DEPARTMENT OF SURGERY RESEARCH HANDBOOK

FOR FACULTY AND RESIDENTS

University of Saskatchewan
Saskatchewan Health Authority

PREAMBLE

This handbook has been designed to facilitate applying for funding and to inform about the steps that need to be taken to apply for a grant. This handbook will be very helpful especially to those individuals that have never written a grant proposal before. Karen E. Mosier was hired as a Research Coordinator to increase research productivity and promote a dynamic research culture within the department. Her position was created to provide mentorship and research support for faculty and residents. She will facilitate, assist, support and enhance educational research capacity by providing practical advice, analysis, interpretation and assistance with identifying opportunities, communicating complex specialized information on major research funding programs, research policies, budgets and implementation issues. She will also provide assistance with the writing of proposals and offer assistance and guidance with obtaining research ethics approvals. **The purpose of this brief guide is to provide quick information for you to read to orient yourself to what funding opportunities you would like to apply for before you contact your Research Coordinator.**

BEFORE YOU APPLY

ELIGIBILITY TO APPLY FOR, HOLD AND ADMINISTER RESEARCH FUNDING

The College of Medicine wants to encourage faculty to conduct research and further enhance the College of Medicine's research profile. Faculty in Clinical Departments are now eligible to apply for, hold and administer research funds provided their appointment includes the statement that he/she is allowed/required to conduct independent research for the College of Medicine. If your current appointment has an end date, you will need to request an updated 'ongoing' appointment letter. Your ongoing appointment will include the following statement: "…faculty appointment with the U or S grants you eligibility to conduct independent research for the College of Medicine…." **You do need to note however that although we are granting you the ability to conduct research on behalf of the College this does not make you eligible to apply for all funding opportunities, as each funding agency has their own requirements. In order to determine your eligibility, it is important that you consult the Office of the Vice Dean Research or your Research Coordinator prior to beginning any application process.**

OPERATIONAL APPROVAL OF RESEARCH

Any research, funded and non-funded, involving Saskatchewan Health Authority - Saskatoon resources and/or conducted in its facilities must receive formal "Operational Approval" before it may begin. This includes any research that utilizes the resources, data, programs and/or services of the Health Authority, its patients/clients/residents, and also includes research conducted in its affiliates and community-based organizations.

Saskatchewan Health Authority Operational Approval process allows for the review and approval of research projects that impact or affects any Saskatoon resources. This includes all research projects conducted by Health Authority employees. There are two main components:
•Proof of Ethical Approval – the University of Saskatchewan Research Ethics Boards provides the ethical review and approval. As part of the Operational Approval process, researchers are required to provide a copy of the Certificate of Approval or Notice of Exemption from Ethics Review from the University of Saskatchewan Research Ethics Board. The researcher is also required to submit a copy of their research ethics application.
•Saskatchewan Health Authority Department/Unit Impact Review – The purpose of this review is to identify which departments in Saskatoon are affected by the research and to determine each department's ability to support the research. This information is collected together on the Operational Approval Application form (below).

How to Obtain Operational Approval

•The researcher completes the Operational Approval Application form. The Operational Approval Application form must be signed by the researcher. If the research is being conducted by a student, the Operational Approval Application form must be submitted under the name of the student's research supervisor.

•All departments affected by the research are identified (Saskatchewan Health Authority Department Impact Assessment) on the Operational Approval Application form. The researcher discusses the potential impact of the research study with the Manager or designate from each department. When the Manager or designate agrees to support the research, and matters such as cost recovery and protocol concerns, etc. have been addressed, the Manager or designate will provide their approval either by a written signature on the Operational Approval Application form OR by an email from their Saskatchewan Health Authority email account. The researcher must obtain the approval of the Manager or designate for each department affected by their research before Operational Approval is granted.

Notification of Operational Approval

Forward the completed application forms electronically to shawna.weeks@saskhealthauthority.ca or by mail to: Research Approval Coordinator, Room 423, Ellis Hall, 103 Hospital Drive, Saskatoon, SK, S7N 0W8.
The "SHA Application for Operational Approval to Conduct a Research Study - Saskatoon" is reviewed for completeness and accuracy. If all of the required information is provided, Operational Approval is usually granted within 3 - 5 workings days from our office receiving the complete application package. A letter indicating Operational Approval has been granted is emailed to the researcher, and a copy is emailed to all of the affected or impacted departments listed on the application form.

Notification of Study Closure

Once all data collection procedures involving SHA resources / services have been completed as per the study protocol, the study is considered closed. Please inform the Research Approval Coordinator once the study has closed.
The Research Approval Coordinator will send an acknowledgement of the closure to the departments affected by the study. The Research Approval Coordinator will also begin the final billing process to facilitate the affected department(s) reimbursement of study costs.

Amended Approval

If a researcher has already received SHA (or SHR) approval for a research project and additional SKHA departments/services/resources will be required or impacted by the study, they are to complete the Application for Amended Approval (MS Word) form. All additional departments are identified and approval is obtained from the manager(s).
Once completed, submit the form to the Research Approval Coordinator and an Amended Approval letter will be sent out to the researcher.

Quality Assurance/Improvement, Program Evaluation and Research

Projects considered quality assurance/improvement or program evaluation may not require operational approval. Operational approval may be required depending on the scope of the project and the impact on SHA resources.

In some instances the U of S REB may waive ethics approval and will provide the researcher with a letter of exemption. If the project has had ethics approval waived but still requires operational approval, documentation of this waiver must be provided with the Operational Approval application.
If you are unclear whether or not your project is research OR if you require operational approval, contact the Research Approval Coordinator for further assistance: telephone 306-655-1442 or email shawna.weeks@saskhealthauthority.ca.

RESEARCH ETHICS BOARD APPROVAL

The University requires that all research conducted by its members conform to the highest ethical standards in the use of human subjects, animals and biohazardous materials. **Any research or study conducted at University facilities, or undertaken by persons connected to the University, involving human subjects, animals or biohazardous materials must be reviewed and approved by the appropriate University of Saskatchewan Research Ethics Board (REB) or Committee.**

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 2 (http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/) **before** the research is started.

Review is required for:

- Research involving living human participants
- 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 visual 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, residents 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.

NOTE: Recently, Human Research Ethics processes moved to the UnivRS online database system. In the near future, all ethics applications will need to be submitted through UnivRS. In the meantime, all ethics review forms must be submitted electronically to Research Services at ethics.office@usask.ca.

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.

- Applications to the Behavioural and Biomedical REBs should be emailed to ethics.office@usask.ca
- Applications to the Animal REB should be emailed to uacc.office@usask.ca
- Paper copies should be mailed to Room 223 Thorvaldson, 110 Science Place, Saskatoon SK S7N 5C9
- The physical location of the office is Room 223 Thorvaldson, 110 Science Place, Saskatoon SK S7N 5C9
- Research Services and Ethics Office phone number: 306-966-2975
- UACC (University Animal Care Committee) phone number: 306-966-4126

All other documents, including, amendments, modifications, annual report forms, study closure forms or unanticipated problem reports can also be submitted by email, followed by a paper copy for those documents requiring a signature. If you are concerned about the security of your emailed documents, please contact the Research Services and Ethics Office and we will discuss arrangements for secure transmission.

CCV

All of the Tri-Councils (CIHR, NSERC and SSHRC) have migrated their legacy CV systems to the Canadian Common CV (CCV). In addition, over two dozen funding agencies, including the Canadian Foundation for Innovation (CFI) and the Saskatchewan Health Research Foundation (SHRF), also use the CCV system. The CCV is a web-based application that provides researchers with a single, common approach to gathering CV information required by a network of federal, provincial and not-for-profit research funding organizations. The CCV's processes, procedures and capabilities allow the input of CV information by researchers and the extraction of the CV data (with consent from the researcher) by member agencies to support their funding application process.

Quick CCV Instructions:
Step 1: Go to https://ccv-cvc.ca/indexresearcher-eng.frm. You will need to go to the top right hand corner and click on Login. If you are a new user, you will need to click on Register. Once you get a username and password set up you can sign in. Using your usask email as the username is highly recommended.
Step 2: Go to the second row of the tool bar legend and hover over CV. Choose funding. Do not choose Generic as it asks for extra information that isn't always required by the funding agency. Click on Funding Source and pick your funding agency e.g., CIHR, SHRF, NSERC. For CV Type you're your type of CV e.g., Principal Investigator, Co-applicant. Click on Load.
Step 3: You will need to manually enter your personal information e.g., language, address, telephone, email, etc. You will need to add your education, recognitions, employment, research funding history, presentations, publications, etc. To begin, start with Identification. Click on the pencil icon. Add the information. Click on done. This will bring you back out. You should see a green check mark beside Identification. Then you can go on to Language Skills. Repeat instructions as above. Do this for each required section. If you see a red X, click on the pencil icon and go back into that section as something needs to be fixed. Once you fix it and click done and come out again you should see a green check mark. **NOTE: There is a way to download most or all of your publications rather than manually typing them all in so ask your Research Coordinator how to do this.**
Step 4: Once you are done entering all your information and you see green check marks beside each section, you can go to the top right and click on Preview. Have a look and if everything looks good you are ready to submit it. You need to submit it in order to get a PDF of your CIHR CV. If it is good after previewing it, click on submit. Check I agree. Write down the confirmation number displayed in green font. e.g., 847443
Step 5: In the second row of the tool bar legend click on History. You will see one or more PDFs. Pick the one that has the same confirmation number. Click on the PDF symbol and open your CIHR CV and then save it to your desk or the appropriate file that you want it in.
NOTE: If you do not submit your CV and you use your Preview CV it will have the big words DRAFT printed across it. This is not acceptable. Please remember to submit your CV in order to avoid this problem.

CCV workshops are given regularly throughout the year so please contact your Research Coordinator to find out the days and times for upcoming CCV workshops.

INTELLECTUAL PROPERTY/COMMERCIALIZATION

Intellectual property refers to the legal rights to ideas, inventions and creations in the industrial, scientific, literary and artistic fields. It also covers symbols, names, images, designs and models used in business. Commercialization is the process of introducing a new product or production method into commerce—making it available on the market. **For any questions regarding IP issues or commercialization of your technology arising from your research, please contact Dr. John Mapletoft, Portfolio Manager, Life Sciences, Innovation Enterprise at 306-966-4584 or at** john.mapletoft@usask.ca**.**

WHERE TO APPLY

TRI-COUNCIL (CIHR, NSERC AND SSHRC)

The Tri-Council Agencies, made up of the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council (SSHRC), are a major source of research funding for post-secondary institutions in Canada. All research that is funded by the Tri-Council Agencies must be in accordance with the Tri-Council Memorandum of Understanding (MOU). This MOU describes the basic requirements for obtaining and maintaining institutional eligibility to administer research funds.

CANADIAN INSTITUTES OF HEALTH RESEARCH

As the Government of Canada's health research investment agency, the Canadian Institutes of Health Research (CIHR) supports excellence across all four pillars of health research: biomedical; clinical; health systems services; and population health. As stated in the *CIHR Act*, CIHR's mandate is to "excel, according to internationally accepted standards of scientific excellence, in the creation of new knowledge and its translation into improved health for Canadians, more effective health services and products and a strengthened Canadian health care system."
http://www.cihr-irsc.gc.ca/e/193.html

To apply for CIHR funding, all applicants must apply through ResearchNet. Current CIHR funding opportunities can also viewed in Research Net.
https://www.researchnet-recherchenet.ca/rnr16/LoginServlet?language=E

NATURAL SCIENCES AND ENGINEERING RESEARCH COUNCIL OF CANADA

NSERC aims to make Canada a country of discoverers and innovators for the benefit of all Canadians. The agency supports university students in their advanced studies, promotes and supports discovery research, and fosters innovation by encouraging Canadian companies to participate and invest in postsecondary research projects. NSERC researchers are on the vanguard of science, building on Canada's long tradition of scientific excellence. The Natural Sciences and Engineering Research Council of Canada (NSERC) helps make Canada a country of discoverers and innovators for the benefit of all Canadians. To check out NSERC's funding opportunities go to their website at: http://www.nserc-crsng.gc.ca/index_eng.asp. To access NSERC's online system go to their Research Portal login page: https://portal-portail.nserc-crsng.gc.ca/s/login.aspx.

SOCIAL SCIENCES AND HUMANITIES RESEARCH COUNCIL OF CANADA

SSHRC-supported research in the social sciences and humanities enhances our understanding of modern social, cultural, technological, environmental, economic and wellness issues. It raises profound questions about who we are as human beings, what we need in order to thrive in complex and challenging times, and where we are headed in the new millennium.

The work SSHRC supports encourages the deepest levels of inquiry. It spurs innovative researchers to learn from one another's disciplines, delve into multiparty collaborations and achieve common goals for the betterment of Canadian society. Research outcomes are shared with communities, businesses and governments, who use this new knowledge to innovate and improve people's lives.

SSHRC also invests directly in Canada's future. Through the social sciences and humanities, students receive the best possible training in critical thinking, complex decision-making and creative exploration. By investing in scholarships, fellowships and research training, SSHRC helps develop Canada's best and brightest scholars and researchers into Canada's future leaders.

http://www.sshrc-crsh.gc.ca/home-accueil-eng.aspx

SHRF

SHRF leads strategic investments in high impact, peer-reviewed health research aligned with provincial needs; builds and broadens Saskatchewan's health research and innovation capacity; and facilitates the use of health research findings for informed decision-making at all levels, from the individual to care providers to policy-makers.

https://shrf.ca/Health-Research/Home

RUH FOUNDATION

The RUH Foundation Research Grant Program supports clinically relevant research projects that will ultimately benefit patients who are, for the most part, treated at Royal University Hospital.

Eligible applicants include:

- SHA-Royal University Hospital allied health care professionals, nurses and physicians with clinical practice at RUH and who are eligible to hold funds at the U of S
- University of Saskatchewan residents and fellows based at RUH as co-applicants with a primary supervisor
- University of Saskatchewan faculty whose study outcomes have direct clinical impact on programs managed primarily at RUH
- Collaborative projects are encouraged
- Priority will be given to research projects demonstrating clear clinical application
- Applicants who demonstrate financial support from other sources including funding and project partners

https://ruhf.org/grants-scholarships/

ARE YOU INTERESTED IN A RESEARCH CAREER AS A CLINICAL INVESTIGATOR?

The Clinician Investigator Program (CIP) is a RCPSC certified program, and is available to residents that have demonstrated interest and potential for a career as a clinical investigator. The program accommodates training in diverse research areas ranging from basic and correlative science studies of disease pathogenesis to epidemiological investigations of social/population determinants of health.
It is expected that each CIP trainee will develop the specific skills and scholarly attitudes required to perform high quality health research. Scholarship implies an in-depth understanding of the area of research and the application of current knowledge to clinical practice. The quality of scholarship in the program will, in part, be demonstrated by a spirit of enquiry during clinical discussion, at the bedside, in clinics or in the community, and in seminars, rounds and conferences.
Two CIP training streams are offered. The Graduate Stream in which applicants enroll in graduate (MSc and PhD) programs at the University of Saskatchewan, and the Postdoctoral Stream designed for residents who already hold a PhD.

How To Apply

All residents who are enrolled in a Royal College Residency Training program are eligible to apply for the CIP. The training involves a minimum of two years of mentored research intensive training that involves enrolment in a graduate degree program (graduate stream), to complete a thesis or equivalent, or in a postdoctoral fellowship program if the trainee already has a graduate degree (postdoctoral stream). To apply, contact Dr. Grant Miller at grant.miller@usask.ca for an online application form - do not use the form in the attached CIP Manual.

For more information including access to the Clinician Investigator Handbook and Special Training Requirements for CIP please see the College of Medicine website:

https://medicine.usask.ca/programs/cip.php

WHAT CAN YOUR RESEARCH COORDINATOR DO FOR YOU?

NAVIGATE YOU THROUGH THE GRANT WRITING PROCESS

The Research Coordinator position was created to provide mentorship and research support for faculty and residentsto promote a dynamic research culture within the department. She can assist you to navigate your way through the grant writing process:

- Identify available research funding sources
- Review grant proposals prior to grant submission
- Assist with budget development and budget justification
- Act as a liaison between faculty members, research groups, external granting agencies, Research Services and Graduate Studies, and internal departments & agencies

HELP YOU TO UNDERSTAND THE U OF S INTERNAL REVIEW PROGRAM

The U of S Internal Review Program is open to all researchers applying to selected funding opportunities. This program is a strategic investment in U of S researcher success and supports institutional aims to encourage and facilitate research excellence. The U of S Internal Review Program aims to provide high quality feedback to researchers in both the early and final stages of grant development.
Our "College of Reviewers"—U of S faculty members with experience adjudicating, reviewing, and/or applying for Tri-Agency funding—provide expert feedback to U of S faculty applying for the following Tri-Agency programs:

- CIHR Project Grant
- CIHR Foundation Grant
- NSERC Discovery Grant
- NSERC RTI
- SSHRC Grants (e.g., Insight, Insight Development, Partnership Development)

https://vpresearch.usask.ca/researchers/internal-review-process.php

Applications to the CFI John R. Evans Leaders Fund (JELF) have a separate internal review process. **For more information on these internal review processes and the associated timelines with each competition please contact your Research Coordinator.**

PROVIDE MENTORSHIP FOR RESEARCH-RELATED ACTIVITIES

The Research Coordinator has been hired to facilitate, assist, support and enhance educational research capacity by providing practical advice and assistance for research-related inquiries. She can provide mentorship and advice in areas such as:

- Surgery Research Awards
- Ethics applications
- Researcher profiles
- Networking with other departments, colleges and universities
- CCV Development
- Engagement with industry
- Surgery Research Intranet

CONTACT INFO

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