

Policies and Guidelines for Research & Researchers at Vancouver Coastal Health Research Institute (VCHRI)

4. Approvals required to conduct research at VCH

In order to begin a research project involving humans at VCH, at least two approvals are required: Approval from one of the UBC Research Ethics Boards (REBs), and Approval to Conduct Research at VCH. For "Affiliated Investigators" (see [Researchers from Affiliated Organizations](#)) VCHRI will usually accept REB approvals from their institutions, but reserves the right to request a second review by the UBC Clinical Research Ethics Board (CREB) based on the level of clinical invasiveness of the proposed project. When such a second review is deemed necessary, application to the UBC CREB would be made by a VCHRI investigator/VCH staff person collaborating with the "Affiliated Investigator".

Researchers should be familiar with the provisions of the TCPS 2 – 2nd edition of *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. The complete text is available at <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

4.1 Obtaining Research Ethics Board (REB) approval

These guidelines apply to all proposed research projects carried out by anyone within Vancouver Coastal Health, whether funded by industry, grants, gifts, internal funds of the health authority or university, or without specific financing. VCH staff or physicians who do not have a UBC appointment and who require research ethics review for their project follow the same process as outlined below, through VCH's affiliation agreement with UBC.

A research project requiring REB review is defined as one in which human subjects (clients, patients, residents) are subjected to a procedure or intervention which goes beyond their need for usual care. This includes, but is not limited to:

Clinical research projects: Research that involves all clinical interventions, such as the testing of drugs, medical devices, and other therapeutic initiatives, obtaining any human tissues for research project, as well as the analysis of clinical data obtained from medical records or studies of a clinical nature involving linkage of data from existing databases. These should be submitted to the Clinical Research Ethics Board (CREB).

Behavioural science research projects: Research that involves invasions of privacy, such as interviews, questionnaires, tests, observations and experimental manipulations in the behavioural

and social sciences. Research that is limited to these types of data collection methods, but which may also include the collection of a subject's health information, must be submitted to the Behavioural Research Ethics Board (BREB) for review.

Notes:

1. If an internal quality improvement (QI) or program evaluation project is being performed at VCH and/or PHC, and the project lead is uncertain if it needs to be reviewed by an REB, before initiating the project, they should download and review the guidance note and checklist at www.vchri.ca/i/doc/Guidance_ResearchEthicsBoard.doc to assist them in their decision making.
2. The UBC REBs do not under any circumstances review nor grant approval for research which has already been conducted. Requests for such review to satisfy, for example, publication requirements, will not be entertained.

To obtain Research Ethics Board approval from a UBC REB, an ethics application must be submitted to the CREB or BREB via RISE, an online system that is used for the submission and tracking of UBC REB applications. Specific application information is available at <http://rise.ubc.ca>. Prior to submitting an application via RISE, a researcher will need to obtain a RISE login. Please contact the CREB or BREB for assistance with this process. Contact information for CREB or BREB managers is located in the contact section of this document. General information regarding UBC research ethics (including meeting dates and deadlines) may be found at: www.ors.ubc.ca/ethics/index.htm.

In some cases, a research project may need to be reviewed by a UBC review committee in addition to an REB. For example, research that involves human blood may require review by both the Bio-hazardous Materials Committee and the Clinical REB. Researchers should contact the manager for the committee or board if this applies to their research (see contact information section).

REB approval is valid for one year. If the research project is to continue beyond one year, it is the responsibility of the researcher to submit a renewal application to the CREB or BREB. If amendments are made to the approved research project protocol, the researcher must submit these amendments to the CREB or BREB for approval. Processes for both annual renewals and amendments are described on the RISE system.

All UBC REBs (CREB, BREB, Providence Healthcare REB and BC Cancer Agency REB) have agreed effective March 21, 2007, that each research project reviewed by a UBC REB should have a single UBC REB of Record. The purpose is to avoid formal research ethics reviews by multiple UBC REBs of the same research project. This situation arises when the same researcher is conducting the research project at more than one institution under the UBC REBs' jurisdiction (e.g. VCH and BCCA).

4.2 Approvals to conduct research at VCH

All research projects and clinical trials involving human subjects that involve the use of VCH services, facilities, staff or patients (or other client populations), or that impact VCH clinical or other service resources (including use of hard copy or electronic records), must receive "Approval to Conduct Research at VCH" from the Vancouver Coastal Health Research Institute (VCHRI) office in the relevant Health Service Delivery Area (HSDA). Before this approval is granted, REB approval must be in place. There are four VCHA HSDAs: Vancouver Acute, Vancouver Community, Richmond Health Services, and Coastal.

Each VCH HSDA manages this process independently for research projects taking place within their sites. If a research project will be conducted within more than one VCH HSDA, the researcher must obtain approval from the VCHRI office in each of the relevant HSDAs. Once approval to conduct research has been granted by the applicable VCHRI office, the research project may begin at that site. The approval process ensures that all research involving humans conducted at VCHA is reviewed from an ethical (REB approval), safety and resource use framework.

To qualify as the Principal Investigator (PI) on a VCH research project, an individual must:

1. have a medical appointment at VCH, or
2. be a VCH employee; or
3. have received a "VCHRI Affiliated Investigator" Appointment (see [Researchers from Affiliated Organizations](#)).

If the PI for the research project does not have a medical appointment at VCH or is not a VCH employee, but does have a faculty appointment at a post-secondary institution that has a research affiliation agreement with VCH (see [Researchers from Affiliated Organizations](#)), the PI may either:

1. apply for a "VCHRI Affiliated Investigator" appointment; or
2. designate a VCH individual as the "Site Investigator at VCH".

4.2 (a) Submission Criteria To Conduct Research At VCH

Research projects which meet any one of the following criteria must be submitted to VCHRI for review and approval:

1. Research projects that are conducted at any VCH HSDA;
2. Research projects where VCH patients/clients/residents/staff are participants in the research project;
3. Research projects where VCH medical staff or employees participate in the conduct of the research project (Note: In this case, criteria #1 and/or criteria #2 must also apply).

4.2 (b) Obtaining Approval To Conduct Research At VCH

Three processes must occur before research is approved and may begin at VCH:

1. Submission to a UBC REB. For "Affiliated Investigators" (see [Researchers from Affiliated Organizations](#)). VCHRI will usually accept REB approvals from their institutions, but reserves the right to request a second review by the UBC CREB based on the level of clinical invasiveness of the proposed project. When such a second review is deemed necessary, application to the UBC CREB would be made by a VCHRI investigator/VCH staff person collaborating with the "Affiliated Investigator".
2. Submission to the VCHRI office of the relevant HSDA(s) for approval to conduct research at VCH, (forms and guidelines for the research approval process at each HSDA are located at www.vchri.ca/s/FormsLogos.asp)
3. Execution of the research project contract/agreement (if applicable).

Submission for approval to conduct research at VCH, REB approval and project contract/agreement review may be initiated in parallel. The project contract/agreement, if applicable, must be signed by the PI, VCH and UBC. Final authorization for research to begin will be given by the appropriate HSDA's VCHRI office when the above three processes are satisfactorily completed.

Applications for approval to conduct research at VCHA should be directed to the VCHRI office of the relevant HSDA as indicated below:

VCH - Vancouver

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VCH - Vancouver (Community)

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VCH - Richmond

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VCH - Coastal

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