North Bay Regional Health Centre / Centre régional de santé de North Bay	Policy/Procedure	
Title Research Ethics Board Review and Submission Requirements for Research Studies	Policy Number ADM-RE-001	
Developer REB Administrator	Category	Administration
	Issue Date	October 1, 1999
	Revision Date	May 2020
	Next Review Date	May 2023

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1.0 Scope of Policy/Procedure

- To ensure a systematic and comprehensive review and approval process for proposed research studies

involving living human participants and research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. The latter also applies to materials derived from living and deceased individuals.

- Describe the Research Ethics Board submission requirements, and the administrative review procedures conducted by the REB.

- Provide a standardized submission, review and oversight process to ensure the researcher is in compliance with relevant regulations, guidelines and policies throughout the ethics review, approval and monitoring process.

- To ensure that all proposed research projects submitted for consideration are reviewed and approved prior to initiation.

- 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".

2.0 Policy Statement

The North Bay Regional Health Centre (NBRHC) Research Ethics Board (REB) is responsible for ensuring that all research conducted under the auspices of the NBRHC meets ethical standards and current guidelines. All research projects involving NBRHC patients, records, or using institutional resources must obtain ethical approval from the NBRHC REB before research can begin.

The NBRHC Research Ethics Board (REB) is delegated with the responsibility for ethics review of research involving living human participants or human biological material and has the authority to approve, disapprove, propose modifications to, or terminate any proposed or ongoing research involving human participants or human biological materials conducted within, or by members of, the organization *(Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 2018)*

All human subject research, involving North Bay Regional Health Centre patients, staff, resources or data:

- Is to be submitted and approved by the North Bay Regional Health Centre Research Ethics Board (REB) before commencement;
- Is required to undergo continuing review and monitoring by the REB
- Must conform to the ethical principles of research as articulated by the *Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans.*
- May be suspended or terminated for cause at the discretion of the REB

No intervention or interaction with human participants in research, including the use of their data, tissue, or the initiation of recruitment, may begin until the NBRHC REB has reviewed and approved the research protocol and issued a certificate of approval. Failure to comply with the requirements of the Research.

3.0 Supporting Documents

Document Title	Document Type	Number
NBRHC Research Project Submission Form	Form	RHC 408
NBRHC Research Agreement Under PHIPA	Agreement	
NBRHC Instructions for use: PHIPA Research Agreement	Form	

4.0 Definitions

Term	Definition
Human biological materials	refers to human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This term applies to materials derived from living and deceased individuals.
Human participants	are those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question.
Minimal Risk	research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in the aspects of their everyday life that relate to the research.
NBRHC	refers to the corporation and includes any site/program where NBRHC services are provided.
NBRHC Patient	refers to all clients, inpatients, outpatients, and residents who are recruited from any NBRHC facility, program or service.
NBRHC Research Ethics Board	is a Board of researchers, community members, lawyers and others with specific expertise, established by NBRHC to review the ethical acceptability of all research within its jurisdiction and under its auspices.
NBRHC Staff	refers to physicians and dentists who hold North Bay Regional Health Centre (NBRHC) appointments and privileges, all NBRHC employees, and those who hold other affiliated appointments at NBRHC, e.g., students / volunteers).
Personal Health Information	Identifying information about an individual where the information relates to the physical or mental health of the individual, including; health history of the individual's family; provision of health care; identifying health care providers; plan of service; payment or eligibility for health care; donation of body part or bodily substance; health card number; substitute decision maker.
Principal Investigator	is the researcher who is responsible for the implementation of the research study, its scientific and ethical conduct and the protection of each research participant.
Research	is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation that includes (a) living human participants; and or human biological materials.
Researcher	means a person who conducts research
Secondary use of information	refers to the use in research of information originally collected for the purpose other than research purposes.

5.0 Procedure/Process

5.1 Equipment and Supplies

- N/A

5.2 Procedure Steps

5.2.1. Authority of the REB

The NBRHC REB is established to review research involving human participants and to ensure that research is designed and conducted in such a manner that it protects the rights, welfare and privacy of research participants. The North Bay Regional Health Centre provides resources to allow for the financial and administrative independence of the Research Ethics Board, and it will respect decisions made by the Research Ethics Board. The North Bay Regional Health Centre cannot overturn any Research Ethics Board decision to reject a research project. REB approval applies to the ethical acceptability of the research, and does not, in itself, constitute authorization for the research to proceed (*Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, TCPS 2 2018).*

5.2.2. Activities that Require REB Review:

- All research involving human participants (patients, their family members, staff, physicians, students);
- All research involving human biological material as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals;
- All research in which access to human participants involves any records maintained at the North Bay Regional Health Centre
- All research carried out under the auspices of the North Bay Regional Health Centre

The following are examples of research involving human participants:

- Administering a drug, taking a blood sample, performing a procedure or doing a test (clinical, therapeutic or otherwise) on a person for the purpose of research rather than treatment;
- Asking people for information whether by telephone, letter, email, internet, survey, questionnaire or face to face interview;
- Using non-public records that contain identifying information previously gathered about individuals either directly or indirectly;
- Access to/using personal health information
- Observing someone's responses or behaviour, either directly or indirectly.

5.2.3. Activities not requiring REB review:

- Research activities that rely exclusively on publically available information when information is legally accessible to the public and protected by law, and there is no reasonable expectation of privacy.
- Research involving observation of people in public arenas where it does not involve a staged intervention or direct interaction with participants, and where there is no reasonable expectation of privacy so long as any dissemination of research results does not allow identification of specific individuals.
- Research that relies exclusively on secondary use of anonymous information, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.
- Quality assurance studies, performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this policy, and do not normally fall within the scope of REB review. There may be circumstances where these activities include a research component. In such cases, these activities would be expected to undergo ethics review by the NBRHC Research Ethics Board.

If a researcher/evaluator is unsure whether his/her project constitutes research and requires NBRHC REB Review, they are to consult the NBRHC REB administration.

5.2.4. Submission of Research Study

Research Ethics Board members rely on the documentation submitted by the Principal Investigator for initial and continuing review of research. The materials provided to the REB must provide sufficient information to conduct the review, and to ensure the project meets ethical principles and mandatory requirements of the Tri-

Council Policy Statement: Ethical Conduct for Research Involving Humans and other applicable regulatory requirements. Consequently, the REB will only consider complete submissions.

Submission Process

Investigators shall submit applications for initial and continuing review for research studies involving humans using the standard NBRHC Research Ethics Boards Submission Form, which can be found on the external NBRHC website and intranet site).

http://www.nbrhc.on.ca/about-nbrhc/research-ethics-board/

All Investigators are required to complete the Tri-Council Policy Statement CORE Tutorial, and submit proof of completion with the Research Ethics Board Research Project Submission Form.

5.2.4.1a Initial Submission

Investigators must submit the Research Ethics Board Research Project Submission form to the REB Office, a minimum of 15 business days prior to the next scheduled REB Meeting (electronic versions are preferred).

All relevant sections of the application including all required accompanying documentation must be complete. Further, original electronic and/or faxed signatures of investigators and NBRHC department heads (for institutional approval of resources) must be included with the submission.

The REB office will not initiate the review process for applications that do not meet the submission requirements. If there are mandatory elements missing the REB will contact the Principal Investigator identified in the application within two weeks of submission to identify the deficiencies.

5.2.4.1b Amendments of Approved Studies

Should the Investigator wish to implement changes to their project, they must submit documentation to inform the REB about the changes. Investigators are to use the "Request for Ethics Approval of Amendment to an Approved Protocol" form and adhere to the requirements outlined within the form.

5.2.4.1c Annual Renewal/Closure to Approved Studies

Investigators who wish to renew their project must submit a completed request for Annual Renewal of an Approved Protocol 30 days before the relevant REB expiration date. Researchers must use the Final Report of an Approved Protocol form to close a research project that is completed prior to its expiry date.

5.2.4.1d Unanticipated Events

The Principal Investigator is required to report to the Research Ethics Board only those local adverse events that are deemed to be unanticipated problems (unexpected, related and involving greater risk that may increase the level of risk to participants, or has other ethical implications that may affect participant's welfare), using the Participant Adverse / Unanticipated Event Notification form, RHC1854.

A Local (Internal) adverse event:
Local adverse events are those adverse events experienced by research participants enrolled by the investigator(s) at one or more centres under the jurisdiction of the REB of Record. In the context of a single-centre clinical trial, all adverse events would be considered *local adverse events.*

Reportable local adverse events (i.e., those that represent unanticipated problems) should be reported to the REB within 15 calendar days of the principal investigator becoming aware of them. Fatal or life-threatening reportable local adverse events should be reported to the REB within in 7 calendar days.

The following local adverse events should not be reported to the REB:

a) Serious adverse events that are considered expected
b) Serious adverse events that are considered not related to the investigational product or research procedures, whether the event is expected or not
c) Non-serious adverse events, whether expected or not

The REB will not collect or post the adverse events that have occurred elsewhere.

5.3 Administrative Review

Upon receipt of Research Project Submission, the REB administrator date stamps and screens the application for completeness. If the submission is incomplete, the REB administrator will follow-up with the investigator to request the required information.

Upon receipt of a complete research project submission, the REB administrator will assign a unique project number, enter the project into the REB database and initiates an electronic Research Ethics Board file that contains the original document and all relevant material.

The submission is then assigned to appropriate reviewer(s) for either full board or delegated review.

For full board review the completed Research Project submission form shall be circulated with the agenda ten business days prior to next scheduled Research Ethics Board meeting to allow time for members to review the application.

5.4 Research Ethics Board Review

Delegated Review - Minimal Risk Research Studies

The NBRHC REB reviews each application in accordance with the level of risk that the proposed study poses to research participants. The higher the risk, the higher level of scrutiny. In accordance with the TCPS2, full Board review is the default requirement for the review of research, unless the REB has determined the research to be minimal risk, and that delegated review by one or more experienced REB members is appropriate. The REB retains the right to determine whether a protocol will receive full board review or delegated review.

Types of minimal risk studies include but are not limited to:

- Studies relying exclusively on secondary use of data (previously collected/existing clinical data, medical records or other personal records - in accordance with applicable privacy legislation.)
- Studies that involve only questionnaires or surveys unless clinical in nature. If the questionnaires involve sensitive information from vulnerable populations or inconvenience, they will generally not qualify for delegated review.

The Chair of the REB, in conjunction with the Administrator, will determine if research meets the criteria for delegated review. (In accordance with article with 6.12 of the TCPS2). Delegated review may be appropriate for minimal risk research and the following categories of research:

- research that is confidently expected to involve minimal risk;
- minimal risk changes to approved research;
- annual renewals of approved minimal risk research;
- annual renewals of more than minimal risk research where the remaining research-attributable risk is minimal. For example, the research will no longer involve new interventions to current participants and no additional participants will be enrolled in the study; and
- annual renewals of more than minimal risk research in which there has been:
  - no significant changes to the research;
  - no increase in risk to (or other ethical implications for) the participants since the most recent review by the full REB; and
  - the REB Chair has determined that the delegated review process is appropriate.

Full Board Review:

Studies not qualifying for delegated review will undergo full board review at convened meetings.

The Research Ethics Board members will submit their evaluation of the research project submission and any recommendations at the Research Ethics Board meeting.

REB Determinations:

After review the REB may make one of the four following determinations as a result of its review of the research:

- Approval: The protocol and accompanying documents are approved as submitted. The research can begin as soon as the Principal Investigator receives the certificate of approval from the NBRHC REB provided that all other institutional requirements have been met. The period of approval will commence on the day the study is approved by an action of the convened REB and will expire one year after the initially approved date.

- Conditional Approval: The Board may decide that a protocol may be approved provided that certain conditions are met or changes be made. The required conditions and reasons for such conditions are sent to the investigator from the REB Chair. When the investigator provides the NBRHC REB with proof that the conditions have been met and the submission documents have been amended, the certificate of approval will be sent to the investigator.

  Researcher(s) are provided a 30 - day time period to respond to and comply with the REB recommendation(s). Failure to do so will result in rescindment of conditional approval.

- Deferral: The REB may choose to defer the decision if the submission does not have sufficient information to arrive at a determination. The application will be brought back to the Full Board after additional information or revisions has been received.

- Rejection: The REB may reject any protocol which does not meet its standards for ethical and scientific review were revision is unlikely to enable the REB to reach a positive determination. No institutional official may approve a project that the REB has rejected. The researcher may request reconsideration and has the right to appeal the REB's decision.

The Research Ethics Board shall make the final determination as to the nature and frequency of continuing Research Ethics Board review and will notify the researcher of the applicable requirement.

5.5 Appeals Process:

The NBRHC REB will reconsider its decision if it requested to do so in writing by the researcher. The researcher may submit additional information and will be invited to attend the REB meeting in person to present the information. If the researcher is still unsatisfied with the REB's decision a written appeal may be submitted Requesting an outside REB review.

Terms of REB Approval:

Research Ethics Board approvals are effective for one year from the meeting date at which the research was approved. In accordance with the TCPS2, at a minimum, continuing research ethics review shall consist of an annual renewal of an approved protocol report (for multi-year research projects) or a final report of an approved protocol (for projects lasting less than one year).

Researchers shall submit to the Research Ethics Board in a timely manner requests for substantive changes to their originally approved research. The Research Ethics Board shall decide on the ethical acceptability of those changes to the research in accordance with a proportionate approach to research ethics board review.

Researchers shall also report to the REB any unanticipated issue or event that may increase the level or risk to participants, or has other ethical implications that affect the participants' welfare.

5.6 Agreement with the Researcher

REB Certification will be provided in the form of a letter from the NBRHC REB Chair or Vice-Chair to the Principal Investigator of the study. Researchers must prescribe to the terms set out in this letter as well as the following:

- Must comply with PHIPA legislation.
- Before the North Bay Regional Health Centre may disclose personal health information to a researcher (if required under the scope of the proposed research), the researcher shall enter into a written agreement (NBRHC Research Agreement under PHIPA) with the NBRHC in which the researcher agrees to comply with the conditions and restrictions, if any, that the NBRHC imposes relating to the use, security, disclosure, return or disposal of the information.
    - A researcher who receives personal health information about an individual from the NBRHC in the context of an approved research protocol, shall agree to:

        (a) comply with the conditions, if any, specified by the Research Ethics Board

        (b) use the information only for the purposes set out in the research project submission;

        (c) not publish or otherwise disclose the information in a form that could reasonably enable a person to ascertain the identity of the individual;

        (d) not make contact or attempt to make contact with the individual, directly or indirectly, unless the NBRHC first obtains the individual's consent to being contacted;

        (e) notify the NBRHC Research Ethics Board immediately in writing if the researcher becomes aware of any breach of confidentiality or privacy as set out in (a) through (d) above or the agreement between the researcher and the NBRHC pertaining to the conditions under which the study may be conducted at the NBRHC;

        (f) comply with the agreement between the researcher and the NBRHC Research Ethics

Board pertaining to the conditions under which the study may be conducted at the NBRHC.

5.7 Failure to Submit a Research Project for REB Review

- The implications for engaging in activities that qualify as research without obtaining REB Review are serious. Results from such studies may not be published unless REB approval was obtained prior to collecting the data. Additionally, conducting research without REB review can constitute research misconduct. It is also against policy to use data derived from unapproved research protocols to satisfy thesis or dissemination requirements unless deemed exempt from REB Review.

- If an investigator begins a project and later finds that the data gathered could contribute to generalizable knowledge, and would like to disseminate this knowledge, they must submit a proposal for REB Review as soon as possible.

6.0 Documentation

- Only document on NBRHC Form Management Team approved or government forms.
- When 'Instructions for Use' accompany forms, document on the form according to the instructions.
- When documentation is to be done electronically ensure that documentation occurs in the applicable Meditech Module(s). Refer to NBRHC policy Down Time- Process for Electronic Documentation" in the event of computers not being available.
- All narrative notes are to be recorded according to the hospital's approved documentation methodology.

7.0 References

- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri Council Policy Statement: Ethical Conduct for Research Involving Humans, TCPS 2 December 2018.

- Bill 31, Personal Health Information Protection Act, 2004

- Canadian Association of Research Ethics Boards (CAREB) Guidance on Reporting of Unanticipated Problems including Adverse Events to Research Ethics Boards in Canada, July 2010.

8.0 Stakeholder Review

Stakeholders	Month/Year Reviewed
NBRHC Research Ethics Board	May 2020
Coordinator, FOI, and Privacy Officer	April 2020
Nursing Practice and Advisory Committee (NPAC)	April 2020
Medical Advisory Committee (MAC)	June 2020

9.0 Approval

Signing Authority Signature	Date Signed
Executive VP, Medical & Chief of Staff	August 24, 2020