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

CIRB AMENDMENT REVIEW APPLICATION

Attachment_B12_AR_App 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 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 ncicirbcontact@emmes.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	_____
Administrative Assistant Name	_____
Administrative Assistant E-mail	_____
Administrative Assistant Phone Number	_____

CONTACT PERSON (Person to contact with questions about this application)

Name	_____
Title	_____
Institution Name	_____
Phone Number	_____
E-mail	_____

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)

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 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: _____

3.0 Participant Notification

If the changes in the amendment are 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), 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.

Is participant notification required?

☐ Yes ☐ No

Indicate the reason below:

☐ 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.
☐ Participants must be informed of the changes (complete the remainder of section 3 below)

3.1 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.)?

_____

3.2 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: Material(s) directed to study participants, including the materials listed above, whether developed by the Study Chair or participating PIs, must be included in the submission and approved by the CIRB prior to distribution except when necessary to eliminate apparent immediate hazards to study participants (per 45 CFR 46.103(b)(4) and 21 CFR 56.108(a)(4)).

3.3 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

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

- ☐ Protocol upon which this application is based (REQUIRED)
- ☐ Consent form with the same Protocol Version Date as the protocol (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
- ☐ Updated Investigator's Brochure
- ☐ New/Updated forms intended to be completed by study participants
- ☐ New/Updated study-specific educational materials

Submit the completed application and the required supporting documents via email to adultcirb@emmes.com, earlyphasecirb@emmes.com, pediatriccirb@emmes.com, or cpccirb@emmes.com within 10 days of CTEP/DCP Approval-On-Hold date.