POLICY III-10	Research	DOMAIN Governance and Ethics
SLT Sponsor: Chief Innovation Officer **Policy Lead:** Manager, Covenant Health Research Centre		**Date Approved:** September 24, 2024 **Date Effective:** September 24, 2024 **Date of Next Review:** September 2027

For further information please contact Covenant Healthpolicy@Covenant Healthhealth.ca

NOTE: The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definition section

Policy Statement:

Covenant Health values the benefits research brings to patients 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.

Participation in research aligns with Covenant Health values, is inherent to our Innovation Strategy and furthers Covenant Health's equity, diversity, and inclusion strategy.

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

Purpose Statement:

The Covenant Health Research Centre (CHRC) aims to build research capacity by providing guidance and support for Covenant researchers, and for research conducted at Covenant Health. This policy provides direction for anyone proposing and conducting research projects or recruiting research participants at any Covenant Health site. This policy also provides 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.

Applicability:

This policy applies 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:

Covenant Health Research Centre will demonstrate compliance with this policy by facilitating and coordinating processes for all Covenant Health research study applications; including to ensure current research ethics approval; Legal, Risk Management, and Finance reviews where applicable; and site operational/administrative reviews.

Covenant Health Leaders will route any research requests to the CHRC, and otherwise will ensure that any research underway is approved to proceed at Covenant Health with proof of review (1. current ethics approval letter issued by an Alberta HIA-designated ethics board, and 2. an operational/administrative approval letter issued by the CHRC):

- Operational reviews are the responsibility of relevant Covenant Health program/department managers;
- Administrative reviews are the responsibility of relevant Covenant Health Senior Site Directors, Administrators or Operating Officers, and are further supported by the Chief Mission Ethics & Spirituality Officer when potential conflicts with the Health Ethics Guide or other organization milieu are identified;
- Financial reviews are the responsibility of Covenant Health Finance;
- Legal reviews are the responsibility of Covenant Health Legal/Risk Management; and
- Permission to approach is the responsibility of Covenant Health clinical staff independent of - not associated with the research project.

Researchers will demonstrate compliance with this policy by submitting all required documentation to the appropriate Alberta HIA-designated research ethics board and once such approval is obtained, then to the CHRC for review. Furthermore, researchers and their designates will refrain from pursuing or initiating any research activity until such time that all required approvals are in place.

Researchers and their designates will conduct their work with integrity - in all aspects of the research enterprise - in an honest, responsible, and accountable manner that reflects Covenant Health Values and Code of Conduct in addition to other relevant discipline, institutional and governance conventions; these include but are not limited to: Alberta HIA, FOIP, Good Clinical Practice ICH E6 (R3), TCPS2, Health Ethics Guide, Health Canada – Division 5, National Institute of Health (NIH), etc.

Principles:

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. In addition, we engage in Section 54 research agreements with researchers to identify and clarify those conditions as outlined above.

Site Access Agreements may also be required; for example, for studies where the Principal Investigator (PI) – and research personnel under their supervision, does not have Covenant privileges and requires access to Covenant sites.

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 appropriately assessed to ensure appropriate supports for clinical health research conducted in Covenant facilities. Covenant complies with Accreditation Canada Leadership Standards, which relevant to research includes organization ethical and operational due diligence.

Covenant is a health system partner with Alberta Health Services (AHS); as a separate legal entity to AHS, any legal contracts, section 54 agreements or site access agreements required for compliance must be negotiated with Covenant directly.

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*…."

And finally demonstrating leadership in partnership with academic institutions, participating in and/or facilitating the conduct of academic research is important to build knowledge that can be of benefit to the broader community.

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.

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:** III-15 Conflict of Interest III-60 Contracts III-50 Intellectual Property III-30 Relationships with Industry I-30 Ethical Decision-making Framework X-20 Collection and Use of Personal or Information X-10 Confidentiality Agreement and Privacy Training X-35 Disclosure of Personal or Information to Third Parties X-60 Transmission of Personal or Information X-65 Transportation of Personal or Information
B.	**Procedures:** III-10.PROC.1 Research Process
C.	**Guidelines:** *Division 5 of the Food and Drug Regulations “Drugs for Clinical Trials Involving Human Subjects (GUI-0100); *General guidelines for accessing paper records; *Participant recruitment guidance for research; and *Vanessa’s Law, SAEs, RLS, and how they apply to researchers at Covenant Health ;
D.	**Job aids:** *ACHRC – research Roadmap; *ACHRC – Glossary; *QI/QA vs Research, and how to distinguish the difference
E.	**Standards:**

	*Tri-Agency Framework: Responsible Conduct of Research (2016); *International Conference on Harmonization GCP-ECH E6 (R3); *Canada Division 5-Drugs for Clinical Trials Involving Human Subjects; *Health Canada medical devices; *Health Ethics Guide; *Health Information Act; *FOIP; *National Institute of Health (NIH) – Research Integrity; and *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