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March 16, 2020

The COVID-19 situation is rapidly evolving around the world. Queen's University administrators as well as our hospital partners (KHSC, Providence Care) are actively monitoring the situation. Although at the present time there are no active cases within our community and KFL&A Public Health continues to advise that the risk to our community remains low, our primary concern is the health and wellbeing of our patients, health care providers, faculty, research staff, students, trainees, and research participants. This is particularly important for ongoing research taking place within our affiliated hospitals.

Based on the directives of the [Faculty of Health Sciences](#), any student, staff or faculty member returning from travel outside Canada must self-isolate for 14 days before returning to work. For those that have returned to Canada within the last 14 days, they must complete what is remaining of the 14 days of self-isolation from the date of their return to Canada. The affiliated hospitals have similar directives for their staff, physicians, learners and volunteers.

If faculty, research staff, students and trainees are feeling unwell, they should be staying home and avoiding contact with other individuals until symptoms are gone.

For more information on the evolving situation please consult both the Queen's University COVID-19 [website](#), Faculty of Health Sciences [website](#) as well as the relevant affiliated hospitals' websites ([KHSC/PCC](#)).

Hospital Based Research

Effective immediately, unless the research study is providing a potentially essential treatment option with a limited enrollment option, enrollment of new research participants into research studies occurring at Kingston Health Sciences Centre (KGH and HDH sites) and Providence Care (including Ongwanada) should be suspended until further notice.

If research participants are required to enter the hospital for research follow-up visits, they should be contacted ahead of time to ensure that they are not showing any clinical symptoms of COVID-19. If they are, the appointment should be rescheduled when signs have resolved.

We are requesting that researchers consider whether their active research protocols can be modified or delayed to limit personal contact, laboratory visits or trips to clinics and hospitals. These modifications must be made in collaboration with the study Sponsor/CRO/Other Academic Institutions where applicable.

Community Based Research

For ongoing research that is occurring within the community (e.g., community and home-based interventions, interviews, focus groups, etc.) there are currently no restrictions on enrollment of new participants. We are however requesting that researchers consider whether their active research protocols can be modified or delayed to limit personal contact. We do recommend postponing studies that cannot afford interruptions given the dynamic nature of the current situation.

For ongoing research protocols, we do recommend that researchers contact their participants to ensure that they are not showing any clinical symptoms of COVID-19. If they are, the interaction should be rescheduled when signs have resolved.

General Considerations

Consideration should be given to whether in-person interactions can be reduced in frequency or be replaced entirely by virtual interactions while maintaining the protocol's scientific validity. Revised participant consent or consent addendums may be required (e.g., to update privacy considerations with use of different communication channels), but these communication changes do not need to be approved by the HSREB prior to implementation. Please note this is not a blanket approval for protocol changes. This correspondence applies only to changes made in response to COVID-19 precautions.

While guidelines and regulations (TCPS2, FDA), require review and approval of research protocol modifications prior to implementation, an exception can be made where the change is necessary to reduce an immediate risk to participant(s) (TCPS2 Article 6.15 and 21 CFR 56.108(a)(4)). Such changes may be implemented immediately, however, where possible, the notification to the REB (HSREB, CTO, OCREB) should be submitted prior to implementing the changes. When submission to the REB is not possible prior to implementation, they must be reported to the HSREB within five business days as per [SOP 408.003 – HSREB Protocol Deviation Reporting](#).

It should be noted that Ethics oversight is the responsibility of the Researcher if they are introducing additional risks or making urgent changes prior to formal HSREB/CTO/OCREB approval.

This change to the REB process will be in place until further notice.

If you have any questions / concerns, where Queen's HSREB is the local REB, please contact either [Jennifer Couture](#), Manager, Research Ethics Compliance or [Crystal McCracken](#), Ethics Compliance Advisor.

For all central REB (CTO, OCREB) studies, please reach out to CTO/OCREB directly for any questions / concerns.

Sincerely,



Andrew Winterborn, DVM DACLAM