SAH Research Approval Checklist

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

Purpose: This is meant to help you navigate through the different requirements needed to begin and complete a research project at Sault Area Hospital. This 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: This is a reminder to all research teams that they are responsible for all potential fees incurred.

Signatures: all signatures must be signed in ink ('wet signature'). Approval letters will not be issued until wet signatures are obtained.

Quality Improvement: The following does not apply to any study that is quality assurance or quality improvement and does not need Research Ethics Board (REB) approval. However, if the researcher intends to publish their work, it will require REB approval.

Requirements: SAH requires the following to be completed on all research projects using all SAH information, resources or personnel.

Forms: Any requirement that has a form is highlighted in red text.

Prior to REB Submission - Gathering study approvals

☐ Email researchreview@sah.on.ca to schedule a brief meeting for your research project where someone will explain and help assist with the steps in this process

☐ Identify the study Principal Investigator (PI) and research assistants (if any). Clearly indicate on the all forms if this is a research project required for school (i.e. NOSM, Master's Degree, etc.)

☐ Acquire written approval from the analytics (previously decision support) manager on the Request for Department Approval (RDA) Form – Feasibility and Analytics

☐ Acquire written approval from privacy and health records on the RDA Form – Health Records (if using patient charts or Meditech)

☐ Acquire written approval on the RDA Form – General from appropriate unit/department manager to conduct study in their area or with their patients (if applicable)

☐ Once the RDA's are signed, a Data Sharing Agreement must be signed by the Principal Investigator, any identified Research Institutions, and SAH

☐ Principal Investigator and all Research Assistants or members of the study team must complete and obtain their TCPS2 training and certificates (https://tcps2core.ca/welcome) if the study is a not a clinical trial, or their Good Clinical Practice (GCP) training if they're conducting a clinical trial.

Please note: if conducting a clinical trial, PI and research team may need to obtain approval from Health Canada using a clinical trial application.

☐ Standard Operating Procedures (SOP) 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).

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

☐ Complete protocol, and include any additional/supplemental materials (consent forms, data collection forms, etc.).

Please note: it should be clearly indicated within the methodologies of the study how information and data will be accessed (i.e. what computer/network) and where it will be stored (i.e. location of locked cabinets, password protected encrypted USB stick, etc.)

☐ Study team must have funding approved (if applicable)

☐ Complete and submit Initial/New Study Application to the REB (deliver original signed applications and forms to ADCP Level 1, Room G1062 or Mailbox #90 at SAH. Electronic copies may be submitted to reb@sah.on.ca in the interim but approval letters will not be issued until 'wet ink' signatures are obtained.)

After REB Approval - Prior to commencing study activities

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

Ongoing during/throughout study

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

☐ Report any protocol deviations or breaches of privacy to the REB promptly after any occurrence

☐ Principal Investigators and Research Teams to maintain training of site SOPs (updated annually)

After study completion

☐ Report study completion to REB using proper Study Completion Form

☐ Report publication to REB using proper Notification Form

Resources & References

SAH Researcher Starter Package
TCPS2-CORE
Good Clinical Practice (required for RCT clinical trials)
Joint GHC/SAH REB Application Guidelines and Forms