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

Instructions for Use: Research Ethics Board Research Project Submission Form

Form Revision: 20/01/20

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).

Research ethics practices are governed by a set of commonly held and valued ethical principles. As the Tri-Council Policy Statement (TCPS) 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 Department, at REBOffice@nbrhc.on.ca or 705-474-8600 ext 2518 and also available at the North Bay Regional Health Centre Research 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. **TCPS2:** 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 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.

The REB Assistant is available for REB consultation providing expertise in relevant legislation and hospital policy

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Research Ethics Board Research Project Submission Form

INTERNAL USE ONLY → ☐ NEW ☐ RESUBMISSION	FILE NUMBER:	DATE RECEIVED:

The REB Office will assign your project a REB Number and mark the date received

#	SECTION A - PROJECT REGISTRATION				
1	**PROJECT TITLE** – Ensure the title entered matches all the documents submitted in the study (Research Protocol, Funding, Questionnaire)				
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	**Institution and Department/ Program**	**Address**	**Phone Number**	**Email Address**
	The Principal Investigator is the individual responsible for the research project	Include affiliated institution.	Include full Mailing address including postal codes.	Please include area codes.	Ensure that reliable email address is included.
	Co-Investigator(s) (if applicable)	**Institution and Department**	**Address**	**Phone Number**	**Email Address**
	Include names of co-investigators.	Include affiliated institution.	Include full Mailing address including postal	Please include area codes.	Ensure that reliable email address is included.

			codes.		
	Study Team Members : Any other individuals that will be accessing study information	**Institution and Department**	**Address**	**Phone Number**	**Email Address**
	Complete all information for each investigator in the study. If the list is longer than three investigators attach a list and submit with the application as an appendix.	**Include affiliated institution.**	**Include full Mailing address including postal codes.**	**Please include area codes.**	**Ensure that reliable email address is included.**
	Alternative Administrative Contact (if applicable) e.g. Study coordinator	**Institution and Department**	**Address**	**Phone Number**	**Email Address**
	Contact who may be handling paperwork and correspondence related to this file, please indicate this person here if it is not the Principal Investigator.	**Include affiliated institution.**	**Include full Mailing address including postal codes.**	**Please include area codes.**	**Ensure that reliable email address is included.**
	To whom should REB Correspondence regarding this protocol be sent? ☐ Principal Investigator ☐ Alternative Administrative Contact **TCPS2 Certificate** (as of January 1, 2020, all applications must include a Tri-Council Policy Sta 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		**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		

*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.

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

☐ **Other: Please Specify:**

☐ **Other, Please Specify:**

4 **NOR WILL**

This section describes the level of research of the study. If the project falls under more than one category, the description can be covered under "other".

Enter

For research conducted in the community, it is the responsibility of the Principal Investigator to acquire administrative consent and additional institutional REB approvals as needed prior to the commencement of the research activity.

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

Review Fees will be applied for Industry Sponsored Research. Contact REBOffice@nbrhc.on.ca for the fee schedule.

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

Researchers are requested to provide details on other institutions ethics reviews and to indicate the status of approval, or if researchers are planning to submit to any other Research Ethics Boards

	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)
	Please refer to Article 7.4 and 3.2 (e) of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.
	c) How will Conflicts of Interest be managed?
	According to Chapter 7 of the TCPS, disclosure of real, potential and perceived conflict of interest should be made to any research participants. When disclosure to the REB is not enough to manage the conflict of interest, the REB's decision will be guided by the institutions policies.

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)**

The start date signifies the beginning of the formal recruitment process and data collection. Completion of the study can be defined as the point at which data collection and analysis has been completed in order to answer the original research question(s). Make sure that dates coincide with REB Review Dates.

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.	
	– **Briefly describe the background leading to the present proposal, using documentation and literature where appropriate (Include sources).** – **Researchers must provide justification for the study including background evidence that explains the need for the study. This section should explain what is unique about the study and what new research questions can be answered in order to support the ethical opinion that the proposed research has value.** – **Please avoid copying and pasting from the protocol itself as length and language may be cumbersome for those who are reviewing the application.**	
	b) What is the significance of the study (e.g. the overall anticipated public and or scientific benefit?)	
	– **Provide description on why the research is being conducted, including direct implications and applications of the study.** – **Describe why the study is important and its potential to inform future research.**	
3	**OBJECTIVES AND HYPOTHESES:** Provide a clear statement of the purpose and objectives of the project, including the research question(s).	
	– **This section requests details on objectives, purpose and hypotheses of the proposal.** – **The objective(s) of the study involve the specific outcomes or endpoints of the research.** – **The purpose should highlight the main reason that the study is being conducted and should include direct applications of the study.** – **The research question(s): are the questions being evaluated in the study. They should be clear and concise and include the population being studied and the intervention used (if applicable).** – **If the project is a clinical trial or a study to test a medical device, researchers should indicate this in the purpose statement.**	
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.).	
	– **This section should outline the research design and describe it.** – **Researchers are asked to indicate all procedures to be used in the study in which participants will be asked to participate. These must be detailed sequentially, as they will occur for the participant and described in terms that will be understood by reviewers of the protocol who may not have specialised knowledge in that area.** **<u>Interview and Surveys:</u>** – ***Survey* documents must be appended to the REB Package.**	

	– ***Interview scripts*** **must include questions and responses. Also, training materials for individuals other than the investigators conducting the interview must be included in the application.** – **In the case of *surveys*, the researcher should indicate if they have been standardized or validated.** – ***Online surveys*****: should you utilize and American based survey sites (e.g. Survey Monkey) please include information on the USA Patriot Act in your *Letter of Information* for participants notifying participants of the potential use of their information.** **Blood, Fluid and Tissue Samples:** – **Procedures must be described in sequence indicating the volume/amount and frequency of sampling.** – **It must be indicated that investigators will follow universal precautions for handling blood and body fluids and sanitizing equipment.** – **The name of the person conducting the procedure must be listed with details on training and qualifications for conducting such procedures.** **Use of Drugs:** – **Information on drug, dosage, frequency and route of administration must be listed.** – **The name of the person conducting the procedure must be listed with details on training and qualifications for conducting such procedures.** **Exercise Training:** – **A description of all tests and procedures must be included** – **Arrangements for provision of medical supervision during testing sessions must be described as well as an emergency procedure.**
	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…
	– **Sequential details are requested on the procedures to be used in recruitment as well as who will be doing the recruitment.** – **Indicate where participants will be recruited (e.g., specific unit at the hospital).** – **A copy of the recruitment notice/poster/email must be appended to the REB application.** – **The hospital's Communications Department may be contacted to post recruitment posters on boards throughout the hospital and to provide an all user staff email through the Mainstreet News. Contact the NBRHC Communications Department at PublicRelations@nbrhc.on.ca.**
	c) Describe the sample size and characteristics (e.g., gender, age range, affiliation and any other special characteristics). List inclusion and exclusion criteria.
	– **Participants in the study must be described in terms of group affiliation, gender, age range and any other identifying characteristics.** – **Special procedures and ethical considerations are required when the study involves vulnerable populations.** – **Indicate the anticipated number of participants to be recruited, justify the sample size on scientific grounds.**

	– **If a formal sample size calculation has not been done, researchers must justify with rationale for the number of participants specified.** – **Inclusion and exclusion criteria need to be included (as applicable).**
	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.
	– **Scripts must be included in the application package and identification of who will be making initial contact with potential participants.**
	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.
	– **Hospital staff or patient contact information may not be supplied to the investigators. Investigators may ask hospital personnel to send the recruitment materials on their behalf. However, this person should not be in a position of authority. For instance, managers and supervisors of staff should not be asked to assist researchers in staff related studies. Additionally, physicians who are also researchers should not recruit their patients for their own study.** – **Researchers must explain the procedures and safeguards in place to minimize such risks.**
	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:
	– **Researchers must describe details on financial or other remuneration of participants (travel, parking, participation time, gift certificates, promotional materials related to the study). The total amount of remuneration should not be so high as to unduly influence participation.**
	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.
	– **The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans: Article 3.7: The Research Ethics Board may approve research without requiring that the researcher obtain the participants consent in accordance with Article 3.1 and 3.5. Where the REB is satisfied and documents that all of the following apply:** o **The research involves no more than minimal risk to the participants;** o **The lack of the participants consent is unlikely to adversely affect the welfare of the participant;** o **It is impossible or impractical to carry out the research and to answer the research question properly, given the design, if the prior consent of the participant is required;** o **Whenever possible and appropriate, after the participants, or at a later time during the study, participants will be debriefed and provided with additional information in accordance to articles**

	3.2 and 3.4, at which point they will have the opportunity to refuse consent in accordance with article 3.1; and **○ The research does not involve a therapeutic intervention, or other clinical or diagnostic intervention.** **– Researcher must outline the nature of the deception and the rationale for its use in the study, and why the study cannot be done using an alternative design.** **– Should deception be used in the study, researchers must provide debriefing to participants (verbally or in the form of a letter) including why deception was needed in the study, what the deception was, and the option to answer any questions in regards to the deception. Following the debriefing process participants are to be asked for their consent to use the data obtained during the course of their participation in the study.**
	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.
	– Describe the methods for with participants will be notified of their right to withdraw from the research and the procedures that will be in place for the participant to exercise this right (consider withdraw at all phases of involvement (after consent but before research activity, during the research study, after the study has been completed) **– Describe what will be done with the participant's data if consent is withdrawn.** **– Describe what will be done with a participants data should they withdraw part way through the study.** **– Describe how a participant would withdraw from the study, who would they contact?** **– It should be highlighted in the consent documents that care services will not be affected should a participant choose to withdraw.** **– If the data from a withdrawn participant will be used, explain why and how.**
	i) Describe how the study data will be analyzed.
	– The proposed statistical evaluations should be outlined in this section. The purpose of this section is to convince the reviewer that the study will yield useful results that will address the objectives of the study.
	j) Should vulnerable populations be used, explain any special considerations to protect their interests. (If applicable)
	– Vulnerable populations: consult with TCPS Article 4.7 on special research considerations with vulnerable populations.
	k) Describe all radioisotopes and how they will be introduced into the body. (If applicable)
	– Describe the types of radiation sources proposed for use in the study (i.e., oncology, radiology, CT, bone densitometry) and how they will be introduced into the body.
	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)
	– Provide an assessment of the risks of radiation exposure. **– Indicate doses of radiation exposure.**

	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.
	– **Will biological specimens be taken? E.g. blood, urine.** – **Who will be collecting specimens?** – **Where will specimens be collected?** – **Describe procedures in place to ensure comfort and safety of participants.** – **Who will safeguard specimens? Where will they be stored? How long will they be retained and stored?** – **How will specimens be destroyed?**
	n) Provide any other relevant information not already described.
	-This section can be used for additional information to be communicated to the REB that wasn't covered through subsections above.
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.
	– **Provide a description of the researcher's and research team's experience(s) and capability for the conduct of the research. This is especially important if the research involves methods that pose greater than minimal risk, collection of sensitive data and/or a vulnerable population.**
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 participant's are well informed of their rights.**
	– **Chapter 3: TCPS: describes the minimum expectations for the research consent process.** – **Researchers must explain the process to be used to inform participants the details of the study as well as the procedures used to obtain consent.** – **Describe who will be the point of contact for the consent process and where the consent process will take place.** – **No consent may be justified where medical records alone are being used for research with no contact being made with participants and there is no potential for their being identified during the research or in presentations of results.** – **If written consent will not be sought from participants it must be justified.**
	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.
	– **When minors are involved as participant's parents or legal guardians must be contacted for consent.** – **Individuals who are cognitively impaired or developmentally challenged may be legally unable to give consent and consent from a legal guardian is required. Note that research must still be explained to persons who are not competent for themselves and they should be given the opportunity to provide their own consent in addition to their legal guardian's consent.**
	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.
	– **Chapter 9: TCPS: Research Involving First Nations, Inuit and Métis Peoples in Canada describes ethical conduct for research involving aboriginal people.** – **Researchers must be clear about the approach they are taking and the contacts they have already made with the communities and people.**
	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.
	– **If researchers would like to re-contact participants about their involvement in the study or for future studies, the plan for re-contact should be described in the initial LOI for participants and that subsequent contact does not oblige them to participate in future studies.**
	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 Assistant, North Bay Regional Health Centre, Tel: 705-474-8600 ext. 2518 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.		
	– **TCPS Chapter 2:Section 2.8 B: Potential Benefits** – **All studies must have benefits in order to justify being conducted. The research must provide a description of known or potential benefits to society, the scientific community and to the participants arising from the completion of the study.** – **Incentives/remuneration for participation in research is not considered benefits to the participant and should not be listed as such.**		
5	**DATA ACCESS, USES, CONFIDENTIALITY AND INTERPRETATION**		
	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		

Researchers must include in the application a complete and clear description of all known risks as well as anticipated risks which might be expected to occur. Researchers are asked to identify various risks that can occur using the checkboxes provided. The researcher must indicate the steps to ensure that risks are managed as reasonably as possible.
Researchers who do not hold the credentials or expertise to deal with participant risks must make arrangements for referral services for dealing with negative impact on participants.
At times a researcher may view risks associated to their study as minimal, however a REB reviewer may see risks differently.

	the principal investigator?) If confidentiality will not be protected, explain why not.
	– **It is best practice, as reflected in Ontario's privacy legislation and the TCPS that Identifiable data provided by an individual must remain confidential. Names associated with raw data should be replaced at the first opportunity with a letter or numerical code.** – **Personal identifiers include both direct and indirect identifiers. Direct identifiers point directly to an individual (Name, OHIP, patient number, address). Indirect identifiers can also point to an individual when paired with other information as linkage may occur.** – **A de-identified data set refers to a data set that has been stripped of all personal identifiers.** **Personal Health Information:** – **When using personal health information investigators must identify all sources of information (medical records, paper charts, etc).** – **Researchers must also attach a copy of the data extraction form which will be used to record the data.** – **Researchers must contact the manager of the data source (e.g. NBRHC clinical records department). Permission of access to these records is contingent on approval of the NBRHC REB)** – **Investigators are to ensure requests for personal health information are in accordance with the Personal Health Information Act.** – **Researchers must make it clear who will have access to identifiable and non-identifiable information. Access to identifiable information must be justified.** – **Identify any individuals or agencies outside the research group that may have/need access to the data and details regarding how this information will be made available.**
	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.
	– **Protection of data is a key concern for the NBRHC REB. Provide a description of all forms of data storage that will be used. For electronic files there is expectation of password protection and secure back-up procedures. Non-electronic information should be kept in a secure cabinet, behind a locked door.** – **In the case where information will be transferred outside of your research group, information should not contain personal identifiers. Also, when transferring electronic files ensure that the information is encrypted and password protected.**
	c) State who will have access to the data.
	– **Identify who will have access to the data, including names**
	d) How long will data be stored?
	– **It is the responsibility of the Principal Investigator to ensure that once data is collected, it is to be securely stored in a locked area and are only to be accessible to authorized personnel.** – **Researchers should ensure that any identifiable data that is collected electronically is on a secure password protected server or stored on a portable device that is both password protected and encrypted.** – **Researchers are to describe both short term storage (during the study) and long term storage (post analysis).** – **Internal Hospital Policy is the retention of research records for 10 years.**
	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.
	– **When no longer required, data must be destroyed in a manner which protects the participant's identities (shredding or records, deleting files).**
	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?
	– **Describe how anonymity and of participants and participating institutions will be maintained in research reports and articles.**
	g) Describe how the data will be used (e.g. publications, pilot for a larger project, program evaluation)
	– **Describe the intended plans for dissemination of research results TCPS 2, Article 3.2f.**
	h) Describe how research participants will be made aware of the findings and how the findings will be disseminated.
	– **Indicate how the results of the study will be communicated to participants or other stakeholders.**

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*

Describe the cooperation and resources necessary from NBRHC to ensure completion of the research project. Be specific, and provide details about the resources you are requesting. Discuss all items with the Department Head of each program/department you are requesting support. Researchers are required to complete this portion of the form.

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:*

This portion of the REB application provides support from NBRHC Management for which the research requires support. A signature is required from each Manager/Supervisor providing support for the study.

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:	

RECRUITMENT MATERIALS:

Recruitment Materials (advertisements, flyers, brochures, and posters) to be distributed to the public must receive NBRHC Research Ethics Board approval before distribution, publication or posting. A description of where the advertisements are to be placed should be provided along with the proposed ad. The REB will evaluate the recruitment materials to ensure that they are not unduly coercive. After approval, all proposed ads must be forwarded to the Communications Office for review of Institutional requirements.

The following items must be included in the writing text:

- ☐ Full title of the research study (may include an opening statement or catch phrase e.g. participants needed)
- ☐ Name of Principal Investigator and affiliation
- ☐ Contact information for further information and how to contact the investigators
- ☐ NBRHC logo needs to be clearly indicated on the recruitment materials. NBRHC logo standards must be adhered to
- ☐ Statement that research has been approved by the North Bay Regional Health Centre Research Ethics Board
- ☐ Purpose of research
- ☐ Brief summary of the main eligibility criteria
- ☐ Time commitment required and frequency of involvement
- ☐ Location where the research will take place
- ☐ Indicate in general terms what all expectations of participation are e.g. interview, computer-based survey, etc…
- ☐ Provide details on financial or other remuneration, if any
- ☐ Size: 8 ½ by 11 inch or 8 ½ by 14 inch are acceptable
- ☐ Use simple lay language
- ☐ When referring to research subjects use research participants
- ☐ Use investigational versus experimental
- ☐ Avoid:
  - (1) Implying favourable outcome or benefit beyond what is included in the Letter of Information/consent
  - (2) Statements that may be considered coercive

CONSENT MATERIALS

Consent shall be informed: Consent documents must adhere to TCPS2 Requirements stipulating that researchers shall provide prospective participants full disclosure of all information necessary for making an informed decision to participate in the research.

- Include information that the individual is being invited to participate in a research project
- State the research purpose
- Identify the researcher(s), and sponsor (as applicable) and contact information for the researcher
- Provide a statement of the purpose of the study
- Outline foreseeable risks of participating in the research and potential benefits to both the participant and the research population.
- Provide an explanation of the expectations of the participant including the time and frequency of involvement
- Provide clear statements informing the participants that participation is voluntary and that they may withdraw at anytime without consequence and information on what will happen with their data should they choose to withdraw.
- Identify contact information for individuals outside the researcher team that participants may contact regarding possible ethical issues with the research:
    - Suggested Language: If you have any concerns regarding your rights as a participant, you are welcome to contact:

      Ashley Foreman
      Research Ethics Board Assistant
      North Bay Regional Health Centre
      50 College Drive, North Bay, On, P1B 5A4
      Phone: 705-474-8600 ext 2518 Fax: 705-495-7956
      Email: REBOffice@nbrhc.on.ca

- Indication of what information will be collected from participants and for what purpose.
- Description that confidentiality will be protected
- Information about any compensation for involvement in the research
- Consent Forms and Information Letters must be written in “lay language”, this ensures that information is presented in a way that is understandable to participants. You can roughly approximate the difficulty of a consent/information letter document in Microsoft Word, under Tools → Options → Spelling and Grammar → ☑ Show Readability Statistics. After successfully completing a spell-check you will be provided the readability statistics (be aware that this is only an approximation and is to be used only as

a general guide).

- Understand that informed consent is not merely a form, it is a process. The information presented in this document must not only educate prospective participants on the research study. It must also enable them to decide whether or not they would like to participate in the research study.

- Regardless of how consent is acquired and documented, the primary focus of ethical concern should be on the quality of the consent process. The basic elements of consent as outlined in this exemplar are typically relevant regardless of process (e.g. hard copy, via email, on the web, presented verbally in person or over the phone). However, keep in mind that not all items are appropriate for every protocol, and some additional items may be requested by the REB as required.

- All consent forms need to be submitted as a final version

- All consent forms must be submitted to hospital letterhead

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CONTINUING REVIEW:

Continuing ethics review is part of the monitor requirements of the Research Ethics Board which help to ensure that researchers are following their submitted protocols.

The REB has implemented forms to facilitate continuing review of research projects. These include:

- **Annual Renewal of an Approved Protocol Form**
- **Amendment Request for an approved Protocol Form**
- **Participant Adverse/Unanticipated Event Notification Form**
- **Final Report of an Approved Protocol**

Before REB approval expires, the research team is required to submit either a study renewal or completion report. The principal investigator will be sent correspondence 30 days before the lapse of their projects approval expiry, reminding them of the need to submit either a study completion or re-approval application.

FORM	EXPLANATION
Final Report of an Approved Protocol	Each approved protocol is required to complete a final report. Researchers must notify the REB when the research project is completed, discontinued or terminated. Research is considered completed when the researcher no longer requires the involvement of the organization.

Annual Renewal of an Approved Protocol Form	**Each REB approval granted is for no longer than one year which is clearly identified in the REB approval letter. If the research team wishes to continue the project beyond the expiry date they must complete a request for annual renewal within 30 days of the expiry of the approval. Failure to apply for renewal status will result in suspension of REB approval.**
Amendment Request for an approved Protocol Form	**Researchers must approve any changes to their protocol before implementation. Examples include:** • **Research Design** • **Research Documentation** • **Research title or objectives** • **Researcher contact information** • **Recruitment methods** • **Number of participants** • **Changes to risks** • **Addition/change in investigator** **Substantial changes to recruitment, risks and research question may constitute re-evaluation of the protocol.**
Participant Adverse/Unanticipated Event Notification Form	**Local serious adverse/unanticipated events arising from the study must immediately be communicated to the REB.**