The Ethical Conduct of Research and Other Studies Involving Human Participants	Manual: Reference Number: *103*
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Classification: *Governance*	
Contact for Interpretation: *Director, Research and Performance Support*	
Source: Research and Performance Support	

See related policies:
Conflict of Interest
Scholarly Integrity
Intellectual Property
Operational Approval for Research
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 Conflict of Interest
Procedure for Policy on Scholarly Integrity
Procedure for Policy on Intellectual Property
Procedure for Policy on Operational Approval for Research
Procedure for Policy on Externally Funded and/or Sponsored Research

1. Policy

1.1 Requirement for Research Ethics Approval

Projects meeting any of the following criteria are deemed research and are subject to this policy:

a) All projects meeting the definition of research as defined in this policy.
b) Projects receiving any form of external funding (e.g., CIHR, industry sponsors, non-profit agencies, grants in aid) when such financing is awarded to support research.
c) Quality assurance, quality improvement, and program evaluation activities when undertaken in fulfillment of student or resident training requirements for research.
d) Case studies involving three or more participants undertaken for investigational purposes (e.g., publication in a scientific journal, presentation at a conference).

e) Case studies involving one or two participants do not require approval from the REB; however, when such case studies are conducted as part of a student project, consultation with Research and Performance Support to determine the need for ethics approval is required.

1.2 Non-Research Activities Exempted from this Policy

Program evaluation, quality improvement, or quality assurance initiatives, **when used exclusively for assessment, management, or improvement purposes within the RQHR**, would typically fall outside the scope of this policy (notwithstanding Section 1.1) and would not require REB approval.

1.3 Requirement for Operational Approval

All Principal Investigators conducting research involving human participants within and/or under the auspices of the RQHR or its Affiliates require a letter of RQHR "Authorization to Conduct Research." See the related Policy and Procedure for Operational Approval for Research.

1.4 Research Requiring Executive Authorization

Special authorization will be required from the Vice-President, Knowledge and Technology Services or designate, to conduct research projects that are outside the criteria for RQHR research projects. The following types of research will not normally be carried out within the RQHR or its Affiliates and would require special authorization:

a) research involving animals;
b) research involving biohazardous substances other than approved radioisotopes; and/or
c) research in which an intention to fully publish the results is prohibited in a contractual agreement with the sponsor/collaborator.

1.5 Principal Investigator Affiliation with RQHR

All research activities require that the Principal Investigator hold an RQHR staff, physician, or Research Associate appointment. Individuals who do not have an RQHR affiliation should follow the procedures in the RQHR *Procedure for Policy on Operational Approval for Research* in order to become a Research Associate.

1.5.1. Any exception to this prerequisite will require the authorization of the Vice President, Knowledge and Technology Services.

1.5.2. Sub-investigators and research staff (paid or unpaid) who do not have an RQHR staff or physician appointment and who will have direct contact with participants and/or access to **directly identifying** personal health information must sign a confidentiality form, to be submitted to the Research Ethics Board Chair, prior to receiving research ethics approval and/or accessing the data. This form is not

required when the individual will have access to anonymous, anonymized, or coded information only (as long as the individual does not have access to the list linking the code to identifying information).

1.6 Relevant Legislation, Guidelines, and Standards

Research conducted within the RQHR must comply with, but is not limited to, 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);
- The Local Authority Freedom of Information and Protection of Privacy Act (LA FOIP)
- 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 Harmonisation (ICH) Guideline for Good Clinical Practice (ICH-GCP);
- 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.

1.7 Compensation of Principal Investigators

Principal Investigators may be compensated for the performance of services in direct connection with a research contract, as long as such compensation does not contravene the RQHR *Policy on Conflict of Interest* or the terms of their research funding.

1.8 Audits of Research

1.8.1. The Director of Research and Performance Support, Chair of the RQHR Research Ethics Board, and/or their designees reserve the right to audit any research conducted within and/or under the auspices of the RQHR, randomly or for cause. RQHR shall investigate any allegation of research misconduct in a timely, impartial, and accountable manner and take appropriate action upon finding that misconduct has occurred, in accordance with the RQHR *Policy on Scholarly Integrity*.

1.8.2. When the Principal Investigator responsible for a study that involves RQHR or Affiliate facilities, resources, patients, long-term care residents, or staff is informed that the study is to be audited by a regulatory agency (e.g., Health Canada, US Food and Drug Administration), the Principal Investigator must promptly notify the Director of Research and Performance Support. After the audit is completed, the Principal Investigator must provide audit results to the Director of Research and Performance Support.

2. Purpose

2.1 The purpose of this policy is to establish the requirements for ethical approval and the ethical conduct of research in the RQHR and its Affiliates. Ethical approval by the RQHR Research Ethics Board ensures that generally accepted ethical guidelines (e.g. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd edition (TCPS 2, 2014); Tri-Agency Framework: Responsible Conduct of Research (2011); and International Conference on Harmonisation (ICH) Guideline for Good Clinical Practice (ICH-GCP)) are met and followed.

2.2 This policy applies to all persons carrying out research-related activities involving human participants within the RQHR or its Affiliates, including research involving:

a) current or former patients, clients, long-term care residents, and/or their personal health information;
b) human biological materials;
c) staff; and/or
d) use of RQHR or Affiliate resources (including, but not limited to, human resources, equipment, facilities, and data).

3. Responsibilities

Principal Investigators are responsible for:

3.1 Ensuring that all required ethics and operational approvals have been obtained prior to commencing any research activities;

3.2 Having all clinical trial agreements, clinical research contracts, confidentiality/non-disclosure agreements, material transfer agreements, data access agreements, and/or any other research-related contracts undergo review by the Director of Research and Performance Support before they are signed;

3.3 Ensuring that they, their sub-investigators, and their research staff (paid or unpaid):

3.3.1 adhere to the ethical guidelines and regulations named in this policy;

3.3.2 are insured against research-related liability (as described in the Procedure for Policy on Operational Approval for Research); and

3.3.3 have the proper education, training, and experience to assume responsibility for a research study.

3.4 If they conduct prospective studies involving patients, ensuring that they, and those to whom they have delegated responsibility for those prospective studies (e.g., sub-investigators, study coordinator), have completed and received certification of training in Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd edition (TCPS 2, 2014);

3.5 If they conduct clinical trials, ensuring that they, and those to whom they have delegated responsibility for those clinical trials (e.g., sub-investigators, study coordinators), have completed and received certification of training in Good Clinical Practice (GCP) and "Health Canada Division 5 – Drugs for Clinical Trials Involving Human Subjects" (in addition to TCPS 2);

3.6 Compensating RQHR for all research-specific costs that were agreed to when departmental and operational approvals were obtained;

3.7 The research-related activities carried out by their sub-investigators and research staff (paid or unpaid) including but not limited to: study development, recruitment, consent procedures, data collection, analysis, reporting, data storage, data transmission, and final disposition of data; and

3.8 Acknowledging the contributions of the RQHR in all presentations and publications arising from the research in which the RQHR made a donation in kind (e.g., time, resources, equipment, and staff).

4. 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 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 Anonymized Data: "The information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low" (TCPS 2, 2014, p. 57).

4.4 Anonymous Data: "The information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low" (TCPS 2, 2014, p. 57).

4.5 Clinical Trial: A research investigation involving human participants, biomedical or behavioural, which may or may not be subject to Health Canada regulation, in which participants are prospectively assigned to one or more conditions in order to study the health-related outcomes. Clinical trials may include research designed to:

- study a drug's or natural health product's effects on the human body (pharmacodynamics);
- study the body's effects on a drug or natural health product, including how it is absorbed, distributed, metabolized, and/or excreted (pharmacokinetics); and/or
- investigate the safety and/or efficacy of a biomedical (e.g., drug, medical device, natural health product) or behavioural intervention (Health Canada, 2013; World Health Organization, n.d.).

4.6 Coded Information: "Direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the Principal Investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary)" (TCPS 2, 2014, p. 57).

4.7 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.

4.8 Directly Identifying Information: "The information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number)" (TCPS 2, 2014, p. 56).

4.9 Good Clinical Practice (GCP): "A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial [participants] are protected" (Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997; p. 5).

4.10 Indirectly Identifying Information: "The information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic)" (TCPS 2, 2014, p. 56).

4.11 Medical Department Head: A physician appointed to oversee the clinical operations of a medical department in the RQHR.

4.12 Operational Approval: Written confirmation in the form of a letter of "Authorization to Conduct Research" from the RQHR Research Approval Coordinator signifying that all necessary departmental approvals and, if applicable, additional Medical/Section Head approvals have been obtained and that the research is authorized to be conducted in the RQHR. Operational approval will not be granted until the study has been approved by the RQHR Research Ethics Board and all conditions according to the related Policy and Procedure for Operational Approval for Research have been met.

4.13 Personal Health Information: As defined in *The Health Information Protection Act*, any information pertaining to the physical or mental health of an individual; any health services he or she has received; and/or biologic material tested, collected, or donated. This includes not only information collected directly during the course of providing health services, but also incidentally collected information and information obtained during registration (Government of Saskatchewan, 2003).

4.14 Principal Investigator (PI): The researcher who assumes primary responsibility for the conduct of a study. For multi-site studies, there may be a study Principal Investigator who oversees the entire study as well as a local Principal Investigator who oversees the conduct of the study at his or her site.

4.15 Program Evaluation: "The systematic collection and analysis of information about program activities, characteristics, and outcomes to make judgments about the program, improve program effectiveness, and/or inform decisions about future programming" (ARECCI Glossary, n.d., p. 2).

4.16 Quality Assurance: "A process in which the activities of an organization and/or program are systematically monitored and evaluated to determine the effectiveness and efficiency of care and service provided. Quality Assurance can identify trends and issues through the systematic monitoring that lead to the development of Quality Improvement projects" (ARECCI Glossary, n.d., p. 3).

4.17 Quality Improvement: "Projects that apply scientific methods, project management and group process tools to analyze data and improve all aspects of service delivery with particular focus on eliminating waste, reducing variation, and improving reliability" (ARECCI Glossary, n.d., p. 3).

4.18 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).

4.19 Research Associate: An individual who is external to the RQHR 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.

4.20 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).

4.21 Section Head: A physician appointed to oversee the clinical operations of a medical section in the RQHR.

4.22 Sponsor: Refers to an individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a study. For unfunded/investigator-initiated projects, the sponsor could be the principal/qualified investigator. For clinical trials, the sponsor is usually responsible for applying for regulatory approval with the Health Protection and Food Branch of Health Canada.

4.23 Study Coordinator: An individual appointed by the Principal Investigator (PI) to manage the day-to-day operations of a study. The study coordinator may undertake some of the responsibilities of the PI as described in this policy, such as coordinating departmental approvals. Ultimately, however, responsibility for all study activities rests with the PI.

4.24 Sub-investigator: Any member of the research team designated and supervised by the Principal Investigator to perform critical study-related procedures and/or to make important study-related decisions (Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997; p. 10).

4.25 Volunteer: An individual who contributes to the conduct of research in the RQHR (e.g., data collection, study coordination, transcription) who is not financially remunerated and who is not conducting these research activities as part of a student or residency requirement for research.

5.0 Revision History

This policy supersedes RHD Policy 3.11.1 titled *Research Involving Human Subjects*.