Procedure for Policy on Operational Approval for Research	Manual: Reference Number: *107-1*
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See related policies: Operational Approval for Research
The Ethical Conduct of Research and Other Studies Involving Human Participants
Externally Funded and/or Sponsored Research

See related procedures: Procedure for Policy on The Ethical Conduct of Research and Other Studies Involving Human Participants
Procedure for Policy on Externally Funded/Sponsored Research

Procedure

1.0 Overview of Approval Process

1.1 All research, funded or unfunded, accessing or using RQHR or affiliated resources or patients (including their personal health information) requires RQHR Operational Approval. The Research Approval Coordinator will issue a letter of "Authorization to Conduct Research" to alert the Principal Investigator and all Department Heads impacted by the research that the study has approval to commence in the RQHR.

1.2 Applications for research ethics review and for operational approval may be submitted simultaneously.

1.3 RQHR operational approval will be issued once all of the following have been received by the RQHR Research Approval Coordinator:

i. A Certificate of Approval or Letter of Acceptance from the RQHR Research Ethics Board;

ii. Signatures (or electronic confirmation, if previously approved by the Research Approval Coordinator) from all Administrative Department Heads whose resources (including, but not limited to, facilities, equipment, supplies, staff) or patients will be utilized in the research and, if applicable, Medical Department or Section Heads whose areas of clinical practice will be impacted by the research, if such

parties have not already signed the application for research ethics review;

iii. Proof of insurance for Principal Investigators and/or types of research not covered by institutional and/or Canadian Medical Protective Association (CMPA) insurance;
iv. Fully executed copies of any clinical trial agreements, clinical research contracts, confidentiality/non-disclosure agreements, material transfer agreements, and/or data access agreements, and any other research-related agreements associated with the conduct of the research within the RQHR or its Affiliates, if applicable;
v. A copy of the Health Canada No Objection Letter (drug trials) or Investigational Testing Authorization (device trials), if applicable;
vi. A copy of the Notice (or letter) of Award and any other documents concerning the regulations or conditions governing the use of the grant or donated funds, if applicable; and
vii. Completed Research Account Application form for any studies requiring administration/management of research funds through the RQHR.

2.0 RQHR Research Ethics Board Approval

2.1 All research projects must be approved by the RQHR Research Ethics Board (REB) for conduct in the RQHR on ethical grounds and in accordance with the RQHR policy on The Ethical Conduct of Research and Other Studies Involving Human Participants.

2.2 If a project receives research ethics approval, one of the following will be issued:

a) A Certificate of Approval; or
b) A Letter of Acceptance of Review, for studies approved by an REB at the University of Saskatchewan or University of Regina, as per the provincial research ethics review harmonization process.

2.3 The RQHR REB will forward an electronic copy of the REB approval to the Principal Investigator and the RQHR Research Approval Coordinator. The Principal Investigator must confirm that the Research Approval Coordinator has received a copy of the Certificate of REB Approval.

3.0 Departmental Approvals

3.1 Signatures must be obtained on the Operational Approval for Research Application Form from all Administrative Department Heads whose departments' resources or patients will be utilized in the conduct of the research. A member of the research team may contact the Research Approval Coordinator if assistance is needed in identifying the appropriate individuals to contact for Departmental Approval.

3.2 Researchers must provide all applicable Administrative Department Heads with a copy of the Operational Approval for Research Application Form and the completed application submitted for research ethics review. Department Heads

may request to review additional information (e.g., case report forms, informed consent forms, study budget etc.).

3.3 When Departmental Approval is required from a Medical Department or Section Head, the Operational Approval for Research Application Form should be completed and submitted to the applicable party for signature. Information regarding financial impact and compensation may be marked "not applicable," if they do not pertain to a specific Department.

3.4 For research involving *only* the use of health records maintained by Health Information Management Services, only the Director of Health Information Management Services must provide operational approval.

3.5 All required operational approval signatures should be submitted to the Research Approval Coordinator. Scanned signatures are acceptable. Alternate arrangements (e.g., email confirmation from the Department Head) are accepted only when prior arrangements have been made with the Research Approval Coordinator.

3.6 Administrative Department Heads are responsible for communicating with managers within their portfolio regarding departmental approvals that will be or have been granted for research that will impact operations within their units/departments.

3.7 In the event that operational approval is revoked by an Administrative Department Head following initial approval, a letter will be issued by the Research Approval Coordinator indicating that the research activity may not continue until the necessary operational approval is reinstated. Confirmation of reinstated operational approval will be required before applications for annual reapproval will be processed by the Research Ethics Board.

3.8 Signing authority for departmental approval rests with the Director of the unit or program whose patients, facilities, resources, or staff will be utilized in the course of the research. For units or programs without a Director, signing authority rests with the Executive Director of that portfolio. If the Director wishes to designate signing authority to a designee on a permanent basis, this must be communicated to the Director of Research and Performance Support.

3.9 Administrative Department Heads should provide the Director of Research and Performance Support with the names of designees who may provide operational approval for research conducted in the RQHR in the Department Head's absence.

4.0 Insurance

4.1 RQHR employees, including investigators employed by RQHR and their research staff, conducting research as part of their RQHR responsibilities are covered by a combination of Canadian Medical Protective Association (CMPA) protection (for physicians) and RQHR liability insurance.

4.2 University of Regina (U of R), University of Saskatchewan (U of S), and Saskatchewan Polytechnic faculty, students, postdoctoral researchers, and research staff conducting research in the RQHR under the auspices of their institution (e.g., U of S faculty conducting research that is funded through a U of S account and/or where the U of S is signatory to a clinical trial agreement or research agreement) are covered by a combination of CMPA protection (for physicians) and their institutional liability insurance.

4.3 Saskatchewan Cancer Agency (SCA) employees, including investigators employed by SCA and their research staff, conducting research as part of their SCA responsibilities are covered by a combination of CMPA protection (for physicians) and SCA liability insurance.

4.4 All physician investigators and their research staff not covered under Section 4.1-4.3 are protected through the investigator's membership in the CMPA when conducting studies within Canada involving patients with medical conditions. The investigator must provide RQHR with documentation of CMPA membership before RQHR operational approval will be granted. The investigator must also show proof within 30 days of membership expiration that the membership is renewed annually. Failure to show proof of renewal will result in revocation of RQHR operational approval.

4.5 Any investigator not covered under Section 4.1-4.3 who is (i) conducting a Phase 0, I, or II clinical trial in a sample of healthy individuals, or (ii) the Principal Investigator on an investigator-initiated study conducted outside of Canada must obtain separate general and medical malpractice liability insurance providing $5,000,000 per occurrence and $5,000,000 total per year. RQHR and the investigator's research staff involved in the study must be included as additional insureds on the policy. The investigator must provide RQHR with documentation of this insurance before RQHR operational approval will be granted. The investigator must also show proof within 30 days of policy expiration that the insurance is renewed annually. Failure to show proof of renewal will result in revocation of RQHR operational approval.

4.6 Faculty, students, post-doctoral researchers, and staff from Canadian post-secondary institutions conducting health systems research not requiring direct patient/client contact (e.g., surveys, health data) in RQHR are covered by their institutional liability insurance.

5.0 Research Contracts and Agreements

5.1 Operational approval will not be granted until all fully executed research contracts have been received by Research and Performance Support. Please refer to the *Procedure for Policy on Externally Funded and/or Sponsored Research* for more information.

6.0 Research Accounts

6.1 If a new research account is required for a research grant or contract, the request for the new account must be submitted to the Research and Performance Support Department on behalf of the awardee. All research grant applications and contracts must be signed by the Director of Research and Performance support and will be forwarded accordingly to the Finance Department for processing. If applicable, the Research Approval Coordinator will not issue a Letter of Operational Approval until a Research Account Application form has been received.

7.0 Granting Approval

7.1 Once all required departmental approvals have been obtained, the proposed study has received approval from the RQHR Research Ethics Board, fully executed copies of all contracts and agreements have been submitted to Research and Performance Support, a Research Account Application form has been submitted, all applicable award notices and No Objection Letters have been received, and proof of insurance has been provided, the Research Approval Coordinator will issue a letter indicating that the project has received operational approval to proceed in the RQHR.

7.2 The letter of "Authorization to Conduct Research" will be issued to the Principal Investigator and copied to the study coordinator, all Department Heads who have granted departmental approval for the research, and the Director of Research and Performance Support.