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**	**Procedure Version No.:** 4	**Effective Date:** April 18, 2018

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) and Simon Fraser University (SFU). 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, SFU 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 (d) requests for data or tissue are 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 "UBC" shall indicate The University of British Columbia and "SFU" shall indicate Simon Fraser University.

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 an undertaking (including pilot studies, exploratory studies, and course-based assignments) intended to extend knowledge through a disciplined inquiry or systematic investigation that includes the following:

1. Living human participants; and/or
2. Human biological materials including tissue and biological fluids. This applies to materials derived from living and deceased individuals.

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 and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes. Determination of exemption is based on regulatory and institutional criteria. Researchers are encouraged to utilize the ARECCI screening tool to help determine whether their project is research vs. QI/QA.

If in doubt about whether a research project is categorized as that involving human subjects, researchers are asked to contact the Manager, Ethical Reviews at 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 and 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 40% 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, UBC and PHC 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, UBC 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/UBC to the best of its ability;
- Particular care must be taken with indemnification and insurance provision of agreements.

Standard Hospital/UBC 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 UBC;
- specific result or development expected;
- ownership of inventions, software, biological materials, know-how, trade secrets or other intellectual property vests in UBC;
- 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 UBC to the best of its ability.

Standard Hospital/UBC indirect costs of 40% 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 UBC;
- rights to intellectual property provided by the sponsor for analysis or evaluation remain with the sponsor;
- UBC 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 UBC to the best of its ability.

Standard Hospital/UBC indirect costs of 40% of total budget will be assessed against project expenditures.

1.2 AUTHORITY TO CONTRACT

Only the Hospital and UBC 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.

For grant-in-aid and Contracts with SFU, only SFU and the Hospital have the legal authority to enter into contracts that are binding on the Institutions. Grant-in-aid and Contracts for research and other projects must be among Providence Health Care Society, SFU 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 or SFU, 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 UBC. 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 UBC. The University-Industry Liaison Office at UBC is also responsible for licenses and other intellectual property agreements.

For all grant-in-aid, contracts and agreements with SFU, new and extensions/amendments, must be documented and negotiated by the grants or contracts department of SFU, Office of Research Services.

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:

i) sponsor;
ii) applicant (principal investigator, who will sign grants though not an individual party);
iii) PHC Vice President Research/UBC Assistant Dean Research; and
iv) 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; and
- 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, UBC or SFU and are not the property of any individual. **See Section 3.1 Responsibilities of Research Trust Account Holders 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 UBC indirect costs (see Section1.9).

All researchers submitting to UBC affiliated Research Ethics Boards (Including the UBC-PHC REB), the REB will be requiring the submission of the clinical trial budget in relation to all privately (industry) sponsored clinical trials. This requirement is being implemented pursuant to the requirements of the Tri-Council Policy Statement 2, 2014 TCPS2 2014 Article 11.11 as well as the National Standard of Canada for Research Ethics Oversight of Biomedical Clinical Trials, CAN/CGSB-191.1-2013 Article 4.4.3.2 (m). The purpose of the review is to ensure that there are no relevant financial conflicts of interest including the use of inappropriate recruitment incentives.

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 and the REB 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/UBC indirect costs of 30% of the total project expenditure**, which are used to support the research infrastructure.

Under the Affiliation Agreement between Providence Health Care Society and SFU, 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 SFU must include **a standard Hospital/SFU indirect costs of 25% of the total project**

expenditure, which are used to support the research infrastructure. For overhead distribution of indirect costs at SFU, refer to SFU Research Policies.

See the Research Support Funds and Indirect Costs information document.

The distribution of indirect costs is as follows:

1. 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.
2. Grants, Service Contracts and Collaborative Research Agreements: 1/2 to UBC, 1/2 to PHCRI (1/4 to PHCRI, 1/4 to the department or centre of the principal investigator, 1/2 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.

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

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

3. **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.

4. **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).

5. **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.

6. **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/UBC 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/UBC 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 ors.ubc.ca by clicking on Funding Opportunities.

2.2 SIGNATURES

All applicants for all grants must complete the Research Project Information Form (RPIF), sign by applicant and obtain the signature of their UBC Department Head and Centre Director if applicable. A current list of UBC Department Heads is available on the UBC Faculty of Medicine website. 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; and
- in the case of co-operative projects, letters of support or commitment from collaborating companies or institutions.

PHCRI Research Facilitation Office will obtain hospital/UBC 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 UBC, SFU or PHCRI, except in the case of Tri-council (CIHR, SSHRC, NSERC) and National Institutes of Health awards which must be held and administered by UBC or SFU.

2.5 OWNERSHIP OF RESEARCH FUNDS

All research grant and contract funds from Foundations, UBC, and other not-for-profit sources are held in trust and managed by the Hospital, or UBC 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) or SFU policy on Research Policies and Guidelines.

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 RESPONSIBILITIES OF THE RESEARCH ACCOUNTING DEPARTMENT

The PHCRI Finance Department 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 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.

3.1 RESPONSIBILITIES OF RESEARCH TRUST ACCOUNT HOLDERS

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 with 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 UBC departments (e.g. Finance, Payroll, Purchasing, Human Resources).

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.

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.

Research Trust Accounts: Due to legal and tax implications, approval to open a research trust account will be granted only if the purpose of the account is to further the mission of PHCRI, facilitate PHCRI's operation and the account holder is a member or a permanent staffer of PHCRI, or a department head of PHC. **The owner of the trust account is Providence Research Institute Trust, no individual can be the owner.**

Eligibility for Research Trust Accounts: Only members of the Hospital's permanent staff may hold Providence 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.

Opening & Amending Accounts: To open a new research trust account, the following documents must be sent to the PHCRI Bookkeeper:

- completed and signed "Research Trust Account Application and Signing Authority Form";
- a copy of the award notice (for grants only);
- the budget for the project and a copy of the contractual agreement with the sponsor outlining their financial commitment; and
- a copy of the terms & conditions governing the use of the funds (for grants only).

The VP Research approves all requests for a new research trust accounts before they are opened.

Account Numbers: When the application is approved, the PHCRI Finance Department will assign and open a trust account that will be reported back to the applicant.

Change in Purpose: Every trust account is established and approved for a specific purpose. If the use or purpose of the trust account is to be altered, written approval must be obtained from the President's office.

Separate Accounts & Common Service Accounts: Funds from different sources may not be placed in the same trust account in order for accurate accounting and statistical records to be maintained. Transfer of funds between projects is prohibited unless authorized by the grantors of the funds. There are two exceptions to the above rule:

1. Cost recovery for services provided by one project from another. This is allowed, as long as the account holder provides appropriate documentation.
2. A Department Head may establish a Common Services Account if s/he considers it to be in the best interests of the research program in his/her department. The request to establish a Common Services Account must be accompanied with the approval from the VP Research and the account holders in the department. The RI Accountant will transfer funds from several grants into a common service account to support technicians, secretarial printing and other services required for the efficient operation of the program. Such transfers of funds must be compatible with the policies of the granting agencies involved. Records of such expenditures must be given to grantees.

Payments/Deposits to Trusts Accounts - **Payment of grant and contract funds:** Cheques received directly by grantees or departments must be forwarded to the PHCRI Finance Department for entry into the UBC database. A PHCRI Bookkeeper 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 principle investigator name. Note that cheques made out to investigators personally are subject to income tax, unless endorsed to Providence Health Care Research Institute Trust.

Closing Trust Accounts: Upon the completion of a study, trust accounts have to be closed. To close out a research trust account complete the "Research Trust Account Closure Form" and forward to PHCRI Finance Department. Any remaining balance must be expensed or transferred within the terms of reference of the account.

Signatory and Spending Authority: The trust account holder must file a "Research Trust Account Application and Signing Authority Form". The principal signatory must be the manager of the trust accounts. Authorized signatories can approve disbursements for expenses that are within the scope of the stated purposes of the trust account. The spending authority levels are as follows:

Research Trust Accounts

Level 1: Up to $5,000		Account Holder and /or Designate
Level 2: $5,001 to $20,000	co-signed:	Department Head
Level 3: $20,001 to $100,000	co-signed:	PHCRI President
Level 4: Over $100,001	co-signed:	PHC CEO

The account manager or principal investigator must be a signatory to all disbursements and other financial commitments as they are responsible for the operation of their trust accounts.

Two signatures are required for disbursements that are over $5,000. In the case that the account holder is a Department Head or Clinical Department Head, obtain approval from the next level up signatory.

Direct payments to any of the signatories, or to third parties for the benefit or enjoyment of any of the signatories, must be approved by the next level up signatory.

Establishing or Changing Signatories: To establish or change signatories, complete a separate Signing Authority Form and provide a specimen of each authority level's signatory. Forward this form to the PHCRI Finance Department.

Responsibilities of Signatories: The responsibilities of signatories are as follows:

- to ensure all transactions are consistent with the use or purpose of the trust account;
- to ensure the account is not overdrawn at any time; and
- to review periodic financial reports of the trust accounts and advise Finance of any discrepancies.

Temporary Delegation of Signing Authority: If the principal signatory will be absent for short periods and the department heads do not wish to assume the authorization of transactions under the stipulated level, temporary arrangements can be made to delegate signing authority. Forward a memo to the Research Institute Accountant stating the reason for the request, a specimen of the delegate's signature and the effective time period.

Absence of Signatory: In the event of long-term absence of a signatory, signing authority will be resolved on an exceptional basis as circumstances warrant.

Receipt of Funds: All payments into the research trust accounts are to be accompanied by appropriate documentation that identifies the source of the funds and any related correspondence from third parties.

Cheques: Cheques are to be made out to Providence Health Care Research Institute Trust in order to avoid income tax implications to the account manager. Attach related correspondence and other documentation. Identify the trust account number or principle investigator name and forward to PHCRI Finance Department.

If cheques received are made payable to a signatory, please contact the Finance Department for instructions on how to endorse the funds to the Providence Health Care Research Institute Trust.

Cash Payments: Cash and copies of related documentation should be deposited at Cashier's office, St. Paul's Hospital (please provide Cashier with the Research Account number). Cashier will issue a receipt which will be forwarded to the PHCRI Finance Department.

Finance Generated Entries: Amounts may be put into an account by way of accounting entries initiated by the PHCRI's Finance Department under the authorization of the Finance Manager. This type of transaction includes allocation of interest income, correction of postings etc.

Transfer Between Accounts: In order to maintain the integrity of each account's financial information, transfers between accounts are not permitted.

In the case that the costs of goods and services benefit more than one account, such costs may be allocated to such accounts with proper supporting documentation.

Disbursement of Funds: Trust accounts can purchase supplies, equipment and services, provided they are within the scope of the designated use or purpose of the account. The acquisition can be processed through the Hospital's Purchasing Department and are subject to the policies and procedures established by the Purchasing Department.

Purchase Requisition: In recognition of the cross appointment of some Clinical Department Heads and some Principal Investigators by the PHCRI and UBC, where appropriate (which includes price advantage), some supplies and equipment may be purchased via UBC. The PHCRI will reimburse UBC upon receipt of the invoice that has been duly approved by the appropriate signatories.

Purchase via St. Paul's Hospital: Purchase Requisition (Form MM066) will be used to obtain most goods and services excluding capital equipment. (See Capital Equipment Purchases on Page 16). The Purchasing Department will issue purchase orders in the usual manner.

- Complete the Purchase Requisition;
- Indicate the estimated cost if known;
- Provide appropriate authorized signatory approval;
- For costs over $5,000, forward the Purchase Requisition and the Confirmation of Capital Funding form to the PHCRI's Finance Department which will verify the fund balance of the account and forward the requisition to Purchasing for action;
- Purchasing will generate a Purchase Order (PO) to the vendor;
- When goods are received, Receiving will make the delivery. Vendors are not allowed to deliver the goods directly to the requisitioner unless special circumstances warrant. In the event that this happens, the packing slip signed by the person who received the goods must be sent to Receiving without delay.

Cheque Requisitions: Use the "Cheque Request Form" when payments are required to pay for non-purchase order related expenses. For example: reimbursement for small supplies purchased by a staff and other miscellaneous expenses.

- Complete a "Cheque Request Form";
- Attach original receipts, invoice or other supporting documentation;
- Obtain authorized signatory approval;
- Forward the form and the supporting documentation to Research Institute Accountant.

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. This section is to be read in conjunction with UBC's policy #83 on Travel and Related Expenses.

Reimbursement for automobile travel will not exceed the costs that would be incurred using economy air travel.

For travel outside North America, prior approval must be obtained from the Vice President of Research or the Director of Research Services, as the case may be. If the traveler is an authorized signatory, approval by the next level up signatory should be obtained.

- Advances can be obtained via use of "Cheque Request Form", if required;
- Complete "Cheque Request Form" within 30 days upon return from trip. Submit original receipts to support the expense and the advance, if any advance was given;
- Economy fare travel is permitted, business class travel is not reimbursable.

Advances: Advances shall be paid back within 90 days of issuance. After 90 days, all outstanding advances will be charged to the corresponding Research Trust account.

HST/GST: The PHCRI's HST or GST rebate status can be extended to the goods and services that are purchased out of these accounts. Only the non-rebatable portion of HST or GST will be charged to these accounts.

Petty Cash: A Petty Cash account may be set-up to cover unexpected/minimal departmental expenses. The Petty Cash account may not exceed a balance of $500.00.

Setting-up the Account

- Submit a “Cheque Request Form” to the Finance Department (no receipts are required at the time of set up).

Replenishing the Account

- Submit a “Cheque Request Form” found in Section 13.2 of this document.

Missing Receipts: All reimbursement requests not supported by original supporting documents will need to have a “Lost Receipts Form” completed and approved prior to reimbursement. The missing receipts form is an acknowledgement by the requestor that they are not using original receipts for reimbursements purposes elsewhere.

Capital Equipment Purchases: Capital equipment acquired with trust funds generally becomes the property of the PHCRI and is included in the PHCRI's Fixed Asset listing, unless the ownership is retained by the fund grantor as specified in the contract.

If an account holder chooses to retain ownership of the equipment subject to approval by the fund grantor, then this becomes a non-PHCRI expenditure and the fund used to pay for this equipment will be considered income to the account holder. The purchase is not entitled to HST rebate and the PHCRI will issue a T4A slip to the account holder. 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. All electrical equipment used in the PHCRI must conform with the regulatory requirement and must be approved by the St. Paul’s Hospital's Maintenance and Biomedical Engineering department.

Definition of Capital Equipment:

- has a useful of life exceeding one year;
- is not intended for resale; and
- has a unit cost greater than $5,000.

Computer Equipment: All computer equipment purchases must be co-ordinated by the Information Systems Services (IS) of the Hospital. IS staff will assess the needs and make recommendation on the equipment selection that will meet the hospital's standards.

Procurement of Capital Equipment: All capital equipment needs to be purchased through Providence Health Care Logistics. The process to purchase capital equipment is as follows:

- complete Purchase Requisition (Form MM066) and confirmation of capital funding form and indicate the cost estimate;
- obtain authorized signatory approval according to the tiered Spending Authority in Section 2;
- forward completed form to Research Institute Accountant who will verify the fund availability and refer to Purchasing for action.

Maintenance of Capital Equipment: Maintenance or service contracts to be purchased for capital equipment should be purchased using the same process as purchasing capital equipment as outlined on Page 16.

- The costs of repair and maintenance for equipment purchased with trust funds will be the financial responsibility of the trust funds.

Payroll Payment for Individuals: Payments to individuals who are employees of the PHCRI are to be processed through the payroll system of PHCRI or UBC, as the case may be, and the costs will be recovered from the trust accounts. Other individuals who are not employees of the PHCRI may be considered as an independent contractor or as an individual with employee status and subject to tax withholdings, etc. See Human Resources Section 8.0 for more information.

The four categories of payment methods to individuals are as follows:

- Independent Contractors: Those who are ruled by Canada Revenue Agency (CRA) to be Independent Contractor must sign an agreement with the Research Institute stating that they have met all the guidelines set out by CRA and will personally assume all financial liability for at-source deductions, penalties and interest if deemed by CRA that they do not meet the criteria of an Independent Contractor;
- Employees of UBC: For individuals whose salary funding comes from UBC the Researcher can hire them through UBC with approval of their UBC Department;
- Employees of PHCRI: For individuals whose salary funding is held at the PHCRI the Researcher can hire them through PHCRI as a term employee and the PHCRI will withhold mandatory at source deductions.

Independent Contractors: CRA determines who is considered an Independent Contractor based on the employment relationship. For more information visit UBC's "Determining Employee/Contractor Status" webpage and consult CRA's "Employee or Self-Employed" Booklet. If you are having difficulty determining who is an independent contractor, contact PHCRI HR to discuss your particular circumstances. See Human Resources Section 7.0 for more information.

Contractors who are able to provide the following information are the very least risk to PHCRI:

- CCRA registered business number,
- Name of company and date it was incorporated,
- Charge 12% for HST on its services,
- WCB registration #, and
- Certificate of public liability insurance.

Care must be exercised in determining whether or not payment will be construed to represent payment to a contractor or a person acting in the capacity of an employee. There may be serious implications to the PHCRI and the principal signatory if transactions are not handled properly. Contact PHCRI Finance Department to review the circumstances regarding each case before the payment or any commitment is made.

All independent contractors and self-employed individuals are required to complete the "Independent Contractor Profile Form" prior to submitting any invoices to Finance for payment. These individuals will be paid by the Providence Health Care's Accounts Payable system. Unless the individual has provided his or her Canada Tax Account Number, T4A slips will be issued at the end of each year for fees, commissions, or other amount paid for services.

Property Insurance: The PHCRI's property insurance policy is extended to cover capital equipment that is owned by the PHCRI. Property or equipment is said to be owned by the PHCRI if it is paid by the PHCRI's funds or donated to the PHCRI and the PHCRI holds title to the property. Coverage is also extended to equipment that is paid for by the trust funds and the title to the equipment is held by the fund grantor under specific stipulation in the contract. Specifically excluded are equipment, furniture and other articles that are privately owned by the principal investigators, etc. In case of insurance claim, the deductible amount is the financial responsibility of the trust account.

Standard Monthly Financial Reporting: The Finance Department of PHCRI will provide standard monthly financial reports to the trust account owners, Clinical department heads and President's Office. Queries regarding transactions should be directed to the PHCRI Finance Department for resolution.

Special Reporting: Out-of-pocket expenses and labour costs may be charged to trust accounts when special reports or audits are required.

Audits: The trust accounts operation and financial statements are subject to audit in conjunction with the normal audits of PHCRI operation. The audit financial statements are presented to the PHCRI's Board for approval.

Income Tax: Providence Research Institute Trust assumes a fiduciary responsibility with regard to all research trust funds and strives to ensure that no transaction in these funds can be construed as facilitating income tax avoidance or evasion.

Signatories are urged to contact the PHCRI's Finance Department to review any transaction that may have an income tax implication. This should be done prior to initiating the transaction.

The PHCRI will issue T4-A's for payments to independent contractors and proprietor physicians in respect of "fees, commissions or other payments for services", unless the recipient has provided the Revenue Canada Tax Account Number of his or her business in the "Independent Contractor Profile Form".

T4-A's will also be issued for any transactions which confer a taxable benefit on an individual or reimburse an individual for expenditures which may not otherwise be tax deductible in the individual's hands. While this does not restrict the signatory from conducting these transactions, it places the onus on the payee to include the T4-A amount or other amounts that a payee receives as his income for tax purpose and justify the expenditure as a deduction there from.

Examples of transactions which may result in a T4-A being issued are:

- payment to an individual not supported by an invoice;
- payment for medical plan insurance policy, car allowance that is not distance based;
- purchase of capital asset where the hospital does not hold title;
- payment for travel/education that may not be considered a tax deductible business expense due to destination, duration and purpose of the trip.

3.2 UNIVERSITY OF BRITISH COLUMBIA

All Research Funds must be received by UBC and deposited into UBC research accounts. UBC delegates to eligible UBC Persons the responsibility for ensuring that these research accounts are managed properly and in accordance with UBC policies, Funding Terms, and any other applicable requirements ("Research Spending Responsibility"). The following UBC Persons are eligible for Research Spending Responsibility:

1. UBC Persons who have a tenure stream faculty appointment as a Professor, Associate Professor, Assistant Professor, Instructor, Senior Instructor, or Professor of Teaching or comparable Emeritus status;
2. UBC Persons who have one of the following faculty term appointments without review and also have the prior written approval of both the appropriate Department Head and Dean: (i) Professor, (ii) Associate Professor, (iii) Assistant Professor, (iv) Instructor, (v) Senior Instructor, (vi) Professor of Teaching, (vii) Adjunct Professor, (viii) Clinical (ix) Honorary or (x) Research Associate;
3. Librarians who have the prior written approval of the University Librarian; and
4. Post-Doctoral Fellows solely where the Funding Terms for a research project specifically require it and they have the prior written approval of both the appropriate Department Head and Dean.

Research Spending Responsibility will not be granted to students or visitors. UBC Persons with positions not addressed above will require the written approval of both their Department Head and Dean (as applicable) and the Provost prior to being granted Research Spending Responsibility.

The Office of Research Services or the University-Industry Liaison Office (as applicable) must ensure that all persons granted Research Spending Responsibility are approved for such Research Spending Responsibility and are legally bound to comply with UBC policies, rules and procedures on the conduct of Research before such Research Spending Responsibility is granted.

Opening and Amending Accounts: No payment may be made from any Research Funds until the opening of a financial research account (or the amendment of an existing account) has been authorized in writing by the Office of Research Services or the University-Industry Liaison Office. Requests for new accounts or amendments, such as budget increases to existing accounts, must be made in writing in accordance with the processes implemented by the relevant office.

Delegation of Research Spending Responsibility: UBC Researchers given Research Spending Responsibility for a UBC research account may delegate their authority to approve expenditures from such research account to another UBC staff or faculty member provided that their Department Head is notified in writing of the delegation. For clarity, any UBC Researcher with Research Spending Responsibility who delegates authority will continue to be responsible for ensuring all transactions in such research account, including all expenditures approved by the person(s) with delegated authority, are fully compliant with Funding Terms, UBC policies and any other applicable requirements.

Payment of Funds: Any Research Funds must be payable directly to UBC. UBC Researchers must not accept funds in support of Research made payable to the UBC Researcher personally. In the event Research Funds are received directly by UBC Researchers such funds should be forwarded to the Vice President, Research and International Portfolio Finance Group.

Responsibility for Financial Statements: Financial statements or claims, if required by the sponsoring agency, will be prepared by the Vice President, Research and International Portfolio Finance Group on the basis of their records. The Responsible Executive may authorize certain UBC employees, or classes of employees, to issue and sign financial statements or claims on behalf of UBC. UBC Researchers may request amendments to such statements or claims if it can be established, with supporting evidence, that the statements or claims are in error.

Payments to Employees: All payments for services to UBC employees (in their capacity as employees) must be paid through the UBC payroll system managed by UBC Financial Operations. Research project budgets must account for required source deductions and employee benefits.

Payments to Independent Contractors: All payments for services in support of UBC Research

made to independent contractors (incorporated or unincorporated) must be paid in accordance with the processes established by UBC Financial Operations.

Purchase of Equipment and Supplies: All purchases of equipment and supplies for UBC Research must be made in accordance with the processes established by UBC Financial Operations.

Travel Expenses: Travel expenses incurred for UBC Research must be incurred and reimbursed in accordance with UBC's Policy #83 (Travel and Related Expenses).

Honoraria: The execution or approval of any applications, grants, donations, or contracts between UBC and a third party that involves the payment of honoraria to UBC Persons must be approved in writing by:

- the Head of Department or Director of the UBC Person; and
- the Dean of the Faculty where the UBC Person holds his or her primary appointment (where applicable).

Where such approval has been obtained, UBC signing officers are authorized to sign or approve such applications, grants, or contracts on behalf of UBC, and UBC staff are authorized to pay such honoraria (in accordance with UBC procedures), subject to the following sentence. Where honoraria for a UBC Person from all third party sources (contracts, grants, etc. whether the funding source is Research related or otherwise and whether the honorarium is for Research activities or otherwise) exceeds one-sixth of the UBC Person's total compensation (excluding benefits) from UBC during the annual period July 1 to June 30, then the approval in writing of the Provost is also required in addition to the approvals listed above.

Separate Accounts: Research Funds from different sources may not be placed in the same UBC account except where permitted by UBC's financial policies and procedures. Transfers between UBC accounts may only be made if a) the transfer is permitted by all 8 applicable Funding Terms and b) is permissible pursuant to the financial policies and procedures of UBC.

3.3 ST. PAUL'S HOSPITAL FOUNDATION

The St. Paul's Hospital Foundation actively fundraises for research under the Providence Health Care Research Institute. Investigators seeking support from the Foundation for research projects must submit a formal request for funding to the Research Leaders Executive Committee. Requests for fundraising efforts need to be approved by the Research Leaders Executive Committee before being placed on the St. Paul's Hospital fundraising goals list. The Research Leaders Executive Committee is comprised of the VP Research, VP Medical Affairs, Research Centre Directors and three (3) nominated members. Applications for funding can be submitted to the VP Research's Executive Assistant: VPResearchSupport@providencehealth.bc.ca.
Applications are reviewed and ranked based on the following criteria:

- Quality of proposal
- Department support
- Fits with strategic plan
- Partnership or other resources
- Duration of funding request and size of request
- Fairness

Please refer to appendix 1 for the application for funding form. To access funding from the Foundation once it has been approved, an investigator must first incur the expense on one of their

eligible Research Accounts. A disbursement form from the foundation must then be completed and the Foundation will reimburse the Research Account for the approved expenses.

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:

- assess if the department is able to support the request;
- develop the budget for the services to be provided;
- develop the mechanism for cost reimbursement;
- send a letter of approval (or rejection) with an associated budget to the Principal Investigator and the PHCRI Research Office, attn: Manager of Ethical Reviews;
- 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 and 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, 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;
4. Confirmation of mandated PHCRI training requirements for all research personnel listed on an REB application.

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

All mandatory courses to meet PHCRI training requirements are available free of charge to all PHC researchers and staff through the CITI program. The PHC Manager, Ethical Reviews has administrative privileges with CITI in order to monitor completion of the required courses.

Required courses will depend on the category of research:

Category A: Non-Interventional Clinical Research studies
- Responsible Conduct of Research (RCR)

Category B: Interventional Clinical Research studies (including Phase IV)
- Responsible Conduct of Research (RCR)
- Good Clinical Practice (GCP)

Category C: Regulated Interventional Clinical Research studies
- Responsible Conduct of Research (RCR)
- Good Clinical Practice (GCP)
- Transportation of Dangerous (TDG) Goods and IATA
- Health Canada Division 5 - Drugs for Clinical Trials Involving Human Subjects

Category D: Investigational Device Studies
- Responsible Conduct of Research (RCR)
- Good Clinical Practice (GCP)

Category E: Natural Health Products
- Responsible Conduct of Research (RCR)
- Good Clinical Practice (GCP)

A review of site personnel qualifications will also be conducted during the Institutional review process to confirm research staff are appropriately trained/qualified to conduct research procedures per current PHC policies (e.g. Medication Administration, Phlebotomy etc.).

Educational Compliance Audits

The PHCRI will proactively assist sites to ensure adherence to Health Canada and PHCRI institutional requirements through random Quality & Compliance Reviews.

CHÉOS employs trained monitors who are PHC staff and who will conduct the reviews in a friendly, cooperative manner and provide written feedback.

The PHCRI can also request an immediate site review if there is a deemed potential risk to participant safety.

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 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 PHC 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.

Scientific Staff appointments to PHC for external researchers must be initiated/approved by the Director of Medical Affairs, Providence Health Care.

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 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 Health Care 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 HARMONIZED ETHICS REVIEW OF MULTI-JURISDICTIONAL RESEARCH

The BC Ethics Harmonization Initiative (BCEHI) is a collaboration among the provincial health authorities (Fraser Health, Interior Health, Island Health, Northern Health) and BC's four major universities (UBC (representing PHC) , SFU, UVIC, UNBC), who collectively conduct more than 80 per cent of the province's human subject ethics reviews.

Effective March 2016, the partners have been conducting harmonized ethics review in accordance with the current Guidance for Harmonized Ethics Review of Multi-Jurisdictional Studies. Minimal Risk and Above Minimal Risk models are found at: https://bcethics.ca/resources/

5.3 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 Council 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.

The REB functions independently of, but in coordination with, each of the University of British Columbia affiliated REBs. See the UBC Office of Research Ethics Policies and Procedures.

The REBs use common application forms created for UBC, and a common on-line system for work-flow, data entry and data storage (the RISe system).

5.4 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.

5.5 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.

5.6 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.

5.7 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

5.8 FREQUENCY OF MEETINGS

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

5.9 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 expertise in relevant research disciplines, fields and methodologies covered by the REB (for biomedical clinical trials, this will include at least one member who practices medicine or dentistry and who is in good standing with their regulatory body);
2. at least one member who is primarily experienced in non-scientific disciplines;
3. at least one member is knowledgeable in ethics;
4. at least one member is knowledgeable in the relevant law (but that member should not be the institution's legal counsel or risk manager). This is mandatory for all UBC-affiliated REBs; and
5. at least one community member who has no affiliation with the institution or the sponsor, and who is not part of the immediate family of a person who is affiliated with the organization;
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.
7. Additional membership as required by applicable legislation or guidelines.

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 upon joining the board a 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.

5.10 DELEGATION OF AUTHORITY

The UBC PHC REB delegates authority to the Chair and/or Associate Chairs to review ethics submissions that meet criteria for delegated 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.

5.11 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. A quorum is defined as a majority (50% +1) of the regular and/or alternate members, including a minimum of five members, representing the scientific, ethical, community, and legal or non-scientific constituencies

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.

5.12 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/clarifications to it;
    c. defer it (defer decision –making on the application and continue the deliberation of the application at a Full Board meeting)
    d. Disapprove it when it fails to meet the ethical standards for approval and where revision is unlikely to enable the REB to reach a positive determination

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.

5.13 DELEGATED REVIEW

By definition, delegated 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 a Delegated 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
Delegated 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 delegated submissions and a fully executed contract or grant-in-aid agreement is required before any sponsored research may begin.

5.14 CONFLICT OF INTEREST- REB MEMBERS

REB Reviewer Assignment

The REB Manager reviews the agenda prior to the REB meeting to identify potential COI;

When the agenda is distributed, REB members are expected to disclose as soon as possible, anyconflicting interest(s) for any of the projects on the agenda;

If a member is unclear as to whether a COI exists, he or she must contact the REB Chair or designee to seek clarification. The REB Chair or designee will determine whether the circumstances should be defined as a COI and the member shall follow the REB's decision regarding any actions required to mitigate his/her real or perceived COI;

If a COI is identified in the reviewer assignments, the project is assigned to another REB member.

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

Delegated Review

The REB Chair or designee will assess projects undergoing the delegated review process to determine potential COI;

REB members involved in the delegated review process are expected to disclose any conflicting interests;

If a COI is identified, the project is assigned to another REB member.

REB Chair

In the event that the REB Chair declares a COI, the Co-Chair or alternate REB member will assume the REB Chair's responsibilities for the specific project(s).

Documentation

REB members sign a Confidentiality of Information and Conflict of Interest Agreement upon joining the REB. The signed Confidentiality of Information and Conflict of Interest Agreement is filed in the UBC-PHC REB office.

5.15 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 delegated 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, or reference to, 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.

5.16 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.

5.17 APPEAL PROCEDURES

In cases when investigators and the REB cannot reach agreement through discussion and reconsideration, the REB will refer the protocol to the Research Ethics Appeal Committee per UBCREB SOP 409: Reconsideration of REB Decisions and Appeal Process Policies and Procedures.

Members of all six (6) UBC affiliated REBs (UBC Behavioural REB; UBC Clinical REB; UBC Okanagan REB; UBC-BC Cancer REB; UBC Children's & Women's REB; & UBC Providence

Health Care REB) shall be eligible for appointment to the Appeal Committee; however, there is no requirement for all or multiple REBs to be represented on the Appeal Committee.

The Chair of the Appeal Committee will communicate the decision of the Appeal Committee in writing, including a summary of the issues, factual findings, conclusions and reasons for the decision to the Researcher, the Chair of the REB, the VPRI and the Director of Research Ethics.

6.0 RESEARCH SPACE

The assignment of research space is under the auspices of the VP Research and should adhere to the following general principles as outlined in the Providence Health Care Corporate Space Policy. This policy applies to all staff, including hospital /facility based physicians and researchers and addresses all planning and decision-making processes related to space allocation for Programs and Services for Providence Health Care located in owned and leased spaces.

1. That space be assigned to departments and not to individuals or groups.
2. That space expansions need to be associated with operating or research dollars, that is to say that all new programs and initiatives need to have "space" dollars. That space be assigned for a definite term that can be renewed based on performance.
3. In the allocation of workspaces for staff, including hospital /facility based physicians and researchers, priority will be given to those staff that will be based and are present at a PHC site (minimum of 70% of the staff's time). The assignment of more than one workspace will not be permitted for staff. In the event that staff works across multiple sites, general-use space available in the form of a touch-down workspace will be available at any particular site.

7.0 HUMAN RESOURCES

The Providence Health Care Research Institute's (PHCRI) Office of Research Services Human Resources is a service to researchers at PHCRI and is here to assist in the hiring of personnel and Independent Contractors.

The Human Resources team provides support for hiring and management of employees of research programs. All independent contractors and PHCRI employees paid with funds held in research trust accounts will have contractors set with this team. We will assist with any HR concerns, including recruitment, performance reviews, terminations, etcetera.

There are three options *for paying personnel in clinical research at Providence Health Care Research Institute: 1) UBC Employees, 2) Independent Contractors/PHCRI Term Employee and 3) PHC paymaster employees, including one-time payments, salary and honoraria.*

7.1 UBC EMPLOYEES

This option is for principal investigators whose funds are held at the university. These appointments are set up and administered through the principal investigator's home UBC department – PHCRI does not have the ability to set up these appointments. If you would like to discuss this option or are unsure of how to find the HR person for your department, feel free to contact PHCRI HR for assistance. Visit the UBC Human Resources Recruitment & Hiring page for details.

7.2 PHC PAYMASTER EMPLOYEES

This option is only for those researchers who have been approved by PHC HR and hold cost centres directly with PHC. All PHC policies and procedures would be followed.
(Detailed hiring steps available). View the PHC Standards of Conduct Policy.

7.3 INDEPENDENT CONTRACTORS/PHCRI TERM EMPLOYEES

1. Independent contractors are a business that provides services to PHCRI and must meet the criteria set out by CRA. See Section 3.1 Responsibilities of Research Trust Account Holders for more information.

2. Term employees are non-union positions. These are fairly flexible positions and most decisions are at the discretion of the principal investigator. To hire someone into a term-contract position at PHCRI, contact Human Resources for assistance. The British Columbia Employment Standards Act is the guiding resource to determine what is required from the employer in these positions and what the rights of the employee are. (Detailed hiring steps available.)

7.4 ONETIME PAYMENTS, SALARY AND HONORARIA

1. One-time payments can be issued if amount does not exceed $5,000.00.

2. Investigators who perform clinical research but do not receive salary support from UBC or the 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 UBC, 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 UBC Finance Department or PHCRI Finance administering the funds must issue T4 or T4A slips, whichever is applicable, to the recipient(s).

7.5 CONFIDENTIALITY AGREEMENTS
These must be signed by all employees. View document here.

8.0 COMMUNICATIONS AND PUBLIC AFFAIRS

8.1 OVERVIEW

The PHCRI Communications Department aims to communicate and raise the profile and awareness of PHCRI's mandate, activities and successes. PHCRI Communications works in co-ordination with communicators at its research centres, affiliated programs and PHC's Department of Communications and Public Affairs to disseminate information that builds the profile and reputation of PHCRI. Two distinct groups are targeted:

1. **Internal Audience:** This includes researchers; research trainees; research support staff; and PHC physicians, staff and allied health professionals.
2. **External Audience:** This includes patients; hospital-related staff; administration; boards; foundations; governments; other health authorities; funding agencies; universities and colleges, in particular UBC and SFU; donor communities; and media.

The Communications Department provides advice, media relations, event planning and communications services for the PHCRI and proactively promotes research and academic studies, programs and services to the community through the traditional media, digital strategies and other marketing strategies. For communications support, refer to the PHC Communications Toolkit or contact the PHCRI Communications Specialist.

To submit research news, announcements or events to the weekly PHCRI E-Blast or PHC News, email research@providencehealth.bc.ca.

8.2 EDITORIAL STANDARDS

PHCRI follows the PHC Editorial Standards Guide, which is designed to provide guidelines for employees on the terminology, language, grammar, capitalization and other editorial decisions that often distract readers and reduce the clarity and professionalism of communications across the organization.

These standards apply to written internal and external communications produced for print and online, issued by PHCRI or individuals acting on behalf of the institute including:

- promotional items
- marketing materials
- general written communications
- office correspondence
- submissions to governing bodies

This guide encourages a common approach to style, recognizing there will always be circumstances where exceptions must be made. It is not intended to apply to academic, scholarly or research writing, which rely on particular standards and guidelines. When questions of style arise in the preparation of certain types of publications and those in specialized subject areas, it is best to consult appropriate reference authorities.

8.3 MEDIA RELATIONS

PHCRI is committed to open communications with representatives of the media within the limits of the *Freedom of Information and Protection of Privacy Act* as it pertains to patient and employee confidentiality.

PHCRI adheres to the PHC Media Policy and as such all media inquiries and requests for interviews pertaining to PHCRI are to be referred to the Communications Department prior to a response. Permission for interviews, photography or access to PHCRI facilities may not be given to any member of the media unless it has been cleared through the Communications Department.

Media are permitted inside PHC facilities only if escorted by a Communications representative or designate who has prior approval from the Communications Department. Media may be permitted outside of PHC facilities unless their activities obstruct access to the facility or cause a disturbance.

In accordance with the *Freedom of Information and Protection of Privacy Act*, details about an individual patient or resident can be released to the media only with the signed consent of the patient, family or adult guardian.

All news releases and other written information for release to the media, including those issued by other agencies operating from PHC, must be routed through and approved by the Communications Department.

9.0 HEALTH INFORMATION FOR RESEARCH

9.1 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.

9.2 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.

9.3 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.

9.4 COMMERCIAL USE OF DATA

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

9.5 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.

9.6 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 UBC 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).

9.7 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.

The UBC-PHC REB schedules random or for-cause audits of research sites by the PHC Privacy Leader to determine compliance with PHC CPF0300: Information Privacy & Confidentiality Policy and with the information provided in the research application. Random audits are performed approximately monthly (one site per month) or for-cause as required.

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 Office will trigger the start of the contract negotiation process.

11.0 APPENDIX

11.1 RECOMMENDED READING

PHC Research Institute website
Providence Health Care website
St. Paul's Foundation website
SFU Office of Research Services website
UBC Faculty of Medicine website
UBC Office of Research Services website
UBC University/Industry Liaison Office website

11.2 GRANTS AND CONTRACTS

Research Project Information Form
Sponsored Initiated Clinical Trial Information Form

11.3 FINANCE

Cheque Request Form
Lost Receipt Form
PHCRI Request for Funding Form
Research Trust Account Application and Signing Authority Form
SPH Foundation Disbursement Form
Research Support Funds and Indirect Costs information document

11.4 ETHICS

Tri-Council Policy Statement Ethical Conduct for Research Involving Humans
UBC Office of Research Ethics website
World Medical Association: Declaration of Helsinki

11.5 RESEARCH SPACE

Providence Health Care Corporate Space Policy

11.6 HUMAN RESOURCES

Confidentiality Agreement
Human Resources Hiring Procedures
Instructions for Setting up PHCRI Employees and Independent Contractors
Steps to Hire a PHC employee

11.7 COMMUNICATIONS

PHC Editorial Standards Guide
PHC Media Policy
Photo Consent Form