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)

Memo to: OHRI Clinical Research Investigators, Staff and Students; REB applicants; OHRI Administration

Date: June 9, 2020

Topic: **OHSN-REB Amendments to Reclassify Contingency Plan; Clarification – Division Head Involvement**

NOTE: This memo contains specific guidance for OHRI but is being shared with all REB applicants for your information regarding the revised Contingency Planning definitions. Those outside TOH/OHRI please ensure you follow your institutional directives for restarting clinical research activities. You will see the revised definitions on any new Clinical Research Registration Forms and OHSN-REB applications.

A. OHSN-REB Amendments to Reclassify Contingency Plan

The Clinical Research Study Classifications were updated in the recently issued Back to Business for Clinical Research: a Framework. As we enter Recovery Phase 1, research groups may be tempted to reclassify their studies to resume recruitment, but they must ensure such requests are appropriate.

Please ensure you have reviewed the document and are confident that your request meets the parameters for reclassification. As such, those studies that meet the criteria will be very few. As an example, it may be appropriate to revise a Class A or B designation to a Class C2 if study **recruitment** can be managed remotely.

The OHRI Clinical Research Facilitators are available to assist (email: CRFacilitators@ohri.ca) and will be involved in assessing the requests made for re-classification of contingency plans. The decision to re-classify will be based on requests that satisfactorily align with the definitions and guidelines in the "Back to Business Framework."

If your research team is requesting to change your contingency plan classification from the original OHSN-REB application / Clinical Research Registration Form (CRRF) then you must do the following:

- **Complete the new Updated Contingency Plan Reclassification Form and submit it via email to REBAdministration@toh.ca.**
    - If your ethics Board of Record (BOR) was the OSHN-REB, the form will be treated as an amendment and your study record will be updated.
    - If your BOR was another REB (i.e., REB application submitted to CTO, OCREB or CHEO REB), the form will be treated as an administrative change to your study, since the contingency question was included in the CRRF registration process.

The new form must be submitted via email to REBAdministration@toh.ca. The form is also found on the OHSN-REB website under the "Forms" tab.

B. <u>Clarification regarding Division Head involvement to resume clinical research activity</u>

As stated in the "Back to Business for Clinical Research: A Framework" document, *"For each study, investigator must seek approval from their Division/Department leads to restart their study."*

The intention is to inform to the Division Heads that certain studies are resuming, as per the guidelines, but there is no requirement for written approval. Each Division or group will manage the resumption of research activities as they see fit in accordance with the framework. Communication is key.