North Bay Regional Health Centre / Centre régional de santé de North Bay

Instructions for Use: Research Ethics Board Research Project Submission Form

Form Revision: 21/09/22

Page 1-2: General Guidelines only, please do not include with application.

The ethical review process is governed by NBRHC Policy: ADM-RE-1: Research Studies

The North Bay Regional Health Centre Research Ethics Board (NBRHC REB) is responsible for ensuring that all research conducted under the auspices of the North Bay Regional Health Centre meets current ethical standards. All research projects involving NBRHC physicians, staff (including staff acting as investigators outside the institution), students (research within the institution or using institutional resources) and patients must obtain ethical approval from the NBRHC REB **before research can begin**. Heads of departments/programs are responsible for ensuring all such research is submitted for ethics review and that Section D, 1) Department/Division/Program Head Support and Awareness portion of this form is filled out and sent to the NBRHC REB Office with the Research Project Submission Form. (electronic copies accepted)

Clinical Trials Ontario (CTO) offers clinical trial researchers and research sponsors a single REB approval process that can be extended to other participating sites. The NBRHC REB is affiliated with CTO and will collaborate in the application process of multi-centred trials.

Research ethics practices are governed by a set of commonly held and valued ethical principles. As the Tri-Council Policy Statement (TCPS 2) has been adopted as a national standard, the North Bay Regional Health Centre Research Ethics Board subscribes to, and is guided by, these principles.

Copies of the all REB forms, guidelines and templates are available through the NBRHC Research Ethics Office, at REBOffice@nbrhc.on.ca or 705-474-8600 ext. 2508 and at the North Bay Regional Health Centre Research Ethics Board Webpage.

Please complete the following form using the NBRHC REB guidance documents. All questions must be answered or indicate “Not Applicable” where relevant to your study. Forms are to be submitted with appended accompanying material to: REBOffice@nbrhc.on.ca

NBRHC REB meets a minimum of 6 times per year or at the call of the Chair. Investigators must submit the REB Submission form to the REB office a minimum of 15 business days prior to the next scheduled REB meeting and electronic versions are preferred.

Please note that a clear and complete protocol description facilitates a timely and efficient review of the protocol. Conversely, vague, confusing or missing elements will delay appropriate consideration and review.

Best wishes for the success of your research.

Instructions for Completion

The narrative sections of this application will expand as material is added. "X's" may be used in sections requiring completion of a checkbox.

1. **TCPS 2: CORE-2022:** As of January 1, 2020, all submissions to the NBRHC Research Ethics Board will require evidence of successful completion of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans Tutorial by all Investigators. A copy of the completion certificate for TCPS 2: CORE-2022 must be included in the submission package.
2. **Language:** Ensure your submission is understandable to those outside of your field of expertise; avoid the use of technical terminology where possible.
3. Attached documents may ***not*** be used in lieu of the standard Research Project Submission Form.
4. Do not delete sections from this application.
5. **Multi-Center Research**: Investigators will be asked to provide proof of approval from each REB they have sought or will be seeking approval from.
6. **Signatures:** Separate and original signature page will be required (PDF Format is acceptable) from Investigators as well as supporting NBRHC delegates (as applicable).
7. **Complete Packages include the following elements:**

- ☐ Completed, typed REB *Research Project Submission Form* including all necessary signatures – no references should be made to another document
- ☐ A Separate Research Proposal (if applicable)
- ☐ Questionnaire/Study Instrument(s)/ forms to be used in carrying out the research
- ☐ Evidence of REB Approval in other jurisdictions where research is to be conducted
- ☐ Consent form(s)/ Assent forms
- ☐ All recruitment tools (e.g. information letters, advertisements, posters and notices, website)
- ☐ Letters of support from collaborating agencies/institutions (if applicable)
- ☐ Proof of award funds (if applicable)

If you have any questions about the REB forms, requirements or processes, please contact: REBOffice@nbrhc.on.ca.

North Bay Regional Health Centre / Centre régional de santé de North Bay	North Bay Regional Health Centre Research Ethics Board Research Project Submission Form	
INTERNAL USE ONLY → ☐ **NEW** ☐ **RESUBMISSION**	**FILE NUMBER:**	**DATE RECEIVED:**

#	SECTION A - PROJECT REGISTRATION				
1	**PROJECT TITLE**				
2	**RESEARCH TEAM:** *In the case of student research, the faculty supervisor assumes the responsibility for adhering to the North Bay Regional Health Centre's policies and must also be listed as Principal Investigator on the project.				
	☐**Principal Investigator (s)** **or** ☐ **Student Investigator:** if student investigator please list Faculty Supervisor in the space provided as well **(Please include CV)**	**Institution and Department/ Program**	**Address**	**Phone Number**	**Email Address**
	Co-Investigator(s) (if applicable)	**Institution and Department**	**Address**	**Phone Number**	**Email Address**
	Study Team Members : Any other individuals that will be accessing study information	**Institution and Department**	**Address**	**Phone Number**	**Email Address**
	Alternative Administrative Contact (if applicable) e.g. Study coordinator	**Institution and Department**	**Address**	**Phone Number**	**Email Address**

To whom should REB Correspondence regarding this protocol be sent?

☐ Principal Investigator
☐ Alternative Administrative Contact

TCPS 2:CORE-2022 Certificate (as of January 1, 2020, all applications must include a Tri-Council Policy Statement Certificate for all Investigators involved in the study) **:** ☐ *Attached*

3 **DESCRIPTION OF RESEARCH** (please choose the appropriate category that pertains to your project)

☐ **Staff Research**
- ☐ NBRHC Staff Initiated Study
- ☐ Collaboration Project with NBRHC Staff

☐ **External to NBRHC Research:**
- ☐ Investigator Initiated Study
- ☐ Clinical Trial

☐ **Student Research**
- ☐ Resident/Fellow
- ☐ Undergrad
- ☐ PhD ☐ Master's

*In the case of student research, the faculty supervisor assumes the responsibility for adhering to the North Bay Regional Health Centre's policies and must be listed as primary co-investigator on the project.

☐ **Other, Please Specify:**

Please Specify the Research Category:

☐ **Retrospective Data Collection:** Studies involving existing personal health information. NO participant contact.

☐ **Prospective Observational:** NO physical exams but involves participant contact

☐ **Observational Study of Biological Specimens Retrospective or prospective:** (blood, urine, tissue, saliva) taken. No administration or use of drug, biologic natural health product or device

☐ **Clinical Intervention Trial:** Administration or use of Drug, biological, device, behavioural, surgical, food, natural health product.

☐ **Other: Please Specify:**

4 **NORTH BAY REGIONAL HEALTH CENTRE FACILITY(IES) AND AREA(S) WHERE RESEARCH WILL BE CARRIED OUT/DATA WILL BE COLLECTED:**

5 **SOURCE OF FUNDING**

a) Is the project currently funded? ☐ Yes ☐ No

If No, please proceed to Section 6.

If YES, (1) What is the period of funding: From _____ To: _____
(2) What is the Name of the Funding Agency: _____

	b) Funding Type: *please note, for industry sponsors a fee may be applied*. ☐ Industry (e.g. Pharmaceutical, Biotech, Medical Test or Device Company) ☐ Government Funding Agency (e.g. National Institute of Health, CIHR, ICES) ☐ Government (e.g. Ministry of Health, Department of Defence) ☐ Charitable Foundation (e.g. Heart and Stroke) ☐ Internal Funding ☐ Other (please specify complete title of funding source): _____ ☐ None
6	**OTHER INSTITUTIONAL ETHICS REVIEW:**
	a) Is this a multi-centred study? ☐ Yes ☐ No b) Has this research been reviewed by another Institution and/or its Research Ethics Board? ☐ Yes ☐ No If yes, what was the outcome? ☐ Approval granted ☐ Approval Pending c) If applicable, list the sources of ethical approval (and attach letters or certificates of approval) d) Will other Research Ethics Boards be asked for approval? ☐ Yes ☐ No If yes, please specify:
7	**CONFLICT OF INTEREST** *Researchers hold trust relationships with research participants, regulatory research sponsors, the North Bay Regional Health Centre, their professional regulatory bodies and society. The Principal Investigator must disclose any and all conflicts of interest (actual, apparent or potential) relating to this project so that the NBRHC REB may appropriately address it to maintain public confidence and ensure integrity of the research.* *It is important to note that a Conflict of Interest does not imply wrong doing. It also does not mean that the research cannot proceed. Many Conflicts of Interest can be managed, but identification of a conflict of interest is needed as well as disclosure to research participants. It is up to the NBRHC REB to determine if the Conflict of Interest will be appropriately managed and if the proposed mitigation measures are adequate.*
	a) Will any of the investigators or their immediate family members receive any personal benefits (for example: remuneration, intellectual property rights, rights of employment, consultancies, board membership, share membership, stock options) as a result of or in connection with this study?
	☐ Yes ☐ No
	b) If Yes, please describe the "personal benefits" below. This excludes benefits which are standard to the conduct of research (e. g. Travel/Conference compensation)
	c) How will Conflicts of Interest be managed?

SECTION B: RESEARCH OVERVIEW: Complete each section under the appropriate heading. Be succinct. DO NOT DIRECT THE BOARD TO "SEE ATTACHED".		
1	**PROJECT DATES (when participant recruitment will start)**	
	Anticipated Start Date: (mm/dd/yyyy)	**Anticipated Date of Completion: (mm/dd/yyyy)**
2	**BACKGROUND AND JUSTIFICATION:**	
	a) Describe the scholarly rationale for the proposed project. Please include context for the research including sources (references), but please do not include a full literature review. This background must be concise and comprehensive for understanding by a non-scientific audience.	
	b) What is the significance of the study (e.g. the overall anticipated public and or scientific benefit?)	
3	**OBJECTIVES AND HYPOTHESES:** Provide a clear statement of the purpose and objectives of the project, including the research question(s).	
4	**STUDY DESIGN AND METHODS:**	
	a) Describe the study design and what will be done to the participants at each stage of the research (e.g. physical manipulation, doses and methods of administration of drugs, physiological tests, paper and pencil tasks, interviews, questionnaires, time requirements, etc.).	
	b) Provide a sequential description of how recruitment will be conducted (e.g. snowball technique, random sampling, telephone, email, advertisement). Include any incentives (financial or other) that will be provided for participation. Include a copy of every document anticipated to be used for recruitment purposes for review (advertisement(s), poster(s), flyer(s), telephone script(s), e-mail text(s), or letter(s), data collection tools, etc…	
	c) Describe the sample size and characteristics (e.g., gender, age range, affiliation and any other special characteristics). List inclusion and exclusion criteria.	
	d) Who will make initial contact with potential participants and how will this contact be made? Attach a copy of the script or any written materials if applicable.	
	e) Identify any physical, psychological, financial or deprivation influence that might be imposed on participants (e.g. if the person or investigator recruiting and conducting recruitment and consent is in a position of authority or trust towards participants). Describe the nature of the relationship (e.g. doctor-patient, supervisor-employee) and explain measures/safeguards that will be put in place to minimize the potential for coercion and how these measures/safeguards will be communicated to participants.	
	f) Compensation of Participants Will participants be compensated financially? ☐ Yes ☐ No	

	Will participants be compensated In-Kind? ☐ Yes ☐ No If **yes** to **either**, please provide details:
	g) If any deception or partial disclosure is involved in the design of this study provide the rationale for the planned deception or partial disclosure. Describe procedures for debriefing participants and attach a copy of the debriefing.
	h) Describe how the participants will be informed of their right to withdraw from the research study. Please outline the procedures that will be followed to allow participants to exercise this right. As well, indicate what will be done with the participants' data if they withdraw part way through the study.
	i) Describe how the study data will be analyzed.
	j) Should vulnerable populations be used, explain any special considerations to protect their interests. (If applicable)
	k) Describe all radioisotopes and how they will be introduced into the body. (If applicable)
	l) Describe radiation exposure and give an assessment of risk if the participant will be exposed to medical devices involving X-Rays. Describe X-Ray dose equivalents. (If applicable)
	m) Describe what biological specimens will be taken and what they will be used for in the research. Identify who will be collecting the specimens, facilities and procedures utilized to ensure the physical comfort and safety of the participants from whom samples will be taken. Explain who will safeguard the specimens, where they will be stored, how long they will be retained and how they will be destroyed.
	n) Provide any other relevant information not already described.
SECTION C: ETHICAL ISSUES	
1	**EXPERIENCE:** Please provide a brief description of the principal investigator's and/or research team's experience with this type of research as well as their credentials.
2	**PARTICIPANT CONSENT:**
	a) Describe the sequential process that the investigator(s) will be using to obtain informed consent, including who will be obtaining the informed consent and how it will be documented. If written consent will not be sought from the participants, please justify this. **Attach a copy of the Letter of Information describing the experimental procedures of the project, as well as the Consent Form to be provided to each participant or agency. Ensure that the study is adequately described in terms understandable to a potential participant and ensure that participants are well informed of their rights.**

	b) If any of the participants are NOT legally competent or are mentally incompetent to consent, describe the process for obtaining consent from the substitute decision maker. Please include the permission/information letter to be provided to the person(s) providing alternate consent. Include a description of who will be obtaining consent and a script of what they will say.		
	c) Describe what measures will be taken to adapt the research protocol to divergent traditions, values, privacy issues, and modes of communication for the targeted group. In cases where verbal consent will be provided rather than written, explain rationale and the alternative means that will be used to document the consent.		
	d) Ongoing Consent: Ongoing consent is required for research that occurs over multiple occasions and/or involves research activities that occur over extended periods of time (more than one point of contact, follow-up interviews, etc.) Should ongoing consent be required, describe how it will be obtained.		
	e) LOI/CONSENT FORMS: Check items ☒ in the following list to ensure that Consent and/or Information Letter contains all required items:		
	☐ NBRHC Logo ☐ Identification of Investigators including contact information ☐ Title of Project ☐ Assurance of confidentiality ☐ Brief but complete description in lay language of the purpose of the project and all procedures ☐ Statement of Risks including how they will be managed ☐ List potential benefits of the study ☐ Language attesting to the participant's right to refuse to participate or withdraw at any time without consequence ☐ State that their future will not in any way be affected by participating or not participating in the study. ☐ State what will happen to data should participants withdraw halfway through the study ☐ Details of compensation (if applicable) ☐ Statement of time required of participant ☐ Offer to answer questions and provide debriefing ☐ Right of the participant to have his/her personal information held confidential ☐ How, where and for how long data will be kept ☐ A statement that participants may contact an official not attached to the research team regarding possible ethical issues or complaints about the research itself **Research Ethics Board Assistant, North Bay Regional Health Centre, Tel: 705-474-8600 ext. 2508 or REBOffice@nbrhc.on.ca** ☐ A place for the participants signature and place for the date consent was given (if written consent is obtained) ☐ RESEARCH CARRIED OUT OVER THE INTERNET: (Fluid Survey, Survey Monkey, Facebook) If using USA based surveys/sites include language stating that participants are aware that their data may be subject to production orders under the USA Patriot Act		
3	**POTENTIAL RISK:** Your research project may cause negative reactions or inconveniences to the research participants. Indicate the risks associated with the study ☒ as compared to usual standard of care and describe the risk and how the risk(s) will be managed using the textbox provided.		
	☐	Physical Risks (including any bodily contact or administration of any substance).	

	☐	Psychological/emotional risks (feeling uncomfortable, embarrassed, anxious or upset). List any resources that will be provided to participants should they require support (e.g. counselling).	
	☐	Social Risks (including possible loss of status, privacy and/or reputation).	
	☐	Legal Risks (e.g. risk of litigation or marginalization).	
	☐	Economic or other inconveniences (expenses incurred for participation).	
	☐	Any risks to participants greater than those the participant might encounter in everyday life that have not been described above.	
4	**POTENTIAL BENEFITS:** Outline any potential direct benefits to the participants arising from their involvement in the research project. As well, comment on any potential benefits the project holds for the scientific/scholarly community or society that would justify involvement of participants in this study.		
5	**DATA ACCESS, USES, CONFIDENTIALITY AND INTERPRETATION**		
	a) Will data be treated as confidential? If so, how will confidentiality and/or anonymity of the raw data (hard copy and electronic) be maintained? (e.g. Will names be deleted and replaced by a code known only to the principal investigator?) If confidentiality will not be protected, explain why not.		
	b) Describe the procedures/safeguards to be used to ensure the confidentiality and security of data both during the collection and analysis or the research.		
	c) State who will have access to the data.		
	d) How long will data be stored?		
	e) Provide details of the final disposal/storage of data, (e.g. how long they will be secured and the disposal method to be used.		
	f) In reports or publications resulting from the use of the data from this study, what steps will be taken to ensure the anonymity of participants or participating institutions?		
	g) Describe how the data will be used (e.g. publications, pilot for a larger project, program evaluation)		
	h) Describe how research participants will be made aware of the findings and how the findings will be disseminated.		

SECTION D: SIGNATURE PAGES

1 DEPARTMENT/DIVISION/PROGRAM HEAD SUPPORT AND AWARENESS:

Does this study require the services or support of any NBRHC department, nursing unit or clinic?

☐ Yes ☐ No

If yes, please complete the information below and have the Dept/Division/Program head complete the attestation below.

NBRHC STAFF AND RESOURCES INVOLVED IN PROJECT:

NAME DEPARTMENTS WHOSE STAFF/RESOURCES ARE TO BE INVOLVED IN THE STUDY (e.g. ER, Pharmacy, Clinical Records, Diagnostic Imaging)	*NAME OF DEPARTMENT HEAD*	*RESOURCES TO BE USED*

DEPARTMENT/PROGRAM HEAD ATTESTATION AND SIGNATURE: (This section cannot be signed by the investigator or co-investigator. An alternative approval signature is required). If more than one department/unit/clinic is used, signatures from all heads of departments/units/clinics must be submitted.

I have read this completed application and support it's submission for ethics review and I am in agreement with the indicated use of staff/resources.

Title (Mr, Mrs, Ms, Dr.):	*Last Name (Print):*	*First Name(Print):*

Signature of Dept/Div/Program Head:	*Date:*

INVESTIGATOR ASSURANCE: **Principal Investigators are to sign this portion on behalf of the research team. Failure to submit the signature pages for your Research Ethics Submission will result in a delay in processing your request for research ethics approval.**		
1.	I attest that the information provided in this application is complete and correct.	
2.	I agree to conduct this research in an ethical manner, and as approved by the North Bay Regional Health Centre Research Ethics Board (NBRHC REB) and that I have the 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. All Co-Investigators have reviewed the protocol content and are in agreement with the protocol as submitted.	
3.	I understand that research projects may not be undertaken until they have received **FINAL** written approval of the **North Bay Regional Health Centre Research Ethics Board.**	
4.	I agree to comply with the ICH GCP, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, and all North Bay Regional Health Centre policies and procedures governing the protection of human participants in research and understand the consequences for myself and the institution for failure to comply.	
5.	On behalf of my research team, I recognize the importance of maintaining the confidentiality of personal health information and privacy of individuals with respect to that information. I will ensure to conduct research in accordance with NBRHC Policies and with the Personal Health Information Protection Act (PHIPA).	
6.	I understand that on-going review of ethics is mandatory and promise to complete annual renewals, completion reports, amendments and report on adverse events in accordance to NBRHC Policy ADM-RE-1	
7.	**SIGNATURE OF PRINCIPAL INVESTIGATOR**	
	SIGNATURE:	DATE:
	PRINT NAME:	
	SIGNATURE OF SUPERVISOR (Required for all students) I have read this protocol and deem it to be complete. I agree to provide the necessary supervision of the student investigator and agree to ensure the continual monitoring requirements of the NBRHC REB as stated above will be adhered to.	
	SIGNATURE:	DATE:
	PRINT NAME:	