

## 2 - Amendment Application Smartform

### Amendment Smartform FAQ

#### FAQ: Questions

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#### FAQ: Answers

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**Q1: How do I handle amendments prior to converting my study to webIRB?**

- A. While the study is on paper, submit any amendments using the paper applications posted under [Forms](#) on the OHRPP website.

**Q2: How do I handle amendments for studies submitted and approved using webIRB?**

- A. Locate the study under the **My IRB Studies** tab (from your webIRB home page) and link to the study workspace by clicking on the study title (in blue). Then, click on the “New Amendment” button in the lower left-hand corner of the workspace. The amendment application smartform will open.

**Q3: How do I track changes to the study application smartform?**

- A. webIRB automatically tracks any changes you make to the study application smartform after the study has been approved by the IRB. Click on “View Changes” in the upper left-hand corner of the amendment workspace to see a listing of the modifications made to the application smartform as part of the amendment.

**Q4: Do I include both clean and marked copies of revised study materials with my amendment?**

- A. Yes. Attach both clean and marked/highlighted copies of revised study materials (consent forms, recruitment flyers, and so on) to the study application smartform.

**Q5: How many amendment applications (for the same study) can I have under review at a time?**

- A. Due to the constraints of the webIRB system, it's advisable to have only one amendment application under review at a time. If, however, you need to submit a second amendment, here are some things to know:
  1. When an amendment is submitted, the sections of the application that are being modified are locked to additional changes until the amendment is reviewed and approved. For example, if you submit an amendment that has modifications to the inclusion criteria and study summary sections, these sections will be locked by the system and no further changes will be possible until you receive your approval letter.
  2. Instead of submitting separate amendment applications for each change, try to group the changes together as much as possible on one amendment application.

Please plan your amendment applications so that you do not have more than two undergoing reviews at a time. If you run into a bind, you can call the IRB Office for assistance.

**Q6: If I withdraw an amendment, can it be reactivated?**

- A. No. If you withdraw an amendment it cannot be reactivated. Use the **Withdraw** activity only if you wish an amendment to be archived (no further actions will be permitted).