Saskatchewan Health Authority Operational Approval Process

February 8, 2019

Saskatchewan Health Authority

Operational Approval Process

Two requirements for Operational Approval (OA):

1. Research ethics review/approval or exemption by a U of S/U of R/SHA Research Ethics Board.
2. Completion of the online SHA Operational Approval to Conduct Research application form.

Saskatchewan Health Authority

Operational Approval Process

- Researcher completes and submits the SHA OA application form (new form effective Feb. 1/19).
- Identifies SHA depts./units involved in the research.
- The SHA OA application should be completed AFTER the REB application has been submitted for research ethics review.

Saskatchewan Health Authority

Operational Approval Process

- Research studies reviewed/approved by the U of S REB are coordinated by the Research Approval Coordinator (RAC) in Saskatoon.

- Research studies reviewed/approved by the SHA or U of R REB are coordinated by the Research Approval Coordinator (RAC) in Regina.

Saskatchewan Health Authority

Operational Approval Process

- The OA application is reviewed for completeness by the RAC. If information is missing the researcher is contacted to provide.
- The RAC sends the OA application, REB application and other relevant information to the SHA Departments – Director, Manager, or Designate for approval.

Saskatchewan Health Authority

Operational Approval Process

Once the ethics certificate or letter of exemption has been issued and the OA application is completed (i.e. SHA operational approval application has been filled out, all required approvals received)…SHA Letter of Authorization to Conduct Research is issued.

Saskatchewan Health Authority

Operational Approval Process

Chart Reviews (Saskatoon - RUH, SCH, SPH Regina – PH, RGH, WRC)

Departmental approval is required from Health Records/HIMS.

Paper charts – chart pulls are coordinated by the Saskatoon Health Records Research Coordinator (Aimee Goss) or Regina HIMS Manager (Lee-Ann Carr)

SCM – SCM research accounts are required for collecting data from electronic patient records.

eHR viewer/eHealth SK – Cannot be accessed for research. Contact eHealth Saskatchewan for assistance.

Saskatchewan Health Authority

Operational Approval Process

Research approval coordinators:

Saskatoon Research Approval Coordinator

Shawna Weeks

(shawna.weeks@saskhealthauthority.ca, 306-655-1442)

Regina Research Approval Coordinator

Jenny Wang

(researchapproval@rqhealth.ca, 306-766-0893)

Saskatchewan Health Authority

Operational Approval Process

Website links:

Former RQHR website:

http://www.rqhealth.ca/department/research-and-performance/operational-approval

Former SHR website:

https://www.saskatoonhealthregion.ca/locations_services/Services/research/Pages/Research-Approval.aspx

Saskatchewan Health Authority

Thank you.... questions?

For more information, visit
saskhealthauthority.ca.

Saskatchewan
Health Authority

Research Ethics Office

Animal Ethics
Human Ethics

ch • Behavioural Research • Biomedical Research • Behavioural Re
ural Research • **Biomedical Research** • Behavioural Research • Bio
rch • Biomedical Research • **Behavioural Research** • Biomedical Re
lical Research • Behavioural Research • Biomedical Research • Beh

Nick Reymond, Behavioural Research Ethics Specialist

Resident Information Session

09 February, 2019

FOR MORE INFORMATION:
ethics.office@usask.ca
306-966-2975

Research Requiring Review

- Research involving living human participants or their data
- Research involving human biological materials as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells from both living and deceased individuals.

FOR MORE INFORMATION:
ethics.office@usask.ca
306-966-2975

Research Exempt from Review

- Publically available information
- Observation of people in public places where there is no expectation of privacy
- Program evaluation
- Secondary use of anonymous data/biological material
- Individual providing information about policies, procedures, practices

FOR MORE INFORMATION:
ethics.office@usask.ca
306-966-2975

Research Ethics Office

Bio

- Medically invasive procedures
- Invasive interventions (including drugs)
- Physical interventions (e.g., exercise and dietary interventions)
- Surgical procedures
- Use of health charts

Beh

- Non-invasive interventions or measurements
- Observational or descriptive research
- Monitoring
- e.g., interviews, questionnaires, focus groups, ethnography

FOR MORE INFORMATION:
ethics.office@usask.ca
306-966-2975

Things to Note

- Meetings and deadline dates: Beh, Bio
- Minimal or above minimal risk
- Give yourself enough time!

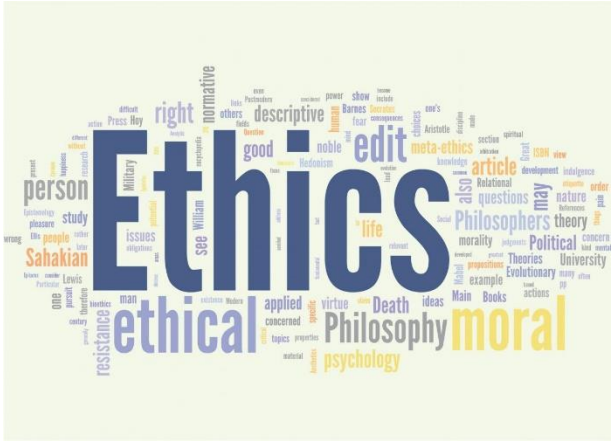
FOR MORE INFORMATION:
ethics.office@usask.ca
306-966-2975

Human Research Ethics

Have Questions? Contact:
Ethics.office@usask.ca
306-966-2975

Nick Reymond (Behavioural)
nick.reymond@usask.ca
306-966-2084

Caitlin Prebble (Biomedical)
caitlin.prebble@usask.ca
306-966-4053



Website
https://vpresearch.usask.ca/researchers/ethics1.php

What you can find on our website:

- *Guides*
- *Forms*
- *Policies and Procedures*
- *Templates*
- *Submission Deadlines*
- *Meeting Dates*
- *Contact Information*

UNIVERSITY OF SASKATCHEWAN

How Do I Get Ethics Approval?

Step 1:
Determine if your project requires Ethics Review.

All research that involves human subjects requires review and approval by a Research Ethics Board (REB) in accordance with the Tri-Council Policy Statement (http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/) **before** the research is started.

Review is required for

- Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses.
- Observation of human behaviour in a natural environment
- Use of identifiable data

Review is not required for

- Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews.
- Quality assurance studies, performance reviews or testing within normal educational requirements
- Publicly available reports, literature, STATS CAN data

Step 2:
Determine which Research Ethics Board your project should be reviewed by.

The University has established two Research Ethics Boards (REBs). The appropriate REB must approve any project involving the use of human subjects.

The Biomedical Research Ethics Board (Bio-REB) is responsible for the review of all protocols involving human subjects which include:

- Medically invasive physical procedures, invasive interventions and invasive measures (includes administration and testing of drugs);
- Physical interventions that have the potential for adverse effects such as drug, exercise and dietary interventions;
- Surgical procedures such as biopsies, the collection of blood or other specimens;
- Use of permanent health charts or records in accordance with provincial legislation.

The Behavioural Research Ethics Board (Beh-REB) is responsible for the review of all protocols involving human subjects which include:

- Non-invasive interventions and measures including interviews, surveys, questionnaires, psychological, social or behavioural interventions, non-invasive physiological measures (e.g. heart rate, blood pressure);
- Observation or descriptive research, including drug, dietary, and exercise protocols that are observational in nature with no intervention;
- Audio and/or video recording or other monitoring.

Step 3:
Assess the risk level of your project (minimal risk or above minimal risk).

Minimal risk means that the risk of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Risks of daily life mean those risks encountered in the daily lives of the subjects of the research, considering their actual life situations, as opposed to the daily life of "normal persons" or of "healthy volunteers" as the case may be.

Step 4:
Submit an ethics application to the Ethics Office.

Researchers and graduate students submitting their research proposals for human ethics review must prepare their submissions according to the appropriate guidelines and forms for the relevant Research Ethics Board located at https://vpresearch.usask.ca/researchers/forms.php
The selection of the correct guidelines for preparation of a research submission is important and is governed by the nature of the research, not the home department of the researcher.

Step 5:
Make the requested revisions as suggested by the Research Ethics Board (if necessary).

During the Ethics Review Process the REB will often respond to the researcher with suggested revisions or modifications to the research protocol, consent form, recruitment protocol, etc. These revisions will need to be made and submitted for review **prior** to ethics approval being granted. When submitting the requested revisions only one copy will need to be submitted to the Ethics Office. Revisions can be submitted electronically. Signatures are not required.

Step 6:
Receive the Certificate of Approval and begin the project.

Approval is issued for the protocol and corresponding documents that are described in the application. Changes to any aspect of this protocol (i.e. a change in research method, recruitment of participants, participant population, consenting process, consent form, etc.) require approval from the appropriate REB. A memo describing the changes and the request for approval for the amended protocol should be addressed to the Chair of the REB, care of the Ethics Office.

If you have any questions, contact the Ethics Office at (306)966-2975.