

Post Approval Activity (PAA) Instructions

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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) application form within RISE. A PAA can be started by clicking the New Post Approval Activity button on the left-hand side of your study homepage.

There are four PAA options:

- **Annual Renewal** – allows for renewal of the ethics application, but does not allow for any changes or amendments to the application.
- **Amendments to Study** – allows for changes to the application, but will not initiate renewal of the application. Changes to an application must be reviewed and approved before they can be conducted.
- **Completion of Behavioural Study** – allows for closure of the application. Note that all ethics applications must be closed when they are complete, and expiry is not the same as closure.
- **Request for Acknowledgement (RFA)** – allows for communication to the Research Ethics Board (REB) when unanticipated events and protocol deviations occur. Note that changes or amendments to the application cannot be included (or submitted) until after the RFA has been resolved.

For all PAA types, although any study team member with online access to the application can begin a PAA, only the Principal Investigator (PI) or a designated signing authority can submit the PAA for review. If additional changes are required after initial submission, anyone with online access can modify and re-submit.

See below for more details.

II. ANNUAL RENEWALS

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2, 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 UBC BREB 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 expiry date; if a study is expired, research activity must cease until the application is renewed. You will receive an automated email notification from RISE 30 days and 14 days before your study expires. The Annual Renewal PAA Coversheet will ask you to fill in details about study progress, including recruitment and unanticipated events. For RISE instructions on how to submit an Annual Renewal PAA [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. If you need to submit changes around the same time as submitting a renewal, you will need to submit two PAAs: an Annual Renewal (to initiate the renewal process), and an Amendments to Study (to propose changes to the application).

When should an application be renewed versus closed?

If participant recruitment and data collection have permanently stopped and you do not anticipate needing to go back to your participant population to confirm data, an active ethics application is no longer required from UBC BREB’s perspective and the file can be closed. Research ethics is not required during the analysis stage, provided the analysis is in line with the approved application. If you do not anticipate further contact with your participant population, submit a Completion of Behavioural Study PAA to close the file.

If recruitment has stopped but you do anticipate needing to go back to your participant population, the application will need to be renewed. Submit an Annual Renewal PAA and indicate the continued contact with participants in Box 1.3 of the PAA coversheet.

If your application involves Secondary Use of Data, the data custodian may require you to maintain ethics approval for the entire duration of your data access. If this is the case, submit an Annual Renewal PAA and indicate the data custodian’s requirement in Box 1.3 of the PAA coversheet.

If you intend to analyse data for a purpose outside of what was originally approved in the application, a new ethics application will need to be submitted. UBC BREB has a truncated application form specific to Secondary Use of Data, which should be used for these cases.

Annual Renewal beyond 5 years

Article 2.8 of the TCPS 2 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 (more than 5 years) often undergo shifts in focus. The sixth and subsequent annual renewals therefore provide an opportunity to ensure your research 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 minor changes are required that are in line with the original application, an Amendment will need to be submitted to update the application. If no changes have occurred, please reproduce the statement below in box 1.8 of the Annual Renewal PAA 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.

Important note: Based on changes to the RISE platform and BREB policies and procedures over time, the BREB may ask for applications that are 10 or more years old to be closed and replaced by a new ethics application submission.

III. 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) an Amendments to Study PAA must be submitted and approved prior to enacting the change. 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 state how your proposed amendment extends, refines, or revises the approved aims/methods/recruitment, etc. A list of study documents that have been added or changed should be included in the PAA coversheet, and changes should be highlighted on the new documents attached to Page 9. For RISE instructions on submitting amendments [click here](#).

Important note: When you are submitting an amendment, do NOT remove information or documents that describe 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. Please add a dated sub-heading (e.g., "September 2024 Amendment") to the bottom of any boxes that need to be amended and indicate the new details below it. Add new versions of documents to Page 9 without removing previous versions that have been used with participants.

When adding new details where the new iteration is largely the same, only the changed detail needs to be indicated under the dated subheading. Information that remains consistent does not need to be repeated. For example, if the initially approved application indicated interviews with individuals between the ages of 20 and 30 and the researcher is looking to add interviews with 30- to 40-year-olds

that follow the same procedures, the added text might say “September 2023 Amendment: Interviews will also be conducted with individuals between the ages of 30 and 40 using the same procedures.”

If previously approved procedures have not been used and will not be used in the study, the information can be removed or over-written. When doing this, please make it clear in the PAA coversheet that these procedures did not and will not take place.

Amending a Study versus Starting a New Study

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.

Changing Study Team Members

Change Principal Investigator (PI)

The only person who can change the Principal Investigator on the study is the current Principal Investigator. (If it is not possible for the current PI to submit the amendment, please contact BREB staff to discuss.) You will not have access to change the PI in Box 1.1 of the ethics application. This will be done by the REB once the amendment is ready for approval.

If the current Principal Investigator is taking a temporary leave or will remain on the study as a co-investigator, include their name in Box 1.3 of the ethics application so they will continue to have access to the application.

If recruitment of research participants is ongoing, you must revise and attach recruitment and consent documents on Page 9 of the ethics application.

In order to change the Principal Investigator on the study:

- Select “yes” in Box 1.5 of the PAA coversheet
- The current Principal Investigator and the new Principal Investigator must sign the [Change to PI form](#), as well as the Department/School Head. Note that as the Department/School Head is authorizing the change, they cannot be the same individual as either the current or new PI
- Attach the form in Box 1.5 of the PAA coversheet
- Address any other required changes (e.g., to Box 1.3 or Page 9 of the ethics application)
- The REB administrator will update the PI on the study when the PAA is approved

Change Co-Investigators and Other Study Team Personnel

Study team personnel other than the PI can be added to Box 1.3, 1.4, or 1.5 of the ethics application, depending on the role they have in the study and whether or not they have a RISE account. Each of these boxes has 2 sections: A allows for the individual to be added to the application, and B is a space for a description of the individual’s role in the study. When adding an individual to any of these boxes,

please be sure to complete both A and B for the appropriate box. All personnel added to the study team are expected to have completed the [TCPS 2 CORE](#).

- Box 1.3 Co-Investigators (Co-Is): Individuals must have a [RISe account](#) to be listed in Box 1.3A. Individuals indicated here will have online access to the application and will be listed on the certificate of approval for UBC BREB studies. These individuals should be listed as co-investigators on all in-use consent forms and other documents indicating the study team.
- Box 1.4 Additional Study Team Members - Online Access: Individuals must have a [RISe account](#) to be listed in Box 1.4A. Individuals indicated here will have online access to the application, but will not be listed on the certificate of approval.
- Box 1.5 Additional Study Team Members - No Online Access: Individuals do not need to have a RISe account to be listed in Box 1.5A. Individuals indicated here will not have online access to the application, so will be unable to read or change the file. They also will not be listed on the certificate of approval.

When updating study team personnel, review Page 8 for information describing access to data and transfer of data, and amend as needed to reflect the updated study team.

Who will get notifications from RISe?

Box 1.2 allows for inclusion of a Primary Contact. Only one individual can be listed in this box, and they must have a [RISe account](#). They and the PI will receive all correspondence and notifications from the REB related to this study. They also have online access to the application. If this individual is considered to be a member of the study team, they also need to be added in Box 1.3, 1.4, or 1.5.

Where do you list Graduate students?

If the research will contribute to a graduate degree, the graduate student should be listed as a Co-Investigator (in Box 1.3) and should be indicated as the Primary Contact (in Box 1.2).

Changing or Adding Funding

If a researcher answers “yes” in their grant application (or RPIF) to the question, “Will Human Subjects be used in this project?” the [Office of Research Services \(ORS\)](#) will require confirmation of ethics approval before funds can be released. When adding funding to an application, keep in mind the following:

- All funding sponsors for a study must be listed on all active consent forms for that study (e.g., “This study is funded by the Canadian Institutes of Health Research (CIHR)”). If consent forms are no longer in use, they do not need to be updated; please indicate this in the PAA coversheet when adding new funding.
- An exact match between the grant/award title and the ethics application title indicated in Box 1.7 is not required. You may list multiple grants from multiple sponsors in one ethics application. A single grant may also be referenced in multiple ethics applications.
 - If the grant title seems to indicate a significantly different topic from what is outlined in the ethics application, a copy of the grant application may be requested in Box 9.1 to ensure funds are being used as intended.
- Update Box 2.2.A if needed to reflect the types of funding received for this research.

- Funding processed by UBC ORS is available to select via the FAS number in Box 2.3.A if the PI of the ethics application is listed as either the PI or an internal Co-I on the FAS record. Contact [ORS](#) if you would like to update the internal Co-Is on the FAS record. Selecting the appropriate funding in this box will allow it to be linked in the system and appear correctly on the approval certificate.
- If funding is not available in Box 2.3.A, look for the funding sponsor in Box 2.4.A, and input the name of the grant/award if it is different from the ethics application title. If the sponsor is not listed, it can be added to RISE by emailing risupport@ors.ubc.ca with the Full Official Sponsor Name, Address, and Site URL.
- As with other areas of the application, do not remove grants that were used for the study, even if the grant has since run out or been terminated. If a grant was added but never awarded to the researchers or never used for this ethics application, it can be removed from the application.

Notes for Truncated Applications

If your study is a Survey Only (Page K) study, you cannot add components such as interviews or focus groups to this application. This form was created to facilitate ethical review of surveys and as such only asks questions relevant to survey studies. Similarly, a Secondary Use of Data Only (Page L) study only asks questions relevant to secondary use of data studies and does not allow adding prospective data collection. If you are looking to add other components to your study, a new ethics application will be required for the other components. You can link back to the existing application in Box 4.3 of the new application to show that they are related.

Full Board versus 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.

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). The TCPS 2 defines minimal risk as, "research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research." It is expected that the majority of research submitted to the BREB will fall into the minimal risk category. However, the BREB retains the right to put any amendment forward for full board review. In such cases, the applicant will be notified of the change in status.

IV. STUDY COMPLETION

Ethics applications should not be left to expire at the end of the research project and must be closed using the Completion of Behavioural Study PAA.

If participant recruitment and data collection have permanently stopped and you do not anticipate needing to go back to your participant population to confirm data, an active ethics application is no longer required and the file can be closed. Research ethics is not required during the analysis stage, provided the analysis is in line with the approved application.

Subject to special considerations for US-funded research (<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html#section-k>) and Secondary Use of Data studies, annual renewal is no longer required as long as the researcher/research team will have no further contact with participants for the purpose of data collection or research (e.g., for data verification). Renewal is not required to analyze data or write up results. Closing a study will not affect your access to your funding.

[Click here](#) for RISE instructions on how to submit a Completion of Behavioural Study PAA.

V. REQUEST FOR ACKNOWLEDGEMENT

Use a Request for Acknowledgement PAA to notify the BREB of an unanticipated event (e.g., the theft or loss of a laptop containing confidential information about participants) or protocol deviation (i.e., when conducted research unexpectedly veers from the approved protocol in a significant way). Any other changes to the study procedures or documents (e.g., recruitment, consent, data collection, or agency approval) must be submitted through an Amendment. [Click here](#) for RISE instructions on how to submit a Request for Acknowledgement.

VI. TURNAROUND TIME

The turnaround time for PAAs 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 to two weeks.

You can see the status of the PAA in the upper left corner of the PAA page under “Current State.”

The screenshot shows the PAA system interface for the University of British Columbia. The top navigation bar includes 'Dashboard' and 'Help'. The breadcrumb trail indicates the user is viewing a 'Demo Renewal' page. On the left sidebar, the 'Current State' is highlighted with a red box and shows 'REBA Screening'. Below this, there are sections for 'Activities' (Inactivate PAA, PI and Staff Comments) and 'Viewing/Printing' (Application - Full). The main content area displays details for PAA (H23-00004-A001) Demo Renewal, including Principal Investigator (Apple, Prinz), Primary Contact (Epple, Prince), Approval Department, Meeting Type, Activity Type (Annual Renewal), Study State (Expired), Study Expiry Date (2023-03-08), and Type of Funding (No Funding).

- **Pre Submission:** The PI and Study Team have not yet been submitted the PAA
- **REBA Screening:** The PAA is in the REB in-box and is being processed by a staff member (REBA)
- **Assigned for Expedited Review:** The application has been assigned to a REB member for expedited/delegated review
- **Changes Required by REBA/Changes Required by REBCC:** The REB has processed the PAA and sent it back to the researcher requesting clarifications or changes
- **Assigned for Full Review:** The application has been scheduled for review at the next Full Board meeting

VII. WHERE TO GET HELP

Contact details for UBC-Affiliated REBs can be accessed from the Home tab of the [Research Ethics website](#).

For RISE application technical support, e-mail risesupport@ors.ubc.ca or call 604 878 7473.