

Documented Institutional Ethics Requirements Sault Area Hospital

Missions and Values

Our hospital, staff, and physicians are committed to growing research capacity for the benefit of the people we serve. Together with our movement toward the deliberate integration of evidence into practice and then into patient care, our expanding contribution to clinical and health sciences research affirms our commitment to our vision: Trusted Partner. Outstanding Care.

Informed Consent Form Requirements*

Representatives of Sault Area Hospital to oversee the conduct of clinical research studies at this location.

Access to Medical Records and Obtaining Consent*

If the Principal Investigator requires feasibility support, they must obtain approval through the Request for Department Approval (RDA) — Feasibility & Analytics form (form #15883). This may be obtained prior to Research Ethics Board (REB) approval to determine if the institution has the patient population to support the research. This report will provide an estimate of the number of participants only and will not include any protected health information (PHI).

All study access to Sault Area Hospital PHI for participant prequalification purposes (i.e., prior to any first patient contact) requires prior REB study approval. Any access to Sault Area Hospital patient PHI for the purposes of research prior to REB-approval is otherwise prohibited.

Pre-screening for research studies does not require consent of the patient nor the permission or knowledge of the patient's Most Responsible Physician/Person (MRP), where Sault Area Hospital considers consent for pre-screening access to Sault Area Hospital PHI would be generally impracticable to obtain or manage.

If the proposed research project requires access to physical (paper) patient charts, the principal investigator must also obtain approval from the Manager of Health Records by completing the Request for Department Approval (RDA)—Health Records form (form #15882). All RDA forms can be found on the research page of the Sault Area Hospital main website.

SAH mandates that either manager or director approval is obtained in the area(s) where the research will take place. This may be done through the RDA -General (Form #15845). Research that is limited to chart reviews should obtain department approval from Health Records.

SRERS Administration Sault Area Hospital

Reminder: Institutional Research Administration Requirements

The CTO Streamlined System provides a streamlined approach to research ethics review. Each participating site must ensure that all necessary institutional authorizations and contracts/agreements are in place prior to beginning the research.

For Sault Area Hospital, online requests for Institutional/Regulatory & Research Requirements visit:

<https://sah.on.ca/programs-services/research/research-approval-pathway-and-forms/>

Research Training

All individuals (e.g., investigators, coordinators, and any other personnel conducting research activities including students, trainees, fellows etc.) involved in research activities at Sault Area Hospital (i.e., any involvement at a site, on behalf of a site, with site participants/charts/identifiable data etc.) are required to complete research training. Please visit the Sault Area Hospital research page or contact the Sault Area Hospital research office at research@sah.on.ca for more details or how to access the required training.

CTO Stream

Collaborators:

The following collaborators must be given a role on the initial study-wide application, called the Clinical Trial Initial Application (CTIA), or Observational Study Initial Application (OSIA) and the Participating Site Initial Application (PSIA):

Email: tassoneco@sah.on.ca

Role: Institutional Representative

Email: VPMA@sah.on.ca

Role: Institutional Representative

Email: research@sah.on.ca

Role: Institution Admin

Email: walden@sah.on.ca

Role: Institutional Representative

This access is automatically granted when the Participating Site Initial Application is created. **When the Sault Area Hospital is the Lead Applicant site the research team should immediately create the PSIA for the Sault Area Hospital (right after creating the CTIA/OSIA).** This will ensure that access is automatically granted as required above, otherwise the research team will need to manually add these roles to the CTIA/OSIA prior to submission.

Institution Representative in application forms

The Primary Institution Representative must be indicated as follows in the applications within CTO Stream:

Title: Dr.
First Name: Stephen
Surname: Smith
Organization: Sault Area Hospital
Address: 750 Great Northern Road
City: Sault Ste. Marie
Province/State: ON
Postcode/Zip: P6B 0A8
Telephone: 705-759-3434
Fax: N/A
Email: VPMA@sah.on.ca

The Secondary Institution Representative must be indicated as follows in the applications within CTO Stream:

Title: Ms.
First Name: Natalie
Surname: Walde
Organization: Sault Area Hospital
Address: 750 Great Northern Road
City: Sault Ste. Marie
Province/State: Ontario
Postcode/Zip: P6B 0A8
Telephone: 705-759-3434 x4402
Fax: N/A
Email: walden@sah.on.ca