The Ottawa Hospital Research Institute | L'Hôpital d'Ottawa Institut de recherche

UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

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)
Civic Box 675, 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9
613-798-5555 ext. 16719 Fax : 613-761-4311 http://www.ohri.ca/ohsn-reb

OHSN-REB Standard Operating Procedure Addendum

Rationale: The OHSN-REB is a member of the Canadian Association of Research Ethics Boards (CAREB), and as approved by the OHSN-REB Executive Committee, has adopted the N2 - CAREB SOPs. To reflect specific OHSN-REB requirements, this addendum complements the N2- CAREB SOP noted below.

N2/CAREB SOP: # 405 – Continuing Review

N2-CAREB SOP Guidelines	OHSN-REB Standard Operating Procedure Addendum
5.3 REB Determinations 3.2: The REB may also make additional determinations, including: • Request changes to the informed consent form(s), • Request changes for the continuing review interval (based on risks), • Impose special precautions (e.g., frequency of monitoring, the requirement for interim reports or duration of approval period), • Require modifications to the research, • Suspend or terminate REB approval.	If recruitment is open at the time of the continuing review and there have been no changes to the consent form in the last 5 years, the REB may request an updated consent form via an Amendment Form submission.
5.4 Continuing Review Applications not Received by the Expiry Date 5.4.1 If an application for continuing review is not submitted by the expiry date, a warning or suspension notice will be issued to the Researcher. When suspended, the Researcher must suspend all research activities as specified by the REB. The responsible REB Office Personnel will follow-up with the Researcher to ensure that the application for continuing review is submitted as soon as possible.	▪ The home page of the investigator's Integrated Research Information System (**IRIS**) has a built in Investigator notification system called the "**Ethics Ticker**". ▪ The Ethics Ticker lists all studies that the investigator has that are set to expire in "90", "60", and "30" days as well as any protocols that have recently expired. ▪ The Ethics Ticker is the investigator's **notification that a study's ethical approval is about to lapse**. ▪ It is the researcher's responsibility to ensure that they review the Ethics Ticker on a regular basis and submit any continuing review form for any project within the "Renewals due in 60 days" category. This will allow sufficient time for any protocols requiring review at a convened REB meeting. ▪ A **warning or suspension letter notice** will be issued to the Researcher once the REB becomes aware the study has expired. ▪ When suspended, the Researcher must **suspend all**

	research activities as specified by the REB and submit a continuing review or study closure form to the REB within 30 days of receipt of the suspension letter. ▪ Participants recruited during expired status - the **Chair/Vice-Chair of the REB will review the investigator's response and provide their ruling as to whether the participants must be withdrawn and/or their data may be used**. ▪ The REB may choose to **close expired studies and request a new application be submitted**.
5.4.3 The Researcher must document the reasons for the lapse and identify the steps taken to prevent future lapses;	Should a study expire, the **REB will require the following information be provided to the REB**: ▪ Either a Continuing Review or Study Closure Form. ▪ Confirmation that all research activity has been suspended. ▪ A detailed explanation for why the study's ethical approval lapsed. ▪ A corrective action plan to ensure that ethical approval does not lapse again. Repeat offenders will be asked to meet with the Chair/Vice-Chair of the REB.

Revision History

Version Number	Effective Date	Summary of Changes
Version 2	January 12, 2022	Administrative changes (logos, rationale, etc.); addition of Section 5.3.
Version 1	September 2, 2015	Initial Version

This N2-CAREB SOP Addendum has been reviewed and approved by the OHSN-REB Administrative Committee.