

Research: Clinical

1. Introduction

1.1. Purpose

This policy describes the process for research proposals and research activities within Providence Health Care (PHC).

1.2. Scope

This policy applies to all individuals conducting research within PHC.

2. Policy

2.1. Overview

All research activities within Providence Health Care (PHC) must conform to the established protocol. Refer to [Appendix A: Corporate Research Protocol](#).

All research proposals are subject to the Corporate Review Process and must be approved by the following:

- The University of British Columbia (UBC)-PHC Research Ethics Board (REB) or one of the other affiliated UBC REBs, if applicable.
- University of British Columbia \ Animal Care Committee, if applicable.
- Vice-President, Research & Academic Affairs (on behalf of the PHC Corporation and the Board of Trustees with the knowledge of the PHCRI Trustees).

2.2. Research Equipment

The Vice-President, Research & Academic Affairs approves the purchase of research equipment. Equipment purchased is the property of the organization in which the funds to purchase the equipment are held. Research equipment which is purchased by the PHC Corporation is the property of the PHC Corporation. Refer to [PHC Research Policies & Procedures](#), Article 3.1.

Investigators

For equipment purchased through PHC Purchasing:

- Set up a research trust account (designated by the account number 137-xxxx) with Providence Research Finance for the research grant.
- Purchase the equipment through St. Paul's Hospital Material Management.

- Ensure that purchases are within the established budget. The Corporation is not responsible for overruns.
- Register the research equipment with Finance for insurance purposes.
- For purchases through the PHC Corporation, the purchasing Principal Investigator (PI) or PI affiliated Centre will be responsible for service contracts and maintenance of equipment.

For equipment purchases outside of PHC Purchasing, the PI should contact the corresponding organization's purchasing department for their respective processes.

3. Responsibilities

3.1. Responsible Functional Officer

The responsible functional officer for research at Providence Health Care is the Vice-President, Research & Academic Affairs.

3.2. Ethical conduct of research involving humans

Any research involving human subjects must be submitted for ethical review and be approved before research may commence. The PHC Policy for Research Involving Human Subjects is provided as follows:

Any clinical or behavioural research involving human subjects that is carried out by a physician, scientist or researcher, dentist or midwife in any category of medical staff at PHC, professional practice staff or other PHC hospital staff, researchers from other institutions conducting research at PHC and students and trainees at PHC must be reviewed and approved by one of the UBC Research Ethics Boards authorized by [Policy LR9: Research and Other Studies Involving Human Subjects](#) or by a Research Ethics Board that has been specifically authorized by the Providence Health Care Vice-President, Research & Academic Affairs, regardless of where the research is conducted. If the clinical or behavioural research involving human subjects meets any of the following criteria, the research must be submitted to and approved by the UBC-PHC Providence Health Care Research Ethics Board or one of the other affiliated UBC REBs:

1. The research is conducted at a PHC site;
2. The research involves PHC patients (patients who have a PHC chart number);
3. The research involves tissue or data held at PHC;
4. The research involves PHC facilities.

3.3. PHC Institutional Approval

All research involving the use of Hospital services/resources must have the approval of the applicable department, research centre or unit that will be impacted by the research

Before any research may be commenced at a PHC site or by a PHC-affiliated Investigator, the research must have the written approval of the PHC Vice-President, Research & Academic Affairs. The decision is contingent upon the receipt of:

1. Certificate of Ethical Approval issued by one of the UBC Research Ethics Boards (UBC PHC REB, UBC CREB, UBC BREB, UBC BCCA REB or REBC Partner Boards);
2. The approval issued by all affected service departments in the hospital;
3. A fully executed sponsored research agreement, approval letter from a public granting agency, notice from the Foundation of an award or donation for the research or other documentation indicating where funding is coming from for all funded projects.

The Investigator therefore must be in possession of the following two documents before research may begin:

1. Certificate of Ethical Approval
2. Institutional Certificate of Final Approval, signed by the PHC Vice President Research

3.4. Principal Investigator

Principal Investigators conducting research at PHC must hold either a PHC staff appointment or a UBC faculty appointment.

Researchers from other institutions, students and trainees must appoint an individual who holds either a PHC staff appointment or a UBC faculty appointment as the principal investigator (PI) for the research, unless the researcher, student or trainee holds a PHC appointment or UBC faculty appointment¹.

- Complete the online [UBC-PHC Research Information Services \(RISe\) application form](#) and indicate in section 11 of the application which hospital facilities you propose to use.
- Submit the complete online application to the appropriate Department for Approval.
- Obtain approval from the Vice-President, Research & Academic Affairs to use the Animal Research Facilities when the research involves the use of animals.
- Establish a budget for the use of Hospital or other facilities' services prior to submitting the proposals to granting agencies, e.g., British Columbia Health Research Foundation (BCHRF), St. Paul's Hospital Foundation or commercial companies.
- Obtain written permission from the Leaders whose facilities will be used in the proposed study.
- Arrange for reimbursement of the facility for any costs involved in the research.

¹ SFU Faculty are allowed to be PI's as well if working at PHC affiliated site (BCCSU primarily).

- Submit one copy of the permission letters/forms from participating services or areas, e.g., Laboratory, ECG, etc., to the Providence Research Facilitation Office.
- Complete and submit a Post Approval Activity – Request for Annual Renewal on RISe annually for ongoing research projects (lasting greater than one year).
- Complete and Submit a Post Approval Activity – Amendments to Study on RISe when there are any changes made to an ongoing study. Approval of these changes by the UBC-PHC REB must be granted prior to implementing any changes to the study.
- Complete and submit a Request for Acknowledgment – Completion of Clinical Study on RISe when research projects are completed or withdrawn.

3.5. Providence Research Facilitation Office

The PHC Research Institute was created in 2005 to facilitate and encourage health research at PHC. The Providence Research Facilitation Office coordinates various aspects of research application to facilitate approval by the Vice-President, Research & Academic Affairs and the University-Industry Liaison Office of UBC.

Responsibilities:

- Coordinate research applications and any necessary information/modification required for ethical approval by the UBC/PHC Research Ethics Board.
- Coordinate space requirements for research projects with the Corporate Director, Strategic Renewal & Capital Assets.
- Coordinate the operational approvals required for the Institutional Certificate of Final Approval by the Vice-President, Research & Academic Affairs.
- Communicate information from annual status reports to services/areas and programs involved in the research project via an Annual Report on Research.

3.6. Vice-President, Research & Academic Affairs

- Review research applications for PHC Institutional Final approval. Consider factors such as ethical approval, impact on Corporate services/areas/programs, budget, space, and funding.
- Inform the PHC Research Leaders of any issues of concern related to the research.

3.7. PHC Research Executive

The PHC Research Executive is composed of Centre Directors, key Centre Principal Investigators (PI's), and PI's not part of an established centre but leading or contributing to significant research endeavours within PHC. This group is utilized by the VP, Research &

Academic Affairs to explore opportunities, to consider challenges and to think strategically as a collective research enterprise rather than individual units.

3.8. PHC Board of Trustees (with the knowledge of the Providence Research Board of Trustees)

- Consider the recommendations of the Research Executive.

4. Compliance

All staff members are responsible for adhering to this policy and monitoring their activities in accordance with the policy. Staff members may warn others if they observe a violation of this policy. Failure by staff to comply with this policy may result in disciplinary action up to and including termination of employment, services or privileges.

5. Supporting Documents

5.1. Guidelines/Procedures/Forms

[PHC Research Policies & Procedures](#)

[UBC Policies & Procedures](#)

6. Definitions

Providence Research is the brand name of the Providence Health Care Research Institute (PHCRI).

7. Appendices

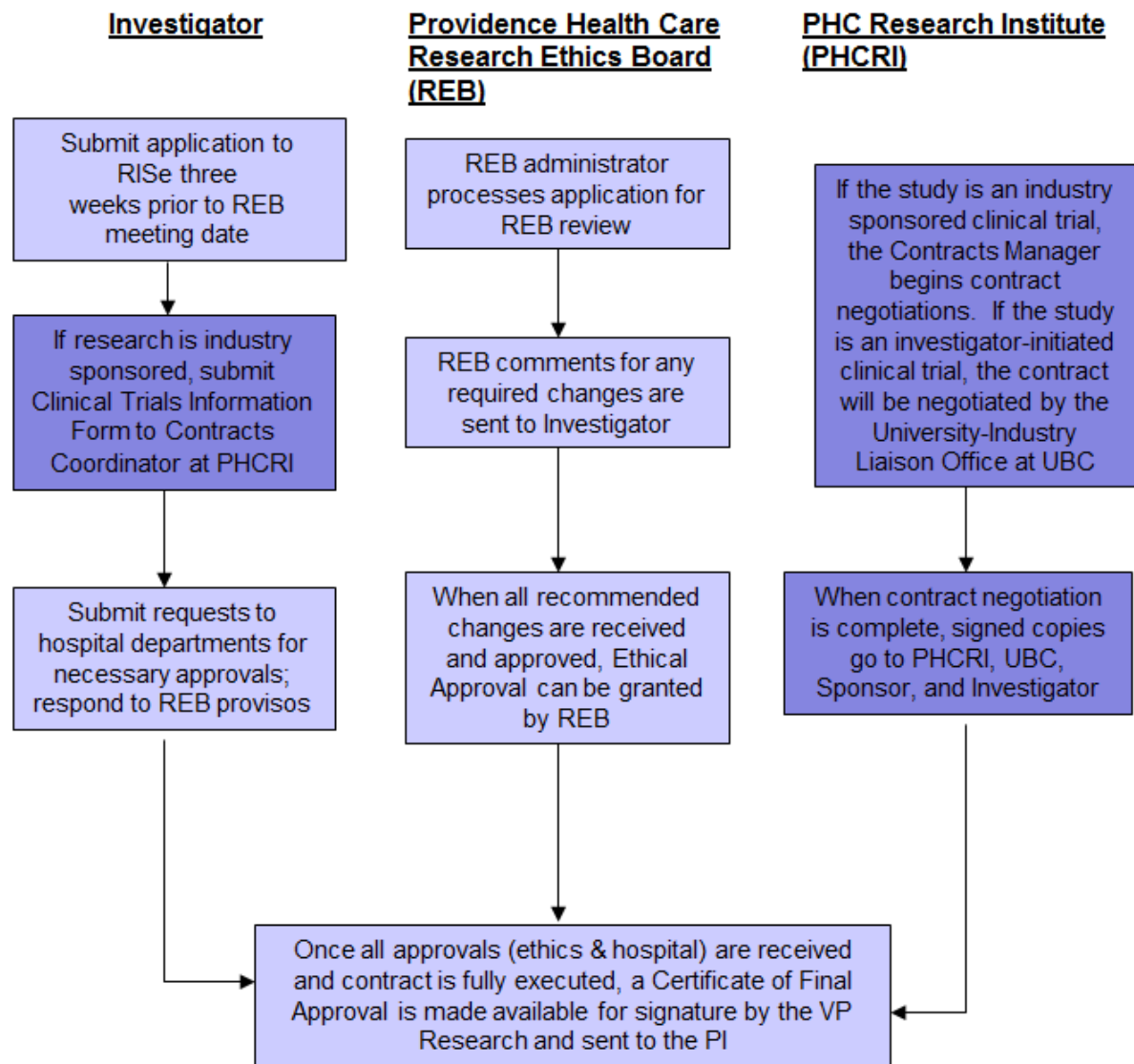
[Appendix A: Corporate Research Protocol](#)

[Appendix B: The Process of Obtaining Study Approval for Research Involving Human Subjects](#)

Appendix A: Corporate Research Protocol

- All research funds are managed through trust accounts held at Providence Health Care Research Institute or UBC in accordance with the applicable terms of reference.
- The Principal Investigator must register the protocol with the Providence Research Facilitation Office.
- Account signatories include the Principal Investigator, Vice-President, Research & Academic Affairs, and the University-Industry Liaison Office Director or delegate.
- Honoraria paid to individuals from commercial enterprises must be declared to the Office of Research Services, UBC only on the recommendation of the Dean of the Faculty, with the approval of the Head of Department or Director and the Vice-President, Research & Academic Affairs. (Refer to [Policy LR2: Research](#), Research 4.11)
- Travel grants which are made directly by commercial enterprises to investigators require the prior approval of the applicable Leader or the Vice-President, Research & Academic Affairs if the person in question is the Leader. Currently, travel expenses are paid in accordance with the granting agency or in accordance with established Corporate policies. (Refer to [UBC Policy 83](#))
- Travel costs which are funded by the Corporation or Corporate Trust Accounts must conform with account budgets and terms of reference.
- Personal benefits are not acceptable, i.e., association and professional memberships, excessive entertainment or meal costs, travel costs for spouses except where there are special circumstances recognized by the Corporation and the granting agency.
- Equipment bought through Corporate accounts belongs to the Corporation.
- Investigators must operate within the established budget. The Corporation is not responsible for overruns. (Refer to [UBC Policy 90: Over-Expenditure on Research and Specific Purpose Trust Project//Grants](#).)
- Any research personnel who assume responsibility for administering patient/resident care and/or who require access to patient/resident records for research purposes must meet the criteria and conditions for employment of their respective professional service within the Corporation.

Appendix B: The Process of Obtaining Study Approval for Research Involving Human Subjects



**PHCRI is not responsible for obtaining the hospital departmental approvals. The Investigator or designate must submit such requests to the departments/services required and follow up with those departments.*

***Final Approval must be granted by the VP Research before the research can begin. Investigators who start studies without final approval do so at their own risk. Ethical Approval is not the same as final approval, only a component of it.*

Effective Date:	Oct 26, 2022			
First Released:	01-May-2000			
Last Revised:	Oct 26, 2022			
Last Reviewed:	Oct 26, 2022			
Approved By:	PHC			
	Senior Leadership Team / Executive Sponsor: VP, Research & Academic Affairs			
Owners:	PHC			
	Research			
Revision History:	Version	Date	Description/ Key Changes	Revised By
	2	May 1, 2016		Research
	3	July 19, 2019	Changes made in response to UBC increasing the indirect costs of research rates for industry funded research in addition to editorial changes	Research
	4	Oct 26, 2022	Minor wording edits and refreshing links	Darryl Knight