NCI Choose 1

REVIEWER WORKSHEET

Expedited Review of
Study Chair Response to CIRB-Required Modifications

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

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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.

STUDY ID: _____

STUDY TITLE: _____

PROTOCOL VERSION DATE: _____

AMENDMENT NUMBER / UPDATE DATE: _____

CIRB EXPIRATION DATE: _____

NAME OF CIRB REVIEWER: _____

ROLE: ☐ Chair ☐ Vice Chair ☐ Designated Reviewer

DATE COMPLETED: _____

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. 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 rationale and required modifications in Question 6)

☐ Forward for review by convened CIRB (provide rationale and a description for key concerns for the CIRB to address in Question 6)

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

6. Comments: _____