| PROCEDURE<br>III-10.PROC.1 | **Research Process** | **DOMAIN**<br>**Governance and Ethics** |
|---|---|---|
| **Sponsor:** Chief Innovation Officer<br><br>**Lead(s):** Manager, Covenant Health Research Centre (CHRC) | | **Date Approved: September 24, 2024**<br>**Date Effective: September 24, 2024**<br>**Date of Next Review: September 2027** |

For further information please contact covenantpolicy@covenanthealth.ca

**Purpose Statement:**

The Research policy III-10 and ancillary processes provide direction for anyone proposing and conducting research projects or recruiting research participants at any Covenant Health site; these also provide direction for leaders who are engaged in the operational/administrative reviews process for research studies, as well as any staff who are engaged with and/or participate in research studies.

**Parent Policy:**

III-10 Research

**Applicability:**

These processes apply to any research activity including a Covenant Health site: where resources are utilized; patients, residents, staff, physicians, or volunteers are involved; and records or data are accessed [see **Exceptions**]. 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 Health site.

**Responsibility:**

All Covenant Health facilities, staff, medical staff, students, volunteers and any other persons acting on behalf of Covenant Health including researchers and their designates, whether directly affiliated with Covenant Health or not.

**Health Ethics Harmonization and Research Ethics Board Exchange (REBX):**

In March 2014, Covenant Health participated with our ACRC partners in signing a provincial reciprocity agreement. Although the primary health ethics board for Covenant Health research remains at the UofA HREB (ARISE platform) in keeping with our tri-partite agreement, ethics reviews from other HIA-designated boards in Alberta will be accepted as equivalent. This is important for Covenant Health researchers who have an academic affiliation with e.g., the University of Alberta or University of Calgary (IRISS platform), and who intend to conduct research at Covenant Health sites.

Furthermore in 2021, the **Research Ethics Board Exchange (REBX)** was launched to facilitate sharing across the REB platforms for multi-site research. Using this mechanism, a lead principal investigator can submit their study as usual and any additional sites – with different site-investigators, can be added regardless of platform (ARISE or IRISS). Ethics review for additional sites – with an approved primary study, would involve review of local and additional documents only.

Alberta HIA-designated boards include:

- **Conjoint Health Research Ethics Board (CHREB)**, using the IRISS platform – University of Calgary
- **Health Research Ethics Board (HREB)**, using the ARISE platform – University of Alberta
- **Health Research Ethics Board of Alberta (HREBA)**, using the IRISS platform – Alberta Innovates
    - Clinical Trials Committee (HREBA-CTC)
    - Community Health Committee (HREBA-CHC)
    - Cancer Committee (HREBA-CC)

**Procedure:**

All research involving or conducted at Covenant Health requires:

1. Ethics review through an Alberta Health Information Act (HIA)-designated ethics board [see **Exceptions**] to assess compliance in accordance with the Tri-Council Policy Statement (TCPS2), Alberta HIA and Freedom of Information and Protection of Privacy Act (FOIP); with achieved ethics approval status renewed annually; and
2. Operational and Administrative review and approval coordinated through the Covenant Health Research Centre, including:
    a. Review through Legal, Risk Management and/or Finance as appropriate when site access agreements are required, when established legal agreements must be reviewed, and/or when an agreement with a sponsor or funder is required;
    b. Operational review to assess feasibility and capacity including adequate staff and other resources, as well as required structure and organization; and
    c. Final administrative review to ensure all other required reviews are completed in compliance with organization values and policies, and in alignment with ethical principles outlined in the Health Ethics Guide.

**Steps include:**

1. Initiate the research ethics review process at an Alberta HIA-designated research ethics board:
    a. If the REB deems that the project does not require ethics review – as established in the TCPS2 – then a letter from that REB stating same will be required to proceed with operational/administrative review.
    b. If not considered research, there may be other types of review required – e.g., QA/QI, consult accordingly.
2. Submit a completed and signed on-line CHRC application intake and attach a completed and signed HIA agreement.
    a. Only signatures from responsible principal investigator will be accepted;
    b. All information fields and checkboxes within forms should be completed; and
    c. All other documents will be accessed through the REB. If there are documents that you have not submitted through the REB and that are necessary to understand site access and impact (e.g., contracts), please submit those to the CHRC as requested.
3. Submit any sponsor and/or granting agency agreement(s) to the CHRC for further Legal/risk management review. These types of documents can also be uploaded as part of the CHRC application intake.
4. Attend an orientation meeting: once both REB and CHRC approvals are in place, the CHRC coordinator will plan for an orientation as appropriate for team - PI and designated staff and impacted Covenant Health unit/department staff as relevant/required.
5. Acknowledge Terms of Reference for a research trust account, if appropriate [Covenant Health

Finance].
6. Ensure that REB approvals are renewed annually prior to the expiry date and throughout the duration of the study.
7. Submit any Adverse Event Reports to the REB and through RLS as appropriate.
8. Submit any amendments to study protocols, agreements, etc. to the REB (as an administrative amendment).
9. Notify the REB when a study is formally closed.
10. Complete and Submit an online Final Report as well as any associated articles and papers.
11. Contact the CHRC for **knowledge exchange** and transfer opportunities/**dissemination** for your study.

## Exceptions:

**Exception to Alberta ethics board review requirements:**

- Quality Assurance/Quality Improvement projects vs research, where screening and **written confirmation** from the HREB at the UofA has established that ethics review is not required. Please note that QA/QI initiatives may require non-research types of screening through the Covenant Health Quality portfolio.

  **Note 1** – As the primary Covenant Health ethics board is the HREB, all requirements for health ethics review outlined will reflect review requirements by the HREB.

  **Note 2** – education institutions other than UofA or UofC, and that wish to conduct research at Covenant Health sites regardless of any local ethics boards, must submit through either the UofA ARISE platform (Covenant Health primary board), or through any of the other Alberta HIA-designated boards. In this regard, some institutions already have affiliation for use of the UofA ARISE platform (e.g., University of Lethbridge, Concordia University, Norquest College, Royal Roads College, St. Stephen's College, etc.). In the absence of a direct agreement with the UofA, guest status for submission is available.

**Exception to CHRC operational review requirements:**

- In cases involving Connect Care data and with no additional impacts whatsoever, only AHS review and approval if required to obtain access. AHS is the sole HIA custodian for data within the Connect Care system.
- In cases involving provincial administrative data that includes Covenant Health sites and with no additional impacts whatsoever, only AHS review and approval is required. AHS is the data manager for administrative data across both AHS and Covenant Health; however, if the Covenant Health analytics team is required to consult, pull, or provide any other function, review is required.
    - The last two data cases listed above are exceptions, and all other health and patient databases and charts for which Covenant Health is the custodian, are covered by this policy and researchers must obtain ethics approval and Covenant Health operational/administrative approval prior to access.

## Definitions:

Dissemination – "involves identifying the appropriate audience and tailoring the message and medium to the audience. Dissemination activities can include such things as summaries for/briefings to stakeholders, education sessions with patients, practitioners and/or policy makers, engaging knowledge users in developing and executing dissemination/implementation plan, tools creation, and media engagement."

Knowledge Exchange (KE) – "Knowledge Exchange refers to the ongoing process whereby information and knowledge are shared between relevant individuals and groups. For knowledge exchange to be effective there must be communication between knowledge users and research to promote mutual learning."

## Acronyms:

ACRC = Alberta Clinical Research Consortium
AHS = Alberta Health Services
ARISE = Alberta Research Information Services
CHREB = Conjoint Health Research Ethics Board
CHRC = Covenant Health Research Centre
HIA = Health Information Act
HREB = Health Research Ethics Board
HREBA = Health Research Ethics Board of Alberta
IRISS = Institutional Research Information Services Solution
NIH = National Institutes of Health
REBX = Research Ethics Board Exchange
TCPS2 = Tri-Council Policy Statement
UofA = University of Alberta
UofC = University of Calgary

| **Relevant Covenant Health Policy and Policy Support Documents:** | |
|---|---|
| **A.** | **Policies:**<br>III-15 Conflict of Interest<br>III-60 Contracts<br>III-50 Intellectual Property<br>III-30 Relationships with Industry<br>I-30 Ethical Decision-making Framework<br>X-20 Collection and Use of Personal or Information<br>X-10 Confidentiality Agreement and Privacy Training<br>X-35 Disclosure of Personal or Information to Third Parties<br>X-60 Transmission of Personal or Information<br>X-65 Transportation of Personal or Information |
| **B.** | **Procedures:** |
| **C.** | **Guidelines:**<br>*Division 5 of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects (GUI-0100);<br>*General guidelines for accessing paper records; |

| | |
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| | *Participant recruitment guidance for research; and<br>*Vanessa's Law, SAEs, RLS, and how they apply to researchers at Covenant Health |
| **D.** | **Job aids:**<br>*ACHRC – research Roadmap;<br>*ACHRC – Glossary;<br>*QI/QA vs Research, and how to distinguish the difference |
| **E.** | **Standards:**<br>*Tri-Agency Framework: Responsible Conduct of Research (2016);<br>*International Conference on Harmonization GCP-ECH E6 (R3);<br>*Canada Division 5-Drugs for Clinical Trials Involving Human Subjects;<br>*Health Canada medical devices;<br>*Health Ethics Guide;<br>*Health Information Act;<br>*FOIP;<br>*National Institute of Health (NIH) – Research Integrity; and<br>*Vanessa's Law; |

**Keywords:**

Research, clinical trials, research ethics, researchers, innovation, medical devices, participants

**References:**

Covenant Health:

- Our Commitment to Ethical Integrity
- Reporting and Learning System (RLS)

Covenant Health Research Centre (CHRC):

- Email research@covenanthealth.ca ; researchprojects@covenanthealth.ca ; researchmanager@covenanthealth.ca ; clinicalresearch@covenanthealth.ca .
- Intake form on-line https://redcap.albertahealthservices.ca/surveys/?s=RALWCPXJEP3XDJWD
- Website http://www.covenanthealth.ca/research-centre and Compassion Net https://www.compassionnet.ca/Page7821.aspx

Alberta:

- Alberta Clinical Research Consortium (ACRC)
- Alberta Health Services (AHS)
- Alberta Research Information Service (ARISE)
- Clinical Trials Alberta (CTA)
- Health Research Ethics Board (HREB)
- Institutional Research Information Services Solution (IRISS)
- REB Exchange (REBX)

**Past Revisions:**

September 11, 2015