NORTH BAY REGIONAL HEALTH CENTRE

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Title Research Studies	**Document No**		ADM-RE-1 *Formerly NBGH ADM 1-190*
	Policy category		Admin-Research and Ethics
	Effective date		
	☒ **New to NBRHC**	☐ **Minor**	☐ **Major**
☒ **Policy/Procedure** ☐ **Protocol** ☐ **Guideline**	**Developer** Manager, Research & Quality Improvement		
Cross References (NBRHC or legacy organization policies) Corporate Privacy Policy for Personal Health Information – Joint ADM 3-05	**Comparable Policy from service provider within NBRHC Facility** Not applicable		

NOTE: This is a **CONTROLLED** document for internal use only, any document appearing in a paper form should **ALWAYS** be checked against the online version prior to use.

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1.0 Purpose

- 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.

- To provide a guide for researchers submitting their Research Project Submission Form for prior approval that outlines the expectations of the Research Ethics Board and the research application submission process.

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

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2.0 Policy Statement

All research undertaken at or under the auspices of the North Bay Regional Health Centre involving living human participants or human biological materials will conform to the ethical principles of research as articulated by the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010.* This applies to staff or students, regardless of where the research is conducted, in accordance with this policy.

The NBRHC Research Ethics Board (REB) is delegated the responsibility for ethics review of research involving living human participants or human biological material. While 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 overlap with research. In such cases, these activities would be expected to undergo ethics review by the NBRHC Research Ethics Board.

The North Bay Regional Health Centre Research Ethics Board 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, December 2010.)*

The North Bay Regional Health Centre will provide 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. An 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, December 2010).*

Failure to comply with the recommendations made by the Research Ethics Board may result in the immediate suspension of ongoing research and/or other disciplinary action.

3.0 Minor Revision History

Not applicable, new policy.

4.0 Definitions

"**Research**" is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

"**Researcher**" means a person who conducts research.

"**Human participants**" are those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question.

"**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.

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5.0 Materials Required

All proposed research projects must be submitted using the North Bay Regional Health Centre Research Project Submission Form (Can be found on "p" drive).

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6.0 Procedure

6.1 Submission of Research Study

- All completed Research Project Submission Forms must be submitted to the Manager, Research and Quality Improvement, a minimum of 30 days prior to the scheduled start of the study (electronic form is acceptable).

- Upon receipt of a properly completed Research Project Submission Form, the Department of Research and Quality Improvement shall initiate a Research Ethics Board file that contains the original document.

- If the proposed Research Project Submission Form is lacking sufficient information for Research Ethics Board review, the applicant shall be informed of the deficiencies. The research project submission shall not be reviewed by the entire Research Ethics Board until the deficiencies noted have been rectified.

- The completed Research Project Submission Form shall be circulated with the agenda ten days prior to the Research Ethics Board meeting to allow time for members to review.

6.2 Research Ethics Board Review

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

- After review and acceptance or rejection of the proposed research project submission by the Research Ethics Board, a motion of approval shall be made. The Research Ethics Board shall provide to the researcher a decision in writing, with reasons, setting out whether the Research Ethics Board has approved or not approved the research project submission, and whether the proposal is subject to any conditions, which must be specified in the 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. At a minimum, continuing research ethics review shall consist of an Annual Renewal of an Approved Protocol Report (for multi-year research projects) and a Final Report of an Approved Protocol (for projects lasting less than one year).

- Researchers shall report to the Research Ethics Board any adverse/ unanticipated event that may increase the level of risk to participants, or has other ethical implications that may affect participant's welfare.

- 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 have the right to request, and the Research Ethics Board has an obligation to provide, prompt reconsideration of decisions affecting a research project.

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6.3 Agreement with Researcher

- 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 an agreement 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.

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7.0 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 NBGH 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.

8.0 Appendices/Educational Materials

Not applicable

9.0 References

1. 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, December 2010.

2. Bill 31, Personal Health Information Protection Act, 2004.

10.0 Content Experts/Stakeholders

Content Expert/Stakeholder	Date Sent
NBRHC Research Ethics Board	June 2011
Chief Privacy Officer	August 2011
Medical Advisory Committee	November 2011
Nursing Practice Committee	October 2011

Professional Practice Committee (District)	November 2011
Professional Practice Committee (Regional Mental Health)	November 2011

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11.0 Signing Authority Approval

Position	Date Signed
Chief Executive Officer	