NCI ADULT/PEDIATRIC CIRB APPLICATION
FOR
CONTINUING REVIEW

OMB#: 0925 – 0625
Expiry Date: 01/31/2014

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 1 hour 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 (0925-0625). Do not return the completed form to this address.

This application, when completed, contains information required by CIRB members to conduct a meaningful review of the study so answer each question as completely as possible. If an answer to any question cannot be provided, please provide an explanation for the missing answer. If you have any questions regarding the completion of this application, please contact the CIRB Helpdesk at 888-657-3711 or ncicirbcontact@emmes.com.

APPLICATION COMPLETION DATE: _____

GROUP STUDY ID NUMBER: $$Study ID$$

STUDY TITLE: $$Study Title$$

PROTOCOL VERSION DATE: _____

This application should be based on the current CIRB-approved Protocol Version Date. Please provide the protocol and the informed consent document with this Protocol Version Date.

STUDY CHAIR	
Name	$$Study Chair name$$, $$Study Chair Degree$$
Title	
Institution/Address	$$Study Chair Address$$
Phone Number	$$InvestPrimaryPhone$$
E-mail	$$InvestEmail$$

FAX Number	$$InvestFAX$$
Administrative Assistant Name	
Administrative Assistant E-mail	
Administrative Assistant Phone Number	

STUDY CO-CHAIR (If applicable)	
Name	
Title	
Institution/Address	
Phone Number	
E-mail	
FAX Number	
Administrative Assistant Name	
Administrative Assistant E-mail	
Administrative Assistant Phone Number	

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

1.0 CIRB Study Status

1.1 Indicate with a check mark the current study status as defined by the CIRB. Please note that CIRB study status definitions differ from CTEP study status definitions. The CIRB definitions are provided for your convenience.

1.1.1 ☐ **Active:** The study has received full approval from CTEP and the CIRB, has been activated by the Cooperative Group, and the study is open to accrual.

Initial Activation Date: _____

1.1.2 ☐ **Approved but Not Yet Activated:** The study has gone through CIRB review and has been fully approved by the CIRB however it has yet to be activated by the Cooperative Group.

1.1.3 ☐ **Temporarily Closed to Accrual:** The study is not completed but is temporarily not accruing participants. Participants currently enrolled in the study continue to receive study intervention and/or are being followed.

Temporary Closure to Accrual Date: _____

1.1.4 ☐ **Temporarily Closed to Accrual and Intervention Suspended:** The study is not completed but is temporarily not accruing participants. Participants currently enrolled have had study intervention suspended.

Temporary Closure/Intervention Suspension Date: _____

1.1.5 ☐ **Closed to Accrual, Participants still Receiving Intervention:** The study has permanently closed to accrual however enrolled participants are still receiving study intervention.

Closure to Accrual Date: _____
Number of participants still on study intervention: _____

1.1.6 ☐ **Closed to Accrual, Participants have Completed Intervention:** The study is permanently closed to accrual and all participants have completed study intervention. Participants are either in the follow-up phase or have finished participation in the study.

Closure to Accrual Date: _____
Number of participants still in follow-up: _____

1.1.7 ☐ **Withdrawn:** The study is withdrawn by the Study Chair prior to CIRB final approval or withdrawn prior to activation by the coordinating Cooperative Group. Once withdrawn, all study activity will be considered completed with the CIRB. If the study is reactivated, it will have to be submitted to the CIRB and reviewed as a new study.

Withdrawal Date: _____

1.1.8 ☐ **Completed:** The study is considered completed with the CIRB only when it has finished its planned course and all of the following are true.

a. The study has been closed to accrual. ☐ Yes ☐ No
b. All participants have completed study intervention. ☐ Yes ☐ No
c. All participants have completed all follow-up activities. ☐ Yes ☐ No
d. Analysis of the data is complete. ☐ Yes ☐ No
e. The study has met its primary objectives and a final study report/publication has been submitted. ☐ Yes ☐ No

If Yes, provide a copy of the final report/publication.

If all of the above five questions have been answered "Yes", the study will be permanently closed with the CIRB. Please go to Section 2.0 and complete the rest of the form as a final report to the CIRB.

1.1.9 ☐ **Administratively Completed:** The study is considered administratively completed with the CIRB when it has been stopped earlier than planned and all of the following are true.

a. The study has been closed to accrual. ☐ Yes ☐ No
b. Participants are no longer receiving study intervention. ☐ Yes ☐ No
c. All follow-up activities have ceased. ☐ Yes ☐ No
d. No further activity or data analyses are being performed. ☐ Yes ☐ No

If the above four questions have been answered "Yes", the study will be permanently closed with the CIRB. Please state why the study was stopped earlier than planned then complete the rest of the form as a final report to the CIRB.

2.0 Enrollment Information

2.1 Accrual target: _____

2.1.1 Number of participants enrolled: _____
2.1.2 Total number of participants currently receiving study intervention: _____
2.1.3 Total number of participants who completed study intervention: _____
2.1.4 Total number of participants still in follow-up: _____
2.1.5 Total number of participants whose study intervention was terminated early or who have chosen to withdraw from the study: _____

Describe *specific* reasons for withdrawals or terminations: _____

2.2 Projected Enrollment Information at Study Institutions

For your convenience, we have retained the NIH formatting so that you can easily include the information in this application.

2.2.1 Describe the target population in terms of ethnicity:

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category Total			

2.2.2 Describe the target population in terms of race:

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
	Sex/Gender		
Racial Categories	**Females**	**Males**	**Total**
American Indian /Alaska Native			
Asian			
Black or African American			
Native Hawaiian or Other Pacific Islander			
White			
Racial Categories: Total of all Subjects			

2.3 Current Enrollment Information at Study Institutions

For your convenience, we have retained the NIH formatting so that you can easily include the information in this application.

PART A. TOTAL ENROLLMENT REPORT: Number of Participants Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	**Sex/Gender**			
	Females	**Males**	**Unknown or Not Reported**	**Total**
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Participants*				
Racial Categories				
American Indian/Alaska Native				
Asian				
Black or African American				
Native Hawaiian or Other Pacific Islander				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	**Females**	**Males**	**Unknown or Not Reported**	**Total**
American Indian or Alaska Native				
Asian				
Black or African American				
Native Hawaiian or Other Pacific Islander				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				

*These totals must agree. **These totals must agree.

2.4 How is overall study recruitment progressing compared to the intended schedule? If concerns exist, what is the plan to address them?

_____

2.5 How is recruitment to the ethnic and racial categories defined in the charts of Section 2.3 progressing compared to the intended schedule as defined in the charts of Section 2.2? If concerns exist, what is the plan to address them?

_____

3.0 Other Study Information

3.1 Have any findings from this study been presented or published other than to a Data and Safety Monitoring Board?

☐ Yes ☐ No

If yes, explain and attach the presentations or publications. _____

3.2 To the Study Chair's knowledge, has any publication or other relevant information relating to participants' risks and benefits on this study become available since the last CIRB review? This would include any new information about the drugs or procedures used in this study, as well as any new information on alternative therapies for the condition being studied.

☐ Yes ☐ No

If yes, explain and attach relevant documents. _____

3.3 Have there been any changes in the research activity, revisions, amendments, or any editorial or administrative updates to the protocol, Cooperative Group model informed consent document, or study participant questionnaires since the last continuing review approval or initial review approval if this is the first review for continuation?

☐ Yes ☐ No

If yes, please list all changes, revisions, amendments, and/or editorial or administrative updates since the last continuing review approval or initial review approval if this is the first review for continuation. Include the respective Protocol Version Dates or Update Dates. _____

3.4 Has the Investigator's Brochure (IB) been updated since the last continuing review approval or initial review approval if this is the first review for continuation?

☐ Yes ☐ No ☐ Not applicable

Please provide the version date of the most current IB: _____

3.5 Have there been any updates or changes since the last continuing review approval, or initial review approval if this is the first review for continuation, to 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?

☐ Yes ☐ No

If yes, explain. _____

3.5.1 Do any of the updates or changes result in new or revised significant financial conflicts of interest as defined in the Conflict of Interest Policy for Cooperative Group Phase 3 Clinical Trials?

☐ Yes ☐ No

If yes, please provide a copy of the Cooperative Group's management plan to address the new or revised conflicts disclosed in question 3.5.

4.0 Adverse Event and Unanticipated Problem Information

4.1 How is the study monitored for safety?
☐ Data and Safety Monitoring Board (DSMB)
☐ Safety monitoring committee
☐ Not applicable, explain. _____

4.1.1 Date of last DSMB or safety monitoring meeting: _____

Attach the current DSMB report supplied to investigators.

4.1.2 Date/approximate date of the next DSMB or safety monitoring meeting: _____

4.2 Has a toxicity summary report been prepared for the study?

☐ Yes ☐ No ☐ Not applicable

If yes, attach a copy of the current toxicity summary report supplied to investigators.

4.3 Since the last continuing review approval, or initial review approval if this is the first review for continuation, have there been any incidents, experiences, participant complaints, or outcomes that indicate participants or others may be at greater risk of harm (physical or otherwise) than previously anticipated?

☐ Yes ☐ No

If Yes, explain. _____

4.4 Have there been any unanticipated problems since the last continuing review approval or initial review approval if this is the first review for continuation?

☐ Yes ☐ No

If yes, has the unanticipated problem been reported to the CIRB?

☐ Yes ☐ No

If No, please provide a description of the unanticipated problem and any corrective action plan implemented. _____

4.5 Since the last continuing review approval, or initial review approval if this is the first review for continuation, has anything occurred to cause the risk-benefit assessment to change?

☐ Yes ☐ No

If Yes, explain. _____

Summary of CIRB-Requested Supporting Documents Required, if applicable

- ☐ Protocol upon which this application is based
- ☐ Informed consent document with the same Protocol Version Date as the protocol
- ☐ Presentations and publications for this study (Question 3.1)
- ☐ Relevant information relating to participants' risks and benefits (Question 3.2)
- ☐ Investigator's Brochure (Question 3.4)
- ☐ Management plan to address new or revised conflicts (Question 3.5.1)
- ☐ Current DSMB/safety monitoring committee report (Question 4.1.1)
- ☐ Current toxicity summary (Question 4.2)

Thank you for completing the NCI Adult/Pediatric CIRB Application for Continuing Review. Please submit the completed application and the required supporting documents via email to either adultcirb@emmes.com or pediatriccirb@emmes.com.