NCI ADULT CIRB- Choose 1

REVIEWER WORKSHEET

COOPERATIVE GROUP RESPONSE TO CIRB REVIEW

STUDY ID:

STUDY TITLE:

NAME OF CIRB REVIEWER:

DATE COMPLETED:

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1. This Cooperative Group response is in reference to (check one):

- ☐ CIRB Stipulations from Initial Review
- ☐ CIRB Stipulations from Amendment/Revision/Update Review
- ☐ CIRB Stipulations from Continuing Review

2. I have reviewed the following documents (check all that apply):

- ☐ Cooperative Group Response Letter/Memo
- ☐ Revised Protocol Version
- ☐ Revised Cooperative Group Informed Consent Document(s)
- ☐ Revised NCI Adult CIRB Application for Treatment Studies or NCI Adult/Pediatric CIRB Application for Ancillary Studies
- ☐ Summary of CIRB Application Revisions

☐ Other (specify): _____

3. Has the Cooperative Group and/or Study Chair adequately addressed the CIRB stipulations and/or recommendations from the prior CIRB review?

☐ Yes
☐ No

4. Did the Cooperative Group response include additional changes aside from the CIRB stipulations and/or recommendations?

☐ Yes (if yes, check all that apply below)
☐ No (if no, skip to Question 6)

5. Do the additional changes alter the risk/benefit ratio to the participants?

☐ Yes
☐ No

6. Please provide your comments and/or concerns (if any) regarding the Cooperative Group response and revised documentation.

_____

7. Please provide your recommendation for CIRB action on the Cooperative Group response and revised documentation.

_____

8. Questions for the Study Team

Questions included below will be sent to the Study Team in advance of the CIRB meeting. Whenever possible, CIRB Operations Office staff will forward responses received prior to the meeting to the primary reviewers and post those responses in ePanel. In order to ensure questions are sent to the Study Chair, questions should be posted here in ePanel at least 36 hours prior to the CIRB meeting.

9. Topics for CIRB Discussion

List below any topics requiring discussion among the CIRB members prior to a final assessment of the study (e.g. whether inclusion of individuals with impaired decision-making is appropriate).

10. Proposed Stipulations

Changes or additional information that the CIRB requires before the study can be approved should be listed below. The changes or requested information must pertain to the regulatory criteria for approval or have a direct impact on the protection of study participants.

11. Recommendations

List recommended changes below. Recommended changes do not relate to the regulatory criteria for approval nor do they relate to protection of study participants. The Study Chair may opt to address the recommendations, or may disregard them.