

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: 235-3372

Amanda Amy
Admin. and RRC Secretary
Ph. 235-3623

Lorie Forbes
Admin. Manager
Ph: 258-1044

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

This newsletter is published on a quarterly basis and is designed to provide an information source for anyone interested in Clinical Research. Please contact Amanda (235-3623) if you would like to be added to / deleted from our mailing list.

Statistics and Medical Research

No article this month.

Statistics 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 by email: dstaley@mts.net or extension 2690.

Update from the Bannatyne Campus Research Ethics Boards – New Clinical Trial Definition

In June 2007 the International Committee of Medical Journal Editors (ICMJE) adopted the WHO's definition of "clinical trial" effective for all subjects enrolled after July 2008 in all applicable trials triggering the requirement for registration on a publicly accessible registry.

The Bannatyne Campus REB will be updating the submission form (question #19) in the near future however in the interim the REB will be reminding researchers of the new definition in our letters of response as required.

The research community has embraced the purpose and mission of the registration process and are well informed with respect to this requirement. The REB does not anticipate that the transition to the new definition will be difficult for those sites conducting trials sponsored by pharmaceutical companies or national funding agencies, as it is apparent to the REB office over the past year that these sponsors and agencies have adopted this new definition by registering their trials. The requirement however, may not be as clear for our researchers conducting local smaller investigator initiated clinical trials and thus the REB will be reminding researchers in letters of response regarding this new requirement for applicable clinical trials.

New definition requiring registration for publication purposes on an acceptable registry:

"A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioral treatments, process-of-care changes, preventive care, etc. "

Old Definition:

"Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and a health outcome. Medical intervention is to be interpreted broadly to include drugs, surgical procedures, devices, behavioral or management studies which have the intent to modify health outcome. A trial must have at least one prospectively assigned concurrent control or comparison group in order to trigger the requirement for registration. In general all Phase III studies will need to be registered. However, Phase I and some Phase II studies are excluded."

There is no longer a requirement to have a comparison or control group, therefore the requirements have definitely been expanded to include a greater number of clinical trials.

The following are links to additional information regarding registering Clinical Trials;

World Health Organization - <http://www.who.int/ictpr/en/>

IMJE position papers - <http://www.icmje.org/icmje.pdf> and <http://www.icmje.org/faq.pdf>

If you have any question regarding the new definition or about going on-line to register please call Shelly Rempel-Rossum at 789-3389

Research Review Committee at St. Boniface General Hospital

Deadlines for RRC Submission

September 24
October 29
November 26

Meeting Date

October 1
November 5
December 3

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 10 (Friday)
November 10
December 1

Meeting date

October 27
November 24
December 15

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

Clinical Research Lecture Series at St. Boniface General Hospital

Lecture Title	Date and Time	Location
Introduction to Clinical Research And Research Ethics	Thursday, November 6, 2008 1:30 PM to 3:30 PM	St. Boniface General Hospital – N1012
Good Clinical Practice (GCP) and Clinical Research Regulations	Thursday, November 20, 2008 1:30 PM to 3:30 PM	St. Boniface General Hospital – N1012
Clinical Research Project and Document Management	Thursday, December 4, 2008 1:30 PM to 3:30 PM	St. Boniface General Hospital – N1026 (NOTE: Space is limited)

Contact Terry Sawicz-Hanesiak at (204) 237-2226 or tsawicz@sbgh.mb.ca to register for one or all of the lectures.

Other Winnipeg Training Events

For additional training information please refer to attached LSAM schedule or visit www.lsam.ca

ASKA Research Training Events

Project Management for the Clinical Research Professional: A two-day workshop

Friday, October 31, 2008 - Saturday, November 1, 2008 - Hilton Hotel, Montreal/Laval, QC

Friday, November 7, 2008 - Saturday, November 8, 2008 - Terminal City Club, Vancouver, BC

Registration Fee: \$1475.00 + GST (CAD)

Visit www.askaresearch.com for more information.



SAVE THE DATE!

**Wednesday, May 20, 2009
International Clinical Trials Day**

More SBGH event details to following in 2009!

Additional Information

Patient Safety Week - September 29 - October 4, 2008

SBGH will be participating in the 2008 Canadian Patient Safety Week which will be held from September 29 - October 4, 2008

Please visit the display in the Atrium & learn about the new Manitoba Institute for Patient Safety Medication Card and how this can improve patient safety at SBGH.

Volunteers will be handing out Medication Cards in the Emergency Department and ACF Med/Surg during Patient Safety Week. The introduction of the Medication Cards in ACF Med/Surg will continue after Patient Safety Week.

FOR PUBLIC AND STAFF

MEDICATION CARD INFORMATION CENTRE DO YOU HAVE A MEDICATION CARD?

Stop by to receive a medication card and at the same time get an overview of the Medication Card and why it is important. Learn how to fill in and use the Medication Card. Receive answers to questions you may have.

Location: Hospital Atrium
Date: Daily, Monday to Friday
September 29 to October 3, 2008
Time: 10:00 am. to 2:00 pm.

Receive your ballot and enter to win a prize!

FOR HEALTH CARE PROVIDERS

MEDICATION CARD PRESENTATION

Presenters: Dr. Jose Francois and Sharon Erickson-Nesmith, WRHA Site Patient Safety Consultant

Learn how to help patients fill in the Medication Card. Receive tips for taking a complete medication history. Learn why reconciling medications is important. Receive tips on improving communication with patients. Receive answers to questions you may have regarding the medication card or medication reconciliation.

Location: BG002
Date: Wednesday, October 1, 2008
Times: 11:45 am. to 12:30 pm.
12:45 pm. to 130 pm.
5:15 pm. to 6:00 pm.

Enter to win a gift voucher valid for a SBGH cardio room membership package.

(Sample - Manitoba Institute for Patient Safety Medication Card – Attached)