

FAQ Amendment

Frequently Asked Questions: Amendment Submission Form

NOTE: For the first action you do with an existing protocol (either CR or amendment), you will need to **FIRST** “create a revision” to your study application. **THEN** create the new submission form for your action. Otherwise the CR or amendment form will not carry forward the information correctly.

- [I have removed a non-NIH collaborator on the amendment form, but it does not show up that I have deleted that person.](#)
- [I am changing the eligibility criterion in the amendment to remove a histology that was previously eligible. How do I answer the question 4.2 “changes in study population”?](#)
- [What do I include in my summary of changes to the IRB for an investigator initiated protocol?](#)

I have removed a non-NIH collaborator on the amendment form, but it does not show up that I have deleted that person.

When you delete a non-NIH collaborator in an amendment there is no way for iRIS to show that person has been deleted. Just be sure to include information in your cover memo about the person being removed.

I am changing the eligibility criterion in the amendment to remove a histology that was previously eligible. How do I answer the question 4.2 “changes in study population”?

Unless you are changing a population of subjects listed with your amendment, you should answer that question as “no.” You would say yes to that question, for example, if you were removing children as a population eligible for this protocol or now adding normal volunteers. Just changing the criterion for a same group of subjects (e.g. adult patients) would not be a change in the population in terms of risk/benefit.

What do I include in my summary of changes to the IRB for an investigator initiated protocol?

- First and foremost, please provide an introductory paragraph that summarizes the purpose of the amendment. If the amendment includes significant changes such as increasing the accrual ceiling, adding a new cohort, moving from phase 1 to phase 2, etc., provide a comprehensive rationale that includes the results of the study to date and why you wish to make this change now.
- With each change, unless administrative, please include a reason /rationale for that change.
- When you itemize each change, you do not need to put both “changed from....” and “changed to”. Instead, be sure you put the section number of each change and a sentence describing the change. This is needed so that the IRB staff and reviewers know where to look in the tracked and clean protocol.
- If you are making a change to a sentence within a paragraph, please do not copy and paste the whole paragraph into your memo. You can say a description of where the change is (e.g., in the 3rd sentence of paragraph 2, the following sentence was modified to state....)
- You can summarize administrative changes such as “the version date and amendment letter have been updated”; there is no need to make these separate line items or be specific about the details.
- If you make typographical/editorial and formatting changes, please just include a sentence that says that—you do not need to delineate where each of those types of changes are in the protocol. (Please note that typographical/editorial corrections are limited to correcting spelling mistakes or correcting grammatical errors; changing the meaning of a phrase or sentence is not an editorial change.)

These guidelines apply to protocols that are written by NCI investigators. If it is a protocol by an outside sponsor, it is still fine to submit the Summary of Changes (SOC) that the sponsor provides.

[FAQs for Routing in iRIS](#)

[FAQs for Study Application](#)

[FAQs for Continuing Review Submission Form](#)

[FAQs for Planned and Cumulative Enrollment Forms](#)

[FAQs for Study Closure Form](#)

These pages will continue to be updated as more information becomes available.

Note: If you have a submission procedure question that isn’t answered within these pages, please contact: nciprotocolsupportoffice@mail.nih.gov