NCI Pediatric CIRB

REVIEWER WORKSHEET

Initial Review of Cooperative Group Protocol

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

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Public reporting burden for this collection of information is estimated to average 3 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. Indicate the documents reviewed (check all that apply):

- ☐ NCI Adult CIRB Application for Treatment Studies or NCI Adult/Pediatric CIRB Application for Ancillary Studies
- ☐ Study Protocol
- ☐ Cooperative Group Model Informed Consent Document(s)
- ☐ Information Sheets
- ☐ Investigator's Brochure
- ☐ Study instruments to be completed by participants
- ☐ Recruitment materials
- ☐ Other (specify _____)

2. Does the study have scientific value?

Point to consider:

- Is the study worthwhile?

_____

3. Does the study have scientific validity?

Points to consider:

- Are the background assumptions that lead to the hypothesis valid?
- Is literature/background described to justify the trial?
- Is the hypothesis or research question clearly stated?
- Is the study design appropriate to prove the hypothesis?
  (Consider sensitive and specific measures of difference, statistical testing, sample size)

_____

4. Does the study have a valid scientific design and yet pose an inappropriate risk for subjects?

Points to consider:

- Is there substantial evidence that one of the arms is inferior to another or to standard/conventional care or will deprive a subject of his/her right to receive a life-prolonging treatment?
- Is it possible that one arm will expose a subject to a serious risk of harm?

_____

5. Are risks to subjects minimized?

Points to consider:

- Does the research design minimize risks to subjects?
- Do the procedures expose subjects to unnecessary risks?
- Are procedures already being performed on the subjects for diagnostic or treatment purposes being used whenever appropriate?
- Can alternative procedures be used that would expose the subjects to fewer risks?

_____

6. Are the risks to subjects reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result?*

Points to consider:

- What is the anticipated level of risk/discomfort/inconvenience to the subject?
- Is there the prospect of direct benefit to the subjects?

*Consider only those risks and benefits that may result from research as opposed to those that may result from therapies not involved in the research.

_____

7. Is the selection of subjects equitable?

Points to consider:

- Who is to be enrolled?
- How will the subjects be identified and recruited?
- Are these subjects appropriate for the protocol?
- What is the rationale for the inclusion/exclusion of specific populations?

_____

8. Are additional safeguards in place for subjects likely to be vulnerable to coercion or undue influence?

Point to consider:

- Are appropriate protections in place for vulnerable subjects (e.g., pregnant women, fetuses, socially – or economically – disadvantaged, decisionally impaired, extremely ill/desperate)?

_____

9. Will informed consent be obtained from the research subjects or their legally authorized representatives?

- **Does the informed consent document include the eight required elements?**
- **Is the consent document understandable to subjects/legal guardian?**
  Is the CIRB requested to waive or alter any informed consent requirement?

_____

Pediatric Risk Assessment

10. Is there adequate provision for monitoring the data collected to ensure the safety of participants?

Point to consider:

- What research oversight process will be used to enhance subject safety? (e.g., data safety monitoring board)

_____

11. Are there adequate provisions to protect the privacy of participants and to maintain the confidentiality of data?

Points to consider:

- Will personally-identifiable research data be protected to the extent possible from unauthorized access or use?
- Are any special privacy and confidentiality issues properly addressed, e.g., use of genetic information?

_____

12. Additional Remarks: _____

Pediatric Risk Assessment

13. 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

14. 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

15. 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: _____

16. 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: _____

17. 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.

18. 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.

19. 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).

20. 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.

21. 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.