

GUIDANCE: WHEN DOES YOUR PROJECT WARRANT REVIEW BY A RESEARCH ETHICS BOARD?

Vancouver Coastal Health (VCH) and Providence Health Care (PHC) are committed to ensuring the protection of individuals and their Personal Information (recorded information, excluding business contact information, about an identifiable individual in electronic or paper format), while enabling the sharing of innovative practice.

As part of that commitment, the VCH and PHC research institutes jointly endorse the following checklist, to be completed for all quality improvement (QI) projects being conducted at VCH and/or PHC, to determine if the project warrants Research Ethics Board (REB) review. **Quality improvement** activities may also be referred to as quality assurance or program evaluation.

Purpose: To assist those working at a VCH or PHC site in determining whether their quality improvement (QI) project/activity meets any criterion that requires that it be submitted to a Research Ethics Board for review.

This applies to: VCH/PHC staff, medical staff (physicians), residents, volunteers, and students, doing projects at a VCH and/or a PHC site. This also applies to the following types of projects:

- projects being conducted by an external contractor for a VCH/PHC program or department
 - the VCH/PHC staff designated as the 'project lead' is responsible for ensuring that this process is followed (including REB submission if required).
- all student projects except for student research projects as the latter automatically require REB approval from an appropriate Research Ethics Board. Appropriate refers to the following: UBC student projects as well as all projects involving PHC must have approval from a UBC REB. VCHRI may accept REB approvals from their other affiliated research institutions (e.g. BCIT, UVIC, SFU and Royal Roads) for non-UBC student projects.
- medical resident projects that fall under the responsibility of a UBC Resident Training Committee (residents from non-UBC programs are considered 'external' and follow the first bullet above)
- any other knowledge generating projects that are in addition to typical programs or services, or Ministry mandated activities
- all multi-organization projects that include VCH and/or PHC

Responsibility: The Project Lead is responsible for completing this checklist and keeping a copy on file for review if requested. VCH/PHC Program Directors/Department Heads are responsible for the projects/initiatives conducted within their portfolios.

Explanations of terms:

A Vancouver Community quality improvement handbook states that **quality improvement (QI)** is about learning what you are doing well and doing it better. It also means finding out what you need to change to meet the needs of those who use your service. They define it as a method of evaluating and improving processes of patient care which emphasizes a multidisciplinary approach to problem solving, and focuses not on individuals, but systems of patient/client care. (based on a National Highway Traffic Safety Administration definition; all found on the Vancouver Community quality improvement intranet site).

On the VCH clinical administrative policy site, quality improvement is defined as the organizational philosophy that seeks to meet and exceed patient, client and resident needs and expectations by using a structured process that selectively identifies and improves all aspects of service to them. It is used in planning, designing, monitoring, analyzing and improving processes and outcomes.

Others have described quality improvement as when the primary purpose is to assess or improve the quality of a treatment, service, or program within an organization (adapted from ARECCI, 2005) and as “systematic, data-guided activities designed to bring about immediate improvements in health care delivery in particular settings (Lynn et al., 2007, pp. 666-7) Lynn et al. goes on to say that quality improvement “is an intrinsic part of good clinical care, in which data from clinician’s own settings guide them in improving their practices.” Mitty (2007, p.98) states that “QI is embedded in the caring enterprise with the goal of immediate improvement in quality. Unlike a research protocol, a QI protocol can be fine-tuned or modified at any point in the process, based on feedback, because it is part of a continuous feedback process inherent in healthcare delivery.”

VCH and PHC are academic health organizations affiliated with UBC, and as such, follow UBC’s definition of research involving human subjects which is “any systematic investigation (including pilot studies, exploratory studies, and course based assignments) to establish facts, principles or generalizable knowledge which involves: living human subjects; or human remains, cadavers, tissues, biological fluids, embryos or fetuses.” It does not include ...“quality assurance studies, performance reviews or testing within normal educational requirements, or activities undertaken for administrative or operational reasons...” unless they include an ‘element of research.’ (UBC Policy 89, <http://www.universitycounsel.ubc.ca/policies/policy89.pdf>) For our purposes, the criteria outlined in the following checklist refer to these ‘elements of research’.

References:

Some questions in the checklist are from, or adapted from, the following sources:
ARECCI Ethics Screening Tool developed by the Alberta Research Ethics Community Consensus Initiative (ARECCI) Network (2005, revised 2008).

Other referemces:

Alberta Research Ethics Community Consensus Initiative. (2005). *ARECCI Recommendations – Final. Protecting People While Increasing Knowledge: Recommendations for a Province wide Approach to Ethics Review of Knowledge Generating Projects (Research, Program Evaluation, and Quality Improvement) in Health Care*. Edmonton, AB. Alberta Heritage Foundation for Medical Research.

Lynn, J., Baily, M., Bottrell, M., Jennings, B., Levine, R.J., Davidoff, F., Casarett, D., Corrigan, J., Fox, E., Wynia, M.K., Agich, G.J., O’Kane, M., Speroff, T., Schyve, P., Batalden, P., Tunis, S., Berlinger, N., Cronenwett, L., Fitzmaurice, M., Neveloff Dubler, N., & James, B. (2007). The ethics of using quality improvement methods in health care. *Annals of Internal Medicine*, 146, 666-673.

Mitty, M. (2007). Hastings Center Special Report: The ethics of using QI methods to improve health care quality and safety. *Journal of Nursing Care Quality*, 22 (2), 97-101.

University of British Columbia (2002). UBC Policy #89: Research and Other Studies Involving Human Subjects. Retrieved April 17, 2009 from UBC Web site:
<http://www.universitycounsel.ubc.ca/policies/policy89.pdf>

Does your project warrant review by a research ethics board?

If you answer “yes”, to any of the following questions, an application to the appropriate Research Ethics Board (REB) should be made. The study/project may not be research but a determination of this by an REB is required.

Questions	(Click on the appropriate YES or NO box)		Yes	No
1. Is the project / study being presented to the public, colleagues, the institution, your department or others as a “research” project; that is, do you consider it research?	<input type="checkbox"/>	<input type="checkbox"/>		
2. Is the project funded by (or being submitted to) a grant/award competition from a funding agency ¹ that requires research ethics review, OR is a sponsored clinical trial (or other clinical research funded by an external source)?	<input type="checkbox"/>	<input type="checkbox"/>		
3. Does the project involve the use of a medical device, drug, or natural health product which requires approval from Health Canada, or another regulatory body?	<input type="checkbox"/>	<input type="checkbox"/>		
4. Is this a student research project (class or thesis) being conducted at a VCH/PHC site and/or by a VCH/PHC staff or student, that does not yet have appropriate REB approval? Appropriate refers to the following: UBC student projects as well as all projects involving PHC must have approval from a UBC REB. VCHRI <u>may</u> accept REB approvals from their other affiliated research institutions (see below) ² for non-UBC student projects.	<input type="checkbox"/>	<input type="checkbox"/>		
5. Does the project involve randomization of participants into different groups to compare interventions (including randomization to a placebo group), or does it involve other systematic sampling techniques to divide participants into different groups for comparison purposes?	<input type="checkbox"/>	<input type="checkbox"/>		
6. Does the project involve a comparison of ‘intervention/treatment’ and ‘control’ settings or groups, either to test a new intervention or to assess the effectiveness of a process change (see note below) ³ ?	<input type="checkbox"/>	<input type="checkbox"/>		
7. Does the project involve pilot testing or evaluation of a new intervention (e.g. drug, device or natural health product), treatment, program for which it would be difficult to estimate a balance of risk and benefit in advance?	<input type="checkbox"/>	<input type="checkbox"/>		
8. Does the project involve the collection and retention of tissue or blood samples, beyond that required for usual care and treatment?	<input type="checkbox"/>	<input type="checkbox"/>		
9. Is the project design and methodology rigorous enough to statistically support generalizations beyond the particular population from which the project sample was drawn?	<input type="checkbox"/>	<input type="checkbox"/>		
10. Does the project involve participants either receiving healthcare procedures/treatments or being asked for personal information, significantly beyond (different from or in addition to) what would be expected in the standard care provided to them as patients/clients?	<input type="checkbox"/>	<input type="checkbox"/>		
11. Is one of your key goals for the project to contribute the results to the academic literature through peer-reviewed publication in a journal that focuses on publishing research studies?	<input type="checkbox"/>	<input type="checkbox"/>		
IF YES to <u>any</u> of the above questions, a submission to a UBC Research Ethics Board is required (as they are the REBs for VCH and PHC). Go to http://www.ors.ubc.ca/ethics/index.htm for more information. IF NO , you must still adhere to VCH/PHC policies pertaining to information privacy and risk.				

If you have any questions please contact the following for VCH or PHC questions respectively:

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Vivienne Bearder, Ethics Review Manager, PHCRI - VBearder@providencehealth.bc.ca

¹ Examples of research funding agencies requiring REB review prior to granting an award: Canadian Institutes of Health Research, Canadian Health Services Research Foundation, and Michael Smith Foundation for Health Research.

² VCHRI’s other affiliated institutions include BCIT, UVIC, SFU and Royal Roads

³ This particular criterion does not refer to retrospective comparison of current practices to past practices such as in a chart review.