

Subject:	Research – Request for Participation	Date Approved:	July 11, 2009
Approved by:	Executive Director	Date Revised:	
Specific to:	All Staff, Board of Directors and Volunteers	Next Review Date:	September 2017

PURPOSE

The North Huron Family Health Team (NHFHT) will exercise due diligence and manage risk with respect to research opportunities involving the organization and/or its patients and staff. All research will be conducted to the standards of the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans and the Research Guidelines of the Personal Health Information Protection Act (PHIPA); these documents may be accessed in the Reception office as companion documents to the NHFHT Administrative Policies and Procedures manual.

Research is defined as a systematic investigation to develop or establish principles, facts or knowledge including developing, testing and evaluating research (PHIPA Toolkit, 2005). The NHFHT supports participation in research in the interest of advancing rural health care.

This policy applies to all research projects approved on or after August 1, 2009 and, in accordance with PHIPA.

DEFINITION

The NHFHT distinguishes between **research** which involves the use of personal health information, tissues and/or biological fluid or which involves a retrospective review which will be presented to an external audience and/or published and **quality assurance activities** which are solely for internal use (e.g. retrospective review of a specific patient population).

PROCESS

Research by a prescribed entity as detailed in PHIPA regulations (e.g. CIHI, ICES, and Cancer Care Ontario) does not require review by a recognized, independent, academic review Board. All research activity involving patients and/or staff through physical participation and/or collection or use of personal health information, tissues or biological fluid must have the approval of a recognized, independent review Board, academic or otherwise as indicated, which meets the composition of a Research Ethics Board as specified under PHIPA; the NHFHT does not have the resources for an internal research ethics board. The purpose of such a review and process is to protect the interests of the subjects involved. Once approval by a recognized, independent review Board, academic or otherwise as indicated, is received, the proposed research must be reviewed by the NHFHT Board of Directors.

RESEARCH - REQUEST FOR PARTICIPATION

Submission of Proposed Research for Consideration by NHFHT Finance & Audit Committee

The following documentation is to be submitted:

- 1) 1-2 page typed or legibly written summary of the research study including:
 - Purpose

- Goals and Objectives
 - Dates of Study
 - Study Design and Methods
 - Anticipated Benefits and/or Risks
 - Impact on Organization with respect to resources
 - If patients, staff and/or physicians will be identified/identifiable (e.g. small sample size)
 - If patients will be contacted
 - Where anticipated results will be presented and/or published
- 2) Research Proposal
 - 3) Research Ethics Board Approval
 - 4) Copies of approval from other organizations for same research, if applicable

The NHFHT Finance & Audit Committee will review submissions for proposed research. All research proposals seeking NHFHT participation will be considered under, but not limited to, the following criteria:

- Adherence to policy, legislation and professional standards
- Required consent of participants as specified under PHIPA
- Assurance that confidentiality and privacy are protected and that individual patients and physicians are not identified or identifiable through sample size or other means
- Avoidance of conflict of interest
- Informed patient consent, including risks
- No evidence of coercion
- No effect on treatment if the patients choose to or not to participate
- No compromise of patient and staff/associate safety
- Engagement/support of minimum of one local physician to undertake responsibility to address any concerns arising during the course of the study
- Pre-determination of allocation of proceeds from study, if any
- Determination of whether the results of the research will be published
- Mechanism to report outcome and evaluation results to the NHFHT Finance & Audit Committee
- Impact on organization with respect to liability and human and financial resources.

RESEARCH - REQUEST FOR PARTICIPATION

The NHFHT Finance & Audit Committee will advise the researcher if the proposed research is approved, not approved or if additional information/documentation and/or consultation are required (e.g. Information Sharing Agreement).

Approval by the NHFHT Board must be in writing prior to the research commencing.

Related NHFHT Administrative Policies and Procedures for consideration in reviewing proposals include:

- Confidentiality
- Release of Personal Health Information
- Conflict of Interest
- Privacy
- Ethics

(form attached)

