NCI Pediatric CIRB

REVIEWER WORKSHEET

Amendment to Cooperative Group Protocol

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

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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:

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1. I have reviewed the following documents (check all that apply):

- ☐ NCI Pediatric CIRB Application for Treatment Studies or NCI Adult/Pediatric CIRB Application for Ancillary Studies
- ☐ Summary of CIRB Application Revisions
- ☐ Summary of Changes related to the Amendment
- ☐ Study Protocol
- ☐ Cooperative Group Model Informed Consent Document(s)
- ☐ Other (specify):

2. The amendment includes the following changes (check all that apply):

- ☐ Increase or decrease in accrual (impacts statistical design)
- ☐ Addition or deletion of a treatment group/arm
- ☐ Addition or deletion of a study drug
- ☐ Change in treatment period/treatment design
- ☐ Changes in the informed consent document(s)
- ☐ Editorial and/or administrative changes
- ☐ Other: _____

3. Please provide a brief summary of the current approved protocol. (Note to reviewer: Not applicable for amendments containing solely editorial and/or administrative changes)

_____

4. Please provide the rationale for the amendment. (Note to reviewer: Not applicable for amendments containing solely editorial and/or administrative changes)

_____

5. Do the changes in the amendment alter the risk/benefit ratio to the participants?

☐ If Yes, explain whether the benefits continue to outweigh the risks.: _____
☐ No
☐ If Uncertain, please explain: _____

6. Do any of the changes in this amendment include significant new findings that might relate to the participant's willingness to continue participation in the research?

☐ If Yes, describe what plans are included to notify/re-consent participants and indicate whether the plans are sufficient.: _____
☐ If No, please explain: _____

7. Please provide your comments and/or concerns regarding the amendment.

_____

8. Please provide your recommendation for CIRB action on the amendment.

_____

Pediatric Risk Assessment

9. 45 CFR 46.404: Research no involving greater than minimal risk

☐ Minimal Risk
Explanation based on study documentation: _____

☐ Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 46.408.
Explanation based on the study documentation: _____

Permission required from

☐ One Parent
☐ Both Parents

10. 45 CFR 46.405: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects

☐ Greater than minimal risk
Explanation based on study documentation: _____

☐ Prospect for direct subject benefit
Explanation based on study documentation: _____

☐ The risk is justified by the anticipated benefit to the subjects
Explanation based on study documentation: _____

☐ The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches
Explanation based on study documentation: _____

☐ Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 46.408.
Explanation based on study documentation: _____

Permission required from

☐ One Parent
☐ Both Parents

11. 45 CFR 46.406: Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition

☐ Greater than minimal risk
Explanation based on study documentation: _____

☐ The risk represents a minor increase over minimal risk
Explanation based on study documentation: _____

☐ The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations
Explanation based on study documentation: _____

☐ The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition
Explanation based on study documentation: _____

☐ Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in 46.408. Both

parents will provide permission.
Explanation based on study documentation: _____

12. 45 CFR 46.407: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children

☐ The IRB does not believe meets the requirements of 46.404, 46.405, 46.406
Explanation based on study documentation: _____

☐ The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children
Explanation based on study documentation: _____

13. 45 CFR 46.408: Requirements for assent by children

☐ Assent requirement waived

☐ Capability of some or all of the children is so limited that they cannot reasonably be consulted
OR

☐ Procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children AND the intervention is available only in the context of the research
OR

☐ Assent may be waived in accord with 45 CFR 46.116
Explanation based on study documentation: _____

☐ Assent required
Age where assent is expected. Standard age ranges will be determined and provided as options.

14. Questions for the Study Team

Questions included below will be sent to the Study Team in advance of the CIRB meeting. Whenever possible, CIRB Operations Office staff will forward responses received prior to the meeting to the primary reviewers and post those responses in ePanel. In order to ensure questions are sent to the Study Chair, questions should be posted here in ePanel at least 36 hours prior to the CIRB meeting.

15. Topics for CIRB Discussion

List below any topics requiring discussion among the CIRB members prior to a final assessment of the study (e.g. whether inclusion of individuals with impaired decision-making is appropriate).

16. Proposed Stipulations

Changes or additional information that the CIRB requires before the study can be approved should be listed below. The changes or requested information must pertain to the regulatory criteria for approval or have a direct impact on the protection of study participants.

17. Recommendations

List recommended changes below. Recommended changes do not relate to the regulatory criteria for approval nor do they relate to protection of study participants. The Study Chair may opt to address the recommendations, or may disregard them.