NCI ADULT CIRB- Choose 1

REVIEWER WORKSHEET

Continuing Review of Cooperative Group Protocol

STUDY ID:

STUDY TITLE:

PROTOCOL VERSION DATE:

NAME OF CIRB REVIEWER:

DATE COMPLETED:

---

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

- ☐ NCI Adult/Pediatric CIRB Application for Continuing Review
- ☐ Study Protocol
- ☐ Cooperative Group Model Informed Consent Document(s)
- ☐ CIRB Approved Informed Consent Document(s)
- ☐ DSMB/Safety Monitoring Committee Report
- ☐ Presentations or publications for the study
- ☐ Relevant information relating to participants' risks and benefits
- ☐ Management plan to address new or revised conflicts of interest
- ☐ Other (specify):

2. Are there any important changes in the risks, benefits, or protocol schedule that you believe have an impact on the CIRB's approval of this protocol?

☐ Yes, please explain:
☐ No

3. In your judgment, do the benefits of this study continue to outweigh the risks?

☐ Yes, please explain:
☐ No, explain:
☐ Uncertain, explain:

4. Do you recommend that the CIRB approve continuation of this study?

☐ Yes
☐ No, explain:
☐ Uncertain, explain:

5. Additional Remarks.

6. 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.

7. 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).

8. 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.

9. 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.