



UBC Okanagan

Behavioural Research Ethics Board

UBC Okanagan BREB

Human Ethics Applications: 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 coversheet, along with a brief overview of the rationale behind these changes. It is helpful if you state 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 documents (alternatively, track changes can be used).

Make sure that you also modify the ethics application to incorporate the changes. Explaining the changes only in the coversheet is not sufficient.

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.

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.

Websites to Add to your Favorites:

Amendment PAA form (view only)

http://www.research.ubc.ca/sites/research.ubc.ca/files/uploads/PAA-Amendments_4.pdf

Post-Approval Guidance notes

<http://www.research.ubc.ca/sites/research.ubc.ca/files/uploads/documents/Ethics/BREB/post-approval%20250guidance%2520notes.pdf>

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Completing an Amendment for your Human Ethics Application

1. Log into RISE and select the study for which you would like to create an amendment.
2. On the left hand side under "I would like to create ..." select "**New Post Approval Activity (PAA)**".
3. From the list of PAA options select "**Amendments to Study**" and click **Continue**.
4. A PAA coversheet will appear. Complete all applicable questions and summarize the amendments you are making to your application.
 - a. Section 1.3: The question asks if the amendment is eligible for delegated review.

Answer YES if the amendment does not increase the level of risk beyond what was originally approved. E.g. if your study was originally minimal risk or required full board review, unless the risk has been increased, answer YES.

Answer NO if the amendment increases the level of risk beyond what was originally approved. E.g. if your study was originally minimal risk and the risk has been increased such that it is now beyond minimal risk, it would require full board review.
5. After completing, select **Save** and **Close**. You will be taken to the amendment homepage.
6. From the left hand side, select "**Edit Application**" to make changes to the ethics application form.
7. When finished, **Save** and **Exit**. Your application and PAA Coversheet will still be open for any edits you may wish to make. At this time it is suggested to review your amendment. To do so, from the left hand side select 'PAA review/print'. At the bottom click on 'view differences'. This will allow you to go through the application and see all of the changes made. This is helpful when completing the last question on the PAA coversheet.
8. As a reminder, ensure that all supporting documents include the current UBC logo.
9. When you are ready to submit your amendment for review, from the left hand side click "**Submit PAA**".
10. The PAA will be sent to the BREB Administrator who will assign it for review.
11. If changes are required, you will be sent a notification from RISE via email.
12. Once approved, a certificate of approval for the amendment will be issued. The expiry date will remain the SAME as what it was for the original study. Amendments do not change the expiry date; only Annual Renewals or Annual Renewals with Amendments do.

<http://breb.ok.ubc.ca>