PEI Research Ethics Board

REPORTING STUDY CLOSURE and/or EARLY TERMINATION (Required on closure or early termination.)

TO: PEI Research Ethics Board **DATE:** _____

FROM: _____ Contact Nos. _____

(Principal Investigator or Designate)

ADDRESS: _____

STUDY TITLE: _____

This study was first granted FULL APPROVAL on _____ (Anniversary Date)

1. Commencement:

- Did the study begin? ☐ Yes ☐ No If No, explain why not: _____

_____

2. **Terminated early:**

- Was the study terminated early? ☐ Yes ☐ No If Yes, Date of termination: _____
- Why was the study terminated early? _____

  _____
- Describe how all subjects have been informed of the termination: _____

  _____
- Have all subjects been informed of any potential risks due to the early closure? ☐ Yes ☐ No ☐ N/A

  If No, explain why not: _____

3. **Study Closure:**

- Date of Study Closure: _____
- What was the final number of study participants recruited? _____
- If there is a major discrepancy between planned and actual participants please comment on possible reasons:

  _____

  _____
- How many subjects chose to withdraw from the study? _____
- Have study subjects been informed of the type of medication they received in the study?

  ☐ Yes ☐ No ☐ N/A If no, when will this occur or why not? _____

  _____
- Have the results been published and/or submitted for publication? ☐ Yes ☐ No ☐ N/A
- If yes, please attach a copy; Title of publication: _____
- If no, why not? _____
- Have the results been presented at a meeting or seminar? ☐ Yes ☐ No ☐ N/A

  If yes, please attach an abstract and specify meeting title & date: _____

  _____
- Where is the data being stored and for how long? _____

  _____
- Who is responsible for maintenance of the records? Contact information: _____

  _____

_____ _____ _____

Signature of Principal Investigator or Designate *Printed Name of PI or Designate* *Date (yyyy/mm/dd)*

NOTE: *Clinical trial data must be stored for 25 years as per Health Canada Clinical Trials Division 5 regulations. Investigator's permission is necessary to destroy these documents after this Closure report is submitted to the REB.*