NCI Adult CIRB

REVIEWER WORKSHEET

Amendment to Cooperative Group Protocol

☐ **Early Phase Emphasis** ☐ **Late Phase Emphasis**

STUDY ID:

STUDY TITLE:

NAME OF CIRB REVIEWER:

DATE COMPLETED:

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

- ☐ NCI Pediatric CIRB Application for Treatment Studies or NCI Adult/Pediatric CIRB Application for Ancillary Studies
- ☐ Summary of CIRB Application Revisions
- ☐ Summary of Changes related to the Amendment
- ☐ Study Protocol
- ☐ Cooperative Group Model Informed Consent Document(s)
- ☐ Other (specify):

2. **The amendment includes the following changes (check all that apply):**

- ☐ Increase or decrease in accrual (impacts statistical design)
- ☐ Addition or deletion of a treatment group/arm
- ☐ Addition or deletion of a study drug
- ☐ Change in treatment period/treatment design
- ☐ Changes in the informed consent document(s)
- ☐ Editorial and/or administrative changes
- ☐ Other: _____

3. **Please provide a brief summary of the current approved protocol. (Note to reviewer: Not applicable for amendments containing solely editorial and/or administrative changes)**

_____

4. **Please provide the rationale for the amendment. (Note to reviewer: Not applicable for amendments containing solely editorial and/or administrative changes)**

_____

5. **Do the changes in the amendment alter the risk/benefit ratio to the participants?**

☐ If Yes, explain whether the benefits continue to outweigh the risks.: _____
☐ No
☐ If Uncertain, please explain: _____

6. **Do any of the changes in this amendment include significant new findings that might relate to the participant's willingness to continue participation in the research?**

☐ If Yes, describe what plans are included to notify/re-consent participants and indicate whether the plans are sufficient.: _____
☐ If No, please explain: _____

7. **Please provide your comments and/or concerns regarding the amendment.**

_____

8. **Please provide your recommendation for CIRB action on the amendment.**

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