

FAQ: The CanReview Agreement

This document provides answers and responses to the most commonly asked questions or comments regarding the CanReview Inter-Institutional Agreement (IIA) and Stream Terms of Service (ToS). It is written in plain language to support informed, confident adoption. For governance or legal precision, the executed IIA/ToS prevails. If you have further questions or would like clarification, please contact: info@canreview.ca.

1. CanReview, CTO and Who Does What

Q1: What is CanReview?

CanReview is a national collaboration that enables a single Research Ethics Board (REB) of Record to review a Clinical Study on behalf of multiple participating provinces and territories. It is a coordinated model rather than a legal entity. Institutions join the model by signing the Inter-Institutional Agreement, which sets out how ethics review is delegated, accepted and overseen across jurisdictions. It has a governance structure including international representatives and pan-Canadian, and cross stakeholder participation, including patient and family representatives throughout. Working groups and additional committees will be established as CanReview progresses.

Q2. Can you clarify Clinical Trials Ontario's (CTO) role in relation to the agreement?

CTO is not a party to the Inter-Institutional Agreement because the IIA governs how institutions delegate and accept ethics review, meet CanReview requirements and share oversight responsibilities. These obligations rest with the participating institutions.

CTO's role is distinct. As a non-profit organization, CTO is the host organization for CanReview. CTO operates the Stream platform and provides program administration services, and that relationship is governed separately through the Terms of Service (ToS) signed between each institution and CTO.

Q3. Is CTO only providing a Terms of Service? Where are broader obligations like REB validation, REB of Record assignment and fees set out?

The ToS covers platform access and CTO's service commitments.

The IIA is where program obligations for institutions are set out, including:

- CanReview Validation Requirements (Schedule A)
- REB of Record assignment process (Exhibit A)
- Fee collection and distribution model (Exhibit A), which CTO administers through Stream
Fee collection rates have historically remained very high at approximately 98 percent.

2. Participation and Roles

Q4. Does every institution have to act as both Recruiting Site and REB Host Institution?

No. An institution may participate as a Recruiting Site only, a REB Host Institution only, or both.

Q5. Who leads the study-wide submission in Stream?

For industry-sponsored studies, the sponsor or contract research organization (CRO) typically designates a lead site. For investigator-initiated studies, the lead investigator or the site receiving funds usually leads the submission.

Q6. Which studies can be submitted to CanReview?

CanReview applies to any study with at least one site in two or more provinces or territories where the participating sites have joined CanReview. Both clinical trials and health related observational studies can be submitted.

Q7. Can private entities or non-academic clinics and private REBs participate?

Private or non-academic organizations may participate if they sign the IIA and meet all operational and validation requirements. Broader community consultation would occur before admitting private REBs.

Q8. Can institutions join later?

Yes. Institutions may join the IIA and ToS any time they are ready. Existing parties will be notified, and attestation materials will be circulated and posted.

Q9. If some sites in a multi-province study haven't joined CanReview, what happens?

Sites that have not joined CanReview continue to follow their local ethics review pathway. CanReview can still be used for participating sites if the two-province condition is met among CanReview institutions.

Q10. How will institutions be supported to take on roles like Country Lead or Provincial Applicant?

The CanReview Central Navigator will support study teams when preparing submissions and understanding role expectations. CanReview will also maintain jurisdictional summaries to help REBs apply province-specific requirements.

3. Governing Laws and Jurisdiction

Q11. Earlier drafts referred to Manitoba law. Why does the final IIA use Ontario law?

Manitoba was initially proposed as a neutral jurisdiction for the IIA, while Ontario law already applied to the ToS. During consultation, institutions expressed a preference for a single governing law across both documents. The IIA was therefore aligned with the ToS under Ontario law to reduce complexity.

Q12. How does CanReview work where external review can't be delegated?

In jurisdictions with legislative or policy barriers to external review, CanReview will use facilitated approaches and enable parallel review through system access. Feedback from these provinces has informed the agreement to reflect local realities and pave the way for future participation as conditions evolve.

4. Compliance, Local Requirements and Privacy

Q13. Who is responsible for complying with provincial differences such as privacy laws or age of consent?

Each site must disclose its local requirements during onboarding. CanReview will maintain provincial jurisdictional summaries to support REBs of Record in applying the correct requirements.

Q14. Will REBs continue to apply their local privacy laws (e.g., PHIPA in Ontario)?

Yes. REBs continue to review in accordance with their local legislative frameworks. Provincial differences are captured through onboarding and jurisdictional summaries.

Q15. Will there be a process to ensure local institutional context is respected?

Yes. Institutions will provide materials describing policies and requirements that are relevant for ethics review at their sites. These inform the REB of Record's review and CanReview's operational processes.

Q16. How are Conflicts of Interest (COI) and local eligibility/training handled when the REB of Record is elsewhere?

Sites complete a local application that includes COI declarations and any required attestations. Institutions remain responsible for training, appointments and contracts. A site may decline participation if its local requirements are not met.

5. Language, Accessibility & Participant Contact

Q17. How will English/French bilingual requirements be handled?

Stream supports both official languages, but REB language capacity varies. Some boards require bilingual participant materials, while most accept English protocols with local French translations where needed. CanReview is exploring options to strengthen bilingual review capacity across the network to ensure consistent implementation.

Q18. How will participants contact an out-of-province REB of Record?

Consent forms will clearly display REB contact information, and additional guidance will address time zones, language access, and cultural considerations, ensuring participants can communicate easily and confidently.

6. Timelines, Review Workflow & Fair Distribution

Q19. What are the core REB timelines? What if an REB can't meet them?

For the initial country-wide review of the study protocol and study-wide materials (e.g., consent template, investigator brochure)

- 2 business days for REBs to accept or decline a study.
- 28 business days to provide initial feedback after acceptance.
- 5 business days for the research team to respond to feedback
 - If the REB determines that further clarification is needed, a 5-day cycle repeats: the PI has 5 business days to respond, and the REB has 5 business days to review. This cycle continues until the site receives approval.
- If an REB cannot meet these timelines, it is expected to decline assignment so the study can be reassigned. The REB will retain its place in the rotation.

For individual site approval:

- 5 business days for delegated review
- 2 business days for the PI to provide any required clarifications or modifications.
- 2 business days for the REB to review the PI's response and issue a decision.
 - If the REB determines that further clarification is needed, a 2-day cycle repeats: the PI has 2 business days to respond, and the REB has 2 business days to review. This cycle continues until the site receives approval.

Q20. What are the consequences of not meeting timelines? Will there be dispute resolution or flexibility in exceptional circumstances?

High-quality submissions and research ethics review processes are paramount to CanReview. The timelines for REB review and research team/investigator responses outlined on the CanReview website have been endorsed by the pan-Canadian/cross stakeholder Timelines and Transparency Tactical team and reflect processes already followed by REBs when circumstances allow. In cases where the review of a study or the responses by the investigators/research teams require additional time to ensure a high-quality ethics review, a process to 'stop the clock' will be employed. In the first year of CanReview operations the focus will be on understanding how the system and timelines are working, and providing supports.

Q21. Are two-day response timelines for a REB to accept or decline studies realistic?

Yes. Ontario has successfully operated under a two-day policy for over a decade. National adoption will allow for flexibility and communication where needed.

Q22. Will exceptions be allowed where delays are outside REB/site control?

Yes. Exceptions will be handled on a case-by-case basis, recognizing that some delays are beyond institutional control.

Q23. How are reviews distributed fairly among REBs?

Industry-sponsored studies are assigned by rotation (unless they require a specialized board). Investigator-initiated studies typically go to the REB at the Principal Investigator's institution, if that REB is serving as CanReview Participating REB and available to conduct the review. CanReview monitors assignment patterns and supports REBs that decline frequently to maintain balanced participation. The REB assignment process is outlined [here](#).

7. Fees, Compensation & Transparency

Q24. Will local REBs be compensated when they are not the REB of Record?

Yes. A national fee schedule provides compensation for both REBs of Record and local REBs when their sites participate in industry-sponsored studies. The fee schedule is available [here](#).

Q25. How will aggregated data be used and published?

The compilation, review and dissemination of aggregated data is crucial for supporting continuing quality improvements and promoting the benefits of CanReview. Aggregated data that is disseminated will focus on timelines, process metrics (e.g., REB vs. investigator intervals) and factors related to timelines. The scope of public reporting will be clearly defined in communications.

Q26. Will investigator names be posted publicly?

No. Transparency focuses on institutional-level data, not personal identifiers.

8. Stream Platform: Data, Security & Continuity

Q27. Why does the Stream privacy policy collect personal and technical data?

Personal data supports account creation and application processes. Technical data helps with troubleshooting and security. The policy provides strong protections. Not all fields are mandatory, allowing some flexibility.

Q28. What information is intended to be stored in Stream? And are patient records included?

Stream holds study applications, protocols, consent forms, participant materials and REB documentation. It is not designed to store clinical charts or patient-level medical records. When REBs require access to participant records (for example, during an on-site assessment), that happens through the Recruiting Site's own systems, under that site's privacy and security requirements.

Q29. Why is the definition of Personal Health Information broad?

The definition is broad enough to accommodate differing provincial privacy statutes and institutional policies across Canada. This helps ensure that information that would be treated as health information in any participating jurisdiction receives appropriate protection. Even with this broad definition, Stream is not intended to hold patient charts or clinical records.

Q30. Where is data stored? Will it move to Canada?

Stream data is currently stored in the United Kingdom, with migration to Canadian servers planned by the end of 2025.

Q31. What security standards apply to Stream?

Security standards are detailed in Exhibit B of the agreement.

Q32. What happens if Stream is unavailable or there is a cyber incident?

The vendor maintains business continuity, backup and disaster recovery processes. Institutions may also keep local copies of key documents. Stream has not experienced major outages in the past decade.

Q33. What protections exist if CTO terminates Stream access?

This question came up earlier in the process, before the termination language was updated. The current agreements already include safeguards to prevent any disruption if CTO ends Stream access.

Under the ToS, if CTO terminates access, institutions are provided a defined period to retrieve their data, and CTO will make reasonable efforts to provide copies of Organization Data on request. Termination of the ToS does not release institutions from obligations under the IIA, and the IIA requires continuity of REB oversight until a new arrangement is in place.

Q34. How will the REB of Record provide required notifications in situations where Stream isn't an appropriate channel?

For certain sensitive matters, such as specific participant complaints or privacy issues, the agreement now requires written notification without tying it to Stream. This allows the REB of Record to contact the Recruiting Site and Principal Investigator directly through the most appropriate written communication method, while Stream remains the system of record for study documentation and status updates.

Q35. Does CTO "flow down" vendor indemnities or insurance obligations to institutions?

CTO is subject to confidentiality obligations that prevent it from disclosing the terms of the contract with the platform's vendor (the "**Vendor Contract**"). CTO can confirm, however, that the Vendor Contract includes commercial terms requiring the vendor to maintain minimum insurance coverage and satisfy various security requirements, together with indemnification obligations.

The Vendor Contract does not extend the benefit of these provisions to institutions. The CanReview Terms of Service include indemnification and liability provisions that meet or exceed the standard expectations for SaaS products and generally align with the provisions found in the Vendor Contract, however.

9. Standards, Schedules & Supporting Materials

Q36. What happens if hyperlinks to REB validation standards or other referenced documents change?

Standards track external policy. CanReview will maintain formal notice mechanisms and strong communications so REBs are alerted and have time to align. Institutions may maintain their own copies of documents.

Q37. How broad was consultation on the draft IIA and ToS?

The draft was shared widely through national networks, including HealthCareCAN, ACT Networks, and targeted provincial outreach. Institutions from nine provinces accessed the agreement, demonstrating strong national engagement. Feedback from these consultations informed revisions to the agreements and this FAQ.

10. Withdrawal, Termination & Force Majeure

Q38. Can an institution fully withdraw from the IIA?

Yes. An institution may end its participation in the IIA by providing written notice as set out in Section 5. Withdrawal applies only to that institution. The IIA requires that REB oversight for ongoing studies continue until a new REB of Record or alternative arrangement is in place. This protects participant safety and avoids gaps in review during the transition.

Q39. What is the difference between withdrawing from a Clinical Study and withdrawing from the IIA?

Study-level withdrawal follows the withdrawal provisions for that specific study and focuses on participant protection.

Withdrawing from the IIA affects future participation in CanReview and does not automatically stop oversight of ongoing studies.

Q40. If a Recruiting Site withdraws delegation, how is oversight transferred?

Section 4 of the IIA sets out the conditions and notice requirements for withdrawing delegation. Stream supports export of relevant documents to facilitate transition of oversight.

Q41. Will REBs of Record audit other institutions, and how are serious adverse events handled?

Off-site audits by REBs of Record are not contemplated in the IIA. Serious adverse events and unanticipated problems are reported to the REB of Record according to applicable regulations and institutional policies, with cross-site visibility in Stream where relevant.

Q42. If a Data Sharing Agreement appears to conflict with the IIA or ToS, which governs?

The IIA and ToS govern ethics reliance and use of Stream. Data Sharing Agreements and other

study-level contracts govern data transfer and conduct of the study. They are intended to be complementary, no overlap is expected.

Q43. Is the force majeure clause (e.g., wildfires, floods) robust enough?

Force majeure covers events beyond a Party's control. Parties must still make reasonable efforts to avoid gaps in ethics oversight, including transitioning oversight when required. The clause was reviewed during consultations and updated.

11. Why Adopt CanReview?

- Faster starts, less duplication. One qualified REB of Record for multi-province studies speeds up site activation and reduces parallel reviews.
- Stronger consistency and transparency. Shared timelines and national performance metrics support better planning.
- Predictability for REBs, sites, and sponsors. A single national framework and clear service standards reduce negotiation cycles and uncertainty.
- Respect for local context. Provincial summaries and a DIER-like process ensure local legal and ethical considerations are preserved.
- Right-sized participation. Institutions can choose their role per study—site, REB host, or both—based on capacity.
- Sustainable resourcing. A national fee schedule and equitable assignment model strengthen REB capacity across Canada.

To learn more and get started with CanReview, please visit:
www.canreview.ca.