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

CIRB CONTINUING REVIEW APPLICATION

Attachment_B14_CR_App OMB #0925-0753 Expiration Date: 06/30/2020

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.**

APPLICATION COMPLETION DATE: _____

STUDY ID: _____

STUDY TITLE: _____

PROTOCOL VERSION DATE: _____
This application should be based on the current CIRB-approved Protocol Version Date.

STUDY CHAIR	
Name	
Institution Name	
Phone Number	
E-mail	
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	

Provide a list of all individuals to be copied on CIRB outcome letters addressed to the Study Chair.

Name	E-mail

Please remember to notify the CIRB if this list updates throughout the approval period in order to ensure all necessary parties receive the proper correspondence from the CIRB.

1.0 CIRB Study Status

1.1 Check the appropriate box below to indicate the CIRB study status. Please note that CIRB study status definitions differ from CTEP/DCP study status definitions.

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

Initial Activation Date: _____

1.1.2 ☐ **Approved but Not Yet Activated:** The study has been fully approved by the CIRB, but is not open to accrual.

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: _____
Describe reason for Temporary Closure: _____

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: _____
Describe reason for Temporary Closure/Intervention Suspension:
_____

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

Closure to Accrual Date: _____
Number of participants 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 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 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 completed with the CIRB only when it has finished its planned course and all of the following are true.

a. The study has been permanently closed to accrual at all study sites.
☐ Yes ☐ No
b. All study participants have completed study intervention and interactions at all study sites.
☐ Yes ☐ No
c. All study-related collection of identifiable private information about the participants is complete at all study sites.
☐ Yes ☐ No
d. Analysis of identifiable data is complete at all study sites.
☐ 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 study report/publication.

If all of the above questions have been answered "Yes", the study will be permanently closed with the CIRB. ***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 complete with the CIRB if the study was stopped earlier than planned and all of the following are true.

a. The study has been permanently closed to accrual at all study sites.
☐ Yes ☐ No

b. All study participants have completed study intervention and interactions at all study sites.
☐ Yes ☐ No

c. All study-related collection of identifiable private information about the participants is complete at all study sites.
☐ Yes ☐ No

d. No further study activity or data analysis will be performed at any study site.
☐ Yes ☐ No

If all of the above questions have been answered "Yes", the study will be permanently closed with the CIRB.
***State why the study was stopped earlier than planned**:*

_____

Go to Section 2.0 and complete the rest of the form as a final report to the CIRB.

1.2 For multiphase studies provide a summary of the study progress (i.e. completed phase I). Include which phase/stage of the study is currently active and the future timelines for moving into additional phases or expansion cohorts if applicable.

_____

☐ N/A

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 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

2.2.1 Provide the protocol section and page number for the Targeted/Planned Enrollment tables for ethnic and racial categories. _____

2.2.2 Are there zeroes in any of the categories in either chart?
☐ Yes ☐ No

If Yes, provide a rationale for the exclusion: _____

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.

Cumulative Inclusion Enrollment Report

Racial Categories	**Ethnic Categories**									**Total**
	Not Hispanic or Latino			**Hispanic or Latino**			**Unknown/Not Reported Ethnicity**			
	Female	Male	Unknown / Not Reported	Female	Male	Unknown / Not Reported	Female	Male	Unknown / Not Reported	
American Indian/Alaska Native										
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More Than One Race										
Unknown or Not Reported										
Total										

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

For the following questions include new relevant information that has become available since the last continuing review approval, or initial review approval if this is the first review for continuation,

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? 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, model consent form, or study participant questionnaires?

☐ 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)/Package Insert been updated?

☐ Yes ☐ No ☐ No IB/Package Insert

If Yes, please provide the drug name and the version date of the most current IB(s) being used: _____

3.5 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. _____

3.5.1 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, please provide a copy of the coordinating group's management plan to address the new or revised conflicts disclosed in Question 3.5.

4.0 Adverse Event and Unanticipated Problem Information

For the following questions include new relevant information that has become available since the last continuing review approval, or initial review approval if this is the first review for continuation,

4.1 How is the study monitored for safety?
☐ Data and Safety Monitoring Board (DSMB)
☐ Safety monitoring committee
☐ Other, explain. _____
☐ 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: _____

4.1.3 If no DSMB is being utilized, state when and how the continued progress of the study was last monitored/reviewed and state results from that discussion.

_____

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.

4.3 For Phase I or I/II studies, have any Dose Limiting Toxicities (DLTs) occurred?

☐ Yes ☐ No ☐ Not applicable

If Yes, did these DLTs cause a change in the accrual status?

☐ Yes ☐ No ☐ Not applicable

If Yes, explain. _____

4.4 For Phase I or I/II studies, provide the following information related to Adverse Events which have occurred to date (a table may be attached if available):

☐ Not applicable (skip to question 4.5)

Number of participants reporting AEs: _____

Of the reported AEs provide the following:

Number of Grade 3: _____
Number of Grade 4: _____
Number of Grade 5: _____
For each Grade 3, 4 or 5 AE summarize in which cohort and dose level the AE's occur. Note if Dose Limiting Toxicity (DLT) was a factor. (e.g. grade 4 oral mucositis, cohort 3, 10 mg/m2): _____

4.5 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. _____

4.6 Have there been any unanticipated problems?

☐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. _____

4.7 Has anything occurred to cause the risk-benefit assessment to change?

☐Yes ☐No

If Yes, explain. _____

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Summary of CIRB-Requested Supporting Documents

- ☐ Protocol upon which this application is based
- ☐ Consent form(s) with the same Protocol Version Date as the protocol
- ☐ Relevant information relating to participants' risks and benefits (Question 3.2)

Provide the following materials if applicable:

- ☐ Presentations and publications for this study (Question 3.1)
- ☐ 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)

Email the completed application and the required supporting documents to adultcirb@emmes.com, earlyphasecirb@emmes.com, pediatriccirb@emmes.com, or cpccirb@emmes.com.