

***Ottawa Health Science Network Research Ethics Board (OHSN-REB) /
Conseil d'éthique de la recherche du réseau de science de la santé d'Ottawa (CÉR-RSSO)***

April 2, 2020

Dear Investigators and Study Teams,

Temporary Changes to REB Approved Human Subjects Research Activities during the COVID-19 Publicly Declared Emergency

While TCPS2 typically requires review and approval of modifications prior to implementation, an exception can be made where the change is necessary to eliminate an immediate risk to participant(s) (Article 6.15). Such changes may be implemented but must be reported to the REB.

Similarly, studies that must comply with the US federal regulations require that the REB review any revision to the protocol before they are implemented except in cases, "where necessary to eliminate apparent immediate hazards to the human subjects." 21 CFR 56.108(a)(4).

Implementation of alternative processes should be consistent with the approved protocol to the extent possible, and Investigators should document the reason for any contingency measures implemented. Investigators should document how restrictions related to COVID-19 led to the changes in study conduct and the duration of those changes and indicate which participants were impacted and how those participants were impacted.

- It is the responsibility of the Investigator to notify industry sponsor/coordinating centre or study sites of applicable changes to study conduct.

When to submit the NEW 'Notification of a Planned Protocol Deviation' form to REB:

When you are carrying out any **temporary** changes to the approved study procedures as a result of the publicly declared emergency, that are deemed by the PI and/or study sponsor **to impose risk to the participants and/or data integrity, these need to be reported to the REB.** Please complete the new "Notification of a Planned Protocol Deviation During a Publicly Declared Emergency" form found on our webpage at <http://www.ohri.ca/ohsn-reb/>. Submissions must be sent via email to your Research Ethics Coordinator or to REBadministration@toh.ca.

- Once the declared emergency is over, study activities must resume as outlined in the Protocol currently approved by the REB. If the implemented changes are planned to continue past the emergency, an Amendment Form must also be submitted.
- If you have already reported such protocol deviations to the REB, you are not required to re-submit using this new form; your previous notification will be held on file. However, for any additional changes or for those not yet reported, please utilize this new form.

When to submit an Amendment Form to REB:

For protocol changes unrelated to COVID-19 emergency and/or related to COVID-19 emergency but permanent (changes will continue after the emergency), an Amendment Form, along with the revised Protocol, should be submitted as usual.

When no submission to REB is required but the changes must be documented in a Note to File (NTF) as well as in the next Continuing Review Form to REB:

- Study holds, recruitment holds, and procedural changes due to the COVID-19 emergency that do not increase risk to participants or adversely affect the integrity of data.
- Changes to recruitment and initial consenting procedures that do not increase risk to participants or adversely affect the integrity of data.
- For Pandemic Classification C2 studies - Use the REB recommended NTF found on the OHSN-REB website, when documenting changes to recruitment and initial consenting procedures. For other NTFs, please use the recommended templates provided by your Clinical Research Administration.
- The Continuing Review Form will be revised to include questions about study conduct and summary of the changes implemented during the COVID-19 emergency.

Research Ethics Office and REB Operations during the COVID-19 Publicly Declared Emergency

- The Research Ethics Office will continue to review all types of submissions.
- REB review will be prioritized for COVID-19 related submissions. If submitting a new application related to COVID-19, let your Research Ethics Coordinator or REBAdministration@toh.ca know immediately upon submission.
 - For OHRI, if you are planning to submit a **new** protocol related to COVID-19 please email Nancy Camack at ncamack@ohri.ca, Dr. R. Saginur, REB Chair at rsaginur@toh.ca, and Dr. B. Cameron, Medical Director for Clinical Research at bcameron@toh.ca to ensure that the submission is appropriately triaged and to coordinate with any potentially conflicting trials.
 - For Heart Institute, if you are planning to submit a **new** protocol related to COVID-19 please email Sharon Finlay, at sfinlay@ottawaheart.ca and Dr. J. Robblee, REB Vice Chair at jrobblee@ottawaheart.ca to ensure that the submission is appropriately triaged and to coordinate with any potentially conflicting trials.
- For all other non-COVID-19 related initial applications, please continue to submit electronically via IRIS. All post approval submissions (the new Notification of a Planned Protocol Deviation Form during COVID-19 Publicly Declared Emergency form, Amendment Form, Continuing Review Form, Reportable Event Form and Study Closure Form) must be submitted via email to your assigned Research Ethics Coordinator or to REBAdministration@toh.ca; do not submit in hardcopy.
 - During the COVID-19 emergency, inked signatures will not be required on REB correspondence. For initial applications, electronic signatures or uploaded email threads from the PI, Co-I or Dep/Div Head signatory confirming they agree to all bullets outlined in the applicable signature page will be accepted. Similarly, if the PI's signature is requested on the response to the REB's Review Letter, an electronic signature or uploaded email confirmation from the PI is acceptable in its place. For post approval forms, the email submission to REB should be sent directly from the PI, or have the PI cc'd.
 - If you have any questions about Clinical Trials Ontario (CTO) studies for which OHSN-REB is **not** the REB of Record, please contact the CTO REB of Record for further guidance.

Sincerely,

Ottawa Health Science Network Research Ethics Board (OHSN-REB)