

	<h2>Research</h2>	<b>Corporate Policy &amp; Procedures Manual</b>
		<b>Policy No.</b> III-10
		<b>Date Approved:</b> April 13, 2011
<b>Approved by:</b>  Executive Lead, Professional Practice & Research		<b>Date Effective:</b> May 1, 2011
		<b>Next Review</b> (3 years from Effective Date) May 2014

**Acronyms utilized within this document**

*Alberta Health Services = AHS*  
*Covenant Health = CH*  
*Covenant Health Research Centre = CHRC*

*Health Information Act = HIA*  
*Health Research Ethics Board = HREB*  
*Human Research Ethics On-line = HERO*  
*University of Alberta = UofA*

**Purpose**

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

**Policy Statement**

*Covenant Health* will support research within CH facilities by facilitating the research review and approval process, by providing 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 CH resources are utilized, and/or CH patients/residents are involved, and/or CH staff, physicians or volunteers are involved, and/or CH records or data are accessed. Recruitment or screening of CH patients/residents at a CH site is also considered a research activity, even if the research study is taking place at a non-CH site.

**Responsibility**

**CH Leaders** will demonstrate compliance with this policy and these procedures by engaging their direct reports in: directing any research requests to the *Covenant Health Research Centre* (CHRC); ensuring that any research underway has the appropriate CHRC approval and current HREB approval.

**The *Covenant Health Research Centre* (CHRC)** will demonstrate compliance with this policy and these procedures by facilitating the process for all CH research study applications, including ensuring HREB approval, Risk Management/Legal approval, operational and administrative approvals.

**Researchers** will demonstrate compliance with this policy and these procedures by submitting all required documentation to the HREB and CHRC, and will refrain from pursuing any research activities until all approvals are in place.

**Review and Approvals:** Operational review and approval are the responsibility of relevant CH department managers; administrative review and approval are the responsibility of relevant Executive 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 CH Risk Management/Legal; ethics review is the responsibility of the HREB, as defined by the Tripartite agreement representing the UofA, AHS and CH.

**Principles**

Covenant Health recognizes the importance of research and the significance of research in fulfilling the Covenant Health vision: *“Covenant Health will positively influence the health of Albertans and be of great service to those in need by working together with compassion, quality and innovation”*.

Research initiatives are included under

**Strategic Direction 1.** *“Live our mission and values in all we do”*;

**Corporate Strategic Objectives 1.2** *“Build a strong working relationship with AHS and other key partners”*;

**Measure:** *“Covenant Health ongoing participation/collaboration with other agencies involved in research”*

**Target:** *“Involvement in at least three interagency opportunities for collaboration at any time during the fiscal year”*

**All research at Covenant Health requires:**

- ethics review and current status approval through the *Health Research Ethics Board (HREB)*, 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 CH Risk Management/Legal;
- operational review and approval to assess feasibility, including adequate staffing and resources;
- administrative review and approval to ensure compliance with organizational values and policies, and including compliance with ethical principals included in the *Health Ethics Guide*.

**Procedure**

**For Researchers** interested in initiating research activities at a CH facility:

- 1) Initiate the research ethics approval process at HREB via the HERO on-line interface program. Ensure that *Covenant Health* is listed as a site under 1.5, 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;
- 2) Submit a 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;
- 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;
- 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 CH 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, if possible;
- 4) If the study is not feasible, advise the CHRC.
- 5) If there are any potential issues with CH 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 CH 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, if possible;
- 5) If the study is not feasible, advise the CHRC.

## Related Documents

- ❖ CHRC Application Form
- ❖ CHRC HIA s.54 Form
- ❖ CHRC Workflow
- ❖ CH Trust Account Terms of Reference

## References

- ❖ CHRC Website: <http://www.caritas.ab.ca/Home/Research/default.htm>
  - CHRC Forms: <http://www.caritas.ab.ca/Home/Research/ForResearchers/CaritasAdministrativeApproval/default.htm>
- ❖ HREB Website: <http://www.hreb.ualberta.ca/>
  - HERO Corridor: <https://hero.ualberta.ca>
- ❖ CHRC email: [research@covenanthealth.ca](mailto:research@covenanthealth.ca)

## Revisions

N/A