CIRB AMENDMENT REVIEW APPLICATION

OMB#: 0925-xxxx Expiration Date: xx/xx/xxxx

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of your participation in the NCI CIRB is protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the NCI CIRB at any time. Refusal to participate will not affect your benefits in any way. The information collected will be kept private to the extent provided by law. Names and other identifiers will not appear in any report of the NCI CIRB. Information provided will be combined for all participants and reported as summaries. You are being requested to complete this instrument so that we can conduct activities involved with the operations of NCI CIRB Initiative.

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-xxxx*). 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	

Please answer the following question in 250 words or less per question.

1.0 Rationale for Amendment

1.1 Provide a brief description of the rationale for this amendment: _____

1.2 Are the changes in response to a CTEP Request for Rapid Amendment?

☐ Yes ☐ No

2.0 Participant Notification

2.1 Are any of the changes in this amendment significant enough to impact a study participant's willingness to continue participation in the research?

☐ Yes ☐ No

If Yes, indicate how participants are to be informed:

- ☐ Participant-directed letter or memo
- ☐ Consent form addendum
- ☐ Updated consent form

NOTE: Material directed to study participants, including the materials listed above, must be approved by the CIRB prior to distribution to 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)).

Submission of material directed to study participants requires a distribution plan.

Summary 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)

The following materials are required, if applicable:

- ☐ Updated recruitment material

- ☐ Updated Investigator's Brochure
- ☐ Updated forms intended to be completed by study participants.
- ☐ Updated study-specific educational materials.
- ☐ Distribution plan for materials directed to current or potential study participants.

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.