



REVIEWER WORKSHEET

Pharmacist Review of Cooperative Group Study

OMB #0925-xxxx Expiration Date: xx/xx/xxxx

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NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 2 hours 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-xxxx*). Do not return the completed form to this address.

STUDY ID:

STUDY TITLE:

NAME OF CIRB REVIEWER:

DATE COMPLETED:

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:**