Frequently asked questions

Research at Covenant

Covenant values the benefits research brings to patients and residents including best practice care and access to new drugs, devices, and other treatments available through participation in research studies; and to staff and physicians in the provision of best practice patient care and for learning…

…All research involving Covenant must be conducted with integrity, comply with national and provincial legislation and standards, and align with Covenant policies and procedures.[1]

*For further information or questions regarding this document or its contents, and/or to engage our team for assistance with research matters, please submit to our **Intake**.*

Contents

[1] https://covenanthealth.ca/sites/default/files/2023-08/policy-III-10-research.pdf

Section: Research operational/administrative review and approval

Operational/administrative review is required for any research activity including a Covenant site: where resources are utilized; patients, residents, staff, physicians, or volunteers are involved; and records or data are accessed. Recruitment or screening of patients or residents and staff are also considered a research activity, even if the research study is conducted at a non-Covenant site.

Operational review is required to ensure that any research study in context is feasible, that any negative impacts on patient care and staffing are mitigated, and capacity or resourcing is assessed to ensure appropriate supports for clinical health research conducted within Covenant sites.

Administrative review is required to ensure that any research aligns with organization mission, vision, values, and including principles described in the Health Ethics Guide. Additionally, administrative review process establishes that any research proposed is compliant with required prerequisites described in **policy**, as well as national and provincial legislation and standards.

Question: I have approval from AHS/NACTRC for my research study. Is Covenant review and approval still required?

Covenant is a distinct legal entity from AHS and with an independent leadership structure. Operational/administrative approval is required for any research studies involving Covenant.

Question: I would like to recruit research participants ONLY at Covenant, with all other study activities taking place external to Covenant sites. Is Covenant review and approval still required?

Recruitment of research participants is a research activity. Covenant review and approval is required before proceeding.

Question: I am not a Covenant-privileged physician or employee. How do I access Covenant sites to conduct my research?

Interventional clinical trials that require a Covenant site for patient-participant access including for example, medication administration or other treatments, will require a local site PI with Covenant privileges.

Other types of studies are assessed on a case-by-case basis and may involve site-access agreements for the PI and their designated team and/or some other type of agreement.

Question: I want to access health information or other forms of data ONLY. Is Covenant review and approval still required?

Covenant is a custodian for patient health information, as outlined within the Health Information Act (HIA). As such, we must conduct our due diligence to be compliant with the HIA; Covenant review is required.

Question: I ONLY want to circulate an on-line survey. Is Covenant review and approval still required?

Yes, operational/administrative review is required to proceed. And if the on-line survey is from another jurisdiction within Canada, Covenant will accept a valid Canadian (TCPS2) REB approval from outside of Alberta.

Question: How long does a Covenant operational/administrative review take?

Research study applications are screened, assessed, and circulated for reviews based on their unique contexts, attributes and requirements - operational impacts, agreements, etc. so it is difficult to generalize application to approval process times.

Our goal is to address your study as soon as the application form is completed – usually the same day and to circulate for reviews soon thereafter.

So, depending upon the complexity of the study and reviews required, we very often provide an approval to proceed within ten business days or less.

Question: I am a designated member of the research team. Can I take the application and get our own signatures to speed things up?

The CHRC is best positioned to screen, circulate, seek feedback, record, compile etc. as well as collect reviews and corresponding signatures for your study across impacted departments and relevant corporate services within Covenant. Signatures sourced from outside of our processes will not be accepted.

Question: I am a designated member of the research team. Can I validate and e-sign the research application on behalf of the PI?

The application intake has recently been re-designed (2025March) to accommodate how research teams complete the form. A designated research team member (or PI) can enter research study information in parts 1, 2, and 3.

However, both the overall application intake and the Section 54 agreement are intended to be signed solely by the individual accountable for the integrity and conduct of the study and its team: the PI. Within the application, the PI must ensure that all submitted information

(parts 1, 2, and 3) accurately represents how the study will be conducted. Additionally, the PI is required to review and agree to the HIA agreement and associated research terms. Signatures from anyone other than the PI will not be accepted.

Question: My research study does not involve accessing health information, do I still have to complete and e-sign the Health Information Act (HIA) agreement?

The Section 54 (HIA) agreement not only complies with HIA requirements – regardless of involving health information - but also outlines a series of Covenant conditions for the conduct of the research study and must be agreed to and signed.

Question: How do I access the Covenant logo to use on approved research study information letter and informed consent form, and other relevant documents?

Contact our office using research@covenanthealth.ca and request the logo and a guidance document outlining use. If you are a Covenant employee or Covenant-privileged physician and you have access to Compassion Net (CNet), you will find logos and associated guidance here.

Section: Ethics review and approval

Covenant subscribes to the ethical principles outlined in the national Tri-Council Policy Statement (TCPS2), the National Institutes of Health (NIH) core values for research integrity, and also research practice as outlined within International Council for Harmonization Good Clinical Practice (GCP) for clinical research. Furthermore, the Alberta Health Information Act (HIA) requires Covenant Health as a custodian to maintain responsibility for access, collection, use and disclosure of health information under its purview, including for the purposes of research. So to safeguard patient privacy and safety in compliance with legislation and best practice, review and current approval from an Alberta HIA-designated ethics board is required.

Covenant also subscribes to the Health Ethics Guide – a collaboration document produced by the Catholic Health Alliance of Canada – which upholds research as important to affirm solidarity with others. The Health Ethics Guide also promotes the broader benefits of research: "*…research must always respect and safeguard the life, dignity and integrity of the persons involved. It should respond to the communities involved and be directed to the benefit of the community as a whole*…."

Question: How do I determine if ethics review and approval is required for my project?

Ethics review is required for all research studies.

If the project is a pilot study, it must be submitted for ethics review prior to proceeding. This is supported within TCPS2 Guidance and furthermore by TCPS2 Article 2.1.

If the project is Quality Assurance/Quality Improvement and it is not clear as to whether ethics review is required, an ethics review determination with **written confirmation** from the HREB at the University of Alberta is required to submit to research@covenanthealth.ca.

Question: I am not affiliated with the University of Alberta or the University of Calgary to access their systems. How do I obtain a CCID for ethics review?

Guest CCIDs are accessible for external applicants: for the University of Alberta ARISE system, or for the University of Calgary IRISS system.

Question: What is REBX and how does it work?

The REB Exchange streamlines the ethics application process for multi-site health research in Alberta and allows for easy collaboration between lead and participating sites (pSites). It is a simple, easy-to-use tool, built into the ethics application platform (ARISE or IRISS).

Question: I have ethics approval from a non-Alberta Canadian REB. Is an Alberta REB review and approval required?

Research studies approved through a non-Alberta Canadian REB and that are proposing to extend into Alberta, do require application through an Alberta REB; however, with a valid Canadian TCPS2 REB approval, only delegated review as opposed to full board review is required (ARISE or IRISS).

Multi-jurisdictional research info Multi-Jurisdictional Research: The Interagency Advisory Panel on Research Ethics (PRE)

Question: The bulk of my research study is completed. Do I have to maintain current ethics approval?

Current ethics approval is necessary to access Covenant sites, staff, participants, health records, etc. or to conduct any other kind of research activities. If access to Covenant is no longer required by the PI/research team, then current ethics is not required.

Consider if the study is not fully completed and there is a risk that some future access may be needed (e.g., validation, follow-up questions), that it is easier to renew than to have to reapply for ethics approval again.

Section: Legal contracts and agreements

The Covenant Legal team assists in reviewing, drafting, and administering all contracts and agreements involving Covenant, and the CHRC Coordinator engages Covenant Legal Counsel for all relevant research studies as required.

Contracts and agreements can be attached to the research application intake or emailed to research@covenanthealth.ca if prior to a study being submitted for operational/administrative review.

Question: Does Covenant have to be a party to my Clinical Trial Agreement (CTA)?

Covenant is a distinct legal entity from AHS, with an independent leadership structure. As such, all corresponding research agreements (e.g HIA Section 54 agreements, Site Access agreements, etc.) must be in place with Covenant. Likewise, and for CTAs, Covenant must be included, either independently or in party with (e.g., AHS) unless established as not required by Covenant Legal Counsel.

All such agreements will be addressed by our Legal Team on a case-by-case basis.

Question: Are wet signatures required for legal agreements at Covenant?

Currently the operational/administrative research review intake which includes the HIA Section 54 agreement only requires intake validation and e-signature by the PI.

Other types of documents and agreements may require a wet signature, and all such requirements will be indicated by the Legal Team at time of request.

Section: Operations - sites and units

All Covenant Health, Covenant Care, and Covenant Living sites can be accessible for research, depending upon study requirements and relevant site suitability. General information regarding all sites can be accessed through the Covenant Canada website. And the latest Covenant Report to the Community contains site-specific information including facts and figures that may be useful to identify an appropriate site for research.

Question: What sites are appropriate for the type of study that I want to conduct?

Covenant Health is one of Canada's largest Catholic providers of healthcare services (acute and continuing care) in hospitals and healthcare centres in both urban and rural communities across Alberta, currently situated in seventeen sites across twelve communities.

Covenant Care is a major provider of supportive living, long-term care, and hospice services, located in eight sites across six communities.

And Covenant Living is a private not-for-profit organization providing independent living options for seniors, including two sites across two communities.

Consult the Covenant Canada website and the latest Covenant Report to the Community for detailed information, or request assistance by emailing research@covenanthealth.ca.

Question: Are there spaces available for me and my team onsite?

Some sites do have drop-down spaces available. If you are seeking assistance in identifying space at a particular site, please submit your request **here**.

Question: My policies are different at my home or affiliated insititution. Which policy am I required to observe?

For research conducted on-site at Covenant, you are required to observe Covenant policy.

Question: My team requires access to Connect Care, who do I contact?

For access to Connect Care, email research.administration@ahs.ca for assistance.