Externally Funded and/or Sponsored Research	Manual: Reference Number: *104*
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Approving Authority: *Keith Dewar*	Revision Dates: *Date reviewed.*
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See related policies:
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 (0300 series of RQHR Policies)

See related procedures:
Procedure for Policy on Externally Funded and/or Sponsored Research
Procedure for Policy on Operational Approval for Research
Department of Finance Procedures (0300 series of RQHR Policies)

1.0 Policy

1.1 All externally funded and/or sponsored research taking place under the auspices of the RQHR or its Affiliates must follow the associated *Procedure for Policy on Externally Funded and/or Sponsored Research*.

1.2 All externally funded and/or sponsored research must obtain Operational Approval from the Director of Research and Performance Support prior to commencement of any research-related activities, in accordance with the RQHR policy on *Operational Approval for Research*.

1.3 Intellectual Property developed by RQHR researchers in the performance of RQHR research will be dealt with in accordance with the RQHR policy on *Intellectual Property*.

1.4 Indirect Costs shall be included in the budget for all externally funded and/or sponsored research, in accordance with the RQHR policy on *Indirect Costs of Research*.

1.5 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*.

2.0 Purpose

2.1 To ensure that all externally funded and/or sponsored research is conducted in accordance with RQHR policies and procedures and all applicable legislation and standards for best practices.

3.0 Responsibilities

3.1 Principal Investigators are responsible for notifying Research and Performance Support of any externally funded and/or sponsored research projects occurring under the auspices of the RQHR or its Affiliates and complying with all relevant policies, procedures, legislation, and standards for best practices.

3.2 RQHR shall be responsible for developing awareness and understanding among RQHR researchers and staff of the expectation to uphold the highest standards of integrity, accountability, and personal responsibility when carrying out research in the RQHR. Education that includes promoting awareness of regulations, policies, and other relevant standards that pertain to research will be offered to RQHR researchers and staff.

3.3 If the RQHR researcher is the Principal Investigator, that Principal Investigator assumes responsibility for all sub-investigators involved in any research-related activities, including development, conduct, analysis, and reporting, whether these are RQHR researchers or researchers not directly affiliated with RQHR.

4.0 Definitions

4.1 Confidentiality Agreement/Non-Disclosure Agreement: An agreement that defines the applicable confidential information and any time limits for maintaining confidentiality and specifies terms by which either party's confidential information is disclosed to the other party.

4.2 **Data Access Agreement:** An agreement setting out conditions under which information may be used and managed over its lifetime. The conditions are applied to the use, linkage, and subsequent re-identification (if possible), protection, destruction, archiving, or return of such information as appropriate to the level of identifiability of the information, the sensitivity of the information, and any other criteria which RQHR may wish to consider.

4.3 **Externally-Sponsored Research:** Refers to research that is initiated and managed by an investigator who assumes the legal and regulatory responsibility for the conduct and management of the research as defined by applicable regulations and laws of the country involved. Externally-sponsored research may be initiated by an RQHR investigator who seeks funding from an external source, or alternatively, may involve a non-RQHR investigator and sponsor who must designate an RQHR-affiliated Principal Investigator to carry out all research activities conducted within the RQHR.

4.4 **Industry-Sponsored Research**: externally-sponsored research whereby the sponsor is a for-profit entity.

4.5 **Not-for-Profit-Sponsored Research**: externally-sponsored research whereby the sponsor is a publicly funded or charitable organization.

4.6 **Investigator-Initiated Clinical Trial Agreements**

- Protocol written by an investigator, either at RQHR or at another institution;
- Funding provided with or without "free" study drug or device;
- Drugs or devices may be provided by the company or may be purchased with the company funds;
- If this is a new drug or device, or new use for an existing drug, the RQHR researcher/Principal Investigator must apply to Health Canada for approval;
- The RQHR retains all intellectual property rights for any research or innovation created or developed by using RQHR facilities or resources, unless otherwise agreed to on a case by case basis. In absence of a prior agreement or contracted terms, all intellectual property originating will be the property of RQHR, in accordance with the RQHR policy on *Intellectual Propert;*
- Publication may be temporarily restricted (within clearly defined limits) to protect commercial interests;
- Amendments to the protocol must be approved by the RQHR Research Ethics Board; and
- Confidential information provided by the company will be protected by the RQHR.

4.7 Industry-Sponsored Clinical Trial Agreement

- An agreement to conduct a clinical study with human participants and the reporting of results back to the Sponsor. Characteristics of such an agreement include:
    - Sponsor-initiated for a Phase 0, I, II, III, or IV trial;
    - Sponsor writes the protocol and owns the compound or device;
    - Agreements have been negotiated and signed by Principal Investigator, Sponsor, and RQHR; and
    - Publication may be temporarily restricted (within clearly defined limits) to protect commercial interests of the Sponsor. In the case of a multi-centre study, publication may be restricted until the study has been reported in full by all centres;
- Confidential information provided by the Sponsor shall be protected by RQHR and the Principal Investigator;
- Indemnification and insurance provisions shall be included in the agreements;
- Amendments to the protocol must be approved by the Sponsor and the RQHR Research Ethics Board; and
- Amendments to the clinical trial agreement must be approved by RQHR.

4.8 Material Transfer Agreement (MTA): An agreement allowing for the transfer of research material (e.g., compounds, antibodies, plasmids, biological samples, etc.) from fellow researchers at other institutions or companies. An MTA is also required if you are sending research material to others outside of the RQHR. An MTA describes acceptable use of the material, as well as how future inventions will be handled. An MTA also deals with potential liability issues connected to the material. Certain terms in this type of agreement may restrict researchers' rights to future inventions arising from the use of such materials.

4.9 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.

4.10 Research Grant: A funding agreement typically focusing on basic, fundamental, curiosity-driven research. Characteristics include:

- Project control lies with the researcher;
- Unrestricted rights, in certain cases, to publish research results;
- Payment issued in advance or in milestone payments;
- Start date of the project is defined; and
- Sponsor is provided with a copy of the final research report.

4.11 **Research Contract:** A funding agreement, often sponsored by industry, for conducting research directed at answering questions typically of an applied nature. Characteristics:

- Defined scope of work;
- Start and end date of project are defined;
- Payment may be made in arrears and tied to milestones/deliverables;
- Contains provisions for confidentiality of information;
- RQHR/Principal Investigator retain the right to publish, but will allow delay for Sponsor review;
- Background intellectual property and ownership are clearly defined;
- Warranty provisions: use reasonable professional standards but do not guarantee results;
- Equipment purchased under the contract is owned by the RQHR;
- Termination provisions are included; and
- Insurance and indemnification provisions are included to protect the RQHR.

4.12 **Sponsor:** The Sponsor is the entity providing the funds to the RQHR Principal Investigator, directly or indirectly, to conduct research. The Sponsor may also be referred to as a "funding agency," "granting agency" or "contractor."

4.13 **Technical Services Contract:** An agreement providing for the delivery of services or the use of RQHR equipment and the reporting of results back to the Sponsor. Characteristics include:

- Use of existing know-how to provide the service;
- Use of RQHR facilities, resources, and/or time;
- Start and end dates of project are defined;
- Payment can be made after services are rendered or tied to deliverables; holdback is often required;
- Service results are the property of the Sponsor; RQHR has the right to use results for teaching, clinical use and non-commercial research projects;
- Warranty provisions: reasonable professional standards but no guarantee of results;
- Contains provisions on confidentiality of information; and
- Insurance and indemnification provisions are included to protect the RQHR.

5.0 Revision History

This is a new policy.