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FOR THE NATIONAL CANCER INSTITUTE

NCI Pediatric CIRB

REVIEWER WORKSHEET

STUDY CHAIR'S RESPONSE TO CIRB REVIEW

Attachment_B28_Ped_Response_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 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 (0925-0753). Do not return the completed form to this address.

STUDY ID:

STUDY TITLE:

NAME OF CIRB REVIEWER:

DATE COMPLETED:

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1. The Study Chair's 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):

- ☐ Study Chair's Response Letter/Memo
- ☐ Revised Protocol Version
- ☐ Revised Model 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): _____

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3. Has the Study Chair adequately addressed the CIRB stipulations and/or recommendations from the prior CIRB review?

☐ Yes
☐ No

4. Did the Study Chair's 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 Study Chair's response and revised documentation.

_____

7. Please provide your recommendation for CIRB action on the Study Chair's response and revised documentation.

_____

8. 45 CFR 46.404: Research not 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 study documentation: _____

Permission required from:

☐ One Parent
☐ Both Parents

9. 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

10. 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: _____

11. 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: _____

12. 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

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

Assent required for those above seven years old.

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

13. 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.

14. 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).

15. 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.

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16. 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.