Procedure for Policy on Externally Funded and/or Sponsored Research	Manual: Reference Number: *104-1*
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See related policies:
Externally Funded and/or Sponsored Research
Operational Approval for Research
Conflict of Interest
Intellectual Property
Scholarly Integrity
Indirect Costs of Research
The Ethical Conduct of Research and Other Studies Involving Human Participants
Privacy and Confidentiality
Department of Finance Policies

See related procedures:
Procedure for Policy on Operational Approval for Research
Procedure for Policy on Indirect Costs of Research
Department of Finance Procedures

Procedure

1.0 Procedures Specific to Investigator-Initiated Externally-Funded Research

1.1 Research Grant Applications and Funds Received

The following procedures apply to:

a. every new application for funding for research-related activities;
b. requests for renewal/supplementation of funding to existing projects; and
c. letters of intent relating to requests for funding.

1.1.1 Required Signatures for Applications

The following procedure applies whether the RQHR researcher applying for funding is the Principal Investigator or a Sub-Investigator.

(i) Every application for funds from an external non-profit source (e.g., federal granting agency) shall be signed in the following order: applicant, Departmental Executive Director or designate (if applicable), RQHR Director of Research and Performance Support.

(ii) The Principal Investigator, Co-Principal Investigator(s), or Sub-Investigator(s), as applicable, must ensure that the required signatures are obtained prior to submitting the application to the granting agency (see 1.1.2). The signatures affirm that:

- the applicant is eligible to apply;
- the information in the application is complete and accurate to the best knowledge of the applicant;
- the applicant has sufficient time, potential participants, space, and resources to conduct the proposed research;
- if an award is granted, RQHR is able and willing to administer the funds on behalf of the granting agency in accordance with the guidelines of the granting agency;
- if an award is granted, the awardee agrees to abide by the award regulations as stipulated by the granting agency;
- if an award is granted, RQHR will not release the funding to the awardee until all award conditions of the granting agency and the RQHR have been met, including regulatory requirements;
- if an award is granted, the awardee will use the award only for the purposes outlined in the research funding application; and
- if an award is granted, the awardee will notify Research and Performance Support and the granting agency should there be any change in their status that affects their eligibility for the award.

1.1.2 Copies of Applications

One complete copy of the application for external funds from a granting agency shall be provided to Research and Performance Support, along with the signature page, for final signature. A photocopy of the application and signature page will be filed with Research and Performance Support and the original will be returned to the Principal Investigator for submission to the funding agency. Note that all other required signatures must first be obtained prior to seeking the signature of the Director of Research and Performance Support. Research and Performance Support will make reasonable efforts to return the signed copy to the applicant

within 5 business days from the date of receipt for subsequent submission to the granting agency (note that Investigators must submit all applications for signature a minimum of 5 business days in advance of the application deadline, in order to ensure sufficient time for completion of signatures).

1.1.3 Notification of Research Grants or Donations Received

All RQHR researchers who receive awards to be administered through the RQHR, either in the form of grant funding, in-kind contributions, or unsolicited donations, shall notify Research and Performance Support by providing the office with a copy of the award notice/letter, as well as copies of any other documents concerning the regulations or conditions governing the use of the grant or donated funds.

2.0 Procedures Applicable to all Investigator- and Sponsor-Initiated Externally-Funded Research

2.1 Contracts

2.1.1 Contractual Arrangements

RQHR researchers are able to share their own research expertise and facilities with industry and government, provided that work is not undertaken in competition with the private sector and that all relevant RQHR research policies and procedures are not breached. Contracts which are binding on RQHR shall include terms and conditions that meet RQHR requirements for managing risk and are consistent with RQHR requirements relating to ethical review, privacy, and confidentiality as governed by the RQHR Policies, including *"The Ethical Conduct of Research and Other Studies Involving Human Participants"* and *"Privacy and Confidentiality."* There are several types of contractual arrangements that RQHR will enter into, including but not limited to:

- **Research Contracts**: May be entered into with either an industry or not-for-profit entity, and will specify the terms and conditions under which the RQHR research will be performed.
- **Technical Service Contracts:** For analytical, testing, or other services requiring little intellectual input or value-added by RQHR, and will specify the terms and conditions under which the RQHR research will be performed.

2.1.2 Consulting Arrangements

RQHR will not enter into consulting arrangements, as these are private arrangements between an agency and an individual. An individual in a consulting arrangement may not use RQHR space, equipment, or facilities to conduct the work under the arrangement without a rental agreement with RQHR, may not use RQHR staff during working hours or the RQHR's name in communications regarding the consulting arrangement. An individual in a consulting arrangement is solely responsible for compensating all staff, including RQHR staff, involved in performing services in connection with a consulting arrangement.

2.1.3 Sponsor-Initiated Arrangements

This procedure applies to any Sponsor-initiated agreement between that Sponsor and an RQHR-affiliated Investigator who is conducting the research within the RQHR.

2.1.3.1 Internal Review and Negotiation

If an RQHR researcher receives a contract from a Sponsor:

a. The RQHR researcher must ensure that the contract is sent to Research and Performance Support for review and negotiation. The Principal Investigator and the Regina Qu'Appelle Regional Health Authority (designated as the "Institution") must both be parties to the contract with the Sponsor.
b. The following information must also be provided with the contract at the time of submission: Sponsor contact information; Principal Investigator contact information, and the contact information for any study coordinators managing correspondence; scope of work for the project, including projected start and end dates; and a budget for the project including overhead, if required.
c. All negotiations with the Sponsor will be conducted by Research and Performance Support on behalf of RQHR and recommendations will be made to the Sponsor/Principal Investigator.

2.1.3.2 Execution

a. The contract will be signed by the RQHR Director of Research and Performance Support upon finalization of the terms of the agreement with the Sponsor.
b. The contract will be fully executed once signed by all parties to the agreement, including, but not limited to: RQHR Principal Investigator, RQHR

Director of Research and Performance Support, and the Sponsor for the study.

c. The Principal Investigator must ensure that a copy of the fully executed contract is received by Research and Performance Support. It will be retained for twenty-five years following study closure, in compliance with Health Canada regulations.

2.1.4 Clinical Trial Agreements

This procedure applies to both Industry-Sponsored Clinical Trial Agreements and Investigator-Initiated Clinical Trial Agreements.

2.1.4.1 Internal Review and Negotiation

a. The RQHR researcher must ensure that the Clinical Trial Agreement [CTA/Contract] is sent to Research and Performance Support for review and negotiation. The Sponsor, RQHR, and the RQHR researcher are parties to the CTA.

b. The following information must also be provided with the CTA at the time of submission: Sponsor contact information; Principal Investigator contact information, and the contact information for any study coordinators managing correspondence; a copy of the Informed Consent Form, if available, or a copy of the study protocol; the ClinicalTrials.gov link, if available; and the proposed budget for the study.

c. All negotiations with the industry Sponsor will be conducted by Research and Performance Support on behalf of RQHR and recommendations will be made to the Sponsor/Principal Investigator.

2.1.4.2 Execution

a. The CTA will be signed by the RQHR Director of Research and Performance Support upon finalization of the terms of the agreement with the Sponsor.

b. The CTA will be fully executed once signed by all parties to the agreement, including, but not limited to: RQHR Principal Investigator, RQHR Director of Research and Performance Support, and the Sponsor for the study.

c. The Principal Investigator must ensure that a copy of the fully executed CTA is received by Research

and Performance Support. It will be retained for twenty-five years following study closure, in compliance with Health Canada regulations.

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2.1.5 Research-Related Agreements

The following procedure applies to the following non-funding agreements:

a. **Confidentiality Agreements/Non-Disclosure Agreements (NDA):** The NDA specifies terms by which either party's confidential information is disclosed to the other party. Normal time limit of confidentiality is a maximum of 15 years.
b. **Material Transfer Agreements (MTA):** The MTA governs the transfer of bio-materials to/from RQHR.
c. **Data Access Agreement (DAA):** For RQHR research that requires the release of personal information from outside of the RQHR, the RQHR researcher must execute a DAA that specifies how the confidentiality of the information released will be protected by the researcher. In order to access personal information within the RQHR, the RQHR researcher must comply with the RQHR policy on *Privacy and Confidentiality*.

2.1.5.1 Internal Review and Negotiation

a. The RQHR researcher must ensure that the NDA, MTA or DAA is sent to Research and Performance Support for review and negotiation. The Sponsor, RQHR and the RQHR researcher are parties to the NDA, MTA or DAA. In the case of an RQHR Investigator-initiated study, Research and Performance Support can assist with drafting an agreement, if no template is provided by another party.
b. The following information must also be provided with the NDA, MTA or DAA at the time of submission: Sponsor contact information; Principal Investigator contact information, and the contact information for any study coordinators managing correspondence; and the scope of work for the project, including projected start and end dates.
c. All negotiations with the Sponsor will be conducted by Research and Performance Support on behalf of RQHR and recommendations will be made to the Sponsor/Principal Investigator.

2.1.5.2 Execution

a. The NDA, MTA or DAA will be signed by the RQHR Director of Research and Performance Support upon finalization of the terms of the agreement with the Sponsor.
b. The NDA, MTA or DAA will be fully executed once signed by all parties to the agreement, including, but not limited to: RQHR Principal Investigator, RQHR Director of Research and Performance Support, and the Sponsor for the study.
c. The Principal Investigator must ensure that a copy of the fully executed NDA, MTA or DAA is received by Research and Performance Support.

2.2 Publication

2.2.1 Results Made Public

RQHR researchers shall ensure that they use reasonable efforts to ensure that results of RQHR research undertaken by RQHR researchers is made public.

2.2.2 Publication of Industry-Sponsored Research

The following considerations and requirements pertain to research with commercial interests such as industry-sponsored research:

a. Where the Sponsor has industrial or commercial rights arising out of the research study which it wishes to protect, or where the Sponsor wishes to be given an opportunity to publish the results of the research before publication by the RQHR researcher (or to approve the publication in advance of publication by the RQHR researcher), time for such protection or publication may be negotiated between the parties.
b. The RQHR researcher shall in any event be free to publish after twenty-four months from the submission of the final report to the Sponsor or termination of the project, whichever is later.
c. If there is any change in the Sponsor's publication from the original report, the name of the RQHR and the RQHR researcher(s) shall not be used in connection with the publication without first informing the RQHR and the RQHR researcher(s) of the change.
d. Any instance where the defense of a thesis by an RQHR researcher who is also a graduate student in an academic program may be delayed by contractual restrictions will be reviewed on a case by case basis by the Director of Research and Performance Support.

Publication of the thesis may be delayed only in accordance with the applicable policies of the graduate student's host university.

e. In exceptional circumstances, the RQHR may authorize the withholding of publications for a period longer than twenty-four months from the submission of the final report to the Sponsor, but in no case shall publications be delayed longer than thirty-six months from the submission of the final report to the Sponsor.

2.2.3 Attribution

a. The RQHR Principal Investigator shall ensure that appropriate recognition, including authorship, is given only to those researchers:
   - who have made an intellectual or practical contribution to the research study, and/or,
   - who may have permitted their unpublished work to be used in the development of the research study.

b. The RQHR Principal Investigator shall ensure that all RQHR researchers involved in any research study which is submitted for publication and who are listed as authors shall see and approve the manuscript before it is submitted.

c. All researchers listed as authors shall be expected to understand the significance of the research conclusions and share responsibility for the content and reliability of the reported information.

2.2.4 Compliance with ICMJE's (International Committee of Medical Journal Editor) Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals

The RQHR Principal Investigator shall ensure that all publications that he or she produces are done in compliance with ICMJE's Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals.

2.3 Financial Administration

2.3.1 Receipt of Sponsored Research Funds

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

b. Cheques received by RQHR awardees or departments must be forwarded to Research and Performance Support for deposit to the appropriate RQHR account.
c. RQHR researchers and other personnel shall not accept personal cheques for research support.

2.3.2 Use of Research Funding

All RQHR researchers who are the recipient of any funds received for conducting research, including grants, contracts, and donations, shall be responsible for the proper management of all funds received from the funding source. Specifically, this includes ensuring that all expenditures conform to the approved budget, with all terms and conditions of the grant or contract, with all regulations of the funding agency, with the policies of RQHR Finance (refer to related documents on Department of Finance Policies and Procedures) and any other RQHR departments that are involved in the administration of the funds, and with the requirement for annual ethical approval.

2.3.3 Research Accounts

All RQHR researchers who receive awards to be administered through the RQHR, either in the form of grant funding, sponsored research, in-kind contributions, or unsolicited donations, shall notify Research and Performance Support by providing the office with a copy of the award notice/letter, as well as copies of any other documents concerning the regulations or conditions governing the use of the grant or donated funds. If a new research account is required for a research grant or contract, the request for the new account must come to the Research and Performance Support Department on behalf of the awardee. The request is to be submitted to the Research Approval Coordinator by way of a completed Research Account Application form. All Research Account Application forms must be signed by the Director of Research and Performance Support and will be forwarded accordingly to the Finance Department for processing. RQHR will establish separate research accounts for funding awarded to RQHR Principal Investigators. Financial statements, if required by the Sponsor, shall be prepared by RQHR Finance according to their records. RQHR Finance shall retain original invoices/vouchers on file for audit purposes.

2.3.3.1 Opening of Accounts for Externally Funded and/or Sponsored Research

The opening of a research account shall be authorized in writing by the Director of Research and Performance Support. A Research Account Application form must be

submitted to Research and Performance Support for review and approval.

2.3.3.2 Use of Funds from Externally Funded and/or Sponsored Research Accounts for Initial Study Year

RQHR Finance shall only make awarded funds available for the first study year from the research account upon receipt of a copy of the RQHR letter of "Authorization to Conduct Research," according to the policy on *Operational Approval for Research*.

2.3.3.3 Use of Funds from Externally Funded and/or Sponsored Research Accounts for Subsequent Study Years

Use of awarded funds for subsequent study years shall be contingent upon a letter of confirmation by the Director of Research and Performance Support that the ethical approval for the research study funded by that grant has been renewed for an additional one year period and that an RQHR Research Ethics Board Certificate of Re-approval has been issued to the grantee, as per the RQHR policy on *The Ethical Conduct of Research and Other Studies Involving Human Participants*. If a study is closed by the Chair of the Research Ethics Board due to non-compliance with the requirement to apply for annual re-approval, the Director of Research and Performance Support and the Finance Department will be notified and the funds will be frozen, until such time as re-approval from the Research Ethics Board has been obtained.

2.4 Obtaining Required Approvals to Conduct Research

2.4.1 Operational Approval

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 may begin. Please refer to RQHR's policy and associated procedure for *Operational Approval for Resea*rch for further information on how to obtain departmental permission.

2.4.2 Authorization to Conduct Research

The RQHR researcher shall not permit any research-related activities to begin until the RQHR letter of "Authorization to

Conduct Research" for the applicable study has been issued. The RQHR researcher must ensure that the following approvals have been completed and/or submitted to Research and Performance Support **BEFORE** research-related procedures are initiated:

a. Notice of Award and any other documents concerning the regulations or conditions governing the use of the grant or donated funds, if applicable;
b. Health Canada No Objection Letter (drug trials) or Investigational Testing Authorization (device trials), if applicable;
c. A copy of the Certificate of Approval from the Research Ethics Board;
d. A fully executed copy of any study-related contracts or agreements, if applicable;
e. A completed Research Account Application, if applicable.

Upon receipt of the applicable approvals, Research and Performance Support shall sign and release a letter of "Authorization to Conduct Research" to the RQHR researcher. This letter is required before any research-related activities can begin.

3.0 External Researchers

3.1 Application for Affiliated RQHR Researcher Status

a. A non-RQHR researcher may apply to Research and Performance Support for the status of Research Associate. The application must include, at a minimum, a current curriculum vitae, an explanation of why the applicant wishes to obtain an RQHR affiliation, evidence of published research or an academic doctoral degree, a brief summary of research activities and interests, keywords describing areas of research interest, and current affiliations and research activities, if any.
b. Research and Performance Support shall undertake a review of the request and shall make a decision, taking into account risk and benefit to RQHR, which will be reported in writing to the applicant.
c. RQHR Research Associate status may be conferred for a period of time, as stipulated by the Vice President of Knowledge and Technology Services or designate.