



Hôpital St-Boniface Hospital

Clinical Trial Research News

From the Office of Clinical Research

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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.

HAPPY NEW YEAR

FROM THE OFFICE OF CLINICAL RESEARCH!

Announcement

Welcome Back Lorie!

Lorie Forbes recently returned from her maternity leave and has resumed her role as Administrative Manager. Lorie can be reached by phone at 258-1044 or by e-mail lforbes@sbgh.mb.ca

Statistics and Medical Research

No Article this issue.

Articles are authored by OCR statistical consultant Doug Staley. Doug teaches statistics at the School of Medical Rehabilitation, University of Manitoba and has conducted medical research at SBGH for more than 25 years. Readers are welcome to submit questions or suggest topics of interest. Doug can be contacted through the OCR, by email: dstaley@mts.net or directly at 237-2690.

International Clinical Trials Day at SBGH – May 20, 2010 – Call for Speakers!

We are currently planning and are looking for individuals involved in research who would be willing to speak at the 2nd Annual International Clinical Trials Day here at St. Boniface General Hospital and Research Centre.

The next International Clinical Trials Day will be celebrated around the world on May 20, 2010. If you are interested in speaking at this event please contact Terry Sawicz-Hanesiak at 237-2226 or e-mail tsawicz@sbgh.mb.ca.

Once we have collected expressions of interest, we will match speakers and sessions/workshops as best we can.

Thank-you in advance for your interest and don't forget to save the date – Thursday, May 20, 2010!

Bannatyne Campus BREB and HREB Policy and Form Update October 2009

The "Health Research Ethics Board (HREB) Policy Statement on Chart Review or Records Reviews" has been finalized and posted on the Bannatyne Campus website

<http://www.umanitoba.ca/faculties/medicine/research/ethics/2086.htm>

The new policy will hopefully simplify the submission and review processes required with the use of a new form that focuses on the ethical and privacy issues relevant to retrospective record review studies. The policy also permits the majority of the qualifying protocols to be reviewed in a "delegated" manner by the Chair of the HREB thereby reducing the number of required copies submitted to the HREB to two. The submission deadline for the protocols that fall under this policy is the same as the full board meeting date, however we encourage researchers to submit upon completion of their package rather than holding on to it until the next submission deadline. Depending on the workflow for the office and HREB Chair, we may be able to start reviewing the package prior to the next deadline.

The main Bannatyne Campus Research Ethics Submission Form (version dated October 1, 2009) has also been updated to provide instructions to first time applicants regarding the new policy for record review studies. There are also a few additional revisions to a couple of questions that will hopefully clarify the intent of the question for the submitters and our reviewers. All revisions have been highlighted in the form.

The forms are "locked" which enables you to tab to each question and check box with ease. To conduct a spell check you must unprotect the document. After you have completed answering all questions, go to "Tools" on the Tool Bar and in the drop down menu select "Unprotect Document". No password is required.

We also remind you to download the forms directly from the website with each submission rather than downloading these new versions of the submission forms to your computer for future use. This will ensure you are using the most recent versions of the submission forms.

If you have any questions regarding these processes please contact Shelly Rempel-Rossum at 789-3389 or e-mail remross@cc.umanitob.ca

Tri-Council Policy Statement - 2ND Draft Released for Final Public Comment

On December 18, 2009, the Interagency Panel on Research Ethics announced the release of the **revised** draft 2nd edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) for further public comment. Chapter 9, "Research Involving Aboriginal Peoples in Canada," was released in November 2009, in advance of the rest of the Policy, in light of the substantial changes made to this chapter and in response to requests made by a number of individuals and groups in the Aboriginal community and the research community at large. Some changes have been made to Chapter 9 since its November release.

Written comments on the draft will be accepted during this 75-day written consultation period that concludes March 1, 2010. The Panel will then prepare a final draft based on those comments. In April 2010, the Panel expects to submit a final revision to the Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC) for their consideration.

A copy of the most recent 2nd edition draft can be downloaded from the following website:

<http://pre.ethics.gc.ca/eng/policy-politique/initiatives/revised-revisee/Default/>

Research Review Committee at St. Boniface General Hospital

Deadlines for RRC Submission

January 6, 2010
January 27, 2010
February 24, 2010

Meeting Date

January 13, 2010
February 3, 2010
March 3, 2010

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

January 11, 2010
February 8, 2010
March 8, 2010

Meeting date

January 25, 2010
February 22, 2010
March 22, 2010

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

Good Clinical Practice Workshop

Date: Tuesday, March 23, 2010
Location: St. Boniface General Hospital – Room N1026
Time: 8:30 am – 4:00 pm

In response to several requests, the Office of Clinical Research is considering presenting another full day Good Clinical Practice workshop. The cost to attend the one day workshop would be \$150 (lunch and break refreshments are included in the registration fee).

Registration will be limited to 20 participants. For more information or to receive a registration form please contact Terry Sawicz-Hanesiak, SBGH – Office of Clinical Research (204) 237-2226 or e-mail 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 a list of scheduled training events please visit their training website:

www.lsam.ca/calendar.cfm

MAGI's Clinical Research Conference - 2010 East - Operations - Regulatory - Contracts - Budgets

Sheraton Boston Hotel - Boston, Massachusetts - May 23-26, 2010

More Information Available at:

<http://www.magiworld.org/events/2010E/>