Saskatchewan Health Authority

Date Effective: October 12, 2021
Date Revised:

SHA-02-006P1

Research Procedure

Related Policy: Research Policy

Scope: Saskatchewan Health Authority

This procedure applies to the team members who are involved with research being conducted within the SHA:

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

Table of Contents

1. Introduction

Research is defined as 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.[1]

The Saskatchewan Health Authority (SHA) is an academic health care organization that aims to provide safe, effective and high-quality care through evidence-based practice, innovative approaches, training and research. Great opportunity exists to establish a more expansive and impactful research program that links with academic, clinical and health system resources across the province. Fostering this work is critical in helping SHA achieve its mission to "Work together to improve our health and well-being. Every day. For everyone."

Research holds tremendous potential to make meaningful differences in the care of our patients, families and communities. It can provide evidence that something works, or equally so, can show something is not effective. Health-system driven research can address provincial priorities and challenges in an evidence-based and results-oriented manner.

1.1. SHA Research Department Services

The SHA Research Department has offices in Regina and Saskatoon. It provides a continuum of services to SHA staff and clinicians including:

- **Research approvals:** Prior to commencing, all research studies that require access to SHA resources, facilities and/or patients (including their personal health information (PHI)) must obtain Research Ethics Board approval and Operational Approval.
    - **Research Ethics Board (REB) approval** ensures that proposed studies have minimized risks to patients and participants, are able to provide results that are ethically and scientifically sound, and that comply with legislation.
    - **Operational Approval (OA)** ensures that the proposed research can be conducted safely within an SHA facility while acknowledging the impacted department's current workload. It also enables SHA to recover direct costs of the proposed research in an open and fair manner.
- **Research contract and funding administration:** SHA Research Funding and Contract Specialists can identify potential funding sources, negotiate research contracts and data sharing agreements, develop a budget for grant proposals, and create and maintain research accounts.
- **Research support services:** Staff researchers initiate and support a variety of clinical and health services research projects within the SHA. They provide assistance with survey design and hosting, study design and implementation, database development, statistical analyses, manuscript writing, and preparing applications for research funding.

It is the researcher's responsibility to refer to the SHA Document Finder when initiating any new study in order to ensure the current version of this handbook is referenced.

2. Roles and responsibilities

2.1. Study team

- Carry out and complete the study as per the REB approved protocol.
- Complete the study under the direction of the Principal Investigator (PI).
- Report breaches of this procedure to the PI and REB.

2.2. Principal Investigator (PI)

- Lead the study team to carry out the study as per the REB approved protocol.
- Comply with the decisions and responsibilities set out by the REB.
- Comply with all applicable policies, procedures, legislation, regulations and standards for best practice.
- Ensure that they, their co-investigators, and their research staff (paid or unpaid) adhere to the ethical guidelines and regulations named in this procedure and in the *Research Policy* (SHA-02-006).
- Ensure that they, their co-investigators, and their staff complete all required certification and training, and that the certificates are current and remain up to date.
- Assume all responsibility for all of the co-investigators and research staff involved in any research-related activities including development, conduct, analysis and reporting.
- Obtain required REB and operational approvals prior to commencing any research activities.
- Report applicable criteria to the REB, including deviations, serious, unexpected adverse events and privacy breaches.
- Report premature termination or suspension of the research to the REB.
- Receive REB approval for any changes to the approved research, except where necessary to eliminate any immediate hazard(s).
- Declare all real, potential, or perceived conflicts of interest to the REB at the time of the initial application and as they arise.
- Share the responsibility of collecting, maintaining, and retaining all research data with the SHA.
- Obtain insurance against research-related liability for yourself and your research staff, if applicable.
- Ensure all research-related contracts undergo review and approval by the Director of Research before being signed.
- Understand the obligations contained within any signed contract.
- Sign all necessary documentation.
- Maintain accurate and complete records according to applicable regulatory requirements and following SHA procedures.
- Notify the SHA Research Department of any externally funded or sponsored studies occurring under the auspices of the SHA.
- Manage all funds received from their funding source by ensuring that all expenditures conform to the approved budget with:
    - all the terms and conditions of the grant or contract;
    - regulations of the funding agency;
    - SHA policies and procedures;

    - SHA departments that are involved in the administration of funds; and
    - requirements for ethical approval.
- Compensate the SHA for all research-specific costs that were agreed to when departmental and OAs were obtained.
- Provide the SHA Director of Research with a copy, link, or citation to any publications derived from the approved research.

2.3. SHA Research Department

- Ensure staff are aware of and adhere to the procedures and guidelines set out in the *Research Policy* (SHA-02-006) and the procedure manual.
- Ensure they complete all required certification and training, and that the certificates are current and remain up to date.
- Ensure the *Research Policy* (SHA-02-006) and procedure manual are up-to date and available for researchers to use.
- Review applications for OA to conduct a research study in the SHA in a timely manner, 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, including the departmental budgets for the study specific activities required for the research.
- Negotiate and coordinate research and research-related contracts with Contract Management for those matters in which coordination is necessary.
- Advise on funding guidelines, proposal development, and internal SHA policies.
- Assist with budgeting and CV preparations.
- Review all funding applications prior to submission to ensure funding agency requirements are met and that the research proposal adheres to the *Research Policy* (SHA-02-006) and procedure.
- Issue a *Letter of Authorization to Conduct Research* once all requirements laid out in the *Research Policy* (SHA-02-006) and procedure manual have been met.
- Develop awareness and understanding among SHA researchers and staff of the expectation to uphold the highest standards of integrity, accountability, and personal responsibility when carrying out research in the SHA.
- Investigate all reported breaches of scholarly integrity.

2.4. SHA REB

- Complete all required certification and training.
- Establish research ethics review processes.
- Provide ethics oversight to ensure the ethical conduct of the research.
- Approve, require modifications to, or disapprove any research activity that falls within its jurisdiction.
- Ensure that SHA policies and procedures protect the rights, safety and welfare of research participants.
- Request, receive and share any information involving the research that the REB considers necessary to fulfill its mandate subject to applicable privacy legislation.
- Maintain confidentiality and respect privacy.

- Conduct continuing ethical review to protect the rights, welfare and privacy of research participants.
- Suspend, place restrictions on, or terminate ethics approval for the research when required.
- Follow guidelines and regulations for ethical conduct of research in Canada.

3. Ethical conduct of research and other studies involving human participants

3.1. Research ethics board

The SHA REB is a body of researchers, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines) that reviews the ethical acceptability of all research involving humans conducted within the SHA's jurisdiction or under its auspices[2]. The REB's guiding principles are[1]:

- **Respect for persons, particularly for the autonomy of research participants.** Respect for autonomy is normally reflected in the requirement to seek free and informed consent from participants both prior to and during their participation in a research project.
- **Concern for welfare of research participants.** Concern for welfare is broadly construed to mean all aspects of a person's life, including their physical and mental health, spiritual well-being, and other elements of their life circumstances. Concern for welfare includes respect for the person's privacy and confidential nature of personal information and PHI. Concern for welfare requires that REBs and researchers adopt an attitude that aims to protect the welfare of research participants, minimize foreseeable risks to participants and their communities, and inform research participants of those risks.
- **Justice requires that people be treated equitably and fairly.** The principles of procedural justice takes into account the vulnerability of the person, differences in power between participant and researcher, and distributive justice seeks to distribute equitably the risks and benefits of research participation.

The SHA REB reviews and oversees research taking place in the SHA, or being conducted by SHA team members, to verify that it meets ethical principles, is scientifically valid, maintains scholarly integrity and complies with all applicable regulations and standards pertaining to human participant protection. Approval from one of the following REBs is necessary before any research begins in the SHA: SHA, University of Saskatchewan (USask), or University of Regina (U of R). Please consult your institutional REB before filling out ethics forms to confirm which provincial REB would be appropriate to apply to.

Selecting a REB for application submission

There is a reciprocity agreement between the REBs of USask, U of R, and the SHA. The PI should check with their local REB to confirm where they should apply for REB approval, however, the following factors are considered in determining the appropriate institution:

- primary affiliation of the Principal Investigator (PI) as it specifically relates to the research for which the ethics review is being conducted;
- affiliation of the co-investigators and/or research trainees;
- owner or provider of the necessary equipment, services, or supplies; and
- institution where the related grant or contract will be held/administered.

SHA REB contact: ResearchEthics.Regina@saskhealthauthority.ca
USask REB contact: ethics.office@usask.ca
U of R REB contact: research.ethics@uregina.ca

3.2. Research that must have REB approval

Studies that meet any of the criteria below need research ethics approval before they begin:

- projects involving living human participants, their biological samples or their health data;
- industry and SHA collaborative projects utilizing PHI that the SHA is trustee of, if it will lead to commercialized products or technologies;
- research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials or stem cells (this applies to materials derived from living and deceased individuals);
- research utilizing retrospective or prospective PHI;
- projects receiving any form of external funding (e.g., Canadian Institutes of Health Research (CIHR), industry sponsors, non-profit agencies, grants in aid) when such financing is awarded to support research;
- any student or resident project being completed for research training requirements, including but not limited to:
    - quality assurance;
    - quality improvement (QI); and
    - program evaluation activities;
- case studies involving three or more participants undertaken for investigational purposes (e.g., publication in a scientific journal, presentation at a conference).

Please note that the REB cannot provide approvals or exemptions once a study has begun. The REB must review the study before research or quality improvement projects are initiated.

3.3. Research-related activities that do not require a research ethics review

The difference between research and non-research activities can sometimes be unclear. In general, program evaluation, QI, or quality assurance initiatives when used only for assessment, management, or improvement within the SHA fall outside the scope of this policy and would not require REB review or REB approval.

Public Health (PH) surveillance, emergency response and evaluation initiatives for the purpose of preventing or controlling disease or injury and improving health or PH programs or services where the intended benefits are primarily for those whose data is accessed and their communities would not constitute research and so would not require REB review.

Projects that have the dual function of local QI or PH initiatives and research such as the creation of new technologies and or generalized knowledge, such as the intent to apply the results beyond the local institution or in other settings, should be submitted for REB review.

Intrinsic components of QI and PH initiatives are shared learning, therefore it is entirely appropriate to disseminate and replicate QI and PH successes, including through channels that are external to an organization. This may include presentations at meetings and publications in professional journals. Therefore, the mere intent to publish the findings of a QI or PH project does not obligate REB review.

However, the line between research and QI can be unclear at times, many projects can have both QI and research components. The REB recommends contacting the REB Chair prior to initiating the project to assure that it is deemed to be a QI or PH initiative and thus does not require REB review. If you are interested in having your project published, the journal may request evidence of REB exemption. Any investigator whose project is determined to be QI or PH surveillance, emergency response or evaluation and have submitted the project for REB review prior to its start, will be issued a letter to state the REB waived its review and the project is REB exempt. **Please note, the SHA REB does not retroactively review projects that have already been completed and cannot provide exemptions retroactively.**

Contact your local REB to find out if your project is considered a research or non-research related activity.

3.4. Types of studies

Above minimal risk studies are studies in which the probability and magnitude of possible harms implied by participation in the research is greater than those encountered by participants in the aspects of their everyday life that relate to the research[1]. Above minimal risk studies must be received by the REB at least 10 business days prior to a scheduled meeting in order to be reviewed at the upcoming meeting; however, there are instances when applications are required earlier (e.g., due to planned office closures). The SHA REB meets on the second Monday of every month.

Some examples of above minimal risk studies are:

- clinical trials with experimental drugs or devices or any other clinical, diagnostic or therapeutic interventions that are not the standard of care.
- tissue and genetic banking repositories.
- Some behavioural studies that entail interaction with research participants, depending on level of risk to participants.
- research that involves interaction with a vulnerable population.

Minimal risk studies are studies in which the "probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research"[1].

Contact ResearchEthics.Regina@saskhealthauthority.ca if you are uncertain whether your project is considered an *above minimal risk* study or a *minimal risk* study.

3.5. Submitting an application

Application forms, templates for consent forms, and detailed guidance on preparing your application and continuing review forms can be found here on the SHA research website. The guidance notes provide details on what is required for applications with different study designs and the requirements that must be met for each type of study.

What to include with the application for research ethics review:

- An *Application for Research Ethics Review Form* signed by the department head (with guidance notes removed);
- The PI must be copied on all correspondence with the REB, particularly for new submissions, amendments, re-approvals and other continuing review documents;
- All applicable recruitment materials, consent forms, data collection tools, master lists, investigator brochures, etc.;
- Supporting clinical trial documentation (e.g., Health Canada regulated device or investigational products trials require a *No Objection Letter*, all clinical trials require a clincialtrials.gov registration number and approvals from other REBs);
- REB approvals from other sites for any multijurisdictional studies;
- McMaster Chart Audit Tutorial certificates for any study team members accessing PHI;
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition[1] tutorial (https://tcps2core.ca/welcome) certificate for all study team members conducting prospective studies involving participants;
- Good Clinical Practice (GCP) and "Health Canada Division 5 – Drugs for Clinical Trials Involving Human Subjects" training (required for all study team members conducting clinical trials);
- Curriculum Vitae (CV) for SHA PIs (for prospective biomedical studies) and also for those PIs proposing to conduct research at SHA for the first time.

Upon submission, all documents must be labeled in the footer with the date and version number.

Above minimal risk studies will receive a response from the REB in 15 to 25 business days.

If the PI wants their application screened by Research Ethics before the REB meeting, they must:

- submit it two business days before the submission deadline;
- send the application to ResearchEthics.Regina@saskhealthauthority.ca; and
- state "request for pre-screening" in the subject line.

Minimal risk studies may be submitted at any time and will be reviewed on an ongoing basis by the REB Chair. Researchers can expect to receive a response from the REB within 5 to 15 business days after receiving an REB file number.

Special authorization may be required from the SHA Vice President, Quality, Safety and Strategy or Executive Director, Academics and Learning for research that has the potential to result in high institutional risk.

Submit applications to ResearchEthics.Regina@saskhealthauthority.ca. Be sure to include all authorizing signatures and related documents.

3.6. Research ethics review

Once an application and all supporting documentation are submitted to the REB, the Chair of the REB will review the application and determine whether the study is considered to be *minimal risk* or *above minimal risk*.

The review of the application (either through a full REB or a delegated review) will result in one of four decisions:

- **Approval**: A *Certificate of Approval* is issued for a term of one year.
- **Provisional approval**: The REB approves the study with some modifications. The revised material will be submitted for: 1) delegated review (i.e. REB Chair can approve if met prior concerns), 2) sub-committee review, or 3) full board review.
- **Deferral or resubmission**: The REB is not able to make a decision. The researchers must submit more information, or make changes, to their application. Once they do, the full REB can make a final decision.
- **Not approved**: The REB does not authorize the research to be conducted in the SHA.

The decision is forwarded to the applicant in a *Notice of Ethical Review* (NER) that outlines any of the requested changes. The REB approval is the first step in the full approval for research. See Section 4, *Operational Approval to Conduct Research in SHA*, for information pertaining to additional approvals required to conduct research in the SHA.

Research ethics approval is granted for one year. Renewals may occur yearly for up to five years. After five years, clinical trials that are still in the process of recruitment and/or interventions will require a re-submission and will be reviewed again by the full REB. If a study is in follow-up phase and there have been no significant changes to the initial submission, the Chair may do a delegated review instead of a full board review. *Minimal risk* studies are assessed on a case-by-case basis. They are also reviewed after five years if there have been significant changes to the initial submission. This is determined by the Chair of the REB.

The PI must submit documents on a regular basis to the REB. These may include:

- annual renewals;
- applications for amendments;
- Health Canada audit reports;
- site monitoring reports;
- unanticipated problem reports (UPR); and
- data safety monitoring board (DSMB) reports.

The Chair of the REB reviews most continuing review submissions, unless significant changes are made to the initially approved submission, in which case the full board would review. The full board REB always reviews UPRs.

Report changes to the REB protocol, or changes to the study team, in an amendment form or change of study team form, requires the PI to be copied on all correspondence in relation to any changes to the originally approved Protocol. The PI is responsible for being aware of all changes with their studies.

All open studies, and further approvals for studies, will be suspended if there are:

- outstanding continuing review documents; or
- breaches of the REB approved protocol.

How to submit an application for research ethics review

Submit your application for ethical approval of research proposals by sending one electronic copy of the completed application form and all attachments to ResearchEthics.Regina@saskhealthauthority.ca. Please note hand written applications will not be accepted. Hard copies of the application and associated documents are not required or accepted.

3.7. Research ethics review fees

Industry sponsored studies have an initial review fee and an annual renewal fee that covers the ongoing review of amendments and other trial documents. The review fee for industry-sponsored studies is $4,000.00. Industry sponsors include for-profit organizations such as pharmaceutical or medical device companies, or agents thereof. The fee covers requests for initial ethical review.

The fee for each annual renewal of industry-sponsored studies is $750.00. This covers the ongoing review of study documents for the approved year. The fee covers:

- amendments and acknowledgements; and
- review of submissions for UPRs.

Once a new industry-sponsored study has an REB file number assigned, the PI will receive an invoice. All documents sent to the REB office must include the exact title of the research study and the PI's name. A *Certificate of Approval* will not be issued until the REB receives payment of the required fee.

Review fees are refunded if research is withdrawn before review by the REB. If the REB has completed their review, and a NER has been issued, the full REB fee is charged.

Waived REB fees

Industry-sponsored studies receiving a grant-in-aid may have their review fees reduced or waived. This includes investigator-initiated studies with partial funding or funding from a non-profit agency (e.g., Saskatchewan Health Research Foundation (SHRF) or Canadian Institute of Health Research (CIHR)). Investigator initiated studies that have minimal industry support such as a supply of drugs or devices, or a very limited amount of funding are exempt from the REB fees. A sub-committee of the REB will assess whether a reduction or waiver of the review fee is possible if there is discrepancy in relation to whether a study is industry-sponsored or not.

3.8. Regulatory and guiding documents

The SHA follows these national and international ethical and regulatory research guidelines:

- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans[1];
- Tri-Agency Framework: Responsible Conduct of Research[3];
- *The Health Information Protection Act* (Saskatchewan)[4] (HIPA);
- *The Local Authority Freedom of Information and Protection of Privacy Act* (Saskatchewan)[5] (LAFOIP);
- Canada's *Food and Drugs Act*, *Food and Drug Regulations* and *Medical Devices Regulations*[6];
- Canada's *Controlled Drugs and Substances Act* and *Narcotic Control Regulations*[7];
- International Conference on Harmonization (ICFDAH) Guideline for Good Clinical Practice (ICH-GCP E6 (R2))[8];

- Canada's *Personal Information Protection and Electronic Documents Act* (PIPEDA)[9];
- *The Saskatchewan Employment* Act and *The Occupational Health and Safety Regulations, 1996*[10]; and
- Code of ethics endorsed by the researcher's professional licensing body or association.

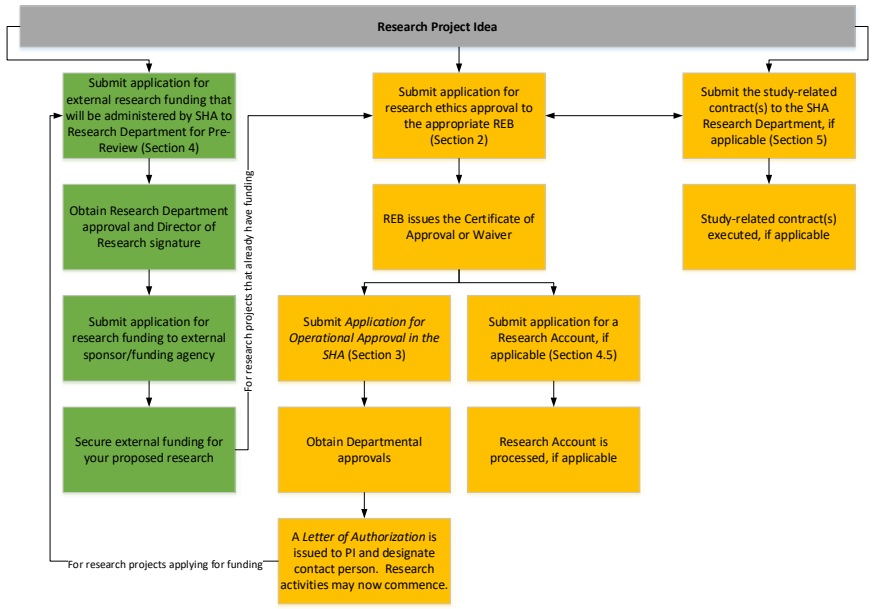
The SHA REB decides how to proceed when the United States or International regulations differ from Canadian regulations and guidelines.

4. Operational approval to conduct research in the SHA

Operational Approval (OA) ensures that the proposed research can be conducted safely within an SHA facility while acknowledging the impacted department's current workload. It also enables the SHA to recover direct costs of the proposed research in an open and fair manner. The process for obtaining OA to conduct research in the SHA (outlined in Figure 1) is:

- **Submit an application for research ethics approval to the appropriate REB.** (Either SHA, U of R or USask - refer to Section 1, Introduction). A *Waiver of REB Review* does not guarantee a waiver of the need for OA. If a research study is exempt from REB approval, the researcher must contact the SHA Research Department to determine if an application for OA is necessary.
- **Submit an application for OA.** This assessment is completed online using the *Application for Operational Approval to Conduct Research in SHA*.
- **Submit study-related contract(s) to the SHA Research Fundingand Contract Specialist**. Submit all study related contracts (if applicable) that have been finalized and executed (refer to Section 6, Research Contracts). Conditional OA may be granted in special circumstances while the contract negotiation is in progress.
- **Submit application for a research account**. Submit the application for an **SHA research account** (if applicable) for processing (refer to Section 5, Obtaining and Managing Research Funds).

Figure 1. Obtaining approvals to conduct research in the SHA.



4.1. Operational approval applications

Submit applications for OA using the *Operational Approval to Conduct Research in the SHA Application Form*. The PI named on the OA application must be the same as on the REB-issued research ethics certificate. Include all relevant attachments with your application.

REDCap™

To facilitate completion, the OA form is available online via a data collection tool created in REDCap™. Researchers can:

- save and re-access partially completed forms;
- share the link to the form with other members of the research team to facilitate the completion of the form; and
- get the PI's signature electronically on the form.

Amendments

Once approved, the PI must submit amendments to studies if they:

- add or remove departments or facilities;
- add or remove research personnel; or
- change the data collected from SHA sources (e.g., Health Information Management Services (HIMS), Sunrise Clinical Manager, administrative data).

The PI submits amendments on the *Amended Operational Approval to Conduct Research Application* form. The PI must also amend and resubmit to the REB.

4.2. Departmental impact assessments

The departmental impact assessment (DIA) section of the OA application requires the PI to list the SHA services within SHA facilities that are required for the study. This includes the use of data when the SHA is the trustee. This allows reviewers to assess if the SHA has the resources to support the research. They must consider existing resources and department priorities. Depending on the nature of the study, it may be worthwhile to discuss a work plan with the departments impacted prior to submitting your OA application. All necessary ethical and operational processes must be complete before the study begins. Departments can refuse to support a study if it will negatively impact their daily work, or their ability to support the SHA's operations.

PIs contemplating research involving affiliate site(s) should contact the SHA Research Department for further discussion. A complete list of affiliate sites can be found in table 3 of *The Provincial Health Authority Administration Regulations*.

Researchers requesting access to SHA Patient/Client Records must submit a copy of the *Data Collection Tool* with their OA application. Currently, eHealth Saskatchewan does not allow the use of eHealth Viewer for research purposes, including data collection. A consultation with Health Information Management Services (HIMS) and Digital Health (DH) managers prior to submission of the REB application is advised to determine whether data is available in patient health charts or SCM.

All tests and procedures that are specific to the study must be clearly identified on the OA application. Matters pertaining to reimbursement of study specific tests and procedures will be addressed during the review and approval process. A costing list for services, tests and procedures being utilized for research is available for researchers at this link.

All tasks required by SHA program(s) for study activities such as disbursement of recruitment material, or staff or patients participating in survey/interview/focus groups, must be outlined on the OA application. Research involving SHA employees as study participants must be developed in consultation with SHA Human Resources (HR) (including staff surveys, focus groups, or interviews). SHA HR will provide feedback regarding the project as necessary. This should occur as early as possible in the research planning phase, ideally before the project has been submitted to the REB or for OA.

The SHA director of the applicable department confirms the costs for all study-related tests/procedures. This includes those that are not on the costing list.

4.3. Departmental approvals

Directors hold the authority to give departmental approval to studies that involve their unit, program, patients, facilities, financials, resources or staff.

The applicable director can designate the authority to give departmental approval to studies on a permanent basis. The Research Department can assist with this. For studies that require approval from several directors in a portfolio the departmental approval may be requested from the Executive Director or Vice President. This will be determined on a case-by-case basis.

An email from the approver's SHA email will be accepted as departmental approval.

4.4. Departmental approval special considerations

If departmental approval is not obtained and the study cannot be accommodated in another facility or program, SHA OA may not be given.

4.5. Authorization to conduct research letter

When the requirements are met, the Research Approval Coordinator (RAC) issues a letter stating the research can begin. The letter is sent to the PI and all SHA departments who authorized the research.

4.6. Withdrawal of departmental approval

If a department removes their approval, the RAC issues a new letter, which is sent to the PI. The letter states the research activity may not continue until OA is reinstated.

4.7. Closure of a departmental approval

When the study is complete the RAC reviews the:

- study services provided by the SHA;
- DIA; and
- departmental approval(s).

This ensures all study related invoices are complete and reimbursed. The RAC will issue any outstanding invoices.

4.8. Research audit

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

It is the PI's responsibility to promptly inform the REB chair if they have been notified of an audit by Health Canada.

4.9. Operational approval additional information

OA Guidance Notes, the *Research Costing List*, and a link to the *Operational Approval Application Form* can be found on SHA Research website.

Additional questions can be addressed to SHA Research Approvals Coordinators:

- Regina/South: ResearchApproval.Regina@saskhealthauthority.ca
  Telephone: 306-766-5802
- Saskatoon/North: Researchapproval.Saskatoon@saskhealthauthority.ca
  Telephone: 306-655-1442

5. Obtaining and managing research funds

Most often, there are costs associated with research studies. These funds can come from provincial, federal or foreign funding agencies, industry funders, or not-for-profit foundations.

The SHA Research Department supports practitioner staff, staff, and learners to develop funding applications. This includes budget development, negotiation of research contracts, and approvals to begin their research studies.

The SHA administers research funding (awarded to SHA affiliated researchers) from the following organizations that have a memorandum of understanding (MOU) with the SHA:

- CIHR;
- SHRF;
- Royal University Hospital Foundation (RUHF);
- Jim Pattison Children's Hospital Foundation (JPCHF); and
- Hospitals of Regina Foundation (HRF).

5.1. Funding sources

CIHR - provides numerous funding opportunities, available on their website, throughout the year for health research in four themes:

- biomedical;
- clinical;
- health systems services; and
- social, cultural, environmental, and population health.

SHRF - offers a variety of opportunities for individual, group, and partnership grants. Please visit the SHRF website for details.

RUHF - offers a variety of opportunities for individual and group grants as well as scholarships. Please visit the RUHF website for details.

JPCHF – is dedicated to raising funds for the enhancement of maternal and children's healthcare in Saskatchewan and Jim Pattison Children's Hospital. For research and equipment grants available through JPCHF please visit their website.

HRF - raises funds to improve health care for the residents of southern Saskatchewan and supports everything from patient care to improving conditions for health-care teams, including education, research and training opportunities for health-care professionals. For more information about HRF, please visit their website.

Alternative Funding Sources - If obtaining funds from CIHR or SHRF is not possible, health researchers should consider applying for alternative funding. Alternative funding sources include private foundations and trusts, community and non-governmental organizations, and not-for-profit associations.

5.2. Funding applications

Preparing a proposal

Some funding agencies provide downloadable tips, PowerPoint presentations and webinars to assist applicants with proposal formats. The SHA Research Department can assist applicants in locating these documents and can provide assistance regarding eligibility, format, specific team requirements, and proposal tips. Additionally, assistance can be provided for proposal preparation with regards to granting agency instructions, language, and clarity. Please contact the SHA Research Department for more information on the services they provide or if you are requesting writing assistance.

Planning a budget

The budget must reflect the direct and indirect costs of the proposed research. Follow budget guidelines for both the funding agency and the SHA when preparing a budget. Contact the Research Department for information on SHA allowable expenses.

The Research Funding and Contracts Specialists review research budgets and proposals to ensure the costs cover the proposed study's expenses.

See *Appendix B: Preparing a Study Budget* for more information.

5.3. Internal review

Funding applications that will be administered by SHA (including but not limited to electronic submissions for SHRF and CIHR competitions) must be submitted to the SHA Research Department Researchapproval.Saskatoon@saskhealthauthority.ca for review.

The internal deadline for a comprehensive review is 5 business days prior to the application deadline.

The amount of assistance provided by the SHA Research Department to researchers that require assistance with their funding application may vary depending on time available, so the earlier applicants connect the better.

Funding applications that require a *Letter of Intent* or any other type of pre-registration document are exempt from this process.

The SHA Research Department is able to provide a *Letter of Acknowledgement* to state that a project has been reviewed and complies with our policies. *Letters of Support* must be provided by a knowledge user for the project.

The principal applicant (lead applicant) may receive suggested revisions from the Research Funding and Contract Specialist. The Director of Research will review the funding application and may grant approval once the PI addresses the revisions. Note that SHA Research Funding and Contract Specialists are available to review proposals at any stage of the application process ahead of the internal deadline.

5.4. Funding application approval

To ensure that all the necessary signatures are obtained in advance of the funding application deadlines, the signature pages, together with the complete copy of the application, must be submitted to the Research Funding and Contract Specialist at least two business days in advance of funding competition deadlines. The PI, Co-PI(s), or Sub-Investigator(s), as applicable, must ensure that the required signatures are obtained prior to submitting the application to the granting agency.

Every application for funding from an external source must be signed in the following order:

- PI/Lead Applicant;
- Departmental Executive Director (if applicable); and
- SHA Director of Research.

The signatures affirm that the:

- applicant is eligible to apply;
- information in the application is complete and accurate to the best knowledge of the applicant;
- applicant has sufficient time, space, and resources to conduct the proposed research;
- SHA is able and willing to administer the funds on behalf of the granting agency in accordance with the guidelines of the granting agency;
- awardee agrees to abide by the award regulations as stipulated by the granting agency;
- SHA will not release the funding to the awardee until all award conditions of the granting agency and SHA are met;
- awardee will use the award only for the purposes outlined in the research funding application; and
- awardee will notify the SHA Research Department and the granting agency should there be any change in their status that affects their eligibility for the award.

The SHA Research Department retains a copy of the application and signature page. The PI submits the original application to the funding agency.

Some funding agencies (e.g., CIHR, SHRF) no longer require the institution signature on the signature pages of its funding application for certain competitions (e.g., operating grants). Given that the application is being submitted through e-approval, hitting the "submit" button constitutes the institutional signature. In these instances, all other signatures must be obtained and uploaded with

the application. Once all required signatures have been obtained, the PI will scan and submit the documents electronically with the electronic funding application.

5.5. Research fund management

Setting up a research account

PIs who receive awards that must be administered through the SHA, such as grant funding, sponsored research, in-kind contributions, or unsolicited donations, must notify the SHA Research Department by providing a copy of the award notice and any other documents concerning the regulations or conditions governing the use of awarded funds.

Use the *Research Account Application* form to send requests for new research accounts.

The SHA creates separate research accounts for funding awarded to SHA PIs. Financial statements, if required by the Research Sponsor, are prepared by the SHA Finance Department. The SHA Finance Department retains original invoices for audit purposes.

Opening of accounts for externally funded or sponsored research

Submit a *Research Account Application* form to SHA Research Department for review and approval. Written authorization will be issued after submission by the Research Funding and Contract Specialist or designate.

Use of funds from externally funded or sponsored research accounts for initial grant year

The SHA Finance Department disburses funds for the first grant year when they receive a copy of the *Authorization to Conduct Research Letter*.

Use of funds from externally funded or sponsored research accounts for subsequent grant years

Use of funds for additional grant years requires yearly renewal of the REB Certificate.

If the chair of the REB closes a study for non-compliance, the funds are frozen until the study is re-approved.

5.6. Study-related income and expenses

All cheques sent to PIs for SHA research must be made payable to the "Saskatchewan Health Authority." Cheques received by SHA awardees or departments must be forwarded to the SHA Research Department to be deposited into the appropriate account. PIs and other team members cannot accept personal cheques for research support.

Research funding must contribute towards the direct costs of the research for which the funds were awarded, and the benefits must be directly attributable to the grant or research contract. Research funds must be used effectively and economically, and the expenses must be essential for the research for which the funds were awarded. The PI must ensure that the study does not exceed the budget and that the Research Sponsor's policies that pertain to study expenses are followed.

Invoices detailing the expenses as well as any supporting documentation (e.g., copies of original receipts) for all expenditures being charged to the study specific research account must be submitted to ResearchContractsRegina@saskhealthauthority.ca for approval. Once the Research Department

has approved study related spending, invoices will be forwarded to the SHA Finance Department for processing and reimbursement. PIs are encouraged to retain all original copies of invoices and receipts for their records.

5.7. Changes to study budget or team members

When a change in budget allocations or team members occurs, the PI should review the terms and conditions of the grant to determine if prior approval of the change is required by the granting agency. If such approval is required, a request for budget or team member change should be prepared by the PI and include the:

- cost categories affected;
- proposed change in budgetary allocations; and
- technical/scientific justification requiring such changes.

SHA Research Department (Researchapproval.saskatoon@saskhealthauthority.ca) must be copied on all communications to the granting agency regarding the request, including informing SHA Research Department if the approval has been granted.

5.8. Financial reporting

Researchers must:

- provide documents to the SHA Finance Department for annual and final financial statements;
- submit financial statement(s) to the SHA Research Department for review and retention; and
- submit financial statements to the Sponsor, as required.

5.9. Closing a research account

When an external research grant or contract ends the remaining balance in the research account must be:

- used as per the funder's terms and conditions;
- moved into the SHA's *General Research Fund* if no conditions exist; and
- closed once the research and disbursement is complete.

The *General Research Fund*:

- advances research at the SHA;
- stimulates new research initiatives; and
- funds research activities occurring in the SHA and led by an SHA investigator.

To close a research account, submit a *Research Account Closure* form to SHA Research Department for review and approval.

Administering residual research funds

Within 90 days of the expiry date of the grant or contract, an SHA Research Administrator will contact the PI to ensure that all relevant and allowable expenses to the grant or contract have been charged appropriately and have been reported in accordance with the terms, conditions, and end date stipulated in the grant or contract.

If required by the terms and conditions of the research grant or contract, any residual research funds will be returned to the research sponsor. The SHA Finance Department will close the account and the SHA Research Department will notify the PI of such closure.

Where there are residual research funds that are not required to be returned to the research sponsor, the PI will receive notification to complete an application form to access the residual research funds and redirect them towards another project. The application will outline the project for which the PI would like to use the residual research funds, as well as a justification for why the funds are required and how they will be used. Requests to access residual research funds are subject to the review and approval of the Vice President, Quality, Safety & Strategy.

If the application is not received by the SHA Research Department within 30 days from the request for an application, the residual research funds will be transferred to the SHA *General Research Fund*.

All expenditures from residual research funds must comply with SHA policies for financial management and align with the identified purpose and budget proposed in the application for the use of the residual research funds.

The PI will have 12 months from the time of approval to use the residual research funds. If additional time is required for completion of the project, an application must be submitted to the SHA Research Department justifying the need for an extension.

If an account remains inactive for 12 months following approval of the use of the residual research funds, those funds will be transferred to the *General Research Fund*.

Distribution of SHA General Research Fund
Funds in the SHA *General Research Fund* will be administered based on a peer-reviewed granting process to fund new studies and/or new investigators within the SHA.

5.10. Institutional Costs

The SHA supports research in its facilities through internal infrastructure, administrative and clerical support, and in some cases, with direct funding awarded from the SHA. Recovery of the indirect costs of research compensates SHA for these expenses.

Indirect costs of research are expenditures incurred in the conduct of research that are not always easy to trace to specific expenses and can include:

- monitoring regulatory and research compliance;
- providing space;
- use and maintenance of equipment;
- providing staff resources from the Research Department, Financial Services or other; and
- sharing costs such as insurance and legal fees.

Unless exempted, research must include an allowance for the indirect costs of research at the SHA using the approved rates. Indirect costs of research must also be included in the budget. The SHA determines indirect costs of research by applying an overhead rate of 30% to its direct costs.

For example, if the direct cost per participant is $100, the budget must state the cost per participant is $130. This accounts for $100 of direct costs plus 30% of indirect costs of research to cover these costs.

The recovery of indirect costs of research applies to all eligible research and service contracts undertaken by SHA employees that are eligible for recovery of indirect costs of research, including:

- research and service contracts and grants from for-profit business and industry;
- federal government contracts, when permitted;
- provincial government contracts, when permitted; and
- any external source of research funding, when permitted.

For information on indirect costs of research and which grants are eligible for indirect costs of research, please contact the SHA Research Department.

Exceptions to the institutional overhead policy
Some examples include:

- private donations, not-for-profit organizations, or tri-council agencies that fund research;
- indirect cost rates that have been published and applied to all Canadian institutions in a standardized fashion;
- contracts that have been made with a company, institute, or other service contractor, the negotiated rate will be applied to all contracts and grants provided by that funder. Such contracts may only be made by the Director of Research.

Other exceptions require the permission of the Director of Research and must be secured in advance of the contract award or grant application.

Distribution of the indirect costs
The SHA Research Department will collect all research overhead and distribute it, as necessary, to recover the indirect costs resulting from research activities within the SHA.

6. Research contracts

Research contracts outline terms relating to study conduct, responsibilities, payment, confidentiality, and liability, among other things.

PIs may request a research contract be drafted on their and on the SHA's behalf, if:

- data that is under the custody and control of the SHA that will be transferred outside of the SHA for the study; or
- a contract is established with a collaborator or sub-site.

If a research sponsor, collaborator, or lead site has provided you with a research contract, you must include it in your *Operational Approval Application*.

Contracts that involve the SHA must:

- include terms and conditions that manage risk;
- adhere to all of the SHA's contracting standards and requirements; and
- align with the *Research Policy* (SHA-02-006) and other related policies.

See *Appendix C: Common Types of Research Contracts* for more information.

6.1. Contract parties

SHA and the PI must be parties to research-related contracts if the PI will be using SHA resources, facilities or patients (including their PHI). Any contract relating to a study that requires SHA OA will typically need to be reviewed by the SHA Research Department. In situations where there are multiple parties (e.g., USask or the Saskatchewan Cancer Agency), the decision about SHA's need to be a party to the contract will be made at the discretion of the SHA. This decision will be made by the SHA based on information from and collaboration with appropriate representatives from the various parties potentially involved in or impacted by the study.

6.2. Contract negotiations

All contracts must be reviewed and approved by the SHA prior to signing. This ensures that the opportunity for negotiation exists, based on the best interests, priorities, policies and procedures, and resources available within SHA.

6.3. Internal review and negotiation

Contracts must involve the SHA Research Department or Contract Management. They will assist with drafting, review and negotiations on behalf of the SHA.

The following information must also be provided with the contract at the time of submission:

- research sponsor contact information;
- PI contact information;
- contact information for any study coordinators managing correspondence;
- scope of work for the project, including projected start and end dates;
- study proposal/protocol, if applicable; and
- budget for the project including indirect costs of research, if required.

Industry sponsored research contracts or investigator initiated clinical trial agreements must also include:

- a copy of the *Informed Consent Form*, if available, or a copy of the study protocol;
- the ClinicalTrials.gov link, if available.

6.4. Contract execution

The Research Funding and Contract Specialist reviews the completed contract. They then submit it to the SHA Director of Research for approval to proceed. The Director of Research will ensure that the approval of the contract follows applicable SHA's policies and procedures. The contract is binding on all parties once signed.

The PI must ensure the SHA Research Department receives a copy of the signed contract. The Research Department will keep a copy of all research contracts in accordance with *Appendix C: Records Retention Schedule* of the *Corporate and Personal Health Information Governance Policy* (SHA-07-004). The Research Department will keep their copy of contracts in relation to clinical trials for twenty-five years after study closure. This retention aligns with Health Canada regulations and *Appendix C: Records Retention Schedule* of the *Corporate and Personal Health Information Governance Policy* (SHA-07-004).

7. Research misconduct

Research misconduct includes, but is not limited to:

- fabrication, falsification, improper destruction of research records;
- plagiarism;
- redundant publications;
- invalid authorship;
- inadequate acknowledgement;
- mismanagement of conflict of interest;
- failure to comply with relevant policies;
- misrepresentation in a funding application; and
- mismanagement of funds.

7.1. Reporting research misconduct

Suspected research misconduct must be reported to the SHA Director of Research.

7.2. Consequences of research misconduct

Research misconduct constitutes failure to follow the Research Policy or the Research Procedure will be dealt with as described in section 12 of this procedure.

8. Data storage and retention of research records

Research records must be retained in sufficient detail to enable the SHA and the involved investigators to respond to questions about research accuracy, authenticity, compliance with pertinent contractual obligations, and the SHA and externally imposed requirements and regulations governing the conduct of the research. The purpose of these procedures is to ensure that the:

- authenticity of all data and other factual information generated in research can be verified; and
- research records containing PI and/or PHI about research participants are stored in a manner which protects the privacy of such information in accordance with the applicable acts/legislation:
    - *The Health Information Protection* Act (HIPA);
    - *The Local Authority Freedom of Information and Protection of Privacy Act* (LA FOIP);
    - The Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans[1]; and
    - other relevant legislation and requirements concerning confidentiality.

SHA HIMS retains patient/client records (source documents) for Health Canada Regulated Trials. PIs are required to notify HIMS upon recruitment of new participants to a clinical trial involving SHA patients to assure that patient/client records are retained by HIMS for the full 25-year Health Canada regulated Clinical Trial retention period. HIMS can also provide certified copies of patient/client records if required for study files, study monitoring visits or Health Canada audits. Please contact your local HIMS staff for details on the processes for assuring study participant patient/client records are retained for the full 25-year period and for attaining certified copies of study participant patient/client records.

Regina: Nina Lindo – nina.lindo@saskhealthauthority.ca

Saskatoon: Aimee Goss – aimee.goss@saskhealthauthority.ca

Applications to the REB require a statement outlining the procedures that investigators will use to securely store research records. It must include the:

- length of time the research records that will be stored;
- location of storage;
- identity of the person responsible for storing the research records;
- procedures that will ensure secure storage; and
- confidential and permanent means of destruction of data once the required data retention period has concluded.

Research records must be documented appropriately, archived for a pre-determined length of time (see *Appendix C: Records Retention Schedule* of the *Corporate and Personal Health Information Governance Policy* (SHA-07-004)), and be made available for review if required to:

- audit compliance with related policies, regulations, or contractual agreements;
- protect the rights of research team members to access records from research in which they participated;
- assist in proving or securing intellectual property rights;
- allow for the investigation of allegations of breaches of the *Research Policy* (SHA-02-006) or this Procedure; and
- assist and enable other administrative or legal proceedings involving the SHA or researchers, or their interests, related to the research.

Clinical trial data that is subject to Health Canada regulation is stored for a minimum of 25 years. The SHA REB may also require the 25-year retention period for non-Health Canada regulated clinical trials.

All other data must be stored for a minimum of 5 years from the date of completion of the study, unless otherwise stipulated by federal or provincial regulations, the terms of a research sponsorship agreement, or the terms of a funding body as stipulated in the funding agreement.

Hard copy files must be stored in a locked filing cabinet or otherwise secured within the PIs office, or according to a method otherwise approved by the REB.

Electronic files must be stored on password-protected SHA computers or network drives with limited access. For laptops and portable media (e.g., flash drives), at a minimum, files containing data and/or PHI

must be password-protected and encrypted to protect against unauthorized access. The user may instead opt to encrypt and password-protect the entire device itself.

Data retention periods specified in the approved research ethics application must be adhered to.

Following the data retention period, all data (regardless of format) must be permanently and confidentially destroyed according to the Authorization for Destruction of Records procedure (SHA-07-004P1).

When an investigator leaves the SHA, they may take a copy of the research records related to their research but must notify the REB and the SHA, and must leave all originals with the SHA Research Department. If a PI leaves the SHA or a project is to be moved to another institution, the REB must be notified of the location of the original research records and of the data storage and retention procedures in the new institution. A data sharing agreement or materials transfer agreement with the SHA will be required for both cases listed above. In some instances (e.g., where institution intellectual property or other interests are involved), such transfer may not be permitted, and any such agreement may require diligent retention by the recipient and continued access by the SHA. The obligations of investigators set out in this document continue to apply if an individual takes copies of research material to their new institution.

9. Principal Investigator insurance requirements

9.1. SHA

SHA staff, including investigators employed by the SHA and their research staff, conducting research as part of their SHA responsibilities are covered by a combination of Canadian Medical Protective Association (CMPA) protection (for practitioner staff) and SHA liability insurance.

9.2. Academic Institutions

Faculty, students, postdoctoral researchers, and research staff conducting research in the SHA under the auspices of their academic institutions (e.g., USask faculty conducting research that is funded through their academic institution account or where the USask is signatory to a clinical trial agreement or research contract) should contact their academic institution for the liability insurance.

9.3. Saskatchewan Cancer Agency (SCA)

SCA employees, including investigators employed by the SCA and their research staff, conducting research as part of their SCA responsibilities should contact the SCA for liability insurance.

9.4. Practitioner staff

All practitioner staff investigators and their research staff that are not covered under SHA, U of R, USask or Saskatchewan Polytechnic insurance policies, may be protected through the investigator's membership in the CMPA when conducting studies within Canada involving patients with medical conditions. The investigator must provide the SHA with documentation of CMPA membership before SHA OA will be granted. The investigator must also show proof within 30 days of membership expiration that the membership is renewed annually. Failure to show proof of renewal will result in revocation of SHA OA.

9.5. Other

Any investigator not covered under one of the above three scenarios who is (i) conducting a Phase 0, I, or II clinical trial in a sample of healthy individuals, or (ii) the PI on an investigator-initiated study conducted outside of Canada must obtain separate general and medical malpractice liability insurance providing $5,000,000 per occurrence.

The SHA and the investigator's research staff involved in the study must be included as additional insureds on the policy. The investigator must provide the SHA with documentation of this insurance before SHA OA will be granted. The investigator must also show proof within 30 days of policy expiration that the insurance is renewed annually. Failure to show proof of renewal will result in revocation of SHA OA.

Faculty, students, post-doctoral researchers, and staff from Canadian post-secondary institutions conducting health systems research not requiring direct patient contact (e.g., surveys, health data) in SHA may be covered by their institutional liability insurance and should inquire with the applicable institution.

Should there be an event that leads to an insurance claim or may lead to an insurance claim, please report it to shaclaims@saskhealthauthority.ca by utilizing the SHA Liability Claim Reporting Form.

10. Intellectual Property (IP)

The SHA Research Department will seek patent protection for any commercialization of findings or scientifically meritorious inventions. The IP will be overseen and managed by the SHA Research Department on behalf of the SHA, and the Research Department will be responsible for resolving any dispute that may arise from the interpretation of the SHA's *Research Policy* (SHA-02-006). If the matter cannot be resolved, the matter will be referred to the Vice President, Quality, Safety and Strategy, who can seek further legal counsel.

Researchers must disclose the nature and extent of their claim to the IP to the SHA Research Department as soon as practical and to the best of their knowledge. In general, where applicable, IP must be filed for protection prior to any publication. The SHA Research Department will ensure compliance with applicable laws and regulations in order to secure IP for all levels of research.

If any obligations are owed to an external party under the terms of a grant or research contract in respect to IP, the IP will be managed according to the terms of the contract. In collaborative research and discoveries with parties outside of the SHA, the IP will generally be jointly owned, subject to any applicable contract terms.

10.1. Public research results

PIs will use reasonable efforts to make the results of their research public. All clinical trials must be registered with www.clinicaltrials.gov. Additionally, any publications or presentations that result from a study must include a statement acknowledging the assistance of the SHA. The use of SHA logo for research publications and presentations must meet the SHA's Visual Identity Standards.

Publication of industry-sponsored research

The following considerations and requirements pertain to research with commercial interests such as industry-sponsored research, the:

- research sponsor and PI can negotiate publication dates;
- PI can publish twenty-four months after the final report is submitted to the research sponsor, or the project is terminated, whichever is later;
- defense of a thesis by a graduate student may be delayed by contractual restrictions;
- publication of a thesis may be delayed in accordance with the policies of the student's host university; and
- publications may be withheld for more than twenty-four months after the final report is submitted to the research sponsor. This delay must not be longer than thirty-six months.

10.2. Attribution

SHA PIs shall ensure that appropriate recognition, including authorship, is given to those researchers who:

- made an intellectual or practical contribution to the research study; or
- permitted their unpublished work to be used in the research study.

The PI ensures that all co-authors approve the manuscript before it is submitted. All researchers listed as authors must understand the significance of the research conclusions and share responsibility for the content and its reliability. Leaders and clinicians that have not contributed substantively to the study should decline invitations to be added to manuscript authorship, or contact the REB Chair if they have questions or concerns about an invitation.

The PI ensures that SHA contributions are acknowledged on all publications and presentations.

The PI ensures all publications of scholarly work in medical journals follow the International Committee of Medical Journal Editor's (ICMJE) recommendations for the conduct, reporting, editing, and publishing.

11. Resources and tools

11.1. Training and courses

McMasters Tutorial: http://ethics.mcmaster.ca/chart/
TCPS 2 Certificate: http://tcps2core.ca/welcome
Good Clinical Practice (GCP): https://www.citiprogram.org/
Health Canada Division 5: https://www.citiprogram.org/

In addition, research training courses are open to SHA employees by registering online with the CITI Program (Collaborative Institutional Training Initiative). The CITI program has been developed and administered by the organization N2 (Network of Networks). All courses available on CITI meet Canadian standards.

Courses available include:

- Good Clinical Practice Course;
- Responsible Conduct of Research (RCR);
- Biomedical Research Ethics Course;
- Social and Behavioral Research Course – Canada;
- Health Canada Division 5 - Drugs For Clinical Trials Involving Human Subjects; and
- Clinical Research Coordinator.

11.2. REDCap™

https://redcap.vanderbilt.edu/consortium/videoplayer.php?video=redcap_overview_brief02&title=Brief%20Overview%20of%20REDCap&referer=redcap.rqhealth.ca

11.3. Sources of funding

Canadian Institutes of Health Research: https://cihr-irsc.gc.ca/
Saskatchewan Health Research Foundation (SHRF): https://www.shrf.ca/funding

11.4. Research contracts

Health Protection and Food Branch of Health Canada: https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch.html

11.5. Insurance requirements

https://www.cmpa-acpm.ca/en/home

11.6. Intellectual Property

http://www.icmje.org/icmje-recommendations.pdf

11.7. Glossary

(Program Evaluation ARECCI Assessment) https://albertainnovates.ca/programs/arecci/

12. Failure to follow this procedure

Failure to follow this procedure will be handled according to:

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

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

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

13. Documents that relate to this content

Policy

SHA-02-006 *Research Policy*

Other
Research Questions and Answers
SHA-03-002 Procurement and Competitive Bidding Policy
SHA-03-003P1 Honorariums and Stipends Procedure
SHA-03-003P4 Travel and Working Sessions Procedure
SHA-07-004 Corporate and Personal Health Information Governance Policy
SHA-07-004P1 Authorization for Destruction of Records Procedure

14. Roles that manage and approve this procedure

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

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

Procedure Owner: Executive Director, Academics and Learning

- Manages this procedure including procedure communication, education, implementation, evaluation and audit.
- Shares responsibility for revisions and renewal with the sponsor.

15. References

1. 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

2. Office for Human Research Protections. Title 45: Public Welfare Part 46 - Protection of Human Subjects. [Internet]. Washington, DC: Department of Health and Human Services; 2018. [cited 2020 Aug 18]; s. 46.102. Available from: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1102

3. Canadian Institutes of Health Research; Natural Sciences and Engineering Research Council of Canada; Social Sciences and Humanities Research Council. Tri-Agency Framework: Responsible Conduct of Research. [Internet]. Ottawa, ON: Secretariat on Responsible Conduct of Research; 2016. [cited 2020 Feb 21]; 24 p. Available from: https://rcr.ethics.gc.ca/eng/documents/Framework2016-CadreReference2016_eng.pdf

4. *The Health Information Protection Act*, SS 1999, c H-0.021.

5. *The Local Authority Freedom of Information and Protection of Privacy Act*, SS 1990-91, c L-27.1.

6. *Food and Drugs Act*, RSC 1985, c F-27.
Food and Drug Regulations, CRC, c 870.
Medical Devices Regulations, SOR/98-282.

7. *Controlled Drugs and Substances Act*, SC 1996, c 19.
Narcotic Control Regulations, CRC, c 1041.

8. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). [Internet]. [Geneva, Switzerland]: ICH; 2016 Nov 9. [cited 2020 Feb 21]; 66 p. Available from: https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

9. *Personal Information Protection and Electronic Documents Act*, SC 2000, c 5.

10. *The Saskatchewan Employment Act*, SS 2013, c S-15.1.
The Occupational Health and Safety Regulations, 1996, RRS c O-1.1 Reg 1.

11. *The Provincial Health Authority Administration Regulations*, RRS c P-30.3 Reg 1.

12. Health Canada. Geneva, CH: World Health Organization; n.d. [cited 2020 Aug 18].

13. University of Regina. Intellectual Property. [Internet]. Regina, SK: U of R; n.d. [cited 2020 Oct 22]. [about 1 screen]. Available from: https://www.uregina.ca/copyright/guidelines/intellectual-property.html

14. 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

15. [Alberta Research Ethics Community Consensus Initiative]. ARECCI Glossary. [Edmonton, AB]: [ARECCI]; n.d. [cited 2020 Aug 18]; p. 2.

16. 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 2021 22 Jul]; Glossary: . Available from: https://ethics.gc.ca/eng/tcps2-eptc2_2018_glossary-glossaire.html

17. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2), November 2016. [cited 2021 Jul 22]; 7-13 p. Available from: https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

18. The Centers for Disease Control and Prevention (CDC), Policy 557 “Distinguishing Public Health Research and Public Health Nonresearch,” 2010. [cited 2021 Jul 22]; 12-13 p. Available from: https://www.cdc.gov/os/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf

19. Canadian Association of Research Ethics Boards. Guidance on Reporting of Unanticipated Problems Including Adverse Events to Research Ethics Boards in Canada July 2010. [cited 2021 Jul 22]; 3 p. Available from: https://careb-accer.org/wp-content/uploads/2020/11/careb_guidance_-_ae_reporting_-_july_2010.pdf

16. Replaced documents

See *Research Policy* (SHA-02-006) Appendix B

Appendix A: Definitions

Above minimal risk studies: Studies in which the probability and magnitude of possible harms implied by participation in the research is greater than those encountered by participants in the aspects of their everyday life that relate to the research.[16]

Affiliate: A prescribed person (see Table 3 of *The Provincial Health Authority Administration Regulations*) providing a health service.[11]

Clinical Trial: A research investigation involving human participants, biomedical or behavioural, which may or may not be subject to Health Canada regulation, in which participants are prospectively assigned to one or more conditions in order to study the health-related outcomes. Clinical trials may include research designed to:

- study a drug's or natural health product's effects on the human body (pharmacodynamics);
- study the body's effects on a drug or natural health product, including how it is absorbed, distributed, metabolized, and/or excreted (pharmacokinetics); and/or
- investigate the safety and/or efficacy of a biomedical (e.g., drug, medical device, natural health product) or behavioural intervention.[12]

Clinical Trial Agreement (CTA)/Clinical Study Agreement (CSA): Outlines the responsibilities of the research sponsor, sub-site (a secondary site where research is taking place), and Principal Investigator. Payment terms, liability, confidentiality, intellectual property, and other provisions are also included in these agreements. In other cases, multi-center studies may require sub-site agreements to outline similar aspects to those of a clinical trial agreement. Funding agreements are intended to outline the payment amounts, schedule, terms, and conditions of funding provided for a study. Data sharing agreements are intended to protect the privacy, use, and disclosure of data from a trustee to a non-trustee, as well as to outline intellectual property, publication, and publicity provisions. Other categories of agreements are possible on a case-by-case basis.

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.

Data and Safety Monitoring Board (DSMB) – A multidisciplinary, expert advisory group established by a research sponsor, that is responsible for safeguarding the interests of participants by reviewing emerging data, assessing the safety and efficacy of clinical trial procedures, and monitoring the overall conduct of a trial.[16]

Delegated Research Ethics Board (REB) Review: The level of REB review assigned to minimal risk research projects. Delegated reviewers are selected from among the REB membership, with the exception of the ethics review of minimal risk student course-based research activities, which can be reviewed by delegates from the student's department, faculty, or an equivalent level. Delegated reviewers who are non-members or non-voting members of the REB must have experience, expertise and knowledge comparable to what is expected of an REB member.[16]

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.

Direct Costs of Research: The budgeted expenditures for carrying out a research activity at the SHA, including (but not limited to):

- equipment and supply costs;
- clinical services provided for study-specific purposes;
- research assistant salaries;
- graduate student stipends;
- per diem payments to the researcher;
- travel costs for study-related events;
- publication costs;
- participant incentives; and
- any other study-related costs outlined in the study budget and approved by the funder or research sponsor.

Emergency Response: A public health activity undertaken in an urgent or emergency situation, usually because of an identified or suspected imminent health threat to the population, but sometimes because the public and/or government authorities perceive an imminent threat that demands immediate action. The primary purpose of the activity is to document the existence and magnitude of a public health problem in the community and to implement appropriate measures to address the problem.[18]

Expiry Date: The date when a grant or contract has reached the end of its term, usually identified within the grant/award letter or contract.

Externally Funded or Sponsored Research: Research that is initiated and managed by an investigator who assumes the legal and regulatory responsibility for the conduct and management of the research as defined by applicable regulations and laws of the country involved. Externally funded or sponsored research may be initiated by a SHA investigator who seeks funding from an external source, or alternatively, may involve a non-SHA investigator and research sponsor who must designate a SHA-affiliated principal investigator to carry out all research activities conducted within SHA.

Falsification: Manipulating, changing, or omitting data, source material, or findings, including graphs and images, which results in inaccurate reported findings or conclusions; the destruction of one's own or another's research data or records to specifically avoid the detection of wrongdoing or in contravention of any agreements, policies, standards, or laws and regulations.

Full Research Ethics Board (REB) Review: The level of REB review assigned to above minimal risk research projects. Conducted by the full membership of the research ethics board, it is the default requirement for the ethics review of research involving humans.[16]

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial [participants] are protected".[17]

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.

Industry-Sponsored Research: Externally-sponsored research whereby the research sponsor is a for-profit entity.

Intellectual Property (IP): The result of intellectual or artistic activity, created by a member of the SHA in a scholarly, professional, or student capacity that can be owned by a person. Some examples of IP are inventions, publications, computer software, works of art, or industrial and artistic designs. Depending on the type of intellectual property, they are protected under different kinds of legislation such as patient, copyright, industrial design, or trademark laws.[14]

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 Nations, 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.

Minimal risk studies: Research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research".[16]

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* (SHA-02-006) and *Research Procedure* for operational approval for research have been met.

Patient/Client Records: Records documenting the assessment, diagnosis, screening and treatment of a client and includes identity of the client, reason for health services encounter, justification for treatment and documented results.

Patient and Family Partners (PFPs): 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[4]:

- 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).

Personal Information: Information about an identifiable individual that is recorded in any form and includes[5]:

- information that relates to the race, creed, religion, colour, sex, sexual orientation, family status or marital status, disability, age, nationality, ancestry or place of origin of the individual;
- information that relates to the education or the criminal or employment history of the individual or information relating to financial transactions in which the individual has been involved;
- information that relates to health care that has been received by the individual or to the health history of the individual;
- any identifying number, symbol or other particular assigned to the individual;
- the home or business address, home or business telephone number, fingerprints or blood type of the individual;
- the personal opinions or views of the individual except where they are about another individual;
- correspondence sent to a local authority by the individual that is implicitly or explicitly of a private or confidential nature, and replies to the correspondence that would reveal the content of the original correspondence, except where the correspondence contains the views or opinions of the individual with respect to another individual;
- the views or opinions of another individual with respect to the individual;
- information that was obtained on a tax return or gathered for the purpose of collecting tax;
- information that describes an individual's finances, assets, liabilities, net worth, bank balance, financial history or activities or credit worthiness; or

- the name of the individual where:
    - it appears with other personal information that relates to the individual; or
    - the disclosure of the name itself would reveal personal information about the individual.

Plagiarism: Presenting and using another published or unpublished work, including theories, concepts, data, source material, or findings, including graphs and images, as one's own without appropriate referencing or acknowledgement; failure to appropriately recognize or acknowledge the contributions of others.

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.

Program Evaluation: The systematic collection and analysis of information about program activities, characteristics, and outcomes to make judgments about the program, improve program effectiveness, and/or inform decisions about future programming.[15]

Quality Assurance: A process in which the activities of an organization and/or program are systematically monitored and evaluated to determine the effectiveness and efficiency of care and service provided. Quality Assurance can identify trends and issues through the systematic monitoring that lead to the development of quality improvement projects.[15]

Quality Improvement: Projects that apply scientific methods, project management and group process tools to analyze data and improve all aspects of service delivery with particular focus on eliminating waste, reducing variation, and improving reliability.[15]

Research: An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. The term 'disciplined inquiry' refers 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.[16]

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[16].

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 Misconduct: Conduct within research activity that opposes the standards and practices that are generally accepted. This may include any of the following:

- plagiarism;
- fabrication;
- falsification; and
- forgery.

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 Sponsor: Refers to an individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a study. For unfunded/investigator-initiated projects, the research sponsor could be the PI. For clinical trials, the research sponsor is usually responsible for applying for regulatory approval with the Health Protection and Food Branch of Health Canada.

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

Residual Research Funds: The funds remaining from a research grant or contract that has terminated or expired, after all direct and indirect costs of the research have been paid.

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 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.

Study Coordinator: An individual appointed by the Principal Investigator to manage the day-to-day operations of a study. The study coordinator may undertake some of the responsibilities of the PI as described in this policy, such as coordinating departmental approvals. Ultimately, however, responsibility for all study activities rests with the PI.

Subinvestigator: Any member of the research team designated and supervised by PI to perform critical study-related procedures and/or to make important study-related decisions.[17]

Surveillance: The ongoing systematic collection, analysis and interpretation of health data, essential to the planning, implementation and evaluation of public health practice, closely integrated to the dissemination of these data to those who need to know and ling to prevention and control.[18]

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, practitioner staff, contracted individuals, Patient Family Partners, Knowledge Keepers, volunteers, learners and contractors.

Unanticipated Problem: any incident, experience, or outcome that meets all of the following criteria:

- **Unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, or the Investigator Brochure; and (b) the characteristics of the research participant population being studied; **and**
- **Related or possibly related** to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the [investigational product(s)] or procedures involved in the research); **and**
- Suggests that the research **places research participants or others at a greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.[19]

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

Appendix B: Preparing a Study Budget

The study budget must reflect the direct and indirect costs of the proposed research accurately.

A fully-developed budget should include, but is not limited to, the following:

Clinical services provided for study-specific purposes
For clinical research, your budget needs to include the costs of any treatments or tests that are above the standard of care. If you need help determining these costs, you can:

- request a cost estimate from the relevant department (lab support, pharmacy, diagnostic imaging etc.); or
- contact the SHA Research Department for a cost list or guidance.

Participant incentives
If your budget will include reimbursement to participants for costs they incur during the study such as parking, meals, overnight accommodations or mileage, you will need to follow the:

- Saskatchewan Centre for Patient Orientated Research (SCPOR) guidelines on patient honoraria;
- SHA Honorariums and Stipends Procedure (SHA-03-003P1) for Patient Family Advisors; and
- funding agency's guidelines to determine the maximum allowance for reimbursement.

Contact the SHA Research Department if you need assistance.

Salaries and benefits
The Budget must include the costs for the study team members' time (i.e., technicians, nurses, research coordinators, research assistants etc.). To accurately budget for these costs, you will:

- follow the guidelines for the competition to determine any established standards for employee salaries; and
- determine the salaries and benefits based on the range appropriate for the position in the SHA if there is no standard in the guidelines.

Contact the SHA Research Department for assistance in determining the appropriate salaries and benefits if needed.

Stipends
Student stipend amounts must conform to:

- limits set by the Research Sponsor, and
- minimum guaranteed amounts set by the university faculty or department.

Consult with the education institution faculty or department regarding these amounts.

Equipment and supplies
If your study requires the purchase of equipment, supplies or services from a third party, see *Procurement and Competitive Bidding* Policy (SHA-03-002).

Research space and infrastructure
If you require additional research space on SHA property for your study, contact the Research Department to discuss associated costs and available space.

Biostatistician support
If you require bio statistical, data management, or database support, contact the Research Department. If you require the support of the biostatistician, schedule an initial face-to-face consultation prior to submitting an application for funding.

This consultation includes:

- review of the proposed methodologies,
- discussion to address any questions, and
- provision of a formal quote document.

Printing and publication costs
Your budget should include costs associated with:

- printing of knowledge translation and dissemination materials (e.g., pamphlets, posters, brochures);and
- publication results in open access and traditional journals.

Travel expenses
If you will have expenses related to travel to the research site, attendance at academic conferences, workshops or meetings, you need to determine eligible expenses to claim. You will need to follow the:

- SHA's *Travel and Working Sessions Procedure* (SHA-03-003P4); and
- regulations of the granting agency posted on the funding agency's website.

If the SHA and granting agency's eligible expenses are different, follow the more stringent eligibility.

Indirect costs of research
Indirect Costs of Research are those expenditures incurred by the SHA in the conduct of research that are not readily identifiable as specific expenditures.

Matching funds
If the Research sponsor guidelines require cost-sharing or matching funds (either cash contribution or in-kind funding support), the PI:

- completes the respective budget sections in the application; and
- provides appropriate letters of support from third-party sources.

The Research Department must approve all matching funds or cost-sharing commitments in advance.

Appendix C: Common Types of Research Contracts

There are several types of contractual arrangements that the SHA may enter into, including but not limited to:

Clinical trial agreement/clinical study agreement (CTA/CSA)
Outlines the responsibilities of the Research Sponsor, sub-site (a secondary site where research is taking place), and PI. Payment terms, liability, confidentiality, intellectual property, and other provisions are also included in these agreements. In other cases, multi-center studies may require sub-site agreements to outline similar aspects to those of a CTA. Funding agreements are intended to outline the payment amounts, schedule, terms, and conditions of funding provided for a study. Data sharing agreements are intended to protect the privacy, use, and disclosure of data from a trustee to a non-trustee, as well as to outline intellectual property, publication, and publicity provisions. Other categories of agreements are possible on a case-by-case basis.

Confidentiality agreement/non-disclosure agreement (CDA/NDA)
An agreement required when a party is exchanging confidential or proprietary information with another party.

The CDA/NDA defines the:
- applicable confidential information;
- obligations of the receiving party in terms of maintaining confidentiality; and
- the period of time during which confidentiality must be maintained.

A CDA/NDA is provided by a research sponsor when they are:
- assessing potential participation by a site in a research protocol (usually clinical trials); or
- considering collaboration with another party.

To ensure a productive collaboration, all parties can evaluate the other parties':
- expertise;
- processes;
- facilities; and
- resources.

Contracting parties can protect and retain their intellectual property when other parties are reviewing study-specific materials and considering participation to ensure that any proprietary or sensitive business information is maintained in confidence.

The NDA specifies terms by which either party's confidential information is disclosed to the other party. Normal time limit of confidentiality is a maximum of 15 years.

Data sharing/transfer/agreement (DSA/DTA)
An agreement setting out the terms and conditions under which data will be shared between parties.

The conditions (as appropriate) are applied to the following with respect to data:
- collection;
- use;
- linkage;

- subsequent re-identification;
- transmission;
- storage;
- protection;
- destruction;
- archiving;
- returning information to an identifiable level;
- sensitivity of the information; and
- other criteria which the SHA may wish to consider.

The SHA is defined as a trustee of PHI under HIPA and as a custodian of PI under LA FOIP. As such, the SHA has an obligation to protect the confidentiality of the information and the privacy of the individuals to whom it relates, as well as to be accountable to individuals with respect to the collection, use, disclosure and exercise of custody and control of PHI.[5]

As a custodian under LA FOIP, the SHA has a duty to protect personal information and may only disclose personal information as defined by LAFOIP. The DSA/DTA ensures that any data disclosed by the SHA is done so in a way that complies with all pertinent privacy legislation and protects the SHA from liability associated with further use or disclosure of the data.

Material transfer agreement (MTA)
An agreement allowing for the transfer of research material (e.g., compounds, antibodies, plasmids, biological samples, etc.) between collaborating SHA researchers and institutions or companies external to the SHA. A MTA describes acceptable use of the material, as well as ownership of any data that results from use of the material.

There are often important considerations to be made in these agreements such as:

- privacy;
- proprietary;
- storage; and
- retention.

A MTA deals with potential liability issues connected to the use of the material. While MTAs can be executed as a stand-alone agreement, material transfer provisions are also commonly incorporated into DSAs or CTAs.

Service agreement (SA)
An agreement providing for the delivery of services by a party, with the expectation of reporting results or other deliverables back to the other party.

SAs are typically used when access to another party is being granted or services are being provided under strict terms and conditions. These include:

- resources;
- facilities; or
- expertise is required.

Consulting arrangements

Consultants must:

- sign a rental agreement before they can use SHA space, equipment, or facilities; and
- compensate all staff, including SHA staff, involved in their consulting arrangement.

Consultants may not use SHA's:

- staff during working hours; or
- name in communications about the consulting arrangement.