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

NCI CIRB
REVIEWER WORKSHEET

Expedited Study Closure Review

Attachment_B36_Exp_Rev_Study_Closure

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.

STUDY ID:

STUDY TITLE:

PROTOCOL VERSION DATE:

CURRENT CIRB EXPIRATION DATE:

NAME OF CIRB REVIEWER:

ROLE: ☐ Chair ☐ Vice Chair ☐ Designated Reviewer

DATE REVIEW COMPLETED:

DATE STUDY CLOSED TO ACCRUAL:

REVIEWER CONFLICT OF INTEREST:

☐ By checking this box, the reviewer confirms there are no conflicts of interest relative to this study per the Conflict of Interest Policy for CIRB Members.

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1. Indicate the documents reviewed (check all that apply):

- ☐ Updated NCI Adult/Pediatric CIRB Application for Continuing Review indicating Status of "Completed" or "Administratively Completed"
- ☐ Study Protocol
- ☐ Model Consent Form(s)
- ☐ CIRB-approved Translated Consent Form(s)
- ☐ DSMB/Safety Monitoring Committee report

- ☐ Toxicity Summary
- ☐ Presentations or publications for the study
- ☐ Final Study Report/Publication
- ☐ Other, please specify

2. Verifying Study Status

Studies may be permanently closed with the CIRB if they have a status of "Completed" or "Administratively Completed." Select either A or B below and check the boxes to verify the requirements for that status in the submitted Continuing Review Application.

☐ **A. Completed – Section 1.1.8 of the Continuing Review Application**

Definition: The study is considered completed with the CIRB only when all of the following are true:

- ☐ The study has been closed to accrual.
- ☐ All participants have completed study intervention.
- ☐ All participants have completed all follow-up activities.
- ☐ Analysis of the data is complete.
- ☐ The study has met its primary objectives and a final study report/publication has been submitted.

☐ **B. Administratively Completed – Section 1.1.9 of the Continuing Review Application**

Definition: The study is considered administratively completed with the CIRB when it has been stopped earlier than planned and all of the following are true:

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

3. Determination:

☐ Approve the permanent closure of the study with the CIRB.

☐ Forward for review by the convened CIRB (provide reason in Question 4)

☐ Reviewer requests additional information before a determination can be made (provide additional information requested in Question 4)

4. Comments: