



NCI ADULT 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: