SAULT AREA HOSPITAL
HÔPITAL DE SAULT-SAINTE-MARIE

MEDICAL POLICY

Sault Area Hospital

ISSUED BY:	Innovation, Quality & Medicine	ISSUE DATE:	January 2022
AUTHORIZED BY:	Senior Leadership Team	REVISION DATE:	
CATEGORY:	Administrative Policy	PAGE:	1 of 4
SUBJECT:	**Research Policy**		

POLICY

1. PURPOSE

The purpose of this policy is to help guide research conducted at Sault Area Hospital (SAH).

2. DEFINITIONS

Research is defined as: a systematic and rigorous process undertaken to answer a specific research question through qualitative and/or quantitative methodologies.

A clinical trial is a type of research defined as: a prospective biomedical or behavioural research study of human subjects that is designed to answer specific questions about biomedical or behavioural interventions (e.g., vaccines, drugs, treatments, devices, or new ways of using known drugs, treatments, or devices, etc.).

The principal investigator (PI) (herein called 'researcher') is the person in charge of the study who is responsible and accountable for the scientific and ethical conduct of the study.[1]

3. SCOPE

This policy applies to all parties conducting research at SAH and includes any research:

3.1 that falls under the direction of and/or is conducted by any SAH employee or physician with privileges at SAH in their capacity of principal investigator
3.2 that uses any hospital property, including information collected from patients and/or staff, their charts/records, investigation results, or information collected through surveys, questionnaires or interviews
3.3 that investigates human participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s) and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy;
3.4 that requires approval from the Joint Group Health Centre (GHC)/SAH Research Ethics Board (REB) before participant recruitment and research data collection may commence
3.5 that is conducted under a Clinical Trial Application and/or Investigational Testing Authorization in Canada and must follow Division 5 of the Health Canada Food and Drug Regulation, and/or Part 3 of the Medical Device Regulations, and/or Part 4 of the Natural Health Product Regulations
3.6 that is subject to inspection by the Regulatory Operations and Enforcement Branch (ROEB) of the Government of Canada;
3.7 that involves the use of the SAH's information that is not already public
3.8 where any portion of the research funding is held or administered by SAH
3.9 with intent to publish as scientific literature.

1. Clinical Trials - Participating - Principal Investigator. (n.d.). Retrieved from https://sunnybrook.ca/research/content/?page=sri-ct-part-3

4 RESPONSIBILITIES OF HOSPITAL LEADERSHIP

4.1 Hospital leadership will work with the principal investigator or delegate to assess the proposed research project and consider the possible impacts, including but not limited to:

- potential benefits of the research for SAH
- participants and their respective roles
- proposed plans for recruitment and consent
- intent to share research findings
- any other potential impacts to SAH

4.2 Hospital leadership will be required to provide their approval for any research project in their unit/department and will abide by the Signing Authority policy (#6.11) and/or Signing Authority – Clinical Trials (#3.11) and Conflict of Interest Policy (#3.1). Written approval will be obtained through a Request for Department Approval (RDA) form (form #15845).

4.3 All research studies require Leadership accountabilities:

- Departmental Managers are responsible for discussing and approving the research with the PI/delegate and completing the RDA. Unit/Department impact of research will be determined on a case-by-case basis as per the proposed project protocol.
  The Departmental Manager also has the responsibility of informing relevant Directors of the research, as well as escalating research activities that are beyond the scope of their authority.
- Directors are responsible for being aware of all research activities in their respective areas of responsibility, challenging research activity deemed inappropriate, and/or supporting Managers and PIs/delegates to resolve issues/take mitigating actions as needed, and escalating issues to Vice Presidents as needed.
- Vice Presidents (VPs) are responsible for being aware of all research activities in their respective areas of responsibility, challenging research activity deemed inappropriate and/or supporting Directors/Managers and PIs/delegates to resolve issues/take mitigating actions as needed, and escalating issues to CEO as needed.
- The CEO is responsible for supporting VPs/Directors/Managers and PIs/delegates to resolve issues, to challenge research activity deemed inappropriate, and/or to take mitigating actions as needed.

4.4 Hospital leadership will ensure that the SAH – Clinical Trials office manages and oversees any clinical trials conducted at SAH.

5 RESPONSIBILITIES OF THE RESEARCHER AND STUDY STAFF

Researchers are responsible for:

5.1 all parties involved under the approved research protocol. These parties include, but are not limited to study staff, agents and internal personnel

5.2 paying any invoices or fees accrued as part of the research project;

5.3 Sharing the research findings through researchreview@sah.on.ca, which will then be shared with hospital administration

5.4 overall management and conduct of the project(s)

5.5 informing the approving REB of any changes in research direction and/or project deliverables and send a copy of the REB approval letter approving the amendment to researchreview@sah.on.ca

5.6 management and supervision of study staff, including medical residents, students or research assistants

5.7 ensuring a safe and secure working environment, including compliance with occupational health and safety legislation and the Canadian Standards Association (CSA) Psychological Health and Safety in the Workplace standard

5.8 complying with external regulatory requirements

5.9 ensuring all conflicts of interest are disclosed and managed, including those of research staff and students

5.10 ensuring compliance with the research sponsor/funding agency regulations, SAH's Standard Operating Procedures (SOPs) governing the management and conduct of research

5.11 any additional responsibilities outlined in any agreements, legislation, policies or forms that may be applicable as identified by SAH, the study sponsor or funding agency

5.12 reporting any privacy concerns or breaches to the privacy office at SAH.

All researchers and study staff will:

5.13 conduct themselves in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) and the Tri-Agency Framework: Responsible Conduct of Research, available on the Government of Canada's website, Health Canada Food and Drug, Medical Device, and Natural Health Productions regulations, as applicable, Good Clinical Practice (GCP), and applicable privacy legislation

5.14 ensure access to adequate resources to conduct the research properly

5.15 conduct themselves according to the REB and Health Canada (if a clinical trial) approved protocols

5.16 ensure they have Health Canada approval to conduct the clinical trial, if applicable

5.17 conduct the research following written SOPs

5.18 conduct themselves in accordance with SAH policies and procedures as they apply to conducting research.

6. OBTAINING HOSPITAL AND RESEARCH ETHICS BOARD APPROVAL (REB)

6.1 The Researcher will obtain SAH and REB approval prior to commencing research

- For information on obtaining SAH approval and an accompanying checklist, visit https://www.sah.on.ca/programs-services/research
- For REB related forms and requirements, visit: https://sah.on.ca/programs-services/research/research-ethics-board-ghc-sah/

6.2 Researchers will not be given access to any SAH systems or data until after approval from SAH and a qualified REB has been obtained.

6.3 SAH/GHC REB ethical approval is effective for one year or per the term designated on the Research Ethics Board Approval letter and subject to yearly renewal at a minimum. As institutional approval is dependent upon the REB approval being in effect, any substantive changes to the research from how it was originally approved may also warrant an amendment to Hospital approval.

Please note: Sections 6.1 and 6.2 may not apply to clinical trials.

7. CURRENCY

7.1 This policy will be reviewed every three years from the original date of approval.

RELATED POLICIES

- Conflict of Interest #3.1
- Signing Authority #6.11
  Signing Authority – Clinical Trials #3.11

RELATED DOCUMENTS

- Research Ethics board Network of Networks (N2) Standard Operating Procedures (SOP)
- Request for Department Approval (RDA) forms

- Agreement to use personal health information for research (also known as the Data Sharing Agreement [DSA])
- Responsible Conduct of Research training, Health Canada Division 5, GCP, Privacy Legislation training and certification is available on CITI through SAH's institutional Network of Networks (N2) account and is available to Researchers.
- A certificate for the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) is available online from the Canadian Government.