NCI CIRB

REVIEWER WORKSHEET

Pharmacist Review of Study

Attachment_B21_Pharm_Rev

OMB# 0925-0753, Expiration Date: 07/31/2021

The purpose of the information collection is to conduct reviews of clinical trial studies. NCI guidelines mandate the participation of institutions in the CIRB for Network group studies. You are being requested to complete this instrument so that we can conduct activities involved with the operations of the NCI CIRB Initiative. Although your participation in Network group research and completion of the forms is voluntary, if you wish to participate in the CIRB, you must complete all questions on the form. The information you provide will be combined for all participants and reported as summaries. It will be kept private to the extent provided by law.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 120 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 (0925-0753). Do not return the completed form to this address.

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:**