How to Create and Submit a Modification (Amendment)

Please Note: Many of the IRB Forms have transitioned into our UVMClick online smartforms. The Amendment form has been retired and transitioned into an online smartform.

How to prepare for this submission:
Make readily available:
- Protocol (with tracked changes)
- Consent form (with tracked changes)
- Drug or Device Brochure (if applicable)
- Data Safety and Monitoring Reports not affecting risk (if applicable)

Create a Modification (Amendment)

1. Navigate to the appropriate protocol and click on the name to open it. For details on this process see the user guide called “Searching for a Protocol or Submission”.

2. Click Create Modification/CR.

3. Select The Modification radio button and hit Continue.

4. Check the option “Other Parts of the Study”. This includes making a change to any part of an approved study (except study team members) or a change in PI

   Note: You can only have one of these types of modifications active at one time.
5. Click Continue (way over on the right side of the screen)

6. Complete all questions. Required questions will be prefixed with a red asterisk.

   **Note:** When filling in the question “Summarize the Modifications” this text will appear on the future approval letter. Please make sure to type the text carefully.

7. Click Continue (way over on the right side of the screen)

8. Make any and all changes directly to the Study screens that you noted in the “Summarize the Modifications” text box. **Continue** to move through the pages and **Finish** on the last page.

---

**TIP:** If you want to VERSION any previously uploaded document, click the UPDATE button, not the add button.

Examples:

**11.** Attach the protocol:
(e.g. industry protocol, human subjects protocol, exempt form, or not human subjects form consent form and recruitment materials will be uploaded in a separate section)

![Example of document versioning](image)

---

**Local Site Documents**

**1. Consent forms:** (include an HHS-approved sample consent document, if applicable)

![Example of document versioning](image)
Submit the Modification to the IRB Office for Processing

After exiting the online smartform by clicking Finish, the status of the submission will still display as “Pre-Submission” and will remain visible in your in-box until submitted to the IRB Office for processing.

**REMEMBER:** Click the activity on the left that says “Submit”. If you do not see an activity called “Submit” that means that you are not designated as the PI or the Proxy.

**Submission Rules:**

- Only the PI and any assigned Proxies have the authority to submit requests to the IRB office. And therefore, they are the only ones who will have the “Submit” activity.
- Only the PI is able to assign a new Proxy. See the user guide called “How to Assign A Proxy” on the UVMClick-IRB website.
- A Proxy must be a member of the study team membership list and have completed the required HS training.

Click the Submit activity

After clicking the Submit activity, certification text will appear. Read the text and click OK.

If there are any required fields that you forgot to enter, the Submit process will display them.

You can use the pop-up to Jump To those particular screens quickly and enter the missing data.
NOTE: These Errors/Warning Messages only appear if required field entry was missing.

When clicking the Submit activity, once all required field entry is complete, certification text will appear. Read the text and click OK.

Once submitted, the status of the Modification is no longer “Pre-Submission”. It has changes to “Pre-Review” indicating it is in the hands of the IRB Office for processing.

You will also note that the Modification is now in View Mode and no longer in Edit mode.

The Modification has now been submitted and removed from your “My Inbox.” It now displays in the IRB Office “My Inbox.”