NCI PEDIATRIC CIRB

REVIEWER WORKSHEET

Expedited Study Closure Review

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:

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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:**