NCI Pediatric CIRB

REVIEWER WORKSHEET

Pharmacist Review of Cooperative Group Study

OMB#: 0925 – 0625
Expiry Date: 01/31/2014

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STUDY ID:

STUDY TITLE:

NAME OF CIRB REVIEWER:

DATE COMPLETED:

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1. **Are the background assumptions that led to use of the study drug(s) valid?**

☐ Yes, describe how:
☐ No, explain why:

2. **Is the intervention designed to minimize risks to study participants?** *(Consider as appropriate: dosage, supportive care, administration and instructions if self-administered)*

☐ Yes, describe how:
☐ No, explain why:

3. **Are the inclusion/exclusion criteria appropriate for the intervention?**

☐ Yes, describe how:
☐ No, explain why:

4. **Has an Investigator's Brochure been provided for each investigational agent used in the study?**

☐ Yes
☐ No, (If no, the CIRB Operations Office will obtain it. Please provide agent name to staff.)

☐ Not Applicable

5. **Comments related to Question 4, if any:**

6. **Is the pharmaceutical information provided in the protocol current and accurate?** *(Including, but not limited to; preparation, administration, contraindications, warnings, drug/food interactions, storage, instructions if self-administered, etc.)*

☐ Yes, describe how:
☐ No, explain why:

7. **Is the dose modification section appropriate and clearly written?**

☐ Yes, describe how:
☐ No, explain why:

8. **Will information be provided to study participants pertaining to drug/food interactions and/or instructions for self-administration for any protocol-specific interventions?**

☐ Yes, describe how:
☐ No (indicate what information the Study Chair should be requested to provide)
☐ Not Applicable

9. **Comments related to Question 8, if any:**

10. **Does the informed consent document accurately describe the study intervention?**

☐ Yes
☐ No, explain why:

11. **Comments related to Question 10, if any:**

12. **Does the informed consent document include the reasonably foreseeable risks related to the intervention?**

☐ Yes
☐ No, explain why:

13. **Comments related to Question 12, if any:**

14. **Is the frequency of risks related to the intervention categorized appropriately?** *(likely, less likely or rare but serious)*

☐ Yes
☐ No, explain why:

15. **Comments related to Question 14, if any:**

16. **Additional Comments:**