**PEI Research Ethics Board**

# CONTINUING REVIEW REPORTING REQUIREMENTS

(Required if study continues beyond one year and past the initial approval date.)

Please note that you are required to file Annual Reports/Requests for re-approval, Protocol Amendments/ Administrative Changes, Revised Consent Forms, new Safety Information (e.g. Serious Adverse Event Reports, changes increasing the risk to subject and/or affecting significantly the conduct of the trial, Investigator Brochure updates, etc..), study closures and/or early terminations on a timely basis.

**Annual Reports & Annual Approval Requests:**

This Board requires that an annual report and request for re-approval to be in place prior to the assigned Anniversary Date. The report should include information on the number of patients screened, enrolled and/or withdrawn; whether recruitment is ongoing; whether all serious adverse events/safety notifications have been reported; whether there have been changes to the protocol, consent form or Investigator's Brochure/Product Monograph or has there been any literature in the past year that may be relevant to the risks of research that have not been submitted for review and if so, why. This Board will grant continued approval in writing. In some instances the Board may request that progress reports be submitted every 3, 4 or 6 months depending on the study.

**Protocol Amendments /Administrative Changes:**

This Board requires that all changes/revisions to an approved protocol must be submitted for review and approval prior to implementation (except deviations from, or changes to the protocol to eliminate immediate hazards to the trial subjects, or when the changes involve only logistical or administrative aspects of the trial). It is very helpful when a rationale or justification for the changes is provided. A list of the changes is required. Any impact on subjects should be described. Any changes to the potential harms/benefits should be described.

**Consent Form Changes:**

This Board requires that all revisions/updates to an approved consent form must be submitted for review and approval prior to implementation. Highlight all changes on the consent form. Please inform the Board of whether the revised consent form is intended for only new subjects or if previously enrolled subjects will need to sign.

**Updated/Revised Investigator Brochures/Product Monographs:**

This Board requires that all updates/changes to the brochures/monographs be submitted for review. This Board will acknowledge receipt of updated documents. (Revised brochures/monographs must be accompanied by a document that summarizes the changes that have been made.)

**Adverse Event or Adverse Drug Reaction Reporting:**

This Board requires investigators to report only adverse drug reactions that are both serious and unexpected. This Board will acknowledge receipt of those reports in writing.

**Study Closure or Early Termination:**

This Board will consider a study to be complete at a site when the study monitor declares the site closed. This Board will acknowledge a site closure in writing and request that a final report/publications be submitted for information.

This Board must be informed of why a study was terminated early.

The Board will want to know how many subjects you expected to recruit and how many were recruited and if any subjects withdrew or were withdrawn. This Board will want to know if all subjects have been informed of the termination and of any potential risks due to the early closure. The Board will want to know if patients will be informed of the type of medication they received while in the study. This Board will want to know if study findings will be presented at any meetings or published. This Board will also want to know where the data is being stored and for how long and who has responsibility for maintenance of the records.