

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.**



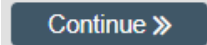
3. Select The Modification radio button and hit Continue.

Modification / Continuing Review / Study Closure


*** What is the purpose of this submission?**

Continuing Review

Modification ←




4. Check the option "Other Parts of the Study".

 To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

Study team member information

Other parts of the study 

Continue >

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

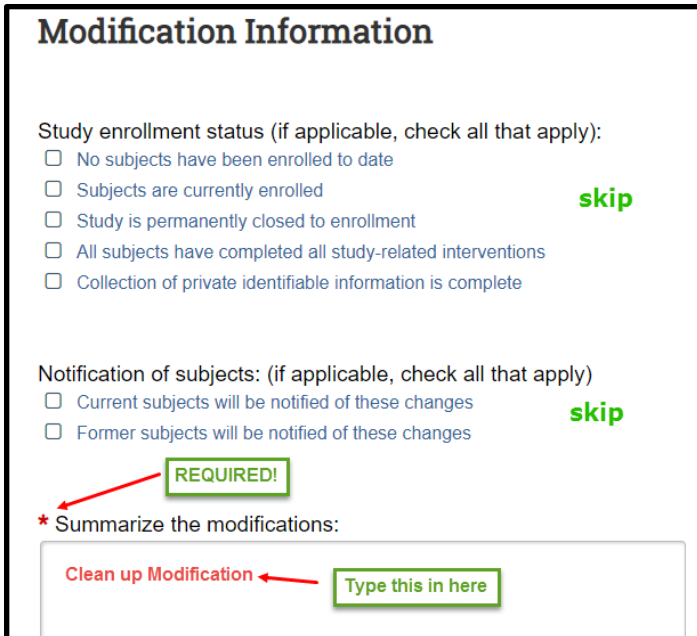
This will take you to the "Modification Information" screen.

NOTE: All questions with a red asterisk are required questions and the **ONLY** questions you should be filling in for this "Clean up Modification"

6. On the Modification Information screen you will need to fill in four required fields

- *Question: "Summarize the Modifications"

- When filling in the question "Summarize the Modifications" please specifically type in "Clean-up Modification".



Scroll to the bottom of the screen

For the Clean up Modification only... We are asking that you answer "No" to these three questions:

- *Question "Will this modification change or add the use of any ... etc."
 - Answer "No"
- *Question "Is this protocol utilizing Clinical Research Center resources?"
 - Answer "No"
- *Question "Is this protocol under the UVM Cancer Center's purview?"
 - Answer "No"

* Will this modification change or add the use of any UVM Medical Center standard of care or protocol-driven, such as laboratory, previously approved billing plan?

Yes No [Clear](#)

If the answer to any part of the above question is Yes, the UVM Medical Center Denise Quint in the UVM Medical Center Integrity and Compliance department

* Is this protocol utilizing Clinical Research Center resources?

Yes No [Clear](#)

* Is this protocol under the UVM Cancer Center's purview?

Yes No [Clear](#)

Continue >>

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

The online smartform will display starting with the **Basic Information** view.

8. On the Basic Information view there are two required fields to fill in.

- *Question “**Brief Description**”

Please enter whatever you provided in the Lay summary originally. This can be copied from InfoEd or the original Common Protocol Cover Form and pasted here if you so choose.

- *Question “**Attach the Protocol**” (found as the last question on this view)

This is where you must upload your most recently approved protocol document and **ONLY** the protocol document. No other document is to be uploaded here. Please upload word versions if possible. The name should be “Protocol Document version *date approved*”

11. * Attach the protocol:
(e.g. industry protocol, human subject consent form and recruitment materials)

+ Add [Click here](#)

Document Category
There are no items to display

[IRB Forms Website](#)

<< Back

Add Attachment

1. * File to attach:

Protocol Document.doc Choose File

2. Name: (if not supplied, the file name will be shown) ?

Protocol Document version xx-xx-xx

3. Version number:

* Required

OK

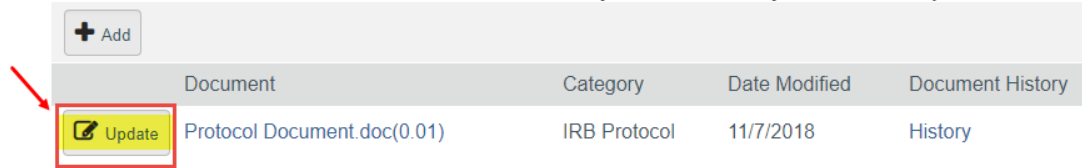
Continue >>

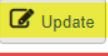
9. Click Continue (way over on the right side of the screen)

The online smartform will display the **Funding Sources** view.

TIP #1: If you want to VERSION an uploaded document, click the UPDATE button, not the add button.

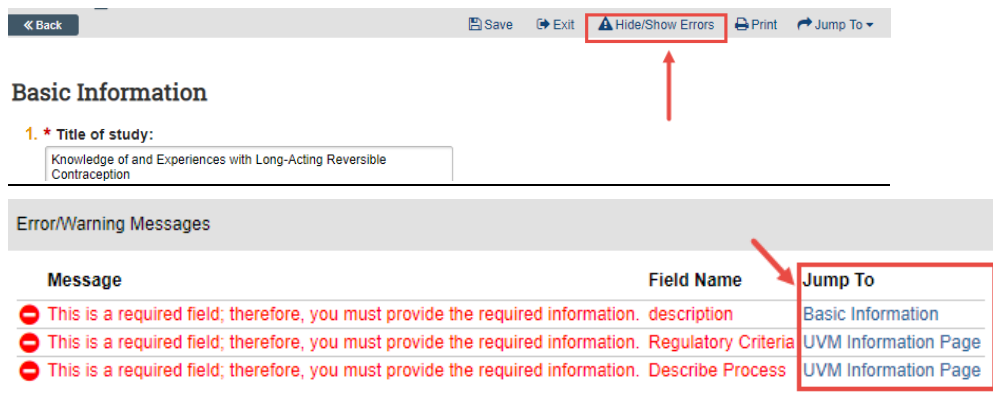
11. * **Attach the protocol:**
(e.g. industry protocol, human subjects protocol, exempt form, or not human subjects form consent form and recruitment materials will be uploaded in a separate section) ?



Document	Category	Date Modified	Document History
 Protocol Document.doc(0.01)	IRB Protocol	11/7/2018	History

TIP #2: Click on the “Hide/Show Errors” option at any time, on any screen.

This will list all mandatory fields that have not yet been completed and the view (Jump To) on which they live. You can click on any view under “jump to” to go to that screen.



Basic Information

1. * Title of study:
Knowledge of and Experiences with Long-Acting Reversible Contraception

Error/Warning Messages

Message	Field Name	Jump To
⊖ This is a required field; therefore, you must provide the required information. description		Basic Information
⊖ This is a required field; therefore, you must provide the required information. Regulatory Criteria		UVM Information Page
⊖ This is a required field; therefore, you must provide the required information. Describe Process		UVM Information Page

10. On the Funding Sources view there is one required question.

- *Question “Is it internal, federal/state or industry funded?”

Select the appropriate radio button. You may find a hint via the listed funding source under question #2.

Funding Sources

1. * Is it internal, federal/state or industry funded? (if you choose "Internal" then you must)

Federal/State
 Industry
 Internal
 Other
[Clear](#)

2. * Funding Sources:

Funding Source	Funding Source Category	Sponsor's
 Biotronik, Inc.	Industry	

If you select “Industry” or “Other”, additional fields will display and one more mandatory field will need to be selected.

*** Which organization will process your funding?**

- Office of Clinical Trials
- Sponsored Projects Administration

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

Continue >>

The online smartform will display the **Study Scope** view.

! **TIP #3:** You can go back and forth through the views via the “Jump-To” if you so choose.

Save Exit Hide/Show Errors Print Jump To

12. On the Study Scope view there are a few questions that are mandatory and need to be filled in. Please answer the missing values as applicable that will match what had been submitted to InfoEd.
(See Tip #1 on the previous page)

Remember: No other changes should be made other than filling in the missing mandatory fields!

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

Continue >>

The online smartform will display the **Research Locations** view.

There should be nothing to do here – simply click Continue

Continue >>

to move to the next view.

IMPORTANT NOTE: The next view is dependent upon previous selections. If drugs, devices, or waivers apply, there will be views for those and they will have their own mandatory fields that will need to be filled in.

Continue through all views filling in all mandatory fields and clicking

Continue >>

to move forward.

! **TIP #4:** When you click the Continue button, it also saves your choices. Additionally, there is a SAVE hyperlink at the top and bottom of every view. You can start a Clean up Modification, save your choices, exit and come back later to finish. You do not have to complete the Clean up Modification all at once (although it is a fairly short and quick process)

Save Exit Hide/Show Errors Print Jump To

14. On the **Local Site Documents** view you will include all the remaining uploads. These should be the **most current** versions of the consent form, **most current** versions of recruitment materials and **most current** versions all remaining supporting documents that may be changed in the future.

If you uploaded a document previously into InfoEd that will never be changed/amended, you do not need to upload it to UVMClick. If you have any questions about what should be uploaded and what shouldn't, please contact your assigned Research Administrator.

Local Site Documents

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

<input type="button" value="+ Add"/>	← Please upload the current STAMPED consent form		
Document	Category	Date Modified	Document History
There are no items to display			

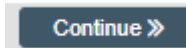
2. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads) ?

<input type="button" value="+ Add"/>	←		
Document	Category	Date Modified	Document History
There are no items to display			

3. **Other attachments:**

<input type="button" value="+ Add"/>	←		
Document	Category	Date Modified	Document History
There are no items to display			

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



The online smartform will display the **Final Page** view.

Once you reach the **Final Page** view

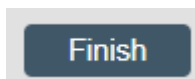
Final Page

You have reached the end of the IRB submission form. Read the next steps carefully:

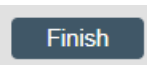
1. **Important! To send the submission for review, click Submit on the next page.**

2. **Click Finish to exit the form.**

16. Simply click



Submit the “Clean-Up” Modification to the IRB Office for Processing

After exiting the online smartform by clicking  , 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.

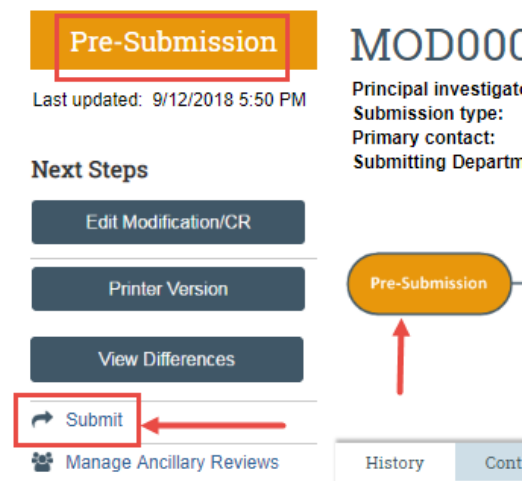
REMEMBER: Click the activity on the left that says “**Submit**”. If you do not see an activity called “Submit” that means that you are not designated as the PI or the Proxy.

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**.



Pre-Submission

Last updated: 9/12/2018 5:50 PM

MOD000

Principal investigator:
Submission type:
Primary contact:
Submitting Department:

Next Steps

Edit Modification/CR

Printer Version

View Differences

Submit

Manage Ancillary Reviews

History Cont

Submit

PRINCIPAL INVESTIGATOR

As Principal Investigator, I assure the Committees on Human Research that the information that is provided is accurate and that I will follow all Human Subjects in Research regulatory regulations as outlined in the University of Vermont IRB Policies and Procedures document.

PRINCIPAL INVESTIGATOR PROXY

- As the proxy assigned by the PI to submit materials for this study, I assure the Research Protections Office that the information that I have provided is accurate.



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. It is no longer in Edit mode.

Pre-Review

Entered IRB: 9/13/2018 9:10 AM
Last updated: 9/13/2018 9:10 AM

Next Steps

- View Modification/CR
- Printer Version
- View Differences

MOD00000055: Mod

Principal investigator: Christopher Morris
Submission type: Modification
Primary contact: Christopher Morris
Submitting Department: Radiology

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graph LR; A[Pre-Submission] --> B[Pre-Review]; B --> C[Clarification Requested]; C --> B;
```

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.

Final Note:

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.

Message	Field Name	Jump To
This is a required field; therefore, you must provide the required information. Change Equip Fac Supplies Personnel		Modification Summary

This is a hyperlink taking you directly to the page with the missing required value

NOTE: Errors/Warning Messages only appear if required (*) field entry is missing.