UVMClick

IRB

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How to Create a New Study

You prepare a new study for IRB review by entering information into a series of online SmartForms. The number of SmartForms included may change based on the answers you provide. The forms tell you where to attach files to provide supporting information.

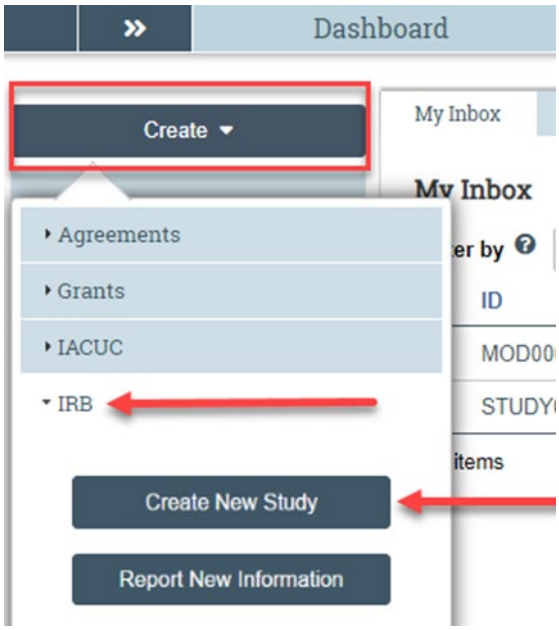
The simplest approach is to follow the forms in order, answering the questions and clicking Continue to save your information and move to the next form. When you reach the end of the series of forms, click the Finish button.

Before you begin, gather files and information about your study such as:

- Supporting information files. See Guidance Materials Required for UVMClick Submissions
- Training and Financial interest status for each of your study team members

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

To create a new study for IRB review:



- 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.**"
- Fill in the applicable boxes and answer the questions on the SmartForm.

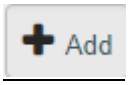
Basic Information Page

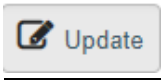
Tip When you create a study, you are automatically assigned to be the Primary Contact who receives all communications from the IRB. (The Principal Investigator you specified also receives all communications.) You can change the primary contact by clicking the activity on the left side of the screen called "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".

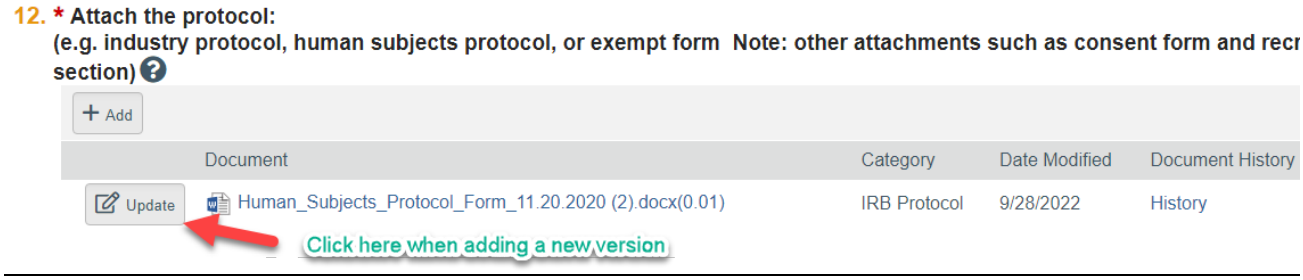
Upload the protocol document on this page – this could be the exemption determination form, or an industry sponsored protocol or an original protocol written by the PI.

Please submit the industry drug or device protocol here and do not transfer information from the sponsor protocol onto our UVM protocol template. The IRB will review the most recent version of the sponsor protocol.

Tip **When uploading any document:**

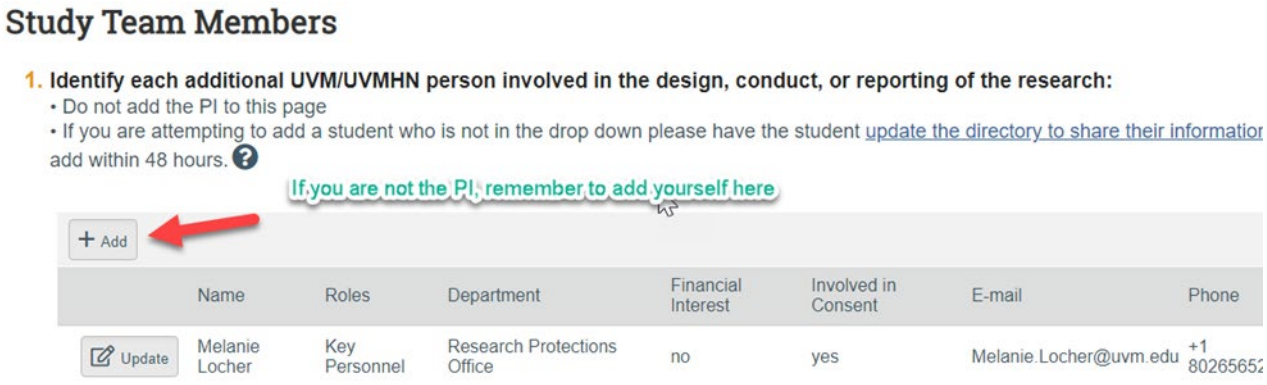
- If you want to ADD a new document line item, click the +ADD  button.

- If you want to VERSION a previously uploaded document, click the UPDATE  button.



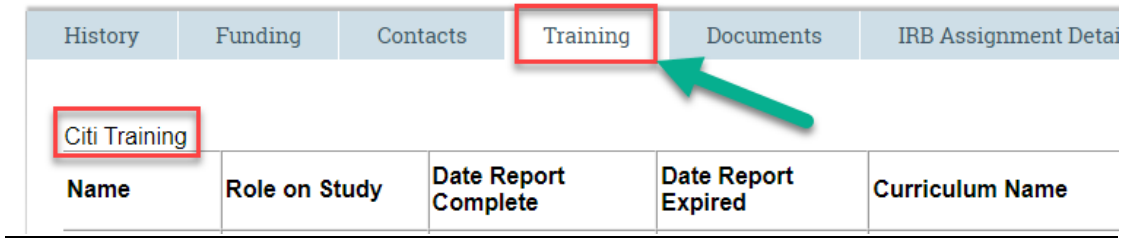
Funding Sources Page

Select "Add" to enter a new funding source such as (NIH, NSF, Medtronic). Be sure to enter the Sponsored Projects Administration's Funding Proposal Number (formatted as FPXXXXXXXX) in the appropriate location. If you have no funding, please enter "internal funding"



IMPORTANT – If you are not the PI, add yourself as a study team member when you get to that screen.

NOTE: 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.



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 follow link for instructions: **Students – How to Sign Up to do Research at UVM (PDF)**
- 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

Click **Continue** to move to the next form.

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.

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 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 are listed below (if relevant to your study) and the screen/view to which the upload belongs.

Basic Information page:

- Human Subjects Research Protocol
- Biological Specimens/Data Repository Protocol
- Exempt Protocol Form
- Qualitative Protocol
- Blood Collection Protocol for Non-Clinical Laboratory Research
- Industry Protocol
- Grant Proposals Lacking Definite Plans for Involvement of Human Subjects

Funding Sources page:

- Grant Applications

Drugs page:

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

Device page:

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

Local Site Documents page:

Consent Forms

- Consent Forms – Medical or behavioral or child assent forms
- Consent Process Documentation forms
- Information sheets
- For non-written consent, a script of the information provided orally to the subjects
- Translated participant facing documents

Recruitment Materials

- Recruitment materials and scripts(flyers, radio ads, social media images/texts)

Other Attachments

- Surveys, diaries, and questionnaires
- Data Management and Security Plan
- Letters of support from external entities where research is to be conducted (schools, prisons)
- Sponsor contracts/agreements (if applicable)
- Privacy Policies for Apps and Databases
- Participant Study Brochures

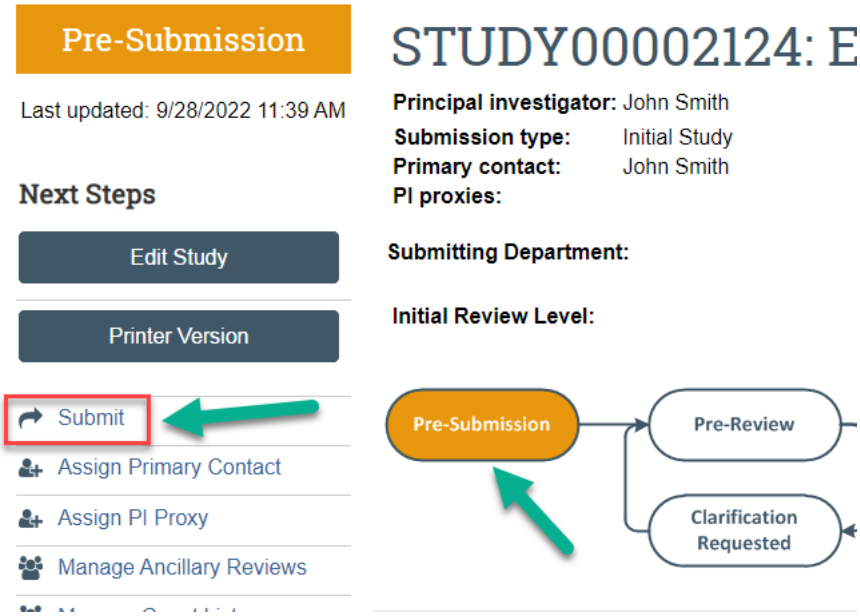
- Wallet Cards
- Any other participant-facing material or documentation the Investigator deems pertinent

Submitting the Study for Review

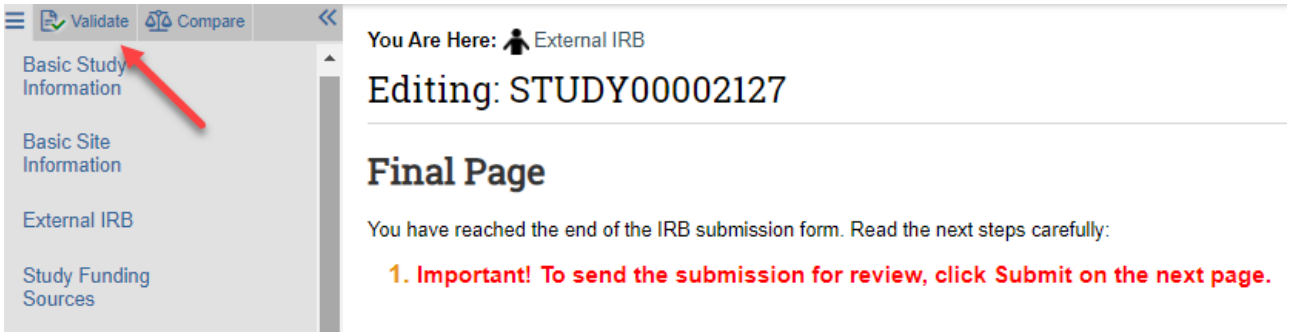
After reaching the final page of a new protocol and clicking "Finish" to exit the study, the status of the protocol will still display as "Pre-Submission" and will remain visible in your "Dashboard - My Inbox" until submitted to the IRB Office for processing.

****Tip**** Prior to submitting the study to the IRB Office, the PI may choose to add a Proxy. Any named Proxy has the authority to edit and submit on behalf of the PI. For more details regarding Proxy assignments, please reference the User Guide called "How to Assign a Proxy".

To submit a finished protocol to the IRB Office for their review and processing, click the activity on the left that says "Submit".

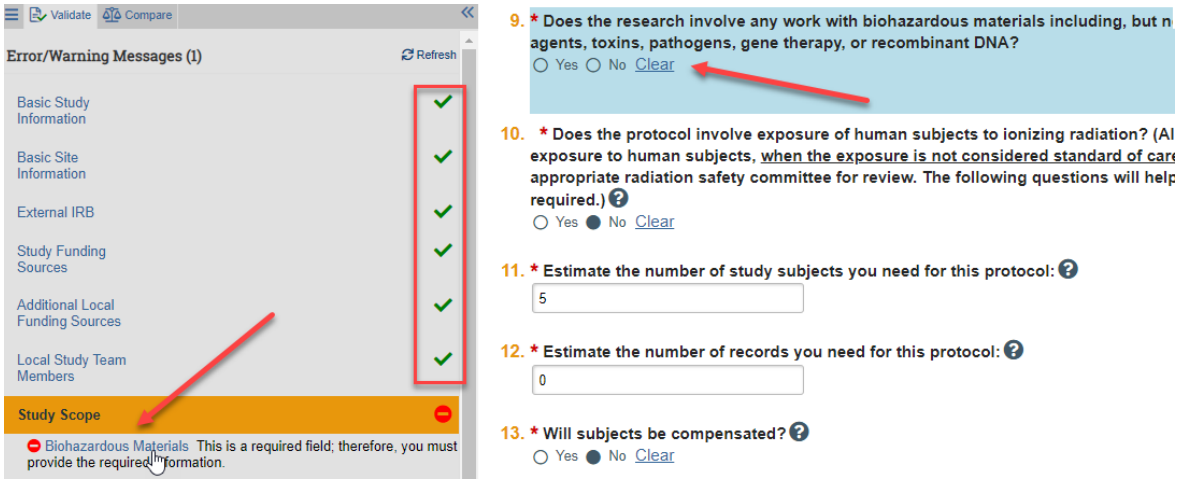


When you reach the Smart Form called "Final Page," click "**Validate"** at the top, left corner of the page. This will search the submission for errors, specifically incomplete required fields.

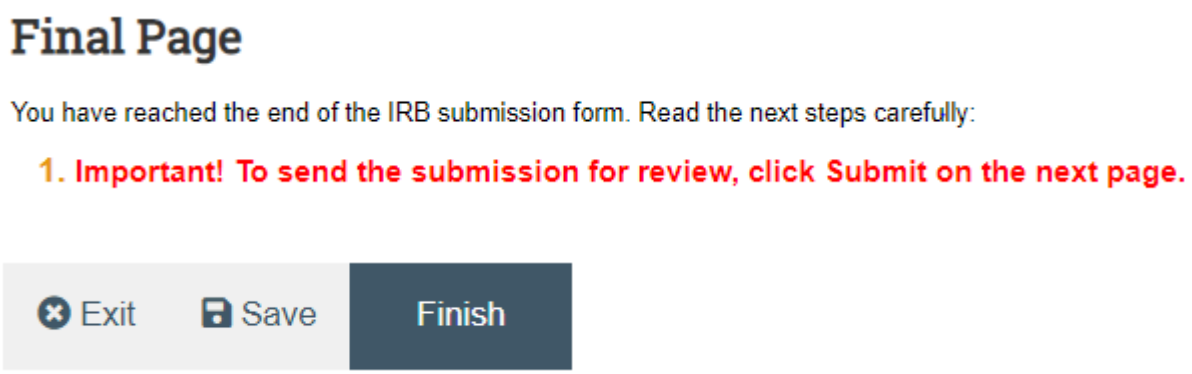


****Tip**** Pages without errors will display a green check "✓"

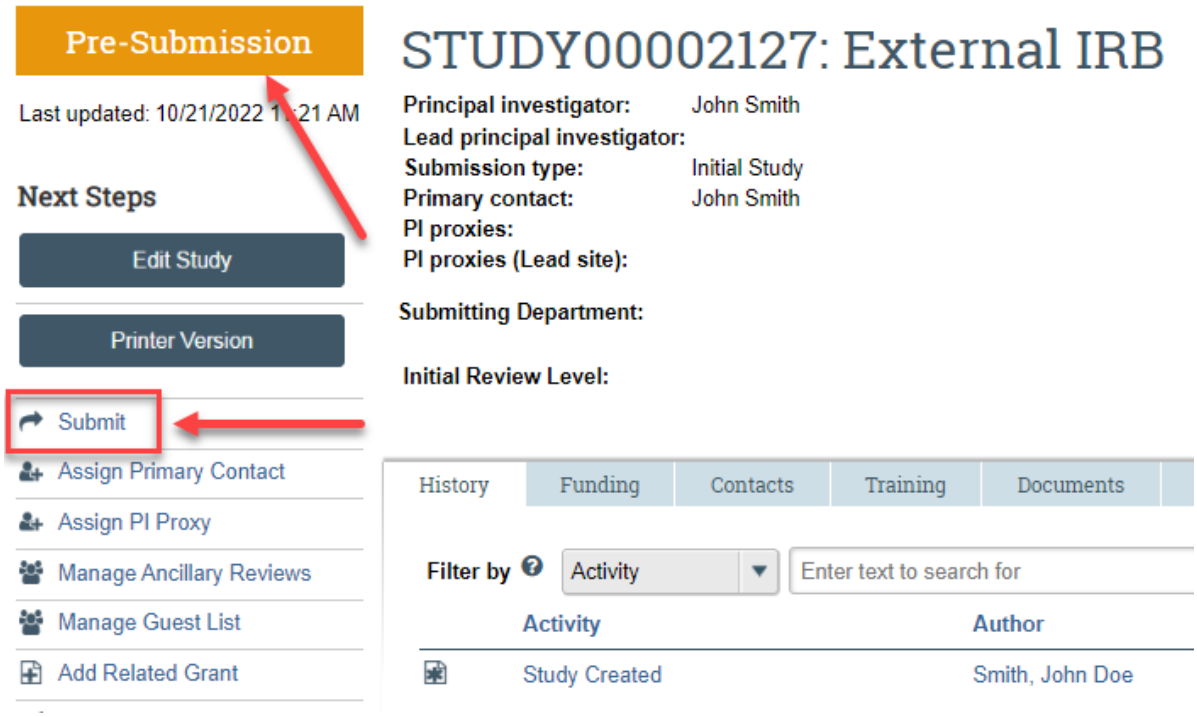
Pages with errors will display a red error sign “ ” and will include a blue hyperlink. You can click on this link to take you directly to the error, which will briefly be highlighted in blue.



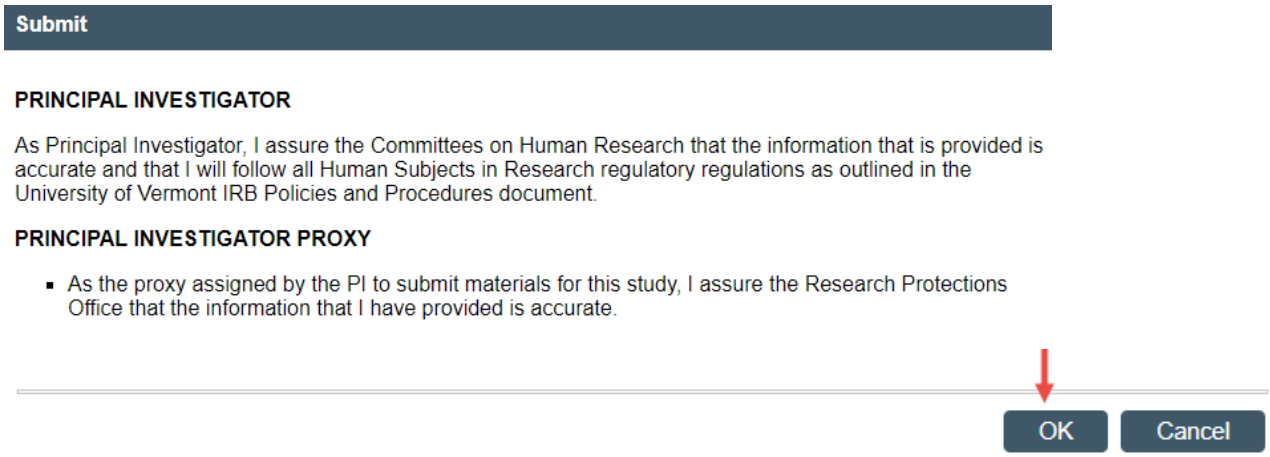
After all errors are corrected, navigate to the Smart Form called “Final Page” and then click “**Finish**” at the bottom, right corner of the page to exit the study. You can continue to edit the study while it is in *Pre-Submission* status and before it is submitted for review. **Important! The study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



Click the activity on the left that says “**Submit**”.

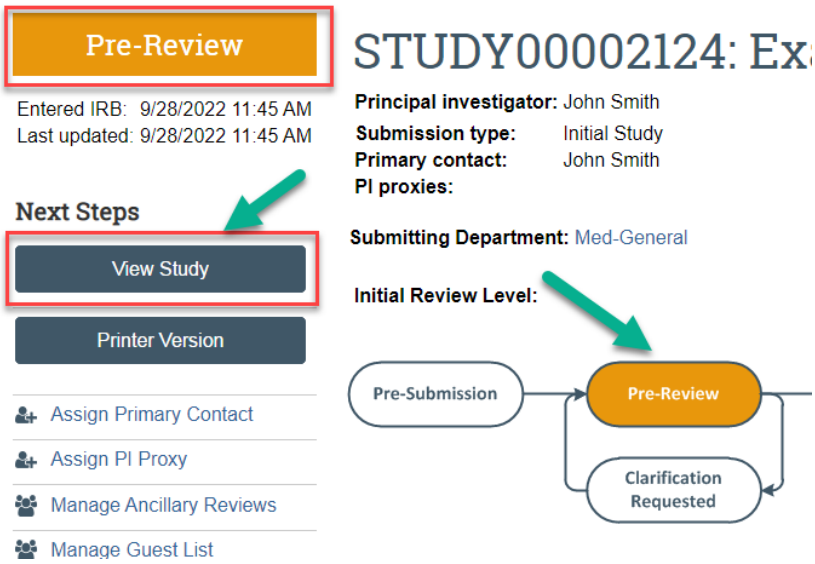


When clicking the "**Submit"** activity, once all required field entry is complete, certification text will appear. Read the text and click "**OK**."



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 Office for processing.

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



The protocol has now been submitted and removed from your "Dashboard." It now displays in the IRB Analyst's "Dashboard."