

BCMHSUS RESEARCH OPERATIONAL APPROVAL TO CONDUCT RESEARCH

GUIDELINES
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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., Redfish Healing Centre, 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) 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 (“BCMHSUS Data”) 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 33(3)(h) 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 *PHSA DAR Form and the PHSA Data Access and Use Terms*), 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 *PHSA DAR 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 Secondary Use Leaders under the terms prescribed in Section 33(3)(h) 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 *PHSA Data Access Request Form*, which can be found here: <https://rc.bcchr.ca/redcap/surveys/?s=YPPEKA87HA>. The PHSA Data Access Form acts as an application form for all studies, including primary and secondary collection of data. Please select the "request data" option, which will lead you to the main page of the application form.
2. A copy of each certificate/written letter of approval from a university research ethics (REB) board and the associated REB application. For UBC-affiliated applicants, please select "BC Mental Health and Substance Use Services (includes Research Institute)" as a site location when completing your ethics application.

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, clinical trials research require submission of a Clinical Trial Agreement contract.
5. On-boarding documents for research personnel who are considered external to PHSA.

Please have all of the above-mentioned documents ready as you will need to upload it directly onto REDCap when submitting your PHSA DAR form. More detailed instructions will be provided in the application, but applicant(s) will be required to combine all items under number 3 and 4 (if applicable) into one single PDF document for upload.

Submission Checklist for a Complete Application:

- PHSA Data Access Request Form
- Checked for Research vs Quality Improvement if unsure about whether project is research using the PHSA Sorting Tool:
<https://rc.bcchr.ca/redcap/surveys/?s=HNWAAKFF97>
- Clinical Trial Agreement contract (*if applicable*)
- All materials to be employed in undertaking the study (including consent form if applicable)
- University Research Ethics Certificate of Approval(s) and ethics application, and/or notification of final ethics review for UBC-affiliated research projects
- On-boarding documents for external research applicant(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/they may consult with the Research Committee for further clarification.

On-Boarding Requirements for Research Personnel. Please note that BCMHSUS requires all research personnel to be on-boarded according to our policies and procedures before research can be conducted within our clinical programs. As each clinical program has their own requirements, please review the BCMHSUS on-boarding document linked [here](#). Due to the fluidity of socio-health and/or other situational circumstances, BCMHSUS may also require additional requirements to be met prior to commencing research at BCMHSUS (e.g., vaccination against COVID-19, flu shots, etc.). This is to ensure the continued safety of both BCMHSUS patients and staff. Any changes and/or additions in requirement will be communicated to applicant(s) in a timely manner.



Consent Form Guidance. For studies that require access to administrative and/or BCMHSUS Data with or without any linkage component, please review the *HDRN Consent Language for BCMHSUS* document attached [here](#). This document provides guidance on how to structure consent forms in a way that ensures consistency in language and alignment with BCMHSUS standards. Consent forms will be reviewed in accordance with the HDRN guidance document; where consenting language is not consistent or in alignment with the guidance document (as applicable), the applicant may be requested to complete the necessary modifications to the consent form prior to obtaining BCMHSUS approval.

Submitting an Application

Applicant(s) are to submit the entire application package (as outlined above) electronically via the REDCap platform.

BCMHSUS Research Committee meetings are held every third Monday of each month or at the call of the Chair. In order to ensure adequate time for the Office of the Research Committee to process and review, new applications must be submitted via REDCap two weeks in advance (i.e., by 4:30 pm of the 1st 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 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, Data Access Committee, and the BC Corrections Research Application Committee (as applicable).

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 weeks following the meeting at which it was reviewed. For UBC-affiliated or harmonized projects, the Office of the Research Committee will upload the approval letter directly on to the RISE System to help ensure proper notification and communication of institutional approval between the UBC REB and BCMHSUS. As such, please ensure your UBC ethics application has "C&W – Mental Health" listed as a site location prior to submission.

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.
- For research projects that require access to BCMHSUS Data, in the form of data extracts, paper-health records, or direct access (e.g. CST Cerner), additional approval is required from the BCMHSUS Data Access Committee. The Office of the Research Committee will liaise with the Data Access Committee to ensure proper approval and thus, requires no additional work from applicant(s). As such applications require approval from both the Research Committee and the Data Access Committee, the onus is on the applicant(s) to submit the application in a manner that reflects their research deadlines/timelines. Once approval has been received by both the Research Committee and Data Access Committee, our Office will issue a final approval letter for your records.
- 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/research-guidelines> and/or review the [BC Corrections Research Application Committee FAQ](#).

Terms of Approval.

Application submission: Upon submission of the PHSA Data Access Request, the applicant must accept the PHSA Data Access and Use Terms (“the Terms”). The Terms is a binding legal document that sets out the responsibilities that apply to an applicant who wishes to access and use BCMHSUS Data for the purposes of conducting research or statistical activities.

Application approval: Once granted, the approval to conduct research at BCMHSUS is valid until the project’s university ethics approval(s) expiry date(s). An approval letter will be circulated to the applicant(s) specifying the terms and conditions of the approval.

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 email ResearchCommittee BCMHSUS@phsa.ca their request for an amendment. The Office of the Research Committee will then email your research team a link to the REDCap form to facilitate the amendment request, which will require detailed information as to the amendment type, etc.. The application for an amendment must be submitted to REDCap a week before the Research Committee meeting (i.e., 2nd 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 at the time of the application. Please note the Research Committee will only review and approve amendments that already have been approved by the university research ethics board. Where the applicant(s) have been approved to access BCMHSUS Data, the amendment will also be reviewed and approved by the Data Access Committee. The Office of the Research Committee will liaise with the Data Access Committee to ensure proper amendment approval; no additional work is required from the applicant(s).

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 Annual Renewal Form* on REDCap, which will be sent to the applicant(s) with their courtesy reminder of study expiry.

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 received 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.

Termination of Study

Project Closure. Applicants are required to notify the Office of the Research Committee of the project's closure by submitting a *Project Closure Form* on REDCap.



Data Archiving and Destruction Form. Applicant(s) with research projects that involve access to BCMHSUS Data will need to submit to the Office of the Research Office the [BCMHSUS Data Archiving and Destruction Form](#) at time of study termination. This form is used to convey a request archive or destroy data provided to a researcher by BCMHSUS for research purposes. Please note that the form should only be completed if the applicant(s) no longer require access to BCMHSUS Data – if access to data is required for analyses or the creation of publication materials, please review and complete the annual renewal process to request an extension of institutional approval and ensure university research ethics approval remains open and up-to-date. Final closure of the research project will be confirmed by BCMHSUS upon receipt of the signed Data Archiving and Destruction Form accompanied by the project closure form on REDCap.

To determine whether data should be archived or destroyed, please consider whether data needs to be retained for any of the following purposes or other purposes not listed:

1. Findings have been published and applicant(s) are required to retain a copy of the data for a standard timeframe in accordance with policies developed by your academic institutional or publisher
2. Applicant(s) may need to engage in data re-collection or re-analysis
3. Applicant(s) anticipate the study data will be re-used for another study or a sub-study

If data needs to be retained for any of the above-mentioned purposes, please archive the data according to the methods listed in the *Data Archiving and Destruction Form*. Please note you **WILL NOT** have access to the BCMHSUS Data once it has been archived. If a project needs to be reopened once data has been archived, you must re-apply to your affiliated university research ethics board, and the BCMHSUS Research Committee and Data Access Committee for review and approval.

For applicant(s) who are not archiving their data, please follow the data destruction procedures listed in the *Data Archiving and Destruction Form*. Please note that data destruction will be required for all types of BCMHSUS Data, including data extracts, and/or any data extracted from paper-based health records and/or electronic health record system.

Pre-Publication Requirements

Where the applicant(s) has been approved to access BCMHSUS Data, the applicant's approval letter will specify if the applicant(s) must adhere to additional requirements for submitting pre-publication materials to BCMHSUS in advance of public dissemination. BCMHSUS is responsible for ensuring appropriate uses of BCMHSUS Data by checking pre-publication materials to confirm:

- Privacy/confidentiality requirements are upheld, including minimum cell sizes, no inadvertent or unapproved identification of specific populations or communities
- There is no gross misuse of the data
- There is a clear connection to the Project and alignment with the stated and approved purpose
- The data is appropriately referenced and a disclaimer is included



This also provides an opportunity for BCMHSUS to learn of, and brief internally, on the research findings.

Where the approval letter specifies pre-publication review requirements:

It is the responsibility of the applicant(s) to inform the Office of the Research Committee any intentions to publish the data and to provide the drafts of such pre-publication materials according to the time table below. This will be applicable to all forms of data release(s), including publications, presentations, and other output types (social media, television/media interviews, etc.).

Type of Research Material	Submission to BCMHSUS required	Citation requirement	Disclaimer requirement	When to submit?
Presentations: seminars, conferences, lectures				
Abstracts	yes	no	no	FYI: At time of submission
Presentations to internal colleagues	no	no	yes	Not required
Presentations - external	yes	yes	yes	Review Required: At least 10 business days prior to presentation
Instructional use (lectures, lab exercises, etc.)	yes	yes	yes	Review Required: At least 10 business days prior to presentation
Publications: articles, op-ed, journals, theses and dissertations				
Article or Op-ed for general public release (newspaper, magazine, blog, wiki, etc.)	yes	yes	yes	At time of submission (at least 45 business days prior to publication/release)
Journal publication, including pre-prints	yes	yes	yes	At time of submission to the journal (initial submission) (at least 45 business days prior to publication/release)
Academic thesis or dissertation material	yes	yes	yes	At time of final submission to committee (at least 45 business days prior to publication)
Other output types				



Radio, television, internet, etc. interview	yes	no	no	No release unless findings previously vetted by BCMHSUS (i.e. published)/ FYI - Only if published
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The following disclaimer language is required to be included in all pre-publication materials (with the exception of conference abstracts):

Disclaimer: "Access to data used in this analysis was approved by BC Mental Health and Substance Use Services. All inferences, opinions, and conclusions drawn in this publication are those of the author(s), and do not necessarily reflect the opinions or policies of BC Mental Health and Substance Use Services, a clinical program of Provincial Health Services Authority."

The following data citation is required to be included in all pre-publication materials to appropriately cite the data source:

Citation format: BC Mental Health and Substance Use Services Data (Year Data was Provided): Title of Dataset. Access Type. Approved by BCMHSUS (Year).

- Example 1: BC Mental Health and Substance Use Services Data (2022): CST Cerner Admissions Data. Direct Access. Approved by BCMHSUS (2022).
- Example 2: BC Mental Health and Substance Use Services Data (2020): Primary Assessment and Care Data. Data Extract. Approved by BCMHSUS (2019)

Where the approval letter specifies no additional pre-publication review requirements:

Where the applicant has not been notified of the above-mentioned pre-publication review requirements in their approval letter, the applicant is required to submit copies of publication materials to the Office of the Research Committee at time of annual renewal/termination as an FYI. These publications materials are not subject to any additional review by BCMHSUS.

Contact Information

For more information about the application process to conduct research at BCMHSUS and/or assistance with regards to the institutional approval process, please contact [ResearchCommittee BCMHSUS@phsa.ca](mailto:ResearchCommittee@phsa.ca).

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:

