

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.

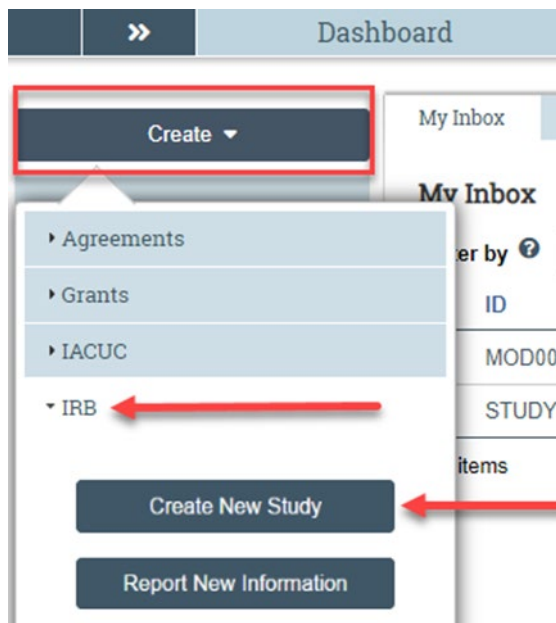
The simplest approach is to follow the forms in order, answering the questions and clicking Continue to save your information and move to the next form. When you reach the end of the series of forms, click the Finish button.

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.

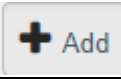
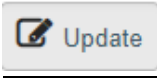
Basic Information Page

****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.

12. * Attach the protocol:
(e.g. industry protocol, human subjects protocol, or exempt form Note: other attachments such as consent form and recr section) ?

+ Add

Document	Category	Date Modified	Document History
 Update  Human_Subjects_Protocol_Form_11.20.2020 (2).docx(0.01)	IRB Protocol	9/28/2022	History

 [Click here when adding a new version](#)

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 FPXXXXXXX) in the appropriate location. If you have no funding, please enter “internal funding”

Study Team Members

1. Identify each additional UVM/UVMHN person involved in the design, conduct, or reporting of the research:
- Do not add the PI to this page
 - If you are attempting to add a student who is not in the drop down please have the student [update the directory to share their information](#) add within 48 hours. ?

[If you are not the PI, remember to add yourself here](#)

+ Add

Name	Roles	Department	Financial Interest	Involved in Consent	E-mail	Phone
 Update Melanie Locher	Key Personnel	Research Protections Office	no	yes	Melanie.Locher@uvm.edu	+1 80265652

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.

History	Funding	Contacts	Training	Documents	IRB Assignment Detail
Citi Training					
Name	Role on Study	Date Report Complete	Date Report Expired	Curriculum Name	

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”.

Pre-Submission

Last updated: 9/28/2022 11:39 AM

Next Steps

Edit Study

Printer Version

Submit

Assign Primary Contact

Assign PI Proxy

Manage Ancillary Reviews

STUDY00002124: E

Principal investigator: John Smith

Submission type: Initial Study

Primary contact: John Smith

PI proxies:

Submitting Department:

Initial Review Level:

Pre-Submission

Pre-Review

Clarification Requested

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.

Validate

Compare

Basic Study Information

Basic Site Information

External IRB

Study Funding Sources

You Are Here: External IRB


Editing: STUDY00002127

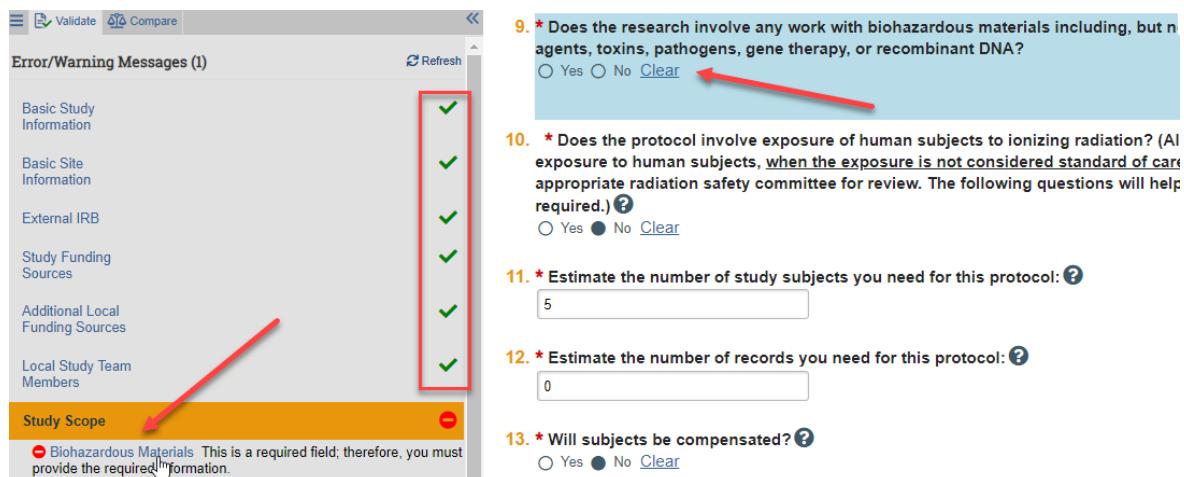
Final Page

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Important! To send the submission for review, click **Submit on the next page.**

****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.



The screenshot shows the IRB submission form interface. On the left, a sidebar lists sections: Basic Study Information, Basic Site Information, External IRB, Study Funding Sources, Additional Local Funding Sources, Local Study Team Members, and Study Scope. The 'Study Scope' section is highlighted in orange and has a red error sign. A red box highlights green checkmarks next to the first six sections. A red arrow points from the 'Study Scope' error message to the survey question 9. The error message reads: "Biohazardous Materials This is a required field; therefore, you must provide the required information." The survey questions are numbered 9 through 13. Question 9 asks: "Does the research involve any work with biohazardous materials including, but not limited to, agents, toxins, pathogens, gene therapy, or recombinant DNA?" with radio buttons for Yes and No, and a 'Clear' link. Question 10 asks: "Does the protocol involve exposure of human subjects to ionizing radiation? (All exposure to human subjects, when the exposure is not considered standard of care, appropriate radiation safety committee for review. The following questions will help required.)" with radio buttons for Yes and No, and a 'Clear' link. Question 11 asks: "Estimate the number of study subjects you need for this protocol:" with a text input field containing the number 5. Question 12 asks: "Estimate the number of records you need for this protocol:" with a text input field containing the number 0. Question 13 asks: "Will subjects be compensated?" with radio buttons for Yes and No, and a 'Clear' link.

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.**

Final Page

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Important! To send the submission for review, click Submit on the next page.



The screenshot shows three buttons: 'Exit' with a close icon, 'Save' with a floppy disk icon, and 'Finish'.

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

Pre-Submission

Last updated: 10/21/2022 11:21 AM

Next Steps

Edit Study

Printer Version

Submit

Assign Primary Contact

Assign PI Proxy

Manage Ancillary Reviews

Manage Guest List

Add Related Grant

STUDY00002127: External IRB

Principal investigator: John Smith

Lead principal investigator:

Submission type: Initial Study

Primary contact: John Smith

PI proxies:

PI proxies (Lead site):

Submitting Department:

Initial Review Level:

HistoryFundingContactsTrainingDocuments

Filter by ⓘActivity▼Enter text to search for

Activity	Author
Study Created	Smith, John Doe

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.

OKCancel

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.

Pre-Review

Entered IRB: 9/28/2022 11:45 AM
Last updated: 9/28/2022 11:45 AM

Next Steps

[View Study](#)

[Printer Version](#)

[Assign Primary Contact](#)

[Assign PI Proxy](#)

[Manage Ancillary Reviews](#)

[Manage Guest List](#)

STUDY00002124: Ex

Principal investigator: John Smith

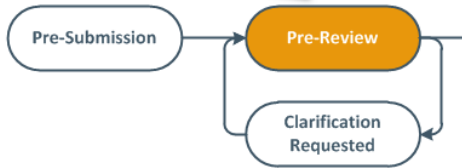
Submission type: Initial Study

Primary contact: John Smith

PI proxies:

Submitting Department: [Med-General](#)

Initial Review Level:



The protocol has now been submitted and removed from your “Dashboard.” It now displays in the IRB Analyst’s “Dashboard.”