SAULT AREA HOSPITAL
HÔPITAL DE SAULT-SAINTE-MARIE

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Sault Area Hospital Research Approval Checklist

Scope: This checklist is intended for those who want to conduct clinical research at SAH.

Purpose: This checklist is meant to help you navigate the requirements needed to begin and complete a research project at SAH. It does not help with the methodology or statistics of the research. It focuses on the administrative requirements necessary to work with SAH's patients, people, and data.

Fees: All research teams are responsible for all potential fees incurred.

Signatures: All signatures must be in ink. Research Ethics Board (REB) approval letters will not be issued until "wet ink" signatures are obtained.

Quality Improvement: This checklist does not apply to any study conducted for quality assurance or quality improvement purposes and does not need REB approval. However, if the researcher intends to publish their work, the proposed study will require REB approval.

Requirements: The following must be completed, where required, on all research projects using all SAH information, resources, or personnel.

Forms: Any requirement that has a form is highlighted in red and double underlined.

Sault Area Hospital Approval

Note: if conducting a Clinical Trial, the Principal Investigator (PI) and research team may need to obtain approval from Health Canada using a Clinical Trial Application.

- ☐ Email the Research Office at research@sah.on.ca to schedule a brief intake meeting for your study.
- ☐ Identify the study's PI and research assistants (if any). Indicate on all forms whether this is a student research project (i.e. NOSM, Master's Degree, etc.).
- ☐ Acquire written approval on the Request for Departmental Approval (RDA)–General Form from the appropriate department/unit manager(s) to conduct your study in their area(s) or with their patients (if applicable).
- ☐ Acquire written approval on the RDA—Health Records Form from the Health Records Manager (if using *paper-based* patient charts).
- ☐ Acquire written approval on the RDA—Feasibility & Analytics Form from the Feasibility and Analytics Manager (if applicable).
- ☐ Send completed RDA(s) to research@sah.on.ca
- ☐ Once the RDAs are signed, a Data Sharing Agreement (DSA) must be signed by the PI, any identified Research Institutions, and SAH. To request the DSA, e-mail research@sah.on.ca.
- ☐ The PI and all research assistants or members of the study team must complete and obtain the relevant training and certificates:
    - TCPS2 training and certificates if the study is not a clinical trial, or
    - Good Clinical Practice (GCP) training if the researcher will conduct a clinical trial

☐ Standard Operating Procedures (SOPs) need to be reviewed at the site where research is being conducted (SAH or GHC) and a training document is signed by all members of the research/study team (updated annually).

Note: the SOPs are copyrighted and cannot be shared (or photocopied/scanned/printed) with anyone outside of SAH and GHC.

Research Ethics Board (REB) Approval

☐ Complete your study protocol. Include any additional/supplemental materials (consent forms, data collection forms, etc.).

- ☐ Clearly indicate on all relevant forms if this is a research project required for a school (ex. NOSM, Master's degree, etc.).
- ☐ Include all applicable signed forms acquired through SAH Approval.

Note: you must clearly indicate within the methodologies of the study how information and data will be accessed (i.e. which computer/network) and where it will be stored (i.e. location of locked cabinets, password protected encrypted stick, etc.).

☐ Study team must have funding approved (if applicable).

☐ Read the Research Ethics Board Guidelines and access the REB Forms.

☐ Complete the REB New Study Application. Deliver the original signed application and forms to ADCP Level 1, Room G1062, or Mailbox #90 at SAH. (You may submit electronic copies to reb@sah.on.ca in the interim, but the REB will not issue approval letters until you submit "wet ink" signed documents).

After REB Approval: Prior to Commencing Study Activities

☐ Complete and submit necessary forms to IT with the assistance of the Department/Unit Manager (including but not limited to the Network Access Request Form and Internet Access Form).

During Study Activities

☐ Report to the REB once per year since the date of approval using the Annual Renewal Application Form. You will receive an e-mail reminder annually from the REB office to renew or close your study.

☐ Report protocol deviations that jeopardize patient safety, study efficacy, or data integrity, or that constitute breaches of privacy/confidentiality, to the REB promptly after any occurrence using the Protocol Deviation Report Form.

☐ Report amendments to the originally-approved REB application, including but not limited to the research question, eligibility criteria, etc. using the Amendment Application Form. (Significant changes may require a new REB application.)

☐ Report any notifications using the Notification Report Form (ex. updated Investigator Brochure).

☐ PI and research team must maintain training of site SOPs (updated bi-annually).

After Study Completion

☐ Report study completion to REB using Study Completion Report Form

☐ Report publication to REB using Notification Report Form