

How to Request Reliance on Another IRB (External IRB)

Requests to rely upon another IRB must be submitted through UVMClick-IRB. These are referenced in Click as External Studies.

You can request to rely on another IRB by entering information into a series of online forms. The number of forms included may change based on the answers you provide. The 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 Manual.

To create a new external 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.

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

****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.

****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.) You can change the primary contact by clicking the activity on the left side of the screen called “Assign Primary Contact”.



External reliance includes at a minimum two institutions, typically a reviewing IRB and multiple IRBs relying on that one IRB, therefore, UVMClick-IRB produces two records. One record is the overarching External Study and the second record is a specific site(s). You will be filling out the necessary forms for each.

External IRB **STUDY00000017: External Study**

Initial approval:
Approval end:
Last updated: 11/2/2018 10:03 AM

Lead principal investigator: System Administrator
Local site: SITE00000002

External IRB: Chicago Area Institutional Review Board
External IRB approval letter: IRB Approval(0.01)
Regulatory authority:

Next Steps: External IRB → Closed

Post-Review **SITE00000002: Site for External Study**

Entered IRB: 11/2/2018 10:09 AM
Last updated: 11/2/2018 10:11 AM

Principal investigator: System Administrator
Submission type: IRB Site
Primary contact: System Administrator
PI proxies:

IRB office: CHRMS (Medical)
IRB coordinator:
Study: STUDY00000017
External study ID:

You can toggle between the two using the links indicated.

3. On the first SMART form page called “Basic Information

For External Studies you must answer all of the required fields and specifically the following questions in this manner. Don’t forget to upload the protocol that has been provided by the lead site. Continue to next page.

8. * Will an external IRB act as the IRB of record for this study?
 Yes No [Clear](#)

9. * What kind of study is this?
 Multi-site study (More than one site will conduct the entire study)
 Collaborative study (each site will conduct a portion of the study)
 Single-site study
[Clear](#)

10. * Attach the protocol:
 (e.g. industry protocol, human subjects protocol, exempt form, or not hur will be uploaded in a separate section) ?

Document	Category	Date Modified
There are no items to display.		

- For External IRB page of the SMART form page only the first field requires completion, all others can be disregarded. Continue to next page.
- Complete the Funding Sources and Study Scope pages and continue.
- Please use the guidance below to correctly complete the Study-Related Documents page.

Study-Related Documents

1. **Consent form templates:** (include an HHS-approved sample consent document, if applicable)

+ Add				
Document	Category	Date Modified	Document History	
Update Local Consent with Required Language(0.01)	Consent Form	11/2/2018	History	
Update Template from Chicago(001)	Consent Form	11/2/2018	History	

At the time of initial submission we would want to see the consent template. The local version can be submitted later.

2. **Recruitment material templates:** (add templates for all material to be seen or heard by subjects, including ads)

+ Add				
Document	Category	Date Modified	Document History	
There are no items to display				

attach if any will be used locally

3. **Other attachments:**

+ Add				
Document	Category	Date Modified	Document History	
Update Information Sheet.docx(0.01)	Information Sheet	11/2/2018	History	
Update Data Management and Security Plan form.docx(0.01)	Data Management Form	11/2/2018	History	
Update Reliance agreement if not SMART IRB.docx(0.01)	Contract/Agreement	11/2/2018	History	

as applicable
required form
only required if the site is not using SMART IRB

7. When you reach the final page, click **Finish** to exit the study. You have successfully created a request for reliance, but it is not ready to be submitted yet.

8. Open the new SITE record as indicated below to enter some site specific information. Click on Edit Study once you are in the site record.

STUDY00000018: External IRB data entry.

Lead principal investigator: Donna Silver
Local site: SITE00000003

External IRB: Chicago Area Institutional Review Board
External IRB approval letter:
Regulatory authority:

Pre-Submission SITE00000003: Site for External IRB data entry.

Last updated: 11/2/2018 1:14 PM

Principal investigator: IRB Site
Submission type: IRB Site
Primary contact:
PI proxies:

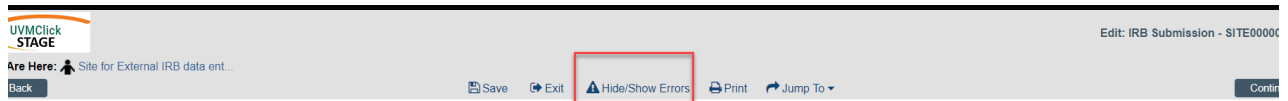
IRB office: CHRMS (Medical)
IRB coordinator:
Study: STUDY00000018
External study ID:

Next Steps

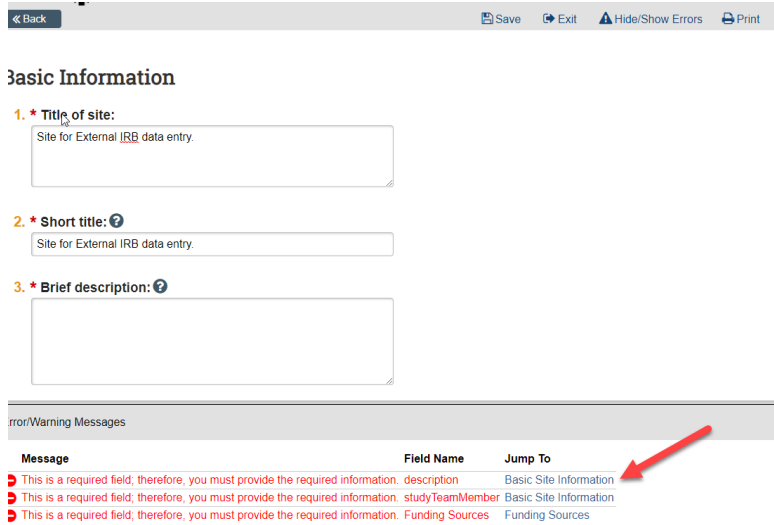
- Edit Site
- Printer Version
- View Differences

Assign Primary Contact

Click on Hide/Show Errors and complete only those additional items.



Below is a picture of what you will see. The fields at the bottom are what you need to complete to finish data entry on this External Study. **There will be many fields that are blank, however these have already been capture under the overarching study. You only need complete the required fields as displayed by the hide/show errors tab.** Click on each blue hyperlink to get to the field that requires completion and then click on Save back at the top of the page.



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.

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

A screenshot of the 'Pre-Submission' activity page for STUDY00000040. The page shows the study status as 'Pre-Submission' and provides details about the principal investigator, submission type, primary contact, and submitting department. A flowchart shows the process from 'Pre-Submission' to 'Pre-Review' and 'Clarification Requested'. A red box highlights the 'Submit' button in the 'Next Steps' section, with a red arrow pointing to it.

Pre-Submission
Last updated: 9/5/2018 2:44 PM

STUDY00000040

Principal investigator: System Administrat
IT Administrator

Submission type: Initial Study

Primary contact: System Administrat

PI proxies:

Submitting Department: Huron Consulting, Ir

Next Steps

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

Flowchart: Pre-Submission → Pre-Review, Clarification Requested

History: Funding, Contacts

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.

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**.

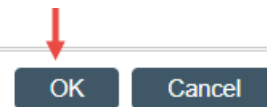
Submit

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.



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

STUDY00000040:]

Entered IRB: 9/10/2018 1:05 PM
Last updated: 9/10/2018 1:05 PM

Principal investigator: System Administrator
IT Administrator

Submission type: Initial Study

Primary contact: System Administrator

PI proxies:

Submitting Department: Huron Consulting, Inc

Next Steps

View Study

Printer Version

View Differences

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graph LR
    A[Pre-Submission] --> B[Pre-Review]
    A --> C[Clarification Requested]
    
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The protocol has now been submitted and removed from your “My Inbox.” It now displays in the IRB Office “My Inbox.”