

Behavioural Ethics Application Guidance Notes

Post Approval Activities



a place of mind

THE UNIVERSITY OF BRITISH COLUMBIA

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I. INTRODUCTION

All progress reports, new information or amendments to an approved study must be submitted using the **Post Approval Activity (PAA)** online application form. This form can be found on the left hand side of your study homepage – just click the [I would like to submit new post approval activity](#) link.

You will then be presented with a list of five PAA options:

- Annual Renewal
- Annual Renewal with Amendments to Study
- Amendments to Study
- Completion of Behavioural Study
- Request for Acknowledgement

Select the appropriate option and then click “continue”.

II. ANNUAL RENEWALS

The Tri-council Policy Statement (2010) article 6.14 states that “The REB shall make the final determination as to the nature and frequency of continuing research ethics review in accordance with a proportionate approach to research ethics review. At minimum, continuing research ethics review shall consist of an annual status report (for multi-year research projects), and an end-of-study report (projects lasting less than one year).”

Every behavioural research ethics application must be renewed via RISE each year using the PAA option ‘Annual Renewal’ for as long as you will continue to have contact with research participants. A renewal should be submitted before the anniversary of the date that is listed on the approval certificate. You will receive an automated notification in RISE 90 days, 60 days and 30 days before your study comes up for renewal. The ‘Annual Renewal’ Post Approval Activity (PAA) Coversheet will ask you to fill in details about study progress, including recruitment and unanticipated events. For instructions on how to submit a PAA Annual Renewal using RISE click [here](#).

Important note: Please note that the summary of the progress of the study is NOT the place to advise the Board of proposed amendments. Use the combined renewal / amendment form instead. If you refer to previously approved amendments in the summary, include the date of BREB approval of those amendments, otherwise, your application will be returned to you with a request to submit an amendment.

6th annual renewal (UBC Behavioural Research Ethics Board only)

Article 2.8 of the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans states that “Following initial REB review and approval, research ethics review shall continue throughout the life of the project”.

Social science, behavioural and humanities studies conducted over a long period of time (>5 years) often undergo shifts in focus. The sixth annual renewal therefore provides an opportunity to look over your application to ensure that it conforms to your approved application. To facilitate this process, the UBC Office of Research Ethics asks that you look carefully over your approved ethics application to ensure that it matches your current study processes and procedures. If the approved study no longer matches the research you are conducting you are required to submit a new application for ethical review. If no changes have occurred, please reproduce the statement below in box 1.7 of the PAA Annual Renewal Coversheet to confirm that your study conforms to the approved procedures:

I confirm that my study conforms to my approved ethics application and that all aspects of the study, including participant recruitment, consent documents, study materials, etc., are up-to-date and reflect how my study is currently being conducted.

III. ANNUAL RENEWAL WITH AMENDMENTS TO THE STUDY

You may request review of an amendment at the same time that you request annual review by selecting the combined ‘Annual Renewal with Amendments to Study’ form. For detailed instructions on submitting an annual renewal with amendments on RISE please click [here](#). See section IV for an overview of amendments.

IV. STUDY AMENDMENTS

Amendments are changes to an ongoing study. If you are changing any part of the study (e.g. co-investigators, title, agency, documentation) you must submit an amendment using the ‘Amendment to Study’ PAA. Any changes to the application should be clearly explained in the PAA coversheet, along with a brief overview of the rationale behind these changes. It is helpful if you stated how your proposed amendment extends, refines or revises the approved aims/methods/recruitment, etc. Any changes to the study documents should be clearly explained in the PAA *and* highlighted on the attached, revised document. For detailed instructions on submitting amendments on RISE please click [here](#).

Amendments to studies should be changes within the scope of the original study, not new studies that are simply related to the original study. If the procedures and data collection described in the original application for ethical review have now been completed, changes that involve **new research questions** and also entail new procedures, measures, or study populations should be submitted in a new application for ethical review. In general, a good rule of thumb is that if you find yourself needing to update boxes on most sections of the application, then it’s probably appropriate that you submit a new application rather than an amendment.

Important note: When you are submitting an amendment, do NOT remove information regarding previously approved procedures if you have used those procedures in the study, even if that component of the study is now complete. The application should encompass all aspects of the study, not merely the new elements for which you are requesting approval.

Amending study team

The only person who can change the Principal Investigator on the study is the current Principal Investigator. Since only the current Principal Investigator can submit the amendment, **do not** change the name of the Principal Investigator in box 1.1 when you edit the full application; otherwise, you will not be able to submit the amendment.

If the current Principal Investigator is taking a temporary leave, include his/ her name in question 1.3 so he/ she will continue to have access to the application.

If recruitment of research participants is ongoing, you must revise and attach recruitment and consent documents in view 9 of the full application.

In order to change the Principal Investigator on the study:

- Select “yes” and then “here” in box 1.2
- Print a copy of the [declaration form](#).
- The current Principal Investigator, the new Principal Investigator and the Department/School Head must sign the declaration form
- Scan and attach the form in box 1.2.
- The REB administrator will update the PI on the study once you have submitted the PAA.

Changes to personnel other than the PI can be submitted using the Amendment PAA form. However, please be aware that if the co-investigators (as opposed to research staff) change, all documents which list them and which are provided to study participants must be updated (e.g. consent, introductory letters, etc.).

Where the amendment is limited to an 'administrative change' (e.g. changes in granting status, staff personnel, contact person, etc.), please include an explicit statement on the PAA coversheet to the effect that the research procedures (including recruitment, consent, etc.) have not been changed in any way.

Submitting amendments for qualitative research (UBC Behavioural Research Ethics Board and Non-US funded research only)

Article 6.15 of the TCPS2 states that “In some types of qualitative research, for example, emergent design, the research design evolves over time, so adjustments to the research are to be expected and need not be reported to the REB, *unless they alter the level of risk or have other ethical implications for participants*” (see application section, Article 6.15). Similarly, article 10.5 states: “In emergent design, some resulting changes to the research design will not merit requiring additional REB review, as they are not necessarily significant changes to the approved research”. For example, if your amendment represents a change to the study design or aims that would not be covered, explained or anticipated by a study participant in the currently approved consent materials (with the exception of

#2 below), then an amendment must be submitted. Examples of changes to qualitative studies that would **NOT** require the submission of an amendment form are as follows:

- 1) Minor changes to survey or interview questions that merely *refine* the questions asked and do NOT change the *overall* focus of the interview or introduce topics that are more sensitive than those already approved (for example, introducing new questions about experiences of abortion in the context of an interview about women's health would require the submission of an amendment);
- 2) Minor changes to the study inclusion or exclusion criteria that do not substantively change the populations being studied; for example, expanding slightly the age range of study participants would not require an amendment, unless you want to include minors in a study previously focusing exclusively on adults. Similarly, if you wanted to expand inclusion criteria for a study of people with type II diabetes from 2 years to 5 years post-diagnosis, this would NOT require the submission of an amendment.
- 3) Minor refinements to recruitment materials that do not change the overall information participants are given about the study would not require the submission of an amendment. For example, if you planned to recruit both men and women in your study at the outset, but have primarily attracted women into the study to date, you could add a statement to your recruitment materials that you are specifically interested in talking to men without the submission of an amendment.

All other changes require the submission of an amendment.

Full board vs. delegated amendments

Important note: Even if your application was originally submitted as a full board study, this does not automatically mean that your amendment has to be reviewed by the full board. If your amendment does not increase the level of risk for participants it is eligible for delegated review, unless your study is US-funded.

Amendments submitted for minimal risk studies are also eligible for delegated review unless they increase the level of risk for study participants *beyond* minimal risk (i.e. beyond what participants would encounter in their everyday lives – please click [here](#) for further information on the definition of minimal risk).

The following questions should be considered when proposing an amendment:

- 1) Does the amendment affect the risks for participants?
- 2) Does the amendment affect recruitment? If so, does the recruitment ad or letter need to be revised?
- 3) Does the amendment affect what the participant is asked to do or the confidentiality of the data? If so, the consent document should be revised and attached.
- 4) Does the consent document adequately reflect the change in time, risk, or confidentiality?
- 5) When reviewed initially did the BREB have any significant concerns about this study that should be considered when reviewing the amendment?

V. STUDY COMPLETION

Subject to special considerations for US-funded research, annual renewal is not required if the researcher/research team will have no further contact with participants for the purpose of data collection or research (e.g. for follow-up or verification). Renewal is not required to analyze data or write a paper. This will not affect your access to the research grant funds for this study, i.e. your grant will not be closed. If you are at this stage in your study, complete the 'Completion of Behavioural Study' PAA. Click [here](#) for instructions on how to submit a study completion on RISE. Click [here](#) for information on when US funded research is no longer required to undergo continuing review.

VI. REQUEST FOR ACKNOWLEDGEMENT

Use the 'Request for Acknowledgement' PAA form to attach a document to the file, such as agency approvals, unanticipated problems (e.g., theft of laptop) or to include miscellaneous correspondence. Any other changes to the study procedures or documents (e.g., recruitment, consent, or data collection) must be submitted through an amendment. Click [here](#) for instructions on how to submit a Request for Acknowledgement on RISE.

VII. TURNAROUND TIME

The turnaround time for post approval activities varies according to the time of year (e.g. vacations, conferences, teaching commitments) and the volume of applications received. On average you can expect a response within one-two weeks.

VIII. KEY CONTACTS

Help with PAA submissions to the UBC Behavioural Research Ethics Board may be obtained from: Shirley Thompson, Manager, BREB (Ph: 604-827-5112, Shirley.Thompson@ors.ubc.ca).

Help with PAA submissions to the UBC Okanagan Behavioural Research Ethics Board may be obtained from: Lisa Shearer, Awards and Ethics Officer (lisa.shearer@ubc.ca; ph: 250 807 8289)

Help with PAA submissions to the BC Cancer Agency Research Ethics Board may be obtained from: Bonnie Shields, Manager, BCCA REB (bshields@bccancer.bc.ca; ph: 604 877 6284)

Help with PAA submissions to the Children's & Women's Hospital Research Ethics Board may be obtained from Jennie Prasad, Manager, C&W REB (jprasad@cfri.ubc.ca; 604 875 2441)

Help with PAA submissions to the PHC Research Ethics Board may be obtained from Michelle Storms, Manager, PHC REB (mstorms@providencehealth.bc.ca; 604 682 2344, ext. 63496)

For technical inquiries about the RISE online application please send an e-mail to risesupport@ors.ubc.ca or call 604 878 7473.