Sunnybrook
HEALTH SCIENCES CENTRE

NOTE TO FILE (NTF)

Title	Addendum to Network of Networks Standard Operating Procedure (N2 SOP) - SOP 024, Investigational Testing Authorization (ITA) for Medical Devices (non-IVDD) and Manufacturer
SOP Code	SOP 024
Effective Date	June 28, 2022
Approved By	Executive Director, Research Integrity & Clinical Research Services
Section 5.9.1	Description below

Background:

Section 5.9 includes the following statement:

- *5.9.1 – "Maintain the records described in Section 81 of the Medical Device Regulations."*

*The "**Applications for Medical Device Investigational Testing Authorizations (ITA) Guidance Document**" includes the following statement:*

2.4.3 – Record keeping:

- *Under section 80 of the Regulations*, the manufacturer or importer of a medical device undergoing investigational testing in Canada must maintain records as detailed under section 81 of the Regulations.* ***The Regulations do not cover the document retention period for clinical institutions.*** *This* ***period should be in line with institutional policies and provincial regulating bodies for the practice of medicine****.*

*****Medical Device Regulations

Addendum related to section 5.9.1:

As the Medical Device Regulations do not address document retention period for clinical institutions, in order to align with Health Canada regulated trials of drugs and natural health products, Sunnybrook strongly recommends a 15 year retention period for clinical trials regulated under a Medical Device ITA unless otherwise advised in writing by the named sponsor of the ITA.

Revision History	
Version Number	**Summary of Changes**
1.0	Original version

This N2 SOP NTF has been reviewed and approved for use by:

Keitha McMurray
Keitha McMurray (Jun 28, 2022 13:22 EDT)

Keitha McMurray
Executive Director, Research Integrity & Clinical Research Services

28-Jun-2022
Date of Signature *(dd-mmm-yyyy)*