OPERATIONAL APPROVAL TO CONDUCT RESEARCH IN THE SASKATCHEWAN HEALTH AUTHORITY

Part 1: IDENTIFICATION

1.1. PROJECT DESCRIPTION

Project Title: _____

Abbreviated Title (if applicable): _____

Anticipated Start Date: _____

Anticipated End Date : _____

◯ Saskatchewan Health Authority (SHA) ◯ Athabasca Health Authority (AHA)

All cities/towns/communities that the research will be conducted in:

_____

Sites/facilities that will be involved: _____

Have you submitted for REB approval?
◯ Yes
◯ No

REB # (if Assigned): _____

Please attach copy of the REB application

Have you received the ethics certificate of approval or letter of exemption
◯ Yes
◯ No

Which REB did you apply to?
◯ University or Regina (U of R) REB
◯ University of Saskatchewan (U of S) REB
◯ Saskatchewan Health Authority (SHA) REB
◯ Other

Please specify _____

Please upload the ethics certificate of approval or letter of exemption

Study participants include:
☐ Inpatients ☐ Outpatients
☐ Long term care residents
☐ Staff ☐ SHA Data

Other: _____

Anticipated number of participants: _____

Is this a Student or Resident Project?
◯ Yes
◯ No

1.2. PRINCIPAL INVESTIGATOR:

Full Name: _____

Affiliation: _____

Department: _____

Email Address: _____

Mailing Address: _____

Telephone Number: _____

Primary Contact for this Study (someone from the research study team who will deal with problems and concerns while the research is ongoing):

◯ Same as above
◯ Not the same as above

Full Name: _____

Telephone Number: _____

Email Address: _____

1.3. PROJECT PERSONNEL: List all Project Personnel who will be directly involved in the research activities occurring in the SHA operated or affiliated facilities:

Full Name: _____

Project Position/Role: _____

Email Address: _____

☐ Add another member

Full Name: _____

Project Position/Role: _____

Email Address: _____

☐ Add another member

Full Name: _____

Project Position/Role: _____

Email Address: _____

☐ Add another member

Full Name: _____

Project Position/Role: _____

Email Address: _____

☐ Add another member

Full Name: _____

Project Position/Role: _____

Email Address: _____

☐ Add another member

Full Name: _____

Project Position/Role: _____

Email Address: _____

PART 2: FUNDING

Source of funds:

Research may be supported internally through the use of departmental resources, facilities, or personnel, however this section refers only to the source of financial support, by which funds are transferred to the Principal Investigator for use in a research study

☐ Not Applicable (if there is no financial support being provided for this study, proceed to Part 3. Please note that studies with no funding that are requesting billable services may be denied Operational Approval)
☐ Industry (for-profit organization)
☐ National Institute of Health (NIH)
☐ Tri-Council Grant (CIHR, SSHRC, NSERC)
☐ Sask. Health Research Foundation (SHRF)
☐ Not-for-profit foundation
☐ Other

Specify funding source, grant competition, or award _____

Status of Funds

◯ Awarded
◯ Pending

Where will the funds be administered?

☐ U of S
☐ U of R
☐ SHA
☐ Other

Please specify: _____

*Note: If funds have been awarded, please attach a copy of the Award Letter to this application and all SHA Departmental study budgets associated with this application.

Name of Sponsor (if different from "source of funds"): _____

PART 3: CONTRACTS

Will there be a contract associated with this research project?

- ◯ Yes
- ◯ No
- ◯ N/A contract already executed with initial application

Type of contract (check all that apply):

- ☐ Confidential Disclosure Agreement (CDA) / Non-disclosure Agreement (NDA)
- ☐ Sub-Site Agreement (SSA)
- ☐ Clinical Trial Agreement (CTA) / Clinical Study Agreement (CSA)
- ☐ Data Sharing Agreement (DSA) / Data Transfer Agreement (DTA)
- ☐ Funding Agreement

Other (Please specify): _____

Please attach the following for legal review and contract negotiation:

1. Research Project Title
2. Contact information for the other party (Principal Investigator/Sponsor or Contracts Office)
3. https://clinicaltrials.gov/ link or protocol number for study (if applicable)
4. Draft agreement provided by Sponsor (or indicate that a new agreement must be drafted) NOTE: MUST BE IN WORD DOCUMENT FORMAT! (so that changes can be tracked)
5. Copy of study protocol and/or consent form and all relevant appendices (e.g. study budget)

PART 4: DEPARTMENTAL IMPACT ASSESSMENT - RESOURCE UTILIZATION:

Resource utilization refers to the utilization of SHA personnel, facilities, or equipment for tests/ procedures/tasks required for clinical research. This applies to study-specific tests or procedures and includes outpatient and inpatient participants. For more information, please refer to the Operational Approval Guidance Notes available at: http://www.rqhealth.ca/department/research-and-performance/operational-approval

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.

Do you intend on using the SHA REDCap for this research project?

- ◯ Yes
- ◯ No

REDCap use start date: _____

REDCap use end date: _____

Primary REDCap user (creating/editing data collection tools) _____

Person Requiring Access: _____

Person Requiring Access: _____

Person Requiring Access: _____

Person Requiring Access: _____

Person Requiring Access: _____

4.2. ACCESS TO EXISTING HEALTH INFORMATION/OR ADMINISTRATIVE DATA

Do you require access to existing health information or administrative data?
◯ Yes
◯ No

It is recommended that you consult with Regina: HIMS (306) 766- 4406 and/or IT (306) 766- 7712; Saskatoon: Health Records Research Analyst (306) 655-1725 prior to seeking operational approval in order to determine the appropriate data source for your research study.

a. Will you be requiring access to hard-copy patient charts for your research study?
◯ Yes
◯ No

Please attach a copy of the Data Collection Tool that will be used to extract your data elements.

i. Approximately how many charts will you need retrieved by health records*? _____

ii. Will you require the generation of a chart list (hard copy or SCM/scanned charts)?
◯ Yes
◯ No

iii. Which sites/facilities will be involved? _____

*Note: 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.

b. Will you be requiring data from an Electronic Source for your research study?
☐ Yes, aggregate report requested
☐ Yes, case level
☐ No

*Note: There are many other health datasets for which SHA is not the data trustee (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 enquire about access.

Please attach a copy of the Data Collection Tool that will be used to extract your data elements.

Indicate the data source (if known): _____

Indicate the data source (if known): _____

What is the time period for which study personnel will require access?

Start date _____

End Date _____

Please list the study personnel that will be accessing information from the electronic patient records:
NOTE: An SCM Research Account will be required to collect information from electronic patient records. Please refer to the Guidance Notes for details.

Full Name: _____

Email Address: _____

Phone Number: _____

☐ Add another member

Full Name: _____

Email Address: _____

Phone Number: _____

☐ Add another member

Full Name: _____

Email Address: _____

Phone Number: _____

☐ Add another member

Full Name: _____

Email Address: _____

Phone Number: _____

☐ Add another member

Full Name: _____

Email Address: _____

Phone Number: _____

☐ Add another member

Full Name: _____

Email Address: _____

Phone Number: _____

☐ Add another member

Full Name: _____

Email Address: _____

Phone Number: _____

c. Health Record Retention- Clinical Drug Trials

Will Health Records/SCM be required to retain patient records (i.e. source documents) for the 25 year retention period as per Health Canada's record retention regulation (section C.05.012 of the Food and Drug Regulations - Division 5 Drugs for Clinical Trials Involving Human Subjects)?

◯ Yes
◯ No

4.3. ACCESS TO LABORATORY SERVICES

a. Will you be requiring Laboratory Services for your research study?
◯ Yes
◯ No

*Note: All research studies requiring Laboratory Services are subject to a $150.00 Lab Utilization Fee. Studies will then be charged on a per sample basis, at a rate dependent on the service being provided. Please refer to the Guidance Notes and associated Research Study Costing List for more detailed information.

b. What service(s) will you require? Please provide a list of the testing to be done and the approximate number of samples required. Be certain to clarify which are standard of care tests and which are specific to your research.

_____

4.4. ACCESS TO MEDICAL IMAGING AND NUCLEAR MEDICINE SERVICES

a. Will you be requiring Medical Imaging and Nuclear Medicine Services for your research study?
◯ Yes ◯ No

*Note: Saskatoon's Medical Imaging & Nuclear Medicine department charges a $300.00 admin fee for all research involving its services.

*Note: Studies will be charged on a per participant basis, at a rate dependent on the service being provided. Please refer to the Guidance Notes and the associated Research Study Costing List for more detailed information.

b. What service(s) will you require? Please provide a list of the testing to be done and the approximate number of samples required. Be certain to clarify which are standard of care tests and which are specific to your research.

_____

4.5. ACCESS TO PHARMACY SERVICES

a. Will you be requiring Pharmacy Services for your research study?
◯ Yes ◯ No

*Note: The availability of Pharmacy Services for research varies greatly throughout the SHA. Please consult the Guidance Notes for site specific information.

b. What service(s) will you require?

_____

4.6. ACCESS TO AMBULATORY OR OTHER SERVICES

a. Will you be requiring any other diagnostic services for your research study that were not mentioned above in Sections 4.1 - 4.3?
◯ Yes ◯ No

*Note: Additional services may be subject to additional fees. Please refer to the Guidance Notes and associated Research Study Costing List for more information.

b. What services will you require?

☐ Specify service

Description of Services Required _____

Approximate Number of Participants _____

☐ Specify service

Description of Services Required _____

Approximate Number of Participants _____

☐ Specify service

Description of Services Required _____

Approximate Number of Participants _____

☐ Specify service

Description of Services Required _____

Approximate Number of Participants _____

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, the individuals in these areas have had an opportunity to assess the impact of the protocol on their area.

Services/resources required?

Long-term Care (Urban) ◯ Yes ◯ No

Description of Services & Estimated Amount of Staff Time Required: _____

Long-term Care (Rural/North) ◯ Yes ◯ No

Description of Services & Estimated Amount of Staff Time Required: _____

Mental Health & Addictions ◯ Yes ◯ No

Description of Services & Estimated Amount of Staff Time Required: _____

Nursing Unit (s) (specify): ◯ Yes ◯ No

Description of Services & Estimated Amount of Staff Time Required: _____

Population & Public Health ◯ Yes ◯ No

Description of Services & Estimated Amount of Staff Time Required: _____

Primary Health Care (Urban) ◯ Yes ◯ No

Description of Services & Estimated Amount of Staff Time Required: _____

Primary Health Care (Rural/North) ◯ Yes ◯ No

Description of Services & Estimated Amount of Staff Time Required: _____

Other: ◯ Yes ◯ No

Description of Services & Estimated Amount of Staff Time Required: _____

Other: ◯ Yes ◯ No

Description of Services & Estimated Amount of Staff Time Required: _____

Other: ◯ Yes ◯ No

Description of Services & Estimated Amount of Staff Time Required: _____

PART 5: DECLARATION BY PRINCIPAL INVESTIGATOR

By signing below, I certify that all information provided herein is accurate and complete. If circumstances should arise that materially affect the accuracy and completeness of the information provided, I will immediately report the new information in writing. I agree to abide to all applicable laws, regulations and international guidelines concerning the conduct of research with humans. I have read, understood and will abide to the Saskatchewan Health Authority Research Policies and Procedures as outlined at:
http://www.rqhealth.ca/department/research-and-performance/research-policies-and-procedures.

PRIVACY AND CONFIDENTIAL INFORMATION DISCLOSURE:
Under the provisions of The Health Information Protection Act (HIPA), and The Local Authority Freedom of Information and Protection of Privacy Act (LA FOIP), the Saskatchewan Health Authority (herein 'SHA') has a duty to establish policies and procedures to protect confidential information which it collects and has under its custody and control. In this respect the SHA must ensure compliance with HIPA and LAFOIP by persons providing services to the SHA, including research participation. As an individual conducting research within the SHA, I understand that I and my research team may have access to confidential information in many formats including, without limitation, electronic, printed, or spoken communication. Confidential information may include, but is not limited to, information relating to:
• Patients - including Personal Health Information (i.e. medical records, diagnoses, conversations, admittance information);
• Employees - including Personal Information (i.e. employment records, disciplinary actions);
• The SHA's business information - confidential information collected for SHA business purposes which includes, but is not limited to, financial and statistical records, strategic plans, internal reports, memos, draft documents, contracts, legal advice, vendor proposals, quality assurance reviews, communications, proprietary technology and computer programs, source code, evaluations; and
• Information about the SHA's business partners and service providers.
Collectively, the above-mentioned information shall be referred to as "Confidential Information."

Accordingly, I acknowledge and agree that my right and that of my research team to view, use, and disclose Confidential Information is subject to THE conditions outlined below. As the Principal Investigator, I agree and acknowledge that I am responsible and accountable for the actions of every member of my research team regarding the collection, use, and disclosure of Confidential Information. All references to "I" below apply equally to me, as the Principal Investigators and to each member of the research team.

1. I will only view, use and disclose Confidential Information on a need-to-know basis to perform my duties as defined by my relationship with the SHA or as required by law:
a) I will not view, use or disclose Confidential Information for which I have no legitimate need-to-know;
b) I will keep all Confidential Information in the strictest of confidence;
c) I will only view and use Confidential Information for the purpose(s) for which I have been granted access, and will only disclose that Confidential Information as permitted by HIPA, LAFOIP, other laws and/or a contractual agreement with the SHA;
d) I will not view or use databases to access my own personal health information held by the SHA;
e) I will not in any way divulge, copy, release, alter, revise, or destroy any Confidential Information except as properly authorized within the scope of my duties with the SHA and as permitted by law or by any of the SHA's policies regarding the release of Confidential Information; and
f) I understand that it is my responsibility to ensure that all Confidential Information in my possession is maintained in a physically secure environment.

2. I will safeguard and will not disclose or share with any other person my access code(s) (password), user IDs, access passcards, keys or any other authorization code or device that allows me access to Confidential Information. I accept responsibility for all activities by all parties undertaken using my codes and devices:
a) I will log off computer systems after use;
b) I will not log on to a system or access Confidential Information to allow another person to view such Information or to use that system;
c) I will report any suspicion or knowledge that my access code, user ID, access card, key or other authorization code or device, or any Confidential Information has been lost, misused or disclosed without SHA's authorization;
d) if I download or transfer computer files containing Confidential Information to any non-SHA authorized computer, data storage device, portable device, mobile device, or other device capable of storing digitized data it shall be done in compliance with HIPA, LA FOIP, any other privacy legislation and the SHA's policies with respect to the treatment of the Confidential Information;
e) I will only print documents containing Confidential Information in a physically secure environment, will not allow other people access to printed Confidential Information, and will store all printed Confidential Information in a physically secure environment; and
f) if I no longer need Confidential Information, I will securely dispose of or destroy the Confidential Information. (Note that physicians may be required to maintain patient files beyond this period for ethical and legal reasons and this is their responsibility).

3. I acknowledge my obligation to report to the SHA Privacy Office and the Research Approval Coordinator any practice by another person that violates these obligations or puts the SHA, its personnel, or its patients at risk of improper access, use or disclosure of Confidential Information.

4. I understand that my use of Confidential Information is subject to monitoring and periodic auditing by the SHA.

5. I agree that I have no right or ownership interest in any Confidential Information referred to in this Declaration.

6. I agree to review and comply with all applicable legislation and SHA's policies respecting privacy, confidentiality and security, as might be amended from time to time.

7. I understand that a failure to comply with any of the confidentiality provisions in this Declaration may result in action being taken against me which may include, but not necessarily limited to, the following:
a) disciplinary action by the SHA which may result in the suspension or revocation of my appointment and privileges, or the termination of my employment;
b) legal action being brought against me by the SHA or by the patient(s) affected by the breach of confidentiality;
c) a complaint or report about me being made to my professional licensing body by the SHA;
d) a complaint being made to the Office of the Privacy Commissioner of Saskatchewan by the SHA; and/or
e) A complaint to a law enforcement agency by the SHA.

In addition to other remedies available, SHA will not provide any further data to the Researcher if any of the conditions set out in this Declaration have been breached and will seize the data already provided. The terms and conditions of this Declaration will be of indefinite duration.

Please Note: Depending on the nature of the research project, a separate contractual agreement between the SHA and the Principal Investigator may be required.

In consideration of being provided access to REDCap, I agree to the following:
• I have reviewed the REDCap Terms of Service for the Saskatchewan Health Authority (SHA) and agree to abide by it.
• I have reviewed the Terms of Use for the REDCap Non-Profit End-User License Agreement which describes the terms of the agreement between Vanderbilt University and the SHA and I agree to abide by such Terms of Use as if I were the Licensee.
• The lists of the persons whom I wish to have access to the software are listed on this form. I will permit these users to have access to the project(s) and I will oversee and remove their access when that permission is no longer required.
• I will resubmit a new REDCap Application to the Operational Approval Co-ordinator (ResearchApproval@rqhealth.ca) when:
o new members are added
o a person has left my group, or no longer requires access to REDCap.
o I am developing a new project separate from the one on this application

It is my duty to take ownership and ensure REDCap is used for its intended purposes by both my team and I.

Signature of Principal Investigator

_____

Date _____

For all general questions regarding operational approval in the Saskatchewan Health Authority, please contact:
Shawna Weeks
Tel: 306-655-1442 Shawna.Weeks@saskhealthauthority.ca

PART 6: ATTACHMENTS

Provide a full and accurate listing of all documents submitted with this application.

REB included (or Letter of Exemption) (in part 1, section 1.1)?
◯ Yes
◯ No

A copy of the REB Application
*Mandatory for all studies

Comments

_____

Protocol (in part 3)
*Mandatory for all Clinical Trials

◯ Yes
◯ N/A

Comments

Funding Award Letter / Notice of Award (in part 2)

*Mandatory for all studies receiving external funds

◯ Yes
◯ N/A

Comments

Research Account Application

*Mandatory for all studies receiving external funds

◯ Yes
◯ N/A

Please upload

Comments

Draft Contract (in part 3)

*Mandatory for all studies involving a research contract

◯ Yes
◯ N/A

Comments

Data Collection Tool (in part 4, section 4.2)

*Mandatory for all studies requesting access to Patient Records

◯ Yes
◯ N/A

Comments

Other:

Comments

Other:

Please review your application carefully before submitting. Once submitted, your application cannot be modified.