



NCI Adult CIRB

REVIEWER WORKSHEET

Amendment to Cooperative Group Protocol

Early Phase Emphasis Late Phase Emphasis

OMB#: 0925 – 0625

Expiry Date: 01/31/2014

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STUDY ID:

STUDY TITLE:

NAME OF CIRB REVIEWER:

DATE COMPLETED:

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.
