



## BC MENTAL HEALTH & SUBSTANCE USE SERVICES REQUEST FOR POST-APPROVAL ACTIVITIES FORM

**Study Title:**

**Principal Investigator:**

**Select reason for submission to the BCMHSUS Research Committee:**

- Amendments to Study     Annual Renewal     Annual Renewal with Amendments     Termination of Study

### **Instructions:**

For amendments to the study protocol, please complete *PART A* of the application. Changes to the study protocol must be documented and highlighted in the appropriate sections of the BCMHSUS Research Approval Form and in any other relevant documents. Please also submit to our office the corresponding ethics approval from which you and your co-investigators are affiliated upon receipt.

For annual renewals, please complete *PART B* of the application and submit to our office any corresponding ethics approval for this annual renewal prior to the expiry date of the study.

For annual renewals with amendments, please complete *PART A and B* of the application. As per above, changes to the study must be documented in the appropriate sections of the relevant forms and corresponding ethics approval must be submitted to our office prior to the expiry date of the study.

If you are terminating the study, please complete *PART C* of the application and submit to our office corresponding termination certificate(s) from the university from which you and your investigators are affiliated, and a copy of your completed study.

*Please note PART D must be completed by all applicants* A cover letter will no longer be required for all post-approval activity submissions. This completed form, along with other documents, must be submitted to the [Coordinator of the BCMHSUS Research Committee](#) no later than a week before the scheduled BCMHSUS Research Committee meeting.



**PART A – AMENDMENTS TO STUDY PROTOCOL**  N/A

1. The nature of the proposed amendment(s) involves change in (select all that apply):

- Research personnel
- Methodology and procedures (e.g., recruitment, sample size, inclusion/exclusion criteria)
- Risks to participants
- Consent process
- Study timeframe (e.g., start/end date)
- Conflict of interest declaration
- Other

2. Briefly summarise the proposed amendment(s) to the study:

3. Provide the rationale(s) for the proposed amendment(s):

**PART B – ANNUAL RENEWAL**  N/A

1. Please provide the rationale as to why an annual renewal is being requested:

2. What is the anticipated date of completion for this study?

3. Does the study involve direct interaction/contact with human participants?

- Yes
- No

4. a. Anticipated number of participants and/or charts to be included:



b. Number of participants and/or charts included in the study to date:

5. Provide a summary of the progress of the study, including study implementation details, whether the study is proceeding as planned, and if there are any issues that pose a challenge to the study meeting its proposed timeframes:

**PART C – TERMINATION OF STUDY**  N/A

1. What is the rationale for terminating the study?

- Study was terminated prematurely due to unforeseen risks/adverse events
- Study was completed as planned (e.g. recruitment and data collection is complete)
- Other (specify):

2. Date of completion:

3. Total number of charts and/or participants accrued:

4. Total number of participants withdrawn from study:

5. a. Were there any unanticipated and/or adverse events during the course of the study?

- Yes
- No

b. If yes, please describe the nature of the unanticipated and/or adverse event:

6. Briefly summarise how long study data will be retained and the procedures for which data will be secured/stored, including electronic files:



7. Briefly summarise the method for which the destruction of data will occur, including when it will be destroyed. If data will not be destroyed, please provide the rationale (e.g. data linkage):

## **PART D – AGREEMENT**

I have read the Tri-Council Policy for Ethical Conduct for Research involving Human Subjects and agree to abide to the policies and procedures outlined therein. My signature certifies that the above information is correct, up-to-date, and that no unapproved procedures will be/were used in this study.

\_\_\_\_\_  
Signature  
Principal Investigator

\_\_\_\_\_  
Date (YY-MM-DD)

## **PART E – APPROVED TERMS AND CONDITION** (to be completed by BC Mental Health & Substance Use Services)

The above post-approval activity is hereby approved. BC Mental Health & Substance Use Services reserves the right to withdraw access to records without prior notice if this becomes necessary under the *Freedom of Information and Protection of Privacy Act*.

\_\_\_\_\_  
Signature  
Chair – BCMHSUS Research Committee

\_\_\_\_\_  
Date (YY-MM-DD)