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MEMORANDUM

DATE:	March 25, 2022
TO:	Island Health Research Community
FROM:	Island Health Research Ethics & Compliance, Clinical and Health Research Ethics Boards
RE:	Retention period reduced for keeping clinical trial records for drugs and natural health products

Health Canada is reducing the retention period for clinical trial records for drugs and natural health products from 25 years to 15 years under the Food and Drug Regulations and Natural Health Products Regulations. This change takes effect as of February 11, 2022.

Previously, clinical trial sponsors had to keep clinical trial records for 25 years. The new shorter period reflects their concerns about the cost and administrative burden the 25-year requirement placed on them.

What sponsors need to know

The period for keeping records starts on the date the record is created. To simplify the process, sponsors may choose to "start the clock" for keeping all study records when the trial is completed or terminated.

Health Canada is consulting stakeholders on the start date through consultations for the plan to modernize the regulation of clinical trials.

The requirement to keep records for 15 years would apply to sponsors of:

- clinical trials of all drugs and natural health products authorized within the past 15 years
- any new clinical trials authorized as of the date of publication (February 11, 2022)

Health Canada will update documents over time to reflect the change to a 15-year record retention period.

Guidance for Sites Conducting Clinical Trials:

As this will impact many studies, sites, and consent documents, amendments to currently approved research will be required. This is not an issue that will impact participant safety, so the changes can be documented over time such as when the next post approval activity or event is submitted for review. Immediate action is not required.

When there is a planned update to an active, recruiting study, please submit revised consent forms for review at that time. Please include whether and how you plan to share the revised information with

participants. This could be re-consenting using a revised consent form (if the consent form was already being updated) or even a verbal update which would be documented in the study file or other communication (e.g. newsletter). Please contact the Research Ethics & Compliance Office (karen.medler@islandhealth.ca) if you would like to discuss a particular study or situation.

When submitting a new study, please adjust your record retention period to 15 years unless otherwise instructed by the sponsor.

Sincerely,

E. Sarah Bennett
Manager, Research Ethics & Compliance