



**BC MENTAL HEALTH  
& SUBSTANCE USE SERVICES**

*Provincial Health Services Authority*

# **BCMHSUS OPERATIONAL APPROVAL TO CONDUCT RESEARCH**

*Guidelines*

*Updated February 2020*



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## Purpose and Scope

The BC Mental Health and Substance Use Services Research Committee (the 'Research Committee') is responsible for the review, approval, and administrative oversight of all research projects undertaken within the clinical programs at BC Mental Health and Substance Use Services (BCMHSUS). Our mandate is to examine the impact that research studies could have on BCMHSUS clinical operations. The Research Committee strives to support the generation of new knowledge through research by providing access to BCMHSUS data, patients etc, whilst protecting patient privacy and minimizing the impact on operations and clinical service delivery. The purpose of this document is to describe the institutional review and approval process for research projects that directly involve BCMHSUS:

- Staff;
- Patients and clients; or
- Data – whether clinical (chart or electronic), administrative, or other

No research of any kind will be permitted unless the appropriate procedures have been followed and the necessary written approval has been received. Please note that this document relates only to BCMHSUS “institutional” approval to conduct research (see Appendix A for a brief summary of the application process). It does not describe the process of applying for university research ethics board (REB) approval. REB approval from the university with which the applicant is affiliated must be received prior to submission to the BCMHSUS Research Committee (the 'Research Committee'). To learn more about the Canadian ethics policies relating to research with human subjects, please go to <https://ethics.gc.ca/eng/home.html>

Submission of an application to BCMHSUS Research Committee is required for the following program(s):

1. British Columbia Forensic Psychiatric Hospital and Regional Clinics
2. Adult Complex Mental Health and Substance Use Services (i.e., Burnaby Centre for Mental Health and Addiction, Heartwood Centre for Women)
3. Correctional Health Services; and
4. BC Corrections, if research project intersects with BC Corrections and directly involves Correctional staff, inmates, or clients; access to Corrections data (e.g., CORNET data), or involves visiting their physical facilities (see page 7)

Please note that requests to conduct research at Cedars at Cobble Hill and Phoenix Society should be submitted to those programs directly – an application need not be submitted to the BCMHSUS Research Committee, unless the project involves access to the clinical data at Cedars and Phoenix. While the BC Psychosis Program is contracted by BCMHSUS, it is operated by the Vancouver Coast Health Authority. As such, research involving the BC Psychosis Program will not require the Research Committee's approval. Should your project involve the BC Psychosis Program, please refer to the policies and procedures at the Vancouver Coast Health Authority Research Institute.

## 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 generalizable knowledge involving human subjects (e.g., patients, family



members, staff) either directly (e.g., as a research participant) or indirectly (e.g., file-based archival studies). Such investigations should be designed and described in a way as to be replicable by others in the clinical and scientific community.

Information-seeking projects or investigations that are conducted primarily for the purpose of quality assurance/improvement, accreditation, educational activities or program/unit evaluations are not considered research activities. If the *primary* purpose of the quality assurance project is for academic presentation or publication, then appropriate university ethics and institutional approval *may* be required. Please note intention to publish is not the sole factor for determining whether a project is research or quality assurance.

In any case where it is not clear if a proposed project constitutes a research activity, it is recommended that the applicant(s) refer to the Tri-Council Policy Statement (see [https://ethics.gc.ca/eng/policy-politique\\_tcps2-eptc2\\_2018.html](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html)) and the Provincial Health Services Authority Project Sorter Tool (see <https://rc.bcchr.ca/redcap/surveys/?s=HNWAAKFF97>).

If it remains unclear, applicant(s) are encouraged to consult with the Research Committee to determine whether an application is warranted and approval required.

## **The Freedom of Information and Protection of Privacy Act, SBC 1992, c. 61**

The Freedom of Information and Protection of Privacy Act, SBC 199, c. 61 (the Act), provides for the disclosure for research or statistical purposes, by British Columbia public bodies, of personal information in their custody or under their control.

Access to and use of records or data – for research or other purposes – in the custody or under the control of the BCMHSUS must be conducted according to the provisions of the Act. The Act both guarantees public access to provincial government ministries records and protects the privacy of individuals identified in these records. For BCMHSUS, this means that all public requests for access to provincial government ministries records (including BCMHSUS) must be reviewed in order to determine whether the records contain personal information that may be restricted. For those requesting access to this type of record, Section 35 of the Act provides an option for researchers to access restricted material by entering into a legal research agreement which governs the conditions of use of such records. Consent from participants may also be an option for accessing those records.

A research agreement (via *BCMHSUS Research Operational Approval Form*), once approved, gives the researcher permission to access the desired records from BCMHSUS. A research agreement can only be granted for bona fide research projects so it is important that the applicant completes and responds in substantial detail to the *BCMHSUS Research Operational Approval Form*.

Under the Act, personal information **may not** be disclosed to any person other than the individual to whom it relates except in certain limited circumstances.

“Personal information” (defined in Schedule 1 of the Act) means recorded information that could potentially identify an individual, including:

- a) The individual’s name, address or telephone number,



- b) The individual's race, national or ethnic origin, colour, or religious or political beliefs or associations,
- c) The individual's age, sex, sexual orientation, marital status or family status,
- d) An identifying number, symbol or other particular assigned to the individual,
- e) The individual's fingerprint, blood type or inheritable characteristics,
- f) Information about the individual's health care history, including a physical or mental disability,
- g) Information about the individual's educational, financial, criminal or employment history,
- h) Anyone else's opinions about the individual, and
- i) The individual's personal views or opinions, except if they are about someone else.

At BCMHSUS, personal information may be disclosed for research or statistical purposes with consent from participants or if approval is obtained by the relevant agency's Provincial Executive Director under the terms prescribed in Section 35 of the Act:

A public body may disclose personal information for a research purpose, including statistical research, only if:

- a) the research purpose cannot reasonably be accomplished unless the personal information is shared or the research purpose has been approved by the Commissioner,
- b) any linkage between records is not harmful to the individual and the benefits derived from the linkage are clearly in the public interest,
- c) the head of the public body concerned has approved conditions relating to:
  - i. the security and confidentiality;
  - ii. the removal or destruction of individual identifiers at the earliest reasonable time;
  - iii. the prohibition of any subsequent use or disclosure of that information in individually identifiable form without the express authorization of that public body
- d) the person to whom that information is disclosed has signed an agreement to comply with the approved conditions, the Act and any of the public body's policies and procedures relating to the confidentiality of personal information.

## **Application Materials Required for Approval to Conduct Research**

A complete application for approval to conduct research at all clinical programs within BCMHSUS must consist of the following:

1. A completed *BCMHSUS Research Operational Approval Form*. Please note processing of an application may be delayed until all applicant(s) have signed Part D of the *Research Operational Approval Form*;
2. A copy of each certificate/written letter of approval from a university research ethics board.

AND/OR

A copy of the 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 the Research Ethics of Canada;



3. All materials to be employed in undertaking the study, including but not limited to: Data collection forms, coding sheets, interview guides, informed consent and/or assent forms, recruitment materials, and other materials relevant to data collection;
4. If applicable, an approval letter from the Executive Director of the BCMHSUS clinical program(s) from which applicant(s) are seeking approval for access to health records;
5. If applicable, a completed *SIM – Research Data Access Request Form* if applicant(s) are seeking approval for access to electronic records;
6. If applicable, clinical trials research requires submission of a Clinical Trial Agreement contract.

#### **Submission Checklist for a Complete Application:**

- BCMHSUS Research Operational Approval Form
- Checked for Research vs Quality Improvement if unsure about whether project is research: <https://rc.bcchr.ca/redcap/surveys/?s=HNWAAKFF97>
- Clinical Trial Agreement contract (*if applicable*)
- Completed Research Data Access Request Form to access electronic records (*if applicable*)
- Approval letter(s) from BCMHSUS clinical program(s) to access health records (*if applicable*)
- All materials to be employed in undertaking the study
- University Research Ethics Certificate of Approval(s)

Other documents should be included as needed based on the guidelines specified above, or if it provides additional information as to the nature of the project and its operational impact on BCMHSUS. For instance, if applicant(s) are seeking data linkage to an external project, the project proposal (and all other relevant materials) of the external project must also be sent along with the application. If applicant(s) are uncertain as to the relevance of a particular document or letter, s/he may consult with the Research Committee for further clarification.

### **Submitting an Application**

Applicant(s) are to submit the entire application package (as outlined above) electronically. Please email the completed submission package to the Coordinator of the BCMHSUS Research Committee (contact information below).

BCMHSUS Research Committee meetings are held every third Monday of each month or at the call of the Chair. In order to ensure that an application is reviewed at a given meeting, new applications must be submitted to our office two weeks in advance (i.e., by 4:30 pm of the 1<sup>st</sup> Monday of each month). If the application has already been approved by the Research Committee and the applicant(s) only seeking approval for amendments and/or an annual renewal, then the application package (including the *BCMHSUS Request for Post-Approval Activities Form*) must be submitted a week before the upcoming Research Committee meeting. Please note that the onus is on the applicant(s) to submit the application in a timely manner so that it meets their research timeline, factoring in the time necessary to obtain approval from the Research Committee.



## Review of Submissions

*Review Process.* Upon receipt, completed applications for approval to conduct research are forwarded to members of the Research Committee for review. Reviewers will present their opinions 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;
- Provisional approval – subject to the submission of further information, clarification and/or minor revisions to the application (see below); or
- Approval.

All such recommendations are subsequently authorized by the Chair of the Research Committee. Official notification of the Committee's decision will be communicated in writing to the applicant(s) in the week following the meeting at which it was reviewed.

*Provisional Approval.* Decisions of provisional approval are made in the following circumstances:

- If the Research Committee requires submission of further information, clarification, and/or minor revisions to the application. Official notification will be sent to the applicant(s) detailing the revisions required before final approval can be provided. Applicant(s) will be required to submit a cover letter detailing the changes made to the application and highlight/track such changes for ease of reference.
- Any research projects that intersect with BC Corrections that directly involves Correctional staff, inmates, or clients; access to Corrections data (e.g., CORNET data); or involves visiting their physical facilities require a submission of a research application to both the Research Committee and the BC Corrections Research Application Committee. Please note that provisional approval from both Committees must be received before final approval from the Research Committee can be provided. The Research Committee will only provide provisional approval for studies that have yet to receive approval from the BC Corrections Research Application Committee. The onus will be on the applicant(s) to submit the application to both Committees. For more information on the application process for BC Corrections, please visit: <https://www2.gov.bc.ca/gov/content/justice/criminal-justice/corrections/research-evaluation>.

*Terms of Approval.* The *BCMHSUS Research Operational Approval Form* is a binding legal document, granting access only to the records specified in Part C and to those individuals noted in Part A, B, and D of the form. Once granted, the approval to conduct research at BCMHSUS is valid until the project's university ethics approval(s) expiry date(s).

Should there be any 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 on-going research projects, as deemed necessary by the Chair.



## Protocol or Study Amendments

In cases where changes to the original project protocol are necessary – as specified in the applications for ethics and institutional approval – the applicant(s) are required to submit a request to the Coordinator for review and approval by the Research Committee. Please fill out the *BCMHSUS Request for Post-Approval Activities Form* and submit to the Coordinator a week before the Research Committee meeting (i.e., 2<sup>nd</sup> Monday of each month). Substantive changes may require a new approval to conduct research process to be initiated. Applicant(s) 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 appropriate university ethics board(s) must be provided to the Coordinator at the time of the application.

## Requests for Extensions

If the project is not yet complete by the end of the approved period, it is the responsibility of the applicant 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 Committee the ethics certificate/official notification of ethics approval for the annual renewal; and
4. Request continuation of the Research Committee's institutional approval to conduct research using the *BCMHSUS Request for Post-Approval Activities Form*.

A courtesy reminder to this effect will be sent to the applicant(s) and the primary contact a month prior to the one-year anniversary of the initial ethics approval. In the case of ethics approval from more than one ethics review board, the reminder notice will be sent one-month prior to the one-year anniversary of the first ethics approval date. Annual renewal or termination of project documents must be sent to the Coordinator a week before the closest committee meeting date of the project expiry date. Should these documents not be received by then, the Chair may suspend approval to conduct research, order data collection to be halted, and no further expenditures will be approved. In the case where the applicant(s) are not granted continued ethics certification for the project, data collection will be terminated.

## Contact Information

For more information about the application process to conduct research at BCMHSUS and/or to submit an application package to the Research Committee, please contact:

**Ms. Karen K. Chu**  
Coordinator, Research Committee  
BC Mental Health and Substance Use Services  
Email: [ResearchCommittee BCMHSUS@phsa.ca](mailto:ResearchCommittee BCMHSUS@phsa.ca)  
Phone: 604-523-7888



## Appendix A: BCMHSUS Operational Approval to Conduct Research Process

Before commencing a research project, applicant(s) must receive institutional approval from the BCMHSUS Research Committee. To obtain institutional approval, the following steps are required:

University Research Ethics Board (REB)  
**Certificate of Approval:** Must be received prior to submitting institutional approval application to the Research Committee.



**BCMHSUS Research Committee Approval:**  
Complete the *BCMHSUS Research Operational Approval Form* if the project directly involves BCMHSUS staff, clients, or data, from the following clinical program areas:

- Adult Complex Mental Health and Substance Use Services
- BC Forensic Psychiatric Hospital and Regional Clinics
- Correctional Health Services

**If project requires BC Corrections approval:**  
an application must also be sought from the BC Corrections Research Application Committee.

<https://www2.gov.bc.ca/gov/content/justice/criminal-justice/corrections/research-evaluation>



**File review:** If proposed project methodology involves review of clinical charts, please include a letter of authorization from applicable programs. Please email [ResearchCommittee BCMHSUS@phsa.ca](mailto:ResearchCommittee BCMHSUS@phsa.ca) for template and contact information.

**Electronic Data:** If project involves access to electronic data, please also complete the *SIM – Research Data Access Request Form*. Please email the Research Committee for the form.



**Submission:** Submit full application, along with relevant documents, to the Research Committee on the 1<sup>st</sup> week of the month.



**Final Approval:** Application will be reviewed at the next scheduled meeting. A decision will be made by the Research Committee and communicated in writing to the applicant.



**Provisional Approval:** If project requires approval from BC Corrections, a decision will be made by the Research Committee and communicated in writing. Final approval will only be provided once the project has been approved by both BCMHSUS and BC Corrections Committees.

