



NCI PEDIATRIC CIRB

REVIEWER WORKSHEET

Expedited Study Closure Review

OMB#: 0925 – 0625

Expiry Date: 01/31/2014

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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:**