

Guidance for Participants, Sponsors, and Researchers: Information about the changes to Clinical Trial Record Retention Periods

On February 11th 2022, Health Canada reduced the amount of time that clinical trial records need to be kept from 25 years to 15 years¹.

These changes apply to clinical trials that involve drugs* and/or natural health products carried out under these regulations.

To help manage this change, the Sunnybrook Research Ethics Office has provided the following general guidance to Researchers:

- New clinical trials affected by this change should keep records for 15 years and this should be reflected in relevant study documents. See the Sunnybrook REB Informed Consent Template for updated language.
- For ongoing clinical trials, participants should have an opportunity to ask questions about this change before it is implemented. Sunnybrook recommends that Researchers wait until January 1, 2023 at which time the record retention period may be changed from 25 to 15 years**, provided:
 - there has been no indication that study participants want their study records kept for 25 years, and
 - the study sponsor agrees with this change.

For questions about this change, please contact the [Manager, Research Ethics](#)

REFERENCE

¹Health Canada (2022, March 28). Notice: Period reduced for keeping clinical trial records for drugs and natural health products. Government of Canada. <https://www.canada.ca/en/health-canada/services/clinical-trials/notice-period-reduced-keeping-records-drugs-natural-health-products.html>

*Includes pharmaceuticals, biologics, gene therapies, cell therapies, blood products, vaccines and radiopharmaceuticals for human use.

**for clinical trials involving pediatric populations, the 15 year record retention period starts after the participant's 18th birthday.