



NCI PEDIATRIC CIRB

REVIEWER WORKSHEET

Expedited Study Closure Review

OMB#: 0925 – 0625

Expiry Date: 01/31/2014

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NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 20 minutes 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 (0925-0625). Do not return the completed form to this address.

STUDY ID:

STUDY TITLE:

PROTOCOL VERSION DATE:

CIRB EXPIRATION DATE:

NAME OF CIRB REVIEWER:

ROLE: Chair Vice Chair Designated Reviewer

DATE REVIEW COMPLETED:

DATE STUDY CLOSED TO ACCRUAL:

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

- Updated NCI Adult/Pediatric CIRB Application for Continuing Review indicating Status of "Completed" or "Administratively Completed"
 Study Protocol
 CIRB's Version of the Consent Form(s) (if applicable)
 Cooperative Group Model Consent Form(s)
 CIRB-approved Translated Consent Form(s)
 DSMB/Safety Monitoring Committee report
 Toxicity Summary
 Presentations or publications for the study
 Final Study Report/Publication
 Other, please specify

2. Verifying Study Status

Studies may be permanently closed with the CIRB if they have a status of “Completed” or “Administratively Completed.” Select either A or B below and check the boxes to verify the requirements for that status in the submitted Continuing Review Application.

A. Completed – Section 1.1.8 of the Continuing Review Application

Definition: The study is considered completed with the CIRB only when all of the following are true:

- The study has been closed to accrual.
- All participants have completed study intervention.
- All participants have completed all follow-up activities.
- Analysis of the data is complete.
- The study has met its primary objectives and a final study report/publication has been submitted.

B. Administratively Completed – Section 1.1.8 of the Continuing Review Application

Definition: The study is considered administratively completed with the CIRB when it has been stopped earlier than planned and all of the following are true:

- The study has been closed to accrual.
- All participants are no longer receiving study intervention.
- All follow-up activities have ceased.
- No further activity or data analyses are being performed.

3. Determination:

- Approve the permanent closure of the study with the CIRB.
- Forward for review by the convened CIRB (provide reason in Question 4)
- Reviewer requests additional information before a determination can be made (provide additional information requested in Question 4)

4. Comments: