STANDARD OPERATING PROCEDURES
Bannatyne Campus Research Ethics Boards

UNIVERSITY OF MANITOBA	**SOP TITLE:** **Updated Safety Information**	Page 1 of 3
		EFFECTIVE DATE: *January 31, 2013*
		SUPERSEDES: *DRAFT August 1. 2011*
		FILE NUMBER: REB – 10B

APPROVAL SIGNATURES

Dr. L. Nicolle, MD. FRCPC
Chair, Biomedical Research Ethics Board
Date: 25 Nov 2013

Dr. J. Arnett, Ph.D.
Chair, Health Research Ethics Board
Date: 21 November 2013

PURPOSE:

To describe the REB's submission requirements and review procedures in relation to submission of updated study safety information or other new information that addresses the risk or potential benefits of research or the consent of participants.

GENERAL DESCRIPTION:

In accordance with Articles 11.8 and 11.9 of the TCPS, researchers are required to promptly report new information that may affect the welfare and consent to the REB and the REB has a responsibility to develop procedures for reviewing such information.

EXAMPLES:

Examples of updated study safety information include, but are not limited to the following:

- Data Safety Monitoring (DSDM) report
- Audit or monitoring report
- Interim study results
- Health Canada, FDA or other regulatory agency study results
- Safety Alerts
- Publication in the literature or other findings
- Revised Investigators Brochures
- Notification of Sponsor suspension or termination of the study
- Changes in the Health Canada or FDA labeling or withdrawal from marketing of a drug, biologic or device used in a research protocol

UNIVERSITY OF MANITOBA	**SOP TITLE:** **Updated Safety Information**	Page 2 of 3
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PROCEDURES:

Initial Application, Review and screening

1.0 The Investigator is to report new updated information to the REB by completing **one** copy of the ***Bannatyne Campus Research Ethics Board Updated Safety Information Form*** along with the accompanying documentation attached. ***Submissions will not be accepted without completion of the Bannatyne Campus Updated Safety Information Reporting Form.*** Acknowledgement of receipt **will not** be issued for these documents. Should the new information require an amendment to study documentation the researchers will be required to complete the *Bannatyne Campus Amendment Forms*. **It should be noted that there is no regulatory requirement for acknowledgement of documents received by the REB.**

2.0 Updated safety information which suggests increased risk and immediate safety concerns to participants should be reported to the REB promptly and no later than **15 days** upon becoming aware of the information as outlined in #1.0. All other updated safety information should be reported to the REB within **30 days** of becoming aware of the report(e.g. DSDM report that suggest trial may continue as planned, New Investigators Brochure that does not require an immediate notification of risks to participants, etc.)

3.0 The ***Bannatyne Campus Research Ethics Board Updated Safety Information Reporting Forms*** is forwarded to the REB coordinator to review the submission and request any clarifications, missing documents or information. The REB coordinator or REB staff will request any missing documentation from the investigator.

4.0 The REB coordinator will screen each submission as to the appropriateness of review by the REB Chair (or designate REB member) with respect to the seriousness and likelihood of the risk to the welfare of local participants. All submissions that suggest there may be increased risks or a requirement for a change to the protocol, procedures of research or the informed consent document will be forwarded to the REB Chair or REB designate for review.

5.0 The Chair may choose to act on the information immediately (e.g., suspend new recruitment, or to suspend all participant involvement in a trial pending further investigation); however, if the Chair determines that immediate action is required, the updated safety information will be reported to the full REB at the next available REB meeting(s). REB members also receive appendices to the previous month's minutes

indicating sites (by ethics reference number) that have submitted updated safety information reviewed by the Chair and REB Coordinator.

6.0 Any changes required to the protocol, consent forms or other study documentation as a result of this updated Safety Information must be reported to the REB on the Bannatyne Campus Research Ethics Board Amendment Form.

Investigator Documentation

1.0 It is the investigator's responsibility to retain copies of the *Bannatyne Campus Research Ethics Boards Updated Safety Information Reporting Forms* and accompanying documentation in the Investigator Study File.

REB Documentation

1.0 All *Bannatyne Campus Research Ethics Boards Updated Safety Information Reporting Forms* will be retained in the REB study file.