next convened CIRB meeting.

d. Does this study only include research that does not include identification of subjects or their responses which would place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, etc.?
☐ Yes
☐ No (If No, stop here. The study will be reviewed at the next convened CIRB meeting.)

e. Does the study fit within one of the expedited review categories below?

Select the applicable Expedited Review Category below (more than one may apply):

If no category applies, the study will be reviewed at the next convened CIRB meeting.

☐ **Category 1:** Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
- ☐ **(a)** Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
- ☐ **(b)** Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Explain how the research fits the requirements of this category: _____

☐ **Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
- ☐ **(a)** from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an eight week period and collection may not occur more frequently than two times per week; or
- ☐ **(b)** from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an eight week period and collection may not occur more frequently than two times per week.

Explain how the research fits the requirements of this category: _____

☐ **Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization. Additional noninvasive procedures: vaginal swabs that do not go beyond the cervical os; rectal swabs that do not go beyond the rectum; and nasal swabs that do not go beyond the nares.

Explain how the research fits the requirements of this category: _____

☐ **Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: *(a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.*

Explain how the research fits the requirements of this category: _____

☐ **Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Explain how the research fits the requirements of this category: _____

☐ **Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.

Explain how the research fits the requirements of this category: _____

☐ **Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Explain how the research fits the requirements of this category: _____

3. Are the following requirements for approval of research satisfied (check the box to verify the information is present)?

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

☐ 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;

Include brief description (if necessary): _____

☐ 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;

Include brief description (if necessary): _____

☐ 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;

Include brief description (if necessary): _____

☐ 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;

Include brief description (if necessary): _____

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

Include brief description (if necessary): _____

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

Include brief description (if necessary): _____

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

Include brief description (if necessary): _____

☐ 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.

Include brief description (if necessary): _____

4. Has the Study Chair requested a waiver of consent, exclusion or alteration of required elements, or waiver of documentation of consent?

☐ No (Go to Question 5)
☐ Yes If Yes, check the applicable boxes below and indicate why the request is appropriate:

☐ **Waiver of consent OR exclusion/alteration of elements of consent**

In order to waive consent or exclude/alter elements of consent, confirm the following:

☐ The research involves no more than minimal risk to the subjects;

☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects;

☐ The research could not practicably be carried out without the waiver or alteration; and

☐ Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Explain why the request is appropriate: _____

☐ **Waiver of documentation of consent**

In order to waive documentation of consent, confirm the following:

☐ The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

☐ The research presents no more than minimal risk of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context.

Explain why the request is appropriate: _____

5. Does the consent form(s) accurately reflect information included in the protocol?

☐ Yes
☐ No (If No, please indicate what information needs to be changed _____)

6. Does the current consent form(s) include the following required elements? (check the box to verify the information is present)

☐ A statement that the study involves research,
☐ an explanation of the purposes of the research and the expected duration of the subject's participation,

☐ a description of the procedures to be followed,
☐ and 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;

☐ 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

☐ 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 reviewer has confirmed that the information being communicated in 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 elements (when applicable, check the box to verify the information is present).

☐ 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

☐ 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; and

☐ The following statement 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)

☐ An explanation of any measures to prevent pregnancy that should be taken while in the study?
☐ Not Applicable

☐ For FDA regulated research, there is a statement that notes the possibility that the FDA may inspect the records?
☐ Not Applicable (for non FDA regulated studies)

7. Determination:

☐ Approve (complete Approval Period section below)

Approval Period: ☐ One year minus one day (Standard as described by the CIRB SOPs)

☐ Other _____ (Provide rationale for less than 1 year in Question 8. Must be approved by the convened CIRB)

☐ Approve Pending Modifications (provide rationale and required modifications in Question 8)

☐ Forward for review by convened CIRB (provide rationale and a description for key concerns for the CIRB to address in Question 8)

☐ Reviewer requests additional information before a determination can be made (provide details on additional information required in Question 8)

☐ Additional determinations (e.g. inclusion of pregnant women, etc.):

_____

8. Comments: _____