

CIRB AMENDMENT REVIEW APPLICATION

OMB #0925-0753 Expiration Date: 3/31/2026

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 15 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.

This application has been designed to meet the regulatory requirements for review, so answer each question as completely as possible.

- **All answers must be in lay language.**
- **If an answer to any question cannot be provided, provide an explanation for the missing answer.**
- **If you have any questions regarding the completion of this application, contact the CIRB Helpdesk at support@ncicirbcontact.zendesk.com or 888-657-3711.**

STUDY ID: _____

STUDY TITLE: _____

PROTOCOL VERSION DATE: _____

Provide the protocol and consent form with this Protocol Version Date.

STUDY CHAIR	
Name	_____
Institution Name	_____
Phone Number	_____
Email	_____

CONTACT PERSON (Person to contact with questions about this application)	
Name	_____
Title	_____
Institution Name	_____
Phone Number	_____
E-mail	_____

What is the eligible population for this study?

- Adult only
- Pediatric only
- Adult and Adolescents and Young Adults (AYA)
- Pediatric and Adolescents and Young Adults (AYA)
- Adult and Pediatric
- Adult, Pediatric, and Adolescents and Young Adults (AYA)

1.0 Type of Submission

- Amendment (complete Sections 2.0 and 3.0)

Are the changes in response to a CTEP Request for Rapid Amendment (RRA)?

- Yes No

- Participant-Directed or Recruitment Material (complete Section 4.0)

Are the changes in response to a CTEP Request for Rapid Amendment (RRA)?

- Yes No

If yes, are the changes made in response to a Type 1 Action Letter?

- Yes, Attach Type 1 Action Letter No

2.0 Description of the Amendment

2.1 Provide a brief description of the changes: _____

2.2 Provide the rationale for the changes: _____

2.3 Are the changes minor? Minor changes do not impact the study design, scientific intent, participant population or participant risk.

- Yes No

2.4 In the Study Chair’s view, do the changes impact the risks or benefits to study participants? (Consider those participants already enrolled in the study, as well as those who may enroll in the future if the study is open to accrual.)

- Yes No

Provide a brief explanation for this assessment: _____

2.5 Are the changes in the amendment in response to significant new findings?

- Yes No

Provide a brief summary of the significant new findings that resulted in the

amendment: _____

- 2.6 Have the financial conflict of interest disclosures of the Study Chair or any persons listed on the protocol who are involved in the development or coordination of the study changed?

Yes No

If yes, explain.

- 2.6.1 Do any of the updates or changes result in new or revised significant financial conflicts of interest as defined in the National Cancer Institute (NCI)/Division of Cancer Treatment and Diagnosis (DCTD) Conflict of Interest Policy for NCI/DCTD-supported Coordinating Group Randomized Phase 2 and Phase 3 Clinical Trials?

Yes No

If Yes, provide a copy of the coordinating group's management plan to address the new or revised conflicts disclosed in Question 2.6.

If No, provide a rationale for why there isn't a new or revised plan in place. _____

- 2.7 Are these changes potentially significant enough to impact a study participant's willingness to continue their participation in the study?

Yes No

Provide a brief explanation for this assessment: _____

- 2.8 Is a [waiver of documentation](#) or [alteration](#) of the informed consent process being requested?

Yes No

If No, continue to section 3.0.

If Yes, complete 2.4.2, 2.4.3

- 2.4.2 Is a [waiver of documentation](#) or [alteration](#) of informed consent requested?

Yes No

- 2.4.3 Is a [full waiver of informed consent](#) requested?

Yes No

A study must meet specific criteria in order to qualify for a [waiver or alteration of the regulatory elements of informed consent](#) or a [waiver of documentation of informed consent](#). The questions below are designed to assist the CIRB in making either or both of these determinations.

INSTRUCTIONS: Answer the following questions. You may cite the protocol section and page number that includes this information:

Waiver or Alteration of Elements of Informed Consent

Only complete this section if you are requesting a full waiver of consent or a waiver or alteration of the required elements of consent.

This form has been designed to meet the regulatory requirements for review, so answer each question as completely as possible.

- All answers must be in lay language.
- If an answer to any question cannot be provided, provide an explanation for the missing answer.
- If you have any questions regarding the completion of this application, contact the CIRB Helpdesk at support@ncicirbcontact.zendesk.com or 888-657-3711 or refer to the Waiver of Consent (WoC) QuickGuide.

Waiver or Alteration of Regulatory Elements of Informed Consent. Only complete this section if you are requesting a full waiver of consent or a waiver or alteration of the required elements of consent.

1. Type of waiver or alteration requested:

Full waiver of consent (*Select only when there is no intent to obtain informed consent prior to participation in the research. Typically used for projects involving the secondary analysis of existing data or projects involving deception*).

Waiver or alteration of required elements of consent. *Check the elements of consent you are requesting to waive or alter:*

Basic Elements (*Unless a waiver is granted, basic elements of consent are required*) [\[45 CFR 46.116\(b\)\]](#):

- 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 that 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
- 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

- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility
 - A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements as Appropriate *(A waiver for these elements is only needed if the elements are applicable to your study. More information can be found here: [\[45 CFR 46.116\(c\)\]](#)):*

- 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 or legally authorized representative'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 that 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
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
- For research involving biospecimens, whether the research will (if known) 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)

Provide the details of the research activities and rationale for waiving or altering the elements of consent checked above:

2. The study involves only research activities that are no more than minimal risk to the subjects [\[46.116\(d\)\(1\) / 46.116\(f\)\(3\)\(i\)\]](#)

Yes No

Provide the details of the research activities and rationale for response:

3. The research activities could not be practicably carried out without the requested waiver or alteration. [\[46.116\(d\)\(3\) / 46.116\(f\)\(3\)\(ii\)\]](#)

Yes No

Provide rationale for this response:

4. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. [\[46.116\(d\)\(3\) / 46.116\(f\)\(3\)\(iii\)\]](#)

Yes No N/A

Provide a rationale for this response:

5. The waiver or alteration will not adversely affect the rights and welfare of the subjects. [\[46.116\(d\)\(2\) / 46.116\(f\)\(3\)\(iv\)\]](#)

Yes No

Provide procedures for how subjects rights and welfare will be protected:

6. Whenever appropriate, subjects or legally authorized representatives will be provided with additional pertinent information after participation. [\[46.116\(d\)\(4\) / 46.116\(f\)\(3\)\(v\)\]](#)

Yes No N/A

Provide a rationale for this response, including a description of how participants or legally authorized representatives will be informed:

Waiver of Documentation of Informed Consent. Only complete this section if you are requesting a waiver of documentation of informed consent (waiver of the signature requirement).

1. The only record linking the subject and the research would be the informed consent form and the principal risk would be the potential harm resulting from a breach of confidentiality. [NOTE: If ‘Yes’, each subject (or legally authorized representative) should be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern]. [\[46.117\(c\)\(1\)\(i\)\]](#)

Yes No

Provide the details of the activity and rationale for response:

2. 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. [\[46.117\(c\)\(1\)\(ii\)\]](#)

Yes No

Provide the details of the activity and rationale for response:

3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative mechanism for documenting that informed consent was obtained. [46.117(c)(1)(iii)]

Yes No N/A

Provide rationale for response:

4. Subjects or legally authorized representatives will be provided with a written statement regarding the research. [NOTE: A “Yes” response is not required but the IRB has the authority to require that a written statement be provided to subjects or legally authorized representatives.] [46.117(c)(2)]

Yes No

Provide rationale for response:

3.0 **Participant Notification**

If the changes in the amendment are:

- in response to a CTEP Request for Rapid Amendment (RRA) (per question 1.0)
- in response to significant new findings (per question 2.5), or
- could impact a study participant’s willingness to continue their participation in the study (per question 2.6),

then participants **must be notified** of the changes or informed of the findings.

At the Study Chair’s discretion, participant notification may be required even if the changes are neither a result of significant new findings nor impact a study participant’s willingness to continue their participation in the study.

3.1 Is participant notification required?

- Yes (complete the remainder of section 3 below)
 No. Indicate the reason below and proceed to section 4:

- There are no participants enrolled.
 Participants do not need to be notified as they are not in response to significant new findings and do not impact a study participant’s willingness to continue in the research.

3.2 Which study participants must be informed of the changes (e.g. *all* participants, only participants who enroll going forward, only participants on intervention, only a certain subset of participants, etc.)?

3.3 How will study participants be informed of the changes:

- Participant-directed letter or memo;
- Consent form addendum to be signed by participants;
- Updated consent form to be signed by participants (re-consent);
- Verbal notification with documentation in study participants' research records (provide the CIRB with information to be provided to PIs to facilitate verbal notification).
- Other: _____

NOTE: In general, material(s) directed to study participants must be included in the submission and approved by the CIRB prior to distribution except:

- when a change is necessary to eliminate apparent immediate hazards to study participants (per 45 CFR 46.103(b)(4) and 21 CFR 56.108(a)(4)), or
- When the material(s) directed to study participants is intended to inform them of significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation.

3.4 When will study participants be informed of the changes? (E.g. as soon as possible, at next study visit, etc.)

4.0 Participant-Directed or Recruitment Material (please refer to the [Submitting Recruitment Material For Review](#) quickguide for more information)

4.1 Provide a brief description of the material being submitted:

4.1.1 If previously approved by the CIRB, provide a brief summary of the changes being made and the reason for the changes:

4.2 Submission of material directed to study participants or potential study participants requires a distribution plan. Provide a brief description of how and when the submitted material will be distributed to study participants or potential study participants: _____

Checklist of CIRB-Requested Supporting Documents

- Word version of Consent form with the same Protocol Version Date as the protocol without change memo (REQUIRED)
- Change Memo (REQUIRED)

Provide the following materials if applicable:

- Participant-directed letter or memo
- Consent form addendum to be signed by participants
- Information to be provided to PIs to facilitate verbal notification of participants.
- New/Updated recruitment material and distribution plan

- New/Updated forms intended to be completed by study participants and distribution plan
- New/Updated study-specific educational materials and distribution plan
- Updated Investigator's Brochure(s)