

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.

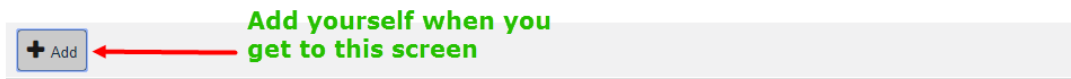
Note: New UVMClick protocols will have a new numbering scheme. Example: “STUDY000001”

****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.)

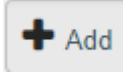
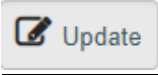
IMPORTANT – Add yourself as a study team member when you get to that screen.

Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research:
(Do not add the PI to this page. Please make sure to include the Primary Contact (if the Primary Contact is not the PI).

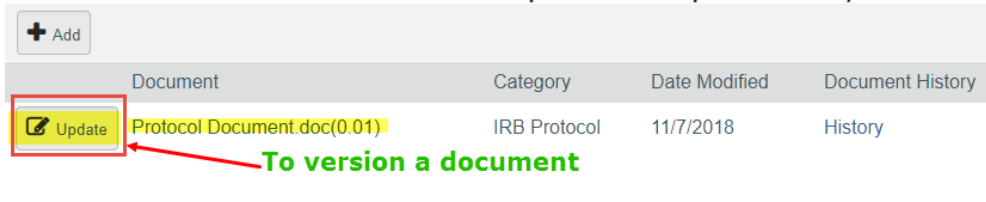



****Tip**** When uploading any document:

- 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:

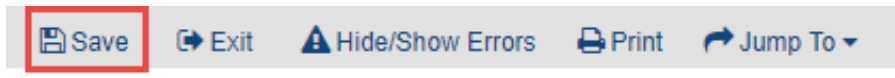
11. * Attach the protocol:
(e.g. industry protocol, human subjects protocol, exempt form, or not human subjects form consent form and recruitment materials will be uploaded in a separate section) ?



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

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”.

Pre-Submission STUDY00000040

Last updated: 9/5/2018 2:44 PM

Principal investigator: System Administrator
IT Administrator

Submission type: Initial Study

Primary contact: System Administrator

PI proxies:

Submitting Department: Huron Consulting, Inc.

Next Steps

- Edit Study
- Printer Version
- View Differences
- Submit**
- Assign Primary Contact
- Manage Ancillary Reviews

History Funding Contacts

Pre-Submission → Pre-Review
Pre-Submission → Clarification Requested

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.

Error/Warning Messages Refresh

Message	Field Name	Jump To
⊖ This is a required field; therefore, you must provide the required information.	Drug Involved	Study Scope
⊖ This is a required field; therefore, you must provide the required information.	Device Involved	Study Scope

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**.

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.

OK Cancel

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 screenshot displays a study protocol interface. At the top left, a yellow box labeled "Pre-Review" is highlighted with a red box. Below it, the text "Entered IRB: 9/10/2018 1:05 PM" and "Last updated: 9/10/2018 1:05 PM" is visible. To the right, the study ID "STUDY00000040:]" is shown. Further right, a list of details includes: "Principal investigator: System Administrator, IT Administrator", "Submission type: Initial Study", "Primary contact: System Administrator", "PI proxies:", and "Submitting Department: Huron Consulting, Inc". Below the details, a "Next Steps" section contains three buttons: "View Study", "Printer Version", and "View Differences". The "View Study" button is highlighted with a red box and a red arrow points to it from the right. To the right of the buttons is a workflow diagram with three nodes: "Pre-Submission", "Pre-Review", and "Clarification Requested". An arrow points from "Pre-Submission" to "Pre-Review", and another arrow points from "Pre-Review" to "Clarification Requested". The "Pre-Review" node is highlighted in orange, and a red arrow points to it from the top.

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
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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.