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| 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 |

# 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.

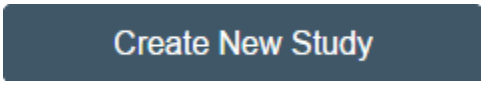
The simplest approach is to follow the forms in order, answering the questions and clicking Continue to save your information and move to the next form. When you reach the end of the series of forms, click the Finish button.

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

- Supporting information files. See Checklist of Information to Attach later in this document.
- Training and Financial interest status for each of your study team members
- For External Studies: Contact information and IRB oversight info for external sites involved in the study

**To create a new study for review:**

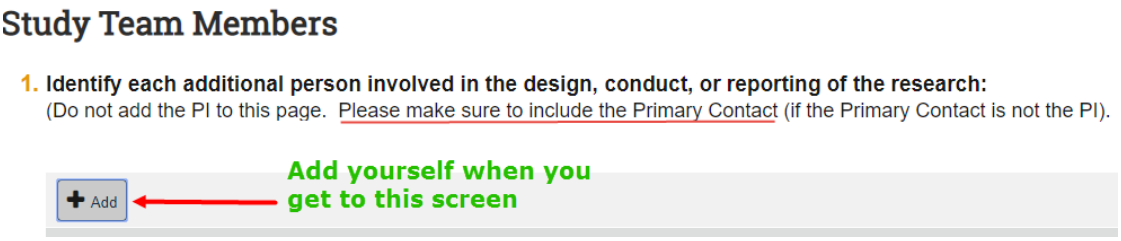
1. From "My Inbox" or the IRB > Submissions screen, Click **Create New Study**.



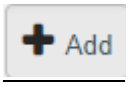

2. Fill in the applicable boxes and answer the questions on the smartforms.
   Note: New UVMClick protocols will have a new numbering scheme. Example: "STUDY000001"

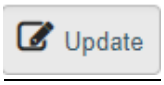
   **Tip** When you create a study, you are assigned to be the primary contact who receives all communications from the IRB on behalf of the study team. (The principal investigator you specified also receives the communications.)

**IMPORTANT** – Add yourself as a study team member when you get to that screen.

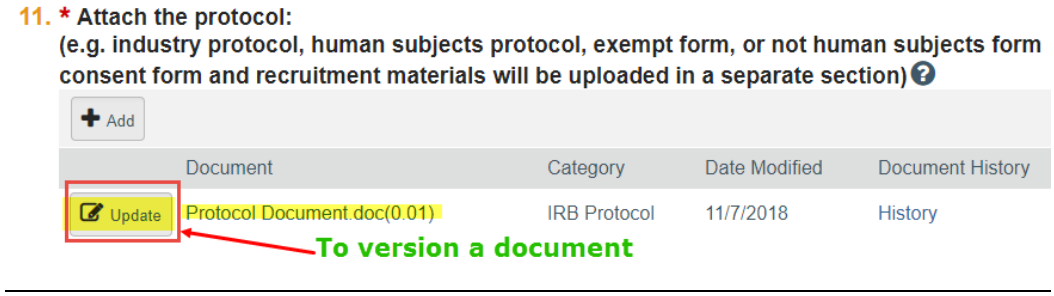


****Tip** When uploading any document:**

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

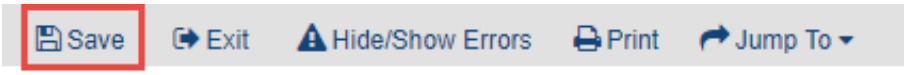

- If you want to VERSION a previously uploaded document, click the UPDATE  button.


Example:




3. 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 the SAVE link at the top of the Smartform. If you do not answer a required question initially, you must return and answer it before you can submit the study to the RPO Office for review.




4. When you reach the final page, click **Finish** to exit the study.

   You can continue to edit the study until you submit it for review.

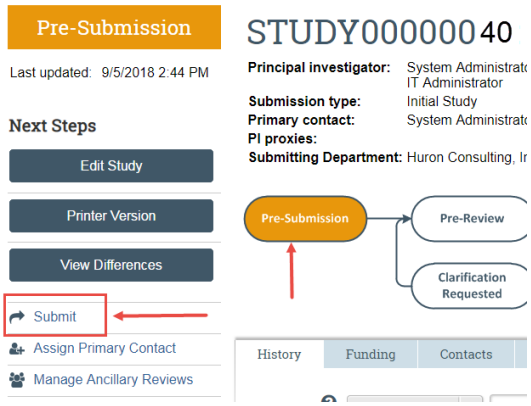
   **Important! The study has not yet been submitted for review**. For instructions, see Submitting the Study for Review below.

# Submitting the Study for Review

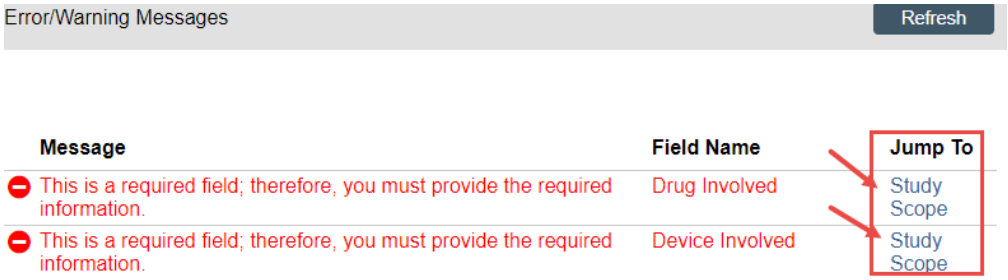
After reaching the final page of a new protocol and clicking "Finish" to exit the study, the status of the protocol will still display as "Pre-Submission" and will remain visible in your "My Inbox" until submitted to the IRB Office for processing.

> **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, make sure the study is open. Click the activity on the left that says "Submit".

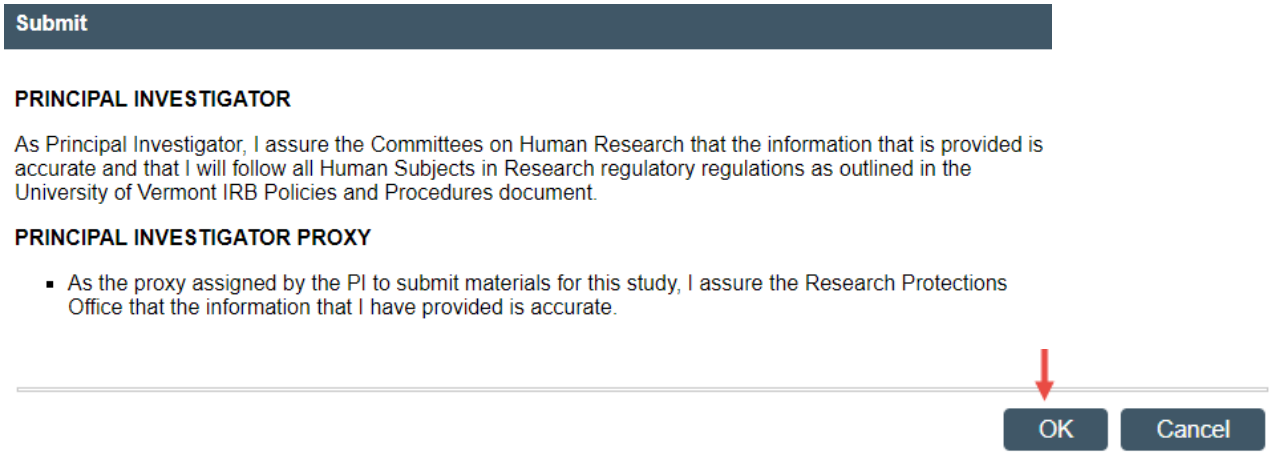



If there are any required fields that you forgot to enter, the Submit process will display them. You can use the pop-up to Jump To those particular screens quickly and enter the missing data.



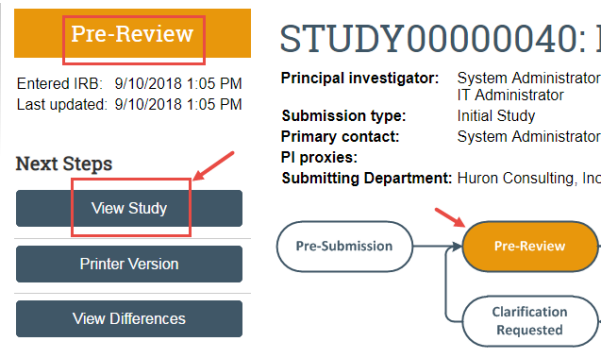

**NOTE:** These Errors/Warning Messages only appear if required field entry was missed.

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 “My Inbox.” It now displays in the IRB Office “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 our IRB website https://www.uvm.edu/rpo/human-subjects-research

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.

## Protocol: (Basic Information view/page)

- Investigator Protocol
- Repository Protocol
- Exempt Protocol Form
- Qualitative Protocol
- Blood Collection Protocol
- Administrative Tool Protocol
- Not Human Subjects Protocol Form
- Industry Protocol

## Funding Information (Edit Funding Source view/page)

- Grant Applications

## Drug Details (Add Drug view/page with each drug, or on main Drugs page if not specific to one drug)

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

## Device Details (Add Device view/page with each device, or on main Device page if not specific to one device)

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

## Recruitment and Consent details: (Local Site Documents view / page)

- Consent Forms
- HHS approved consent document
- For non-written consent, a script of the information provided orally to the subjects
- Foreign-language versions of materials for subjects
- Evaluation instruments and surveys
- Advertisements
- Recruitment materials and scripts

**Other suggested relevant documents: (**Local Site Documents **view/page)**

- Study surveys/questionnaires
- Data Management Form
- Sponsor contracts/agreements
- Letters of support
- Drug or Device Annual Report
- Drug or Device Data and Safety Monitoring Report
- Device Brochure Revision
- Drug or Device FDA Approval
- Investigational Drug Brochure
- Humanitarian User Device (HUD) Labeling Change
- DSMB Minutes
- EMRAP Agreement

**NOTE:** Many of the IRB Forms have transitioned into our UVMClick online smartforms. Forms that have been deprecated and are now online entry within UVMClick include:

- Common Protocol Cover Form
- Amendment Form
- PI Change Form
- Key Personnel Form
- Continuing Review Form
- Unanticipated Problem Involving Risk Form
- New Safety Information Form
- Waiver of Documentation / Informed Consent
- Partial Waiver of Authorization for Recruitment Purposes

As these forms are no longer uploaded documents, they have been removed from the IRB Forms website and therefore manual signatures are no longer required.