



Creating a Follow On Submission in RAS A Companion Guide

Follow on submissions include changes to study personnel, amendments (changes) to approved protocols, annual renewals, protocol closures, and reporting unanticipated issues and events (REB event).

TCPS2 (Art. 2.8) states that ethics review must continue throughout the study to ensure that all stages are ethically acceptable. This guide provides clarifications and helpful tips to ensure compliance with the requirements of continuing research ethics review within the RAS system. Not all questions in the Research Administration System (RAS) system are included as not all questions require further clarification. Please refer to this information as you craft your responses. The text in **black** is the question you will respond to. The direction in **green** clarifies what the Research Ethics Board (REB) is asking for. The direction in **blue** provides information relating to changing additional protocol material. Text in **red** denotes things you should not do.

NOTE: As you move through the tabs, you will see a number of “Yes” or “No” questions. Your responses may open additional tabs or text boxes which require your attention. If you change your answer to the “Yes” or “No” questions, these tabs or text boxes may disappear. Any responses you entered will not be saved.

TIP: Changes made to the approved protocol may require edits to multiple sections of/attachments to the protocol. You must make all appropriate changes before submitting your request.

As the system’s text boxes do not allow for formatting, we recommend using spacing and capital letters to create headings.

Contents

Contents.....	1
PERSONNEL CHANGE.....	2
AMENDMENT.....	2
MIGRATED AMENDMENT/PERSONNEL CHANGE	3
Personnel Change:	3
Amendment:.....	3
RENEWAL.....	4
PROTOCOL CLOSURE.....	5
REB EVENT.....	5

PERSONNEL CHANGE

Personnel Changes Summary

Research Personnel

Attachments

NOTE: Do not use the Personnel Change function if the PI is changing. You must submit an "Amendment" instead.

- Please provide a brief summary of the requested changes
 - Briefly describe the personnel changes you are making and provide the reasons for these changes.
- Does this change affect documents participants will see (ie. recruitment poster, consent form)?
 - If 'Yes', attach new versions of the documents in the attachments tab (e.g., consent forms, recruitment material, debriefing forms, interview questions). The only changes to these documents should be the addition/removal of personnel. Any other changes should be made through an amendment.

AMENDMENT

Amendment Summary

Summary

Research Personnel

Attachments

- Please provide a brief summary of the requested changes.
 - Using lay language, outline all the changes you plan to make to your study.
- Please provide a justification for these changes.
 - Provide the rationale for the changes you outline in the previous question.
- Will there be changes to the number of participants?
 - If 'Yes', a new box will appear. Outline what the change will be and provide a rationale for the change in the number of participants.
 - Ensure that these changes are also made under the 'Participants' Tab.
- Will there be any changes in recruitment?
 - If 'Yes', a new box will appear. Outline the changes and provide a rationale for changing the original recruitment strategy.
 - Ensure that these changes are also made under the 'Recruitment' Tab.
- Will there be changes in recruitment material?
 - If 'Yes', a new box will appear. Outline the changes and provide a rationale for changing the recruitment material.
- Will there be any changes to the consent form?
 - If 'Yes', a new box will appear. Outline what the changes will be and provide a rationale for the changes to the consent form.
 - Ensure that these changes are also made under the 'Consent' Tab.
- Will participants need to be re-consented?

- If 'Yes', a new box will appear. Outline how you will re-consent participants. Provide information on how you will contact participants to inform them of changes or obtain new consent.

NOTE: Page 25 of the [RAS training document](#) explains how to properly upload marked-up versions of your attachments.

MIGRATED AMENDMENT/PERSONNEL CHANGE

Amendment / Personnel Changes Summary	Research Personnel	Attachments
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Information under this section is **only for protocols that were approved before the launch of RAS in June 2020**. These protocols will have an HS designation and an identifier that starts with P, J, E, R1 or R2.

NOTE: If you are changing your protocol and personnel, click the 'Amendment' option.

NOTE: If you have manual attachments that you are updating or replacing, you must replace the previous versions with new ones. **Do not upload new versions as new attachments.**

Personnel Change:

- Please provide a brief summary of the requested changes
 - Briefly describe the personnel changes you are making and provide the reasons for these changes.
- Does this change affect documents participants will see (ie. recruitment poster, consent form)?
 - If 'Yes', attach new versions of the documents in the attachments tab. The only changes to these documents should be the addition/removal of personnel. Any other changes should be made through an amendment.

Amendment:

NOTE: Use bold or italics for any changes in your responses. Ensure that you are attaching the revised version in the 'Attachments' tab. **Make sure you are attaching any new/updated documents (e.g., recruitment material, consent forms, interview questions).** If you are changing your protocol and changing personnel, use the 'Amendment' option.

- Please provide a brief summary of the requested changes.
 - Using lay language, outline all the changes you plan to make to your study.
- Please provide a justification for these changes.
 - Provide the rationale for the changes you outline in the previous question.
- Will there be changes to the number of participants?
 - If 'Yes', a new box will appear. Outline what the change will be and provide a rationale for the change in the number of participants.
- Will there be any changes in recruitment?
 - If 'Yes', a new box will appear. Outline what the changes will be and provide a rationale for changing the original recruitment strategy.
- Will there be changes in recruitment material?

- If 'Yes', a new box will appear. Outline the changes and provide a rationale for changing the recruitment material.
- Will there be any changes to the consent form?
 - If 'Yes', a new box will appear. Outline what the changes will be and provide a rationale for the changes to the consent form.
- Will participants need to be re-consented?
 - If 'Yes', a new box will appear. Outline how you will re-consent participants. Provide information on how you will contact participants to inform them of changes or obtain new consent.

RENEWAL

NOTE: As per Article 6.14 of the TCPS 2, protocols are approved for one year only. The protocol expiry date can be found on the Protocol Approval letter. Any protocols that will continue beyond that date must be renewed. It is the responsibility of the researcher to ensure that they do not continue the study without an active ethics protocol.

Undertaking research with human participants without an active approval is a breach of the TCPS2, the University's Ethics of Research Involving Human's Policy, and the University's Responsible Conduct of Research Policy.

To initiate a renewal, a Renewal Request must be submitted in RAS. We recommend submitting the request within the final month of the protocol date's expiry. Once approved, a Renewal Approval letter will be issued. A researcher cannot continue their research activities until the Renewal Approval letter has been received.

NOTE: New or revised documents should not be uploaded during the renewal review.

- Have there been changes to the protocol design that have not been approved by the REB?
 - If 'Yes', a new question will appear asking if an amendment has already been submitted. If the answer is 'No', you must also submit an amendment with your requested changes. **Do NOT include information on your protocol changes in the renewal request.**
- Provide a brief summary of the progress of the study.
 - Describe what research activities have taken place so far and what activities are still ongoing or need to be completed.
- Provide a brief justification for the renewal request.
 - In one or two sentences, describe why you need a renewal. **Do NOT include personal health information about yourself or team members.**

PROTOCOL CLOSURE

Protocol Closure

Attachments

NOTE: When a study has concluded or when it has been terminated for any reason, PIs must submit a protocol closure form to the REB to indicate that continuing ethics review is no longer required. For more information on when to close a study, visit our [website](#).

- Is communication with participants complete (ex. recruitment, data collection, summary of findings, member checking)?
 - If 'No', please withdraw and submit a renewal request. Continuing ethics review is required when communication with participants is ongoing.
- Please provide a brief summary of the outcome of the study and progress in meeting the study objectives.
 - Describe your progress in the study and specify whether and how the study objectives have been met. Indicate whether and how study findings/results have been disseminated. If the study was terminated, provide specific details on why the study was terminated.
- Were there any problems encountered in this study?
 - Answer 'No' if there were no problems encountered, no protocol deviations, and/or no adverse events.
 - Answer 'Yes' if there were any unanticipated problems, protocol deviations, and/or adverse events.
 - If 'Yes', a new box will open below. Describe in detail the unanticipated problem, deviation and/or adverse event, explain how you approached it, and discuss the outcomes.
- Were these previously reported to the REB?
 - If 'No', a new box will open below. Explain why the problems, protocol deviations, and/or adverse events were not reported to the REB.

REB EVENT

REB Event

Attachments

- Description of Event
 - Describe in detail what occurred. Provide all relevant information, including dates, times, and names of research team personnel. **Do NOT include the names of participants.**
- What actions will be taken to rectify this event?
 - Outline any changes or actions to your study you plan to implement. These should be reviewed and approved by the REB unless there is a need to immediately address any risk of harm to participants. **Do NOT implement any actions listed until the REB has acknowledged/approved them.**

- Have you notified any other offices of this event (i.e.. Privacy and Access Office)?
 - In the box below, outline the office you have contacted. If you haven't contacted any offices, state your rationale.
- Does the protocol require changes to prevent this event from occurring again?
 - 'If Yes', a new box will appear. Outline briefly what you propose change and indicate that once the REB event is acknowledged, you will submit an Amendment with the proposed or REB-prescribed changes.