TITLE:	**RESEARCH ETHICS REVIEW POLICY**
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VERSION:	1.0
EFFECTIVE DATE:	15 APR 2013
SUPERCEDES/REPLACES:	n/a
FRAMEWORK:	GCP, TCPS2, Health Canada
NEXT REVIEW DATE:	15 APR 2014
SIGNATORIES:	Contained on last page of original document

1 PURPOSE

The purpose of this policy is to define the *research*[1] projects that will be reviewed by the Vancouver Island Health Authority (VIHA) *Research Ethics Board* (REB) and how that review and approval will be conducted, documented, and communicated.

2 SCOPE AND APPLICABILITY

2.1 VIHA has both a legal and ethical responsibility to ensure that research carried out involving VIHA personnel, patients/clients, or resources meets appropriate research ethical standards.

2.2 VIHA REB will only review *human research* projects that are conducted within VIHA's jurisdiction (involves VIHA facilities, patients, residents, clients, staff, physicians, current data holdings or other resources) or under its protection or patronage by contract or other defined and documented relationship.

2.3 This policy applies to researchers submitting projects for review by the REB, as defined within the policy, and defines the roles and responsibilities of VIHA REB members, and employees of VIHA who support the operation of the REB.

3 REFERENCES AND ASSOCIATED DOCUMENTS

3.1 References

Health Canada, Good Clinical Practice: Consolidated Guideline ICH Topic E6

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)

[1] Terms that are italicized can be accessed through hyperlink to the Definitions Section 11. To return to the location in the document where the term was first used, click on the hyperlink in the Definitions section.

4 REB STRUCTURE AND JURISDICTION

4.1 VIHA maintains two Research Ethics Boards (REBs) to provide reviews of all human research within the scope as defined in Section 2.2. The two VIHA REBs are the Clinical Research Ethics Board (CREB) and the Health Research Ethics Board (HREB).

4.2 In addition, the VIHA REBs review research projects jointly with other institution's REBs where the research project proposed involves the resources of both institutions. Joint reviews are managed within established subcommittees and governed by a Memorandum of Understanding (MOU).

4.3 For research that is multi-centre, every effort will be made to incorporate the harmonized ethical review processes that are currently under development within BC. This may include using select projects for review under the pilot processes.

5 REQUIREMENT FOR REB REVIEW

5.1 Researchers will be advised to utilize forms and other support tools provided by VIHA for the submission of research applications for ethical review.

5.2 The following requires ethical review and approval by VIHA REB before the research commences:

(a) research involving living *human participants*;

(b) research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals; and

(c) research that is conducted at a VIHA facility or involving VIHA patients, clients, staff, physicians, current data holdings and other resources.

5.3 Exceptions may be made in cases where outsourced services are required for specialized research with established research institutions, for example laboratory or imaging support, including but not limited to the BC Cancer Agency. Such exceptions will be documented.

5.4 Researchers will be advised to consult the VIHA REB directly if in any doubt about whether the project requires ethical review by the VIHA REB.

6 EXEMPT FROM REB REVIEW

6.1 Research that relies exclusively on publicly available information does not require REB review when:

(a) the information is legally accessible to the public and appropriately protected by law; or

(b) the information is publicly accessible and there is no reasonable expectation of privacy.

6.2 REB review is not required for research involving the observation of people in public places where:

(a) it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;

(b) individuals or groups targeted for observation have no reasonable expectation of privacy; and

(c) any dissemination of research results does not allow identification of specific individuals.

6.3 REB review is not required for research that relies exclusively on secondary use of *anonymous information*, or anonymous human biological materials, so long as the process of recording or dissemination of results does not generate identifiable information.

6.4 REB review is not required for *quality assurance* and *quality improvement* studies, program evaluation activities, performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes.

6.5 REB review is not required for projects analyzing *creative practice* activities. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.

7 PEER AND SCHOLARLY REVIEW

7.1 The REB will satisfy itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research.

7.2 The extent of the review for scholarly standards that is required for medical research that does not involve more than minimal risk will be determined by the REB performing the ethical review. REBs will typically use a standard of *proportionate review*, defining the degree of scholarly review needed on the degree of risk to human subjects.

7.3 In order to facilitate a timely review, researchers will be advised that any research considered above minimal risk would benefit from having a scholarly or peer review performed prior to submission to the REB, and demonstration of this review process will be viewed favourably by the REB. The REB assumes that grant funded or sponsored research applications have undergone adequate review by scientific advisors.

7.4 The REB will take into consideration professional peer-review assessments associated with:

- Research supervisor or thesis committee for student research, or
- A peer review committee where it exists.

8 REB REVIEW PROCESS

8.1 The REBs will conduct reviews that are proportionate to the level of risk that is proposed by the research with respect to both the magnitude of the potential harm and the probability or

likelihood of the harm occurring. Risk will be deemed either *minimal risk* or above minimal risk, and weighed against the stated benefits of the research.

8.2 Types of review will vary based on the level of risk, and will be conducted as:

- **Office Review** - Reviewed by the Research Ethics Coordinator.
- **Executive Review** – Reviewed by the Research Ethics Coordinator and the Chair of the relevant Board.
- **Delegated Review** – The review shall be delegated to one or more experienced reviewers from among REB members. Delegated review procedures may be used in unique circumstances for research involving minimal risk, and for minor changes in approved research.
- **Full Board Review** – All members of the Board will receive the application prior to the Board Meeting. Primay and secondary reviewers will be assigned to lead the review discussion at the full Board Meeting.

8.3 It is the intention of VIHA to ensure that, where a human participant is involved in research:

(a) Respect is shown for the dignity of research participants;
(b) Selection of participants is fair;
(c) Vulnerable persons are protected against abuse, exploitation and discrimination;
(d) Foreseeable harms will not outweigh the anticipated benefits;
(e) Research participants will not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and socially important aims that cannot be realized without human participants;
(f) Standards for *privacy* and *confidentiality* are observed with respect to access, control, use and dissemination of personal information;
(g) The reseach ethical review process is fair and independent of VIHA's other administrative decision-making processes; and
(h) Actual and potential conflicts of interest of researchers and individuals in the review process are made known and dealt with appropriately.

8.4 During the conduct of a review, the REB will:

(a) Review submissions based upon fully detailed research applications, either in a regular meeting of the REB or through delegated review;
(b) Consider the scientific or technical quality of the research as necessary to assess the risks and benefits of the research as proposed;
(c) Confirm privacy of research participants and confidentiality of data meets all institutional and regulatory requirements;
(d) Function impartially, providing a fair hearing to those involved and providing reasoned and appropriately documented opinions and decisions;
(e) Accommodate reasonable requests from researchers to participate in discussions about their applications, but those researchers may not be present when the REB is making its decision;

(f) Make decisions by consensus. When consensus cannot be achieved the decision will be made by majority vote;

(g) Communicate to the researcher in writing for all transactions including approvals, required modifications, rejections, terminations, and requests or notifications concerning receipt of *Sponsor* required submission documents; and

(h) If considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

8.5 When all outstanding issues have been addressed to the REB's satisfaction, a certificate of approval for one (1) year is issued to the investigator confirming ethical approval.

8.6 Should the researcher and the REB not reach agreement, further reconsideration may be requested, followed by an appeal process. VIHA has a reciprocal agreement with Fraser Health Authority REB to provide research ethics applicants at each of the health authorities with an appeal mechanism for decisions of its respective REB, in compliance with TCPS2.

9 FREQUENCY OF REVIEW

9.1 REB review is considered ongoing throughout the life of the project.

9.2 Continuing review will consist of at least the submission by the researcher of a succinct annual status report to the REB. Researchers will be advised to utilize formal templates found on the REB website for progress communication including but not limited to: annual approval, closure reports, safety reports, unanticipated problems, protocol waivers and protocol deviations.

9.3 For research posing more than minimal risk, the REB may require progress reports at predetermined intervals shorter than one year. The rigour of the review will be in accordance with a proportionate approach to ethical assessment.

9.4 The continuing review of research exceeding the threshold of minimal risk, in addition to annual review might include:

- Formal review of the process of free and informed consent;
- Establishment of a safety monitoring committee; and/or
- Periodic review by a third party of the documents generated by the study.

9.5 Researchers will be advised to promptly notify the REB when the project concludes.

10 REPORTING

10.1 The REB will promptly notify the investigator in writing of research related decisions/opinions and the reasons for those decisions/opinions.

10.2 The REB will make publicly available all procedures related to the processes for application, reconsideration, appeals, reporting safety and unanticipated problems, amendments, annual review, and study closure.

10.3 In order to assist internal and external audits or research monitoring, and to facilitate reconsideration or appeals, the record of decisions/minutes will be accessible to authorized representatives of VIHA, researchers, regulatory authorities and funding agencies.

11 DEFINITIONS AND ABBREVIATIONS

11.1 **Anonymous information**: The information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

11.2 **Confidentiality:** The duty of confidentiality refers to the obligation of an individual or organization to safeguard information entrusted to it by another. It includes obligations to protect information from unauthorized access, use, disclosure, modification, loss or theft.

11.3 **Creative Practice:** A process through which an artist makes or interprets a work, or works, of art. It may also include a study of the process of how a work of art is generated.

11.4 **Human participants**: Those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question.

11.5 **Human research**: Involves human participants, remains, tissues, biological fluids, embryos, fetuses and other biological materials including human DNA, RNA or DNA and RNA fragments.

11.6 **Minimal risk**: The probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

11.7 **Privacy:** Privacy refers to an individual's right to be free from intrusion or interference by others.

11.8 **Proportionate review:** Ethical review based on the general principle that the more invasive the research, the greater should be the care in assessing the research. The concept of minimal risk provides a foundation for proportionate review.

11.9 **Quality Assurance**: Quality assurance is a systematic approach to review of practices and procedures in order to identify possible improvements and to provide a mechanism to bring them about.

11.10 **Quality Improvement**: A set of related activities designed to achieve measurable improvement in processes and outcomes of care. Improvements are achieved through interventions that target health care providers, practitioners, plans, and/or beneficiaries.

11.11 **Research**: Any systematic investigation (including pilot studies, exploratory studies, and course based assignments) to establish facts, principles or generalizable knowledge.

11.12 **Research Ethics Board (REB)**: "*A body of researchers, community members, and others with specific expertise (e.g. in ethics, in relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices*." (TCPS 2, Glossary)

11.13 **Sponsor**: **"***An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial*." (ICH E6)

12 APPENDICES

NA

13 SUMMARY OF CHANGES

Version	Effective Date	Change Description
1.0	15 APR 2013	New Policy