



Clinical Trial Research News

From the Office of Clinical Research

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This newsletter is published on a bi-monthly basis and is designed to provide an information source for anyone interested in Clinical Research. Please contact Trish Berry if you would like to be added to / deleted from our mailing list.

WELCOME!!!

To Trish Berry, our new Administrative Secretary in the Office of Clinical Research. Some of you may already know Trish from her previous position in Biochemistry. Trish started working with us on February 5th and has already become a very valued member of our team. Trish has also taken on the responsibility of Recording Secretary for the Research Review Committee as part of her position. Trish can be reached at extension 3623 if you have any questions regarding your submission to RRC. Please join us welcoming Trish to Clinical Research.

Statistics and Medical Research

Doug Staley is taking a break from contributing to our newsletter at this time. We look forward to his future articles.

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

The Bannatyne Campus Research Ethics Board (REB)

The Bannatyne Campus Research Ethics Board (REB) Office has recently updated the Research Ethics Submission form to address administrative issues as well as rephrasing a few sections to provide clarity on a few important REB requirements.

The January 10, 2007 version of the form must be used from this point forward when submitting to a Bannatyne Campus Research Ethics Board. If you have already started filling in an older version of the form related to an upcoming submission we will accept the older version for the February deadline, however older versions will not be accepted after March 1, 2007.

All revisions are highlighted in the form and include the following:

Health Canada Approval

- * This section has been rephrased to assist research ethics board administrative staff to quickly screen submissions to determine whether the protocol involves natural health products, drugs or devices and thus assist the REB in determining whether appropriate Health Canada approval is required.

Clinical Trial Registration

- * Check box added to indicate pending status of registration.

Recruitment

- * Administrative correction made to indicate 5 copies of advertisements are required rather than 6 as previously indicated.

Research Using Personal Health Information Collected as Part of Manitoba Health

- * Contact information updated.

Biological Specimens

- * The definition of biological samples was added to the section.

Privacy and Confidentiality

- * Clarified wording to ensure researchers included a discussion re confidentiality provision required for personal data/information as well as personal health information collected for research projects.

If you have any questions regarding these updates, please call our office at 789-3255.

Shelly Rempel-Rossum RN, BN
Bannatyne Campus REB Coordinator

e-mail: <<mailto:remross@ms.umanitoba.ca>> remross@ms.umanitoba.ca
<http://www.umanitoba.ca/faculties/medicine/research/ethics>

SoCRA Exam – Saturday May 12, 2007 – St. Boniface General Hospital, Room NG034

The Society of Clinical Research Associates, Inc. (SoCRA) is a non-profit, professional organization dedicated to the continuing education and development of clinical research professionals. The express aim of SoCRA is to provide training and continuing education for clinical research professionals and to establish and maintain an international certification program for clinical research professionals.

For those who are interested in obtaining SoCRA Certification and writing your exam here in Winnipeg (Sat May 12/07 - 10 AM to 2 PM) please register directly with SoCRA to confirm your spot and to obtain your study material.

There is a limit of 25 seats and the registration deadline is March 30/07.

More information is available at;
http://www.socra.org/html/certific.htm#Examination_Schedule

A special "Thanks" goes to Brendon Foot at Medicure for coordinating the date with SoCRA!

Research Review Committee at St. Boniface Hospital

Deadlines for RRC Submission

March 28th
April 25th
May 30th

Meeting Date

April 4th
May 2nd
June 6th

PLEASE NOTE THERE IS NO MEETING IN JULY

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

Deadline for REB Submissions

March 12th
April 16th
May 14th

Meeting date

March 26th
April 30th
May 28th

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

Upcoming Workshops

Clinical Research Ethics - Tuesday, March 6, 2007

The history and principles of ethics and regulatory issues as they relate to human research will serve as the basis for this 2 hour lecture. Informed consent, privacy and confidentiality, conflict within the research team, conflict of interest and the role of Research Ethics Boards will also be presented.

Facilitators: April Hughes, Administrator Director
Terry Sawicz-Hanesiak, Regulatory Affairs/Quality Assurance
Office of Clinical Research, St. Boniface General Hospital

Date/Time: Tuesday, March 6, 2007, 1330 – 1530 hrs

Location: Room N1012 – Theatre A
Education Building (431 Tache Ave), St. Boniface General Hospital (409 Tache Ave)

Cost: **FREE**

Registration: Call Terry Sawicz-Hanesiak 237-2226 or e-mail tsawicz@sbgh.mb.ca

Guidelines, Policies & Regulations in the Conduct of Clinical Research - Tuesday, April 3, 2007

This 2 hour lecture will review the regulatory environment that directs the developmental process for taking a drug from bench discovery through human research and on to market. An overview of the historical evolution of today's regulatory environment will serve as the basis for why the regulations exist as they do. Quality control/monitoring and quality assurance/auditing will also be discussed.

Facilitators: April Hughes, Administrator Director
Terry Sawicz-Hanesiak, Regulatory Affairs/Quality Assurance
Office of Clinical Research, St. Boniface General Hospital

Date/Time: Tuesday, April 3, 2007, 1330 – 1530 hrs

Location: Room N1012 – Theatre A
Education Building (431 Tache), St. Boniface General Hospital (409 Tache Ave)

Cost: **FREE**

Registration: Call Terry Sawicz-Hanesiak 237-2226 or e-mail tsawicz@sbgh.mb.ca

Project and Documentation Management for Clinical Research - Tuesday, May 8, 2007

Rules, Roles and responsibilities will serve as the basis for project and documentation management of clinical research studies, be they drug, device or outcomes research. Topics covered will be:

- Pre-Study Planning, REB and Institutional Approvals
- Study Documents (Protocol, ICF, etc.)
- Source Documents and Data Collection Forms
- Informed Consent Process, Subject visits, Study Close out

Facilitators: April Hughes, Administrator Director
Terry Sawicz-Hanesiak, Regulatory Affairs/Quality Assurance
Office of Clinical Research
St. Boniface General Hospital

Date/Time: Tuesday, May 8, 2007, 1330 – 1530 hrs

Location: Room N1012 – Theatre A
Education Building (431 Tache), St. Boniface General Hospital (409 Tache Ave)

Cost: FREE

Registration: Call Terry Sawicz-Hanesiak 237-2226 or e-mail tsawicz@sbgh.mb.ca

Good Clinical Practice Workshop – Wednesday May 9, 2007

In response to several requests, the Office of Clinical Research we will be presenting a full day Good Clinical Practice workshop on **Wednesday May 9, 2007 – 8:30 AM to 4:00 PM.**

We are happy to once again have this workshop sponsored by the Health Care Products Association of Manitoba (HCPAM).

The cost to attend the one day workshop is \$150 (breakfast, lunch and break refreshments are included). Registration will be limited to 30 participants. For more information or to obtain a registration package for the workshops contact:

Terry Sawicz-Hanesiak, SBGH – Office of Clinical Research
(204) 237-2226 or e-mail tsawicz@sbgh.mb.ca

Special Announcement – Heal Rounds – Visiting Speaker

On March 15th from 1200-1300 hours at the Samuel Cohen Auditorium, Saint Boniface Research Centre (351 Tache Avenue) with a link to the PsychHealth Auditorium at the Health Sciences Centre (771 Bannatyne Avenue). This presentation will also be available through the MB Telehealth system.

Title: Ethical Reflections on Resource Allocation

Speaker: Nuala Kenny OC, MD, FRCPC – Professor, Departments of Bioethics and Pediatrics, Dalhousie University.

This reflection will focus on some of the fundamental ethical issues inherent in the allocation of shared and limited health care resources at the macro (Medicare), meso (institution/organization) and micro (bedside/individual patient) levels here in Canada. Dr. Nuala Patricia Kenny was born in New York and entered the Sisters of Charity of Halifax in 1962. After an extensive career in pediatrics and medical education, Dr. Kenny founded the Department of Bioethics at Dalhousie in 1996. She now devotes herself to bioethics full-time. Dr. Kenny is internationally recognized as a medical educator and lecturer on fundamental ethics questions in health care and policy.

Occupational Health & Safety

Occupational Health and Safety see about 150 employees each year who have had significant blood and body fluid exposures. As prompt attention to these exposures is required, it is important that those at risk are knowledgeable about the process to follow when they occur.

A laminated poster detailing instructions to follow when an exposure occurs can be ordered from Purchasing (#7102-4100-4) and placed in a prominent location on units. An informational brochure with frequently asked questions and answers has also been developed and is available by calling Occupational Health and Safety at 2439. Both the poster and brochure are attached.

All exposures that occur Monday-Friday 0730-1600 should be reported to Occupational Health and Safety. For exposures occurring outside those hours, the Hospital Supervisor should be paged at 2053. Further details can be found in the Administrative Manual Policy #VI-305 *Blood and Body Fluid Exposures (Post Exposure Prophylaxis) PEP*.

For further information please contact Occupational Health and Safety at 2439.

HISP UPDATE

Time is running out for HISP training, with only a few weeks left before our go-live date. There has been concern expressed that overall only 59% of SBGH staff have been scheduled to attend the required HISP training. It is important to note that you will not be provided with a password or access to the system until you have completed training. The Office of Clinical Research has been asked to ensure that all research staff are aware of training options and that all staff have taken the required training. We are asking that you please set up a time for your training yourselves, based on your schedules and availability.

To schedule your training, please contact Agatha Szentag at aszenta@wrha.mb.ca. Enrollment in classes is not confirmed until you receive a confirmation from Agatha. Please note that you will be emailed if requested spots are not available and that staff will then need to be rescheduled.

Comments?

Please feel free to add your contribution to our newsletter. All submissions can be directed to Noreen at 235-3813 or emailed to nallsopp@sbgh.mb.ca. We welcome your feedback and contributions.

BLOOD AND BODY FLUID EXPOSURE

Hepatitis B, Hepatitis C and HIV can be spread by direct contact with:

- Blood
- Semen and vaginal secretions
- Fluids that are around the brain, spinal cord, joints, lungs and heart
- Urine, vomit and saliva that have blood which you can see

FIRST AID FOR BLOOD AND BODY FLUID EXPOSURES:

IF you are poked/cut with a soiled sharp (needle) or instrument:

- Encourage bleeding from the puncture site
- Wash the wound with soap and water

IF body fluids splash into your eyes:

- Wash the eye thoroughly with cool water

IF the splash was to your mouth:

- Rinse your mouth with cool water

IF it was a splash to an open area on your skin:

- Wash the area with soap and water

REMEMBER:

- ✓ **REPORT** the exposure to your manager/supervisor **IMMEDIATELY**
- ✓ **PICK UP** "INFORMATION FOR EXPOSED WORKER PACKAGE" at:
 - Occupational Health & Safety located at TG002B
(Monday to Friday 0730 - 1600 hours - Phone: 2439)
 - Contact Hospital Supervisor located at TG123
(Evenings, Nights and Weekends - Page through the switchboard at 2053 if needed)
- ✓ **FOLLOW** the instructions on the package

**? If you have questions and would like more information about
Blood and Body Fluid Exposures, please contact the
SBGH Occupational Health & Safety at 237-2439. ?**

Health Canada Approval for Clinical Trials

(Revised February 13, 2007)

Certain clinical trials involving drugs, medical devices or natural health products may require an application for regulatory approval be filed with Health Canada prior to the recruitment of the first study subject.

Food and Drugs

Clinical researchers must be familiar with the details of the "[Regulations Amending the Food and Drug Act Regulations](#)" (1024 – Clinical Trials, Part C, Division 5) of September 1, 2001" (which were amended to require sponsor submission of a clinical trial application (CTA) for drug trials, a reduced default time for Health Canada review of applications, sponsor compliance with Good Clinical Practices (GCP), and Health Canada inspections/compliance verifications. These regulations apply to clinical trials (Phase I – Phase III) for both new investigational drugs and some marketed drugs.

It is important to note, that the use of marketed drugs outside of the approved indication (i.e. new age group, new disease entity or new dose range) now require Health Canada approval for use in a clinical trial, whether investigator or industry initiated

Following receipt of a CTA by a study sponsor and Health Canada's internal review, either a 'No objection letter' (NOL) or 'Not satisfactory notice' is issued by Health Canada. Any protocol amendments following the initial approval of the trial must also be submitted to Health Canada for approval. The Biomedical Research Ethics Board (BREB) withholds the certificate of final ethical approval pending receipt of a copy of the study's 'No objection letter' for new study submissions and subsequent applicable protocol amendments.

Medical Devices

Clinical trials involving medical devices require a similar but separate process under the [Medical Device Regulations](#); however REB approval is required by Health Canada prior to the Bureau releasing the Investigational Testing Authorization (ITA) letter. Following receipt of the ITA by the sponsor/Investigator, the BREB requests that the site forward a copy of this letter to the office.

Natural Health Products

A similar Health Canada review and approval process exists for clinical trials involving natural health products. Under the [Natural Health Product Regulations](#), which came into effect on January 1, 2004, natural health products (NHPs) are defined as:

- Vitamins and minerals
- Herbal remedies
- Homeopathic medicines
- Traditional medicines such as traditional Chinese medicines
- Probiotics, and
- Other products like amino acids and essential fatty acids.

Submissions satisfying the NHP Directorate's requirements will be issued a "Notice of Authorization" to commence the trial. The Biomedical Research Ethics Board (BREB) withholds the certificate of final ethical approval pending receipt of a copy of the study's Notice of Authorization for new study submissions and subsequent applicable protocol amendments.

For further information, please refer to their Web site at:

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/clin/index_e.html

If there is any uncertainty as to whether a trial involving drugs, food, medical devices and/or natural health products requires Health Canada approval the researcher is encouraged to contact Health Canada.

Health Canada REB Attestation Form

The University of Manitoba Health Research Ethics Board (HREB) and Biomedical Research Ethics Board (BREB) will not sign the Health Canada REB Attestation Form. The University of Manitoba HREB/BREB currently uses an Ethics Approval certificate that contains the required attestation as per Health Canada

regulations and this should be used by the sponsor in lieu of the Health Canada REB Attestation Form. We refer you to Section 14(b) of the Guidance for Clinical Trial Sponsors: Clinical Trial Application dated 2003/06/25 which states, "Research Ethics Board(s) may wish to use the Research Ethics Board Attestation(s) or develop similar documentation that meets the requirement of Part C, Division 5 of the Food and Drug Regulations".

Clinical Record Retention

Some clinical trial records must be retained for a period of 25 years post study closure.

Updated guidance effective June 15, 2006 regarding the retention of records and the conditions under which they are to be made available for monitoring, auditing and inspection related to clinical trials can be found at the following Health Canada website:

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/docs/gui_68_tc-tm_e.html

Health Canada guidance documents

[Guidance for clinical trial sponsors/clinical trial applications](#)

[Preparation of an Application for Investigational Testing - Medical Devices](#)

[Preparation of an Application for Investigational Testing - in vitro Diagnostics Devices](#)

[Clinical Trials for Natural Health Products – Guidance Document](#)

HEALrounds

A SPECIAL

Health Ethics And Law rounds

Thursday March 15th, 12-1 pm

Samuel Cohen Auditorium

Saint Boniface Research Centre, 351 Tache
with video-link to the PsychHealth Auditorium
771 Bannatyne

“Ethical Reflections on Resource Allocation”

by Dr. Nuala Kenny
OC, MD, FRCPC

This presentation will focus on some fundamental ethical issues inherent in the allocation of shared and limited health care resources at the macro (Medicare), meso (institution/organization) and micro (bedside/individual patient) levels here in Canada.

Dr. Kenny was born in New York and entered the Sisters of Charity of Halifax in 1962. After an extensive career in pediatrics and medical education, Dr. Kenny founded the Department of Bioethics at Dalhousie University in 1996 where she now devotes herself to bioethics full-time. Dr. Kenny is internationally recognized as a medical educator and lecturer on fundamental ethics questions in health care and policy.

Principal Sponsor of this event is WRHA Ethics Services. Additional support provided by Health Care Ethics Services of Saint Boniface General Hospital and HSC Clinical Ethics Services.