



BC Mental Health &  
Addiction Services

An Agency of the Provincial Health Services Authority

# APPROVAL TO CONDUCT RESEARCH

## Guidelines

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## Purpose

The purpose of this document is to provide a detailed description of the internal procedures and policies of BC Mental Health and Addiction Services (BCMHAS) relating to the institutional review process for research projects involving hospital/clinic staff and/or patients. No research will be permitted at the hospital/clinics unless the appropriate procedures have been followed and the necessary written permission has been obtained.

It is important to underline that this document relates only to processes pertaining to internal, or “institutional” research approval. Researchers seeking approval to conduct a proposed study must also obtain the necessary ethics approvals from each and every academic institution (e.g., university) with which they or their co-investigators are affiliated. While it is not the role of the BCMHAS Research Committees to oversee these processes, BCMHAS research approval will be withheld until written confirmation of ethics is received by the committee.

## Definition of Research Activity

“Research activity” is defined as a systematic investigation (including but not limited to pilot studies, exploratory studies, program-based clinical outcomes studies) intended to establish facts, principles, or generalisable knowledge involving human subjects (e.g., patients, family members, staff) either directly (e.g., as a research participant) or indirectly (e.g., chart-based archival studies). Such investigations should be designed and described in such a way as to be replicable by others in the clinical and scientific community.

**Any research activity that takes place at Riverview Hospital (RVH), the Forensic Psychiatric Hospital (FPH) or Forensic Psychiatric Services Commission (FPSC) outpatient clinics, or involves a BCMHAS patient or staff member, whether as participant, collaborator, or investigator, requires submission of a research proposal for review and approval using the process outlined in the following section, entitled “Application for Approval to Conduct Research”. Individuals submitting such an application should consult the Research Approval policy and Research Integrity policy. These policies are available from the Research department.**

Information-seeking or investigations that are conducted for the purposes of quality assurance/improvement, accreditation, educational activities or program/unit reviews are not considered research activities. However, if it is anticipated that findings stemming from such investigations may be published or presented to an external audience, both the appropriate university ethics and institutional approval to conduct research should be obtained prior to the onset of data collection. In the case where an investigation is not clearly a “research activity”, please contact the Manager, Research for further clarification.

## Application for Approval to Conduct Research

### Recommendations

Discussing the feasibility and logistics of your proposed research with the relevant program/unit manager/director and unit staff is highly recommended.

### Requirements for RVH

A complete application for approval to conduct research at RVH consists of the following:

- a cover letter from the applicant (Principal Investigator) indicating that approval to conduct research is being sought, as well as any relevant other details particular to the submission, for example regarding ethics submissions, reference to specific enclosures (such as letters of support or letters from a student's supervisor, non-standardized/validated tests or rating scales that form the object of research inquiry, etc.);
- a completed *Approval to Conduct Research* form;
- a research proposal that in its entirety does not exceed 20 pages in length (see Proposal section below);
- a copy of each and every application for ethics approval related to the proposed project;
- a copy of each and every certificate or written letter from a university ethics review board indicating ethics approval for the proposed project. If ethics approval is being sought concurrently, or in any case has not yet been received by the applicant, s/he should indicate in the cover letter that official notification of ethics approval will be forwarded as soon as it is received;

or

a copy of a letter of approval from a regional health authority or other institutional ethics committee whose standards of ethics review are consistent with those outlined in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, published by Interagency Advisory Panel of Research Ethics of Canada<sup>1</sup>;

- if applicable, a copy of the same participant consent form (on letterhead indicating RVH and other institutions as applicable) that has been approved/submitted for approval to the appropriate ethics boards;
- a completed and signed *Freedom of Information* form<sup>2</sup>;

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<sup>1</sup> This document is a very useful resource to aid in the understanding of Canadian ethics policies relating to research with human subjects, including the complex and sometimes confusing area of freedom of information and protection of privacy of research subjects. The document is available on-line at the following website:  
<http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>

<sup>2</sup> Please see the website of the Office of the Information and Privacy Commissioner of British Columbia, at:  
<http://www.oipcbc.org/legislation.htm> for more information on current legislation regarding freedom of information and protection of privacy.

- if applicable, student initiated research requires the name and signature of the responsible supervisor;
- for researchers not affiliated with RVH, the identification of an appropriate RVH contact person for the proposed study. If necessary, the Research department will assist in the selection and appointment of such a contact person;
- if applicable, clinical trials research requires submission of a Clinical Trial Agreement contract.

**In summary, *at minimum*, a complete application consists of the following items:**

- \_\_\_ **cover letter**
- \_\_\_ ***Approval to Conduct Research* form**
- \_\_\_ ***Freedom of Information* form**
- \_\_\_ **research proposal**
- \_\_\_ **consent form**
- \_\_\_ **application for ethics approval**
- \_\_\_ **official notification of ethics approval**

Other documents should be included as needed based on the guidelines specified above, or as the researcher sees fit, given the particularities of the proposed study. If the researcher is uncertain as to the relevance of a particular document or letter, s/he may consult the Research department for further clarification.

For the sake of expediency, it is recommended that proposals be submitted concurrently to RVH and the appropriate ethics review board(s).

## **Requirements for FPSC**

A complete application for approval to conduct research at FPSC consists of the following:

- a cover letter from the applicant (Principal Investigator) indicating that approval to conduct research is being sought, as well as any relevant other details particular to the submission, for example regarding ethics submissions, reference to specific enclosures (such as letters of support or letters from a student's supervisor, non-standardized/validated tests or rating scales that form the object of research inquiry, etc.);
- a completed *Approval to Conduct Research* form;
- a completed *Application and Agreement for Research*;
- a copy of each and every application for ethics approval related to the proposed project;
- a copy of each and every certificate or written letter from a university ethics review board indicating ethics approval for the proposed project. If ethics approval is being sought concurrently, or in any case has not yet been received by the applicant, s/he

should indicate in the cover letter that official notification of ethics approval will be forwarded as soon as it is received;

or

a copy of a letter of approval from a regional health authority or other institutional ethics committee whose standards of ethics review are consistent with those outlined in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, published by Interagency Advisory Panel of Research Ethics of Canada<sup>3</sup>;

- if applicable, a copy of the same participant consent form (on letterhead indicating FPSC and other institutions as applicable) that has been approved/submitted for approval to the appropriate ethics boards;
- if applicable, student initiated research requires the name and signature of the responsible supervisor;
- for researchers not affiliated with FPSC, the identification of an appropriate BCMHAS contact person for the proposed study. If necessary, the Research department will assist in the selection and appointment of such a contact person;
- if applicable, clinical trials research requires submission of a Clinical Trial Agreement contract.

**In summary, *at minimum*, a complete application consists of the following items:**

- \_\_\_ **cover letter**
- \_\_\_ ***Approval to Conduct Research* form**
- \_\_\_ ***Application and Agreement for Research***
- \_\_\_ **consent form**
- \_\_\_ **application for ethics approval**
- \_\_\_ **official notification of ethics approval**

Other documents should be included as needed based on the guidelines specified above, or as the researcher sees fit, given the particularities of the proposed study. If the researcher is uncertain as to the relevance of a particular document or letter, s/he may consult the Research department for further clarification.

For the sake of expediency, it is recommended that proposals be submitted concurrently to FPSC and the appropriate ethics review board(s).

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<sup>3</sup> This document is a very useful resource to aid in the understanding of Canadian ethics policies relating to research with human subjects, including the complex and sometimes confusing area of freedom of information and protection of privacy of research subjects. The document is available on-line at the following website:  
<http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>

## **Submitting an Application**

Assuming the proposed study meets the definition of “Research Activity” (see p.2), and all necessary forms and a research proposal have been completed, the Principal Investigator should submit the entire package to:

Research Department  
BC Mental Health & Addiction Services  
201 – 601 West Broadway  
Vancouver, BC V5Z 4C2  
Fax: 604-707-6399  
E-mail: [research@bcmhs.bc.ca](mailto:research@bcmhs.bc.ca)

Applicants are encouraged to submit the entire application electronically and to send the signed hard copies by mail. If you have any questions about the submission process, please email the BCMHAS Research Department at: [research@bcmhs.bc.ca](mailto:research@bcmhs.bc.ca).

FPSC Submissions are reviewed at the FPSC Research Committee (RC) meetings which generally take place on the third Monday of each month. In order to ensure that an application is reviewed at a given meeting, it should be submitted at the latest two weeks prior to the meeting, that is, by the second Monday of the month.

RVH Submissions are reviewed by the Riverview Research Committee, which meets at the call of the chair.

## **Review of Submissions**

### **Review Process**

Once received and reviewed for completeness by the Manager of Research, applications for approval to conduct research are forwarded to the members of the RC for scientific review. Reviewers will present their reviews at the forthcoming committee meeting. A discussion of the proposal will ensue and the committee will make a recommendation of one of the following decisions: denial of approval, conditional approval (subject to the submission of further information and/or minor revisions), or approval. All such recommendations are subsequently authorized by the Director of Research at BCMHAS. Notification of the committee’s decision will be sent to the applicant in the week following the meeting at which it was reviewed.

### **Terms of Approval**

Once granted, the approval to conduct research at BCMHAS is valid until either the project’s university ethics approval expiry or to the end of the project’s data collection, whichever comes first.

At the end of the approved period, if the study is not yet complete, it is the responsibility of the Principal Investigator to:

- 1) submit the required annual status report to the appropriate ethics review board(s);
- 2) apply for a renewal of the ethics approval from the appropriate ethics review board(s);
- 3) submit to the Research Manager 1 copy of the annual status report and 1 copy of the application for ethics renewal; and
- 4) request a continuation of the RC's institutional approval to conduct research.

Once received, a copy of the new ethics certificate/notification of approval must be submitted to the Manager. A reminder notice to this effect will be sent to the researcher in the 3-month period prior to the 1-year anniversary of the initial ethics approval.<sup>4</sup> If this documentation is not received by the Manager one month prior to this 1-year anniversary date, a second reminder will be sent to the researcher. This reminder will include a warning to the effect that if the report is not received by the anniversary date, the RC approval to conduct research and the release of funds (if applicable) will be suspended until such time that the necessary approval(s) and documentation are received. Should these not be received by the anniversary date, the office of the Manager will suspend the approval to conduct research, order data collection to be halted, and no further expenditures will be approved. In the case where the researcher is not granted continued ethics certification for the project, data collection will be terminated and the Manager will notify Finance to freeze the funds.

## Appeal Process

When an application is denied approval applicants may appeal the decision by contacting the Director of Research to present their case. The Director may elect either to present the proposed study anew to the Research Committee, or to uphold the denial of approval. There is no further appeal process, and such a decision is final.

## Protocol or Guideline Changes

In the case of any changes to the original study protocol – as specified in the applications for ethics and institutional approval – the researcher is required to submit a request for approval to the Research Manager, for review and approval by the RC, and authorization by the Director of Research. Substantive changes may require a new approval to conduct research process to be initiated. Researchers are also required to adhere to the appropriate ethics review board(s) guidelines regarding protocol changes. Copies of all documentation regarding amendment approval requests and their approval/certification by the ethics board(s) must be provided to the Research Manager.

In the case of changes to the ***Approval to Conduct Research Guidelines*** or to the approval process itself, researchers will be notified and given adequate time in which to conform to the changes for any ongoing research projects, as deemed necessary by the Manager.

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<sup>4</sup> In the case of ethics approval from more than one ethics review board, the reminder notice will be sent within the 3-month period prior to the one-year anniversary of the *first* ethics approval date.