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Application for Research Approval Guidelines

This document is meant to assist in the completion of the Northern Health Research Review Committee (RRC) *Application for Research Approval* and *Application for Operational Approval for Research*.

Research at Northern Health requires two approvals to proceed:

1. Research Ethics Approval
2. Northern Health Operational Approval

This *Application for Research Approval* covers both research ethics and operational approval requirements. It is an electronic form that can be completed in Adobe Acrobat. To maneuver through the form, use your mouse; i.e., click the button to select. To fill in a checkbox, use the button of your mouse.

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 Operational Approval Form*. 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 Notes 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 Operational Approval Form 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.

The question numbers referenced in parentheses next to each heading in these Guidelines correspond to the *Application for Research Approval.*

SECTION A – TYPE OF APPLICATION

Review the Research Risk Assessment Guidelines and indicate whether your research project is Minimal Risk or Above Minimal Risk. Space is provided if you would like to explain or justify your selection.

SECTION B – APPLICANT INFORMATION

Please identify the names and Program/Department/School and institutional affiliations of all research project/study team members, as well as contact information for the Principal Researcher. When the Principal Researcher is a student, the supervisor's name, title/position and signature are also required.

SECTION C – RESEARCH PROJECT DETAILS

Project Information (Questions 1–4)

Please indicate:

- The anticipated start date and completion date (Question 1). The start date should be after Research Review Committee approval is received.
- The title of the project (Question 2)
- The type of project (i.e., undergraduate research, undergraduate classroom project, graduate research, graduate student classroom project,post doctoral research, faculty research, faculty classroom project, Resident or Intern Research Project, or Other) (Question 3)
- Funding for the project: from which organization and the amount (Question 4)

Research Ethics Board approval (Question 5)

Please identify whether or not this research project has received approval from, or is currently under review by, a Research Ethics Board (REB). If the research has been submitted to an REB, identify the REB and the study ID/file number (if available). If REB approval has already been granted, attach a copy of the certificate of approval. If REB approval is pending, indicate what REB is reviewing the proposal, and anticipated review date.

When the researcher is affiliated with an academic institution, review and approval from that university/academic/institutional REB is required prior to final approval issued by the NH RRC. You can apply for review by the RRC concurrent with your application to another academic REB. In this situation, please indicate that approval from the REB is "Pending". The RRC will issue final approval for the study to proceed in Northern Health once evidence of REB approval has been provided.

When the researchers are not affiliated with an academic institution, application for approval should be submitted directly to the RRC.

Research team member ethics education

Research team members must be familiar with the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS2). Please indicate whether or not they have taken a recognized course in research ethics and/or have completed the online tutorial for the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans. The tutorial can be completed at http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/.

Study Purpose and Methods (Questions 6–8)

Provide a description of the **purpose of your research** (Question 6; maximum 300 words). State the research questions/hypothesis and rationale for doing the study.

Provide a **summary of your research methods** (Question 7; maximum: 500 words). Please include a copy of your research proposal as part of your application package (if applicable). The summary of methods should address the following points as appropriate:

- What methodology or protocol will be followed in conducting this research?
- What information will be collected, and where and how will it be obtained?
- What is the plan for analysis?

Provide the relevant additional documentation necessary for this review process, which may include (Question 8):

- Research Project Proposal
- Data / Information Gathering Protocol
- Interview Protocol
- Questionnaire / Survey
- Clinical Trial Protocol
- Information Sheet
- Consent Forms
- Other relevant documentation

If your study uses an emergent design in data collection, final versions of questionnaires or interview protocols must be submitted to the Research Review Committee as soon as they become available.

Do **not** include the Northern Health logo on study materials unless the Principal Investigator has a formal affiliation with Northern Health. If the Principal Investigator is independent of Northern Health other than the Research Review Committee's review/approval then the logo should not be used. This includes Northern Health staff who are undertaking research for academic purposes (e.g., graduate or post doctoral research) and Clinical Resident research. If the research is "Northern Health research" (i.e., commissioned by the organization), the logo is permitted on research materials.

Study population and recruitment (Question 9)

a. Who will be recruited?
   - Describe and justify the inclusion and exclusion criteria for selection of participants. Refer to Chapter 4 of the TCPS 2 for more information about appropriate inclusion and inappropriate exclusion.

b. How many participants will be asked to/will take part in the study?
   - Identify the number of total participants and the participants at Northern Health sites
   - Describe and justify the sampling plan and sample size(s) for the study, including within Northern Health and elsewhere. Inappropriate sampling may pose an ethical issue (e.g., too small, too large, non-random).

c. How will participants be recruited?
   - How will prospective participants be identified?
   - Who will be contacting them?
   - How will they be contacted, presented with information about the study and invited to participate?
     - By letter (enclose a copy)
     - Advertisement, poster, flyer (enclose a copy)
     - Other (explain)

d. If research participants are considered members of a vulnerable group please describe and add any measures to reduce risk of vulnerability during recruitment, enrolment and interventions. Refer to Article 4.7 of the TCPS 2 for more information.

e. If the research participants will be participating as representatives of, or on behalf of, an Aboriginal group, please identify the group(s) and attach a letter of consent from the appropriate authority. Refer to Chapter 9 of the TCPS 2 for more information on research involving the First Nations, Inuit and Metis Peoples of Canada.

Conflict of Interest (Question 10)

Is there an actual, perceived or potential conflict of interest regarding any of the research team members, staff members and/or participants in the study? (e.g., personal/financial benefits that the investigators and/or partners/immediate family members will receive connected to this research project; investigator holds a title/position that is senior to potential participants that might influence the recruitment and/or consent).

If an actual, perceived or potential conflict of interest exists, please describe the conflict and how it will be addressed.

Researchers can refer to Chapter 7 of the TCPS 2 for more information on conflicts of interest.

Risks and Benefits (Questions 11-12)

- What are the potential and anticipated risks of the proposed research? Identify all physical, psychological/emotional, social and legal risks and outline the steps taken to manage and/or minimize them.
- Describe the immediate and longer term benefits of the research/study to participants, to the community, to Northern Health, to the researcher, and to society at large.

The Consent Process (Questions 13-16)

Refer to Chapter 3 of the TCPS 2 for information about free, informed and ongoing consent of research participants.

Applications should address the following points:

- Will the participants be able to give free and informed consent on their own behalf? (Consider physical or mental condition, age, language, incarceration or other barriers). If participants will not be competent to give consent, describe how the issue of consent will be addressed. (Question 13)
- Will written consent be obtained from participants? (Question 14)
    - If no, document the procedure by which free and informed consent will be obtained in the absence of written consent.
    - If yes, attach a copy of consent form or the questions/statements to be recorded. Consider how long the individual will have to decide whether or not to participate. Each participant must receive one copy of the signed consent form at the time of signing. A checklist of items to be addressed in your information sheet or consent form is provided on Page 11 of these Guidelines and on the UNBC Research website.
- Will participants be receiving any compensation or remuneration for their involvement in the study? If yes, in what form and how much? (Question 15)
- Does the research design involve any form of deception of the participants? (Question 16)
    - If yes, describe and justify the proposed deception.

Data Security (Question 17)

Describe the procedures for maintaining confidentiality of hard copy and electronic data/personal information throughout the course of the study.

- What type of information will be collected?
    - Will the project obtain identifiable personal information on research participants?
    - Consider if any modes of observation (e.g. photographs or videos) or access to information (e.g. sound recordings) that allow identification of particular participants.
    - Will there be any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records?
- How long will the information be retained?

- Where will the information be stored?
- How will the information be secured?
- Who will have access to the information?
- How will the information be disclosed, and to whom?
- How and when will the information/data be destroyed?

Refer to Chapter 5 of the TCPS 2 for more information on privacy and confidentiality.

Feedback to Participants and Results Dissemination (Questions 18-19)

Describe how you plan to disseminate the results of this research (e.g., presentations, publications, policy briefs, educational outreach/strategies, media, clinical practice guidelines, community of practice/networks, etc.) (Question 18)

Indicate how you intend to follow-up with participants and participating staff members/departments upon the completion of your project/study; i.e., how they will be debriefed, opportunity for review of materials prior to publication; as well as any presentations and knowledge translation and exchange activities planned for the dissemination of the findings. (Question 19)

Research Support Staff Confidentiality (Question 20)

If research assistants and/or transcribers will be hired for the research project ensure that a confidentiality & non-disclosure agreement has been signed by each person.

Refer to Chapter 5 of the TCPS 2 for more information on privacy and confidentiality.

Research Contracts (Question 21)

Indicate if research contracts will be signed in connection with this project (e.g., contracts for academic research commissioned by Northern Health or another organization, data sharing agreements, clinical research sub-site agreements). Please ensure that confidentiality agreements are signed in accordance with the contract if appropriate.

SECTION D – NORTHERN HEALTH OPERATIONAL APPROVAL

*** See Page 9 of these Guidelines for more information about who can grant operational approval, and the roles and responsibilities of the researcher and Northern Health Approval Manager(s).*

Select the Northern Health services or support required to conduct this research from the checklist provided on the form. Choose all that apply and provide a brief description of each requirement.

Identify the Northern Health hospital department(s) and/or community site(s) where the research will be carried out and that will be impacted by this study (e.g. asked to provide research-related services/resources), detail the services that you require from each of the departments/sites and obtain the signature from the person with appropriate authorization for each department/site. 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.

The RRC requires the researcher to obtain operational approval from the Manager or Director in the Northern Health hospital department(s) and community site(s) that will be impacted by the proposed research. This individual should have the appropriate authority to support the research being undertaken in the region and the potential organizational impact. Additional information about who can grant operational approval, and the roles and responsibilities of the researcher and Northern Health Approval Manager(s) can be found on page 9 of these Guidelines.

If the project requires secondary data from Northern Health's Health Information Management Services (Health Records/HIMS), a Data/Chart Request form, signed by the HIMS Department, must be submitted with your RRC application. For regional/multi-site studies in Northern Health, contact Dee-Ann.Stickel@northernhealth.ca. For single site only, contact Health-Information-Services@northernhealth.ca

Dissemination of information through Northern Health

Northern Health requests receipt of the final report/publication related to the study for our files and for deposit at the Northern Health Regional Library. Please check the box to indicate that you acknowledge this provision.

Northern Health also maintains a database of research undertaken in the health authority; therefore, the following information from your application may be publicly available: 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. Please check the box to indicate that you acknowledge this provision.

Research approved by the Northern Health Research Review Committee is categorized and listed on the Northern Health website and in the Research Annual Report. On the *Application for Research Approval*, please select one to three categories that **best describe** your study by checking on the appropriate box (es). The categories are defined below:

- *Aboriginal health* (research about the health of First Nations populations)
- *Acute care* (research on hospital-based care)
- *Cancer* (research that falls in the cancer care continuum of prevention, screening, treatment and palliation)
- *Child & youth* (research focused on the health of children and youth)
- *Chronic disease* (research on disease that is long lasting or recurrent; e.g., diabetes, cardiovascular disease, chronic respiratory diseases, chronic kidney disease, arthritis; *note: cancer is a separate category – cancer research can appear here as a secondary category*)
- *Corporate/business services* (e.g., information & technology services, telehealth, capital planning, finance; *note: health human resources is a separate category*)
- *Critical care* (i.e., emergency, trauma, intensive care)
- *Diagnostics* (i.e., lab, biomedical engineering, diagnostic imaging)
- *Dietetics*
- *Elder care* (research with the elderly population, on issues of elder health)
- *Health services/systems* (research on the organization of health services and health system transformation)
- *Health human resources* (e.g., staffing models and organization, staff development (training, education), recruitment & retention, workplace health & safety)
- *Home care* (wound care, palliative care, disability services, elder care, etc. that takes place in the patient's home)
- *Medication management* (research focusing on the prescription, dispensing, administration, or safe use of medications in health care)
- *Mental health and addictions*
- *Nursing*
- *Palliative care* (i.e., end of life care)
- *Patient-oriented research* (i.e., defined by the Canadian Institutes for Healthcare Research as "a continuum of research that engages patients as partners, focuses on patient-identified priorities and improves patient outcomes. This research, conducted by multidisciplinary teams in partnership with relevant stakeholders, aims to apply the knowledge generated to improve healthcare systems and practices.")
- *Perinatal* (research on the time period from conception through pregnancy, delivery, post partum, and early parenting steps)
- *Pharmacy*
- *Primary health care*

- *Public and population health* (e.g., social determinants of health, communicable disease prevention & management, preventive public health, health promotion)
- *Rehabilitation* (physiotherapy, occupational therapy, speech language therapy)
- *Surgical services*

SECTION E – SIGNATURES

Signatures from the Principal Researcher, Northern Health Manager(s)/Director(s), and Supervisor (if the researcher is a student) are required for this application. Signature pages can be scanned and emailed to researchcommittee@northernhealth.ca or faxed to 250 565-2640 attention: Research Review Committee. Northern Health operational approval can be provided via an email from the appropriate Manager(s)/Director(s) to researchcommittee@northernhealth.ca.

APPLICATION REVIEW AND APPROVAL

Applications received before deadline will be reviewed at the next meeting. Application deadlines and meeting dates are posted on the Research Review Committee website.

In making its decision, the Research Review Committee takes into consideration whether or not ethical principles and standards respecting the personal welfare and rights of research participants have been recognized and accommodated, as well as the impact of the proposed research on the Northern Health organization. Research at Northern Health requires both research ethics approval and operational approval to proceed.

The Northern Health Research Review Committee will either approve or not approve the application. Following the meeting, the Principal Investigator (and Faculty Supervisor where applicable) will receive a letter of decision from the RRC.

Approved – The Principal Investigator will be notified in writing that the project has been approved to proceed, with a copy to each Northern Health Department/Site Manager who signed the Application for Research Approval. The researcher should confirm with each Department/Site Manager receipt of the approval notification. The project may commence ONLY after written approval has been received.

Not Approved – The Principal Investigator will be notified, in writing, that the project has not been approved with an explanation as to why. The letter will outline specific items to be addressed/clarified in order for the project to proceed and a request for the PI to respond to these items. Information received in response to this letter will be reviewed by the RRC upon receipt.

The RRC reserves the right not to approve any projects it determines are not within Northern Health Research Policies and Principles and/or do not adhere to the Tri-Council Policy Statement for the Ethical Conduct of Research Involving Humans. The RRC will work with researchers to endeavor to resolve any perceived shortcomings in the research review application and protocol. The researcher has the right to request, and the RRC has an obligation to provide, reconsideration of a decision affecting a research project.

Once the conditions for research ethics approval and operational 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.

Changes and Amendments

Any and all changes to the design and conduct of your research protocol should be forwarded to the RRC for notification, review and approval.

Submitting your Application

Please submit your completed application to researchcommittee@northernhealth.ca.

You can also mail or fax the application and/or signature page(s) to:

Northern Health Research Review Committee
600 – 299 Victoria Street
Prince George, BC V2L 5B8
Fax: 250.565.2640

Northern Health Operational Approval for Research Projects

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

All research conducted within, or for Northern Health (NH) must be approved by the Northern Health Research Review Committee (RRC). The RRC is also directed to consider the impact of the research on the NH organization. As such, the researcher must obtain operational approval as part of the *Application for Research Approval* to the RRC. This ensures that there is knowledge about and support for the research happening in the region, as well as acceptance of risk and acknowledgement of benefit.

How do I obtain Operational Approval?

Complete the Application for Operational Approval for Research. The form will ask for the following information:

- Project title and purpose of the research
- Names, contact information and signatures of Principal Investigator and, if applicable, Academic Supervisor
- Names of additional Investigators and, if applicable, the Primary Contact for the study
- Research Ethics Board(s) reviewing the study, REB file number, and current status of REB review/approval
- Identification and description of the NH services or support required to conduct the research
- Identification of the specific departments/sites from which services or support is required and signatures from NH manager(s) responsible for department authorization. In lieu of signatures, an email from the Manager(s) can be submitted to researchcommittee@northernhealth.ca.
- Acknowledgement of information that will be shared, and identification of categories for the study

Who Grants Operational Approval for Northern Health?

Operational approval is granted by the Manager or Director in the NH hospital department(s) and community site(s) that will be impacted by the proposed research (i.e. where the research is taking place), or an appropriate Executive level staff person. The individual has appropriate authority to assess the impact and to support the dedication of resources (e.g., human or financial resources, space in the facility) to the project (if applicable). Some projects may require approval from more than one Manager or Director.

Operational approval cannot come from the researcher or a co-investigator on the project. It is a conflict of interest to approve NH resources for a project while acting as a primary researcher or co-investigator on that project. NH staff are encouraged to pursue research opportunities as principal or co-investigators, but for the purposes of the RRC's review for ethical merit and organizational impact, there must be approval for this activity by another NH employee with appropriate authority to avoid potential conflict of interest.

What is the Role of the Northern Health "Approval" Manager?

- To review the research project to determine the organizational impact and whether their area is able to support the research.
- To sign the researcher's *Application for Operational Approval for Research* indicating the resources (e.g. human or financial resources, space) required to conduct the research can be provided and that the activities can be executed while normal service delivery for patient care is maintained. Approval may also be provided by sending an email to researchcommittee@northernhealth.ca citing the study name (and file number if available).

    - If the required services will have sufficient impact as to require recovery from the research study budget to offset NH operating costs, the department and researcher will negotiate these costs.
- To indicate (by providing approval) a willingness to participate and support the research study. The approval also acknowledges that the individual will support knowledge translation[1] (i.e., bringing the research to practice and decision-making). This may include: assistance with dissemination of findings within the organization, discussion about and, as appropriate, implementation of recommendations from the research, supporting Northern Health staff in co-authoring publications, providing venues for workshops or presentations, or other ways that the knowledge generated from the research in our region is appropriately shared and contributes to policy and practice improvements.
- To 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.

*Note: a letter of support from the department manager is **not** required. Approval may be provided by either signing the Application for Operational Approval for Research or by sending an email to researchcommittee@northernhealth.ca citing the study name (and file number if available).*

What are the Responsibilities of the Researcher?

The researcher must submit an *Application for Research Approval* to the Northern Health Research Review Committee. This requires the researcher to

- Identify the NH department/site(s) that will be asked to provide services or support required to conduct the research;
- Contact the individual department/site managers to review the details of the services required from the department and for specific department requirements and fee schedules (where applicable);
- Obtain operational approval from the individual with signing authority for the specific department/site (the individual signs the *Application for Operational Approval for Research* or sends an email to researchcommittee@northernhealth.ca to provide approval);
- Confirm that the NH service department(s) impacted by the research have received a copy of the RRC's *Letter of Approval* before services, previously negotiated, are provided; and,
- Ensure all other required agreements are signed (e.g. privacy, confidentiality, data/chart request)

The research project may commence in Northern Health ONLY after the Research Review Committee has issued written approval that all conditions for operational and research ethics approval have been met.

For more information on the Research Review Committee and its process or assistance in identifying appropriate Northern Health Managers to contact regarding Operational Approval, contact researchcommittee@northernhealth.ca

[1] Knowledge translation is about turning knowledge into action – it enables evidence-informed decision-making and practice. The most frequently cited definition of knowledge translation comes from the Canadian Institutes for Health Research: "*knowledge translation is the exchange, synthesis and ethically-sound application of knowledge - within a complex system of interactions among researchers and users - to accelerate the capture of the benefits of research for Canadians through improved health, more effective services and products, and a strengthened health care system (Knowledge Translation Strategy 2004-2009: Innovation in action. Retrieved July 28, 2008 from: http://www.cihr-irsc.gc.ca/e/26574.html)*

Checklist for Consent Process/Information Sheets

**Adapted from the University of Northern BC Research Ethics Board Application Checklist*

Each participant and/or participant community must be provided the following information in either the Consent Process and/or in a separate information letter:

- ❑ purpose and goals of the research
- ❑ how the participant was chosen
- ❑ what the participant will be asked to do
- ❑ who will have access to participants' responses
- ❑ the voluntary nature of participation (including participant's right to withdraw at any time) and what will happen with their information if they withdraw
- ❑ potential benefits from the study
- ❑ potential risks (if any) from the study
- ❑ how anonymity is addressed
- ❑ how confidentiality is addressed
- ❑ how information is stored, for how long, and how will it be destroyed
- ❑ if the participant is being recorded and the recording is not to be destroyed then a release for further use of the recording should be obtained.
- ❑ name and phone number of person to contact in case questions arise
- ❑ how to get copy of research results
- ❑ indication that any complaints about the project should be directed to the appropriate Office (typically the Office of Research/Office of Research Ethics of the Principal Investigator's institution)

Do **not** include the Northern Health logo on study materials unless the Principal Investigator has a formal affiliation with Northern Health. If the Principal Investigator is independent of Northern Health other than the Research Review Committee's review/approval then the logo should not be used. This includes Northern Health staff who are undertaking research for academic purposes (e.g., graduate or post doctoral research) and Clinical Resident research. If the research is "Northern Health research" (i.e., commissioned by the organization), the logo is permitted on research materials.