**NCI Pediatric CIRB**

**REVIEWER WORKSHEET**

**COOPERATIVE GROUP RESPONSE TO CIRB REVIEW**

OMB#: 0925 – 0625

Expiry Date: 01/31/2014

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**STUDY ID:**

**STUDY TITLE:**

**NAME OF CIRB REVIEWER:**

**DATE COMPLETED:**

1. **This Cooperative Group response is in reference to (check one):**

CIRB Stipulations from Initial Review

CIRB Stipulations from Amendment/Revision/Update Review

CIRB Stipulations from Continuing Review

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

Cooperative Group Response Letter/Memo

Revised Protocol Version

Revised Cooperative Group Informed Consent Document(s)

Revised NCI Adult CIRB Application for Treatment Studies or NCI Adult/Pediatric CIRB Application for Ancillary Studies

Summary of CIRB Application Revisions

Other (specify):

1. **Has the Cooperative Group and/or Study Chair adequately addressed the CIRB stipulations and/or recommendations from the prior CIRB review?**

Yes

No

1. **Did the Cooperative Group response include additional changes aside from the CIRB stipulations and/or recommendations?**

Yes (if yes, check all that apply below)

No (if no, skip to Question 6)

1. **Do the additional changes alter the risk/benefit ratio to the participants?**

Yes

No

1. **Please provide your comments and/or concerns (if any) regarding the Cooperative Group response and revised documentation.**

1. **Please provide your recommendation for CIRB action on the Cooperative Group response and revised documentation.**

1. **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

1. **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

1. **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:        

1. **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:

1. **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 for those above seven years old.**

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