



NCI Pediatric CIRB

REVIEWER WORKSHEET

COOPERATIVE GROUP RESPONSE TO CIRB REVIEW

OMB#: 0925 – 0625

Expiry Date: 01/31/2014

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STUDY ID:

STUDY TITLE:

NAME OF CIRB REVIEWER:

DATE COMPLETED:

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.
