Research Policies & Procedures

Effective January 1, 2017

Regina Qu'Appelle
HEALTH REGION

What are the new policies/procedures?

1. Ethical Conduct of Research and Other Studies Involving Human Participants
2. Operational Approval for Research
3. Scholarly Integrity
4. Intellectual Property
5. Data Storage and Retention
6. Externally Funded and/or Sponsored Research
7. Indirect Costs of Research

1. The Ethical Conduct of Research and Other Studies Involving Human Participants

Supersedes RHD Policy 3.11.1: "*Research Involving Human Subjects*"

Research is defined as:

"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)

Applicable to research involving:

- Current or former patients, clients, long-term care residents, and/or their personal health information
- Human biological materials
- Staff
- Use of RQHR or Affiliate resources

The following require Research Ethics approval:

1. Projects meeting definition of research
2. Projects receiving external funding to support research
3. Quality assurance, quality improvement, and program evaluation performed by student or resident when undertaken in fulfillment of student or resident training requirements for research
4. Case studies involving three or more participants

How to apply for Research Ethics approval:

1. Go to www.rqhr-rps.ca/research-ethics/reb-forms/ to download the appropriate REB Application Form
    a) Application to Access Existing Health Information
    b) Application for Biomedical Research Ethics Review
    c) Application for Behavioral Research Ethics Review

2. Submit the completed application to ResearchEthics@rqhealth.ca. In addition to the application form, the following may also be required:
    a) All applicable recruitment materials
    b) Supporting documentation
    c) All applicable training certificates of completion
    d) CV for Principal Investigator

The policy states that:

- Principal Investigator (PI) must hold an RQHR staff, physician, or Research Associate appointment

- Research must comply with provincial, federal, and international legislation, guidelines, and standards, such as:
  - ✓ Saskatchewan's Health Information Protection Act (HIPA)
  - ✓ Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd edition
  - ✓ International Conference on Harmonization Guideline for Good Clinical Practice (ICH-GCP)

The policy states that:

- PI may be compensated for research, as long as it doesn't contravene RQHR policy on Conflict of Interest or the terms of the research funding

- RQHR designees reserve the right to audit any research conducted within and/or under auspices of RQHR

- PI must inform Research and Performance Support of any external audit taking place

The **fee for ethical review** of industry-sponsored studies is now **$3,500.00**

If the research study is withdrawn or terminated after a review by the Research Ethics Board has taken place, half of the fee will be retained and half will be refunded.

2. Operational Approval for Research

Operational Approval for Research

"Operational Approval" refers to:

The process by which each Department impacted by the research provides their approval for the study to take place. The following considerations are made:

- Is it feasible?
- Do we have the capacity?
- Can we afford it?
- Do we have the personnel?
- Do we have the space?
- Do we have all of the other necessary resources?

The policy states that:

- All research, funded or unfunded, accessing or using RQHR or affiliated resources or patients (including their PHI) requires RQHR Operational Approval

- A letter of "Authorization to Conduct Research" will be issued to alert the PI and all Department Heads and/or Executive Directors impacted by the research that the study has approval to commence in the RQHR

Operational Approval for Research

Letter of Authorization to Conduct Research issued by Research and Performance Support and conditional upon:

- ✓ Completed application form
- ✓ Approval by applicable signatories
- ✓ Research Ethics approval
- ✓ Funding information
- ✓ Finalized research contracts
- ✓ Completed Research Account application form

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Operational Approval for Research

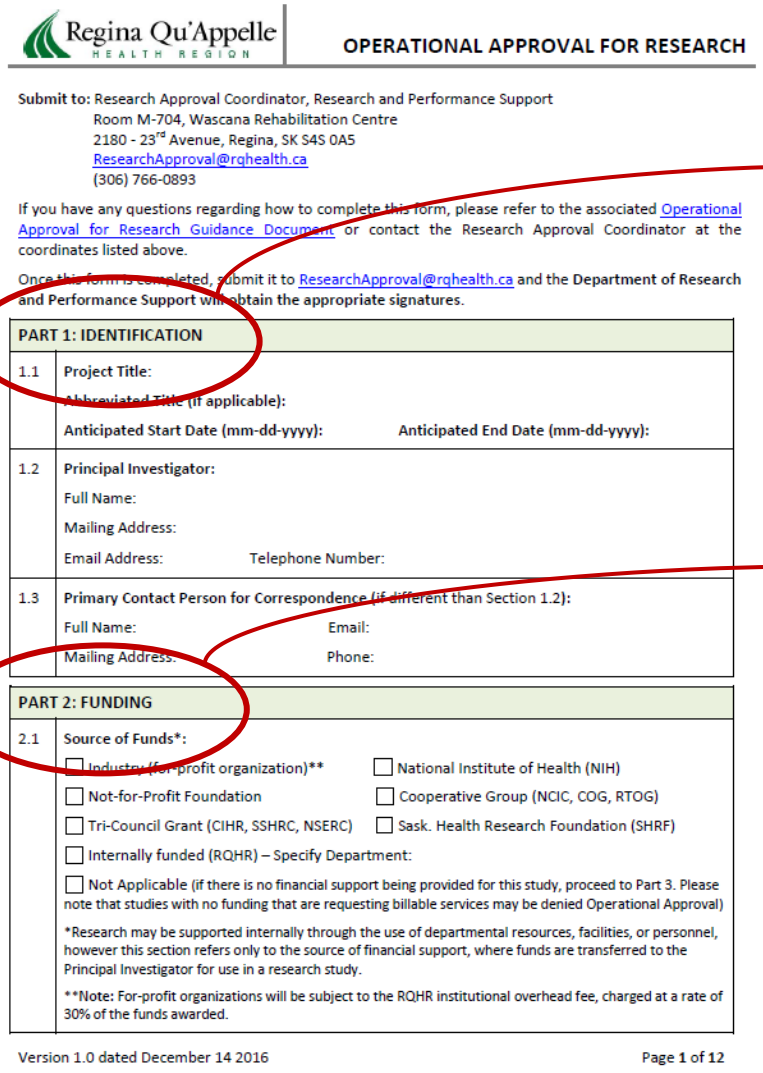
Complete the Operational Approval for Research Application Form

Submit the form to ResearchApproval@rqhealth.ca

Application form will be routed to appropriate departments for signature

Letter of Authorization to Conduct Research will be issued once requirements for Operational Approval are met

Operational Approval for Research



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OPERATIONAL APPROVAL FOR RESEARCH

Submit to: Research Approval Coordinator, Research and Performance Support
Room M-704, Wascana Rehabilitation Centre
2180 - 23rd Avenue, Regina, SK S4S 0A5
ResearchApproval@rqhealth.ca
(306) 766-0893

If you have any questions regarding how to complete this form, please refer to the associated Operational Approval for Research Guidance Document or contact the Research Approval Coordinator at the coordinates listed above.

Once this form is completed, submit it to ResearchApproval@rqhealth.ca and the Department of Research and Performance Support will obtain the appropriate signatures.

PART 1: IDENTIFICATION

1.1 **Project Title:**
Abbreviated Title (if applicable):
Anticipated Start Date (mm-dd-yyyy): **Anticipated End Date (mm-dd-yyyy):**

1.2 **Principal Investigator:**
Full Name:
Mailing Address:
Email Address: Telephone Number:

1.3 **Primary Contact Person for Correspondence (if different than Section 1.2):**
Full Name: Email:
Mailing Address: Phone:

PART 2: FUNDING

2.1 **Source of Funds*:**
☐ Industry (for-profit organization)** ☐ National Institute of Health (NIH)
☐ Not-for-Profit Foundation ☐ Cooperative Group (NCIC, COG, RTOG)
☐ Tri-Council Grant (CIHR, SSHRC, NSERC) ☐ Sask. Health Research Foundation (SHRF)
☐ Internally funded (RQHR) – Specify Department:
☐ Not Applicable (if there is no financial support being provided for this study, proceed to Part 3. Please note that studies with no funding that are requesting billable services may be denied Operational Approval)

*Research may be supported internally through the use of departmental resources, facilities, or personnel, however this section refers only to the source of financial support, where funds are transferred to the Principal Investigator for use in a research study.

**Note: For-profit organizations will be subject to the RQHR institutional overhead fee, charged at a rate of 30% of the funds awarded.

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Part 1: Identification

- Identifies who is responsible for the study
- Allows us to link application to REB file

Part 2: Funding

- Identifies source of funds in order to:
  - Determine applicable fees
  - Assess need for Research Account
  - Determine if appropriate funding is in place to support research

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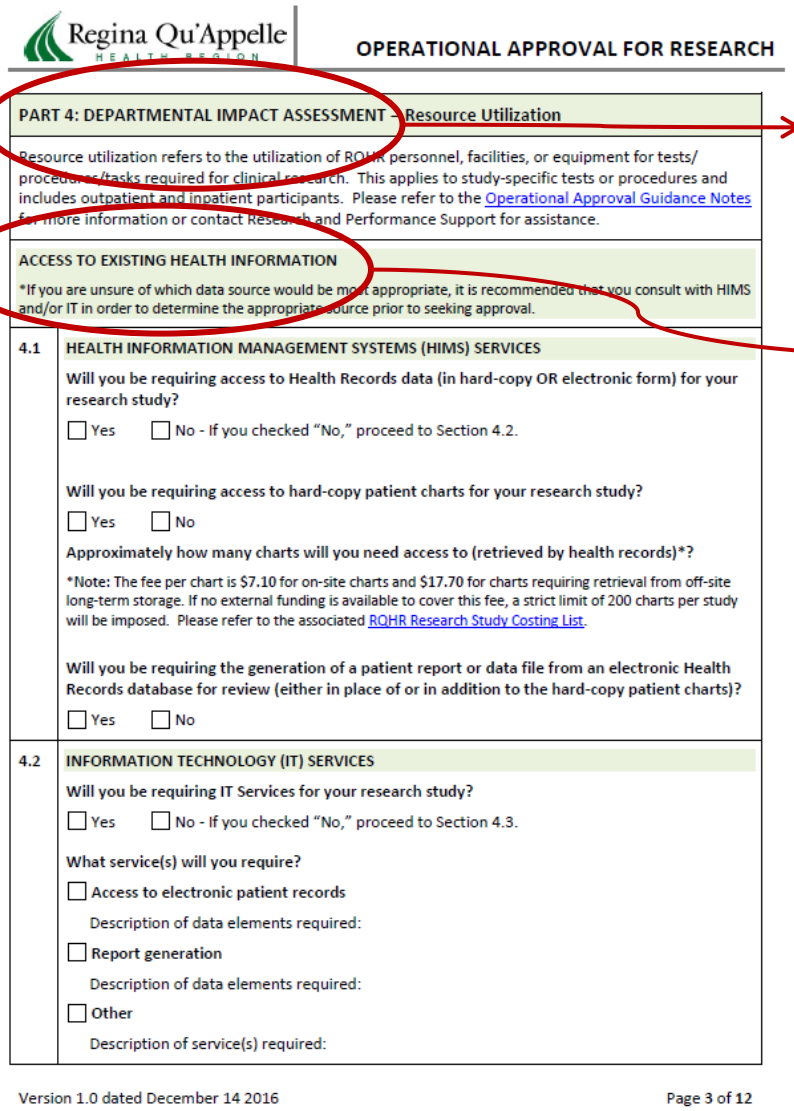
2.2	**Provide name of funding source:**
2.3	**Status of Funds:** ☐ Awarded ☐ Pending *Note: If funds have been awarded, please attach a copy of the Award Letter to this application.
2.4	**Name of Sponsor (if different from funding source in 2.2):**
2.5	**If you are in receipt of funding to support your research, you must open an RQHR Research Account to manage your project funds** (to administer and manage funds through the RQHR). ➢ Please complete a Research Account Application Form and attach it to this application

PART 3: CONTRACTS	
3.1	**Will there be a contract associated with this research project?** ☐ Yes ☐ No If you checked "No," proceed to Part 4.
3.2	**Type of contract (check all that apply):** ☐ Confidential Disclosure Agreement (CDA) / Non-disclosure Agreement (NDA) ☐ Sub-Site Agreement (SSA) ☐ Clinical Trial Agreement (CTA) / Clinical Study Agreement (CSA) ☐ Data Sharing Agreement (DSA) / Data Transfer Agreement (DTA) ☐ Funding Agreement ☐ Other (please specify):
3.3	**If you indicated "yes" to 3.1, please submit the following by email to the Research Contract Specialist (Megan.Vanstone@rqhealth.ca) for legal review and contract negotiation:** ➢ Research Project Title ➢ Contact information for the other party (Principal Investigator/Sponsor and Contracts Office) ➢ https://clinicaltrials.gov/ link or protocol number for study (if applicable) ➢ Draft agreement provided by Sponsor (or indicate that a new agreement must be drafted) **NOTE: MUST BE IN WORD DOCUMENT FORMAT!** (so that changes can be tracked) ➢ Copy of study protocol and/or consent form and all relevant appendices (e.g. study budget)
3.4	**Contract-related comments for consideration:**

Part 3: Contracts

- Identifies need for contract review
- Provides appropriate information to facilitate negotiations

Operational Approval for Research



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OPERATIONAL APPROVAL FOR RESEARCH

PART 4: DEPARTMENTAL IMPACT ASSESSMENT – Resource Utilization

Resource utilization refers to the utilization of RQHR personnel, facilities, or equipment for tests/ procedures/tasks required for clinical research. This applies to study-specific tests or procedures and includes outpatient and inpatient participants. Please refer to the Operational Approval Guidance Notes for more information or contact Research and Performance Support for assistance.

ACCESS TO EXISTING HEALTH INFORMATION

*If you are unsure of which data source would be most appropriate, it is recommended that you consult with HIMS and/or IT in order to determine the appropriate source prior to seeking approval.

4.1 HEALTH INFORMATION MANAGEMENT SYSTEMS (HIMS) SERVICES

Will you be requiring access to Health Records data (in hard-copy OR electronic form) for your research study?

☐ Yes ☐ No - If you checked "No," proceed to Section 4.2.

Will you be requiring access to hard-copy patient charts for your research study?

☐ Yes ☐ No

Approximately how many charts will you need access to (retrieved by health records)*?

*Note: The fee per chart is $7.10 for on-site charts and $17.70 for charts requiring retrieval from off-site long-term storage. If no external funding is available to cover this fee, a strict limit of 200 charts per study will be imposed. Please refer to the associated RQHR Research Study Costing List.

Will you be requiring the generation of a patient report or data file from an electronic Health Records database for review (either in place of or in addition to the hard-copy patient charts)?

☐ Yes ☐ No

4.2 INFORMATION TECHNOLOGY (IT) SERVICES

Will you be requiring IT Services for your research study?

☐ Yes ☐ No - If you checked "No," proceed to Section 4.3.

What service(s) will you require?

☐ **Access to electronic patient records**

Description of data elements required:

☐ **Report generation**

Description of data elements required:

☐ **Other**

Description of service(s) required:

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Part 4: Departmental Impact Assessment

- Disclosure of resource utilization (services required)

❑ Access to existing health information

- Health Information Management Systems (HIMS) – Hard-copy health records
- Information Technology (IT) – Electronic patient records (SCM, EBM, etc.)

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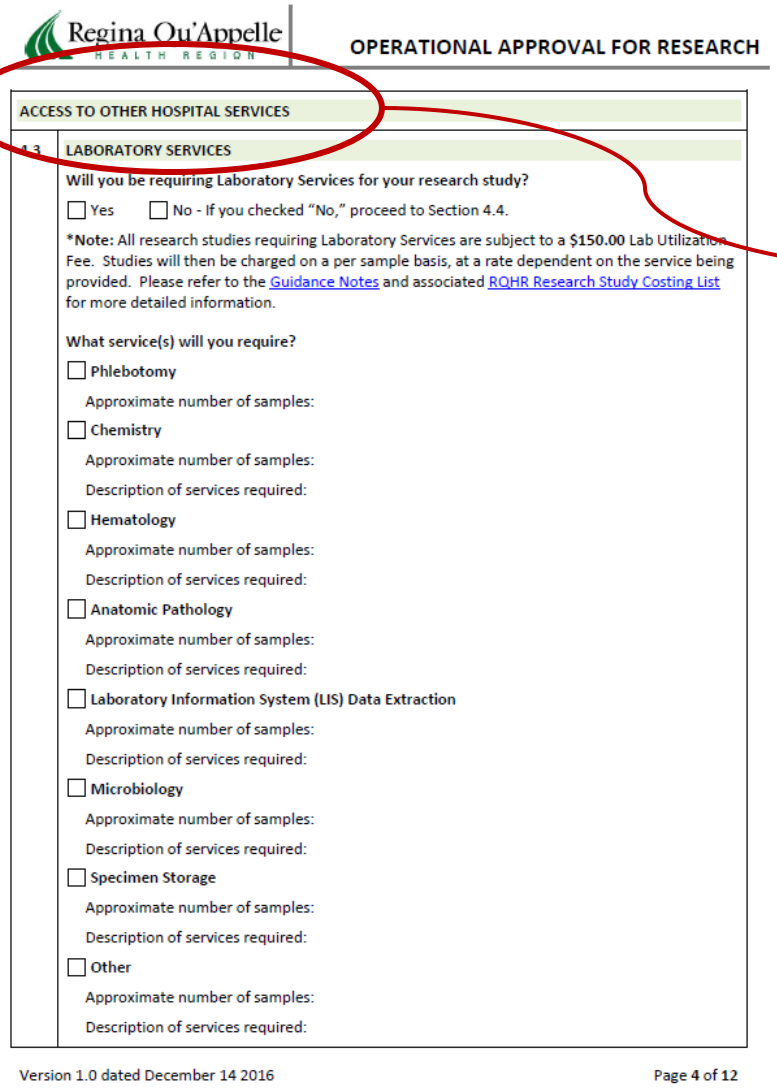

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ACCESS TO OTHER HOSPITAL SERVICES

4.3 LABORATORY SERVICES

Will you be requiring Laboratory Services for your research study?

☐ Yes ☐ No - If you checked "No," proceed to Section 4.4.

*Note: All research studies requiring Laboratory Services are subject to a $150.00 Lab Utilization Fee. Studies will then be charged on a per sample basis, at a rate dependent on the service being provided. Please refer to the Guidance Notes and associated RQHR Research Study Costing List for more detailed information.

What service(s) will you require?

☐ Phlebotomy
Approximate number of samples:

☐ Chemistry
Approximate number of samples:
Description of services required:

☐ Hematology
Approximate number of samples:
Description of services required:

☐ Anatomic Pathology
Approximate number of samples:
Description of services required:

☐ Laboratory Information System (LIS) Data Extraction
Approximate number of samples:
Description of services required:

☐ Microbiology
Approximate number of samples:
Description of services required:

☐ Specimen Storage
Approximate number of samples:
Description of services required:

☐ Other
Approximate number of samples:
Description of services required:

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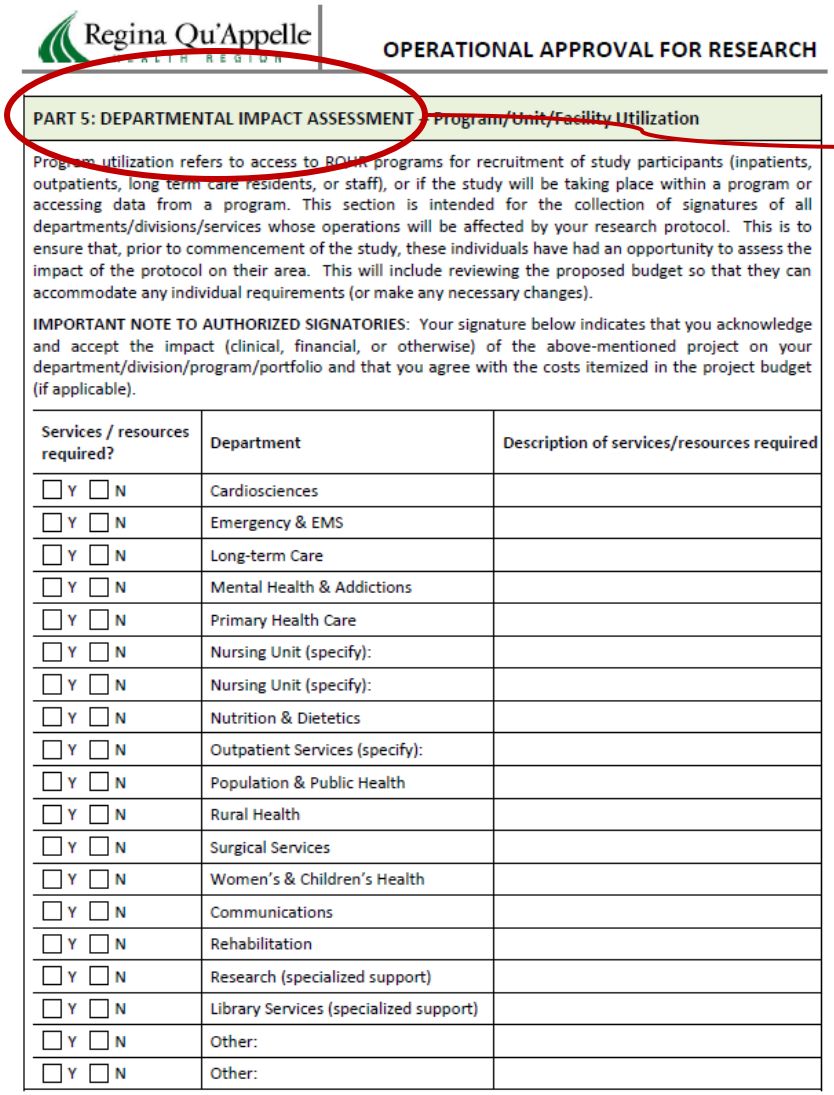
Part 4: Departmental Impact Assessment

- Disclosure of resource utilization (services required)

❑ Access to Other Hospital Services

- Laboratory Services – phlebotomy, chemistry, hematology, LIS data extraction, etc.
- Medical Imaging and Nuclear Medicine Services – X-ray, MRI, CT scan, etc.
- Pharmacy Services – dispensing study drug, maintaining/storing study drug, randomization, etc.
- Ambulatory or Other Diagnostic Services – ECG, ECHO, EEG, etc.

Operational Approval for Research



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OPERATIONAL APPROVAL FOR RESEARCH

PART 5: DEPARTMENTAL IMPACT ASSESSMENT – Program/Unit/Facility Utilization

Program utilization refers to access to RQHR programs for recruitment of study participants (inpatients, outpatients, long term care residents, or staff), or if the study will be taking place within a program or accessing data from a program. This section is intended for the collection of signatures of all departments/divisions/services whose operations will be affected by your research protocol. This is to ensure that, prior to commencement of the study, these individuals have had an opportunity to assess the impact of the protocol on their area. This will include reviewing the proposed budget so that they can accommodate any individual requirements (or make any necessary changes).

IMPORTANT NOTE TO AUTHORIZED SIGNATORIES: Your signature below indicates that you acknowledge and accept the impact (clinical, financial, or otherwise) of the above-mentioned project on your department/division/program/portfolio and that you agree with the costs itemized in the project budget (if applicable).

Services / resources required?	Department	Description of services/resources required
☐ Y ☐ N	Cardiosciences	
☐ Y ☐ N	Emergency & EMS	
☐ Y ☐ N	Long-term Care	
☐ Y ☐ N	Mental Health & Addictions	
☐ Y ☐ N	Primary Health Care	
☐ Y ☐ N	Nursing Unit (specify):	
☐ Y ☐ N	Nursing Unit (specify):	
☐ Y ☐ N	Nutrition & Dietetics	
☐ Y ☐ N	Outpatient Services (specify):	
☐ Y ☐ N	Population & Public Health	
☐ Y ☐ N	Rural Health	
☐ Y ☐ N	Surgical Services	
☐ Y ☐ N	Women's & Children's Health	
☐ Y ☐ N	Communications	
☐ Y ☐ N	Rehabilitation	
☐ Y ☐ N	Research (specialized support)	
☐ Y ☐ N	Library Services (specialized support)	
☐ Y ☐ N	Other:	
☐ Y ☐ N	Other:	

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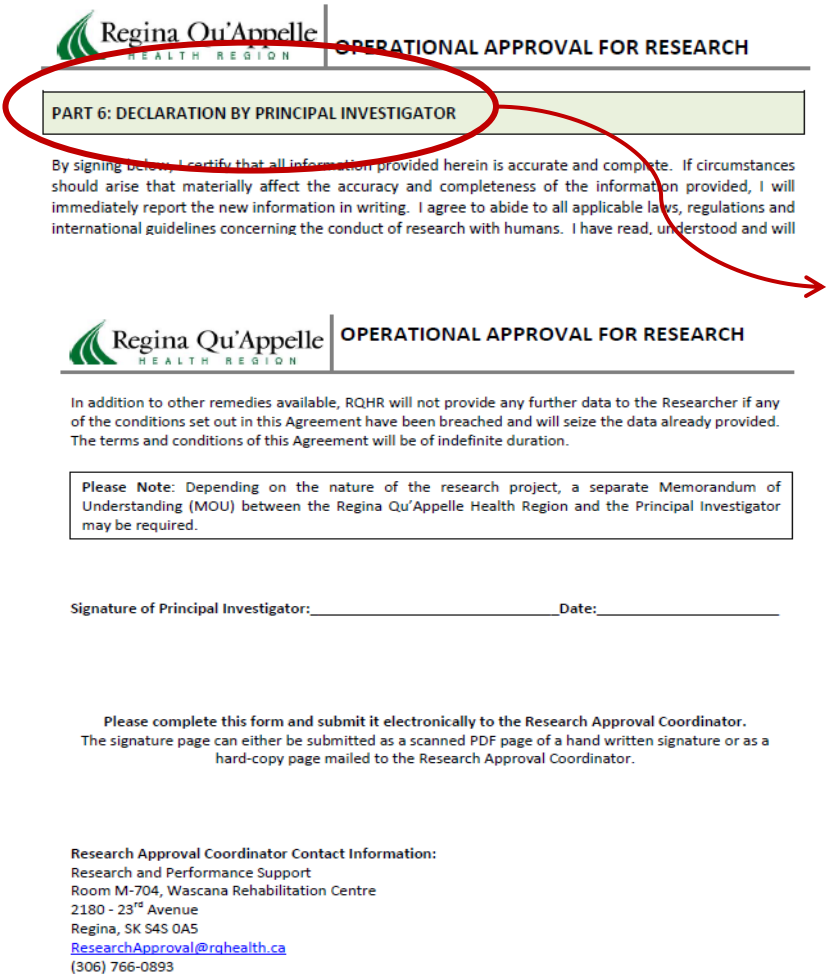
Part 5: Departmental Impact Assessment

- Disclosure of program/unit/facility utilization
  - ❑ Access to RQHR programs for recruitment of study participants
  - ❑ Access to data from a program
  - ❑ Access to space within a department
  - ❑ Assistance from clinical staff to facilitate research

Operational Approval for Research



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OPERATIONAL APPROVAL FOR RESEARCH

PART 6: DECLARATION BY PRINCIPAL INVESTIGATOR

By signing below, I certify that all information provided herein is accurate and complete. If circumstances should arise that materially affect the accuracy and completeness of the information provided, I will immediately report the new information in writing. I agree to abide to all applicable laws, regulations and international guidelines concerning the conduct of research with humans. I have read, understood and will

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In addition to other remedies available, RQHR will not provide any further data to the Researcher if any of the conditions set out in this Agreement have been breached and will seize the data already provided. The terms and conditions of this Agreement will be of indefinite duration.

Please Note: Depending on the nature of the research project, a separate Memorandum of Understanding (MOU) between the Regina Qu'Appelle Health Region and the Principal Investigator may be required.

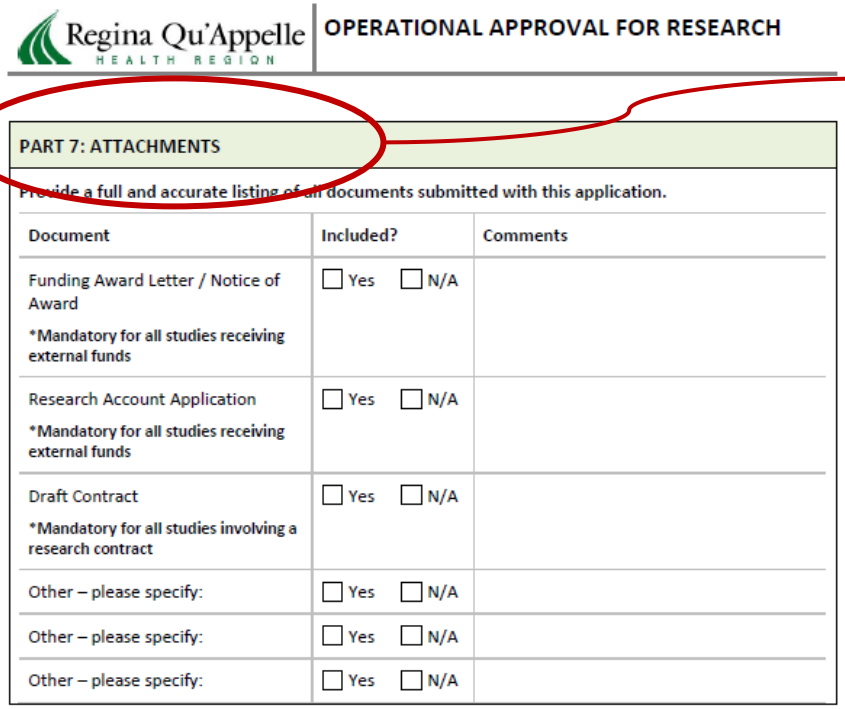
Signature of Principal Investigator:_____ **Date:**_____

Please complete this form and submit it electronically to the Research Approval Coordinator.
The signature page can either be submitted as a scanned PDF page of a hand written signature or as a hard-copy page mailed to the Research Approval Coordinator.

Research Approval Coordinator Contact Information:
Research and Performance Support
Room M-704, Wascana Rehabilitation Centre
2180 - 23rd Avenue
Regina, SK S4S 0A5
ResearchApproval@rqhealth.ca
(306) 766-0893

Part 6: Declaration by Principal Investigator

- Privacy and confidential information disclosure



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PART 7: ATTACHMENTS

Provide a full and accurate listing of all documents submitted with this application.

Document	Included?	Comments
Funding Award Letter / Notice of Award *Mandatory for all studies receiving external funds	☐ Yes ☐ N/A	
Research Account Application *Mandatory for all studies receiving external funds	☐ Yes ☐ N/A	
Draft Contract *Mandatory for all studies involving a research contract	☐ Yes ☐ N/A	
Other – please specify:	☐ Yes ☐ N/A	
Other – please specify:	☐ Yes ☐ N/A	
Other – please specify:	☐ Yes ☐ N/A	

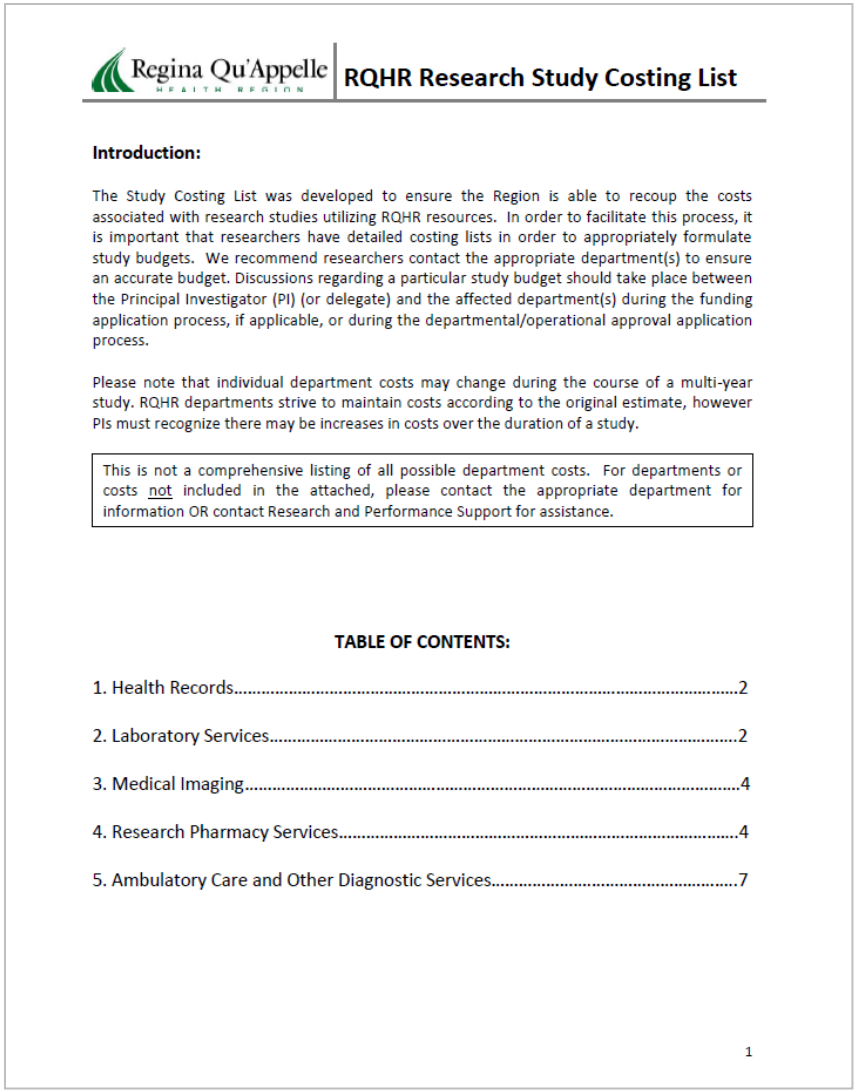
Part 7: Attachments

- Include any additional documentation required for the complete review of your application:
  - ❑ Funding award letter
  - ❑ Research Account Application form
  - ❑ Contract requiring review
  - ❑ REB approval from another institution
  - ❑ Study budget
  - ❑ Health Canada No Objection Letter
  - ❑ Proof of insurance

Operational Approval for Research

A costing list for standard research procedures/services has been developed and a centralized invoicing process for study-related expenses will be implemented

Available at http://www.rqhr-rps.ca/.



Regina Qu'Appelle HEALTH REGION

RQHR Research Study Costing List

Introduction:

The Study Costing List was developed to ensure the Region is able to recoup the costs associated with research studies utilizing RQHR resources. In order to facilitate this process, it is important that researchers have detailed costing lists in order to appropriately formulate study budgets. We recommend researchers contact the appropriate department(s) to ensure an accurate budget. Discussions regarding a particular study budget should take place between the Principal Investigator (PI) (or delegate) and the affected department(s) during the funding application process, if applicable, or during the departmental/operational approval application process.

Please note that individual department costs may change during the course of a multi-year study. RQHR departments strive to maintain costs according to the original estimate, however PIs must recognize there may be increases in costs over the duration of a study.

This is not a comprehensive listing of all possible department costs. For departments or costs not included in the attached, please contact the appropriate department for information OR contact Research and Performance Support for assistance.

TABLE OF CONTENTS:

1

3. Scholarly Integrity

The policy states that:

- Any fabrication, falsification, destruction of research records, plagiarism, invalid authorship, inadequate acknowledgement, mismanagement of conflict of interest, failure to comply with relevant policies, misrepresentation in a funding application, and/or mismanagement of funds will be considered a breach of Scholarly Integrity

- Allegations of misconduct will be investigated

Examples of misconduct:

- Conducting research prior to obtaining necessary approvals (REB, operational, contractual, etc.)
- Performing research activities that deviate from the approved protocol
- Manipulating (or omitting) data to reach a desired result
- Failing to acknowledge a collaborator or member of the research team, funding agency, or the RQHR for their contributions to the research
- Invalid authorship (not reflective of contributions)
  - Recommended guidelines: the International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals
- Failing to properly maintain, store, or retain research data

Potential consequences of misconduct:

- Withdrawing relevant publications;
- Notifying publishers of publications in which the involved research was reported;
- Notifying co-investigators, collaborators, students, and other project personnel of the decision;
- Ensuring the unit(s) involved is informed of appropriate practices for promoting the proper conduct of research;
- Informing any outside funding sponsor(s) of the results of the inquiry and of actions to be taken; and/or
- Preventing any future participation in research.

How do I report a suspected breach?

- Notify a Senior Administrator of the RQHR (your Manager, department's Director, Executive Director, etc.)
- It is the responsibility of the Senior Administrator to notify the Director of Research and Performance Support of the allegation, who will then perform an assessment and determine course of action (investigation, hearing, informal resolution)

4. Intellectual Property

What is Intellectual Property?

- "Creations of Mind" including, but not limited to:
  - Manuscripts
  - Inventions
  - Surveys

- Something that may involve a patent, copyright, trademark, etc.

Intellectual Property

The policy states that:

The RQHR retains all intellectual property rights for any research or innovation created or developed through the use of RQHR facilities or resources, unless otherwise agreed to on a case by case basis.

5. Data Storage and Retention

What is a "data"?

- Any information collected in the process of conducting the research protocol

What is a "research record"?

- Any documents and other records and materials recorded by or for an investigator that are necessary to document, reconstruct, evaluate, and validate research results and the events and processes leading to the acquisition of those results.
  - Survey documents/questionnaires/interview notes/transcripts
  - Recruitment materials/data
  - Project-related correspondence

Data Storage and Retention

Research records must be:

- Documented appropriately
- Archived for defined periods of time
  - 5 years from the date of completion of the study for most research
  - 25 years from the date of completion of the study for clinical trials
- Made available for review if required
  (e.g. for auditing purposes, securing IP, investigating allegations of breaches of policies, assisting/enabling administrative or legal proceedings relating to research)

Data Storage and Retention

PI is responsible for the collection, maintenance, and secure retention of research records in accordance with the associated procedure and applicable privacy legislation

6. Externally Funded and/or Sponsored Research

Externally Funded and/or Sponsored Research

What is "external funding"?

Any source of funds provided by an agency/organization outside of the RQHR.

Examples of funding agencies:

- Publically-funded government agencies
- Not-for-profit organizations
- For-profit organizations
- Private donors

What is a "Sponsor"?

- The entity providing the funds to the RQHR Principal Investigator, directly or indirectly, to conduct research (can also be referred to as the "funding agency," "granting agency," or "contractor").

OR

- In the context of a clinical trial, an individual, institution, company or organization that takes responsibility for initiating, managing, or financing the trial but does not actually conduct the investigation.

The policy states that:

- All externally funded and/or sponsored research taking place under the auspices of the RQHR or its Affiliates must follow all RQHR research policies and procedures
- PI responsible for notifying Research and Performance Support of any externally funded and/or sponsored research projects
- PI assumes responsibility for all sub-investigators involved in research-related activities
- Reasonable efforts should be made to ensure that results of RQHR research is made public

Research Accounts

- All RQHR researchers in receipt of funds for conducting research must hold their funds in a RQHR research account

- All cheques sent to RQHR researchers for RQHR research must be made payable to the "Regina Qu'Appelle Health Region."

- Cheques received by RQHR awardees or departments must be forwarded to Research and Performance Support for deposit to the appropriate RQHR account

Externally Funded and/or Sponsored Research

One complete copy of the application for external funds from a granting agency must be provided to Research and Performance Support

All RQHR researchers who receive awards to be administered through the RQHR must notify Research and Performance Support by providing the office with a copy of the award notice/letter

Externally Funded and/or Sponsored Research

All research-related contracts **MUST** be submitted to Research and Performance Support for review and negotiation

In most cases, the Sponsor (or collaborating Institution), RQHR, and the researcher are separate parties to any research agreements

The RQHR signatory for any research-related contract is the Director or Research and Performance Support

7. Indirect Costs of Research

What are "indirect costs" of research?

The costs incurred by an organization to support a research infrastructure. Includes (but is not limited to):

- Insurance
- Legal costs
- Financial services
- Monitoring regulatory compliance

Indirect Costs of Research

The policy states that:

- A recovery charge (institutional overhead) for indirect costs is applied to eligible research grants and service contracts

- A **rate of 30% of total direct costs** will be recovered from the following funding sources:
  - Research and service contracts and grants from for-profit business and industry;
  - Federal government contracts, when permitted;
  - Provincial government contracts, when permitted; and
  - Any external source of research funding, when permitted.

Indirect Costs of Research

Research funded by private donations, not-for-profit organizations, or Tri-Council Agencies are exempt from overhead fees

Building the overhead rate into study budgets is the responsibility of the PI and is essential to ensure that indirect costs recovery does not affect your study funds

*It is highly recommended that RQHR researchers seek assistance with this from Research and Performance Support

Where Can I Find Out More?

- http://www.rqhr-rps.ca/
- Through the RQHR intranet, "policies" page: http://rhdintranet/rqhr/policies.htm

Questions?

- ResearchApproval@rqhealth.ca
- ResearchEthics@rqhealth.ca
- Research&Performance@rqhealth.ca