



FORM E

COUNCIL FOR SCIENTIFIC AND INDUSTRIAL RESEARCH INSTITUTIONAL REVIEW BOARD STUDY CLOSURE FORM

(Please type in your responses and submit 11 hardcopies of all documents)

Title of study:

Certified Protocol Number (CPN):

Principal Investigator:

Co- Investigators:

Initial Date of Approval:

Duration of Project:

Enrollment:

a. Total number of participants enrolled:

b. Number of participants discontinued:

- By investigator:
- Voluntarily:
- Due to SAE:
- Other reasons (Please specify):

c. Total number of participants who completed the study:

Answer the following questions by checking the boxes and attach a memo explaining any yes answers.

- | | NO | YES |
|---|--------------------------|--------------------------|
| 1. Have there been any complaints received from anyone about the study?
(Participants, Parents/Guardians, Community Members, Staff, etc) | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Did the anticipated risks or benefits change during the study? | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Did this study have a Data Safety and Monitoring Board?
If yes, attach the most recent report from the board. | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Was your study audited or monitored by the CSIRIRB or any other agency?
If yes, please attach a copy of the findings and any corrective actions that have been implemented as a result of this audit or monitoring. | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Are there any publication regarding this study?
If yes, please attach an abstract, quoting the reference publication. | <input type="checkbox"/> | <input type="checkbox"/> |

Why is this study being closed? (Check one)

- | | | |
|--|--------------------------|--------------------------|
| Data analysis complete | <input type="checkbox"/> | <input type="checkbox"/> |
| Interim analysis determined study is not safe or efficacious
<input type="checkbox"/> | <input type="checkbox"/> | |
| No funding, time constraints or personnel to do the study | <input type="checkbox"/> | <input type="checkbox"/> |
| Others (Please explain) | <input type="checkbox"/> | <input type="checkbox"/> |
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NB: A cover letter requesting for closure of study and a 2-3-page detailed final report should be attached to the study closure form. The report should have an introduction, methodology, final results, discussion, a section stating whether or not the study objectives have been made, recommendations, conclusions and conclusion

Signature of Principal Investigator

Date