Navigating Ethics for Research Studies

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Innovation & Development Commons Brown Bag Lunch
March 30, 2017
UNBC-Northern Health Partnership

2016

UNBC

173

H: 21

12% - Health funder

43

H: 38

UNBC PI/Co-I - 33%
Research in Northern BC

Research by CIHR Theme, 2016

- Health Services Research: 65%
- Clinical Research: 12%
- Population Health Research: 23%
- Biomedical Research: 0%

Top 10 Categories of Research Reviewed

- Population and Public Health
- Primary Healthcare
- Perinatal Youth
- Chronic Disease
- Mental Health and Addictions
- Elder Care
- Acute Care
- Health Human Resources
- Aboriginal Health
- Cancer

% of studies

- 2010-2015
- 2016
Research in Northern BC – 2016 Examples

- Determining the Prevalence of Problematic Substance Use in Pregnancy: A Retrospective Chart Review and Situational Analysis (Dr. S. Mitchell, UBC Obstetrics & Gynaecology)
- Gap Analysis of Outpatient Parenteral Antimicrobial Therapy Services in Northern Health (B. Barr, UBC Pharmacy)
- Pursuing Integration: Case Studies of Organizational Transformation (Dr. P. Kumar, UNBC Mathematics)
- Putting the POWERPLAY advantage to work. The development and optimization of a workspace mental wellness module for men in northern and rural locations (Dr. C. Seaton, UNBC Psychology)
- The NORTH Clinic Experience: Patient experiences of participating in a novel and non-traditional cardiac rehabilitation program (D. Banner-Lukaris, UNBC Nursing)
Overview – Research Ethics Presentation

WHY?

+ LA PLACE

HOW?

bcehi

BC Ethics Harmonization Initiative

UNBC UNIVERSITY OF NORTHERN BRITISH COLUMBIA

northern health
Research Ethics at UNBC

WHY: Federal, Provincial and University Levels

The people of Canada through Acts of Parliament wish to promote research that is conducted according to the highest ethical standards.

Value of respect for human dignity

- Respect for Persons
- Concern for Welfare
- Justice

Ethical Conduct for Research Involving Humans

TCPS2 2014
Common Resources within Canada:

Tri Council Policy Statement:

TCPS2 2014

The full 210 page Policy Statement as .pdf

CORE Tutorial Certificate Available

TCPS 2 (2014) - Table of Contents

• Acknowledgements
• Introduction


The following PDF document offers details on the changes made to TCPS 2 in the 2014 version:

Highlights of Changes (2014) (PDF 36KB)

TCPS 2 (2014) - Table of Contents

• A. Establishment of Research Ethics Boards
• B. Procedures for Research Ethics Board Review
• C. Reconsideration and Appeals
• D. Research Ethics Review during Publicly Declared Emergencies
• Chapter 7

Panel on Research Ethics
www.pre.ethics.gc.ca

Canada
Login to CORE / Create Account

Best viewed at a screen resolution of 1280 x 720 pixels.
Your Research

Idea + Place

Research Ethics + Operational Approvals

UNBC

Northern Health
HOW: Finding UNBC Research Ethics Forms and Resources

- Select Research Page, Ethics & Safety, Human Subjects

- UNBC Research Ethics
  - REB Renewal and/or Amendment Application
  - BCEHI Coversheet for Harmonized Research Ethics Review
  - Research Risk Assessment Guidelines (pdf)
  - Information Letter / Consent Form Guidelines
  - Information Letter / Consent Form Template
  - Information Letter / Consent Form Checklist
  - Sample Confidentiality and Non-Disclosure Agreement

NH Operational Approval Process

Surveys

Using Fluid Surveys
UNBC Forms, Resources & Links

RESEARCH ETHICS & SAFETY: HUMAN SUBJECTS

UNBC Research Ethics

BRE: Brief Research Ethics Review

- REC Committee for Authorized Research Ethics Review
- Research Risk Assessment Guidelines
- Information Letter / Consent Form Guidelines
- Information Letter / Consent Form Template
- Information Letter / Consent Form Checklist

Northern Health Authority

- NH Application for Operational Approval

NH OPERATIONAL APPROVAL PROCESS

USING FLUID SURVEYS
When is Northern Health involved?

NH Research Review Committee

Research at Northern Health requires two approvals to proceed:

- Research Ethics Approval
- Northern Health Operational Approval

Research ethics and operational approvals can be pursued simultaneously. Once the conditions for research ethics and operational approval are met, a letter of approval from the Research Review Committee will be emailed to the Principal Investigator and the Northern Health managers who provided operational approval for the research.

About the Research Review Committee

All research conducted within or for Northern Health (NH) must be reviewed and approved by the Northern Health Research Review Committee (RRC). The RRC is mandated by NH policy to approve, reject, propose modifications to or terminate any proposed or ongoing research involving humans that is conducted in NH facilities/programs; by NH staff or physicians; or with NH staff, physicians and/or patients.

Dates

<table>
<thead>
<tr>
<th>2016 Research Review Committee</th>
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<tbody>
<tr>
<td><strong>Appis. Deadline</strong></td>
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<tr>
<td>Jan 13, 2017</td>
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<tr>
<td>Feb 10, 2017</td>
</tr>
<tr>
<td>Mar 7, 2017</td>
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<tr>
<td>Apr 10, 2017</td>
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<td>May 8, 2017</td>
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<td>Jun 9, 2017</td>
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*Applications submitted by the deadline will be reviewed within 2 weeks.
Operational Approval

- Operational Approval Guidelines
- Operational Approval Form
- Medical data and charts

Northern Health Operational Approval for Research

Northern Health supports partnership and participation in research activities, for evidence-based practice. We use knowledge generated from research to improve the quality we deliver, and as a vehicle to create change in our region and encourage excellence.

All research conducted within, or for Northern Health (NH) must be approved by the Research Review Committee (RRC). The RRC is also directed to consider the impact of research on the NH organization. As such, the researcher must obtain operational approval as per "for Research Approval" to the RRC. This ensures that there is knowledge about and acceptance of risk and acknowledgment of privileges in NH facilities.

How do I obtain Operational Approval?

Signature pages can be added to this form and sent to the Research Review Committee.

Refer to the Northern Health Operational Approval for Research Projects Information Sheet for information on who can grant operational approval and the roles and responsibilities of the Researcher and the Northern Health Approval Manager.

Title of Project

UNBC UNIVERSITY OF NORTHERN BRITISH COLUMBIA
Operational Approval Managers

As the person responsible for Department Authorization, my signature confirms that:

- I am the appropriate person to provide operational approval on behalf of Northern Health for this research.
- Resources (e.g. human or financial resources, space) required to conduct the research can be provided and the activities can be executed while service delivery is maintained. Cost recovery agreements have been negotiated with the researcher if required.
- I will communicate to the appropriate people in the organization that the research is happening and is supported by Northern Health, and how the organization is supporting this research
- I will support knowledge translation (i.e., bringing the research to practice and decision-making)
I’ve filled in the forms... then what?

Submit your Application to UNBC REB for processing.

Minimal Risk:

• Rolling electronic submission of signed application to reb@unbc.ca
• Allow two weeks for a response from the REB

Above Minimal Risk:

• Submission deadlines posted on website along with meeting dates, 8 copies of all documents to be delivered to the Office of Research Room 2018.

Joint Research Project Involving Northern Health...
If Joint Research Involving UNBC & NH

Complete UNBC REB Application
Complete NH application for Operational Approval

Submit UNBC REB New application to UNBC REB
Submit both to: researchcommittee@northernhealth.ca

UNBC REB response time is dependent on the Level of Risk for the Application.
If revisions are needed, approval will be possible once they are completed.
HARMONIZATION

Multiple Jurisdictions Involved
Define the Roles of Research Team Members, AND Team Members Institution for ethics review

Complete Cover Sheet for Harmonized Research Ethics Review found on our webpage, and through bcethics.ca/resources

Timelines vary with number of institutions involved

ONE letter of provisos will be issued from the BoR to the PI for the study.
Joint, Harmonized or Single Research Ethics Reviews:

- **Northern Health Operational Approval Application if NH Staff, Facilities or Data involved.**
  - Northern Health Research Review Committee Reviews for Operational Considerations
  - Response to Researcher from Northern Health

- **Northern Health and UNBC Joint Review**
  - If UNBC Researcher and NH Staff, Facilities or Data involved
  - NH Research Review Committee Concurrent Review
  - UNBC REB Concurrent Review
  - Single Response to Researcher from UNBC and NH with provisos from both

- **Harmonized Review between members of the BC Harmonization Initiative (All Regional Health authorities, UNBC, UBC, UVic and SFU)**
  - BCEHI Coversheet sent to all involved REB’s to determine the Board of Record (BoR) 5 in example
  - REB Reviews Application submitted to BoR (REB 1)
  - REB Reviews (REB 2, REB 3, REB 4, REB 5 Reviews)
  - Single Response to Researcher from BoR including provisos from all REBs involved.

- **UNBC Application**
  - UNBC REB Reviews for Compliance with TCP82
  - Response sent to Researcher from UNBC with any provisos

**Key**

- **Application by Researcher**
- **Review**
- **Response back to Researcher: provisos or approval**
NMP Faculty, Clinical Students & Residents

UBC Research Ethics Boards

Guidance Notes on the Streamlined process for:
UBC Family Practice Residents, UBC Dietetic Interns, UBC Pharmacy Residents, and UBC Summer Medical Students Research Projects.

https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes
Amendments, Renewals & Board of Record

For all Studies:

Changes to The Study $\rightarrow$ Amendment

If involving NH, researcher sends once approved

Study approval coming to end date $\rightarrow$ Renewal

Renewal with Amendments

Board of Record for Harmonized Studies:

Submit Amendments and Renewals through the BoR

- partner institutions are consulted or notified as determined when BoR was established
Knowledge translation & exchange
Contact

Northern Health:
e-mail: ResearchCommittee@northernhealth.ca
Webpage: https://northernhealth.ca/YourHealth/Research/NHResearchReviewCommittee.aspx

UNBC Research Ethics Board:
E-mail: reb@unbc.ca

QUESTIONS?

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