Policy: Research

Number: SHA-02-006
Scope: Saskatchewan Health Authority

Date Effective: October 12, 2021
Date Revised:

This policy applies to the following team members:

- Staff
- Practitioner Staff
- Contracted Individuals
- Patient Family Partners
- Knowledge Keepers
- Volunteers
- Learners
- Contractors

(See Appendix A for Definitions)

1. Purpose

The purpose of this policy is to ensure that research that is conducted within the Saskatchewan Health Authority (SHA) meets ethical, legal, and scientific requirements as set out in *Research Procedure* (SHA-02-006P1).

2. Principles

2.1. The SHA is committed to transparency and accountability to preserve and enhance public trust and confidence in research.

2.2. Research conducted at the SHA must be scientifically valid.

2.3. Research must meet ethical principles. These include:

- respect for persons;
- concern for their welfare; and
- ensuring that participants are treated equally.

2.4. Research conducted by the SHA must comply with all applicable regulations and standards including those listed in the *Research Procedure* (SHA-02-006P1) that pertain to human participant protection.

3. Policy

3.1. Research conducted within the SHA must receive prior approval from one of the following Research Ethics Boards (REBs):

- SHA;
- University of Saskatchewan; or
- University of Regina.

3.2. Research that uses SHA resources or facilities, team members or patients (including their Personal Health Information (PHI)) requires SHA operational approval before research can begin.

3.3. Research must comply with applicable provincial, federal, and international legislation, guidelines, and standards.

3.4. Team members must follow the ethical values implied in all activities related to learning, teaching, research and service.

3.5. A recovery charge to recoup the indirect costs of research may be applied to research grants and research contracts.

3.6. The SHA retains all intellectual property (IP) rights for any research or innovation created or developed using SHA resources or facilities, team members or patients. However, if any obligations are owed to an external party under the terms of a grant or research contract that has been approved by the SHA in respect to IP, the IP will be managed in accordance with the terms of a contract.

3.7. The SHA Director of Research and chair of the SHA REB reserve the right to audit any research conducted within and/or under the auspices of the SHA, randomly or for cause.

4. Roles and responsibilities

4.1. **Team members**

- Complete required training for the team member's role in the research study.
- Report breaches of this policy and the *Research Procedure* (SHA-02-006P1) to their supervisor, REB chair or Human Resources contact.

4.2. **Principal investigator (PI)**

- Confirm they, their co-investigators, learners, and their research staff (paid and unpaid) are aware of and adhere to the procedures and guidelines outlined in this policy and the *Research Procedure* (SHA-02-006P1).
- Confirm they, their co-investigators, learners, and their research staff (paid and unpaid) complete all certifications and training required for their research prior to conducting any study related procedures, and that training certificates are up to date.
- Obtain all required ethics and operational approvals prior to commencing any research activities.
- Ensure all research-related contracts undergo review by the SHA Research Department before they are signed by the PI. Depending on the level of risk to the SHA, the SHA Research Department may seek executive authorization at the appropriate level.
- Ensure they, and their research staff, are insured against research-related liability.
- Compensate the SHA for all research-specific costs that were agreed to when contract and/or operational approval was obtained.
- Collect, maintain, and securely retain research records in accordance with *Appendix C: Records Retention Schedule* of the *Corporate and Personal Health Information Governance Policy* (SHA-07-004) and applicable privacy legislation.

- Provide the SHA Director of Research with a copy of any publications and/or presentations derived from the approved research, including the appropriate citation(s).

4.3. **Directors of SHA departments approving research**

- Follow the procedures and guidelines set out in the Research Policy and the *Research Procedure* (SHA-02-006P1).
- Evaluate and approve or deny research feasibility through the departmental impact assessment/operational approval process as outlined in the *Research Procedure* (SHA-02-006P1).
- Provide a budget outlining the costs associated with the research specific activities.
- Provide letters of support for high priority research to PIs developing an application for research funding, if required and appropriate.
- Authorize involvement of their staff in the research.
- Report any concerns regarding breaches of this policy and the *Research Procedure* (SHA-02-006P1) to the SHA Research Department.

4.4. **SHA Research Department**

- Follow the procedures and guidelines set out in this policy and the *Research Procedure* (SHA-02-006P1).
- Complete all required certifications and training, and that the certificates are current and up-to-date.
- Keep this policy and the *Research Procedure* (SHA-02-006P1) up-to-date and available for researchers to use.
- Review the *Application for Operational Approval to Conduct a Research Study in the SHA*, confirming that all required information has been provided, and that all SHA departments involved in the research have been identified.
- Obtain departmental approvals required for research projects, including the departmental budgets for the study specific activities required for the research. Where departmental approval is not obtained, advise the researcher.
- Negotiate and coordinate research contracts with SHA Contract Management for those matters for which coordination is necessary.
- Review all funding applications prior to submission to funding agencies to ensure funding agency requirements are met and that the research proposal follows this policy and the *Research Procedure* (SHA-02-006P1).
- Issue a *Letter of Authorization to Conduct Research* once all requirements in the Research Policy and the *Research Procedure* (SHA-02-006P1) have been met.
- Encourage researchers and staff to uphold the highest standards of integrity, accountability, and personal responsibility when conducting research in the SHA.
- Investigate all reported breaches of scholarly integrity.

4.5. **SHA REB**

- Follow the procedures and guidelines set out in this policy and the *Research Procedure* (SHA-02-006P1).
- Complete all required certification and training in accordance with SHA REB requirements.
- Establish ethics review processes that are consistent with other provincial REBs.
- Conduct ethical reviews to protect the rights, welfare and privacy of research participants.

- Approve, request revisions to, or decline any research activity that falls within its jurisdiction.
- Request, receive and share any information involving the research that the REB considers necessary to fulfill its mandate, subject to applicable privacy legislation.
- Suspend or terminate the ethics approval for the research or place restrictions on the research, where appropriate.
- Take any actions considered reasonably necessary, and consistent with policies and procedures, to ensure the protection of the rights, safety, well-being and privacy of participants in research conducted under the REBs jurisdiction.
- Conduct reviews independently and report to the SHA's Chief Executive Officer.

5. Failure to follow this policy

Failure to follow this policy will be handled according to:

- collective bargaining agreements;
- applicable legislation, regulations, policies, procedures and processes; and/or
- SHA Practitioner Staff Bylaws.

Breach of this policy may result in discipline up to and including termination/revocation of:

- employment;
- contractual relationship;
- practitioner staff appointment; and/or
- privileges.

6. Documents that relate to this content

Policy
Appendix A: Definitions
Appendix B: Replaced Documents

Procedures
SHA-02-006P1 *Research Procedure*

Other
SHA-07-004 *Corporate and Personal Health Information Governance Policy*
SHA-02-006 *Research Policy Questions and Answers*

7. Roles that manage and approve this policy

Policy Sponsors: Vice President, Safety and Strategy;
Chief Medical Officer.

- Approve the policy and related content.
- Share responsibility for revisions and renewal with the owner.

Policy Owner: Executive Director, Academics and Learning

- Manage this policy including policy communication, education, implementation, evaluation and audit.
- Share responsibility for revisions and renewal with the sponsor.

8. References

N/A

Appendix A: Definitions

Contracted Individuals: Individuals providing services in his or her personal capacity or through a sole proprietorship pursuant to a contractual relationship with the SHA.

Contractor: An incorporated entity providing services pursuant to a contractual relationship with the Saskatchewan Health Authority, including franchise owners.

Departmental Approval: Confirmation from an SHA Director whose operations will be affected by the conduct of the research. Departmental approval signifies that the program accepts the impact (clinical, financial, or otherwise) of the proposed study on their department, division, or program, and that they agree with the costs related to that department itemized in the study budget.

Indirect Costs of Research (Institutional Costs): SHA expenditures incurred to benefit and support research. These can include:

- regulatory and research compliance;
- maintenance and servicing (utilities);
- use and maintenance of equipment;
- Insurance;
- legal services;
- SHA Research Department services;
- Contract Management;
- Financial Services;
- Human Resources;
- Purchasing, Facilities Management, and auxiliary services; and
- Library Services and resources.

Intellectual Property Rights: Various avenues through which to acknowledge and secure intellectual property, such as copyright, trademarks, patents, trade secrets, computer coding, and industrial designs.

Knowledge Keepers (First Nation, Métis and Inuit Elders): There is a spiritual understanding combined with sacred and ancient knowledge within the Knowledge Keepers. Knowledge Keepers have attained a high degree of wisdom, knowledge and understanding of First Nation, Métis, or Inuit history, traditional teachings, ceremonies, and healing practices. They are role models within their communities by leading a healthy lifestyle and are acknowledged by the community as Knowledge Keepers. In the Cree language, we call them Kiteehayahk.

Learners: Clinical and Non-clinical student placements.

Operational Approval: Written confirmation in the form of an *Authorization to Conduct Research Letter* from the SHA Research Approval Coordinator signifying that all necessary departmental approvals and, if applicable, additional medical/section head approvals have been obtained and that the research is authorized to be conducted in the SHA. Operational approval will not be granted until the study has been approved by the appropriate REB and all conditions according to the *Research Policy* and the *Research Procedure* (SHA-02-006P1) for operational approval for research have been met.

Patient and Family Partners (PFP): Patient Family Partners (PFPs) have healthcare experience(s) as a patient/resident/client, or a family member/support person. PFPs partner with the SHA to:

- develop policies, programs, and practices affecting patients;
- improve the quality and safety of the patient experience; and
- embed people/patient & family centered care across the SHA.

Personal Health Information (PHI): Means, with respect to an individual, whether living or deceased[1]:

- information with respect to the physical and mental health of the individual;
- information with respect to any health service provided to the individual;
- information with respect to the donation by the individual of any body part or any bodily substance of the individual or information derived from the testing or examination of a body part or bodily substance of the individual;
- information collected:
    - in the course of providing health services to the individual; or
    - incidentally to the provision of health services to the individual;
- registration information (e.g. demographic information).

Practitioner Staff: Qualified members of a health profession who are legally entitled to practice in Saskatchewan and who have been granted privileges by the SHA.

Principal Investigator (PI): The researcher who has overall accountability for the research conducted at an SHA site, despite who is the awardee of a sponsored research agreement (whether a grant or a contract). The PI is always considered the supervisor of the research team.

Research: An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. The term 'disciplined inquiry' refers to an inquiry that is conducted with the expectation that the method, results and conclusions will be able to withstand the scrutiny of the relevant research community.[2]

Research Activity: Research, scholarship, and/or creative activity carried out in the course of work or training in SHA. This may include any of the following: written material, laboratory work, computer work, coding, research materials, research results, oral reports, presentations, or reporting.

Research Ethics Board (REB): A body of researchers, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices[3].

Research Grant: Funding provided for the purpose of supporting a specific initiative, typically awarded based on successful review of predetermined criteria. Research grants typically focus on basic, fundamental, curiosity-driven research. Characteristics can include (but are not limited to):

- project control lies with the researcher;
- unrestricted rights, in certain cases, to publish research results;
- payment issued in advance or in milestone payments;
- start date of the project is defined; and
- funder is provided with a copy of the final research report.

Research Records: Any documents and other records and materials recorded by or for an investigator that are necessary to document, reconstruct, evaluate, and validate research results and the events and processes leading to the acquisition of those results. Research records may be in many forms including, but not limited to: laboratory notebooks, survey documents, questionnaires, interview notes, transcripts, machine-generated data or performance outputs, recruitment materials, consent forms, correspondence, other documents, computer files, audio or video recordings, photographs including negatives, slides, x-ray films, samples of compounds, organisms (including cell lines, microorganisms, viruses, plants, animals) and components of organisms.

Research Staff: paid or un-paid personnel conducting the research study under the supervision of the Principal Investigator.

Scholarly Integrity: A commitment to the fundamental values of honesty, trust, fairness, and responsibility while conducting any research activity.

SHA Resources or Facilities: Include, but are not limited to: physical structures, laboratories, capital equipment, human biological materials, personal health information, services, and personnel.

Staff: SHA employees and practitioner staff. Staff include in-scope, out-of-scope, full-time, part-time and casual staff in all facilities owned, operated and leased by the SHA as well as SHA staff working in the community.

Team/Team Member: In the context of SHA policy, 'the team' represents all individuals working, volunteering, or learning within the SHA. This could include staff, contractors, contracted individuals, Patient Family Partners, Knowledge Keepers, volunteers and learners.

Volunteer: A person who provides services to individuals or groups within the SHA, with no financial gain.

References

1. The Health Information Protection Act, SS 1999, c H-0.021. s. 2(m).

2. Health Canada. Guidance for Industry Good Clinical Practice: Consolidated Guideline ICH Topic E6 [Internet]. Ottawa ON: Minister of Health; 1997. [cited 2020 Oct 22]; p. 10. Available from: https://stjoestoronto.ca/wp-content/uploads/2016/01/gcp_guideline.pdf

3. Canadian Institutes of Health Research; Natural Sciences and Engineering Research Council of Canada; Social Sciences and Humanities Research Council. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. [Internet]. Ottawa, ON: Secretariat on Responsible Conduct of Research; 2018. [cited 2020 Feb 21]; 231 p. Available from: https://ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf

4. Saskatchewan. Patient and Family Advisor Program. Patient and family advisor handbook [Internet]. Regina, SK: Saskatchewan Ministry of Health, n.d. [cited 2019 Dec 30]. 8 p. Available from: http://publications.gov.sk.ca/documents/13/108850-patient-family-advisor-handbook.pdf

Appendix B: Replaced Documents

SHA policy and procedure replaces all related:

- departmental,
- unit, or
- former regional documents.

Teams may need to update local work standards to make sure they are not different from SHA policy and procedure before they continue to use them.

This policy replaces or partially replaces the following former regional health authority policies, procedures, forms or other related documents including but not limited to:

Research Policy (SHA-02-006) Full Repeals

Cypress	Research	2-395
Cypress	Research	5-4
Five Hills	Research and Education	8.3
Five Hills	Research Policy	AM-30
Heartland	Ethics Research Checklist	A01-01.01.01Fm
Heartland	Research Ethics & Integrity	A01-01.01
Keewatin	Ethics – Research Approval Policy	GP17
Regina	Data Storage and Retention Policy	102
Regina	Ethical Conduct of Research and Other Studies Involving Human Participants	103
Regina	Ethical Conduct of Research Procedure	103-1
Regina	Externally Funded and/or Sponsored Research Policy Procedure	104-1
Regina	Externally Funded Sponsored Research Policy	104
Regina	Indirect Costs of Research Policy	105
Regina	Indirect Costs of Research Procedure	105-1
Regina	Intellectual Property	106
Regina	Intellectual Property Procedure	106-1
Regina	Operational Approval for Research Policy	107
Regina	Operational Approval for Research Procedure	107-1
Regina	Procedure for Policy on Data Storage and Retention	102-1
Regina	Scholarly Integrity Policy	108
Regina	Scholarly Integrity Procedure	108-1
Saskatoon	Research	7311-100-001
Saskatoon	Responsible Conduct of Research	7311-100-002

Research Policy (SHA-02-006) Partial Repeals:
None