Submit a Clean-Up Modification
For all active protocols that have been converted to UVMClick

To enable future submissions on a current APPROVED protocol that has been converted you must first create and submit what is referred to as a “Clean-Up Modification” before being able to submit any other requests on your protocol. This is a process to sync up UVMClick with what exists in the InfoEd system. NO NEW changes can be submitted for review at this time. The Research Administrators will use this “Clean-up” submission to make sure it matches what has already been previously approved.

This is a Modification request that requires you to open the applicable UVMClick protocol and complete required fields (indicated by a red asterisk) in the new Smartform. The Smartform is otherwise known as a short-version of the “Common Protocol Cover Form (CPCF)” and replaces the old CPCF.

NOTE: Not all old CPCF information was stored in the previous database which is why the information will need to be added to the new Smartform.

How to prepare for this submission:
Make readily available:
  • Approved Common Protocol Cover Form (for reference),
  • Approved Waiver Request (for reference),
  • Approved and Stamped Informed Consent Form (to be uploaded into UVMClick)
  • Approved protocol (to be uploaded into UVMClick)

Create a “Clean-Up” Modification

1. Navigate to the appropriate converted active 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 on the upper left of view.

3. Select The Modification radio button and hit Continue.
4. Check the option “Other Parts of the Study”.

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

6. Complete the two questions prefixed with a red asterisk.

   • *Question: “Summarize the Modifications”
     - When filling in the question “Summarize the Modifications” please note that
       This is a “Clean-up” Modification.
       **NO NEW information can be submitted for review at this time.**
   • *Question “Will this modification change or add the use of any ... etc.”
     - Answer “No”

7. Click Continue (way over on the right side of the screen)
   The online smartform will display starting with the Basic Information view.

8. Click on the “Hide/Show Errors” option.
   This will list mandatory fields (Field Name) that need to be completed and the view (Jump To) on which they live.
   You can click on any view under “jump to”.

9. A required field on the Basic Information view is the very last question. This is where you must upload your most recently approved protocol document. Please upload word versions if possible.
10.

11. Scroll through each “Jump-To” view and complete all fields noted with a red asterisk (*) that are blank. Click “Save” on each view once required field entry is completed.

12. All uploads, other than the protocol document, must be uploaded on the Local Site Document view. For example: Your last approved consent form(s), recruitment material and information sheets.

13. Once all fields have been entered and views have been saved, click Exit.
Summit the “Clean-Up” Modification to the IRB Office for Processing

After exiting the online smartform, the status of the submission will 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 there are any required fields that you missed, the Submit process will display them. You can use the pop-up to Jump To those particular screens to enter the missing data.

**NOTE:** Errors/Warning Messages only appear if required (*) field entry is missing. After clicking the Submit activity, certification text will appear. Read the text and click OK.

Once submitted, the status of the Modification is no longer in a “Pre-Submission” state. The request changes to “Pre-Review” indicating it has been submitted for review by IRB.
This Modification submission is now in View Mode. No longer in Edit mode.

The “Clean-up” Modification has now been submitted and removed from your In-Box. It now displays in the In-Box for the IRB Office to process.