The Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB) Newsletter 2019

Dear Colleagues,

This has been a dynamic year for the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board. Kathy Reed retired in July 2018 and Jennifer Couture transitioned into the role of Manager, Research Ethics Compliance in August 2018. Additionally, Michelle Salamone started as Ethics Coordinator in September 2018, and Crystal McCracken joined the team as Ethics Compliance Advisor in October 2018. The HSREB has also revised and launched three application forms and four event forms within the last year. These new forms are available when you log in to TRAQ.

In April, 2019, I attended the Canadian Association of Research Ethics Boards (CAREB) conference. This was a fantastic opportunity to network with other REB Chairs to share knowledge and resources. Jennifer Couture, Manager, Research Ethics Compliance, co-led a workshop in collaboration with the Centre for Addiction and Mental Health (CAMH). The goal of the session was to co-create a strategy to enhance concrete supports for REBs and the research community, for research involving Indigenous communities. On May 9, 2019, the first e-mail was circulated on behalf of the 'Naalak Network.' Naalak is an Inuttitut word meaning 'to listen and to pay close attention.' The Naalak Network is a virtual linkage of researchers, REBs and Indigenous communities who share a common desire to enhance the ethical conduct of research/review with Indigenous Peoples.

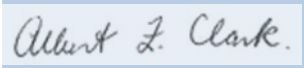
Important HSREB Processing Updates

- **A NEW LOI/Consent Form** checklist and updated ICF templates are available on HSREB's website under 'Informed Consent Form Resources.' Please use these tools to ensure your LOI/CF has all of the required elements.
- **Annual Renewals** – Consent forms will be reviewed **every 5 years** at the time of renewal to ensure the information is up to date and that it contains the current required elements.
- **Annual Renewal Event Form Submission** – Renewals will no longer be accepted if submitted more than 30 days in advance of the expiry date, with the exception of Full Board submissions. As of May 27, 2019, renewals will be sent back to the study team with a request to re-submit the event form within 30 days of the ethics clearance expiry date.
- **Initial Clearance Letter Document Details** – Initial ethics clearance letters will be automatically generated from TRAQ using the document titles and version dates as entered and uploaded through TRAQ by study team members. **Please ensure study document titles and version dates are entered accurately in TRAQ.**
- **Cannabis Research** – on October 17, 2018, cannabis was legalized for recreational use in Canada. Cannabis studies involving human participants must receive approval from Queen's Environmental Health and Safety in addition to obtaining ethical clearance. Please refer to the Cannabis Research Information Sheet for more details on the requirements for cannabis research involving human participants.
- **Reporting Criteria for Suspensions/Terminations in Ethics Clearance** – The HSREB does not mandate that suspensions due to lapses in ethics clearance be reported to Health Canada or the U.S. Food and Drug Administration (FDA) for regulated studies. The Ethics Office will terminate ethics clearance for studies when the lapse in ethics clearance surpasses 10 business days. Terminations due to a lapse in ethics clearance **do require** notification to Health Canada and/or the FDA as applicable.
- **Serious Adverse Events** – only SAEs that meet reporting criteria as outlined in SOP 410 Reporting Adverse Events will be acknowledged by the HSREB.

If you would like to join the network, please e-mail naalak@nunatukavut.ca. There are also numerous resources available on the Naalak Network.

We will continue to communicate developments, tools and new resources as they arise. Thank you to the HSREB community for your continued commitment to conducting ethical research.

Kind regards,



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Mandatory Ethics Training

- Following consultation the University and QUFA through the Joint Committee for the Administration of the Agreement (JCAA) for the Queen's-QUFA Collective Agreement, the Office of Research Ethics Compliance will be implementing mandatory research ethics training for all research team members, **including faculty**, **librarians, and archivists**, effective **December 2, 2019**.
- **All faculty, librarians, archivists, and research team members applying for ethics clearance will be required to complete the Course on Research Ethics (CORE tutorial) and provide evidence of ethics training by uploading a CORE completion certificate into the TRAQ ethics application system.**
- Starting **December 2, 2019** all **NEW** Ethics applications that are submitted without evidence of ethics training for all team members will be returned to the applicant with a request to complete the mandatory ethics training.
- Equivalent ethics training certificates may suffice in lieu of CORE certificates (e.g., Good Clinical Practice, CITI Biomedical Research Ethics Tutorial).
- **This requirement will not be retroactive and will only impact NEW applications submitted for ethics review.**

Monthly TRAQ & Ethics Training Sessions

- Crystal McCracken and the TRAQ help desk will be running sessions to help Researchers learn about the REB application forms. Please visit the TRAQ website for information about the monthly training sessions.
- The next session is scheduled for June 27, 2019.

HSREB Recruitment

- The HSREB is looking for a member knowledgeable in law to serve on the HSREB as an alternate member. Please contact Jennifer Couture, Manager, Research Ethics Compliance for more information.

Clinical Trials Ontario

- **ICF Template Requirement** – Beginning May 1, 2019, CTO will be screening Provincial consent forms to ensure they follow the structure and format of the CTO ICF template. If the ICF does not match the CTO template, the application will be screened as incomplete by CTO and returned to the applicant.
- **CTO Re-Qualification Visit** – Clinical Trials Ontario (CTO) conducted a re-qualification visit in May 2018. The HSREB CTO qualification status remains active until May 27, 2021.

The U.S. Final Rule

- The U.S. Department of Health and Human Services (HHS) has implemented the Final Rule to replace the Common Rule with a compliance date of January 21, 2019. All studies subject to the US Code of Federal regulations will need to include a summary of 'Key Information' at the beginning of each consent form. Refer to CITI's website for Final Rule Resources.

Visit HSREB's Website to find the most recent versions of HSREB's Checklists, Resources and Guidance Documents!

In 2017/2018 HSREB reviewed:
599 NEW Applications - 1088 Amendments - 1632 Renewals