Guidance Notes

What is Saskatchewan Health Authority (SHA) Operational Approval to Conduct Research?

Review and approval of research projects that impact or affects any SHA resources/facility(s). This includes all research projects conducted by SHA employees.

The requirements for obtaining SHA Operational Approval (OA) for research are twofold:

1. Assurance of research ethics approval from the appropriate Research Ethics Board (REB) must be provided before OA can be granted. Research ethics approval must be obtained from one of the following Saskatchewan Research Ethics Boards: SHA (located in Regina), University of Regina or University of Saskatchewan. **Do not submit your SHA Operational Approval application until AFTER the REB application has been submitted for review to the appropriate REB.**

2. The Principal Investigator (PI) must complete and submit the SHA Application for Operational Approval to Conduct a Research Study. The purpose of the application is to ensure that research using SHA or affiliated resources or patients occurs with the approval of the appropriate authorities, as well as to ensure that all research occurring within the SHA meets the requirements of the applicable policies, legislation, and guidelines for conducting responsible research. It is essential to determine whether the SHA has the appropriate resources in place to support the research question or hypothesis, that the areas being affected have an opportunity to review the project details and assess their impact, and to ensure that all necessary ethical and operational processes have been completed **prior to the commencement of the project.**

   Please note: **A waiver of REB review does not guarantee a waiver of the need for OA**. If your research study is exempt from REB review, you must contact the Research Approval Coordinator to determine if an application for OA is necessary.

Research Approval Coordinator Contact Information:
Regina/South: researchapproval.regina@saskhealthauthority.ca , telephone: (306)766-0893
Saskatoon/North: researchapproval.saskatoon@saskhealthauthority.ca, telephone: (306)-655-1442

Submitting Your Application for Operational Approval

Begin your application for Operational Approval AFTER the research ethics application has been submitted.

All applications for OA are submitted using the Operational Approval to Conduct Research Application Form, accompanied by all applicable attachments. REDCap is the on-line server used to complete the OA

form. The form can be saved and accessed again for completion, please ensure you record the RETURN CODE in order to access the form to make changes. The link to the form and the RETURN CODE can be shared with other members of the research team to facilitate the completion of the form. The PI must provide an e-signature on the form. Once a completed application is received, the Research Approval Coordinator(s) will email the PI and Primary Contact to confirm receipt of the application, provide the OA number assigned to the applicant and provide a PDF copy of the application for the PI's record. The Research Approval Coordinator(s) will also review the application for completion and will contact the PI and Primary Contact if there is missing information or documents.

Approval for amendments to a study that has already received OA is required when changes to the study results in SHA facilities/departments being added or removed from the research project. Amendments also need to be submitted if there are changes (additions or deletions) to the data being collected from SHA sources (e.g. Health Records, SCM, administrative data). Amendments to the OA are submitted using the Amended Operational Approval to Conduct Research Application form. The corresponding REB amendments should accompany the amendment application for OA.

Letter of Authorization to Conduct Research

No project may commence prior to receipt of the Letter of Authorization to Conduct Research. This letter demonstrates that SHA OA has been granted and the letter will not be issued until the following have been received by the Research Approval Coordinator:

a) A completed Operational Approval to Conduct Research Application Form;
b) All applicable approvals from SHA managers or designates whose resources (including, but not limited to, facilities, equipment, supplies, staff) or patients will be utilized in the research and, if applicable, Medical Department or Section Heads (or designates) whose areas of clinical practice will be impacted by the research, if such parties have not already signed the application for research ethics review;
c) A Certificate of Approval or Letter of Exemption from the Research Ethics Board;
d) A copy of the Health Canada No Objection Letter (drug trials) or Investigational Testing Authorization (device trials), if applicable;
e) A copy of the Notice (or letter) of Award and any other documents concerning the regulations or conditions governing the use of the grant or donated funds, if applicable;
f) A completed Research Account Application form for any studies requiring administration/management of research funds through the SHA;
g) A fully executed copy of any clinical trial agreement, clinical research contract, confidentiality/non-disclosure agreement, material transfer agreement, and/or data access agreement, and any other research-related agreements associated with the conduct of the research within the SHA or its Affiliates, if applicable; and
h) Proof of insurance for PIs and/or types of research not covered by institutional and/or Canadian Medical Protective Association (CMPA) insurance.

Once all required documents have been received, the Letter of Authorization to Conduct Research will be issued to the PI and copied to the study coordinator, all signatories who have granted departmental approval for the research, and the Director of Research.

How to Use the Guidance Notes with the Application Form

The following Guidance Notes (GNs) are intended to ensure that applicants have the necessary information to be able to fill out the Application for Operational Approval to Conduct Research correctly. The Guidance Notes are numbered to correspond with the numbers listed in the OA Application Form. It is the responsibility of the investigator(s) to ensure that the information contained in each Guidance Note is applied in a manner appropriate to each individual project for both the Application Form and any accompanying documentation.

Please note: All investigators are responsible for understanding and adhering to the SHA Research Policies and Procedures, the Tri-Council Policy Statement, 2nd Edition (TCPS 2)[1], and all other relevant guidelines. These Guidance Notes are not intended to be a substitute for this responsibility. Please refer to the original documents for complete information.

Operational Approval to Conduct Research Application Form

PART 1: IDENTIFICATION

GUIDANCE NOTE 1.1: PROJECT DESCRIPTION

The title of the project should accurately reflect the nature of the study and should be the same as the title provided in the Research Ethics Board Application. The Project Title should also correspond to the title of any consent form(s) or related material submitted in association with this study. If the title is long (as is often the case for Clinical Trials), please include an abbreviated title for quick reference by those involved in the study. Also indicate the anticipated start and end date for the project; this is important for departments providing approval for the project as they will need to be aware of the length of time they are committing to a project.

Enter the locations/sites/facilities where the research will be carried out under this approval. The project cannot begin until you receive approval from the facilities specified. It will be the responsibility of the Research Approval Coordinator(s) to facilitate obtaining the necessary approvals from these SHA facilities. Indicate who the study participants will be (inpatient, outpatient, long term care resident or staff) and the number you expect to recruit for this study. For retrospective reviews include the number of patient records you wish to review/include in your analysis.

Indicate if the project has been submitted for Research Ethics Board (REB) approval and which REB in Saskatchewan has received the application. The REB application should be attached to the application and the ethics certificate of approval or letter of exemption if this has been issued.

GUIDANCE NOTE 1.2: PRINCIPAL INVESTIGATOR

"Principal InvestigatorI (PI)" is the individual who is ultimately responsible for the research and the actions of those acting with delegated authority. He/she is the person responsible for the conduct of the project at a research institution or the responsible leader of the team.

The PI for a project must notify the Research Approval Coordinator in writing when this responsibility is going to be assumed by a different investigator. PIs must also ensure that a process is put into place to ensure the ongoing safety of research participants in the event that the PI leaves or retires from their SHA affiliated position and the project remains ongoing.

The PI named on the SHA OA application must be the same as the SHA/University of Saskatchewan/University of Regina REB-issued research ethics certificate. The PI is required to sign the SHA Operational Approval to Conduct Research application form.

The Research Approval Coordinator will send all correspondence related to OA to the email address provided for the PI. If there is someone on the study team other than the PI who will be the primary contact for the research (i.e. resident, student, coordinator), please provide their contact information in this section.

GUIDANCE NOTE 1.3: PROJECT PERSONNEL

Include the name, role, and contact information for all individuals that will be participating in the project (e.g. co-investigators, study coordinators, students, residents, research assistants, etc.).

PART 2: FUNDING

GUIDANCE NOTE: SOURCE OF FUNDS

Source of funds refers to the agency/sponsor of the proposed research that will be providing the funds needed to undertake the project.

Please refer to the SHA (Former RQHR) Policy and Procedure for Externally Funded and/or Sponsored Research, as well as the Policy and Procedure for Indirect Costs of Research for further details.

Specify the name of the funder (if it's an industry sponsor, what's the company name? If it's a not-for-profit organization, what's the organization's name?) or, if it's a public funding source (CIHR, SHRF, etc.), specify the name of the grant/award (e.g. SHRF Collaborative Innovation Development Grant, CIHR Operating Grant, etc.).

GUIDANCE NOTE: FUNDING STATUS AND ADMINISTRATION

Indicate whether or not the funds have been awarded. If a Notice of Award or Award Letter has been issued, please forward a copy to the Research Approval Coordinator. Investigators must send a letter to the Research Approval Coordinator informing him/her of any changes or additions to the funding

source(s).

Specify whether or not the U of S, U of R or SHA will be administering the funds for this study. If an SHA Research Account is required, please fill out a Research Account Application form available at:

Invoicing for SHA Departmental Service fees will occur every three months once SHA OA has been granted. These conditions and fees will be outlined in the Letter of Authorization to Conduct Research at the time of approval.

GUIDANCE NOTE: NAME OF SPONSOR
In the case of a clinical trial, the "Sponsor" refers to an individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of the study. For unfunded/investigator-initiated projects, the sponsor could be the principal/qualified investigator. The sponsor is usually responsible for applying for regulatory approval with the Health Protection and Food Branch of Health Canada.

PART 3: CONTRACTS

GUIDANCE NOTE: NEED FOR A CONTRACT
In many cases, particularly for clinical trial research, research contracts are required to outline terms relating to study conduct, responsibilities, payment, confidentiality, and liability, among other things. Data Sharing Agreements are also becoming more common as data is shared between Institutions through collaborative projects. If a Sponsor, collaborator, or lead site in the case of a multi-site study has provided you with a research agreement, you must indicate so in this section and allow for institutional review of the contract. If you are the PI of a research study and you require transfer of data outside of the SHA or an agreement established with a collaborating or subsite, you may request that a research agreement be drafted on your (and the SHA's) behalf.

GUIDANCE NOTE: TYPE OF CONTRACTS
Identify the type(s) of contract(s) that will be associated with the research study. In the case of sponsor-initiated clinical trials, a Clinical Trial Agreement (CTA) or Clinical Study Agreement (CSA) is typically required to outline the responsibilities of the sponsor, sub-site, and PI. Payment terms, liability, confidentiality, intellectual property, and other terms 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 research project.

If data will be linked between programs/units/organizations include this information on the SHA OA Application form. If identifiable information needs to be used to link data then a data sharing agreement may be required if the data sources being linked involve more than one trustee of the data. Data Sharing Agreements are intended to protect the privacy, use, and disclosure of shared data, as well as to outline intellectual property, publication, and publicity provisions.

GUIDANCE NOTE 3.3: CONTRACT REVIEW AND NEGOTIATION

The Saskatchewan Health Authority must be a party to any research-related agreements using SHA or affiliated resources or patients (including their personal health information). All contracts must undergo review by the SHA prior to signing, in order to ensure that the opportunity for negotiation exists, based on the best interests, priorities, policies and procedures, and resources available within the Authority.

PART 4: DEPARTMENTAL IMPACT ASSESSMENT – Resource Utilization

This section of the application is intended to collect information about the SHA services required for a research project, including the use of data when SHA is the trustee/custodian. These tests/procedures are usually performed on an outpatient basis but may also involve inpatients. Tests/procedures that are study specific must be clearly identified. Matters pertaining to reimbursement of study specific tests/procedures will be addressed during the review and approval process. The SHA manager/designate for the unit may provide a study budget for all study specific tests/procedures. If you are unsure which SHA services your research will be utilizing, please contact the Research Approval Coordinator for assistance.

Note: Please refer to the associated Research Costing List for a detailed breakdown of fees associated with Departmental Services used for research.

GUIDANCE NOTE 4.1: SHA REDCap

REDCap (Research Electronic Data Capture) is a secure web based data collection platform for building and managing online surveys and databases with the server located in the former Regina Qu'Appelle Health Region (RQHR).

For projects that have Research Ethics Board Approval, the process is part of the OA Application. For all potential users, REDCap Account Administration involves a separate application form that must be completed and submitted to the Research Approval Coordinator(researchapproval@rqhealth.ca). The intention of this application is to act as confirmation that the PI of the project recognizes it is his/her duty to take responsibility for all users associated with the project and ensure REDCap is used for its intended purposes. PIs agree to abide by the SHA Terms of Service and the Terms of Use for REDCap through Vanderbilt University.

Please note that individuals should not be contacting the REDCap administrator to request accounts. Accounts will be authorized, only once documentation of a REDCap application is received by the Research Approval Coordinator.

Additional information regarding the process for SHA REDCap applications can be accessed here: http://www.rqhealth.ca/department/research-and-performance/operational-approval.

GUIDANCE NOTE 4.2: ACCESS TO EXISTING HEALTH INFORMATION/OR ADMINISTRATIVE DATA

Regina: It is recommended that you consult with HIMS (306) 766- 4406 and/or IT (306) 766- 7712 prior to seeking OA in order to determine the appropriate data source for your research study.

Saskatoon: It is recommended that researchers consult with the Health Records Research Analyst (306-655-1725, Royal University Hospital Health Records Dept.) while planning their research to discuss their health record data needs. The Health Records Research Analyst can determine whether the patient population can be identified electronically (i.e. a patient list can be created based on the inclusion/exclusion criteria) and whether the number of records needed for the project are available.

The approval for health records/SCM is provided through the Health Records Research Analyst's office located at Royal University Hospital. This approval applies to hospital records/SCM at Royal University Hospital, Saskatoon City Hospital, and St. Paul's Hospital. If you require access to health records at other SHA sites or clinics, please contact the Research Approval Coordinator for assistance.

You do not require SHA health records approval to access the health records under the trusteeship of a physician's office/practice (i.e. physician EMR).

For all other sites/Health Records: Please contact the Research Approval Coordinator for assistance.

4.2 a. Hardcopy-Copy Patient Charts

If your research study requires access to hard-copy patient charts for review, you must complete section **4.2a** on the OA Application Form and authorization for your request will be sought from the Health Records Department. Please make sure to specify the site/facility where the charts will be pulled from.

The fee per chart is **$7.10 for on-site charts and **$17.70** for charts requiring retrieval from off-site long-term storage. If no external funding is available to cover this fee, a strict limit of 200 charts per study will be imposed. Please refer to the associated Research Study Costing List for more information.

Please Note:

- Effective April 3, 2017 the Health Records Departments at Royal University Hospital, Saskatoon City Hospital, and St. Paul's Hospital stopped filing paper copies of any documents available electronically (lab results, medical imaging reports, dictated and transcribed reports).
- Effective June 1, 2017 all charts for patients discharged on or after June 1/17 from Royal University Hospital are scanned and only available electronically through SCM.

4.2 b. Data from an Electronic Source

In place of (or in addition to) access to the patient chart, you may request the generation of a report or data file from an electronic Health Records database (such as the Discharge Abstract Database [DAD], National Ambulatory Care Reporting System [NACRS], etc.), which can summarize the number (and

identity) of patients meeting a certain eligibility criteria. ***Please note:*** there are many health datasets that the SHA is not a data trustee of (cancer, vital statistics, etc.). If you are interested in using these datasets within your research project, please connect with the correct organization in order to inquire about access.

If you are requesting access to view EPR, you must submit a copy of your Data Collection Tool with your application for OA. This is essential to determine whether or not the required data elements are available through existing EPR applications. In certain cases, User Access to an electronic application may not be required; IT Services is also capable of generating reports for particular data elements.

In order to use SCM for research, a research account is required for the research personnel who need to access SCM for data collection, even if they have a current SCM account for clinical use.

Saskatoon SCM access: The request for the research account(s) will be submitted to SHA IT services by the Research Approval Coordinator and authorized by SHA Privacy. The SCM research account(s) will remain active as per the data collection start and end date as indicated on the SHA OA application form.

Regina SCM access: Once OA is granted, a User Request Form must be submitted through IT to gain access and schedule training for the approved EPR applications. **DO NOT COMPLETE THE USER REQUEST FORM UNTIL YOU'VE OBTAINED YOUR OPERATIONAL APPROVAL LETTER.** When you have obtained your Letter of Authorization to Conduct Research submit your User Request Form, be sure to indicate in the "Comments" section of the form that the request is related to a research project and indicate the file number associated with your Operational Approval Letter.

4.2 c. Health Record Retention – Clinical Drug Trials

PIs are to maintain their participants' study related health records (source records) in the original form or as certified copies of the originals as part of the participant study record for 25 years post study. These include: laboratory reports; medical imaging reports and pharmacy records from inpatient visits. Health Records has a work standard/procedure for retaining health records for the 25 year retention period or providing certified copies of source documents. If you are conducting a clinical trial and the 25 year retention period applies, this must be indicated on the form.

GUIDANCE NOTE 4.3: LABORATORY SERVICES

If your research study requires blood draws, sample processing and/or storage, sample testing, or retrospective access to Laboratory testing information (i.e. data extraction, tissue blocks and/or slides), you must complete section 4.3 on the OA Application Form and authorization for your request will be sought from the Department of Laboratory Services.

Please contact the manager/lab tech for the division you require for assistance in determining the lab approval(s) required for your project. Laboratory Medicine charges a $150.00 Lab Utilization Fee on all research. The researcher will be invoiced for this fee three months after the study has received SHA OA.

Please contact Laboratory Services for an estimate on the study-specific lab tests you require for your project. All Laboratory Services rates are reviewed on an annual basis and may be subject to change.

Regina:

Lab	Contact Phone Number
Regina General Hospital and/or Pasqua Hospital	306-766-4475
Roy Romanow Provincial Lab	306-787-9404

Saskatoon:

Unit	Site	Contact Phone Number
Chemistry, Phlebotomy	Royal University Hospital	306-655-1794/655-2909
Chemistry, Phlebotomy	Saskatoon City & St. Paul's Hospital	306-655-5230
Microbiology & Diagnostic Molecular Pathology	Royal University Hospital	306-655-1772
Transfusion Medicine, Cytogenetics, Hematology	Royal University Hospital	306-655-2187
Anatomic Pathology	Saskatoon City Hospital Royal University Hospital	306-655-8233
Laboratory Information System	Saskatoon City Hospital	306-655-8516

For all other sites: Please contact the Research Approval Coordinator for assistance.

GUIDANCE NOTE 4.4: MEDICAL IMAGING AND NUCLEAR MEDICINE SERVICES

If your research study requires medical imaging and/or nuclear medicine services, you must complete section 4.4 and indicate the tests required for each patient and the number of study specific tests per patient. Authorization for your request will be sought from the Department of Medical Imaging. Please refer to associated Research Costing List for a breakdown of test and departmental charges.

Regina: Prices vary depending on the body part to be scanned and the procedure required. For specific prices, please refer to Research Costing List or contact the Medical Imaging Department (306) 766-0687 for more information. Please note that fees may require adjustments following the initial study review, as unforeseen circumstances that affect costing may occur following the site initiation visit and start-up of research projects.

Saskatoon: Medical Imaging charges a $300.00 Administration Fee on all research. The researcher will be invoiced for this fee three months after the study has received SHA OA. Prices vary depending on the body part to be scanned and the procedure required. For specific prices, please refer to the Research Costing List or Contact the Medical Imaging Department (306) 655-1829 for more information.

For all other sites: Please contact the Research Approval Coordinator for assistance.

GUIDANCE NOTE 4.5: PHARMACY SERVICES

Regina: The only service currently available to support drug research in Regina is the storage of Investigational Product which includes availability of monitored refrigerators/freezer, this does not include ordering product or maintaining drug inventory logs. It will be the study team's responsibility to perform these functions during the department's hours of operation.

If reports of 24h temperature logs for Pharmacy Department refrigerators/freezer are required, please contact Dan Helmond (Regina General Hospital) Dan.Helmond@saskhealthauthority.ca or Elton Preikchat (Pasqua Hospital) Elton.Preikchat@saskhealthauthority.ca

Saskatoon: The Special Services Pharmacy provides pharmacy services for studies involving medications (inpatient or outpatient). These studies are usually industry-sponsored or grant-funded.

Unit	Site	Contact Phone Number
Clinical Trials/Special Access Pharmacy	Royal University Hospital	306-655-2013

For all other sites: Please contact the Research Approval Coordinator for assistance.

GUIDANCE NOTE 4.6: AMBULATORY OR OTHER SERVICES

If your research study requires additional SHA services such as Ambulatory Care Services or other diagnostic or procedural services, you must complete section 4.6 and specify the nature of the service(s) required. Authorization will then be sought from the appropriate Department Head(s), Executive Directors, or Designate(s).

GUIDANCE NOTE 4.7: PROGRAM/UNIT/FACILITY UTILIZATION

Program utilization refers to access to SHA programs for recruitment of study participants (inpatients, outpatients, long term care residents, or staff), or if the study will be taking place within a program. This section is intended for the identification of departments/divisions/services whose operations will be affected by your research protocol. This is to ensure that, prior to commencement of the study, these individuals have had an opportunity to assess the impact of the protocol on their area.

In this section, list all the tasks required by the Program(s) for the study. For example, disbursement of recruitment material, participating in survey/interview/focus group, SHA staff (e.g. nursing, therapist) performing study-related procedures. Please specify which tasks are study specific. For study specific tasks, please provide the estimated time required if SHA staff will be performing these tasks. This information will assist the Executive Director/Director/Manager in determining their department's ability to participate in the research.

This section is also applicable for studies involving health care professionals, administrative staff as study participants, providing data or as part of the research team. This includes research involving the Senior Leadership Team (VP/CEO) and/or the Operational Leadership Team (Directors). Please contact

your Regional Research Approval Coordinator for more information.

If you are unsure which program(s) you require approval from for your research project or you are unable to find the unit you are looking for on this list, please contact your Regional Research Approval Coordinator for assistance.

PART 5: DECLARATION BY PI

GUIDANCE NOTE 5: DECLARATION BY PI
Applications will not be accepted without the signature of the PI. This signature is provided as an e-signature on the OA form.

It is important that the PI reviews the Declaration prior to signing off in order to understand their responsibilities for conducting research involving SHA. All members of the research team should be made aware of the expectations for the use and disclosure of SHA confidential information (patient information, employee information, SHA business information). This includes the responsibilities for viewing, use and disclosure of SHA confidential information. Please contact the Research Approval Coordinator if there are any questions regarding the Declaration.

PART 6: ATTACHMENTS

GUIDANCE NOTE 6: ATTACHED DOCUMENTS
Please indicate any attachments that are intended to accompany the application for Operational Approval for Research and be sure to submit them along with the application.