Attachment 6B:

NCI Pediatric CIRB

REVIEWER FINDINGS

INITIAL REVIEW OF COOPERATIVE GROUP PROTOCOL

OMB#: 0925 – xxxx **Expiry Date: xx/xx/xxxx**

STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized under 42 USC 285a. While your participation is completely voluntary, to participate in the NCI CIRB, completion of this form is required. Data collected as part of the NCI CIRB review is private and protected by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be kept private under the Privacy Act and will be presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 4 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.

NCI Pediatric CIRB

REVIEWER FINDINGS

INITIAL REVIEW OF COOPERATIVE GROUP PROTOCOL

DOCUMENT NAME:

DOCUMENT DESCRIPTION:

Name of Reviewer:

Date Completed:

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**

☐ **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)**

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2. Does this protocol have scientific value?
Is the study worthwhile?

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3. Does the protocol have scientific validity?

- **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?

- **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?

- **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? *

- **What is the perceived 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 would result from alternative therapies not involved in the research.)**

7. Is the selection of subjects equitable?

- **Who is to be enrolled?**
- **How will 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?

- **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 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?**

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

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

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

- **Will personally-identifiable research data be protected to the extent possible from 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:

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permission required from:

☒ **One parent**

☒ **Both parents**

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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:

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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

☐ **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.