UVMClick Website	**https://www.uvm.edu/ovpr/uvmclick**	**Email Support**	**UVMClick@uvm.edu**
UVMClick Login	**https://irb.connect.uvm.edu/IRB**	**Phone Support**	**(802) 656-5040**

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:

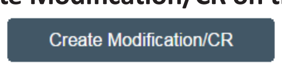
Make readily available:

- 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)

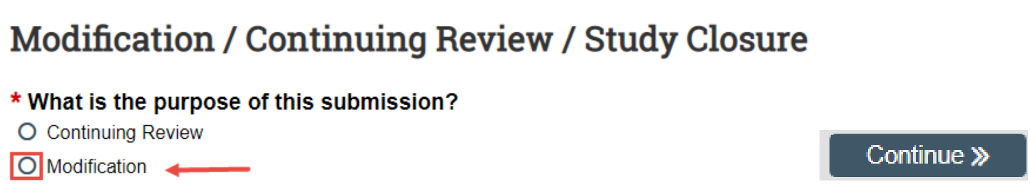
Create a “Clean-Up” Modification

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”.

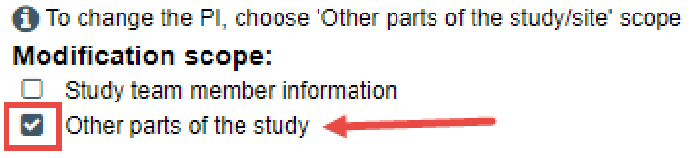
2. Click **Create Modification/CR on the upper left of view**.



3. Select The Modification radio button and hit Continue.



4. Check the option “Other Parts of the Study”.



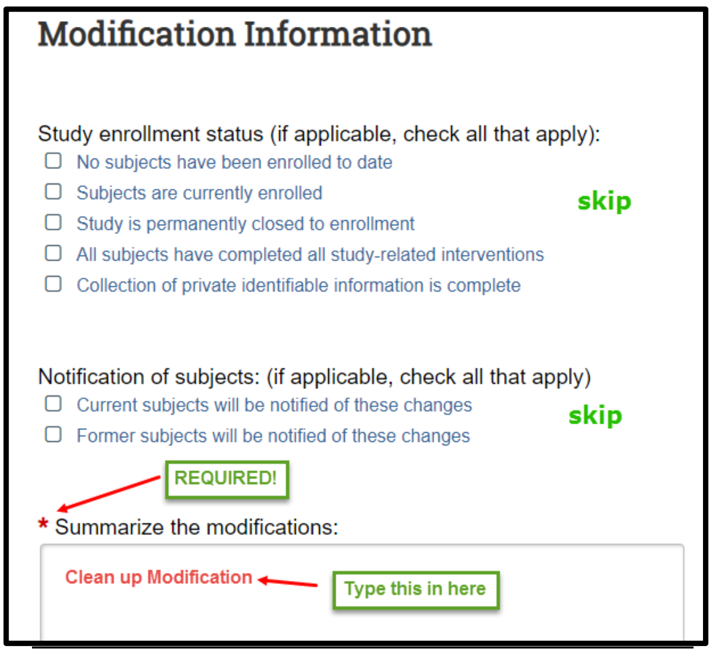
5. Click Continue (way over on the right side of the screen) 

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

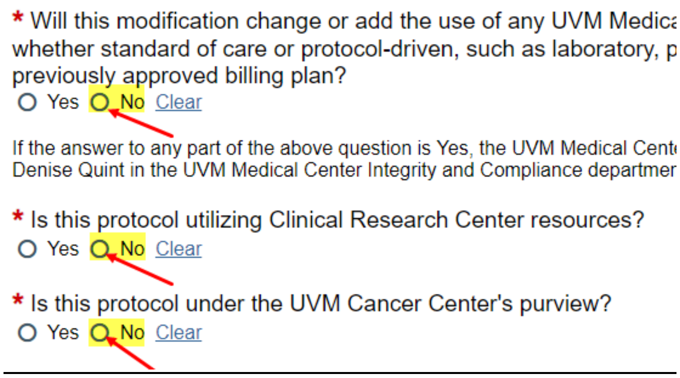
- *Question: “**Summarize the Modifications**”
  - When filling in the question “Summarize the Modifications” please specifically type in “Clean-up Modification”**.**



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”



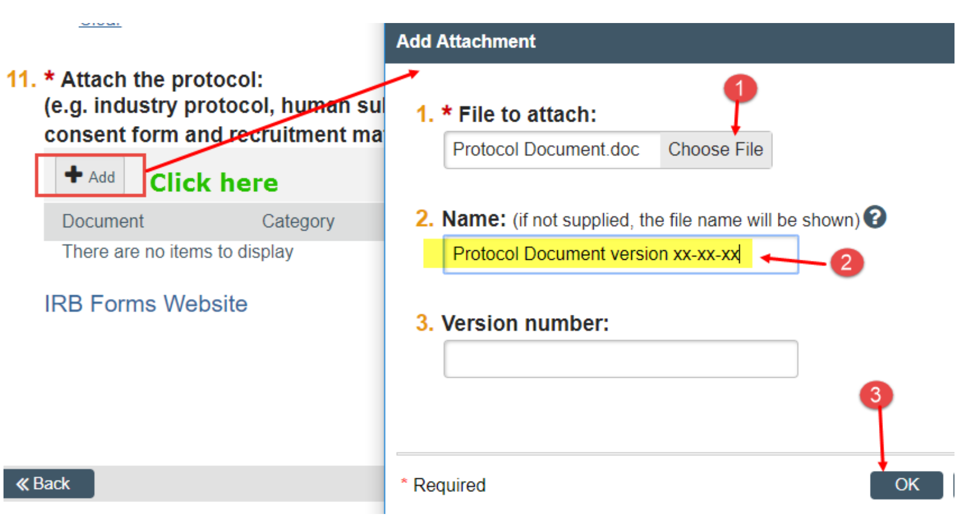
7. Click Continue (way over on the right side of the screen) 

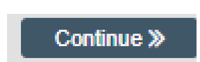
   The online smartform will display starting with the **Basic Information** view.

8. On the Basic Information view there are <u>two required fields</u> 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)

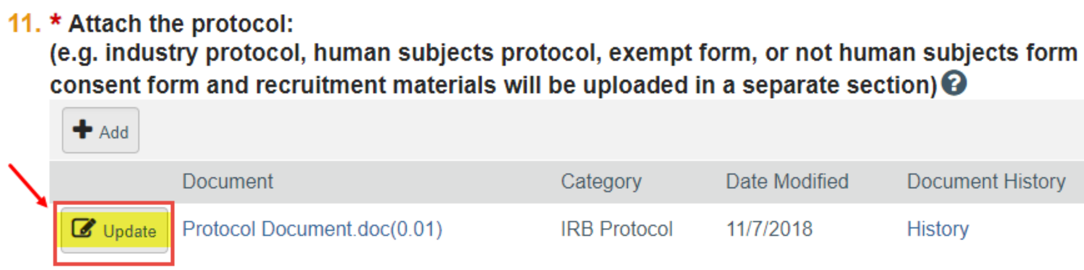
     This is where you must upload your most recently approved protocol document and **ONLY** the protocol document. No other document is to be uploaded here. Please upload word versions if possible. The name should be "Protocol Document version *<u>date approved</u>*"



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

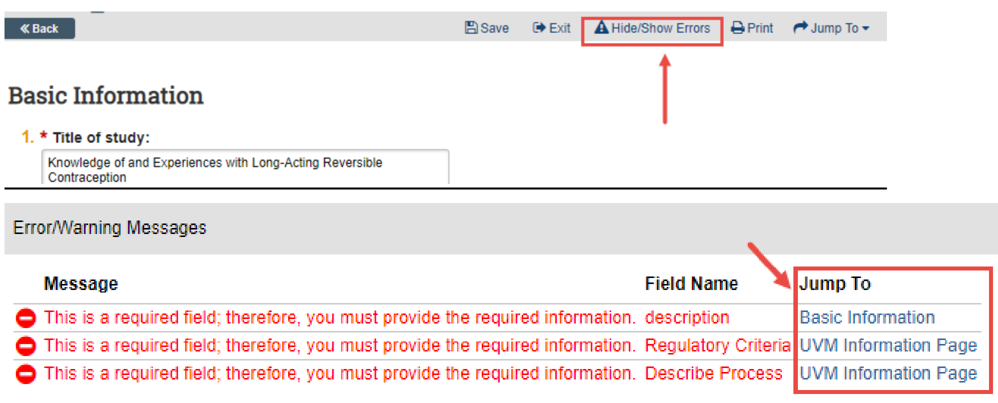
   The online smartform will display the **Funding Sources** view.

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



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

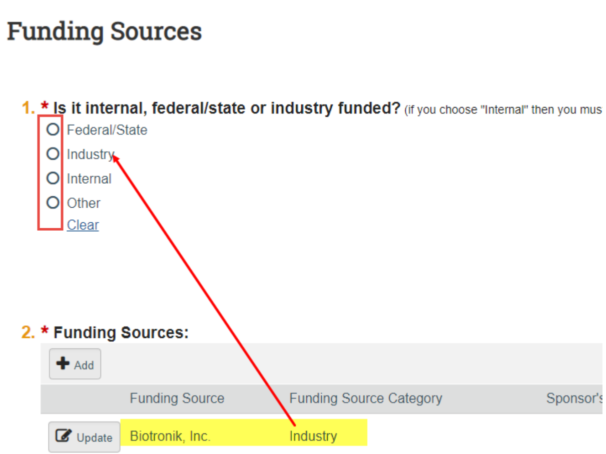
This will list all mandatory fields that have not yet been completed and the view (Jump To) on which they live. You can click on any view under "jump to" to go to that screen.



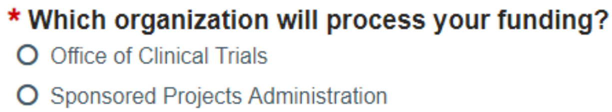
10. On the Funding Sources view there is one required question.

- *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.



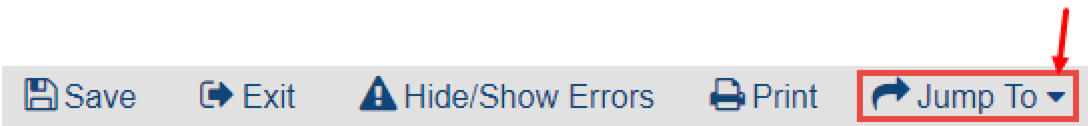
If you select “Industry” or “Other”, additional fields will display and one more mandatory field will need to be selected.



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

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.



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) 

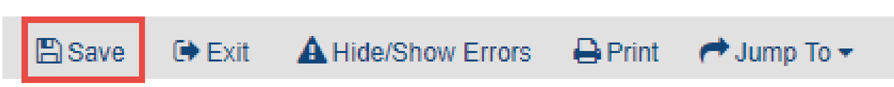
The online smartform will display the **Research Locations** view.

There should be nothing to do here – simply click Continue  to move to the next view.

<u>IMPORTANT NOTE:</u> 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.

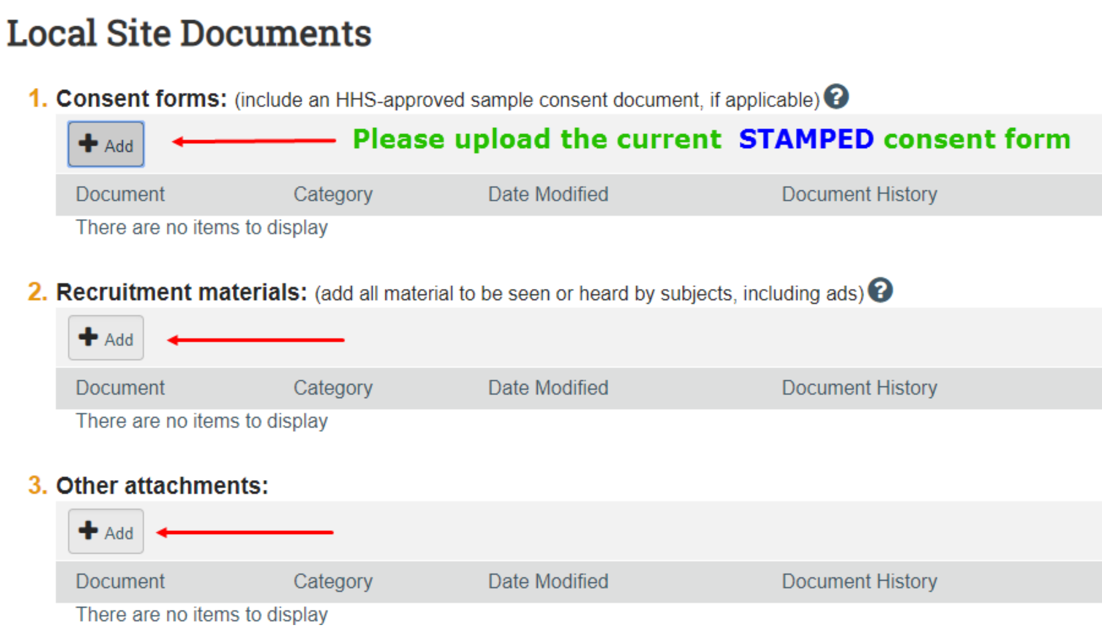
Continue through all views filling in all mandatory fields and clicking  to move forward.

! **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)



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.

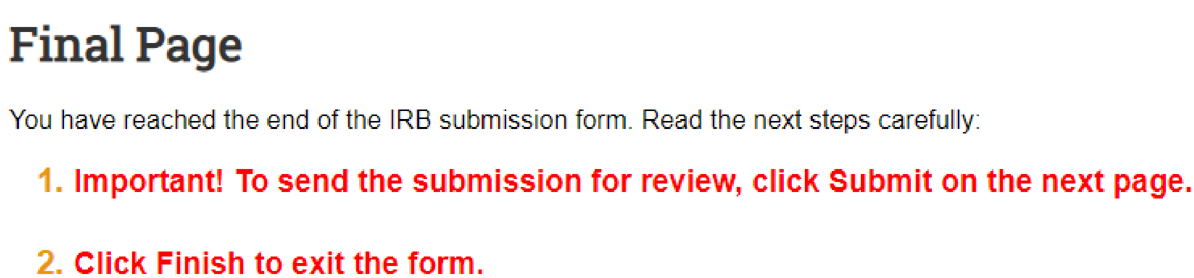
If you uploaded a document previously into InfoEd that will never be changed/amended, you do not need to upload it to UVMClick. If you have any questions about what should be uploaded and what shouldn't, please contact your assigned Research Administrator.



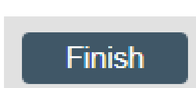
15. Click Continue (way over on the right side of the screen)

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

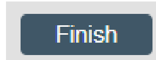
Once you reach the **Final Page** view



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.

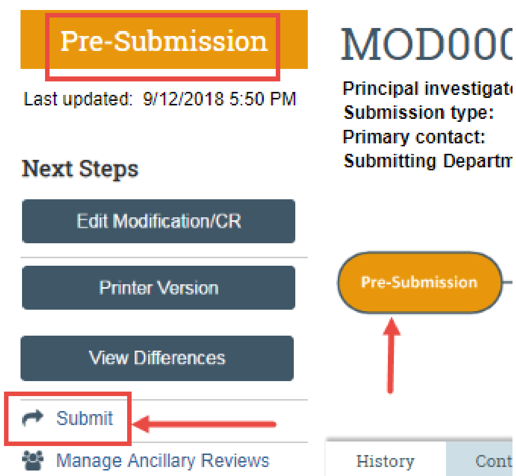
REMEMBER: Click the activity on the left that says “**Submit**”. If you do not see an activity called “Submit” that means that you are not designated as the PI or the Proxy.

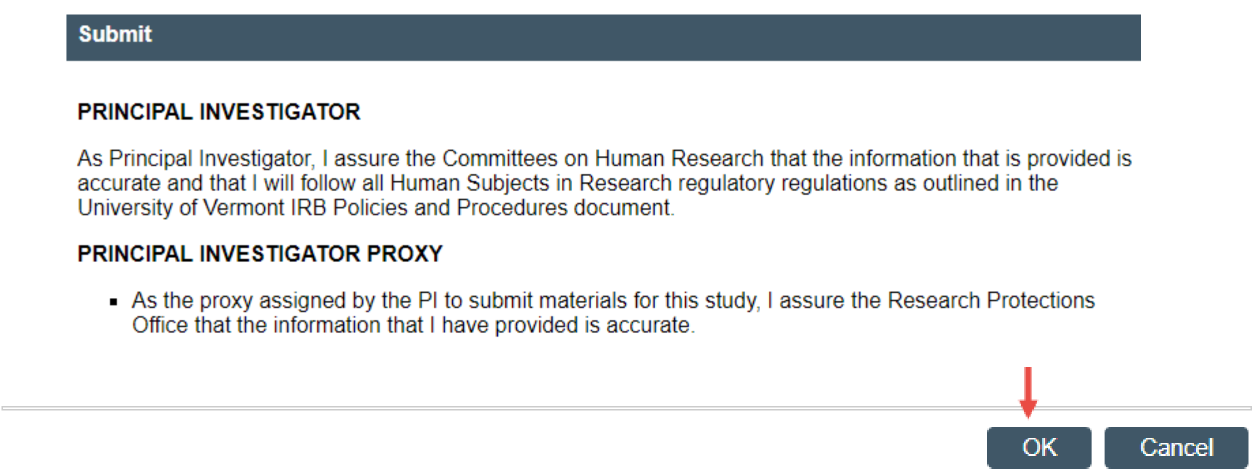
Submission Rules:

- 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

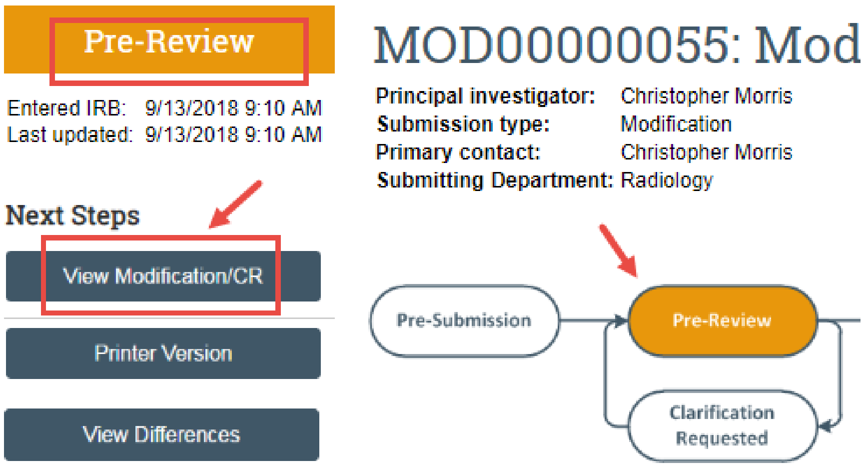
After clicking the **Submit** activity, certification text will appear. Read the text and click **OK**.





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.

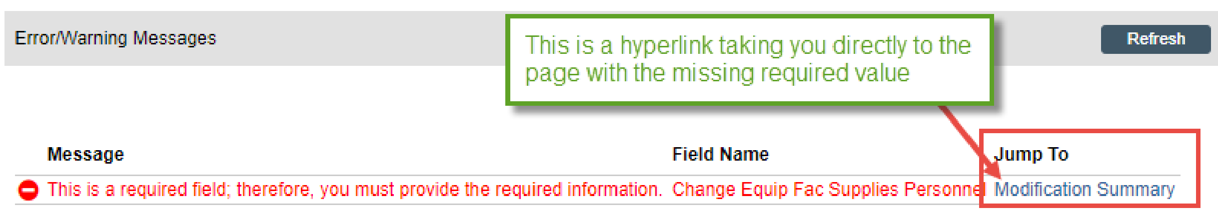
This Modification submission is now in View Mode. It is no longer in Edit mode.



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.



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