Sunnybrook
HEALTH SCIENCES CENTRE

Sunnybrook REB Standard Operating Procedure Addendum

The Sunnybrook REB has adopted the N2/CAREB REB SOPs and in order to reflect specific Sunnybrook REB requirements, this addendum complements the N2/CAREB REB SOP noted below.

N2/CAREB REB SOP:
801 – Researcher Qualifications and Responsibilities

N2/CAREB REB SOP	Sunnybrook REB SOP Addendum
5.1.2 If applicable, the Researcher must be a physician with a specialty qualification in their field and with current professional qualifications entitling them to provide health care under the applicable laws;	• For Investigator-Initiated regulated trials, if the Researcher applying to the REB is not the Qualified Investigator (QI) as defined by Health Canada, the Sunnybrook QI must be clearly designated on the REB application (i.e. listed as a Co-Investigator).
5.2.1 The Researcher is responsible for complying with the decisions and responsibilities set out by the REB. In addition, it is the Researcher's responsibility to comply with all applicable regulations and ensure that (if applicable):	• All clinical trials or research that is considered to be more than minimal risk will have at least one appropriately qualified co-investigator or sub-investigator designated and supervised by the Researcher to perform critical trial-related procedure and/or make important trial-related decisions, and who has agreed to be listed on the REB application and applicable delegation log. • Clinical trials are registered in a registry that is compliant with the criteria set by the World Health Organization or International Committee of Medical Journal Editors and that the number assigned to the trial upon registration is provided to the REB. • The Researcher is responsible for notifying the REB of any inspections conducted by a regulatory authority involving research study(ies) overseen by the REB.
5.2.1 Note: (if applicable) The obligations of a Researcher holding a Clinical Trial Application (CTA) with Health Canada (i.e., sponsor-Researcher) include both those of a sponsor and those of a Researcher.	• For Sunnybrook Research Institute (SRI) Investigator-initiated regulated Clinical Trials, SRI is designated the sponsor on the Clinical Trial Application to Health Canada. For each such Clinical Trial, SRI and QI will enter into an agreement to which SRI delegates some of its sponsor responsibilities to the SRI QI.

Revision History	
Effective Date	**Summary of Changes**

March 1, 2018	Original version
December 12, 2023	No revisions needed
March 28 2024	Addition of responsibility of Researcher to notify REB of inspections

This N2/CAREB REB SOP addendum has been reviewed and approved for use by:

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