



## NCI Pediatric CIRB

### REVIEWER WORKSHEET

#### Continuing Review of Cooperative Group Protocol

OMB#: 0925 – 0625

Expiry Date: 01/31/2014

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#### NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

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**STUDY ID:**

**STUDY TITLE:**

**NAME OF CIRB REVIEWER:**

**DATE COMPLETED:**

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**1. I have reviewed the following documents (check all that apply):**

- NCI Adult/Pediatric CIRB Application for Continuing Review
- Study Protocol
- Cooperative Group Model Informed Consent Document(s)
- CIRB Approved Informed Consent Document(s)
- DSMB/Safety Monitoring Committee Report
- Presentations or publications for the study
- Relevant information relating to participants' risks and benefits
- Management plan to address new or revised conflicts of interest
- Other (specify): \_\_\_\_\_

**2. Are there any important changes in the risks, benefits, or protocol schedule that you believe have an impact on the CIRB's approval of this protocol?**

- No
- Yes

\_\_\_\_\_

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

- Yes  
 No  
 Uncertain

4. If No or Uncertain, please explain:

5. Do you recommend that the CIRB approve continuation of this study?

- Yes  
 No  
 Uncertain

6. If No or Uncertain, please explain: \_\_\_\_\_

7. Additional Remarks. \_\_\_\_\_

#### Pediatric Risk Assessment

8. 45 CFR 46.404: Research no 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 the 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**
- 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.