# Shared Health Research Application: Guidelines for Completion

## GENERAL INFORMATION

- Applications must be received at least 10 business days prior to the committee meeting, by 9 AM on the submission day. Meeting dates and submission deadlines are posted online.
- The project must be described on the Shared Health Application in a way that is consistent with how it was portrayed on the Research Ethics Board (REB) application
- For an application to be considered complete, **all questions must be filled out and answers must be factually complete and contextually appropriate**. Referencing the protocol or other documents, copying and pasting sections from the protocol or other documents, answering partially or in a way that is not contextually sound will not be considered an adequate answer.
- Incomplete applications will not be forwarded to the committee for review. If an application is incomplete, you will receive a response identifying the sections of the application that need to be adjusted.
- **Use lay terms and avoid medical jargon and acronyms** so that all reviewers have a clear understanding of the content.
- Some drop-down menus on the form allow for text to be entered if the item applicable to the project is not listed.

## WHAT IS INCLUDED IN THIS DOCUMENT

- Guidelines for completion of (1) Shared Health Research Application
- Guidelines for completion of (2) Shared Health Research Application Amendment Form and (3) Change in Personnel Form
    - See these guidelines for general instructions and then refer back to the main application guidelines for instructions on how to fill out individual sections

**For information on required documents for inclusion in submission, see the Shared Health Research and Innovation website or email SHResearch@sharedhealthmb.ca**

**Version Date: June 2023**

Shared health
Soins communs
Manitoba

# Shared Health Research Application

## New Submission

*This application form is to be used for projects which have not been submitted previously to Shared Health, HSC, Diagnostic Services or WRHA.*

Date 1-Jan-23

Is this project part of a Program of Research? ◯ Yes ◉ No

Research proposals for a program of research usually describe an area of research rather than a discrete, time limited project. Individual projects within the Program must be reviewed on a project by project basis, however, these will not necessarily require separate and distinct approvals from an ethics board if (1) the individual projects are well described in the original ethics approval for the Program, and; (2) there are no changes to the protocol originally approved by the ethics board. Programs of Research are approved 'in-principle' only

Specify the status of the University of Manitoba Research Ethics Board (REB) submission?
◉ Submitted
◯ Approved
◯ Not Submitted
Ethics Number If already known

Specify the REB
◯ Biomedical Research Ethics Board (BREB)
◉ Health Research Ethics Board (HREB)
◯ Other

**Total study duration** Anticipated Start Date Project start date Anticipated End Date Project end date

**Protocol Title**

This title must correspond to the project name on study documents such as the consent form, and has to be consistent with the title used with other regulatory bodies such as the REB (i.e. project has to go by one name).

| **Protocol Number** | **Version Number** | **Version Date** |
|---|---|---|
| Most studies typically don't have a protocol number (with the exception of clinical trials). However, version and date should be provided. This allows for tracking future updated/amended versions of protocol. | e.g. V1.2 | e.g. 15-Apr-22 |

**Protocol Objective**

*Provide a clear statement of the purpose and objectives of the study*

The "WHAT" question: Provide a brief statement about the project written in lay language. Explain WHAT the project is setting out to do, what it is trying to accomplish. Describe its purpose and list its specific research questions, objectives, and hypotheses that will be tested. This section may also include the context/background and rationale for the project

If this application is for a program of research, list and describe the planned research projects within the program

**Protocol Design**

*Provide a step-by-step summary of the design and procedures of the research. Include details of any specific manipulations, interventions, measures, drug names/therapeutic classifications, etc.*

The "HOW" question: Explain HOW the research project is designed and organized to accomplish its goals and answer its research questions. Focus in particular on the proposed methodology, interventions, how data will be collected, etc. If participants are involved, describe their involvement in a step-by-step manner

**Sample Size**

What is the estimated sample size for the entire study? The total number of participants/cases included in the study that are the subject of data collection and analysis (e.g. number of participants enrolled, charts reviewed). If the project is part of a multi-center initiative, specify the projected number of participants/cases for all sites

*Justify the sample size on scientific grounds. If a formal sample size calculation was not used, give a rationale for the proposed number of participants.*

Explain the rationale for the proposed sample size based on statistical considerations (e.g. how was it determined that the sample size is statistically sufficient).

**Data Analysis**

Primary Analysis - Outline how the data from the study will be analyzed.

How will the obtained data be analyzed in order to answer the research questions proposed by the study?Is secondary analysis of study data anticipated? (Note: secondary analysis requires further approval.)

- (•) Yes
- ( ) No

Outline what plans there are for future use of the data. Is it anticipated that the research data will be used for other purposes in the future (e.g. for other projects)

**Risk**

Considering the level of risk this research involves and the vulnerability of the study population, make selections below that represent those levels of risk.

| | | | |
|---|---|---|---|
| Participant Vulnerability | ( ) Low<br>(•) Medium<br>( ) High | Research Risk | ( ) Low<br>(•) Medium<br>( ) High |

Consider the level of risk the research involves and the vulnerability of the study population.

Participant vulnerability refers to a diminished ability to fully safeguard one's own interests in the context of a specific project (TCPS 2, 2018).

Research risk should factor in the type of potential harm that might results (e.g. psychological or informational), the magnitude or seriousness of the harm (e.g. transient or permanent), and the probability of occurrence of the harm (e.g. likely or remote).

A project is considered to be low risk if the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research (TCPS 2, 2018).

## Contact Details

If PI is a student, check off this box and fill out advisor information section that appears below/on the next page

Principal Investigator — The lead researcher ultimately responsible for the conduct of the study. PI is responsible for members of the research team, administration of research funds, and for ensuring that research activities are carried out in accordance with applicable laws, regulations, and policies of research sponsors, affiliated organizations (e.g. university, college, hospital, etc.), and the institution(s) where research is conducted.

PI is a student ☐

Institutional Affiliation: e.g. U of M, SH, WRHA

Department: Department within the affiliated institution

Phone: Professional phone number

Email: Professional email

Address: Reliable, professional address that is actively monitored and is suitable for receiving confidential mail

Has this person signed the PHIA Pledge of Confidentiality within 3 years? ◉ Yes ○ No — All members of the research team and research staff need to have completed PHIA training within the past 3 years

Will this person have access to line-level data? ◉ Yes ○ No — Line-level data is participant/individual-level data as opposed to aggregate data which describes whole groups

Will this person be accessing or extracting Personal Health Information from the health system? ◉ Yes ○ No

Is this person going to be accessing/extracting any personal health information (e.g. demographics, family/ medical/medication history, diagnoses, test results, mental health conditions, etc.) from any health system databases - paper or electronic based - for research purposes

Will this person require access to clinical information systems for research purposes? — Is this person going to be accessing clinical information systems for research purposes (note that clinical and research roles may overlap) ◉ Yes ○ No

Specify systems — List all healthcare systems this person will be accessing for research purposes - including those they already have access to (e.g. Accuro, ARIA, EMR)

Identify the data access level: Directly identifying information

Specify the highest, most revealing level of information which will be accessed by a particular researcher (e.g. anyone accessing healthcare information systems/databases would always have access to Directly Identifying Information):

ANONYMOUS INFORMATION
Data collected anonymously that never had identifiers associated with it (e.g. anonymous surveys). The risk of identification of individuals is low or very low.

ANONYMIZED INFORMATION
Data that is irrevocably stripped of direct identifiers. There is no code that would allow future re-linkage to participants/cases and the risk of re-identification is low or very low.

CODED INFORMATION
Data that is stripped of direct identifiers and each participant/case is labeled with a unique code. Re-linkage is possible if necessary with the use of a "master list" retained by the principal investigator. This list links the codes with the true identity of the participants/cases.

INDIRECTLY IDENTIFYING INFORMATION
Data that can be reasonably expected to identify an individual/case through a combination of indirect identifiers (e.g. the combination of date of birth, place of residence, unique personal characteristics).

DIRECTLY IDENTIFYING INFORMATION
Data that identifies a specific individual through direct identifiers (e.g. name, social insurance number, personal health number).

Describe the access details — For the "DESCRIBE THE ACCESS DETAILS" question, outline what kind of information will the researcher have access to (e.g. interviews, surveys, master list, participants' charts, demographics, test results, etc.).

Think about what kind of data is being accessed and collected during the course of the study and what each person will have access to.

Will this person have remote access to data? ◉ Yes ○ No — Will this person have access to data from outside the institution they are affiliated with?

Will this person be obtaining consent? ◉ Yes ○ No

Will this person be tasked with obtaining consent from participants?

Describe the duties of this person

Describe the role the researcher in the research project, their duties and responsibilities, especially with respect to contact with participants, data access, collection, extraction, analysis, dissemination of findings, etc (e.g. obtains consent from participants, collects patient data from EMR)

***Research Personnel*** + -

Role: Co-Investigator

Name

Use the +/- buttons to list all members of the research team and staff directly involved in the project. The list must be consistent with the personnel currently listed with REB, otherwise a copy of Change of Personnel application submitted to REB is required. Fill out the rest of the information according to the guidelines in the PI section

Institutional Affiliation

Department

Phone

Email

Address

Has this person signed the PHIA Pledge of Confidentiality within 3 years? ○ Yes ○ No

Will this person have access to line-level data? ○ Yes ○ No

Will this person be accessing or extracting Personal Health Information from the health system? ○ Yes ○ No

Will this person require access to clinical information systems for research purposes? ○ Yes ○ No Specify systems

Will this person have remote access to data? ○ Yes ○ No

Will this person be obtaining consent? ○ Yes ○ No

Describe the duties of this person

In case of general questions, contact

Member of the research team who should be contacted in case of general questions about the project

In case of patient visit questions, contact

Member of the research team who should be contacted in case of questions related to participants, study visits, etc. This person will be listed as a contact on the Diagnostic Services research requisitions (e.g. lab requisitions) if applicable.

Results are to be forwarded to

Secure Fax Number

Used for faxing confidential participant results

## Project Information

Type of Research (select all that apply)

- [x] Faculty Research
- [ ] Post-doctoral Research
- [ ] Trainee Research (Intern/Resident)
- [ ] Honour's Thesis
- [ ] PhD Thesis/Master's Thesis
- [ ] Course Assignment
- [ ] Clinician Based or Health System Research (non-academic)
- [ ] Other

Indicate which of the following best describes the type of investigation proposed (select all that apply)

For "type of investigation proposed", continue with selection until no new options appear. Select the closest option possible, knowing that the options offered may not capture the type of your research exactly

- [x] Primary research
  - [ ] Basic research
  - [x] Clinical Research
    - [ ] Experimental/Clinical Study
    - [x] Observational Study
      - [ ] Therapy study (without intervention)
      - [ ] Prognostic study
      - [x] Diagnostic study
      - [ ] Observational study with drugs
      - [ ] Secondary data analysis
      - [ ] Case series
      - [ ] Single case report
  - [ ] Epidemiological Research
- [ ] Secondary research

Primary Shared Health Site/Service Location — Shared Health institution at which research is being conducted and/or that is primarily affected by the project (e.g. HSC, SBH, SOGH)

Additional Impacted Shared Health Site(s)/Service Location(s) — Additional Shared Health Institutions affected by the project

Estimated screening period / recruitment phase of project — The period during which enrollment and screening is expected to take place (e.g. project may run for 4 years but only expects to recruit and screen new participants until the end of year 2)

| | | | |
|---|---|---|---|
| Number of screened participants expected to impact Shared Health | Per site | Total within SH | If project is based out of SH institution and/or utilizes ANY SH services or data, list the projected number of participants screened |
| Maximum enrolled participants expected to impact Shared Health | Per site | Total within SH | If project is based out of SH institution and/or utilizes ANY SH services or data, list the projected number of participants enrolled/ recruited |
| If the above two don't apply, how many requests are expected to impact Shared Health | Per site | Total within SH | e.g. number of cases |

How will the initial list of potential participants/cases by identified? Describe in detail how the project will gain access to potential participants/cases to be included in the study (e.g. posters, existing records, having a member of the research team who is a treating physician to identify eligible participants, etc.)

Will existing records be used or accessed to identify potential participants?

- (•) Yes
- ( ) No

Describe how permission will be obtained from the trustee to access, collect and/or use this information for this purpose.

If SH is not the trustee of the information, permission must be obtained before this application can be forwarded to the committee

Will the study involve direct access to potential study participants?

- (•) Yes
- ( ) No

How will prospective participants be screened? Screening is the process of determining whether participants/cases meet the eligibility criteria to be included in the study (i.e. establishing eligibility). Describe the screening process in detail and outline what the inclusion/exclusion criteria are (e.g. how will you decide which participants/cases qualify to be included in the study). (e.g. INCLUSION CRITERIA: gender – female, age - ≥18, diagnosis – adenocarcinoma in situ, EXCLUSION CRITERIA: surgical history – not treated with conization)

How will prospective participants be recruited? Describe the process of participant recruitment in detail (i.e. how will eligible individuals be invited to participate in the study)

Who will contact prospective participants and how will this be done? List the members of the research team directly involved in and responsible for participant recruitment. Explain how they will solicit participant involvement in the project from the initial contact to consent

Describe the consent process for participants who can give fully informed consent. Provide a step-by-step description of where and how consent will be obtained.

Describe how consent will be obtained from participants who are capable of giving informed consent and how this will happen in practical terms (when, where, how). You may also describe how it will be obtained on behalf of those who can't give informed consent

Will participants be in-patients?
- ○ Yes
- ○ No
- ◉ Partially

Are participants SH staff?
- ○ Yes
- ○ No
- ◉ Partially

Are all participant visits during regular dayshift, Monday-Friday?
- ○ Yes
- ◉ No

List the services that may occur on off-hours and provide rationale If any Shared Health services are required outside of regular weekday work hours, they must be outlined here. Provide justification for this request.

Will First Nations populations be a focus of interest, or is there intent to stratify analyses or outcomes by First Nations populations, or will the study population include a high proportion of First Nations people?
- ◉ Yes
- ○ No

Describe how this study will support respectful relationships, collaboration, and engagement, as outlined in:
- The First Nations principles of OCAP®
- Tri-Council Policy Statement -- Chapter 9
- Framework for Research Engagement with First Nation, Metis, and Inuit

Answer "yes" in case of any direct or indirect focus on the First Nations people. For more information, follow the above links. Do you have letters of support/Band Council Resolutions and data sharing agreements/research agreements outlining the respectful relationship and partnership with the appropriate parties?
- ◉ Yes
- ○ No

Is this research study regional in scope?
- ◉ Yes
- ○ No

Will Metis populations be a focus of interest, or is there intent to stratify analyses or outcomes by Metis populations, or will the study population include a high proportion of Metis people?
- ◉ Yes
- ○ No

Describe how this study will support respectful relationships, collaboration, and engagement, as outlined in:
- Tri-Council Policy Statement -- Chapter 9
- Framework for Research Engagement with First Nation, Metis, and Inuit

Answer "yes" in case of any direct or indirect focus on the Metis people. For more information, follow the above links.
Do you have letters of support and data sharing agreements/research agreements outlining the respectful relationship and partnership with the appropriate parties?
- ◉ Yes
- ○ No

Will Inuit populations be a focus of interest, or is there intent to stratify analyses or outcomes by Inuit populations, or will the study population include a high proportion of Inuit?
- ◉ Yes
- ○ No

Describe how this study will support respectful relationships, collaboration, and engagement, as outlined in:
- Tri-Council Policy Statement -- Chapter 9
- Framework for Research Engagement with First Nation, Metis, and Inuit

Answer "yes" in case of any direct or indirect focus on the Inuit people. For more information, follow the above links.
Do you have letters of support and data sharing agreements/research agreements outlining the respectful relationship and partnership with the appropriate parties?
- ◉ Yes
- ○ No

What services will be required? **List ALL tests and services that are ABOVE standard of care (either altogether or at certain timepoints)**

☒ Phlebotomy / Specimen Collection Services

Phlebotomy / Specimen Collection Services are required for ☐ In-Patients ☒ Outpatients

Who will be responsible for Phlebotomy / Specimen Collection Services? ☒ SH Lab Staff ☐ SH Nursing Staff ☐ Research Nurse

☒ Other

☒ Diagnostic Services

- ☒ Diagnostic Imaging
  - ☒ Radiology
    - ☐ Radiologist Reports
    - ☒ MRI - Clinical
    - ☐ MRI - Specialized
    - ☐ Nuclear Medicine/PET-CT
    - ☐ X-Ray/Ultrasound
    - ☐ CT
    - ☐ Guided Biopsy
    - ☐ Angiography
    - ☐ Radiography
    - ☐ Data Handling
    - ☐ Other Time Requests
  - ☐ Cardiology
  - ☐ Neurology
- ☒ Laboratory Services
  - ☒ Local Testing
  - ☒ Central Lab Processing / Shipping
  - ☒ Pathology

☒ Health Sciences Center Services

- ☒ Hospital In-Patient Nursing
- ☒ Ambulatory Care Clinics / Day Care
- ☐ Pharmacy
- ☒ Health Information Services
- ☐ Additional Services

☒ WRHA Facilities & Resources

Will posters and/or recruitment material be displayed within SH? ◉ Yes ○ No

Specify Location(s): Specify where posters will be posted within SH/WRHA facilities

## Diagnostic Imaging

### *Radiology*

Is a Radiologist/Nuclear Medicine Physician required for this study?
- ○ Yes
- ◉ No

Is there a preference for a Radiologist/Nuclear Medicine Physician?
- ○ Yes
- ◉ No

List those tests or procedures performed, which are *above* standard of care [+] [-]

Tests or Procedures: Use the drop-down menu to specify the radiology test/procedure to be performed

Specific Visit(s): List the specific study visits during which the specified test/procedure is required (e.g. Screening, Week 8, Progression, End of Treatment, etc.). Only list those time points at which the required test/procedure is above standard of care

Site (if not applicable to all): If different from primary site

Specific conditions for requirement of procedure if not required for all: If the test/procedure is not required for all participants, outline the conditions under which it is indicated for certain participants

Specify body part(s): List the body part(s) targeted by the required test/procedure

Is the procedure being done as per standard of care
- ◉ Yes
- ○ No

Should the procedure be performed the way it would normally be done if ordered clinically (i.e. as per clinical standard)

Is a Radiologist / Nuclear Medicine Physician report required?
- ○ Yes
- ◉ No

## Laboratory Services

### *Local Testing (excluding pathology)*

List those tests or procedures performed in-house by the SH Diagnostic Services lab(s), which are *above* standard of care

| Test Names or Procedures | Specific Visit(s) | Site (if not applicable at all) |
|---|---|---|
| List all required in-house tests performed by Shared Health labs that are above standard of care (either altogether or for specific visits).<br><br>IMPORTANT: Consult the Lab Information Manual (LIM) and use test names as they appear ~~in LIM. Tests n~~ot listed in LIM are not offered by Shared Health. | For each test, list the study visit(s)/ timepoints during which the test will be ordered (e.g. Screening, Week 8, Progression, End of Treatment) | List the site(s) at which the testing is to be performed if different from the main site |
| **EXAMPLE* (tests grouped by study visits)*<br><br>*Biochemistry: Sodium, Potassium, Direct Bilirubin, Total Bilirubin, Calcium*<br><br>*Hematology: Prothrombin time (INR)* | *Screening (baseline), Week 8, EOT (end of treatment)* | *HSC, SBH* |
| *Biochemistry: Sodium, Calcium*<br><br>*Biochemistry (urine): Urinalysis (dipstick only)* | *Week 4* | *HSC, SBH* |

### *Central Lab Processing / Shipping (excluding pathology)*

Is Shared Health Laboratory Staff responsible for sample processing and/or shipping? Processing Yes Shipping Partially

Describe sample processing and/or shipping services to be done by Shared Health Laboratory Staff

If SH labs are required to process/store/ship samples that will be tested elsewhere, Lab Manual must be provided as part of submission

### *Pathology*

Specify details of specimens required

Disease site group: Choose the anatomical type of specimen (e.g. Gastrointestinal, Genitourinary, Head & Neck)

Type of Tissue: Normal/Tumor Tissue Obtained: Archival/Newly Obtained

Specimen Required - Primary: Specify the primary (preferred) request for procedure/deliverables

Specimen Required - Alternative: Specify an alternative request in case primary request cannot be granted

Timepoints: Specify the timepoints/visits during which the procedure/deliverables are required (e.g. Screening, Week 8, Progression, End of Treatment) and during which they are above standard of care. (see examples below)

Disease site group: **EXAMPLE* Genitourinary*

Type of Tissue: *Tumour* Tissue Obtained: *Archival (retrospective)*

Specimen Required - Primary: *1 FFPE tumor block*

Specimen Required - Alternative: *20 unstained, unbaked, charged slides at 4 micron thickness & 1 H&E slide*

Timepoints: Screening

Disease site group **EXAMPLE* (Cont) Genitourinary*

Type of Tissue *Tumour* Tissue Obtained *Newly Obtained (prospective)*

Specimen Required - Primary *1 FFPE tumor block from each biopsy site & 1 freshly obtained tissue in formalin*

Specimen Required - Alternative *n/a* + -

Timepoints *Recurrence / Progression*

Data Required

Pathology Data ◯ Yes ◉ No

Patient Related Parameters ◯ Yes ◉ No

Terms of Agreement (to be completed by each Designated Pathologist)

1. ◉ Research as part of non-clinical workload
   ◯ Research work in lieu of clinical workload, as approved by SH Pathology Medical Director
2. Time Estimate (per case) — The amount of time estimated by project/ collaborating pathologist for review of each case

**IMPORTANT:** It is no longer necessary to recruit SH pathologist for projects with pathology component. If no collaborating SH pathologist is recruited, pathology requests will be reviewed by an assigned index pathologist who will review tissue availability and release samples. Index pathologist will not be responsible for familiarizing themselves with any special project requirements beyond basic information on study requisition. In case of elaborate tissue selection criteria, it is still advised to recruit a SH pathologist

Designated Pathologist

Name Read the fine print below for more info Signature Date

Add Additional Pathologist

*The Designated Pathologist must have an appointment at the hospital site from which tissue will be obtained. The Designated Pathologist is aware of the tissue requirements outlined in the protocol and agrees to be the main pathology contact person in partnership with the Principal Investigator, and will be responsible for the selection of tissue (blocks/slides) to be released. If research work is being done in lieu of clinical workload, approval by the SH Pathology Medical Director will be required. The SH Research & Innovation will file the appropriate documentation to obtain this approval.*

## Health Sciences Center Services

Specify the main areas within HSC where study activities will be carried out including office space

Specify the HSC building(s) and room(s) where the study will be conducted

NOTE: Locations of services previously described in detail such as HSC phlebotomy lab or MRI department do not need to be listed here

### *Hospital In-Patient Nursing*

Indicate which nursing services are required: + -

Unit(s) Specify which nursing units will be involved specifically (use +/- to add sections if multiple nursing units involved with different activities) . Below specify the activities/services that are required of them:

Activity
- ☒ Administer study drugs
- ☒ Blood Pressure
- ☐ Cardiac Monitoring
- ☐ Establishing of Vascular Access Device (i.e. PICC)
- ☐ Vital Signs
- ☐ IV Therapy
- ☐ Respirations
- ☐ Infusion of Meds
- ☐ Fluid Intake/Output
- ☐ Documentation
- ☐ Other
- ☐ Heart Rate
- ☐ Temperature
- ☐ Ambulation
- ☐ Frequent Observation
- ☐ Establishing of IV

Frequency Specify the frequency of every activity selected above (e.g. check blood pressure every 4 hours, administer study drugs every 12 hours)

Position ☐ Research Nurse ☒ Staff Nurse ☐ Other

Participant Age ☒ Adult ☐ Pediatric

Will the study increase Nurse:Patient Ratio (1:1, 2:1, 4:1, 6:1, Other) ○ Yes ◉ No

What incremental supplies are required? List the one-time use/disposable supplies that are required to carry out the required tasks and whether these will be provided by the study (e.g. intravenous cannula, catheter, copy paper)

### *Ambulatory Care Clinics / Day Care*

Indicate which units or clinics will be providing service, which are *above* standard of care + -

Unit(s) or Clinic(s) For this section, refer to instructions found in the "Hospital In-Patient Nursing" section above

Activity
- ☐ Receiving & Registering
- ☐ Patient Education
- ☐ Appointment Scheduling
- ☐ Participant Enrollment
- ☐ Medical Record Management
- ☐ Other
- ☐ Assessment

Frequency

Position ☐ Clerk ☐ RN ☐ Assistant ☐ Other

#### *Health Information Services*

Will information from individual patient charts or medical records be required? ◉ Yes ○ No

Describe Outline in detail what kind of information will be collected from each chart

Explain how patient charts or medical records to be extracted will be identified How will the HIS know which charts to select. How will you instruct them regarding what you need.

Will a list of required charts or medical records be provided to the organization maintaining the records for extraction? ◉ Yes ○ No

Approximately how many charts or medical records will be required? e.g. 100

Who will be the person/people responsible for accessing and extracting the patient charts or medical records? Which member(s) of the research team will extract the information from the records once they are made available by HIS

Will Health Information Services be required to produce a list of chart numbers (based on criteria that you provide)? ○ Yes ◉ No

Comments/Other information relevant to chart review

## WRHA Facilities & Resources

Are any WRHA or affiliated facility resources required including employee participation, space, equipment, or money: (•) Yes ( ) No

Specify and indicate how much, how many and for what period of time:

Outline in detail the requirements for facility resources, staff involvement, the use of space, equipment, or WRHA funding (e.g. HSC ER nurses will be interviewed outside of their shift)

It is incumbent upon the researcher to negotiate the dedication of WRHA resources to this project prior to submission. Please include a written statement of support from the Managers directly in control of all the resources required. In cases where a manager is also a co-investigator, the level of support must come from at least one level above that individual.

Is there written support from the program area? (•) Yes ( ) No

Will the study involve correspondence with potential participants that is mailed out? ( ) Yes (•) No

Will information from individual patient charts or medical records be required? ( ) Yes (•) No

Explain how patient charts or medical records to be extracted will be identified. If patient records from WRHA institutions are required (other than those obtained from HSC Health Information Services), specify how the charts/records will be identified

Will a list of required charts or medical records be provided to the organization maintaining the records for extraction? (•) Yes ( ) No

Approximately how many charts or medical records will be required? e.g. 100

Who will be the person/people responsible for accessing and extracting the patient charts or medical records?

Will Health Information Services be required to produce a list of chart numbers (based on criteria that you provide)? ( ) Yes (•) No

## Data Access and Disclosure Plan

Shared Health and WRHA Data Access and Disclosure Plan
(RAAC Spec Sheet for Populating Data Sharing Researcher Agreements)

Date 1-Jan-23 **This section is pre-populated by information entered in the "Contact Details" section**

Principal Investigator The lead researcher ultimately responsible for the conduct of the study. PI is responsible PI is a student ☐

Institutional Affiliation e.g. U of M, SH, WRHA Department Department within the affiliated institution

Phone Email Professional phone number & email

Address Reliable, professional address that is actively monitored and is suitable for receiving confidential mail

Data Elements, Disclosure and Supports

1. Specify the total date range for the data required e.g. Jan 2000 to e.g. Dec 2025

   Specify the date range of the required Shared Health/WRHA data that will be accessed and/or extracted for research purposes. The date range can be purely retrospective or end in the future if SH/WRHA data collected during the lifetime of the project is going to be reviewed (e.g. research team wants to review retrospective data collected between Jan 2000 and now. They also wish to continue looking at prospective patient data in Accuro that will be collected in the future during the lifetime of the project, and they will do so until the end of the project in Dec 2025. The date range correct date range for them is Jan 2000 - Dec 2025).

   Specify the Inclusion/Exclusion criteria related to data elements

   Outline which characteristics expressed as data elements will serve as inclusion/exclusion criteria determining eligibility as SH/WRHA data is reviewed (e.g. INCLUSION CRITERIA: gender – female, age - ≥18, diagnosis – adenocarcinoma in situ, EXCLUSION CRITERIA: surgical history – not treated with conization)

   Is a control group required to be extracted for this study? ◉ Yes ○ No

   Describe the matching ratio and criteria for the control group and provide a rationale for the specific parameters requested

   If the project requires that a control group is created using SH/WRHA data, outline the required characteristics and justification

2. Complete the Data Extraction Form which summarizes all the data fields expected to be received and/or accessed
3. Complete the Data Flow Table which summarizes how the data will be sent from one institution to another
4. Complete the Data Security Table which summarizes how data security will be maintained

## *Data Details Form*

+ -

| Name of Database / System Requested | Data Trustee (Shared Health, WRHA, etc.) | Service Provider (HIS, Self-discolsure, etc.) | Data Fields / Variables | Date Range of Data Requested | Rationale |
|---|---|---|---|---|---|
| List all health databases/systems accessed for research pusposes, including those that the research team already has access to as part of their clinical or research capacity. List system individually and be specific (e.g. list Accuro instead of EMR) | List the institution that is the trustee of the data<br><br>NOTE: Individuals are not data trustees, ~~institut~~ions are. | The individual/ department who is directly accessing and/or extracting information from the system/database (e..g. HIS, data analyst). If a member of the research team is accessing the data directly, put "self-disclosure" | Specify all accessed / extracted data items These can be listed in a separate document such as Data Collection / Extraction Sheet | Specify the date of the oldest and newest information that will be accessed/extracted from a particular database/system (The date range can be purely retrospective or can end in the future if SH/WRHA data is going to be accessed prospectively during the course of the project) | Explain why it is necessary for the research project to access each of the listed databases/ systems and to view/ extract the outlined data items |

## *Data Flow*

Will data be moved from one location to another? (•) Yes ( ) No

Whenever Shared Health / WRHA data is accessed from or sent to another location - either physically or electronically - this is considered data flow and must be declared here. This includes accessing Shared Health/WRHA databases outside of Shared Health/WRHA (such as from a U of M location) or extracting data onto laptop or flash drive and keeping or accessing it outside of the trustee's premises and servers

Complete the following data flow table and clearly indicate at what stage personal health information will be de-identified. The Personal Health Information Act requires that every disclosure by a trustee of personal health information must be limited to the minimum amount of information necessary to accomplish the purpose for which it is disclosed.

+ -

Information Flow Number 1

Information flow number depends the level of information flow, it is not linear numbering system (e.g. think of a family tree where different family members in the same generation would be on the same level).

Sender Organization The trustee of the data (e.g. SH or WRHA)

Receiver Organization The organization that is receiving the data from the trustee (e.g. U of M)

Describe the data being transferred

Outline what data is being accessed/extracted/transferred and whether the data is directly identifying, de-identified, coded, etc.

*EXAMPLE*
*DIRECTLY IDENTIFYING DATA: participant's name, DOB, data indicating eligibility, medical and surgical history, medication history, pathology/lab/diagnostic imaging reports*

Method used to securely transfer data

How will data be transferred from the sender organization to the receiving site *(e.g. secure network connection)*

Description of functions performed at this location

What tasks will be performed at the receiving site *(e.g. extraction of information, coding of data, statistical data clean-up, storage of coded data and master list)*

Will the sender keep a copy of the transferred data? (•) Yes ( ) No

Does any member of the research team have access to the data at the receiving location? (•) Yes ( ) No

Information Flow Number 2

Sender Organization **EXAMPLE* (Cont) University of Manitoba*

Receiver Organization *Study Sponsor*

Describe the data being transferred *CODED DATA STRIPPED OF DIRECT IDENTIFIERS: participant code, age, data indicating eligibility, medical and surgical history, pathology/lab/imaging reports*

Method used to securely transfer data *REDCap*

Description of functions performed at this location *Data analysis, writing of manuscript, publication of research results*

Will the sender keep a copy of the transferred data? (•) Yes ( ) No

Does any member of the research team have access to the data at the receiving location? ( ) Yes (•) No

## *Data Security*

Identify the physical locations where data will be used or accessed by the research team, and storage sites (if different).

+ -

Location *e.g. University of Manitoba*

Address *Physical location(s) where data will be accessed and/or stored*

How will data be stored during the study?

- [ ] Hard copies
- [x] Digital files, Onsite server
- [ ] Personal computer
- [ ] CD/DVD
- [ ] Laptop
- [ ] Digital files, Offsite server
- [x] Portable hard drive
- [ ] USB
- [ ] Other

Anticipated date of destruction

Will data be accessed remotely? (•) Yes ( ) No

Where will Master Key be kept? *e.g. Principal Investigator's office - Room 123A Buller Bldg.*

What is the anticipated length of time that the research team will have access to the data ? Start End

When will access to electronic system housing the data be terminated for the research team?

How long will the study data be retained after the analysis is completed (number of years)?

Describe what will happen to the data at the end of the study and, if applicable, the procedures used to destroy study data contained in written records, videotapes, computers files and questionnaires, etc.

*e.g. Physical copies will be pulverized, data saved on portable hard drive will be deleted and hard drive formatted*

Identify all agencies or collaborators who will have access to the data (including medical records) at each stage of collection, processing, and analysis for the purpose of monitoring and/or auditing of data.

Any other entities with whom study data will be shared (e.g. collaborating universities, etc.)

## Funding / Billing Information

Indicate funding status
- (•) Received Funding
- ( ) SeekingFunding
- ( ) No Funding

Is this project Industry or For-Profit Funded?
- (•) Yes, wholly
- ( ) Yes, partially
- ( ) No

+ -

Fund will be administered by e.g. University of Manitoba

Special considerations

Primary Billing Contact

Name Contact for all billing inquiries whose name will appear on any relevant invoices

Phone Professional phone number Email Professional email address

Address Reliable, professional address that is actively monitored and is suitable for receiving confidential mail

## Other Information

Describe any other information relevant to this application

## Declaration

I hereby declare that the information provided in this application is true and correct to the best of my knowledge and belief. In case any information given in this application proves to be false or incorrect, I shall be responsible for the consequences, including but not limited to, delay in approval or rejection in full of this application.

For projects requiring identifiable personal health information:

Where identifiable personal health information is requested, I declare that this research cannot be done without using identifiable personal health information, and that it is impossible or impractical to obtain consent from the people the personal health information is about.

The lead researcher ultimately responsible for the conduct of

## Documents

Provide a listing of all documents that will be included with this application. Required documentation is listed on the SH Research and Innovation website.

| Type | Title/Name | Version Number and/or Date |
|---|---|---|
| | All applicable documents that are part of the submission must be listed in this table | |

# Shared Health Research Application

## Amendment

*This application form is to be used for project amendments which impact or alter the original services requested.*

Date

SH Reference Number

Principal Investigator

Protocol Title

Type of Submission ☒ Amendment ☐ Extension ☐ Alternative Site ☐ Documentation ☐ Participant/Case Increase

Note: the basic principle of this form is to (1) select all areas/elements of the project under "Amendment Summary" that have changed and (2) to outline in each section on the following pages what is different compared to the initial submission and/or subsequent amendments.
For definitions of the items under "Amendment Summary", please see the corresponding sections of the main application.

## Amendment Summary

*Identify all areas that will be impacted by the proposed change.*

**Protocol Information**

- ☐ Study Duration
- ☐ Protocol Title
- ☐ Protocol Objective
- ☐ Protocol Design
- ☐ Sample Size
- ☐ Data Analysis
- ☐ Risk

**Project/Population Information**

- ☐ Shared Health Site/Service Location
- ☐ Number of Participants / Cases
- ☐ Participant/Case Information
- ☐ First Nations Population
- ☐ Metis Population
- ☐ Inuit Population

**Service Information**

- ☐ Phlebotomy / Specimen Collection
- ☒ Diagnostic Imaging - Radiology
- ☐ Diagnostic Imaging - Cardiology
- ☐ Diagnostic Imaging - Neurology
- ☐ Laboratory Services - Local Testing
- ☐ Laboratory Services - Central Lab Processing / Shipping
- ☐ Laboratory Services - Pathology
- ☐ Health Sciences Center - Location
- ☐ Health Sciences Center - Hospital In-Patient Nursing
- ☐ Health Sciences Center - Ambulatory Care Clinics / Day Care
- ☐ Health Sciences Center - Pharmacy
- ☐ Health Sciences Center - Health Information Services
- ☐ Health Sciences Center - Additional Services
- ☐ WRHA Facilities & Resources

- ☐ Poster and/or Recruitment Material Displayed
- ☐ Funding
- ☐ Data
- ☐ Documents

## Rationale

Provide Rationale for proposed changes above.

For each applicable area/element selected above, explain why the proposed changes are happening

*In the following sections, provide details of the proposed changes. In some sections an outline of the current state is required as well.*

In each section, think about what is changing compared to the initial application and/or subsequent amendments. Unless requested, do not outline what remains the same. When making changes to existing services such as radiology, laboratory testing, pathology, etc, describe what needs to be removed, added, or changed in comparison to what the project is already getting.

EXAMPLE (A): In the example below, a project has been approved for MRI of brain at HSC at the time of participant screening, but now they want to request CT of the same instead. To capture this, they first describe the existing service (1) and choose "Remove" next to "Status". Next, they use the "+/-" button to add another subsection and (2) describe their request for CT.

## *Diagnostic Imaging - Radiology*

Is a Radiologist/Nuclear Medicine Physician required for this study? ○ Yes ◉ No

Use "+/-" buttons to add subsections

(1) List those tests or procedures performed, which are *above* standard of care [+] [-]

Tests or Procedures: MRI-Clinical — Status: Remove

Specific Visit(s): Screening

Site (if not applicable to all): HSC

Specific conditions for requirement of procedure if not required for all: n/a

Specify body part(s): Brain

Is the procedure being done as per standard of care ◉ Yes ○ No

Is a Radiologist / Nuclear Medicine Physician report required? ○ Yes ◉ No

(2) Tests or Procedures: MRI-Clinical — Status: Add

Specific Visit(s): End of Treatment (EOT)

Site (if not applicable to all): HSC

Specific conditions for requirement of procedure if not required for all: n/a

Specify body part(s): Brain

Is the procedure being done as per standard of care ◉ Yes ○ No

Is a Radiologist / Nuclear Medicine Physician report required? ○ Yes ◉ No

EXAMPLE (B): A project is approved for CT of Brain at HSC but wants to now change it to Lumbar Spine. Instead of removing the existing approved service and adding a new services which is the same with the exception of scanned body part, the research team chooses to outline the new request and select "Change" next to "Status". Use this option only when the existing and new requests are sufficiently similar.

Tests or Procedures: CT — Status: Change

Specific Visit(s): Screening

Site (if not applicable to all): HSC

Specific conditions for requirement of procedure if not required for all: n/a

Specify body part(s): Lumbar Spine

Is the procedure being done as per standard of care ◉ Yes ○ No

Is a Radiologist / Nuclear Medicine Physician report required? ○ Yes ◉ No

## Other Information

Describe any other information relevant to this application

## Declaration

I hereby declare that the information provided in this application is true and correct to the best of my knowledge and belief. In case any information given in this application proves to be false or incorrect, I shall be responsible for the consequences, including but not limited to, delay in approval or rejection in full of this application. I understand that, if applicable, overhead charges may be applied based on current Shared Health rates.

For projects requiring identifiable personal health information:

Where identifiable personal health information is requested, I declare that this research cannot be done without using identifiable personal health information, and that it is impossible or impractical to obtain consent from the people the personal health information is about.

Completed by:

Amendment application may be signed by the PI or main study coordinator

# Shared Health Research Application

## Change in Personnel

*This application form is to be used to add, remove or alter the personnel/duties involved in a project*

Date

SH Reference Number

Principal Investigator

**Protocol Title**

Use this form in the event of personnel changes. List all members of the research team who have been (1) added , (2) removed, or (3) whose information has changed since the initial application and/or subsequent Change in Personnel forms.

For detailed instructions on how to fill out individual items below, please see the corresponding sections of the main application.

Use "+/-" buttons to add additional people + -

### *Contact Detail Changes*

Role

Status Choose (1) Add, (2) Remove, or (3) Change

Name

Institutional Affiliation

Department

Phone

Email

Address

Has this person signed the PHIA Pledge of Confidentiality within 3 years? ◯ Yes ◯ No

Will this person have access to line-level data? ◯ Yes ◯ No

Will this person be accessing or extracting Personal Health Information from the health system? ◯ Yes ◯ No

Will this person require access to clinical information systems for research purposes? ◯ Yes ◯ No Specify systems

Will this person have remote access to data? ◯ Yes ◯ No

Will this person be obtaining consent? ◯ Yes ◯ No

Describe the duties of this person

---

In case of general questions, contact

In case of patient visit questions, contact

Results are to be forwarded to

Secure Fax Number

## Other Information

Describe any other information relevant to this application

## Declaration

I hereby declare that the information provided in this application is true and correct to the best of my knowledge and belief. In case any information given in this application proves to be false or incorrect, I shall be responsible for the consequences, including but not limited to, delay in approval or rejection in full of this application.

This application can only be signed by the PI