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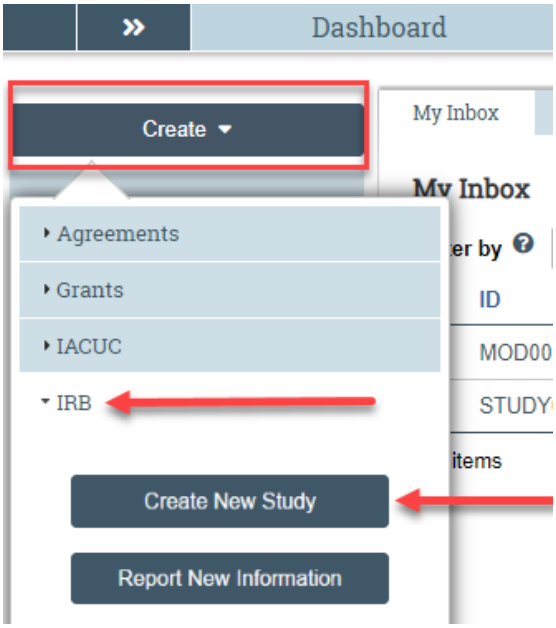
How to Request Reliance on an External IRB (Single IRB)

The Common Rule of 2018 requires that federally funded, non-Exempt studies being conducted at multiple sites rely on a single IRB for review and approval. This single IRB may be another, external institution or a commercial IRB. Contact the IRB Reliance Administrator to determine if UVM will act as the single IRB when UVM is the lead site; this is required early in study development/grant submission since only the UVM IRB can make the decision about whether the institution will act as the single IRB.

Requests to rely upon another IRB must be submitted through UVMClick by creating a new study. These are referenced in Click as External IRB Studies. The number of Click Smart Forms (Click pages) included may change based on the answers you provide. The Smart Forms tell you where to attach files to provide supporting information. **Before you begin,** gather files and information about your study as required in Section 13.3 of the Policies and Procedures Manual. See "Checklist of Information to Attach" at the end of this document for examples of supporting files to upload into Click. Contact the IRB Reliance Administrator with any questions.

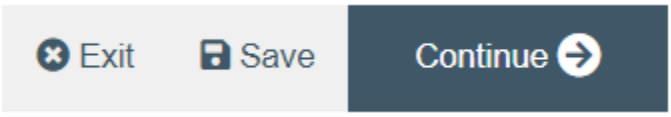
To CREATE a new External IRB Study:

1. From the Dashboard tab, click on "**Create**" on the left side of the screen. Select "**IRB**" from the drop down menu, and click on "**Create New Study.**"

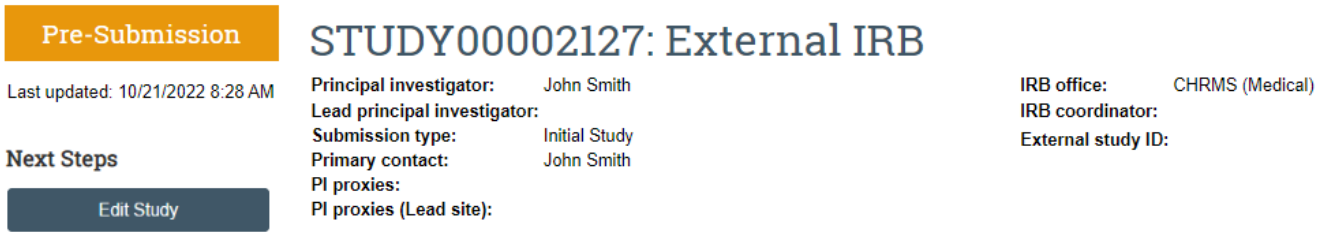


Tip When you create a study, you are automatically assigned to be the Primary Contact who receives all communications from the IRB. (The Principal Investigator you specified also receives all communications.) You can change the primary contact by clicking the activity on the left side of the screen called "**Assign Primary Contact**." Additionally, the PI may designate a PI Proxy, from the listed Study Team Members, to edit and submit on their behalf in Click by selecting "**Assign PI Proxy**." For more details regarding Proxy assignments, reference the User Guide "How to Assign a Proxy".

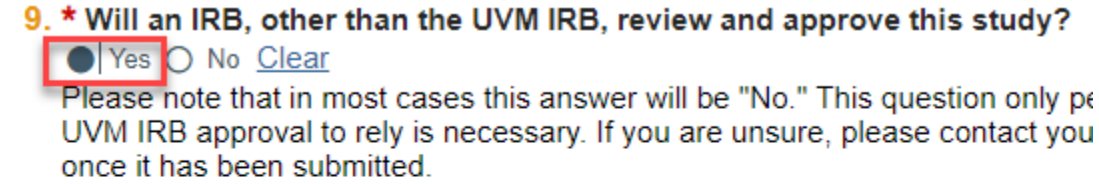
2. Answer all questions and hit "**Continue**" at the bottom, right corner of each page.

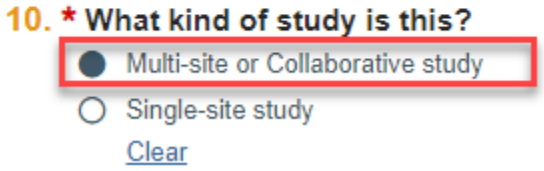


****Tip**** A red asterisk (*) precedes each question that requires an answer. If you cannot answer a required question at this time, or if you need to stop and continue at a later time, click "**Save"** and "**Exit**" at the bottom, right corner of the page. This will keep the study in *Pre-Submission* status. If you do not answer a required question initially, you must return by clicking "**Edit Study**" and answer all required questions before you can submit the study to the IRB for review.



3. <u>On the first Smart Form page called "Basic Information":</u> For External IRB Studies you must answer the following questions in the manner shown below. Don't forget to upload the most recent study protocol that has been <u>approved</u> by the External IRB and provided to you by the lead site, coordinating center, or External IRB. When Q9 is answered "yes," a new question will populate as Q6 asking for the Lead principal investigator. This refers to the PI at the lead site and can be left blank. It will change the numbers to the questions in the screenshot below to 10 and 11. Continue to next page.



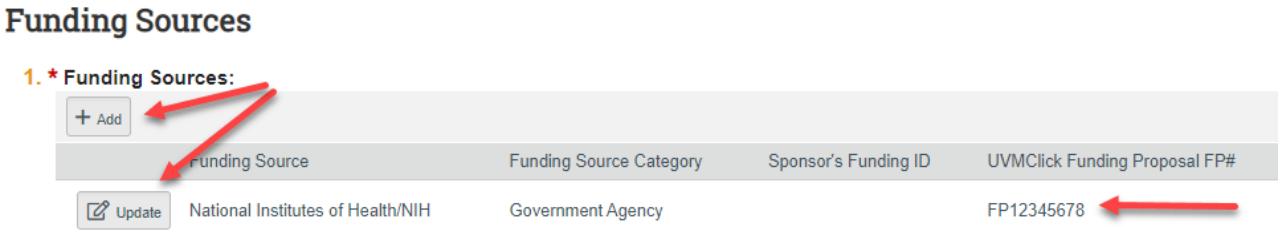


4. <u>On the Smart Form page called "Basic Local Site Information":</u> describe the local study activities if they are different from the study-wide protocol. For example, if our local site will not participate in specific procedures or sub-studies, this information should be provided. Local consent processes should be added here. If the local site will participate in all protocol-specified activities, simply enter "All."

5. <u>On the Smart Form page called "External IRB":</u> for Question 1, enter the External IRB (also called the Single IRB, the IRB of record, or the Reviewing IRB) by starting to type the name in the text box, or by click on **"…"** and selecting the IRB from the list. If you do not see your External IRB listed, please contact the <u>IRB Reliance Administrator</u>. In Question 3, please provide justification for using a Single IRB for review, using the help text

as guidance. “ ”

6. There are two Funding Sources pages in an External IRB submission: a Study Funding Sources page and an Additional Local Funding Sources page. At this time, we are asking that you only enter funding information on the Study Funding Sources page. Select “**Add**” to enter a new funding source, or “**Update**” to modify an existing source. Be sure to enter the Sponsored Projects Administration’s Funding Proposal Number (formatted as FPXXXXXXXX) in the appropriate location.

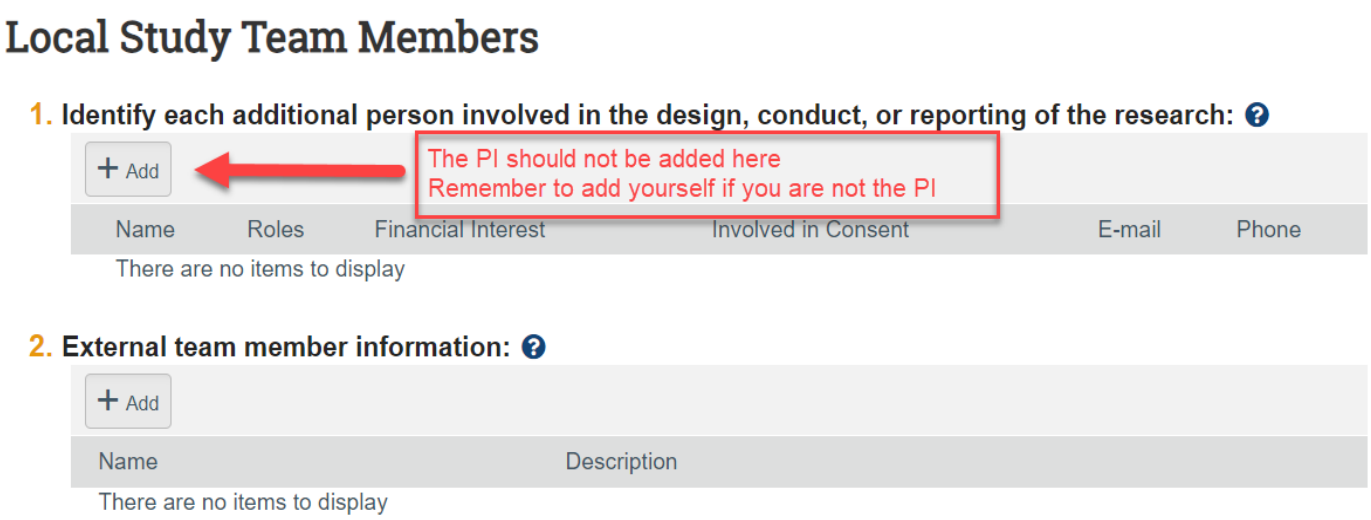


7. On the Smart Form page called “Local Study Team Members”: Add all key personnel after confirming that their required CITI training is complete/up to date. Do not add the PI to this page.

   Tip If you are not the PI, add yourself as a study team member.

   Tip If the PI is a student, please assign the role of Faculty Sponsor to the appropriate study team member. Only one person can be listed as faculty sponsor.

   Tip Do not add team members from other participating sites under the “External team member information” section. They must be added to their own IRB submission with their institution or the External IRB. This page only applies to local study team members.



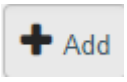
Tip **If a study team member is not showing up as an option to add:**

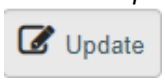
- Students will not appear in UVMClick unless they have allowed the UVM Directory to share their data. Please reference the User Guide: “UVM Students Conducting Research at UVM/UVMMC”
- External study team members that are not employed by UVM nor affiliated with UVM through the affiliation agreement (e.g. UVM Health Network), must have approval from the department, Dean and Provost levels to conduct research on behalf of UVM. These individuals must be added to the protocol as External Study Team Members following Collaborations with External Investigators and contact the IRB Reliance Administrator to

determine if an Individual Investigator Agreement is required.

8. On the Smart Form page called "Study Scope": complete all questions. For Question 8, be specific about the local plan for recruitment, as the description in the protocol provided by the lead site likely won't be adequate or accurate to local recruitment methods.
9. On the Smart Form page called "Research Locations": please add only locations relevant to our UVM/UVMMC site.
10. Complete the Smart Form pages called "Drugs" and "Devices" as applicable.
11. There are two Documents pages in an External IRB submission: Study-Related Documents and Local Site Documents. At this time, we are asking that you only upload documents on the Local Site Documents page. Please See "Checklist of Information to Attach" at the end of this document for examples of supporting files to upload into Click.

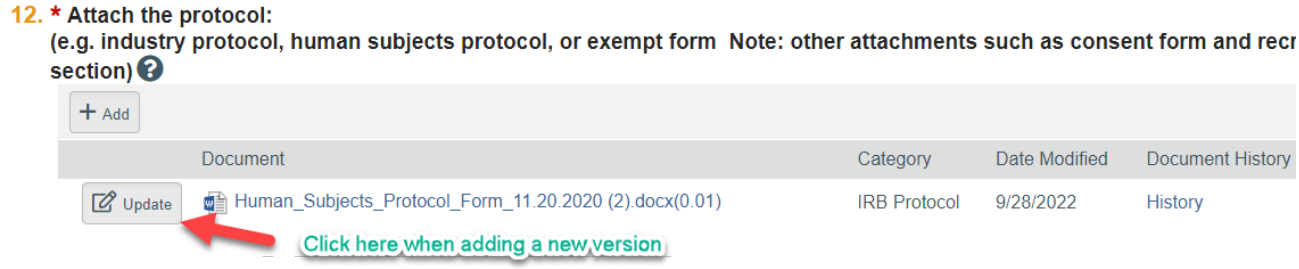
****Tip** When uploading any document:**

- If you want to ADD a *brand new* document, click the "**+ADD**" 

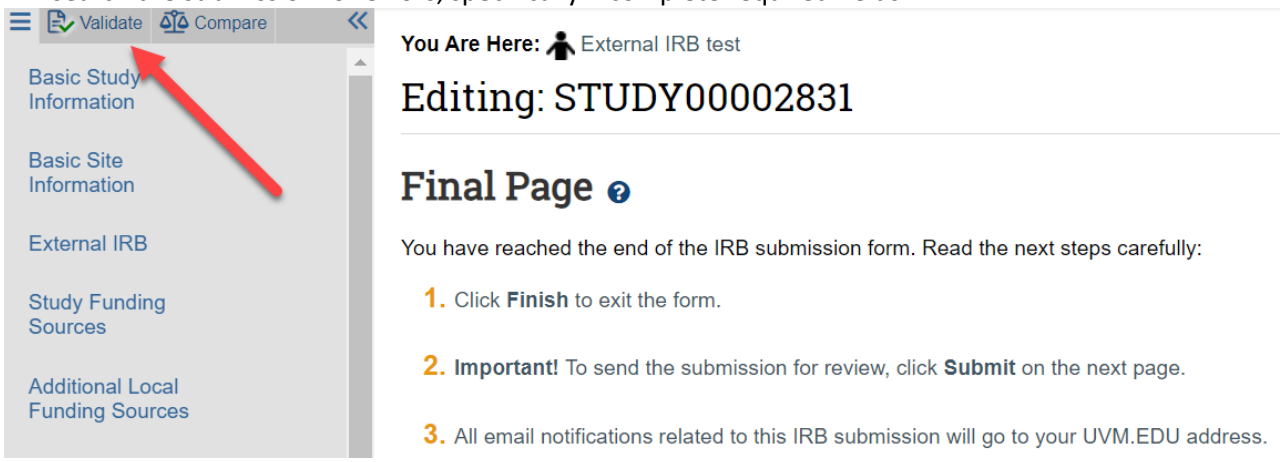
button.
- If you want to VERSION a *previously uploaded document* (i.e. upload an edited/amended version), click the "**UPDATE**" 

button. Do not delete previous versions of a document. When done correctly, only the most recent version title of a document will be visible under the Document column, but the previous versions remain accessible in the "**History"** link to the right of the document.

Example:

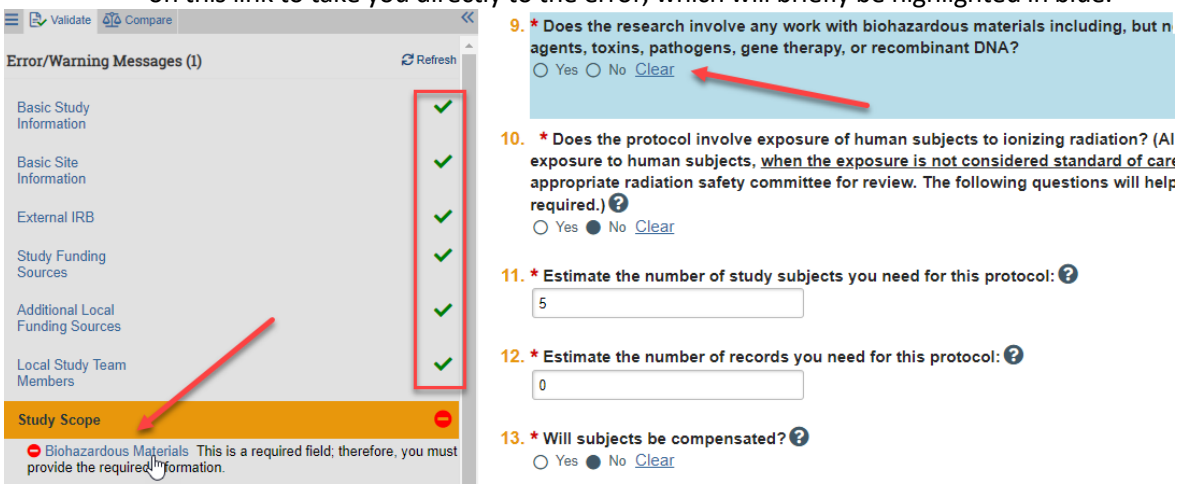


12. When you reach the Smart Form called "Final Page," click "**Validate"** at the top, left corner of the page. This will search the submission for errors, specifically incomplete required fields.



****Tip**** Pages without errors will display a green check "  "

Pages with errors will display a red error sign "  " and will include a blue hyperlink. You can click on this link to take you directly to the error, which will briefly be highlighted in blue.

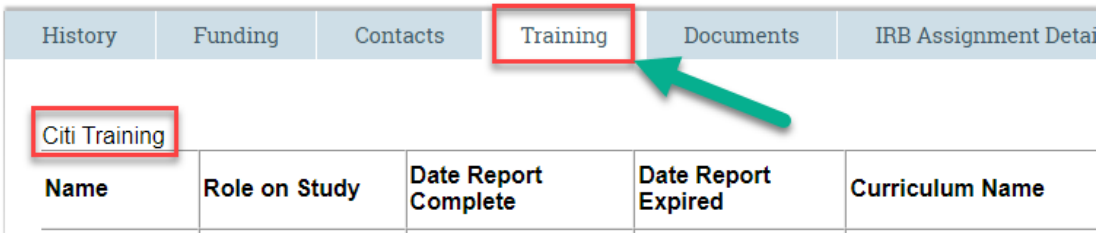


13. After all errors are corrected, navigate to the Smart Form called "Final Page" and then click "**Finish**" at the bottom, right corner of the page to exit the Smart Form pages. You can continue to edit the study while it is in *Pre-Submission* status and before it is submitted for review. **Important! The study has not yet been submitted for review.**

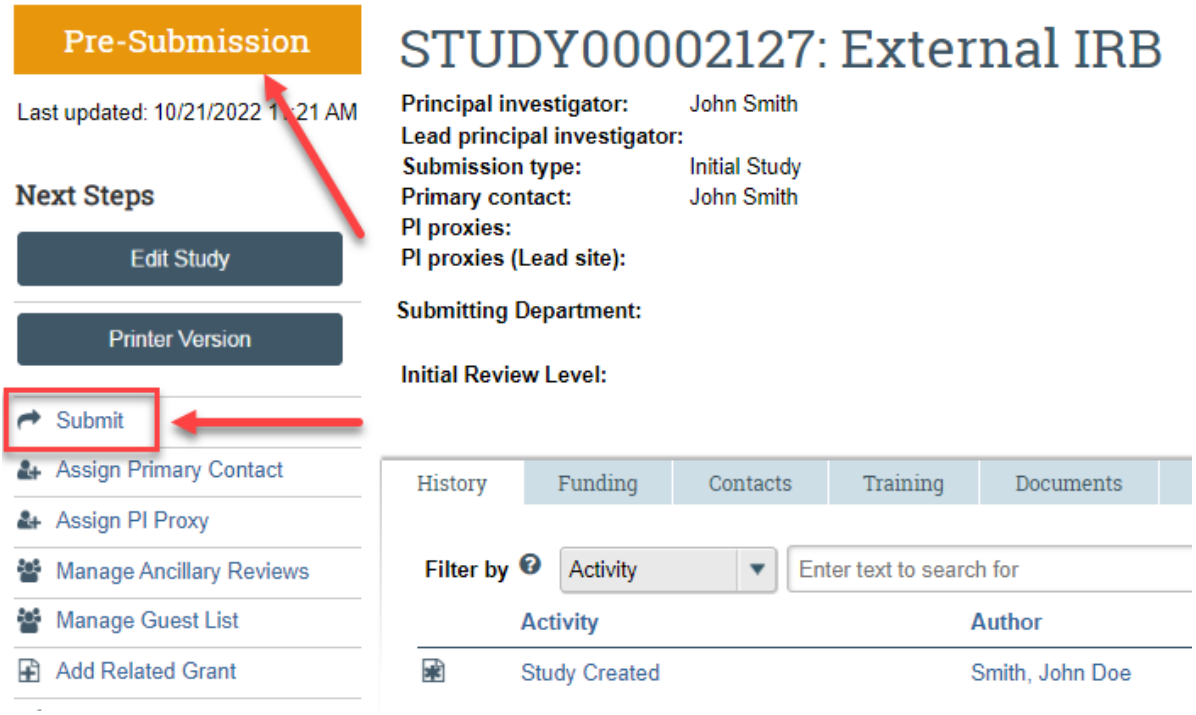
To SUBMIT an External IRB Study for review:

After reaching the Final Page and clicking "**Finish**" to exit the study, the status of the protocol will still display as *Pre-Submission* and will remain visible in your "Dashboard > My Inbox" until submitted to the IRB for processing.

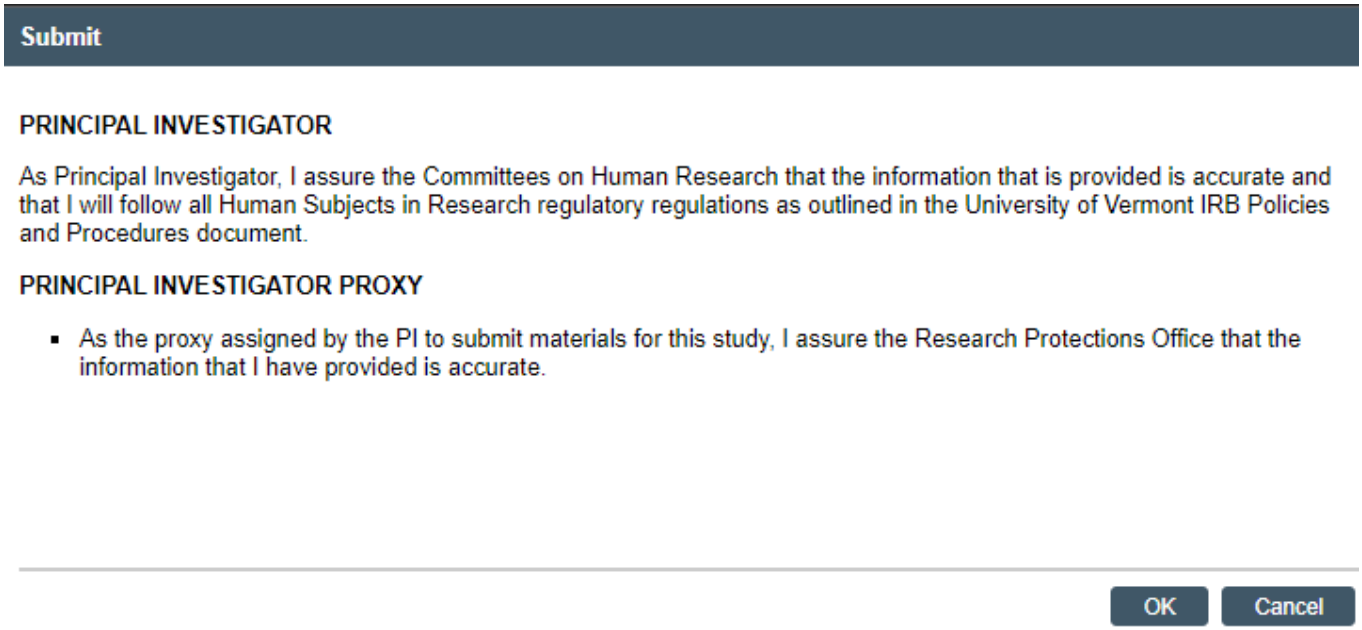
NOTE: Please use the Training tab to confirm all required key personnel training is complete prior to submitting the study for review. Submissions will not be released until all training is complete.



Click the activity on the left that says "**Submit**".

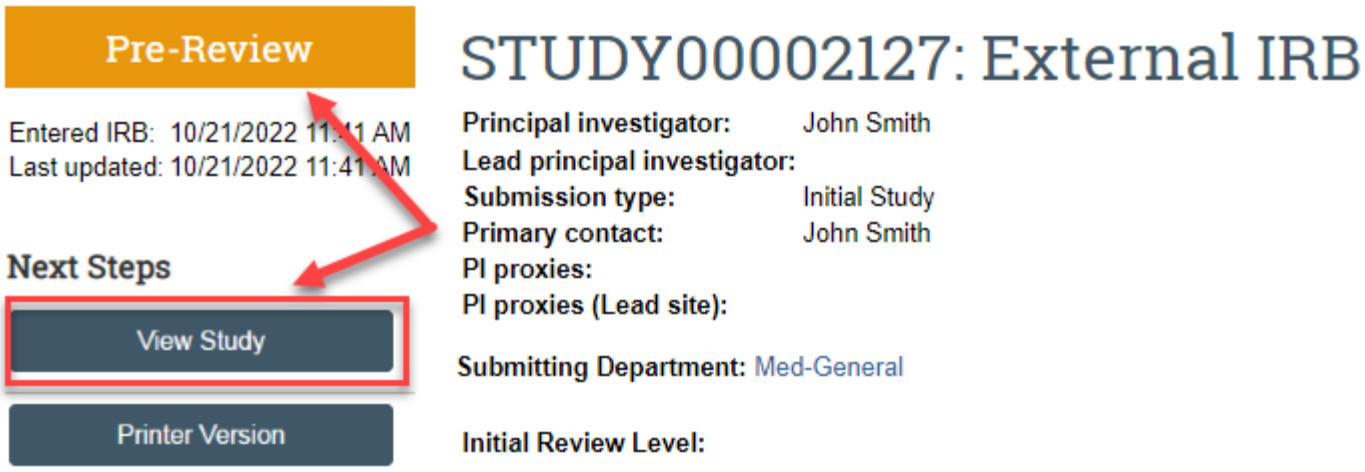


When clicking the "**Submit"** activity, once all required field entry is complete, certification text will appear. Read the text and click "**OK**."



The status of the protocol is no longer "*Pre-Submission*". It has changed to "*Pre-Review*" indicating it is in the hands of the IRB for review.

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



The External IRB has now been submitted and removed from your "Dashboard > My Inbox." It now displays in the IRB Reliance Administrator's "Dashboard > My Inbox."

Checklist of Information to Attach:

Be prepared to attach several files to your study. While editing the study, several views provide places to attach related files. Applicable template files can be found on the Forms Library of our IRB website.

When attaching each file, name it as you want it to appear on the IRB approval letter. Examples of what to attach for an External IRB study are listed below (if relevant to your study) and the screen/view to which the upload belongs.

Basic Information page:

- Protocol approved by External IRB

Funding Sources page:

- Grant Applications

Drugs page:

- IND
- FDA approval
- Communication from the FDA or sponsor with the IND number
- Drug data and safety monitoring report
- Investigational drug brochure
- Drug annual report

Device page:

- IDE or HDE
- Device FDA approval
- Communication from the FDA or sponsor with the IDE / HDE number
- Humanitarian Use Device (HUD) labeling change
- Device data and safety monitoring report
- Device brochure revision
- Device annual report

Local Site Documents page:

1. Consent Forms

- Consent Form template approved by External IRB

- Local Consent Form based on the approved template, including UVM required local content (see in the Forms Library the document labeled "Consent/HIPAA Checklist for Required Language"
- Additional consent templates and local context documents, such as: verbal consent scripts, information sheets, assent forms, long-form or short-form consents for Non-English Speaking participants, and consent process documentation forms

2. Recruitment Materials

- Recruitment materials and scripts edited to be used locally (study-wide recruitment materials do not have to be submitted for local context review)

3. Other Attachments

- Request to Rely Form
- Local Context Form (if required by External IRB and not already completed)
- Reliance Agreement (if not already completed)
- Data Management and Security Plan
- Study-level Approval Memo from External IRB
- Local Site Approval Memo from External IRB (after local context review is completed)
- HIPAA Authorization Form (if UVM is acting as the Privacy Board instead of the External IRB)