

Change to Health Canada Record Retention Requirements

- Health Canada has reduced the period for keeping clinical trial records for drugs and natural health products from 25 years to 15 years.
- Change came into force on February 11, 2022
- Requirement applies to:
 - clinical trials of all drugs and natural health products with ongoing record retention obligations prior to February 11, 2022
 - any new clinical trials authorized on or after February 11, 2022



Guidance for Research Teams

Participant Notification

- Inform enrolled participants at the next contact point; document the exchange in the participant's research file
- Participants whose participation has ended do not need to be contacted about this change

Guidance for Research Teams

Consent Form

- Update the study consent form to reflect the new retention period
- If the *only* change is changing the retention period from 25 years to 15 years, the revised consent does not need to be submitted to the REB
 - Document the administrative change in a note to file in your study documentation and include with a future REB amendment, if there is one