Attachment 6F:

NCI Pediatric CIRB

REVIEWER FINDINGS

AMENDMENT TO 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 1.5 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

AMENDMENT TO COOPERATIVE GROUP PROTOCOL

DOCUMENT NAME:

DOCUMENT DESCRIPTION:

Name of 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)**

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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 (specify)**

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?

- ☉ **Yes**
- ☉ **No**

6. In your judgment, do the benefits of this study continue to outweigh the risks?

- ☉ **Yes**
- ☉ **If No, please explain**
- ☉ **If Uncertain, 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 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:

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permission required from:

☉ **One parent**

☉ **Both parents**

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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**

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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:

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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:

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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:

Subjects are infants.

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