Northern Health Regional Office
600-299 Victoria Street, Prince George, BC V2L 5B8
Telephone (250) 565-2649, Fax: (250) 565-2640, www.northernhealth.ca

Application for Research Approval

Submit your completed Application for Research Approval electronically to ResearchCommittee@northernhealth.ca.

Please mail or fax the original signature pages (with Researcher, Northern Health Department/Site Manager(s), and Supervisor signatures where appropriate) to:

Northern Health Research Review Committee
600 – 299 Victoria Street
Prince George, BC V2L 5B8
Fax: 250 565-2640

Research at Northern Health requires two approvals to proceed:

1. Research Ethics Approval
2. Northern Health Operational Approval

This *Application for Research Approval* form covers both research ethics and operational approval requirements.

This form has been adapted from the University of Northern British Columbia's *Research Ethics Protocol for Research with Human Participants: New Applications.* Hyperlinks throughout the document will take you to UNBC Research Ethics supporting documents accepted by Northern Health and to relevant articles of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2).

If your research is affiliated with the **University of Northern British Columbia (UNBC),** you can submit your completed *UNBC Research Ethics Board New Application Form* (and accompanying documents) together with the *Northern Health Application for Operational Approval for Research*. You are required to submit your application to both the UNBC REB and Northern Health Research Review Committee. You can submit to both institutions at the same time. Visit the UNBC Office of Research at www.unbc.ca/research for information about their research services and Research Ethics Board.

UBC Family Practice Resident, Pharmacy Resident, Dietetic Intern and Summer Medical Student Research Projects should refer to the UBC Guidance Note for ethics review of these studies. You will complete an initial application in the UBC RISe system which will be reviewed by both UBC and Northern Health, and also complete the *Northern Health Application for Operational Approval for Research* and submit it to researchcommittee@northernhealth.ca .

If your research requires ethics approval from **multiple organizations in BC** (Universities and Health Authorities) you may be able to proceed with a harmonized ethics review process. Learn more at http://bcethics.ca.

SECTION A – TYPE OF APPLICATION

Review the Research Risk Assessment Guidelines and identify if the application is:
☐ Minimal Risk
☐ Above Minimal Risk

Justification for Risk Assessment (optional)

The space below offers you the opportunity to elaborate on the level of risk you have assigned the study. This provides an important way of justifying your risk assessment, especially if you feel that your study might be considered sensitive and risky to an outsider, but you have evidence to suggest that it is not. If you choose not to avail yourself of this option, please simply write N/A.

SECTION B – APPLICANT INFORMATION (Please complete all sections that apply)

Principal Investigator: • For students, please include the name of your Supervisor below			
Program/Department/School:			
Institution			
Phone Number:		Email:	
Supervisor's Name:		Email	

Please append additional pages with co-investigators' names, if necessary

Co-Investigator(s):	☐ separate page(s) attached		
Program/Department/School:			
Institution			
Phone Number:		Email:	

SECTION C – RESEARCH PROJECT DETAILS

1. Project Dates:

Expected Project Start Date:
* This date should be *after* RRC Approval is received

Expected Project Completion Date:

2. Title of Project:

3. Type of Project:

Undergraduate
☐ Research (including Honours Thesis) ☐ Classroom Project (Undergraduate student)

Graduate
☐ Research (including Thesis/Dissertations/Projects) ☐ Classroom Project (Graduate student)

Post Doctoral
☐ Research

Faculty
☐ Research ☐ Classroom Project (Faculty)

Other
☐ Resident or Intern Research Project
☐ Other (please specify):

4. Source of Funding:

Please refer to TCPS2, Article 7.4, for more information on Financial Conflicts of Interest**.**

5. Has this study received Research Ethics Board approval at another institution?

☐ **Yes or Pending** Identify the Research Ethics Board and the Study ID/file number:

Submit a copy of the Certificate of approval with this application once approved.

☐ **No**

Investigators, research team members and research project staff have taken a recognized course in research ethics and/or have completed the online tutorial regarding the Tri-Council Policy Statement on Ethical Conduct for Research involving Humans,

☐ Yes ☐ No ☐ Pending

6. **Purpose of Research:** Describe the purpose of the proposed project. State the hypotheses/research questions to be examined. The rationale for doing the study must be clear. (Max. 300 words)

7. **Summary of Methods**: Please describe all formal and informal procedures to be used. Describe the information to be collected, where and how it will be obtained and how it will be analyzed. Please include a description of your own role in the research and that of any of your team members. (Max. 500 words)

8. Please append a complete copy of the research project proposal, including any interview protocols, questionnaires, or other research instruments (e.g. focus group scripts, participant screening tests, etc.) to be used in the study.

Attachments:

☐ Research Project Proposal

☐ Data Collection Forms/Protocols (please list):
(As per TCPS2, Article 10.5, in studies using emergent design in data collection, final versions of questionnaires or interview schedules must be submitted to the REB as soon as they become available)

☐ Other (please specify):

9. **Study Population and Recruitment**:

a. Who is being recruited and what are the criteria for their selection (inclusion)? What participants will be excluded from participation?

b. How many participants will be recruited for the study?
In total (entire study, all sites):
At Northern Health:

Inappropriate sampling (e.g., too small, too large, non-random) may pose an ethical issue. Describe and justify the sampling plan and sample size(s) for the study, including within Northern Health and elsewhere.

c. How will participants be recruited? Please specify *both* how potential participants will be identified *and* (if applicable) the means by which they will be contacted. Please also append a copy of any recruitment materials (e.g. posters, letters, and media advertisements, etc.).

d. Are any participants considered members of a (potentially) vulnerable group? Please see TCPS2, Article 4.7 for more information.

☐ Yes
☐ No

If yes, please describe and add any measures to reduce risk of vulnerability during recruitment, enrolment, and interventions.

e. Will the research involve any Aboriginal (First Nations, Inuit or Métis) community or territory? Refer to TCPS2, Chapter 9 for more information on Research Involving the First Nations, Inuit and Métis Peoples of Canada.

☐ **Yes** Please specify and include any letters of support from communities.

☐ **No**

10. Conflict of Interest:

a. Do any of the researchers conducting this study occupy multiple roles with respect to potential participants (e.g. acting as both a researcher and a therapist, health care provider, caregiver, teacher, advisor, consultant, supervisor, manager, student, employer, etc.) that may create a real, potential, or perceived conflict of interest that could affect the integrity of the research? Please refer to TCPS2, Article 7.4 for more information on Researchers & Conflicts of Interest.

☐ **Yes** Please provide details in the space below.

☐ **No**

b. Describe how any conflicts of interest identified above will be avoided, minimized or managed.

☐ Not applicable

c. Will the researcher(s), members of the research team, and/or their partners or immediate family members receive any personal benefits (for example a financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options etc.) in connection with this study?

☐ **Yes** Please describe the benefits below. (Do not include conference and travel expense coverage, possible academic promotion, or other benefits which are part of the conduct of research generally).

☐ **No**

11. Possible Risks:

a. Please indicate all potential risks to participants as individuals or as members of a community that may arise from this research:

i.	Physical risks (e.g. any bodily contact or administration of any substance):	☐	Yes	☐ No
ii.	Psychological/emotional risks (e.g. feeling uncomfortable, embarrassed, or upset):	☐	Yes	☐ No
iii.	Social risks (e.g. loss of status, privacy and/or reputation):	☐	Yes	☐ No
iv.	Legal risks (e.g. researcher's obligation to report certain unlawful activities):	☐	Yes	☐ No

b. Please briefly describe each of the risks noted above and outline the steps that will be taken to manage and/or minimize them.

12. Possible Benefits:

- Describe any potential direct benefits to participants from their involvement in the project
- Describe any potential benefits to the community and/ or Northern Health (e.g. capacity building)
- Comment on the potential benefits to the scientific/scholarly community or society that would justify involvement of participants in this study

13. **Will participants be competent to give consent?** Please refer to TCPS2, Chapter 3, Section C for more information on the Consent Process and TCPS2, Chapter 4, Section B for more information on Research Involving Children, the Elderly and Participants Who Lack the Capacity to Consent for Themselves.

☐ **Yes**

☐ **No** (e.g. Children and cognitively impaired people.) How will the issue of consent be addressed? Give a brief summary below.

14. **Will consent be obtained from each participant either in writing or recorded?** Please see TCPS2, Article 3.12, Chapter 5, Section D and Article 10.2 for information.

☐ **Yes** Please attach a copy of the Consent Form and (if applicable) the Information Letter to be distributed to participants. Each participant must receive one copy of the signed consent form. Note: *A Consent Form and/or Information Letter Checklist* are available at http://www.unbc.ca/sites/default/files/sections/research/checklist.pdf, as well as a *Sample Information Letter/Consent Form* (*note: please replace UNBC logo as appropriate)*. If Consent is to be obtained verbally, please explain the process for administering and recording that consent.

☐ **No** Please provide justification below for why consent will not be obtained

15. **Will participants be compensated?** Please refer to TCPS2, Article 3.1 for information on Incentives.

☐ **Yes** How? Provide a brief summary.
(If providing an honorarium, please indicate the approximate amount

☐ **No**

16. **Does the project involve any deception?** Please see TCPS2, Chapter 3, Section B for information on Departures from General Principles of Consent.

☐ **Yes** Justify the use of deception and indicate how disclosure and/or debriefing will be addressed.

☐ **No**

17. **Data Security:** Describe the procedures for maintaining confidentiality of hard copy and electronic data/personal information throughout the course of the study. *What information will be kept, how long will it be retained, where will it be stored, how will it be secured, who will have access, how will it be disclosed and to whom, and how and when will it be destroyed?*

18. **How do you plan to disseminate the results?** (e.g., presentations, publications, policy briefs, educational outreach/strategies, media, clinical practice guidelines, community of practice/networks, etc.)

19. **How do you propose to distribute results to participants?** (e.g. Will you be providing the opportunity to have your thesis and/or summary report mailed or emailed to participants, or informing participants that your thesis will be available in the library?) Please see TCPS2, Article 4.7 (section on Equitable Distribution of Research Benefits) for more information.

20. Will Research Assistants and/or Transcribers be hired for this project? Please see TCPS2, Chapter 5 for information on Privacy and Confidentiality

☐ **Yes** Please attach a Confidentiality & Non-Disclosure Agreement
☐ **No**

21. Will any research contract(s) be signed in connection with this project?

☐ **Yes** Please attach a copy of the research contract. **Note**: It is the researcher's responsibility to ensure that there are no conflicts between the research contract and the information provided to research participants in the project information/consent forms.
☐ **No**

Section D: Northern Health Operational Approval

**Please refer to the Application for Research Guidelines for information about Northern Health Operational Approval for Research Projects.*

Where will the research be carried out (i.e., specific sites, facilities)?

Please select the Northern Health services or support required to conduct this research (choose all that apply and provide a description):

☐ Only requesting approval to post an advertisement/recruitment material

☐ Northern Health staff will be invited to participate in the study

☐ Northern Health staff will be required to assist in the conduct of the study

☐ Space in Northern Health sites is required for this study

☐ Information owned or maintained by Northern Health is required for this study

☐ Equipment owned or maintained by Northern Health is required for this study

☐ Other direct involvement or requirement of support or service from Northern Health department(s) or staff

Please identify the specific NH hospital department(s) and community site(s) that will be impacted or participating in this study (e.g. that are being asked to provide research-related services/resources).

An email from the Northern Health manager can be submitted to researchcommittee@northernhealth.ca in lieu of a signature on this form. Cite the study title and file number (if available) in the email. Please indicate on the "signature and date" line below if approval will be provided via email.

If the project requires **secondary data from Health Information Management Services (Health Records)**, contact: Dee-Ann.Stickel@northernhealth.ca (Regional/multi-site), or Melanie.Baker@northernhealth.ca (University Hospital of Northern BC, Prince George site only)

For assistance in obtaining the name of the appropriate NH Department/Site Manager that should provide Operational Approval of your application, please contact researchcommittee@northernhealth.ca

1. **Department/Site:**

Detail the services required from this department/site

Person Responsible for Department Authorization

Name & Title

Email address

Signature & Date

2. Department/Site:

Detail the services required from this department/site

Person Responsible for Department Authorization

Name & Title

Email address

Signature & Date

3. Department/Site:

Detail the services required from this department/site

Person Responsible for Department Authorization

Name & Title

Email address

Signature & Date

Please check the following boxes to acknowledge:

☐ *Northern Health requests a copy of the final study for our files and/or placement at the Northern Health Library and sponsoring facility use.*
At project completion, I will provide a copy of the final report to Northern Health.

☐ *Northern Health maintains a database of research undertaken in the health authority.*
I understand that upon approval of my research application by the Northern Health Research Review Committee, the following information will be posted on the Northern Health website: project title, names and institutions of Investigators, location of research (sites), name and title of Northern Health operational approval manager(s), and project start and completion dates.

Studies are categorized on the Northern Health website and annual reporting. Please select 1-3 categories that best describe your study. (Refer to Application Guidelines for category descriptions).

☐ Aboriginal health
☐ Acute care
☐ Cancer
☐ Child & youth
☐ Chronic disease
☐ Corporate/business services
☐ Critical care (ED, trauma)
☐ Diagnostics
☐ Dietetics
☐ Elder care
☐ Health services/systems
☐ Health human resources
☐ Home care
☐ Medication management
☐ Mental health & addictions
☐ Nursing
☐ Palliative care
☐ Patient-oriented research
☐ Perinatal
☐ Pharmacy
☐ Primary health care
☐ Public & population health
☐ Rehabilitation
☐ Surgical services

☐ Other:

Additional information or comments

Once the conditions for operational approval and research ethics approval have been met, a letter from the Research Review Committee will be emailed to the Principal Investigator and the Northern Health manager(s) who provided operational approval for the research.

SECTION E – SIGNATURES

As the **Principal Investigator** on this project, my signature confirms that I will comply with the Tri-Council Policy Statement and all Northern Health policies and procedures governing the protection of human participants in research, including but not limited to, ensuring that:

- the project is performed by qualified and appropriately trained personnel;
- no changes to the RRC cleared protocol or consent form/statement are implemented without notification to the RRC of the proposed changes and receipt of the subsequent RRC clearance; and
- significant adverse effects to research participants are promptly reported to the RRC;

As a **Student Researcher**, in addition to the above, my signature also confirms that I am a registered student in good standing. My project proposal has been reviewed and cleared by my advisory committee (where applicable). If my status as a student changes, I will inform the RRC. For all students, the signature of a Faculty Supervisor is also required.

Signature of Principal Investigator: _____ Date: _____

As a **Faculty Supervisor**, I certify that the information provided in this application is complete and correct, and I certify the scientific merit of the research project.

I understand that as principal Faculty Supervisor, I have ultimate responsibility for the conduct of the study, the ethical performance of the project and the protection of the rights and welfare of human participants. I agree to comply with the Tri-Council Policy Statement and all Northern Health policies and procedures governing the protection of human participants in research, including, but not limited to, ensuring that:

- the project is performed by qualified and appropriately trained personnel;
- no changes to the RRC cleared protocol or consent form/statement are implemented without notification to the RRC of the proposed changes and receipt of the subsequent RRC clearance; and
- significant adverse effects to research participants are promptly reported to the RRC;

Signature of Faculty Supervisor: _____ Date: _____

SUPPORTING DOCUMENT CHECKLIST

Please indicate which of the following supporting documents are included with this application (add extra lines where necessary). Ensure that all documents are clearly labeled.

- ☐ Other REB approvals
- ☐ Consents from Aboriginal groups or organizations
- ☐ Other consents (please specify) _____
- ☐ Research contract(s)
- ☐ Participant information letter(s)
- ☐ Participant consent form(s)
- ☐ Research assistant/transcriber confidentiality agreement(s)
- ☐ Participant recruitment materials (e.g. posters, letters, email scripts, etc.)
- ☐ Questionnaires or survey instruments; interview scripts/questions
- ☐ Research proposal
- ☐ Other (please specify) _____
- ☐ Other (please specify) _____