



### Dear Faculty Members:

This newsletter describes several important changes in procedures, policies, and personnel of the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB). Please share with your research associates, staff, and students involved in human participant research.

### HSREB is now a Clinical Trials Ontario (CTO) Qualified Research Ethics Board

Principal Investigators interested in conducting or joining multicentre clinical trials that involve 2 or more Ontario centres must use CTO's streamlined research ethics review system. For more information, contact the HSREB or Erin Bell, Program Coordinator, CTO (E: [erin.bell@ctontario.ca](mailto:erin.bell@ctontario.ca); T: 416-673-6670). Further information about CTO can be found at [www.ctontario.ca](http://www.ctontario.ca).

### Website

Ethics Office staff have been working hard to update and improve the [HSREB website](#). Our goal is to provide more educational assistance to those completing application forms and more examples of materials for participants. We appreciate your feedback and ideas for additional improvements

### HSREB Standard Operating Procedures (SOPs)

The HSREB is constantly revising its SOPs. The SOPs are public for review on the HSREB website. We encourage you to review them and check back regularly for updates.

### HSREB Ethics Submission Form

The HSREB Ethics Submission Form has been revised and will be live on Tuesday, April 12, 2016. This process should have minimal impact on the majority of researchers. We have revised the information tabs on the questions to provide better guidance to those filling out the form, and have also removed redundant questions and clarified other questions. If you have any questions regarding changes to the submission form, please contact Elizabeth Heinricks at 613-533-2988 x 32988 or [elizabeth.heinricks@queensu.ca](mailto:elizabeth.heinricks@queensu.ca). If you experience any technical problems, such as lost information in your submission form, please contact the TRAQ Help Desk: [traq@queensu.ca](mailto:traq@queensu.ca) or call or (613) 533-6000 x 78426.

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## Submission Form Attachments

The HSREB has developed two new forms to assist in the ethics review process:

- **The Scientific/Peer Review Form:** A scientific/peer review or its equivalent will be required for all submissions going to HSREB Full Board Review.
- **The Protocol Deviation Reporting Form:** For more information about events that require protocol deviation reporting, see HSREB SOP v.408.001 HSREB Protocol Deviation Reporting.

The forms can be found in the TRAQ system in the Researcher Portal as well as on the HSREB website under Templates.



## Serious Adverse Event (SAE) Reporting

The HSREB has revised its SAE reporting protocol. All local SAEs are still required to be reported, however, only external unexpected SAEs will be required to be reported to the HSREB as per FDA regulations and current industry best practices. For more information about reporting SAEs, see HSREB SOP v.410.001 HSREB Reporting Adverse Events.

## Medical Education Research

Medical education research projects involving medical students as participants requires the approval of Dr. Sanfilippo (communicate with Dr. Sanfilippo or via Theresa Suart – [theresa.suart@queensu.ca](mailto:theresa.suart@queensu.ca) or 613-533-6000 ext. 75485 in the UGME office). Ethics approval is not given until their approval is received.

## Ethics Clearance Renewal.

All researchers who have ethics clearance for a study must close the ethics application in TRAQ by submitting a Renewal Form upon completion of the study. In accordance with standard industry best practices, the HSREB will require that all active study projects that have received ethics clearance from the HSREB submit their annual renewals 2 weeks in advance of their annual renewal date to enable review and continued ethics clearance without interruption.

When an ethics application has lapsed, all participant recruitment must stop until ethics clearance has been renewed. If a renewal lapses, upon receipt of a letter from the Ethics Compliance Advisor, you will have 10 business days in which to submit your renewal. A notice that your ethics clearance renewal lapsed will be added to your file. Failure to respond to the Lapsed Letter will result in a final termination letter. Five days after the date of this letter your ethics clearance will be closed. For more information see HSREB [SOPs v. 405.001 Renewal of Ethics Clearance](#) and [v.407.002 Suspension or Termination of HSREB Ethical Clearance](#).



### Open Access

Open access policies are being implemented by the Tri-Agency (CIHR, NSERC, and SSHRC) and numerous funding agencies and institutions worldwide. To help researchers initiate data management plans, data retention plans, and open access to data, please search the Queen's Library Open Access page (<http://library.queensu.ca/scholcomm/open-access>) or contact Sharon Murphy, at the Library Research Data Centre at 613-533-2836 or [murphys@queensu.ca](mailto:murphys@queensu.ca).

### New 1-800 contact number

All future participant documents (e.g., Informed Consent Form) that provide an HSREB contact phone number should provide the new phone number: 1-844-535-2988

### Education and future department visits

We are very pleased to have Mr. Anthony Wright (Ethics Compliance Advisor) assist the HSREB through his work in website development, new policies, and SOP development. Anthony and Dr. Albert Clark, Chair of HSREB, are available to visit your department to convey the essence of these important new procedures through an educational or exchange session. Please contact Anthony at 613-533-6000 x 78223 or [wrighta@queensu.ca](mailto:wrighta@queensu.ca) to arrange a suitable time.

### Welcome

I would like to welcome Elizabeth Heinrichs as the new HSREB Ethics and Office Assistant. She is a welcomed addition to the Ethics Office and will be helping Kathy Reed, HSREB Ethics Coordinator, with day-to-day operations. Elizabeth Heinrichs' contact information is: Tel 613-533-2988 x 32988 or Email [elizabeth.heinrichs@queensu.ca](mailto:elizabeth.heinrichs@queensu.ca)

On behalf of the HSREB,

Dr. Albert Clark  
HSREB Chair

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