

Change to Health Canada Record Retention Period

Effective February 11 2022, Health Canada is reducing the retention period for clinical trial records from 25 years to 15 years.

All studies being closed on or after February 11 2022 in ReDA (Lawson Approval software), which are Health Canada regulated, will be retained for 15 years.

Additional Considerations

External Sponsors

- The Sponsor is ultimately responsible for the conduct of the trial and would be notified in the event of a regulatory inspection.
- If you are working with on a Health Canada regulated trial with an external sponsor (industry or investigator-initiated), confirm understanding of local site record retention requirements.

In consultation with Western University's Health Sciences Research Ethics Board, the most common Board of Record for Lawson, they have the following guidance;

- No amendment is required specifically for this change in record retention.
- If you are submitting an amendment for another reason, this may be changed.
- If you are submitting an end of study (EOS) notice to the REB, comment if the retention of the records will be modified.
- Ensure it is documented in your study files, if there will be a change from 25 to 15 years retention of the records.

Researchers are asked to consult with other Boards of Records about their policies moving forward.

Reference: <https://www.canada.ca/en/health-canada/services/clinical-trials/notice-period-reduced-keeping-records-drugs-natural-health-products.html>