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

NCI CIRB
REVIEWER WORKSHEET

Expedited Review of
Study Chair Response to CIRB-Required Modifications

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 30 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:

CIRB EXPIRATION DATE:

NAME OF CIRB REVIEWER:

ROLE: ☐ Chair ☐ Vice Chair ☐ Designated Reviewer

DATE FORM COMPLETED:

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1. The response is submitted in reference to CIRB-required modification(s) resulting from:

- ☐ Initial Review by the CIRB
- ☐ Amendment Review by the CIRB
- ☐ Continuing Review by the CIRB
- ☐ Recruitment Materials Review by the CIRB
- ☐ Other: _____

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

Required:

- ☐ CIRB outcome letter listing CIRB-required modification

☐ Study Chair Response Letter

Additional Documents:

☐ CIRB meeting minutes (if applicable). Meeting date: _____
☐ Updated NCI CIRB Application for Treatment Studies or NCI CIRB Application for Ancillary Studies (not applicable for studies permanently closed to accrual)
☐ Updated Summary of CIRB Application revisions (not applicable for studies permanently closed to accrual)
☐ Updated Summary of Changes/Change Memo (if response is related to an amendment)
☐ Updated Study Protocol(s)
☐ Updated Consent Form(s)
☐ Other, please specify _____

3. Does the response adequately address all modifications required by the CIRB?

☐ Yes
☐ No. If no, respond to the questions below:

a. Was a satisfactory justification provided for not addressing all modifications required by the CIRB?
   ☐ Yes
   ☐ No. Indicate which modifications must be completed: _____

4. Does the response include modifications in addition to those required by the CIRB?

☐ Yes. If yes, respond to the questions below:

a. Are the additional modifications administrative/editorial in nature only?
   ☐ Yes. Proceed to Question 5.
   ☐ No. Proceed to b.

b. Describe how the changes are minor: _____

c. Do the changes negatively impact the risk/benefit ratio?
   ☐ Yes. If yes, the response must be reviewed by the convened CIRB.
   ☐ No.

☐ No.

5. Determination:

☐ Approve

☐ Approve Pending Modifications (provide required modifications in Question 6)

☐ Forward for review by convened CIRB (provide reason in Question 6)

☐ Reviewer requests additional information before a determination can be made (provide details on additional information required in Question 6)

6. Comments: _____