

Operational Approval for Research	Manual:
	Reference Number: <i>107</i>
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Approving Authority: <i>Keith Dewar</i>	Revision Dates: <i>Date reviewed.</i>
Classification: <i>Governance</i>	
Contact for Interpretation: <i>Director, Research and Performance Support</i>	
Source: <i>Research and Performance Support</i>	

See related policies: The Ethical Conduct of Research and Other Studies Involving Human Participants
Externally Funded and/or Sponsored Research

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

1.0 Policy

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 Research conducted within the RQHR must comply with the following provincial, federal, and international legislation, guidelines, and standards, as applicable:

- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd edition (TCPS 2, 2014);
- Tri-Agency Framework: Responsible Conduct of Research (2011);
- Saskatchewan’s Health Information Protection Act (HIPA, 2003);
- Canada’s Food and Drugs Act and Regulations and Medical Device Regulations;
- Canada’s Narcotic Controlled Drugs and Substances Act and Narcotic Control Regulations;
- International Conference on Harmonization (ICH) Guideline for Good Clinical Practice;
- Canada’s Personal Information Protection and electronic Documents Act (PIPEDA);

- Saskatchewan’s Occupational Health and Safety provincial legislation;
- RQHR’s Living Our Values: Healthy People, Families, and Communities; and
- Any code of ethics endorsed by the researcher’s professional licensing body or association.

2.0 Purpose

- 2.1 To ensure that no research using RQHR or affiliated resources or patients occurs without the prior knowledge and approval of the appropriate authorities.
- 2.2 To ensure that all research occurring within the RQHR meets the requirements of the applicable policies, legislation, and guidelines for conducting responsible research.

3.0 Responsibilities

- 3.1 Region personnel will inform Research and Performance Support at the RQHR of any research activities or research collaborations with internal or external partners which involve RQHR resources or facilities.
- 3.2 Region personnel who wish to conduct research within the RQHR must apply for Operational Approval according to the associated “*Procedures for Policy on Operational Approval for Research.*”
- 3.3 The RQHR researcher must seek to obtain the written permission of the senior administrator for his/her unit for any research-related study proposed by him/her or proposed by a student working under his/her direction that could be defined as research. This permission must be obtained before any research-related activities commence.
- 3.4. The Department of Research and Performance Support will review all requests for Operational Approval of Research and will issue a letter of “Authorization to Conduct Research” when approval has been granted.

4.0 Definitions

- 4.1 **Administrative Department Head:** The Director or, when a Director has not been appointed, the Executive Director, who oversees the operations of a program, department, or affiliate within the Regina Qu’Appelle Health Region (RQHR).
- 4.2 **Affiliate:** An individual who is the operator of a not-for-profit special care home or a hospital that was approved or licensed prior to *The Regional Health Services Act* of Saskatchewan came into force, as well as successors to that operator (Government of Saskatchewan, 2002).
- 4.3 **Departmental Approval:** Written confirmation from an Administrative Department Head whose operations will be affected by the conduct of the

research. Departmental approval signifies that the Administrative Department Head accepts the impact (clinical, financial, or otherwise) of the proposed study on his or her department, division, or program, and that he or she agrees with the costs itemized in the study budget.

- 4.4 Medical Department Head:** A physician appointed to oversee the clinical operations of a medical department in the RQHR.
- 4.5 Principal Investigator (PI):** The Principal Investigator is the RQHR researcher who is deemed to have overall accountability for the research conducted at an RQHR site, despite who is the awardee of a sponsored research agreement (whether a grant or a contract). The Principal Investigator is always considered the supervisor of the research team.
- 4.6 Research:** An investigation conducted through a disciplined inquiry or systematic investigation for the purposes of contributing to or developing generalizable knowledge (Department of Health and Human Services, 2009, Title 45 Section 46.102; TCPS 2, 2014, p. 15).
- 4.7 Research Activity:** research, scholarship, and/or creative activity carried out in the course of work or training in the RQHR. This may include any of the following: written material, laboratory work, computer work, coding, research materials, research results, oral reports, presentations, or reporting.
- 4.8 Research Associate:** An individual who is external to the Regina Qu'Appelle Health Region who has been granted permission to be a Principal Investigator on research conducted within the RQHR. Research Associate appointments are made by the Vice President of Knowledge and Technology Services and the Director of Research and Performance Support.
- 4.9 Research Ethics Board (REB):** "A body of researchers, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices" (TCPS 2, 2014, p. 196).
- 4.10 RQHR Personnel:** any person employed, training, teaching, or using RQHR resources or facilities, including but not limited to:
- a) RQHR employees;
 - b) practitioner staff;
 - c) contractors;
 - d) students;
 - e) residents;
 - f) volunteers; and
 - g) RQHR research associates
- 4.12 RQHR Resources and Facilities:** include, but are not limited to: physical structures, laboratories, capital equipment, human biological materials, personal health information, services, and personnel.

5.0 Revision History

This is a new policy.