



Creating a Follow On Submission in RAS A Companion Guide: Amendments

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 |
| AMENDMENT | 1 |
| MIGRATED AMENDMENT | 2 |
| Migrated Protocol Amendment:..... | 2 |

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

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|---------------------------------------|--------------------|-------------|
| 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.**

Migrated Protocol 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.