



Research Ethics ~ Spring 2011

Welcome to the Spring 2011 edition of the Research Ethics Newsletter! We hope to publish the newsletter quarterly each year, in the Spring, Summer, Fall and Winter. If you would like to join our e-distribution list, please contact Lorraine at lorraine.trischuk@viha.ca

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Welcome back, Margo!

Margo Farren will be returning to VIHA and assuming her position as Research Ethics Coordinator on April 1, 2011. Margo has been on a 6-month leave working as Project Manager for the BC Ethics Harmonization Initiative (see [page 3](#) for BCEHI update).

We look forward to her return!

New Serious Adverse Events Reporting Tool



Why?

This new, short 2-page form has been developed in response to the problem of over-reporting of individual non-local (external) serious adverse events to the VIHA REB. These reports often include little or no contextual information or analysis in order for the REB to make meaningful judgments concerning the risk to research subjects.

The introduction of this form will standardize reporting to the VIHA REB, and ensure more meaningful information is included to assist the REB in its assessment.

When do we start using the new form?

Effective April 1, 2011 the VIHA REB will only review **LOCAL** serious adverse events and other unanticipated problems as reported on the new form.

What do Health Canada and the Tri-Council Policy Statement say about the new reporting tool?

There is no Health Canada regulation for reporting external adverse events to the REB.

"It is the REB's responsibility to establish procedures for reviewing safety reports and new information, to determine how they will respond to increased risks to participants, and to be ready to implement these responses as needed. Responses shall be relative to the seriousness and likelihood of the risk to the welfare of participants within their jurisdiction. REBs may advise researchers as to the steps they must take to eliminate or mitigate newly reported risks, and how this information should be shared with participants" (see Tri-Council Policy Statement 2 - Chapter 11, CLINICAL RESEARCH, Article 11.8).

ICH requirements will also be met if unanticipated problems are reported to the REB as required on the new form.

What/when do we need to report?

Unanticipated Problems: Any incident, experience or outcome that is unexpected (in terms of nature, severity or frequency) + related or possibly related + places subjects at a greater risk of physical or psychological harm.

"The most exciting phrase to hear in science, the one that heralds new discoveries, is not 'Eureka!' but rather, 'hmm... that's funny...'"
Isaac Asimov



New Serious Adverse Events Reporting Tool cont...

Local Serious Adverse Events: An Serious Adverse Events that occurs at sites for which the VIHA REB is the board of record, and involves VIHA facilities or VIHA research subjects. Reporting to the REB should be prompt but in any case no later than 15 calendar days of the PI becoming aware of the Serious Adverse Events; 7 days if the Serious Adverse Events is fatal or life-threatening.

Sponsor-Issued Safety Reports: Summary reports created by the sponsor that include a concise summary highlighting the main points of concern, analysis, and the evolving safety profile of the investigational product.

What if our sponsor insists that the REB receive/acknowledge non-local Serious Adverse Events ?

Incomplete submissions or individual non-local event reports will not be accepted and will be returned to the investigator with a copy of the guidance document. Individual non-local reports will not be acknowledged by the REB office.



BC Ethics Harmonization Update

The BC Ethics Harmonization Initiative (BCEHI), a 5 year project funded annually by Michael Smith Foundation for Health Research, is approaching the end of its first year of activities. Following VIHA's approval for a 6-month leave of absence, Margo Farren, VIHA Research Ethics Coordinator, was hired October 1st as the BCEHI project manager. The project's overall objective is to develop and implement an effective, coordinated, value-added approach to ethical approval of human research. The focus of Year 1 has been to conduct 2 different pilots to evaluate different collaborative review processes aimed at reducing researcher burden and improving collective REB approval timelines for multicentre health research projects requiring multiple REB approvals. The results of these pilots will inform the next phase of activities. Also during Year 1 a BCEHI Open House was held in downtown Vancouver to engage the entire BC REB community in BCEHI activities. The event coincided with the first educational workshop hosted by the Ottawa-based Secretariat on Research Ethics (SRE) on the revised Tri-Council Policy Statement on Ethical Conduct of Research in Humans (Tri-Council Policy Statement 2). Travel and accommodation subsidies were made available by both the BCEHI and SRE to support REB member participation in the 2 day event. For further information on the BCEHI and its activities please contact bcehi@uvic.ca



"Contrary to what Asimov says, the most exciting phrase in science, the one that heralds new discoveries, is not 'Eureka' or 'That's funny...'. It's, 'Your research grant has been approved.'"

John Alejandro King



Q & A

'Q & A' is a column that will be featured in each issue of the Research Ethics newsletter. This is where you can find answers to frequently asked research ethics questions. Have a question? Email it to: lorraine.trischuk@viha.ca.

Q: Why can't our office receive an acknowledgement of receipt for our (INSERT NAME OF WHATEVER DOCUMENT YOU'RE LOOKING FOR HERE) submission dated November 3, 2006?

A: Unless what you are looking for is readily accessible (in an open, active study file), painstaking effort will need to be taken to find it. All closed studies from a previous year, old Serious Adverse Events submissions and other boxes of paper-generated goodness are sent to our archive to be stored for 25-years. Yes, 25-years (Health Canada regulations). About the same length of time needed to find your (INSERT NAME OF WHATEVER DOCUMENT YOU'RE LOOKING FOR HERE) from 2006.

If your sponsor needs an acknowledgement for something that's been sent to us more than a year ago, please re-submit.

Lastly, we are quite frequently being asked to pull something that has already been acknowledged/faxed. Please note that our fax machine is set up to print out an error report if any documents being sent do not transmit. Please double-check your files before requesting an acknowledgement.

Q: How long does it take for my application for research to be reviewed?

A: All applications for research go through a review process. The CREB applications are reviewed at our monthly CREB meetings (see [submission deadlines/meeting dates](#) on our website), and the HREB & Joint UVic-VIHA applications are reviewed as they come in.

CREB responses: You should hear from our office via email 2 to 3 days following the monthly meeting which your application was reviewed.

HREB & Joint UVic-VIHA responses: We allow our Board members 2 full weeks to review new applications. You should hear back from our office via email 3 to 4 weeks after we receive your application.

Are you using old forms?

Recently updated Research Ethics forms, policies and other helpful information can be found at:
www.viha.ca/rnd/research_ethics



The Boards

The Research Ethics office facilitates the operations of two ethics Boards, in addition to a third ethics committee which is a harmonized effort between Uvic and VIHA

The CREB

Members of the Clinical Research Ethics Board review applications for research that are identified as higher than minimal risk and will utilize VIHA facilities, patients, residents, clients, staff or resources.

This includes clinical trials of drugs, medical devices and natural health products.

On average, our office receives 3 to 6 CREB applications per month.

The HREB

Members of the Health Research Ethics Board review applications for research that do not involve any clinical intervention and will utilize VIHA facilities, patients, residents, clients, staff or resources.

On average, our office receives 2 to 4 HREB applications per month.

The Joint Uvic-VIHA Subcommittee

Members of the Joint Uvic-VIHA Subcommittee review applications that involve *both* Uvic faculty, staff or students in addition to VIHA facilities, patients, residents, clients, staff or resources.

On average, our office receives 2 to 4 Joint applications per month.

Interested in becoming a Board member?

The Research Ethics office is actively recruiting members for each of our Boards. In addition to providing an important service to research subjects, our Board members review, approve and monitor all research that involves VIHA patients, residents, resources, clients and staff to ensure that scientific and ethical standards are met.

Responsibilities include:

- Attending at least 75% of all scheduled monthly meetings
- Completion of the Tri-Council Policy Statement online tutorial (2nd edition version coming this spring)
- Participation in VIHA sponsored professional development activities (e.g., the annual Board member educational retreat)
- Maintaining confidentiality in all Board matters

Board members do not participate in the review and approval process of their own submissions.

Our Research Ethics Coordinator (Ami Bitschy until March 31, 2011 / Margo Faren after that date) will be happy to answer any questions you may have or give you more information. Please contact our office at 250-370-8620.

Did You Know?

The [2nd edition of the Tri-Council Policy Statement](#) is now available online.



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All human research that is conducted by members of the VIHA or that involves VIHA facilities, patients, residents, clients, staff or resources, requires research and ethical approval prior to commencement.

Human research involving human participants, remains, cadavers, tissues, biological fluids, embryos, fetuses and other biological materials including human DNA, RNA or DNA and RNA fragments is subject to research and ethical approval.

VIHA requires ethical approval to ensure all human research complies with ethical principles and standards.



Healthy People, Healthy Island Communities, Seamless Service

A special thank you to Ami Bitschy who has filled some rather large shoes in the Research Ethics office over the past few months as the Acting Research Ethics Coordinator.

Please help us congratulate Ami on her new position at UVic's Centre on Aging.

Good luck, Ami!

We would also like to thank all of our researchers and research staff for their collegiality, professionalism and patience with longer than usual response times this past winter. Much appreciated!

