

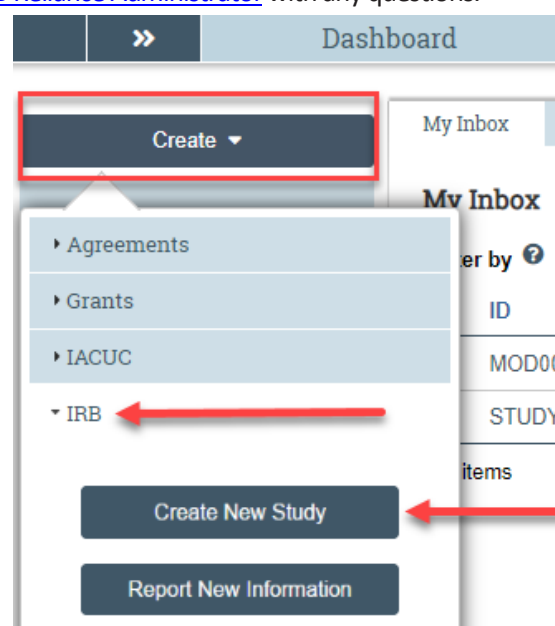
How to Request Reliance on an External IRB (Single IRB)

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. At UVM, this single IRB may be another, external institution or a commercial IRB (the UVM IRB does not act as the IRB of record for other study sites at this time). 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”.

 [Assign Primary Contact](#)

 [Assign PI 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.

Pre-Submission

Last updated: 10/21/2022 8:28 AM

Next Steps

Edit Study

STUDY00002127: External IRB

Principal investigator: John Smith
Lead principal investigator:
Submission type: Initial Study
Primary contact: John Smith
PI proxies:
PI proxies (Lead site):

IRB office: CHRMS (Medical)
IRB coordinator:
External study ID:

- On the first Smart Form page, called **“Basic Information”**: For External IRB Studies you must answer the following questions in the manner shown below. Don’t forget to upload the study protocol that has been approved by the External IRB and provided by the lead site. Continue to next page.

9. * Will an IRB, other than the UVM IRB, review and approve this study?

☒ Yes ☐ No [Clear](#)


Please note that in most cases this answer will be "No." This question only p
UVM IRB approval to rely is necessary. If you are unsure, please contact you
once it has been submitted.

10. * What kind of study is this?

☒ Multi-site or Collaborative study

☐ Single-site study

[Clear](#)

- On the Smart Form page called **“Basic Local Site Information”**: 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. If the local site will participate in all protocol-specified activities, simply enter **“All.”**
- On the Smart Form page called **“External IRB”**: 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 [IRB Reliance Administrator](#). In Question 3, please provide justification for using a Single IRB for review, using the help text as guidance. “  ”
- 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 FPXXXXXXX) in the appropriate location.

Funding Sources

1. * Funding Sources:

Funding Source	Funding Source Category	Sponsor's Funding ID	UVMClick Funding Proposal FP#
National Institutes of Health/NIH	Government Agency		FP12345678

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.

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. ?

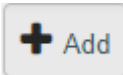
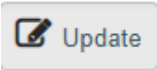
If you are not the PI, remember to add yourself here

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

****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 follow link for instructions: [Students – How to Sign Up to do Research at UVM \(PDF\)](#)
 - All key personnel need a UVM Net ID in order to be added to the study team. Please follow link for request form: [Request for UVM Net ID form \(DOC\)](#).
 - Please note, if you are trying to add key personnel who are not affiliated with UVM/UVMHN, see [Section 13.10 of the Policies and Procedures Manual](#) about Collaborating Community Partners, and contact the [IRB Reliance Administrator](#) to determine if an Individual Investigator Agreement is required.
8. On the Smart Form called "Study Scope": complete all questions. For Question 8, be specific about the local plan for recruitment, as the description likely won't be adequate in the protocol provided by the lead site.
9. On the Smart Form called "Research Locations": please add only locations relevant to our UVM/UVMHC site.
10. Complete the Smart Forms 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:

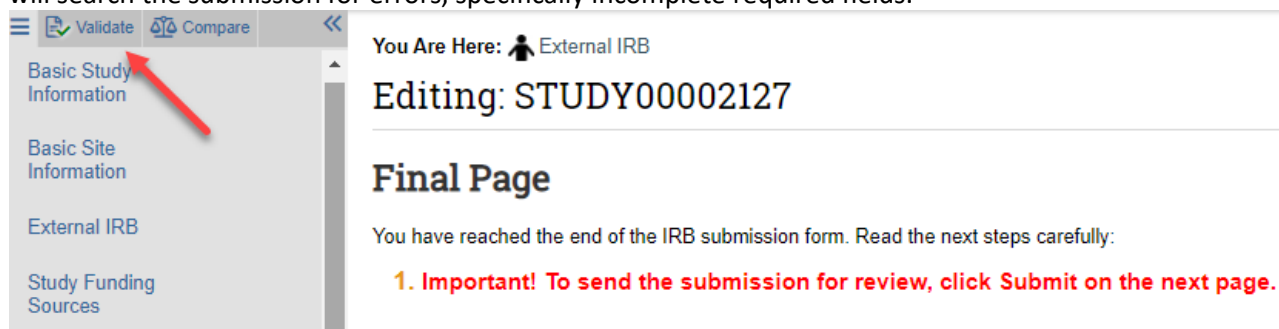
12. * Attach the protocol:

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

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

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


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.

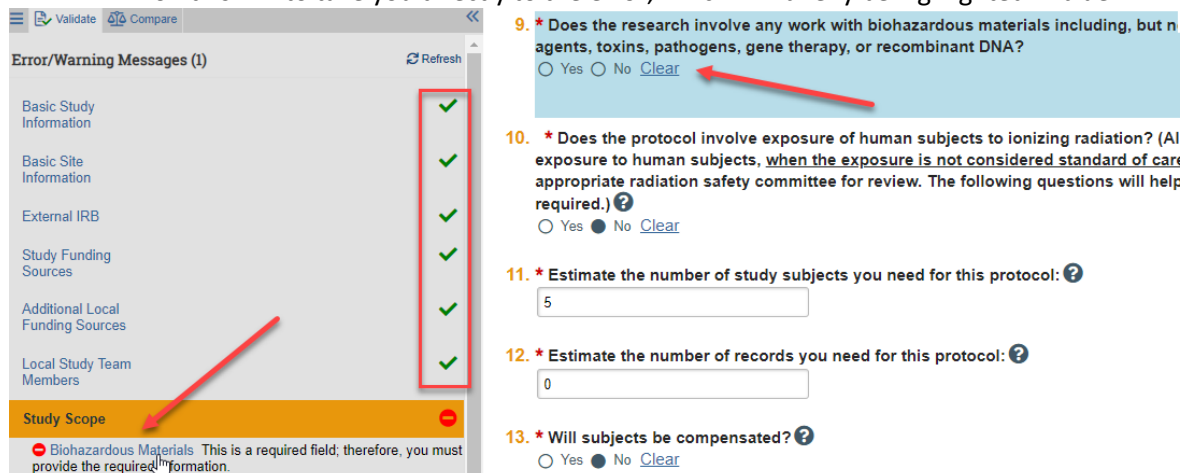


The screenshot shows the 'Final Page' of the IRB submission form. On the left sidebar, the 'Validate' button is highlighted with a red arrow. The main content area shows 'You Are Here: External IRB' and 'Editing: STUDY00002127'. Below this, it says 'Final Page' and 'You have reached the end of the IRB submission form. Read the next steps carefully:'. A red instruction box states: '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.



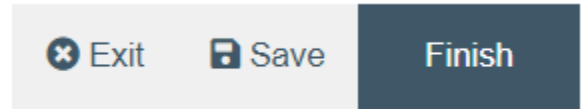
The screenshot shows the 'Error/Warning Messages (1)' section on the left sidebar, which is highlighted with a red arrow. The main content area displays a list of questions with their validation status. Questions 9, 10, 11, 12, and 13 are marked with green checkmarks, while question 13 is marked with a red error sign. A red arrow points to the 'Clear' link next to question 9. The error message for question 13 states: 'Biohazardous Materials This is a required field; therefore, you must provide the required information.'

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 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.**



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.

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

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

ActivityAuthor

Study CreatedSmith, 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.

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 for review.

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

Pre-Review

Entered IRB: 10/21/2022 11:41 AM
Last updated: 10/21/2022 11:41 AM

Next Steps

View Study

Printer Version

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: Med-General
Initial Review Level:

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 our IRB website <https://www.uvm.edu/rpo/uvmclick-irb-forms-library>

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. **Required forms specific to External IRB studies are highlighted in yellow.**

Basic Information page:

- **Protocol approved by External IRB**

Funding Sources page:

- Grant Applications – from UVM/UVMHN only

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 [“Consent/HIPAA Checklist for Required Language \(DOCX\)”](#))
- 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 to be used locally**

3. Other Attachments

- **Request to Rely Form**
- **Local Context Form** (if required by External IRB)
- **Reliance Agreement** (if not using SMART IRB)
- **Data Management and Security Plan**
- **Study/Lead Site 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)
- DSMB Reports
- Privacy Policies for Apps and Databases
- Surveys and questionnaires
- Letters of support
- Participant Study Brochures & Wallet Cards