Covenant Health	Research	Corporate Policy & Procedures Manual
		Policy No. III-10
		Date Approved: August 31, 2015
Approved by: Senior Operating Officer – Rural Services, Executive Lead for Research		**Date Effective:** September 11, 2015
		Next Review (3 years from Effective Date) September 2018

Acronyms utilized within this document

Alberta Health Services = AHS
Canadian Institutes of Health Research = CIHR
Conjoint Health Research Ethics Board = CHREB
Covenant Health Research Centre = CHRC
Health Information Act = HIA
Health Research Ethics Board = HREB
Health Research Ethics Board of Alberta = HREBA
Institutional Research Information Services Solution = IRISS
National Institutes of Health = NIH
Research Ethics Management On-line = REMO
University of Alberta = UofA
University of Calgary = UofC

Purpose

This policy will provide direction and process for any individuals either proposing research projects or recruiting for research participants at any Covenant Health site. This policy will also provide direction for staff and/or physicians who are engaged in the review and approval process for research studies.

Policy Statement

The CHRC will support research within Covenant Health facilities by facilitating the research review and approval process, by providing access to research education and knowledge transfer opportunities, and by developing initiatives that promote research, engage researchers, and enhance overall capacity for research.

Applicability

This policy applies to any research activities initiated and/or carried out at a Covenant Health site: where resources are utilized, and/or patients/residents are involved, and/or staff, physicians or volunteers are involved, and/or records or data are accessed. Recruitment or screening of patients/residents is also considered a research activity, even if the research study is taking place at a non-Covenant Health site.

Responsibility

Covenant Health Leaders will demonstrate compliance with this policy and these procedures by engaging their direct reports in directing any research requests to the CHRC; and ensuring that any research underway has the appropriate CHRC approval and current research ethics approval.

The CHRC will demonstrate compliance with this policy and these procedures by facilitating the process for all Covenant Health research study applications, including ensuring research ethics approval, Risk Management/Legal review and approval, as well as operational and administrative approvals.

Researchers will demonstrate compliance with this policy and these procedures by submitting all required documentation to the appropriate HIA-designated research ethics board and the CHRC, and will refrain from pursuing any research activities until all approvals are in place.

Researchers and designates will carry out their work with integrity in all aspects of the research enterprise by conducting research in an honest and responsible - accountable manner that reflects the Covenant Health Values and Code of Conduct; in addition to other relevant discipline, institutional, and governance conventions. These include but are not limited to: CIHR and NIH.

Review and Approvals: Operational review and approval are the responsibility of relevant Covenant Health department managers; administrative review and approval are the responsibility of relevant Directors or Senior Operating Officers, supported by the Vice President, Mission, Ethics and Spirituality if there are any potential conflicts with the *Health Ethics Guide*; organizational risk, legal review and approval are the responsibility of Finance-Risk Management/Legal. Research ethics review – primary, is the responsibility of the HREB, as defined by the Tripartite agreement representing the UofA, AHS and Covenant Health. **See Ethics Harmonization.**

Principles

Covenant Health recognizes the importance of research and the significance of research in fulfilling the Covenant Health vision, "*Inspired by our mission of service, we will be leaders and partners in transforming health care and creating vibrant communities of health and healing*".

All research at Covenant Health requires:

- ethics review and current status approval through a HIA-designated health research ethics board, to assess compliance in accordance with the *Tri-Council Policy Statement, Health Information Act and Freedom of Information and Protection of Privacy Act*;
- review and approval through Covenant Health Finance-Risk Management/ Legal;
- operational review and approval to assess feasibility, including adequate staffing and resources; and
- administrative review and approval to ensure compliance with organizational values and policies, and including compliance with ethical principals included in the *Health Ethics Guide*.

Ethics Harmonization

In March 2014, Covenant Health participated with our ACRC partners in signing a provincial reciprocity agreement. Although the primary ethics board for Covenant Health research remains at the UofA HREB 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 association with (eg. UofC), and who intend to conduct research at Covenant Health facilities. (NOTE: Previous to this agreement, these researchers would have had to apply to two boards (i.e. the UofA HREB and the UofC HREBA), where now only one application is required.)

HIA designated boards include:

- Conjoint Health Research Ethics Board (CHREB) – University of Calgary
- Health Research Ethics Board (HREB) – University of Alberta
- Health Research Ethics Board of Alberta (HREBA) – Alberta Innovates-Health Solutions
  - Clinical Trials Committee (HREBA-CTC)
  - Community Health Committee (HREBA-CHC)
  - Cancer Committee (HREBA-CC)

Note: As the primary Covenant Health ethics board is the HREB, all requirements for ethics review outlined in the Procedure section will reflect review requirements by the HREB.

Procedure

For Researchers interested in initiating research activities at a Covenant Health facility:

1) Initiate the research ethics approval process at HREB (or relevant HIA-designated ethics board) via the REMO on-line interface program. Ensure that Covenant Health is listed as a site under 1.6, 2.0;
   a) If HREB deems that the project does not require an ethics review, a letter from HREB stating same will be required to proceed;
   b) If another HIA-designated ethics board has already reviewed the study, relevant documents and approval letters can be utilized.
2) Submit a signed CHRC application form as well as a signed HIA agreement to the CHRC office;
3) Submit any sponsor or granting agency agreement to the CHRC for Risk Management/Legal Review;
4) Submit relevant protocols and quotation requests to Lab, Pharmacy or Diagnostic Imaging services as appropriate;
5) Once both HREB and CHRC approvals are in place, contact the manager responsible for the department(s) impacted by your study to arrange for an orientation(s) to your study. Be prepared to provide HREB and CHRC approval documents to the department(s) to verify approval;
6) Acknowledge Terms of Reference and establishment of Research Trust Account if appropriate;
7) Ensure that HREB approval is renewed every year prior to the expiry date, throughout the duration of the study;
8) Submit any Adverse Event Reports to HREB;
9) Submit any amendments to study protocols, agreements, etc. to both HREB and the CHRC;
10) Notify both HREB and CHRC when the study is formally closed;
11) Contact the CHRC for knowledge transfer opportunities for your study; and
12) Submit a final study report to the CHRC for file.

For CH Staff or Physicians contacted by researchers for access to their area of responsibility – equipment and/or other resources; staff, physicians and/or volunteers; patients and/or residents; data and/or records:

1) Request an approval letter as provided by the CHRC, as well as a current approval letter as provided by the HREB;
2) If the above documents are not available, contact the CHRC office to inquire if such approvals are in place and/or to request copies;
3) If approvals are not in place, direct the researcher to the CHRC office;
4) Once all approvals have been confirmed, arrange for an orientation with the researcher and/or designate (i.e. research coordinator), to support the study relative to your department and staffing;
5) If there are any potential issues with Covenant Health mission, vision and values, including the ethical principals described in the *Health Ethics Guide,* consult with the appropriate Executive Director or Senior Operating Officer.

For CH Managers, Supervisors or any other positions that involve operational authority, and who are asked to review a research proposal for their area of responsibility:

1) Review the provided study information with particular attention to department impact relative to staffing, resources, patients/residents, etc., and assess feasibility;
2) If any questions, contact the CHRC for clarification;
3) If the study is feasible, sign where appropriate on the study application and return to the CHRC within five working days;
4) If the study is not feasible, advise the CHRC within five working days.

5) If there are any potential issues with Covenant Health mission, vision and values, including the ethical principals described in the *Health Ethics Guide,* consult with the appropriate Executive Director or Senior Operating Officer.

For CH Executive Directors, Senior Operating Officers or any other positions that involve institutional and/or corporate authority, and who are asked to review a research proposal for their area of responsibility:

1) Review the provided study information with particular attention to facility impact relative to funding, resource allocation, structure and organization, policies, etc;
2) Review the provided study information with particular attention to compliance with *Covenant Health* mission, vision and values, including the ethical principals described in the *Health Ethics Guide*. If there are any potential conflicts, consult with the Vice President for Spirituality, Mission and Ethics.
3) If any questions, contact the CHRC for clarification;
4) If the study is feasible, sign where appropriate on the study application and return to the CHRC within five working days;
5) If the study is not feasible, advise the CHRC within five working days.

Related Documents

- CHRC Application Form
- CHRC HIA s.54 Form
- CHRC Workflow
- Covenant Health "Trust Account Terms of Reference"
- Covenant Health "Our Commitment to Ethical Integrity" http://www.covenanthealth.ca/ethics-centre
- Canada - The Tri-Agency Framework: Responsible Conduct of Research http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/#32
- United States – National Institutes of Health: Research Integrity http://grants.nih.gov/grants/research_integrity/index.htm

References

- CHRC Website: http://www.covenanthealth.ca/research-centre
- CHRC Forms: http://www.covenanthealth.ca/research-centre/research-administration/research-policy-process
- HREB Website: http://www.hreb.ualberta.ca/
  - REMO Corridor: http://remo.ualberta.ca/
- CHRC email: research@covenanthealth.ca

Revisions

September 1, 2011