NCI PEDIATRIC CIRB

REVIEWER WORKSHEET

Expedited Amendment Review

STUDY ID: _____

STUDY TITLE: _____

PROTOCOL VERSION DATE: _____

AMENDMENT NUMBER / UPDATE DATE: _____

CIRB EXPIRATION DATE: _____

NAME OF CIRB REVIEWER: _____

ROLE: ☐ Chair ☐ Vice Chair ☐ Designated Reviewer

DATE COMPLETED: _____

REVIEWER CONFLICT OF INTEREST:

☐ By checking this box, the reviewer confirms there are no conflicts of interest relative to this study per the Conflict of Interest Policy for CIRB Members.

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1. Prior Pediatric CIRB Determinations:

Pediatric Risk Determination: Choose 1

Assent Requirement: Choose 1 _____

Parental Permission Requirement: Choose 1

Note: Modifications to the Pediatric Risk Determination, Assent Requirement, or Parental Permission Requirement must be reviewed by the convened CIRB.

2. Indicate the documents reviewed (check all that apply):

- ☐ NCI Adult/Pediatric CIRB Application for Treatment Studies or NCI Adult/Pediatric CIRB Application for Ancillary Studies (not applicable for studies permanently closed to accrual)
- ☐ Summary of CIRB Application revisions (not applicable for studies permanently closed to accrual)
- ☐ Summary of changes related to the amendment (Change Memo)
- ☐ Study Protocol(s) (clean and tracked, when available)
- ☐ Consent Form(s)
- ☐ Other, please specify _____

3. Describe the changes included in the amendment as well as the rationale for the changes:

_____

4. Only amendments that include minor changes may be approved by expedited review; any changes that are not minor must be reviewed by the convened CIRB. The CIRB SOPs define minor changes as those that do not negatively impact the risk/benefit ratio.

4a. Do the changes in the amendment negatively impact the risk/benefit ratio?

☐ Yes (If Yes, stop here. The amendment will be reviewed at the next convened CIRB meeting and may be assigned to another reviewer.)
☐ No

4b. Describe why the changes are considered minor:

They are considered minor because:

☐ The changes are editorial or administrative and do not affect the scientific intent of the study, study design, patient risk, or protection of human subjects.

☐ The changes are in response to a CTEP Request for Rapid Amendment and may be expedited per the Memo from OHRP to Dr. Abrams, dated September 29, 2008.

☐ Other, please describe: _____

5. Does the current consent form(s) accurately reflect information included in the protocol?

☐ Yes
☐ No (If No, please indicate what information needs to be added:_____)

6. Are the following requirements for approval of research satisfied? (check the boxes to verify that the requirements for approval of research are satisfied)

☐ Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

☐ Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility;

☐ Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons;

☐ Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116;

☐ Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117;

☐ When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;

☐ When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;

☐ When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

7. Does the current consent form(s) include the following required and additional elements? (check the boxes to verify the information is present)

☐ A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

☐ A description of any reasonably foreseeable risks or discomforts to the subject;

☐ A description of any benefits to the subject or to others which may reasonably be expected from the research;

☐ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

☐ A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

☐ For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

☐ An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

☐ A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

☐ A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

☐ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

☐ Any additional costs to the subject that may result from participation in the research;

☐ The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

☐ A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;

☐ The approximate number of subjects involved in the study; and

☐ The following statement for trials activated after 03/12/12: “A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.” (☐Not applicable)

8. Are there any significant new findings that might relate to the participant’s willingness to continue taking part in the study?

☐ Yes (If Yes, describe what plans are included to notify or re-consent participants and indicate whether the plans are sufficient:_____)

☐ No

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

☐ Yes

☐ No (If No, stop here. The amendment will be reviewed at the next convened CIRB meeting.)

10. Determinations:

a. Pediatric Risk, Assent, and Parental Permission Determinations

Note: Modifications to the Pediatric Risk Determination, Assent Requirement, or Parental Permission Requirement must be reviewed by the convened CIRB.

i. Pediatric Risk Determination: Choose 1
- ☐ Confirm prior risk determination.
- ☐ Change the risk determination. If changing the risk determination, select the desired risk categorization above and provide a rationale for the change: _____

ii. Assent Requirement: Choose 1 _____
- ☐ Confirm prior assent requirement.
- ☐ Change the assent requirement. If changing the assent requirement, select the desired age above and provide a rationale for the change: _____

iii. Parental Permission Requirement: Choose 1
- ☐ Confirm prior parental permission requirement
- ☐ Change the parental permission requirement. If changing the parental permission requirement, select the requirement above and provide a rationale for the changes: _____

b. Review Determination

☐ Approve

☐ Approve Pending Modifications (provide required modifications in Question 11)

☐ Forward for review by convened CIRB (provide reason in Question 11)

☐ Reviewer requests additional information before a determination can be made (provide details on additional information required in Question 11)

11. Comments: _____