



Hôpital St-Boniface Hospital

# Clinical Trial Research News

From the Office of Clinical Research

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## To Contact Us:

**Dr. Bram Ramjiawan, Ph. D.**  
Director, Research Innovation  
And Regulatory Affairs  
Ph: 235-3206

**Karen Swanson**  
Admin Secretary SBRC  
Ph. 235-3206

**Lorie Forbes**  
Admin. Manager  
Ph. 258-1044

**Terry Sawicz-Hanesiak**  
Regulatory Affairs / QA Associate  
Ph: 237-2226

**Douglas Staley**  
Statistical Consultant  
Phone: 237-2690 or 0Hdstaley@mts.net

*This newsletter is published on a quarterly basis and is an information source for anyone interested in Clinical Research. Please contact Terry (237-2226) if you would like to be added to / deleted from our mailing list.*

## HEALTH RESEARCH ETHICS BOARD (HREB) – New Submission Process

Under the ROSE project, the Bannatyne Office of Human Ethics has adopted a new electronic software system to store and manage all ethics related documentation. We recognize changes to procedures are challenging and we are asking for your assistance and cooperation as we move to implement the new system. Details of the changes follow below.

The introduction of the software began at the end of August 2011. Currently, no change in the review process is being implemented - only the way the office is storing ethics related documentation is changing. In this transition, all submissions will continue to include the required number of hard copies listed on the website **with the addition of a CD, DVD or memory stick containing all documentation that is being submitted in the hard copy.**

To prepare the CD or DVD for submission please create a folder for your specific study on a new CD or DVD and place all study-related documents into this folder. When transferring files to the CD or DVD please copy over the document files so they are in the same order as the hard copy submission. If you choose to submit the documents on a memory stick, please use a new stick and save the information in the same way as described for the CD or DVD. Essentially the electronic copy, whether CD, DVD or memory stick, must mirror the hard copy.

To help manage the many submissions that come into the office it is essential that you label the CD or memory stick with the PI's last name and first initial as well as the human ethics reference number (if you have it).

If you have questions or are unable to transfer the files to either a CD, DVD or a memory stick, please contact **Chris Silivestru at 474-9724** or at:

[Chris\\_Silivestru@umanitoba.ca](mailto:Chris_Silivestru@umanitoba.ca)

## Draft Implementation of new reporting requirements for Adverse Events, Unanticipated Problems and Updated Safety Information to Bannatyne Campus Research Ethics Boards

***Please begin implementing this immediately.***

### Rational and Background for new Reporting Requirements

The University of Manitoba, Bannatyne Campus Research Ethics Board (REB) have developed amended procedures (DRAFT) relating to the reporting of adverse events and safety information to the REB based on the Canadian Association of Research Ethics Boards Guidance on Reporting of Unanticipated Problems including Adverse Events to Research Ethics Boards in Canada. The guidance document was developed in response to concerns raised by the REB

community in Canada regarding the over-reporting of adverse events, in particular, the increasingly large volumes of individual external (non-local) adverse event reports as well the need to standardize reporting to REBs across the country. The Bannatyne forms have also been modified to ensure there is appropriate documentation of the REB's review of these events.

Please begin submitting the adverse events as per the new Draft procedures and forms immediately. The new forms will replace our previous Non-local SAE, Local SAE and Investigators Brochure Forms. You will note that there is a section on each form which provides documentation for REB review. **These forms must be used to ensure the REB documents their review requirements.** We will review the DRAFT processes in approximately 6 months.

**Adverse Event Collection/Reporting of Unanticipated Problems is required for all studies**  
***(New Bannatyne Forms)***

Adverse Event or Unanticipated Problems collection and reporting are **required for all research studies regardless of whether it is a clinical or non-clinical trial, sponsor or investigator initiated.** Adverse event collection should document unfavorable changes in current health status of the research participant or any incident, experience or outcome that suggests that the research may place participants or others at a greater risk of harm (including physical, psychological, economic or social harm). The investigator must ensure the protocol outlines how adverse events will be defined, documented and monitored at the site and subsequently reported to the sponsor(s), Health Canada, applicable regulatory authorities (e.g. FDA, US Department of Health and Human Services) and the Research Ethics Board (REB). The investigator should review the Health Canada website for guidance on reporting requirements to regulatory agencies.

**Updated Safety Information Reporting Requirements** ***(New Bannatyne Form)***

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 of participants to the REB and the REB has a responsibility to develop procedures for reviewing such information. Examples of updated study safety information to be reported 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 (*previous versions of IB forms will be replaced with Updated Safety Information Reporting Forms*)
- 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

**All Forms and Standard Operating Procedures can be found on the Bannatyne Campus Website under the Continuing Review box link titled Adverse Event Reporting and Safety Information and will be posted on the Forms and Templates page.**

<http://umanitoba.ca/faculties/medicine/ethics/Adverse%20Event%20Reporting%20and%20Safety%20Information.html>

**Do not download these forms to your computer for future use.** We ask that you download the forms with each submission to ensure the most current version of the forms are used.

**Research Review Committee at St. Boniface Hospital**

**Deadlines for RRC Submission**

October 26, 2011  
November 30, 2011

**Meeting Date**

November 2, 2011  
December 7, 2011

**Submissions to the RRC must be received in N1004 by 11:00 AM on the deadline date.**

Contact the RRC at 235-3623 with any questions you may have regarding your RRC submission. Please always refer to the Office of Clinical Research and RRC web site for the most recent submission forms and updates.

<http://www.sbr.ca/content/blogcategory/87/132/>

## The Biomedical (BREB) / Health Research Ethics Board (HREB) Submissions

### Deadline for REB Submissions

October 11, 2011  
November 14, 2011  
November 28, 2011

### Meeting Date

October 24, 2011  
November 28, 2011  
December 12, 2011

Contact **Ethics** at **789-3255** with any questions you may have regarding your REB submission. Please always refer to the Research Ethics Board web site for the most recent submission forms and updates.

<http://www.umanitoba.ca/faculties/medicine/research/ethics/index.html>

## Education and Training Events

### Fall 2011 – Clinical Research 3 Part Lecture Series at St. Boniface Hospital

Interested in getting involved in Clinical Research? Clinical research refers to all research conducted with human subjects. These comprehensive introductory courses are specially designed for individuals with little to no previous research experience or those wanting a “refresher” on the latest information. The courses will present an overview of the language of clinical research, project design, roles and responsibilities of the Investigator and the research staff, and the regulatory and ethical environment for the conduct of clinical research.

Lecture Title	Date and Time	Location
Introduction to Clinical Research And Research Ethics	Tuesday, November 1, 2011 1:00 PM to 3:00 PM	St. Boniface Hospital Room N1012
Good Clinical Practice (GCP) and Clinical Research Regulations	Tuesday, November 15, 2011 1:00 PM to 3:00 PM	St. Boniface Hospital Room N1012
Clinical Research Project and Document Management	Tuesday, November 29, 2010 1:00 PM to 3:00 PM	St. Boniface Hospital Room N1012

There is no charge to attend the lecture series but registration is required. For more information or to register contact Terry Sawicz-Hanesiak at (204) 237-2226 or [tsawicz@sbgh.mb.ca](mailto:tsawicz@sbgh.mb.ca).

### Life Science Association of Manitoba (LSAM) – Training Events

Through an industry led steering committee, LSAM offers a variety of courses and training resources so that companies can effectively train their employees to meet their current needs. LSAM has offered 1141 courses and trained more than 11,700 individuals since 1994. To view more details about this session and a list of other scheduled training events please visit their training website: [www.lsam.ca/calendar.cfm](http://www.lsam.ca/calendar.cfm)

## ***Ethical Considerations in Research***

**Wednesday October 12, 2011**

**1:00 – 3:30 pm**

**Samuel Cohen Auditorium, St. Boniface Research Centre  
351 Tache Avenue, Winnipeg**

**(See attached poster for more information – All are welcome to attend!)**