PROVIDENCE HEALTH CARE Research Institute Pursuing real life health solutions St. Paul's Hospital 1081 Burrard Street Vancouver, BC Canada V6Z 1Y6 Tel 604 806 9608 Fax 604 806 9605 www.providenceresearch.ca	**Authorized Procedures** **Approved by the PHCRI Board of Trustees**	**Procedure Version No.:** 3	**Effective Date:** November 24, 2016
Title: **Providence Health Care Research Policies & Procedures**			
Related Procedures, Materials, and Notes: Originated by: Providence Health Care Research Institute Research Facilitation Office (PHCRI RFO)			

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HOSPITAL RESEARCH INVOLVING HUMANS POLICIES & PROCEDURES

Providence Health Care Society (PHC) is a multi-site Catholic teaching and research hospital organization affiliated with the University of British Columbia (UBC). As such, Providence Health Care Research Policy is written to be as consistent as possible with UBC Research Policy. The purpose of this policy is to describe the authority, responsibility and procedures for all research involving humans at PHC.

These policies are effective across all PHC sites and apply to all PHC staff, physicians, UBC faculty, and students/trainees who work at a Providence site. They also apply if (a) any services are provided by PHC (b) any part of the research takes place at a PHC site, (c) any part of the research involves PHC patients or staff, and if (d) requests for data or tissue is involved, regardless of where the research is being conducted.

The term "hospital" shall hereafter refer to any and all sites of Providence Health Care Society, and "university" shall indicate the University of British Columbia.

PHCRI

In 2005, PHC launched the Providence Health Care Research Institute (PHCRI) to facilitate and encourage health research at PHC. The PHC Research Institute provides research support services to all researchers at Providence Health Care through its PHCRI Research Facilitation Office.

It is the responsibility of everyone conducting research at PHC to ensure that human subjects are treated with compassion and respect and that the procedures outlined in this policy document are followed. Management and any staff providing services to support research involving humans will ensure that processes and systems are in compliance with PHC policies, procedures, regulatory requirements and ethical guidelines including the Catholic Health Association of Canada Health Ethics Guide.

PHCRI VISION

At the Providence Health Care Research Institute our vision is to dramatically improve the treatment and overall health of patients and residents at Providence Health Care and beyond, through relevant, ethical and inspired health research

PHCRI MISSION

The PHC research community finds solutions to questions that arise from PHC care settings using high quality research. We acknowledge the rapidly changing health care environment and embrace the challenges it provides. We prioritize prevention, treatment and outcomes research questions that are relevant to PHC's populations of emphasis. We mentor and train new researchers. We encourage novel research approaches such as inter-disciplinary and inter-professional collaborations, knowledge transfer, and partnerships with patients and communities.

DEFINITION OF RESEARCH INVOLVING HUMANS

Research involving human subjects is defined as any systemic investigation (including pilot studies, exploratory studies, and course based assignments) to establish facts, principles, or generalizable knowledge, which involves:

1. living human subjects
2. human remains, cadavers, tissues, or biological fluids

Providence Health Care will not sanction any research involving the use of embryos or foetuses/foetal tissue.

Research involving human subjects does not involve:

Quality assurance studies, performance reviews, or testing within normal educational requirements, or activities undertaken by the University or Providence Health Care for administrative or operational reasons

If in doubt about whether a research project is categorized as that involving human subjects, researchers are asked to contact the Manager, Ethical Reviews in the PHCRI for clarification.

RESPONSIBLE FUNCTIONAL OFFICER

The responsible functional officer for research at Providence Health Care is the Vice President of Research & Academic Affairs and the President of the PHCRI. This person is also the Associate Dean of Research, UBC Faculty of Medicine.

POLICIES & PROCEDURES

1.0 SPONSORED RESEARCH

1.1 DEFINITIONS:

Sponsored research is carried out under the terms of a written agreement or contract, which generally:

- defines in specific terms the work to be carried out for the contracting agency
- includes a budget that restricts, by category, the payment of actual expenditures and indirect costs, except that some portion of the allocated funds may be withheld until the contracted work is complete and a final report submitted
- specifies publication restrictions; and
- outlines ownership clauses that give the sponsor ownership or control over any intellectual property or data that is created.

Persons engaging in sponsored (contract) research should be aware that contracts are inherently more restrictive than grants and that great care must be taken in the management of contract funds.

For the purpose of this document and these policies & procedures, the following definitions will be used:

Unrestricted Grant-in-Aid

- in support of the general research activities of an individual researcher or group of researchers
- no specific result required or expected by the sponsor
- no rights in inventions or other intellectual property accrue to the sponsor
- no restriction on publication of results
- no restriction on use of funds
- no information confidential to the sponsor will be accepted
- substantial advance payment with no requirement for invoicing or detailed administrative reporting

Indirect costs of 30% is charged on unrestricted grants-in-aid. If the sponsor places restrictions on a grant such as publication restrictions, ownership of data, or claiming rights to intellectual property, the University and Providence must treat it as a different type of agreement such as a clinical trial agreement, service agreement or collaborative research contract.

Clinical Trial Agreement

- patient-based clinical research
- agreements signed by company, Hospital, University and principal investigator
- publication may be temporarily restricted (within clearly defined limits) to protect commercial interests
- confidential information provided by the sponsor will be protected by the Hospital/University to the best of its ability
- Particular care must be taken with indemnification and insurance provision of agreements

Standard Hospital/University indirect costs of 30% of total budget will be assessed against project expenditures. This rate is non-negotiable.

Collaborative Research Agreement

- work to be done defined jointly by the sponsor and the University
- specific result or development expected
- ownership of inventions, software, biological materials, know-how, trade secrets or other intellectual property vests in the University
- sponsors can be granted an option for a royalty-bearing license to such property
- publication may be temporarily restricted (within clearly defined limits) to protect commercial interests
- confidential information provided by the sponsor will be protected by the University to the best of its ability

Standard Hospital/University indirect costs of 30% of total budget will be assessed against project expenditures.

Service Agreements

- for analytical, testing or other services requiring little or no intellectual input or value added by the University
- rights to intellectual property provided by the sponsor for analysis or evaluation remain with the sponsor
- the University will not carry out routine analyses, testing or product evaluation in competition with private industry or contract research agencies
- confidential information provided by the sponsor will be protected by the University to the best of its ability

Standard Hospital/University indirect costs of 30% of total budget will be assessed against project expenditures.

1.2 AUTHORITY TO CONTRACT

Only the Hospital and the University have the legal authority to enter into contracts that are binding on the institutions. Contracts for research and other projects must be among Providence Health Care Society, UBC, and the sponsoring agency.

In the case of clinical trial agreements only, the principal investigator is a party to the agreement. This means that the investigator assumes personal responsibility for carrying out the agreement, which is not the case for grant-in-aid or other agreements.

Contracts may not be written in the name of an individual department or member of a department. The wording of research contracts must clearly indicate and distinguish between the responsibilities of the hospital, UBC, the principal investigator, and the sponsoring agency.

1.3 CONTRACT NEGOTIATION

All contracts for clinical trials from commercial sources, both new and extensions/amendments, must be negotiated and documented in writing by the Clinical Research Contracts Manager in the PHCRI Research Facilitation Office, who reviews same on behalf of the hospital and the university. All other agreements, and amendments to existing agreements, from commercial sources, and from government agencies and academic centres requiring formal written contracts, both new and extensions and amendments, must be negotiated and documented in writing by the designated Managers in the University Industry Liaison Office at UBC, who reviews same on behalf of the hospital and the university The University-Industry Liaison Office at UBC is also responsible for licenses and other intellectual property agreements.

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Procedures for Initiation of a Clinical Trial Agreement :

Once an investigator has a verbal agreement to participate in a commercially sponsored research project, s/he must forward a completed "**Sponsor Initiated Clinical Trial Information Form (CTIF)**" declaration form to the Clinical Research Contracts Manager, PHCRI Research Facilitation Office. The Clinical Research Contracts Manager will then contact the sponsor and begin negotiating the contract or grant.

The PHCRI Research Facilitation Office will forward certain other types of agreements such as Material Transfer Agreements, Grant Agreements, Service Contracts and Collaborative Research Agreements to the University Industry Liaison Office for review.

1.4 EXECUTION OF DOCUMENTS

The PHC Board of Trustees or its delegate must execute all written documents to which Providence Health Care Society is a party. The PHC Vice President Research has been delegated the responsibility of signing all contracts for research and related projects.

Procedures for Execution of Documents

Every grant or contract for funds (new or extension/renewal/amendment) from a commercial sponsor must be signed by:
(1) sponsor
(2) applicant (principal investigator, who will sign grants though not an individual party)
(3) PHC Vice President Research/UBC Assistant Dean Research
(4) Managing Director of the UBC University/Industry Liaison Office or Associate Director of the UBC University/Industry Liaison Office

This applies equally to:
- funding requests for new projects
- requests for renewal or supplemental funding for existing projects
- requests made by letter or by written proposal, as well as those prepared on pre-printed forms

Copies of Contracts & Grants:

Each signatory to a grant or contract will receive for their records a signed copy of said grant or contract.

1.5 OWNERSHIP OF CONTRACT FUNDS

Contract funds are held in trust by the Hospital or the University and are not the property of any individual.
See Section 3.0 Research Trust Accounts for more detailed information.

1.6 RIGHT OF TERMINATION

The Hospital has the right to terminate the research if the Hospital determines in its discretion that the conduct of the research prejudices or has prejudiced the interests of the Hospital. In the event that an investigator wishes to appeal the Hospital's decision to terminate a study, a letter clearly stating the rationale for such an appeal must be sent by the investigator to the PHCRI Research Facilitation Office. Appeals must be filed within 30 days of receiving notice of the Hospital's intent to terminate the study.

1.7 BUDGETS

Budgets should reflect all of the costs associated with carrying out a research project, including personnel costs, services (e.g. laboratory, pharmacy, radiology etc), and reimbursement to study subjects for out-of-pocket expenses. Budgets must also include Hospital and University indirect costs (see Section1.9).

1.8 BUDGET AMENDMENTS

Contracts often permit little budget flexibility. If budget alterations of the contract are necessary during the term of the contract, it is the investigator's responsibility to request a contract amendment from the sponsoring agency or company.

The Clinical Research Contracts Manager must review the budget amendment and all parties sign off on the amendment prior to it taking effect.

1.9 INDIRECT COSTS

- Under the Affiliation Agreement between Providence Health Care Society and UBC, indirect funds generated as a result of commercially funded research at PHC is divided between the two institutions. Every grant, clinical trial agreement, service agreement, or collaborative research agreement funded by a commercial agency and administered by either Providence Health Care or UBC must include **a standard Hospital/University indirect costs of 30% of the total project expenditure**, which are used to support the research infrastructure.

The distribution of indirect costs is as follows:

(a) Clinical Trial Agreements: 1/5 to UBC, 1/5 to Research Services, 1/5 to the department or centre of the principal investigator, 2/5 to the investigator
(b) Grants, Service Contracts and Collaborative Research Agreements: ½ to UBC, ½ to PHCRI (¼ to PHCRI, ¼ to the department or centre of the principal investigator, ½ to the principal investigator)

1.10 USE OF INDIRECT FUNDS

The Hospital has a fiduciary responsibility to ensure that indirect funds are used for their intended (i.e. research) purposes. The Vice President of Research must approve the use of funds from the indirect account.

(**a) The Providence portion** of indirect funds will be used for operating costs for Research Services and Providence-wide research related expenses.

(**b) The investigator's portion** of funds must be used to enhance and strengthen the research infrastructure of the investigator's research program.

(**c) The department portion** of indirect funds is to be used for fostering clinical research within the department. The funds should be spent to benefit the common research goals of the department. Pooled use of funds with investigators is encouraged to achieve research goals of the department and investigators.

(d) Acceptable expenses: Examples of research expenses which may be charged to investigator and department indirect funds accounts are:

- salaries for research assistants and support staff
- educational expenses related to investigator's field of research
- equipment, preferably shared, which will enhance the research capabilities of the department/unit
- service contracts for research related equipment
- start-up funds such as fellowships or scholarships for new investigators, preferably pooled with other investigators, department heads, or UBC
- reasonable development expenses towards securing research opportunities (e.g. expenses related to grant-writing)

(e) Ineligible expenses: Examples of expenses that cannot be charged to these funds are:

- personal support for the investigator responsible for generating the funds
- non-mandatory staff benefits costs such as living expenses, seasonal bonuses, etc.
- non research-related expenses

(f) Management of indirect funds: Indirect funds will be pooled in a common trust fund. The PHCRI Research Facilitation Office will manage the trust fund and signing authority will rest with the Vice President Research. Procedures for accessing funds are:

i) investigators will be notified at the end of each fiscal year of the amount of indirect funds available to them
ii) submitting a written request to the VP Research for an expense that meets the above guidelines. Invoices related to the request should be attached to each request.
iii) If the request is approved, the VP Research will forward the approved request for payment.

1.11 LIMITATION OF PUBLICATION

A sponsor may be given the right under the terms of the formal contractual agreement to publish research results or to approve such publication in advance. In any case:

- The hospital/university shall be completely free to publish after a maximum of 12 months from termination of the project or submission of the final report, whichever is later; and
- No restriction shall prohibit or delay in any way the use of research results by graduate students for theses or other academic purposes

Delays in publication at the request of sponsor are permissible only if the public interest is best served by such a delay or if patent protection is being sought.

1.12 CONFIDENTIAL DATA

If, under the terms of a formal contract, a sponsor agrees to provide data essential to the research which is clearly labeled "Confidential Data", the hospital/university will accept such a contract and observe such confidentiality provided that the results of the research may be published without identifiable reference to the confidential data and that no limitation are placed on the publication of results other than those outlined.

2.0 GRANTS FROM NON-PROFIT AGENCIES

2.1 APPLICATION FORMS

Application forms for internal grants funded by the St. Paul's Hospital Foundation are available from the PHCRI Research Facilitation Office. Applications for external operating and personnel grants from other public granting agencies are available from the individual agencies. A list of upcoming funding opportunities can be found at http://www.ors.ubc.ca/ by clicking on "Funding Opportunities".
https://ors.dp7prod.webi.it.ubc.ca/funding-opportunities/upcoming-funding-opportunities

2.2 SIGNATURES

All applicants for all grants must complete the Research Project Information Form (RPIF) (https://research.ubc.ca/support-resources/forms-tools-resources/research-project-information-form), sign by applicant and obtain the signature of their University Department Head and Centre Director if applicable. A current list of UBC Department Heads is available on the UBC Faculty of Medicine website (download:https://mednet.med.ubc.ca/Research/GrantApplications/forms/Documents/Signing%20Authorities%20for%20FoM%20Rsch%20Grant%20Appl.pdf . The applicant must then submit the RPIF to the PHCRI Research Facilitation Office for the signature of the Vice President Research/ Associate Dean Research, Faculty of Medicine (FOM), together with copies of the following:

- title page with application details
- abstract or summary of project
- budget pages and all budget justification
- signature page
- in the case of co-operative projects, letters of support or commitment from collaborating companies or institutions
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PHCRI Research Facilitation Office will obtain hospital/university signatures and return the grant paperwork to applicant to mail out to sponsoring Agency.

Applications presented without complete signatures and copies of the above documents will not be processed.

2.3 DISTRIBUTION OF GRANT APPLICATIONS

Applicants are responsible for duplication and mailing of research proposals to the relevant funding agencies.

This applies equally to:

- funding requests for new projects
- requests for renewal or supplemental funding for existing projects
- requests made by letter or by written proposal, as well as those prepared on pre-printed forms
- all professional staff awards and fellowships
- post doctoral fellowships
- all graduate or undergraduate scholarships and fellowships which include a research allowance
- grants from public or commercial agencies

2.4 ADMINISTRATION OF GRANTS

The Grantee (Principal Investigator) has the option of having the funds administered by the University or PHC Research Institute, except in the case of Tri-council (CIHR, SSHRC, NSERC) and National Institutes of Health awards which must be held and administered by the University.

2.5 OWNERSHIP OF RESEARCH FUNDS

All research grant and contract funds from Foundations, the University, and other not-for-profit sources are held in trust and managed by the Hospital or University and are not the property of any individual.

2.6 RESPONSIBILITY FOR USE OF FUNDS

The Grantee (Principal Investigator) is responsible for the proper use of the funds in accordance to the terms and conditions of the grant or contract. Please refer to UBC policy on the Administration of trust funds and over-expenditures for detailed procedures (Policy 90).

2.7 UNSOLICITED DONATIONS

If a donation is given and the donor specifies that it be used for a specific research project, that request shall be honoured. The St. Paul's Hospital Foundation will receive and administer the donation as per its Policies & Procedures. Prior to receiving and receipting the designated donation the Foundation will assure the research work has the final approval of the hospital.

Donations that are given for general research purposes shall be discussed with the Vice President Research, who may direct it to an appropriate endowment or project in consultation with the Research Leaders Committee.

3.0 RESEARCH TRUST ACCOUNTS

This section should be read in conjunction with the UBC Policy #90 on the Administration of Trust Funds and Over-expenditures.

3.1 ELIGIBILITY FOR HOSPITAL ACCOUNTS

Only Faculty appointees (Assistant Professor or higher) and Centre Directors of the Hospital may hold PHC Research Institute research trust accounts. Accounts will not be opened for post-doctoral fellows, students, visitors, or temporary staff. For accounting and statistical reasons, awards from different sources may not be placed in the same Hospital trust account.

3.2 OPENING & AMENDING ACCOUNTS

To open a new research trust account, the following documents must be sent to the PHC Research Institute:

- "**Request for New Account**" form (available from the PHCRI Research Facilitation Office
- a copy of the award notice or a copy of the contract
- the budget for the project

- a copy of the terms & conditions governing the use of the funds (for grants only)
- completed "**Signing Authority**" form

The VP Research must sign requests for a new trust account before they are opened.

3.3 RESPONSIBILITIES OF ACCOUNT HOLDERS

(a) **Proper use of funds:** The account holder (principal investigator to whom a grant or contract is awarded) is responsible for the proper use of all funds held in trust in his/her name. The account holder must ensure that all expenditures conform to the approved budget, with all terms and conditions of the grant or contract, with all regulations of the sponsoring agency, and with the regulations of the relevant Hospital and University departments (e.g. Finance, Payroll, Purchasing, Human Resources).

(b) **Personal benefits:** Expenditures for the personal benefit of the account holder or other parties are not allowed. These include association and professional memberships, or travel costs for spouses.

(c) **Over-expenditures are not allowed:** Funding for research projects must be pre-paid. The principal investigator must secure sufficient funding to meet the disbursement requirements at all times. Over-expenditures are not permitted. Invoices exceeding the balance in the account will not be processed and will be returned to the account holder. The Hospital and the University will not be responsible for overruns.

(d) **Payment of grant and contract funds:** Cheques received directly by grantees or departments must be forwarded to the PHCRI Research Facilitation Office for entry into the UBC database. PHCRI will deposit the cheques to the appropriate account. All cheques for research and other projects must be made payable to "**Providence Health Care Research Institute Trust**" and identified with the research trust account number (or name of project if account not known). Note that cheques made out to investigators personally are subject to income tax, unless endorsed to Providence Health Care Research Institute Trust.

3.4 RESPONSIBILITIES OF THE PHCRI FINANCE DEPARTMENT

The PHCRI Research Facilitation Office will prepare monthly revenue and expense reports according to their records and in the Hospital's standard format. Account holders may request amendments to such reports if it can be established, with supporting evidence that the reports are in error. The PHCRI ORS Finance Department will not undertake the provision of copies of vouchers or invoices to a sponsoring agency. Original vouchers and invoices are kept on file for audit purposes only. Researchers should make copies of original documents for their files. Financial statements of research trust accounts will be audited annually.

3.5 ACCOUNT SIGNATORIES

Account holders must sign all requests for disbursements from trust accounts. For disbursements greater than $5,000, the Department Head of the Account Holder must co-sign. Where the account holder is also the department head, the VP Research must co-sign. For disbursements greater than $20,000, the VP Research must co-sign.

3.6 SEPARATE ACCOUNTS & COMMON SERVICES ACCOUNTS

Funds from different sources may not be placed in the same trust account in order that accurate accounting and statistical records may be maintained. Transfer of funds between projects is prohibited unless authorized by the grantors of the funds.

3.7 TRAVEL EXPENSES

Travel expenses will be paid in accordance with the regulations of the granting agency. If the agency has no specific regulations, reimbursement will be in accordance with University policy, at current rates; reimbursement for automobile travel will not exceed the costs that would be incurred using economy air travel. The rate for reimbursement of personal vehicle use is $0.41/km (UBC policy as of March 18,2008). See UBC policy on Travel and Entertainment for more information.

3.8 PURCHASE OF EQUIPMENT AND SUPPLIES

Purchases of equipment and supplies must be purchased through the Hospital or University Purchasing departments. No physician, staff or student may obligate the Hospital for the purchase of goods or services. All equipment so purchased is the property of the Hospital, included in the Hospital capital asset listing and covered by the Hospital's insurance. PHC's and UBC's insurers do not cover any loss or damage to equipment that is not purchased by either institution's Purchasing department.

4.0 USE OF HOSPITAL/INSTITUTIONAL SERVICES

All research involving the use of Hospital services must have the approval of the departments providing the service. Services will be provided on a cost recovery basis.

4.1 RESPONSIBILITIES OF THE INVESTIGATOR

The investigator will obtain the fee schedule from the departments from which services are required in order to incorporate accurate costs into the budget for the grant application or contract negotiation. The investigator shall also make arrangements with the relevant department heads for the provision of services and the reimbursement of the hospital for the costs incurred by the departments to support the research.

4.2 RESPONSIBILITIES OF THE DEPARTMENTS

Departments that receive a request for service in support of a research project must:

i) assess if the department is able to support the request
ii) develop the budget for the services to be provided
iii) develop the mechanism for cost reimbursement
iv) send a letter of approval (or rejection) with an associated budget to the principal investigator and the PHCRI Research Facilitation Office, attn: Manager of Ethical Reviews.
v) provide the services as requested and approved

4.3 EXCEPTIONS FOR LABORATORY APPROVAL

In the event that written standards exist for lab tests to be done for a given disease state AND it is the case that the ONLY lab tests being done for a research project are those standard tests, laboratory approval is required for the research project but the approval process is expedited.

4.4 DOCUMENTATION OF INSTITUTIONAL APPROVAL

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. The decision of the PHC Vice President, Research 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, or UBC BCCA REB).
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 Final Certificate of Approval, signed by the PHC VP of Research.

5.0 ETHICAL CONDUCT OF RESEARCH INVOLVING HUMANS

Providence Health Care Policy for Research Involving Human Subjects:

Any research involving human subjects must be submitted for ethical review and be approved before research may commence. The Providence Health Care 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 Providence Health Care (“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 UBC Policy #89 or by a Research Ethics Board that has been specifically authorized by the Providence Health Care Vice President of Research and 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.

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

Researchers from other institutions, students and trainees must appoint an individual who holds either a Providence Health Care 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 appointment.

5.1 ONE RESEARCH ETHICS BOARD OF RECORD – UBC REBs

Effective March 21, 2007, all UBC Research Ethics Boards (UBC PHC REB, UBC CREB, UBC BREB and UBC BCCA REB) agreed that each research application reviewed by a UBC REB should have a single REB of Record. This is a change in procedure from the previous policy of Reciprocal Review between the UBC Research Ethics Boards.

The purpose of implementing one REB of Record is to avoid the requirement for multiple formal ethical reviews of the same research study. The need to identify one of several possible REBs to be the REB of Record arises when **the same Principal Investigator** is conducting research at more than one institution under the UBC REBs' jurisdiction.

Under this new policy, the UBC REB that initially reviews a research study normally becomes the REB of Record for the study, but occasionally a project is referred to another of the UBC REBs. Once established as the REB of Record, that REB should deal with all subsequent ethical supervision of that study. This means that the investigator is only required to submit all post approval activity submissions (amendments, annual renewals, etc.) to one REB, regardless of whether or not the research is being conducted at another institution under UBC REBs' jurisdiction.

The Providence Health Care Research Ethics Board should normally be the **REB of Record** for all research studies carried out at a Providence Healthcare site, and for research studies carried out at other sites (i.e. VGH, Women's and Children's), by Principal Investigators who hold Providence Healthcare staff appointments.

To ensure that institutional specific ethics requirements are met, the Chair of any of the REBs may view the application and study documents approved by the REB of Record. If the UBC PHC REB Chair has questions or concerns, these will be directed to the REB Chair of the REB of Record for resolution. The UBC PHC REB Chair may refer a question or concern to the REB of Record at any time (i.e. before or after the study has been approved by the REB of Record).

Under the process of one REB of Record, researchers are still required to obtain approval from the appropriate institution prior to commencing research.

5.2 AUTHORITY OF THE UBC PHC RESEARCH ETHICS BOARD

The UBC Vice President of Research, in accordance with UBC Policy #89 (Research and Other Studies Involving Human Subjects), has authorized the UBC Providence Health Care Research Ethics Board (UBC PHC REB) to function as the Research Ethics Board for Providence Health Care. The UBC Providence Health Care Research Ethics Board has the authority to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects that is conducted within or by members of Providence Health Care or UBC.

As required by the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, this includes, but is not limited to:

1. Research on new medications and surgical techniques
2. Therapeutic interventions
3. Diagnostic procedures or tests
4. Screening or treatment techniques
5. DNA/tissue banking
6. Behavioral research
7. Any other research involving human subjects or biological material originating from humans

Research involving the secondary use of identifiable personal data for research purposes will also be included within this definition of types of research that must be reviewed by the UBC PHC REB.

The UBC PHC REB will comply with the requirements of the Tri-Council Policy Statement, Health Canada regulations (Division 5 Part C.05.001), the guidelines described in the most current International Committee on Harmonization, and where applicable, the requirements of both the Office of Human Research Protection and the Food and Drug Administration of the United States.

5.3 REPORTING STRUCTURE

The UBC PHC REB reports to the Vice President Research UBC and through the Vice President Research and Academic Affairs Providence Health Care to the Board of Directors of Providence Health Care.

The UBC Providence Health Care Research Ethics Board (UBC PHC REB) must provide annual reports to the Vice President Research UBC and to the Board of Directors Providence Health Care on its activities and other matters requested by the Vice President Research UBC or the Board of Directors Providence Health Care.

5.4 PURPOSE

1. To provide scientific and ethical review of clinical and behavioral research proposed and conducted at Providence Health Care.
2. To ensure that the highest standards of scientific research and ethics will apply to all research involving human subjects at Providence Health Care.

5.5 MEMBERSHIP APPOINTMENT

The UBC PHC REB Chair, in consultation with the Associate Chair, and after prior consultation with the Providence Health Care VP of Research and Academic Affairs, will nominate members to the UBC PHC REB

The Vice President Research UBC in collaboration with the Vice President Research and Academic Affairs of Providence Health Care will make appointments to the UBC Providence Health Care Research Ethics Board (UBC PHC REB). It will be normal to make an initial appointment for three years, with the possibility of one renewal for a further three-year term. Terms of individual members should be staggered to ensure continuity of the REB expertise.

The Vice President Research UBC in collaboration with the Vice President Research and Academic Affairs Providence Health Care will appoint the Chair of the Providence Health Care Research Ethics Board, normally from amongst the membership of the UBC PHC REB for a three-year term as Chair, renewable for a further three years. The UBC PHC REB Chair will be a member of the UBC Research Ethics Policy Advisory Board.

The Vice President Research UBC in collaboration with the Vice President Research and Academic Affairs of Providence Health Care will appoint an Associate Chair(s) of the Providence Health Care Research Ethics Board, who can chair meetings and make decisions in the absence of the Chair. Normally the Associate Chair will be chosen from amongst the membership of the UBC PHC REB for a three-year term as Associate Chair, renewable for a further three years.

5.6 TERMS OF CHAIRMANSHIP, ASSOCIATE CHAIRMANSHIP AND MEMBERS

Chair: Normally three (3) years, renewable once
Associate Chair: Normally three (3) years, renewable once
Members: Normally three (3) years, renewable once

5.7 FREQUENCY OF MEETINGS

Meetings are normally held monthly ,and if otherwise required, at the call of the Chair.

5.8 MEMBERSHIP OF THE RESEARCH ETHICS BOARD

Membership of the UBC PHC REB will conform to the requirements of the Tri-Council Policy on Research Ethics Boards, Health Canada regulations and UBC Policy #89.

The REB shall consist of at least five members, including both men and women, of whom:

1. At least two members have broad expertise in the methods or areas of research that are covered by the REB;
2. At least one member knowledgeable in ethics
3. At least one member knowledgeable in law relevant to biomedical research; this is advisable but not mandatory for other areas of research
4. At least one member who has no affiliation with the institution, but is recruited from the community served by the institution
5. At least one member with primary experience and expertise in a non-scientific discipline
6. In accordance with Health Canada – Natural Health Products Directorate. When a REB reviews a research proposal involving the use of a natural product that has been formulated for therapeutic purposes the REB must include a member knowledgeable in complementary or alternative health care.

The UBC PHC REB will also conform to the following Health Canada requirements that the majority of members must be Canadian citizens or permanent residents under the Immigration Act.

The membership will normally include representation from the following groups:

1. Nursing
2. Pharmacological Sciences or Pharmacy
3. Members who represent Providence Health Care's six areas of emphasis, which include Cardiac/Lung, HIV AIDS, Urban Health, Nephrology, Aging and Mental Health.

All members of the UBC-Providence Health Care Research Ethics Board (UBC PHC REB) will be expected to lodge with the Chair of the UBC PHC REB an annual statement of any potential conflict of interest relevant to University REB matters. All members will be required to confirm in writing that they have no substantial financial interest in any potential sponsors of trials or other research that may be conducted at Providence Health Care nor do they have a relationship with any potential sponsor that might reasonably be interpreted to place them in a conflict of interest. In particular, equity holdings in potential sponsors, receipt of compensation for consulting or speaker's fees in excess of re-imbursement for actual costs (including reasonable, modest fees for time expended) will not be allowed. Members will be expected to adhere to the Conflict of Interest Policy of UBC.

Members will be provided with appropriate guideline material at the time that they join the research ethics board. This material includes the guidelines as published in UBC Policies #89 and

#97, the Tri-Council Policy Statement, the requirements of Health Canada, the ICH – Good Clinical Practices Guideline the U.S. Office of Human Research Protection, the Food and Drug Administration of the United States.

5.9 DELEGATION OF AUTHORITY

The UBC PHC REB delegates authority to the Chair and/or Associate Chairs to review ethics submissions that meet criteria for expedited review, such as minimal risk applications, serious adverse events, protocol deviations, annual renewals, and any other REB correspondence that requires acknowledgement.

The UBC PHC REB delegates authority to the Associate Chair(s) to act on behalf of the Chair in the absence of the Chair.

5.10 QUORUM

A quorum of the REB sufficient to take actions requiring full board participation must have members from each of the separate groups listed below.

1. At least two members have broad expertise in the methods or areas of research that are covered by the REB;
2. At least one member knowledgeable in ethics
3. At least one member knowledgeable in law relevant to biomedical research; this is advisable but not mandatory for other areas of research
4. At least one member who has no affiliation with the institution, but is recruited from the community served by the institution
5. At least one member with primary experience and expertise in a non-scientific discipline
6. In accordance with Health Canada – Natural Health Products Directorate. When a REB reviews a research proposal involving the use of a natural product that has been formulated for therapeutic purposes the REB must include a member knowledgeable in complementary or alternative health care.

All actions requiring full board approval will be made with at least two members from group 1, and at least one of the members from each of groups 2 through 5, and 6 if applicable. Decisions regarding the disposition of a study will be reached by consensus. If consensus is not reached, the Chair calls for a vote and the following criteria must be met in order approval to be granted.

1. At least a majority of members plus one must vote in favor and
2. Within the majority of members plus one, at least five of the members with the appropriate representative capacities stipulated under section C.05.001 of the Food and Drug Regulations as stipulated in the list above, must vote in favor of the approval.

5.11 FUNCTIONS

1. To ensure protection of the rights, safety and well-being of research subjects

2. To evaluate all proposed clinical and behavioral research for ethical validity

3. To consider the scientific or technical quality of the research as necessary to assess risks and benefits of the research as proposed.
4. To read and evaluate each complete application and to decide whether to:

    a. approve it;

b. require modifications to it;
c. reject it; or
d. terminate it

5. To ensure effective liaison is maintained between this Board and other bodies. To assure these relevant bodies that, where applicable, studies submitted will be supplied for their information and comment.

6. To conduct at least annual review of all ongoing UBC PHC REB approved research in accordance with Canadian and U.S. Guidelines in order to assess the progress of the investigations, and, where necessary, recommend their modification or discontinuance.

7. To, at the discretion of the board, conduct more frequent review of research judged to be higher risk, in order to assess the progress of the investigations, and, where necessary, recommend their modification or discontinuance.

8. To review protocol revisions, serious adverse event reports, consent form changes, protocol deviations and any other relevant communications applicable to UBC PHC REB approved studies

9. To respect the confidentiality of communications made to the Board and to assure investigators specifically that it will not distribute any of the protocols or other research related material(s) and privileged data outside of relevant bodies within Providence Health Care.

10. To ensure that no conflict of interest is present that would interfere with the impartial judgment of actions of the investigators, sponsors and participants in research. To ensure that no conflict of interest is present that would interfere with the impartial judgment or actions of the UBC PHC REB itself.

11. To review the release of new drugs under the “compassionate release” category. The Chair or Associate Chair of the UBC PHC Research Ethics Board may review requests for release of drugs through the Special Access Program of Health Canada on a compassionate release basis. The UBC PHC Research Ethics Board will provide such review if requested by the principal investigator or sponsoring company.

5.12 EXPEDITED REVIEW

By definition, expedited review requires only the Chair/Associate Chair of the REB or a subgroup of the full committee to review the submission and does not need to wait for the next full board REB meeting to be reviewed.

The Chair/Associate Chair of the REB will grant an Expedited review under certain circumstances. Those circumstances include:

1. Collections of hair, nail clippings, deciduous teeth, excreta, salivary secretions, additional swabs, or other external secretions that have been collected in a non-invasive manner and that may also be collected as part of routine clinical care.

2. Placenta or amniotic fluid collected as a consequence of childbirth

3. Data recorded using non-invasive procedures (e.g. EEG, EKG, MRI, or x-rays not exceeding radiation exposure equivalent to one return transcontinental air flight) , but not

including questionnaires requesting sensitive information from vulnerable populations or involving significant nuisance or inconvenience.;

4. Blood samples collected by venipuncture or a central line installed as part of clinical care;

5. Output data obtained as a result of moderate exercise undertaken by healthy volunteers;

6. Output data obtained as a result of maximal exercise undertaken by healthy volunteers who are less than 40 years old, and the CREB has approved a safety protocol.

7. Clinical data collected prospectively as part of clinical care.

Study of existing data, documents, records, pathological specimens or diagnostic specimens Expedited review may also be used:

1. for the applicant's response to provisos issued by the Research Ethics Board
2. amendments
3. annual review
4. open label extensions

The Chair/Associate Chair may determine that any of the above categories should be reviewed at a formal Research Ethics Board meeting.

Note: Hospital Department approvals are still required for expedited submissions and a fully executed contract or grant-in-aid agreement is required before any sponsored research may begin.

5.13 CONFLICT OF INTEREST

If the REB is reviewing research in which a member of the REB has a personal interest (e.g. as an investigator or entrepreneur), that member must not be present when the REB is discussing or making its decision.

5.14 REVIEW OF ONGOING RESEARCH

Ethical approval of research projects shall normally be granted for one year from the date of review. In circumstances in which the REB considers the research to be high risk, ethical approval may be granted for a period less than one year. Ongoing research (lasting greater that one year) shall be subject of continuing ethics review. Investigators shall submit, annually, a status report to the REB. The status report must include at a minimum:

1. If the annual renewal qualifies for expedited review
2. If the study involves enrollment of human subjects
3. If the study is currently open to enrollment
4. The number of subjects, including controls, enrolled at the institutions covered by the UBC ethics approval
5. The number of subjects, including controls, enrolled in the entire study
6. The number of normal subjects enrolled at the institutions covered by UBC ethics approval
7. The number of normal subjects enrolled in the entire study

In addition, the report must include a copy of the current approved consent form if enrollment is currently open or will be open in the future, and a brief summary on the progress of the study.

5.15 RESEARCH IN EMERGENCY HEALTH SITUATIONS

In accordance with the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, research in emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved.

The UBC Providence Health Care REB may allow research that involves health emergencies to be carried out without the free and informed consent of the subject or of his/her authorized third party if ALL of the following apply:

(1) a serious threat to the prospective subject requires immediate intervention, and
(2) either no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison with standard care, and
(3) either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the subject, and
(4) the prospective subject is unconscious or lacks capacity to understand risks, methods and purposes of the research, and
(5) third party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so, and
(6) no relevant prior directive by the subject is known to exist.

5.16 APPEAL PROCEDURES

In cases when investigators and the REB cannot reach agreement through discussion and reconsideration, the REB will refer the protocol to the Conjoint Policy, Education and Appeals Committee of UBC. If that committee approves the proposal, the REB Chair will issue a Certificate of Ethical Approval.

6.0 PERSONAL CONTRACTS

Personal contracts for research and other services negotiated between an individual and an external agency without the involvement of the hospital will not be accepted for administration by the hospital. Similarly, hospital patients, staff and facilities including the Research Ethics Board may not be used for work carried out under such contracts.

To be accepted for administration by the hospital, the PHCRI Research Facilitation Office must be involved in the establishment of the contracts, work statements, budgets, and the negotiation of contracts. The investigator must elect to turn over the trusteeship of the funds to the hospital, and such trusteeship must be mutually agreeable between the hospital and the agency.

7.0 RESEARCH SPACE

The assignment of research space is under the auspices of the VP Research and should adhere to the following general principles.

a. That space be assigned to individuals or groups and not to departments.
b. That the assignment be based on the productivity of the investigators and their research operating grant support (for basic research) or the portion of research grant for personnel support (for clinical research).
c. That space be assigned for a definite term that can be renewed based on performance.
d. That a review/reallocation process be set up one year prior to the end of each term. This review process should recommend to the VP Research as to whether or not the space assignment should be renewed or modified.

8.0 HEALTH INFORMATION FOR RESEARCH

8.1 DEFINITIONS

For purposes of this policy, a **Database** is defined as a collection of interrelated, shared and controlled data that can be processed by one or more application systems; or a collection of logically related data stored together in one or more computerized files.

Health Information is defined as confidential facts or data that apply to the health status of an individual and/or to the treatment or care provided to that individual that is held or collected by a health care professional or health care organization.

A **Hospital database** is defined as health information on registered Providence Health Care inpatients and outpatients contained in any database, whether or not it was developed by Information Services or by other groups within the hospital. Ownership of this data resides exclusively with Providence Health Care.

8.2 OWNERSHIP OF MANIPULATED OR MODIFIED DATA

Hospital patient data which has been modified or manipulated by groups within the hospital who have developed their own patient-based databases, registries etc. for research or patient care purposes are the property of the hospital. However, if the manipulated data is to be used for publication purposes, these data will remain confidential until the data has been accepted for publication, after which any reasonable request for access to this data will be provided.

8.3 OWNERSHIP OF DATA LINKED WITH EXTERNAL SERVICES

Databases that are linked to external sources such as Pharmanet or MSP are the primary property of Providence Health Care and are subject to the same ownership restrictions as outlined in 9.2 above. If sources external to Providence Health Care wish to access Providence data via a linkage with some external database, the same procedure for access will be followed as for internal access.

8.4 COMMERCIAL USE OF DATA

Commercial use of Providence Health Care data is strictly prohibited outside of defined and approved research purposes.

8.5 PUBLICATION OF DATA

Results of all research generated using Providence Health Care patient information is publishable only when all appropriate research policies and procedures have been followed and patient confidentiality has been ensured. Published data must not identify the patients in any way, either by name, initials, or other unique identifiers.

8.6 ACCESS TO DATA

Requests for chart review (including electronic access via optical electronic disk) will be handled in the same way as has been customary for hardcopy reviews. Specifically, all chart review applications for retrospective studies, either in hardcopy or electronic form, require the completion of a Request for Chart Review form to the Leader of Health Records.

Conditions and criteria for allowing access and prioritizing access to health information include: 1) confirmation that the request ensures patient confidentiality; 2) the request is necessary to pursue research which is consistent with the strategic plan of the Hospital; 3) the proposed questions are scientifically valid; 4) patient consent is obtained; and 5) if the database is part of a hospital or university program, approval is obtained from the Director of that program.

If the costs are going to be incurred by Information Services, Medical Records other program/department in accommodating such requests, priority will be given to those individuals or groups who have funding to cover the costs of these services. Each of the departments that grant access to such information may determine the costs associated with the work entailed with these requests. It is the responsibility of the researcher requesting the information to reimburse the relevant department(s).

8.7 CONFIDENTIALITY OF DATA

As with all research and other activities, assuring patient confidentiality is of utmost importance. As a result, it is the responsibility of all principal investigators and associated research personnel to maintain patient confidentiality of all information to which they are privy in the context of their research activities. Specifically, this requires that patients not be identified in <u>any way</u> in all reports and/or documents generated through the research activity (e.g., no names, initials, or other unique patient identifiers). In addition, it is the responsibility of all investigators and research personnel to be familiar with the Freedom of Information and Protection of Privacy Act and other relevant applicable legislation, regulations and other requirements concerning confidentiality and privacy.

9.0 SALARY AND HONORARIA

Investigators who perform clinical research but do not receive salary support from the university or hospital may receive salary or honorarium consistent with fund availability and budgetary estimates from research contracts. If such salary or honoraria is not processed through an affiliate university, it must be reviewed by PHCRI Human Resources prior to payment. Salary or honoraria must be based on hours worked rather than the number of patients recruited and must be built into the budget and signed off by the department head. In all cases, UBC Policies on Salary and Honoraria will apply. All honoraria paid out must be accompanied by the appropriate documentation. The Hospital or University Finance Department or PHCRI Finance administering the funds must issue T4 or T4A slips, whichever is applicable, to the recipient(s).

All employees involved in research at PHCRI must be either appointed through an affiliate university, or have their appointment reviewed by PHCRI Human Resources prior to payment to ensure employment standards and CRA guidelines are being met. All employee salary and honoraria paid directly from PHCRI research trust accounts must be processed through PHCRI Human Resources and PHCRI Finance must issue T4 slips to the recipient(s).

10.0 CONFLICT OF INTEREST

Any person involved in research conducted at or under the auspices of Providence Health Care, including investigators, research assistants, or any other individual involved in research, will be bound by the Providence Corporate Policy on Conflict of Interest (CPF0400). In addition, UBC employees and faculty members are bound by UBC Policy #97: Conflict of Interest. For all commercially sponsored research, a "**Sponsor Initiated Clinical Trial Information Form (CTIF)** must be completed; submission of this form to PHCRI Research Facilitation Office will trigger the start of the contract negotiation process.

11.0 SOURCE DOCUMENTS AND RECOMMENDED READING

Therapeutic Products Directorate Guidelines/ICH Harmonized tripartite Guideline Good Clinical Practice: consolidated Guideline
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php

Tri-Council Policy Statement Ethical Conduct for Research Involving Humans
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default

World Medical Organization Declaration of Helsinki Amended version October 2013
http://www.wma.net/en/30publications/10policies/b3/

UBC Office of Research Services website www.ors.ubc.ca

UBC University/Industry Liaison Office website www.uilo.ubc.ca

PHC Research Institute website www.providenceresearch.ca

UBC Faculty of Medicine website
https://mednet.med.ubc.ca/Research/GrantApplications/Pages/default.aspx