



NCI Pediatric CIRB

REVIEWER WORKSHEET

COOPERATIVE GROUP RESPONSE TO CIRB REVIEW

OMB#: 0925 – 0625

Expiry Date: 01/31/2014

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NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0625). Do not return the completed form to this address.

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.
