Contents

Research Enterprise Solutions (RES) - IRB User Guide

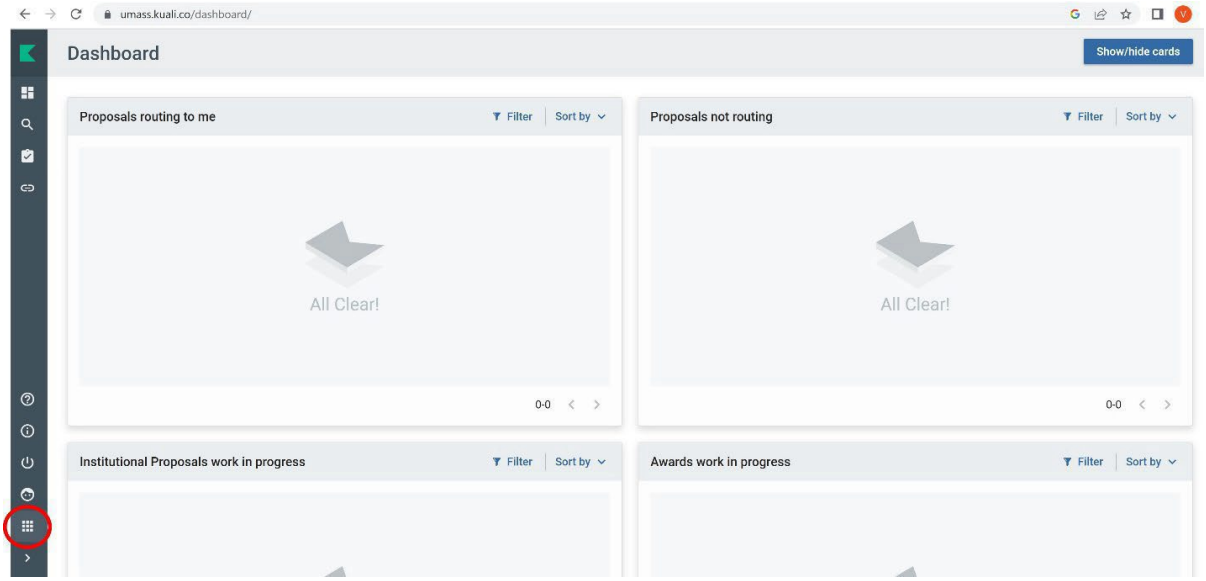
The Research Enterprise Solutions (RES) IRB module streamlines the development of protocols and facilitates best practices in protocol management throughout the research lifecycle. RES facilitates fast, clear, and specific communication between the IRB, researchers, and the Human Research Protection Office, to ensure efficiency and compliance. REs is designed to be intuitive – the simple interface design should allow researchers to quickly create and manage protocols. Some key features of the RES system include:

- **Auto saving** of your progress – no need to click "Save" since the system autosaves every few seconds
- **Drag and drop** functionality – when file uploads are required, researchers have the option of dragging and dropping files or navigating to their location on their computers
- **Built-in logic** (smart form) – the protocol adapts depending on your answers to some questions; for example, if your study uses HIPAA data, additional HIPAA-relevant questions are triggered
- **One form** for Exempt, Expedited, and Full Board studies
- **Attachment** of requested documents in their relevant sections
- **Targeted IRB comments** in their specific sections identifying issues in that section
- **Integration with other systems** – no need for an IRB-specific login account; use your RES ID and password for integration with the human subjects training CITI records, integration with the grants and proposal management RES modules, and future integration with conflict of interest RES module
- **Newly revised Reportable Events section** (Unanticipated Problems, Serious Adverse Events, Incidental Findings)

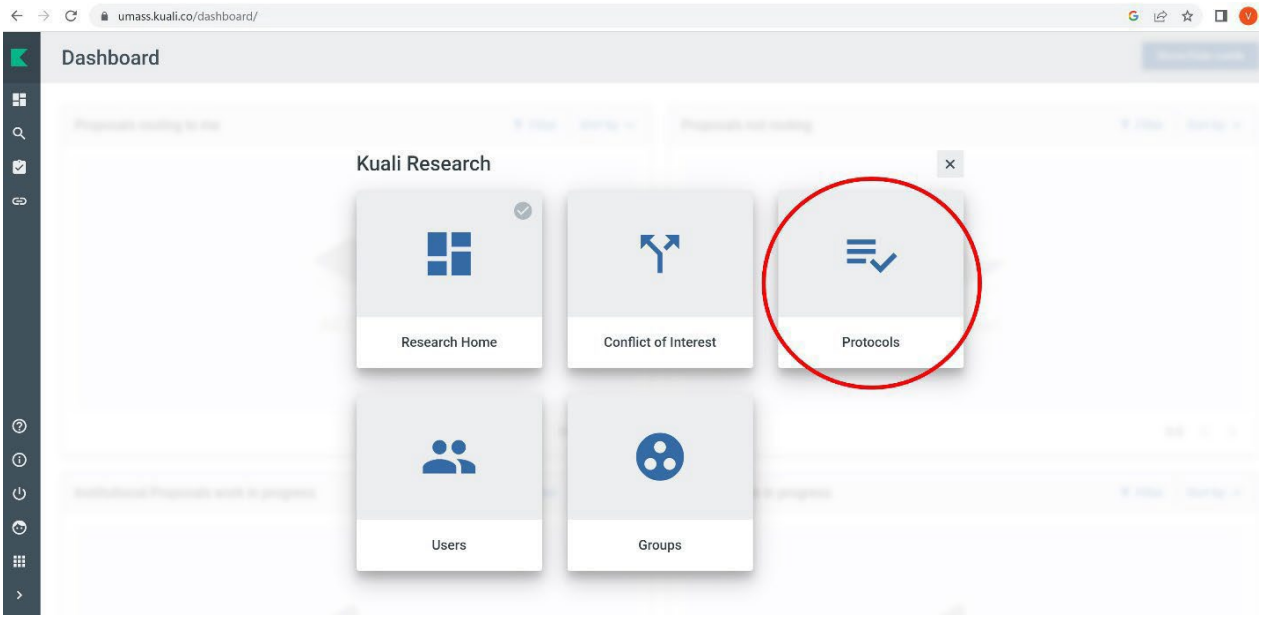
Creating a New IRB Protocol

Log into Research Enterprise Solutions using your RES ID and password.

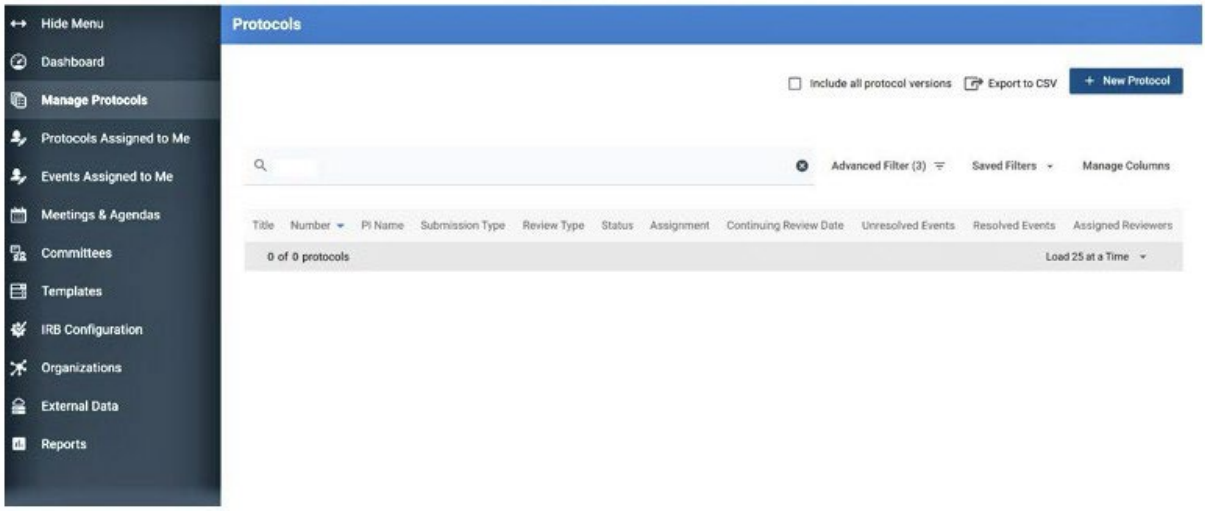
Once logged in, Select Switch Apps on the lower left margin.



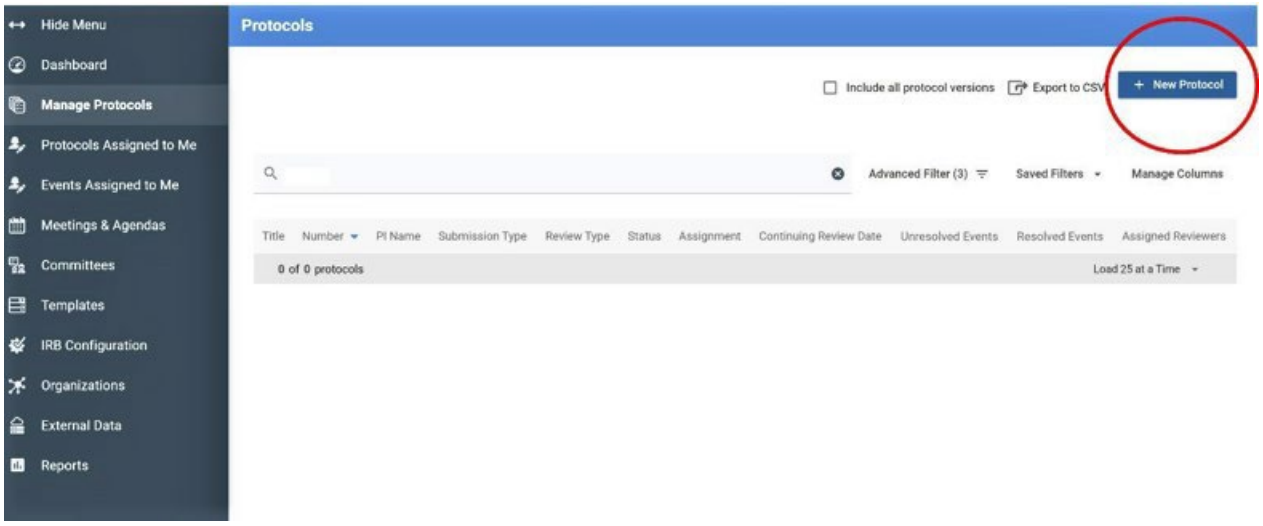
Select the tile called Protocols.



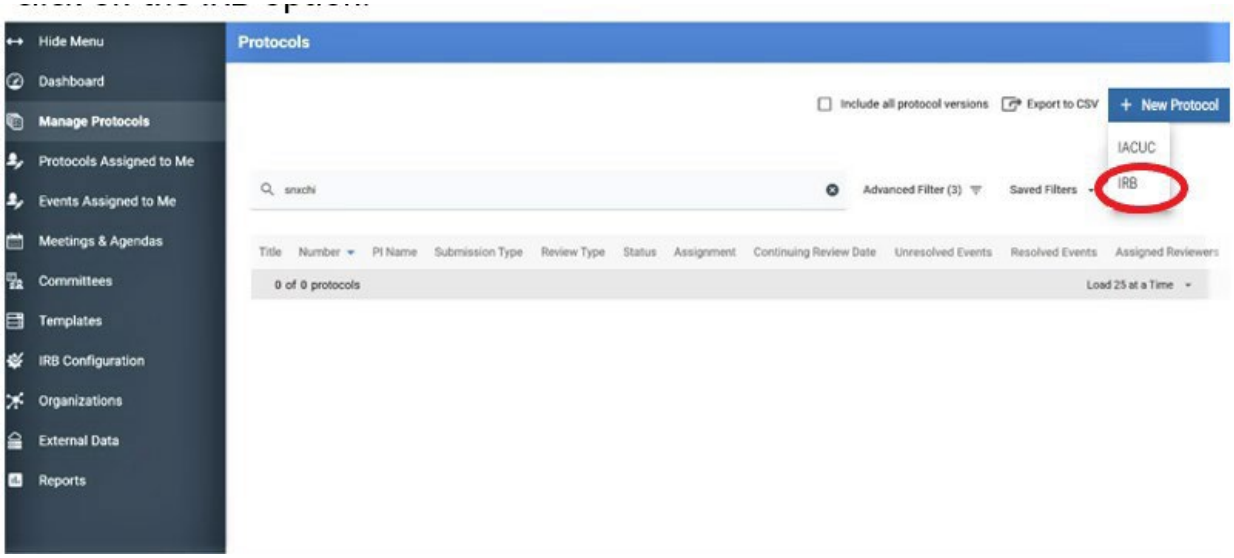
You will see a dashboard that looks like this:



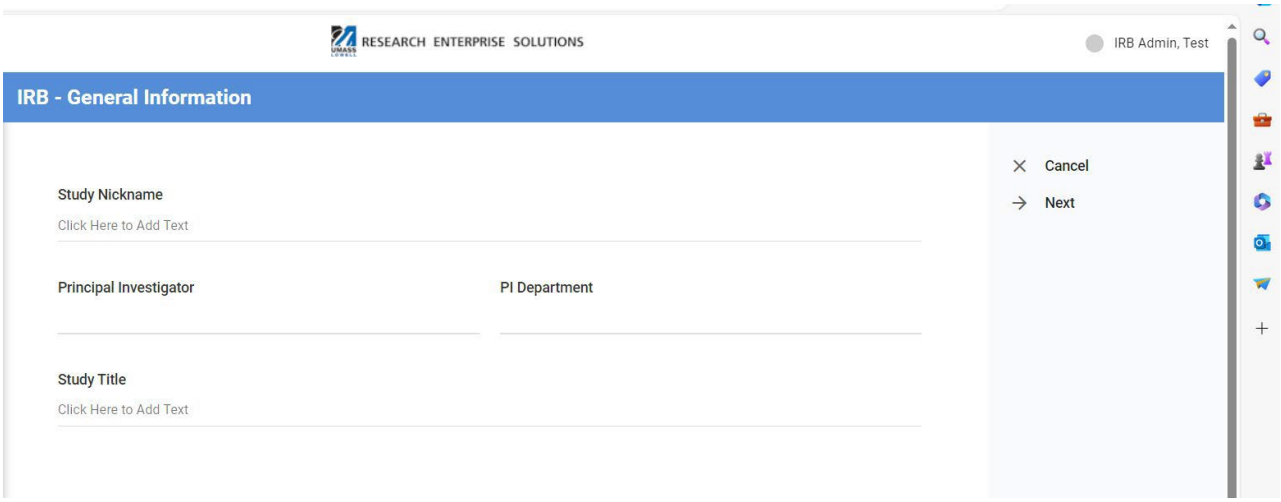
Note the option on the far right to create a new protocol, click the **+New Protocol** button:



Clicking on the **+New Protocol** button will trigger a small pop-up, click on the IRB option.

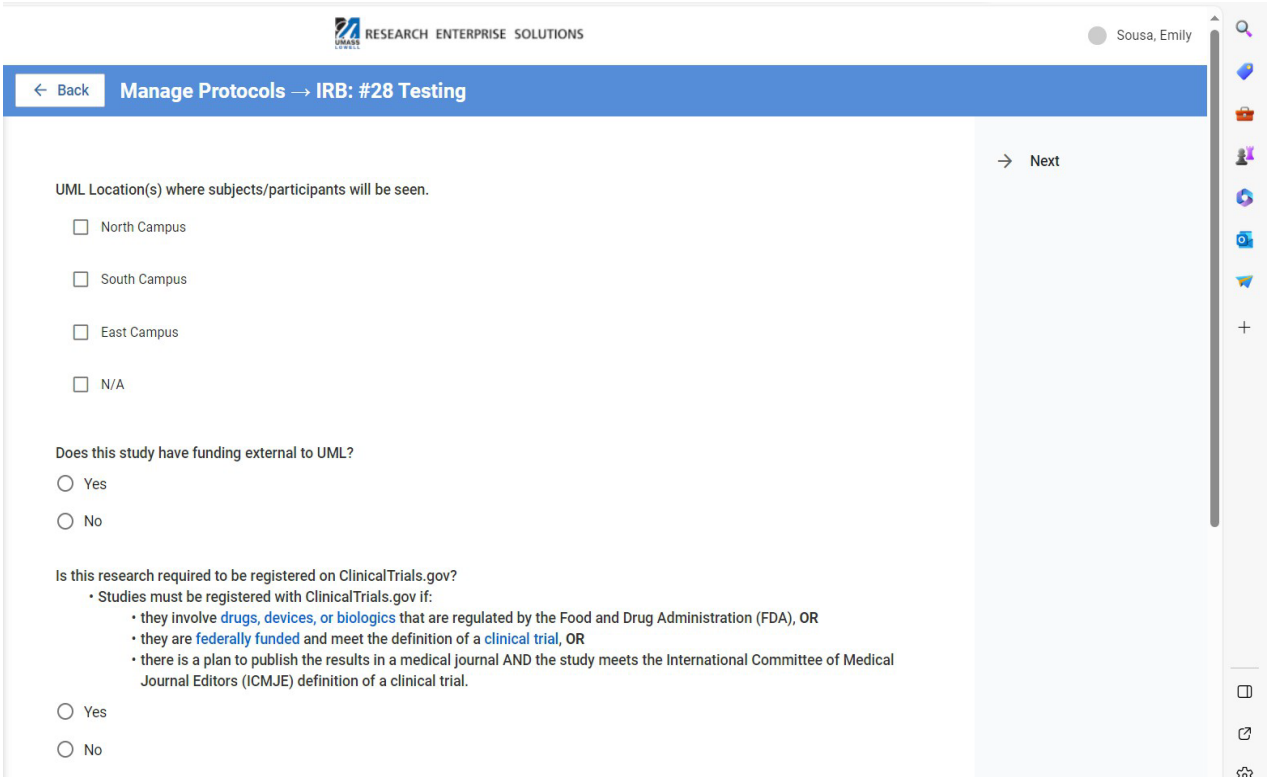


Enter the Study Nickname, Principal Investigator (only faculty can serve as PI's, students are listed as research personnel in another screen). Enter PI Department if it does not automatically populate and the Study Title. Click

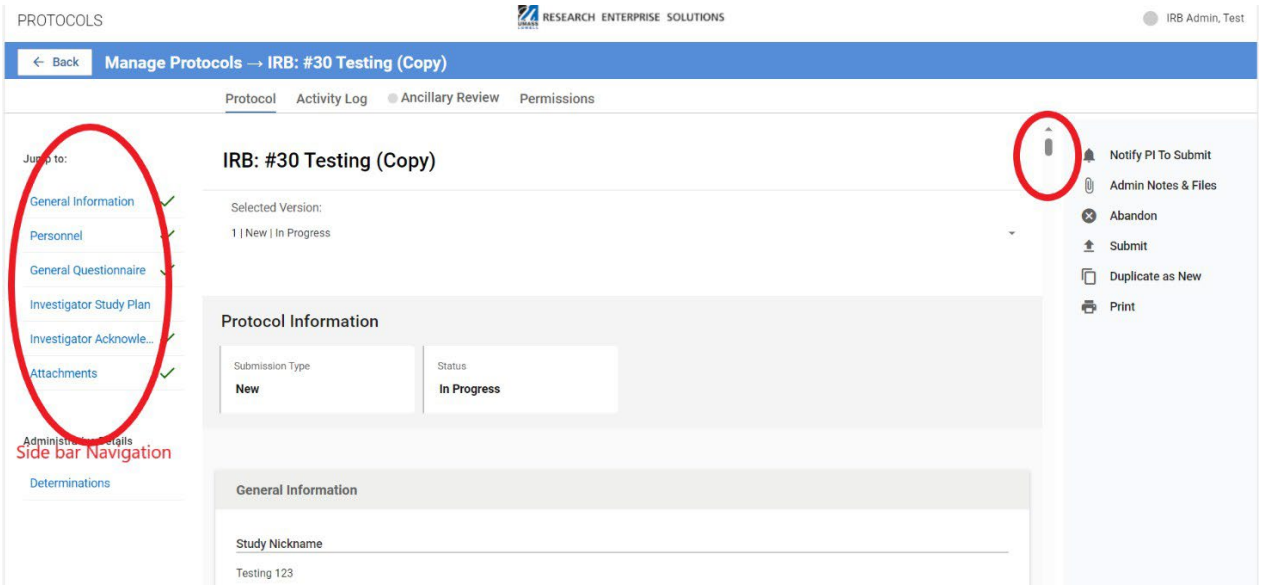


"Next" in the upper right corner.

The RES system will then proceed to ask a couple of general questions, location of where subjects will be seen, funding, etc. Click "Next" when all questions have been answered.



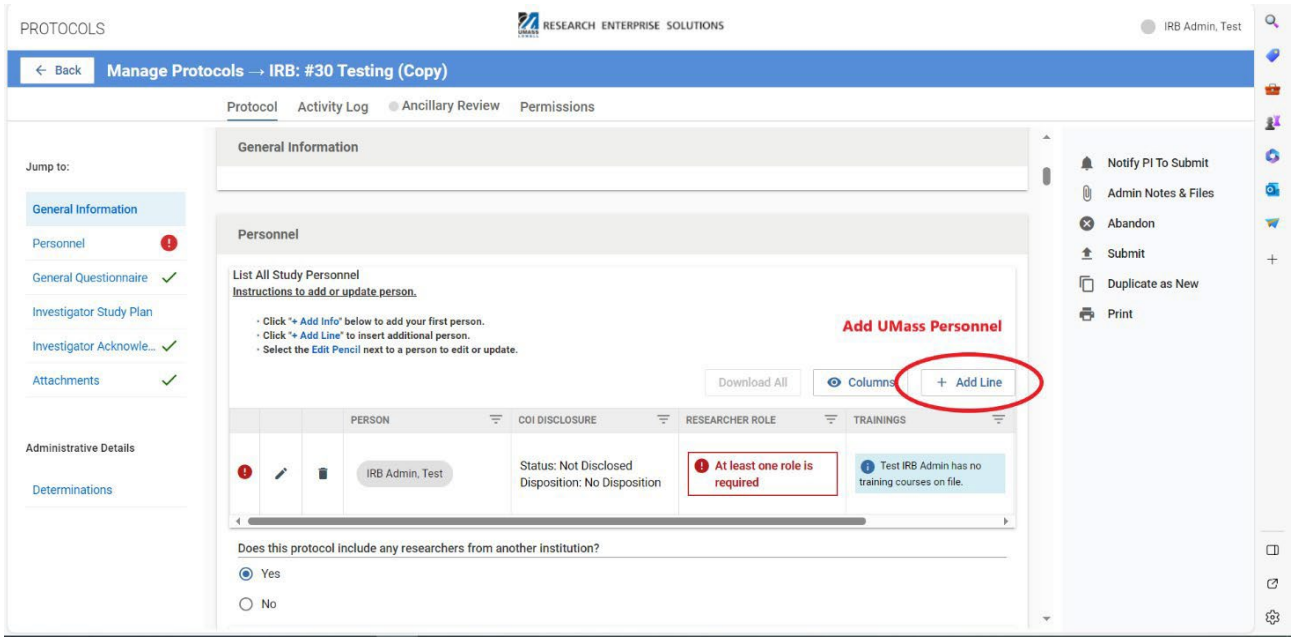
After answering the questions on the previous screen, you will be taken to a single scrollable page that contains the entirety of the protocol. On the left- hand side of the screen you will see a sidebar listing all the sections of the protocol. No matter what section of the protocol you are in, you can use this sidebar to quickly navigate to another section.



Adding Study Personnel, Locations, and Funding

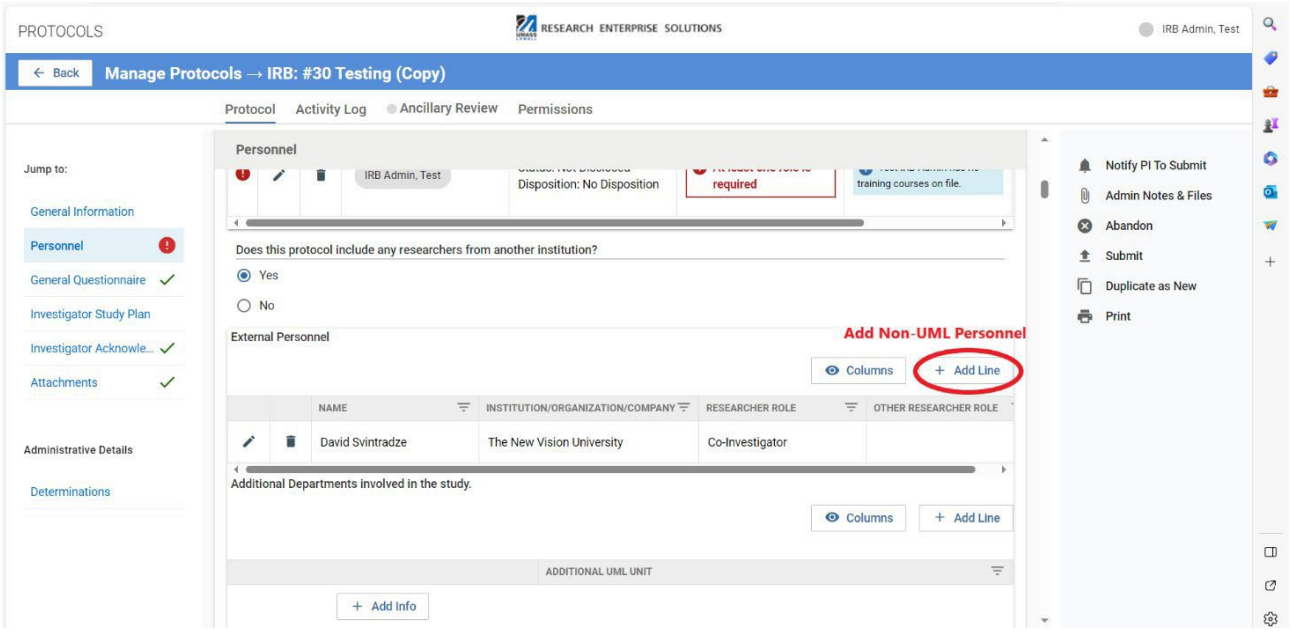
If you need to include additional personnel, scroll down and click on the **+ Add Line** button in the Personnel section. If the personnel you're adding are not affiliated with UMass Lowell, click on the **+ Add Line** button under the External Personnel section.

NOTE: Your CITI certificate will automatically appear as long as your CITI account is linked to your UML SSO. For directions on linking your CITI account, visit:
https://www.uml.edu/research/integrity/training/citi.aspx

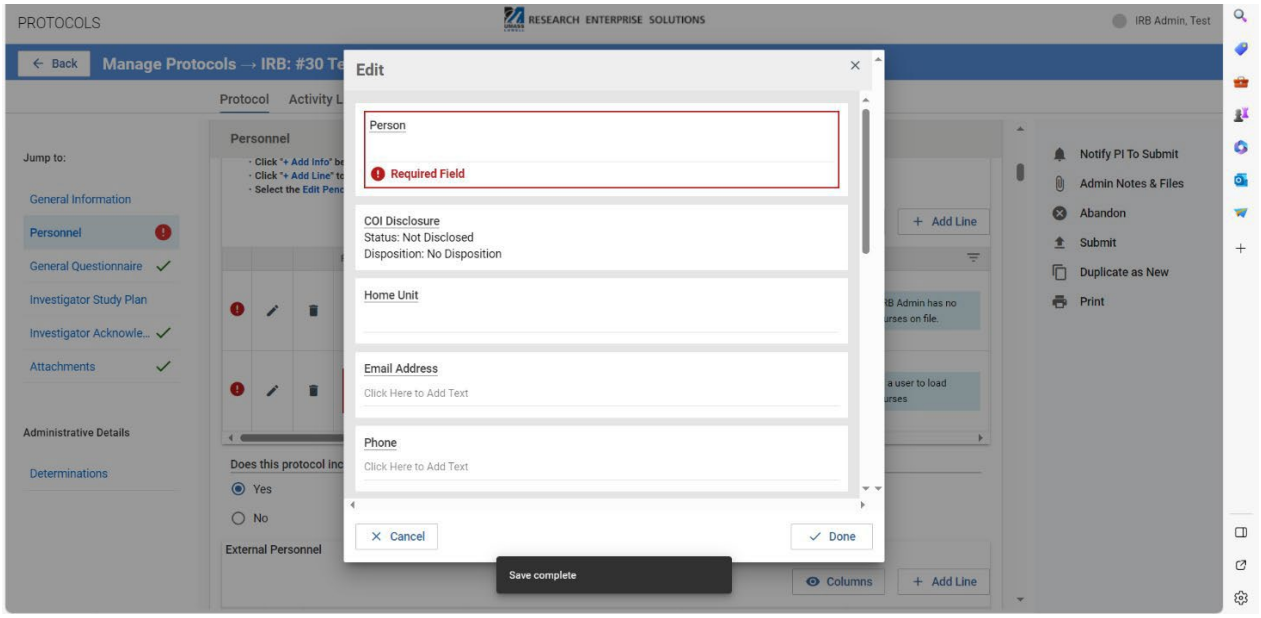


Adding UMass Personnel:

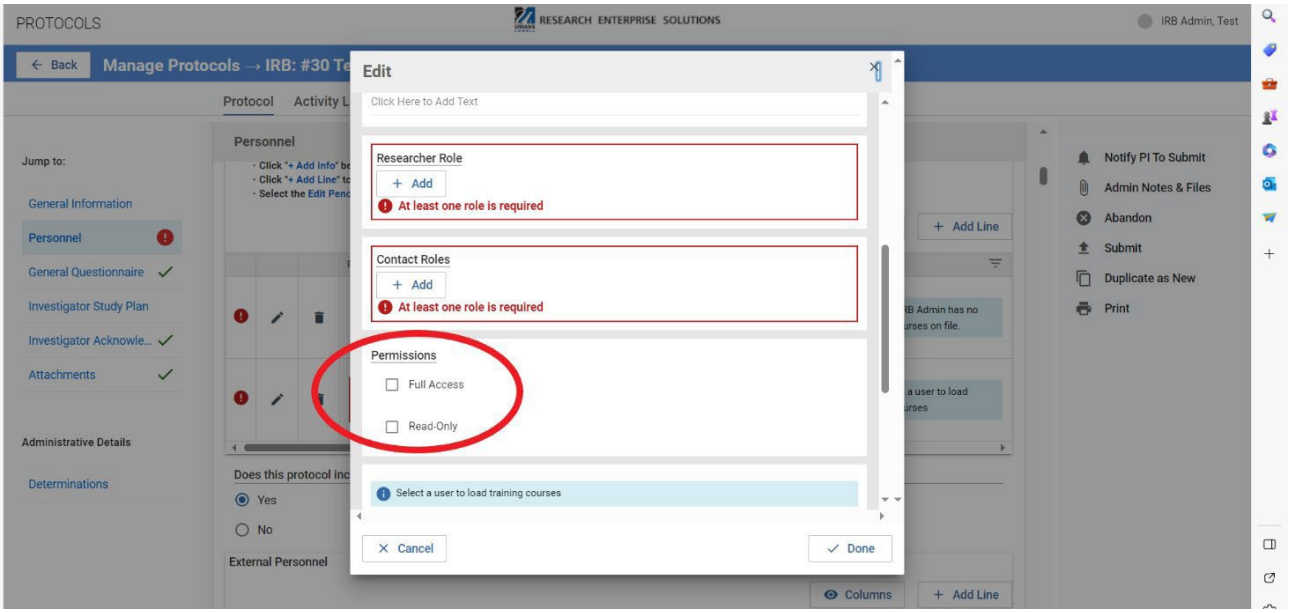
Adding Non-UMass Personnel:



Be sure to fill out the red sections in this pop-up box - these are required and without them, the protocol will malfunction when you hit "Submit."
You can also assign protocol permission-level for that particular individual.



Those issued Full Access will be able to edit the protocol.



Next, please indicate if any personnel listed on this protocol or their Immediate Family have a financial conflict of interest related to the research.

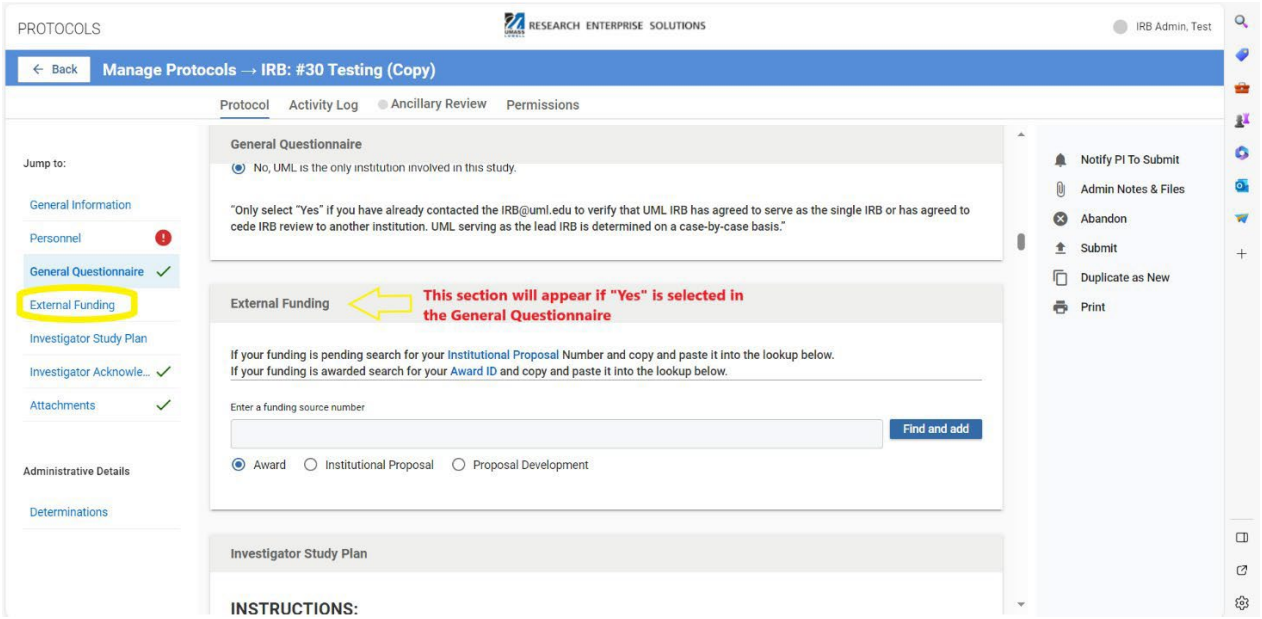
You will review your answers to the general questions asked earlier regarding funding, location of where subjects will be seen, etc.

If your funding is pending search for your Institutional Proposal Number and copy and paste it into the lookup below.

If your funding is awarded search for your Award ID and copy and paste it into the lookup below.

When searching for an Institutional Proposal or Award ID, click the hyperlink and you can find it using the PeopleSoft number. Copy and paste the PeopleSoft number into the "Account ID" field and click search.

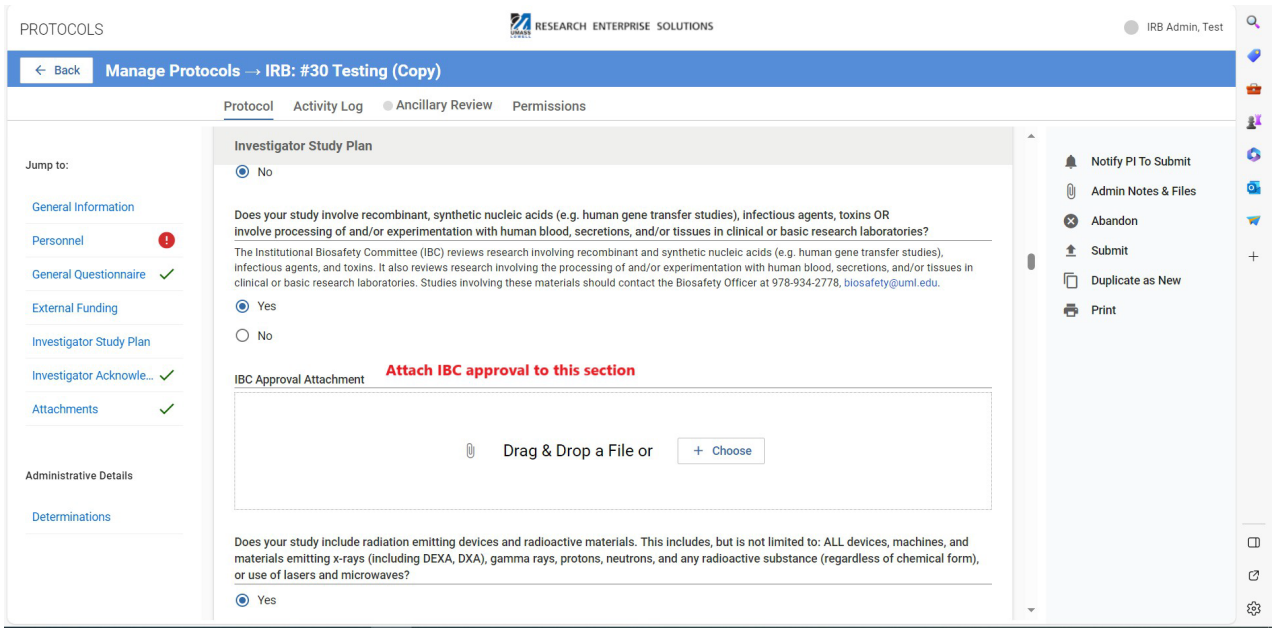
To help search for IPs and Awards by title, you can use wildcards. These are represented as "*" asterisks and by placing them around a word, it will search for that word anywhere in the title. For example, if you type "*Tech*" into the Award or IP title field, it will show you all results that have the word Tech in the title, including when its part of the word Technology.



Investigator Study Plan

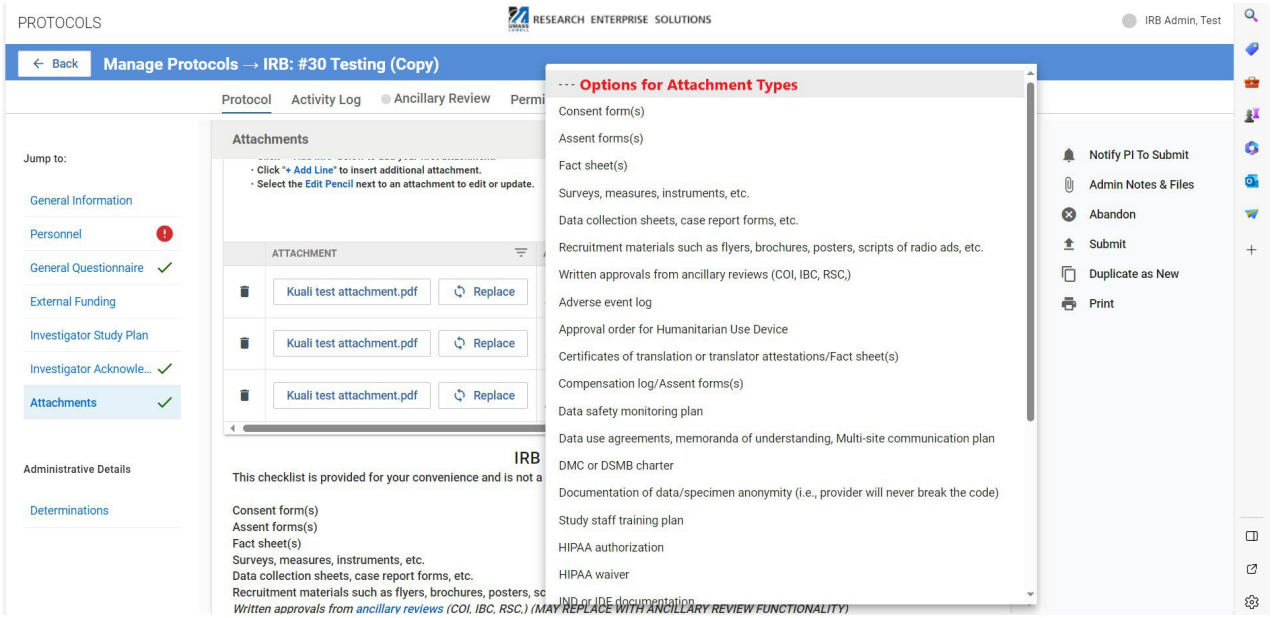
The Investigator Study Plan will collect information about the research background, objectives, outcomes, recruitment, consent, data analysis and
confidentiality measures. It is the HRP-504 form with additional questions.

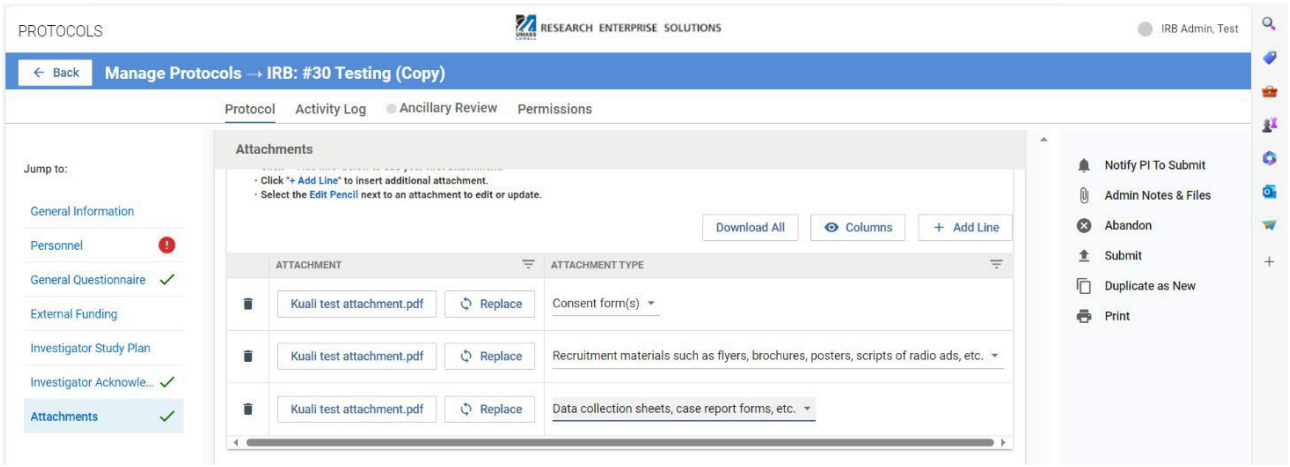
The first section consists of "Yes" or "No" questions. For those questions which "Yes" is answered, there are sections to upload applicable materials, e.g. IBC approval.



After you have checked the boxes in the "Investigator Acknowledgement" Section, you will proceed to the "Attachments" section. In this section you will upload all supporting documentation e.g., recruitment materials (flyers, emails, SONA posting, Prolific/MTurk "HIT" descriptions, verbal scripts, etc.), consent/assent forms, data collection materials (surveys, questionnaires), HIPAA Authorization/Waiver of Authorization (if applicable). Clicking on **+Add Line** will allow you to add materials. Do not submit all materials in one attachment, separate the attachments as Word documents and add the applicable "Attachment Type".

Uploading Attachments

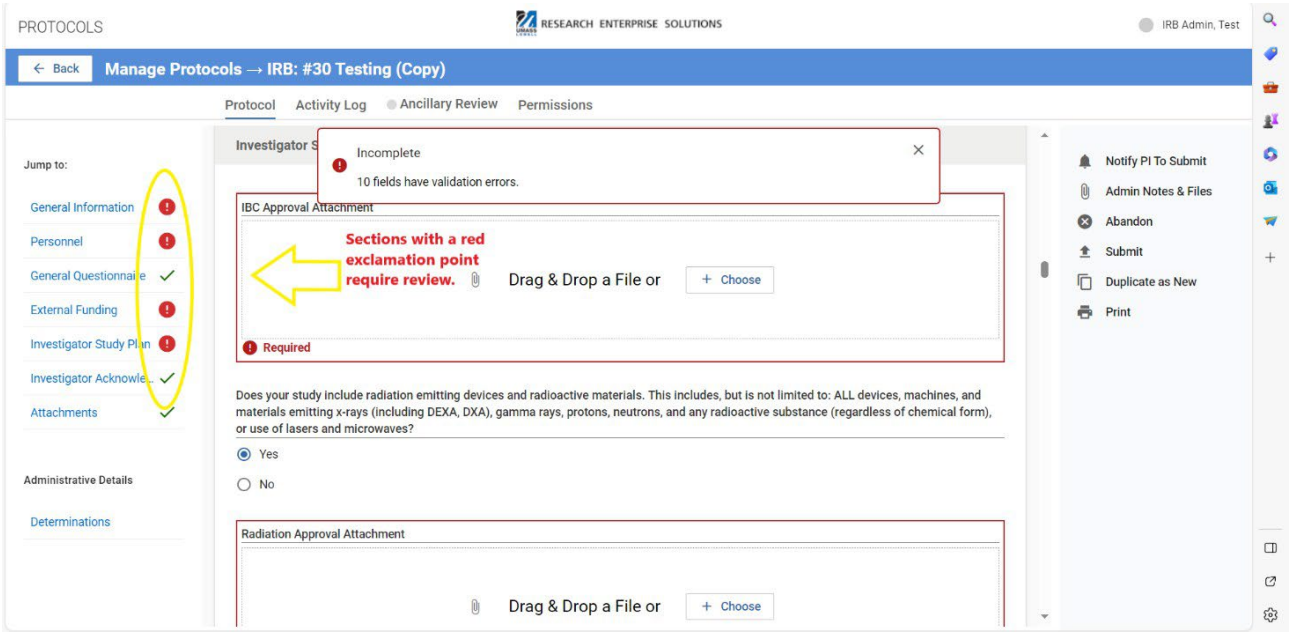




If you need to replace a document, click the "Replace" button and upload the revised/ correct document.

Submitting a Protocol

Once you're ready to submit the protocol, clicking the Submit button will let you know whether any required fields have been left unanswered (for example, see the red rectangle messages below). Only the PI is able to "Submit" the Protocol.

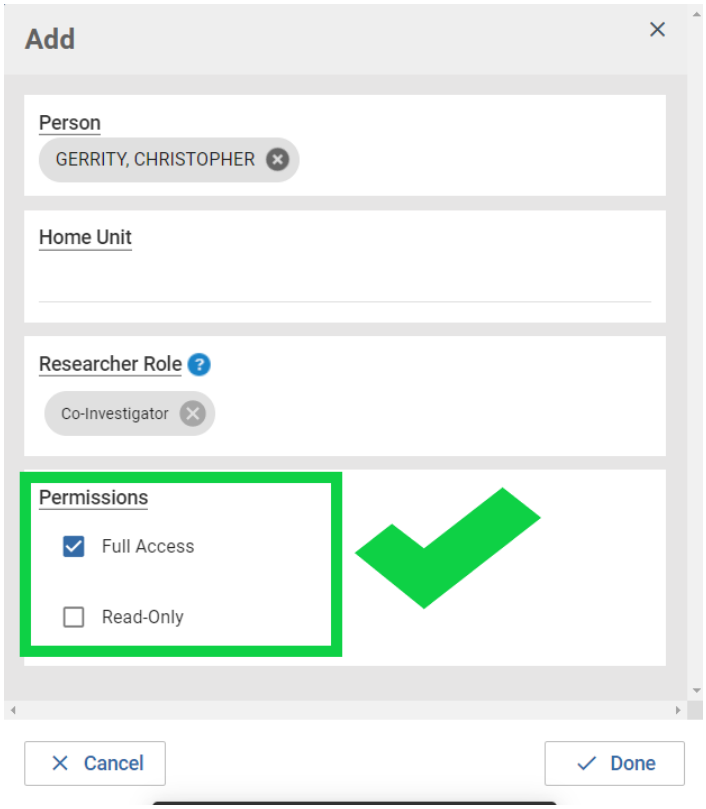


Additionally, scrolling through the protocol, you will see highlighted in red the section(s) in question. Answer all required questions – only then will the system allow you to Submit the protocol for review.

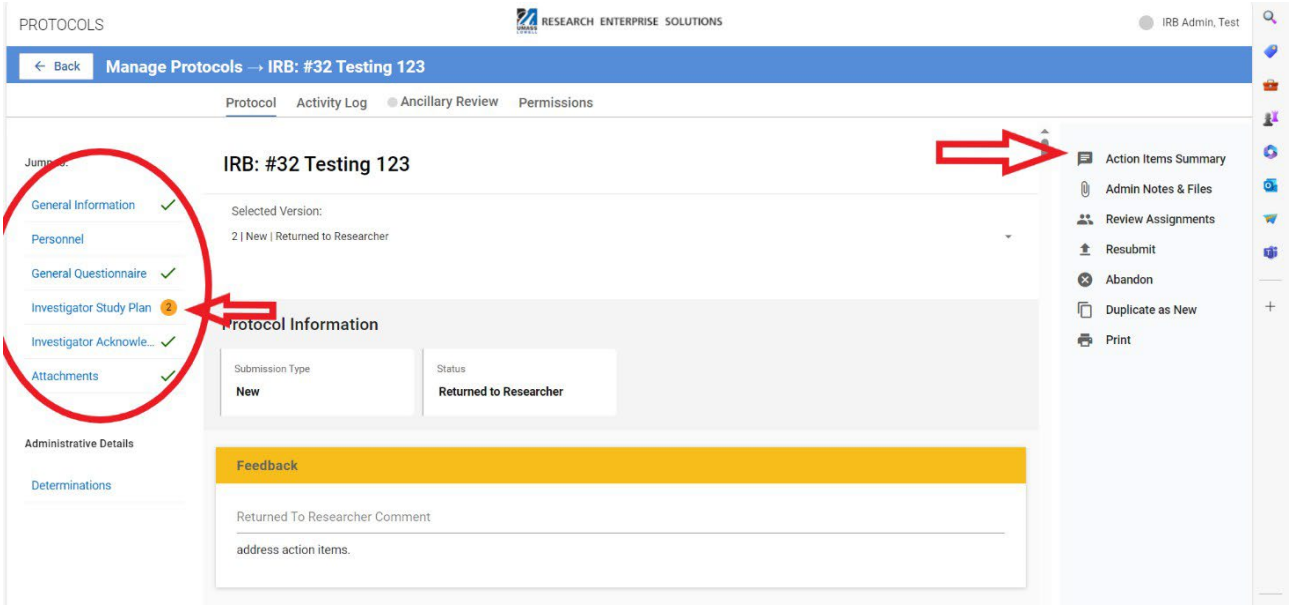
How to Address Action Items

After submitting an application, the IRB Office will conduct the review and may assign "Action Items" to sections with questions about answers or require updates or revisions. The study team will receive a notification that the IRB reviewer requires revisions. The research team member can either log directly into the protocol from the link in the notification email or log into RES IRB and access the protocol from their Manage Protocols Screen.

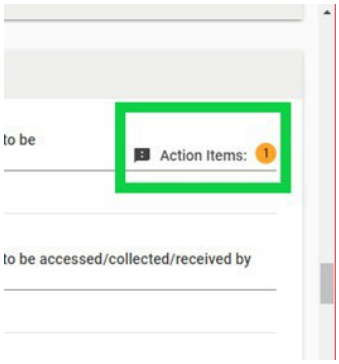
Important: Study Personnel permissions must be set to "Full Access" only. Please make sure to un-check the system default of "Read Only".



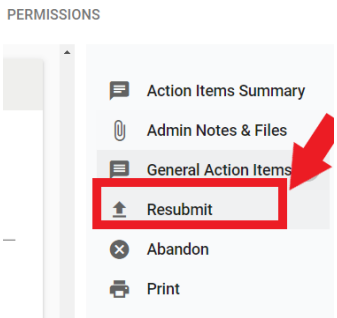
Once you've logged in and accessed the protocol requiring revisions on the screen you may have a "Feedback" comment and you will see one or more yellow circles with a number on sections in the navigation column on the left hand side of the screen (Red Box below). These are the sections that require revisions. You can also access a summary of the action items by clicking "Action Items Summary" on the right hand side.



Within that section, you will find the words "Action Items:" with a yellow circle and number (Green Box below). You can click on those words to open the comment(s) from the IRB reviewer on the right side of your screen (Red Box below):

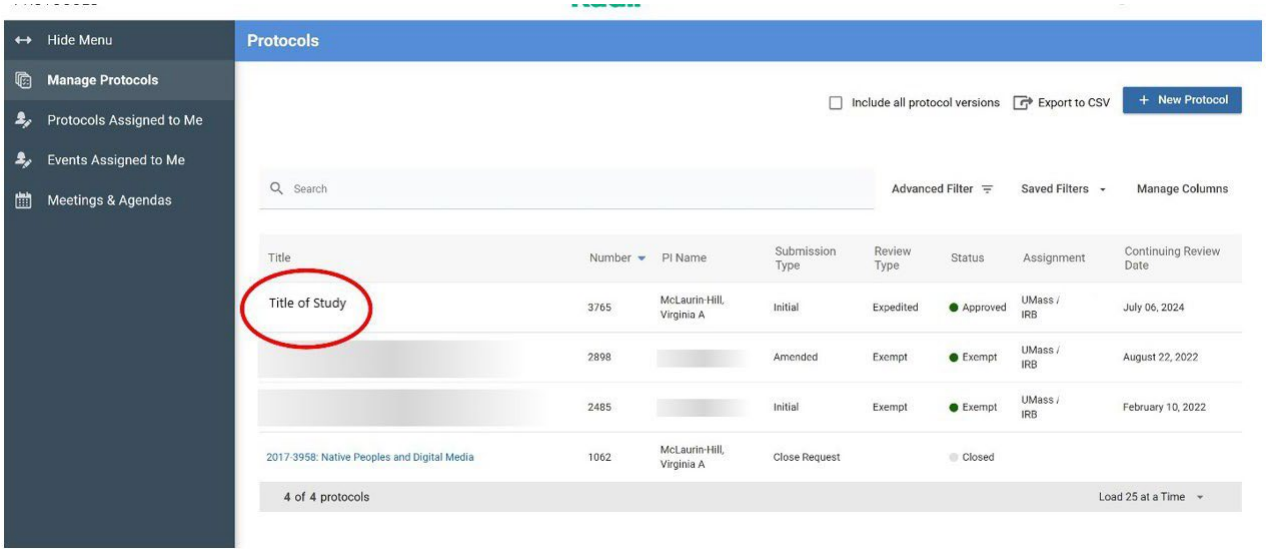


After responding to all "Action Items" or "General Action Items" and performing all requested updates, changes or corrections you can Resubmit your application by clicking the button in the top right (Red Box & Arrow below).

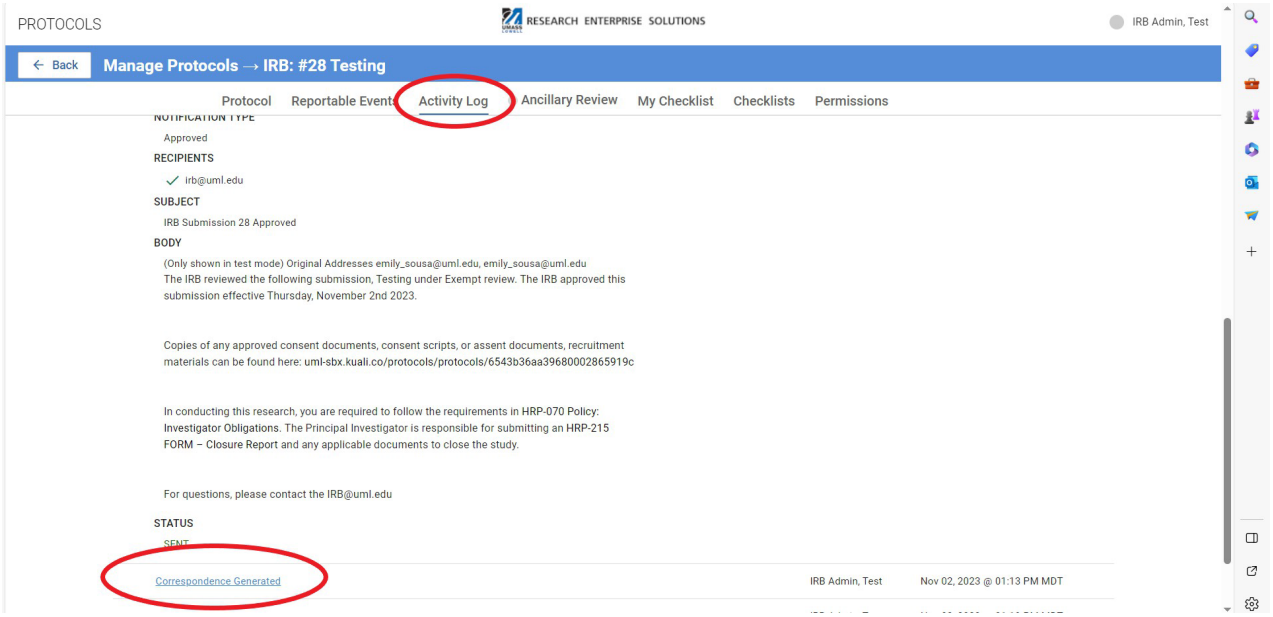


How to Access Your Approval Letter and Approved Documents

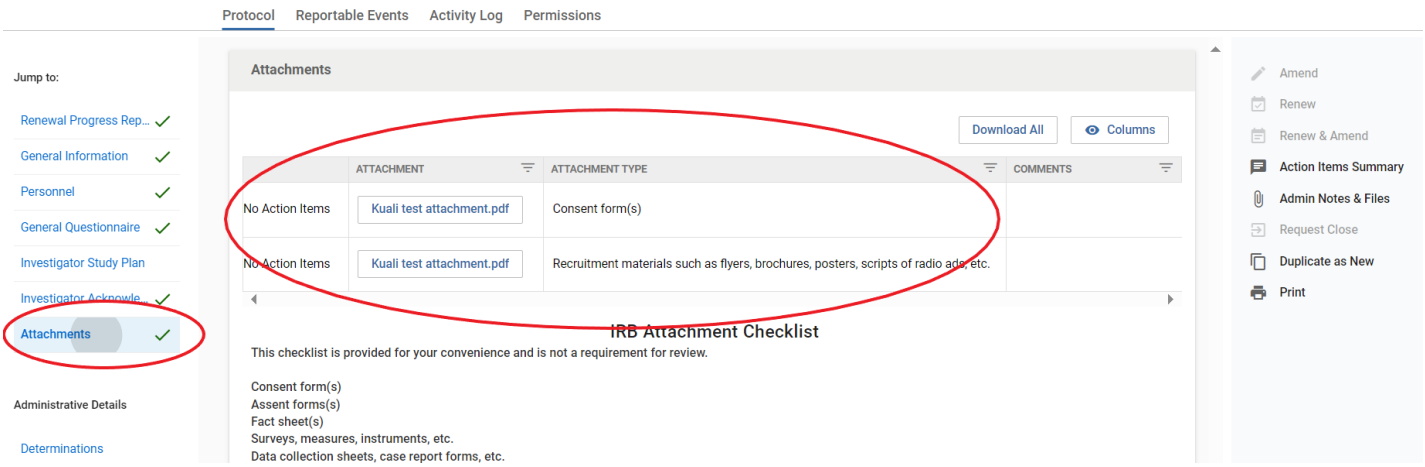
Log in to your RES IRB via the email notification received or via the IRB Res Dashboard and click on the title of the approved protocol for which you want to access the Approval Letter.



Once you've opened the protocol, click on the **Activity Log** on top of the screen. This page will show you all the actions taken. Scroll all the way to the bottom of the screen and here you will see "Correspondence Generated". This link will open a new tab and your approval memo can be printed using "Ctrl P" and then saving the document as a pdf.



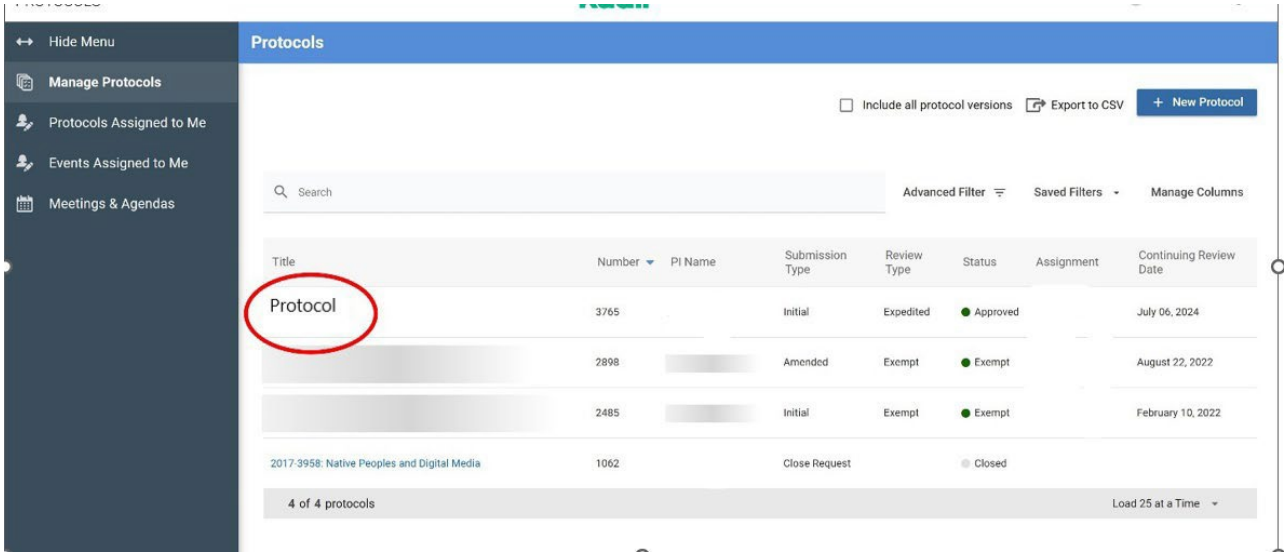
To access approved attachments, such as consent forms, recruitment, etc., click “Protocol” at the top of the screen, navigate to “Attachments” on the left side navigation bar. Here you will find the approved documents available for downloading. NOTE: only pdfs will contain an IRB stamp.



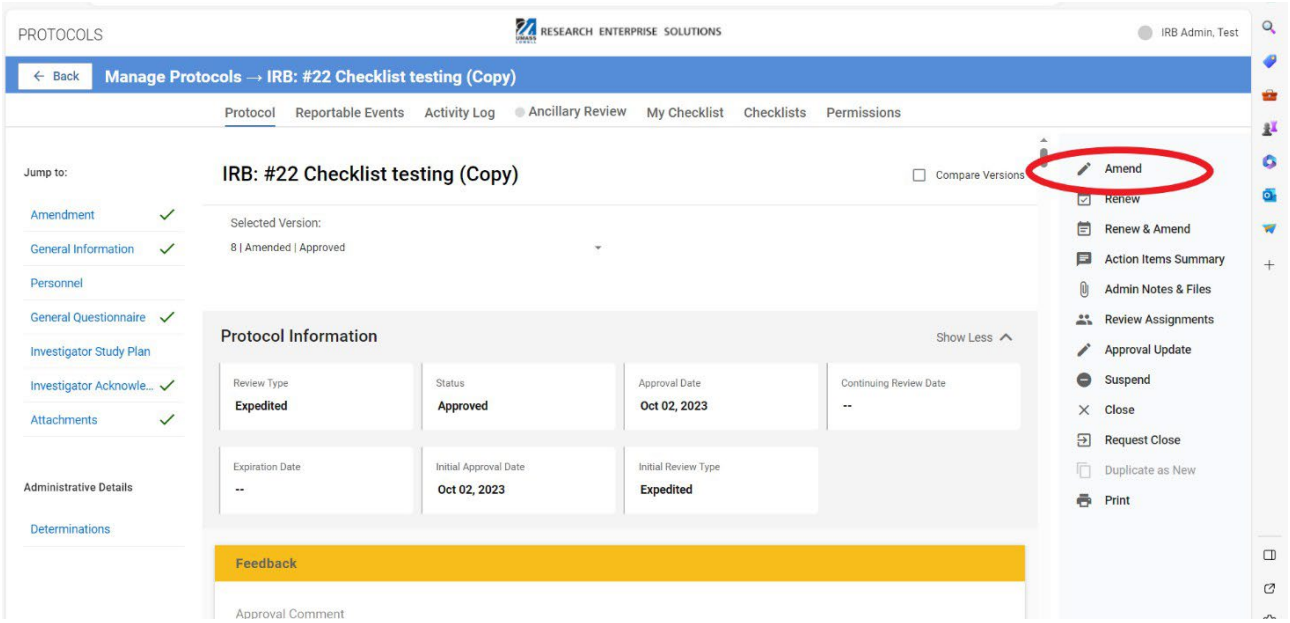
How to "Amend" Your Protocol

After your protocol is approved, changes you wish to make to Expedited/Committee reviewed studies must be reviewed by the IRB. If your study was issued an Exempt determination, and you wish to make changes, please email the IRB@uml.edu to verify that the revisions will not change the Exempt determination.

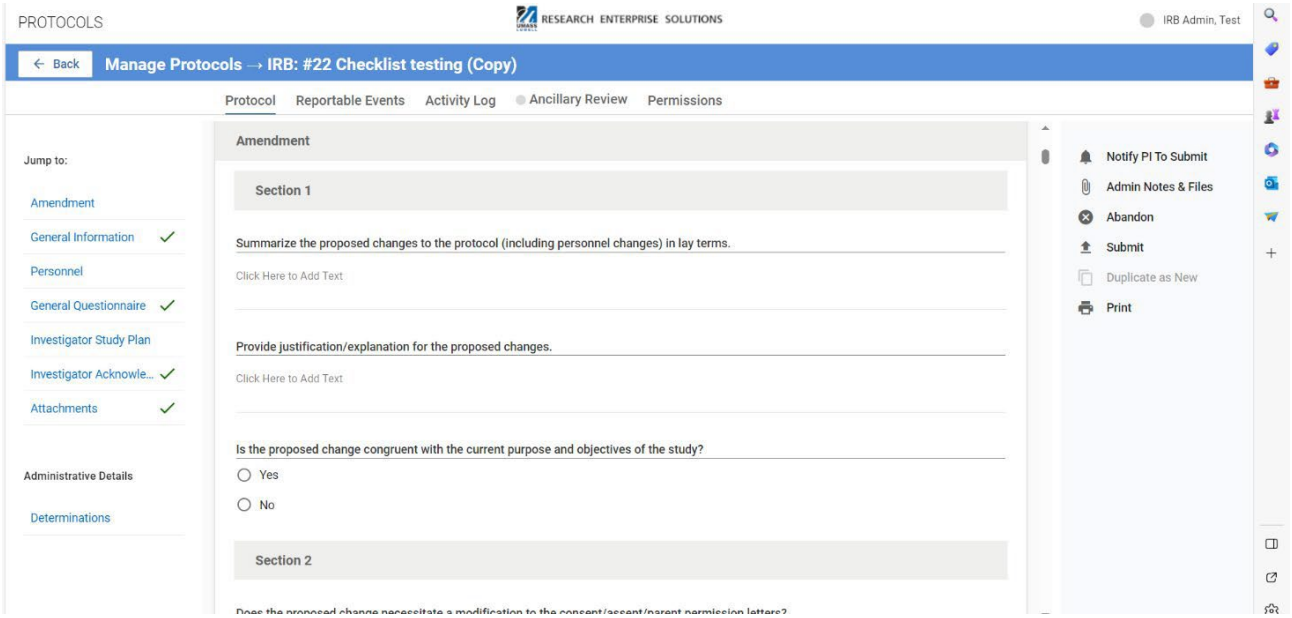
Log in to your RES IRB Dashboard and click on the title of the protocol you want to Amend.



In the right sidebar (see red circle below), select "Amend".

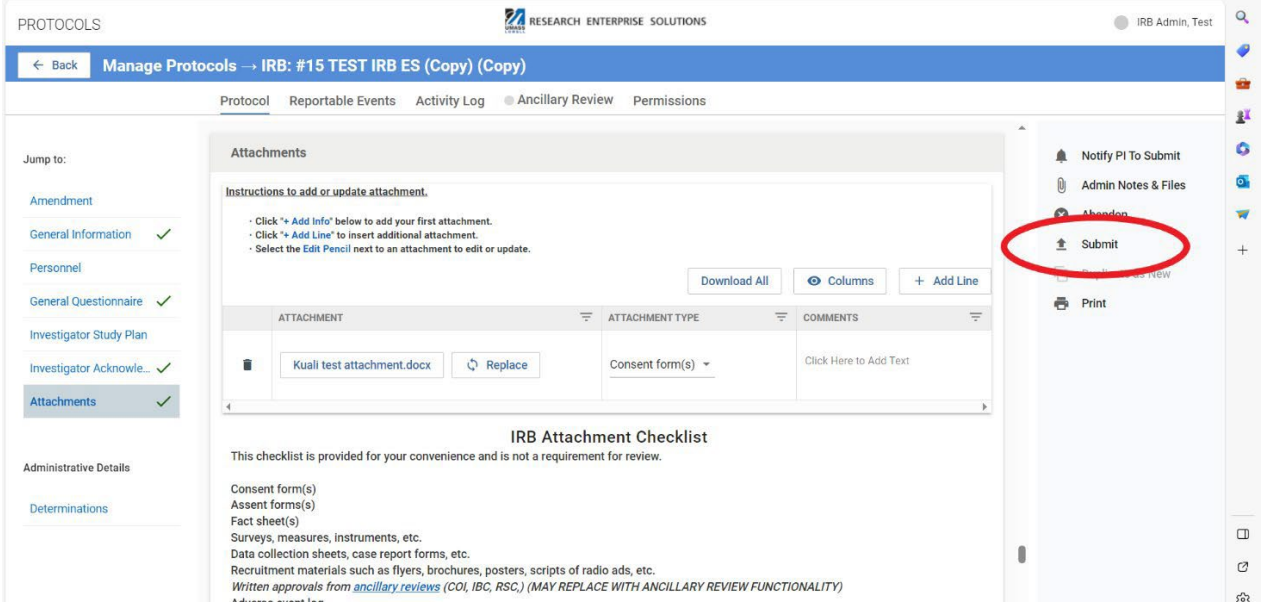


Selecting Amend will take you to the Amend form. You will be asked to summarize your proposed changes and justify these requests.



The Amend form will be followed by the previously-approved version of your protocol; please edit any sections in the body of the protocol to reflect the changes you are making. For example, if your previously approved protocol only requested 20-30 participants but you are now requesting 50 participants, be sure to reflect the change in the body of the protocol in any relevant sections.

Also, if your requested changes alter any of the previously approved documents, or necessitate new documents, these documents need to be included. Under the "Jump to" section on the left side of the screen, select the "Attachments" tab to replace and/or upload new documents. Please

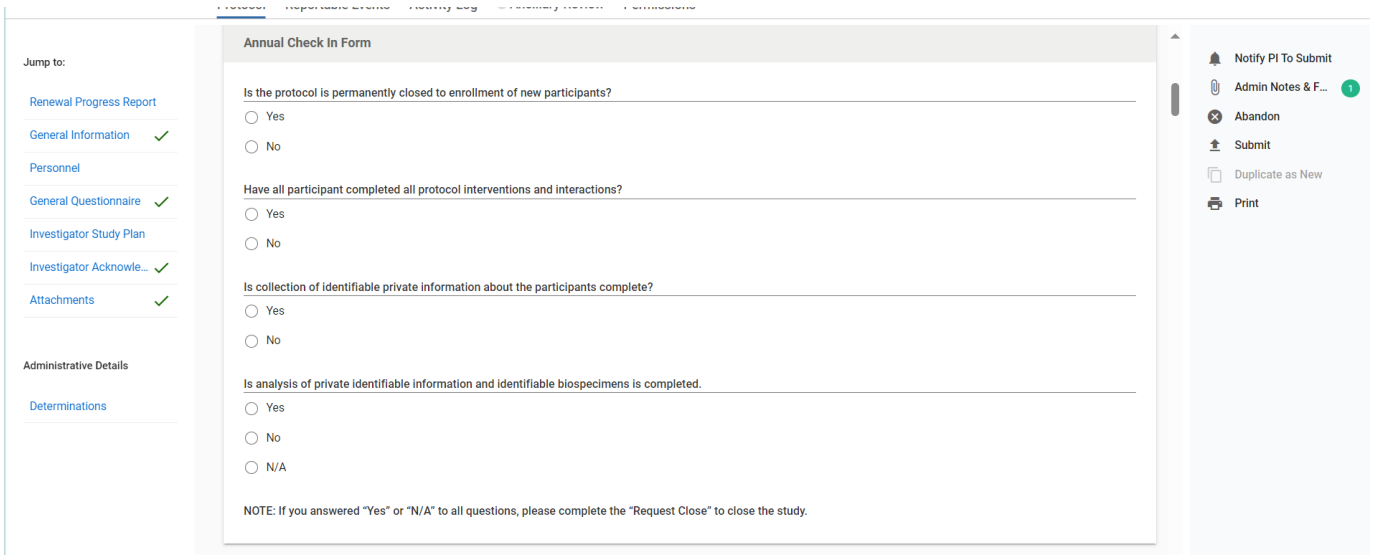


ensure that changes to previously approved attachments are reflected via "tracked changes". Once you've edited the protocol to reflect all changes and uploaded your revised or new documents (if applicable), you may submit your Amend form for IRB review.

How to Submit an "Annual Status Check-in"

Log into RES IRB Dashboard using the link received in the email notification.

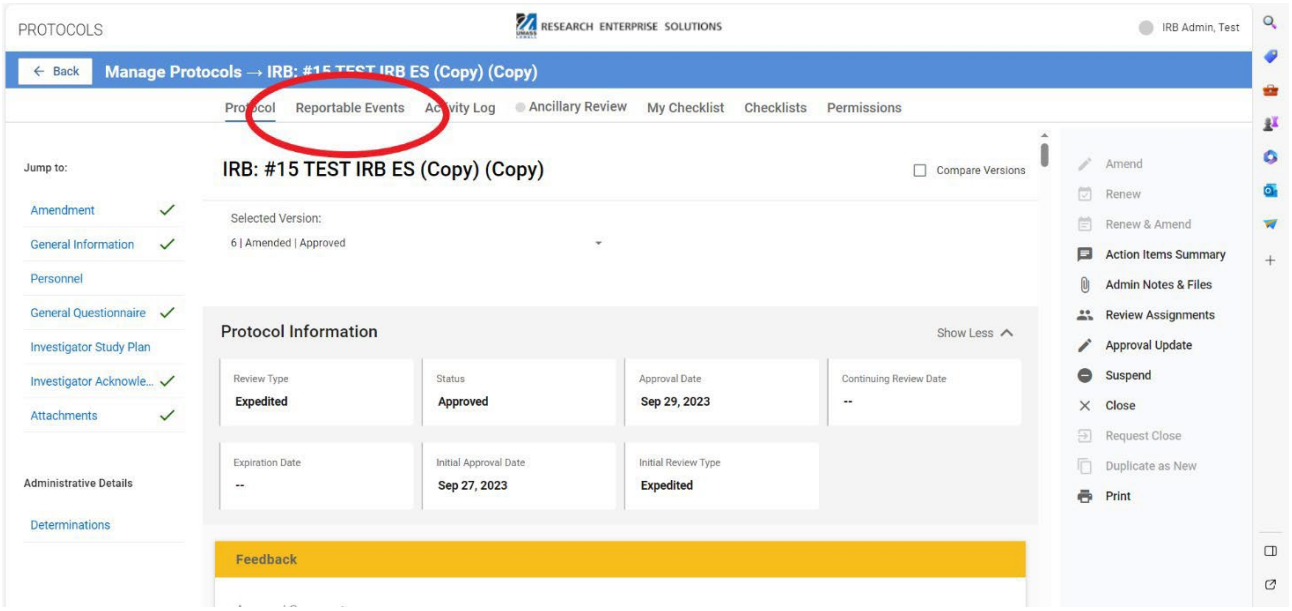
Once logged in, click "Renew" on the right hand side bar. You will be asked "Which of the following are you submitting?" you will check "Annual Check-in". You will then be prompted to answer the four questions in the Annual Check-in Form. After you've answered all questions, click "Submit" on the right side bar.



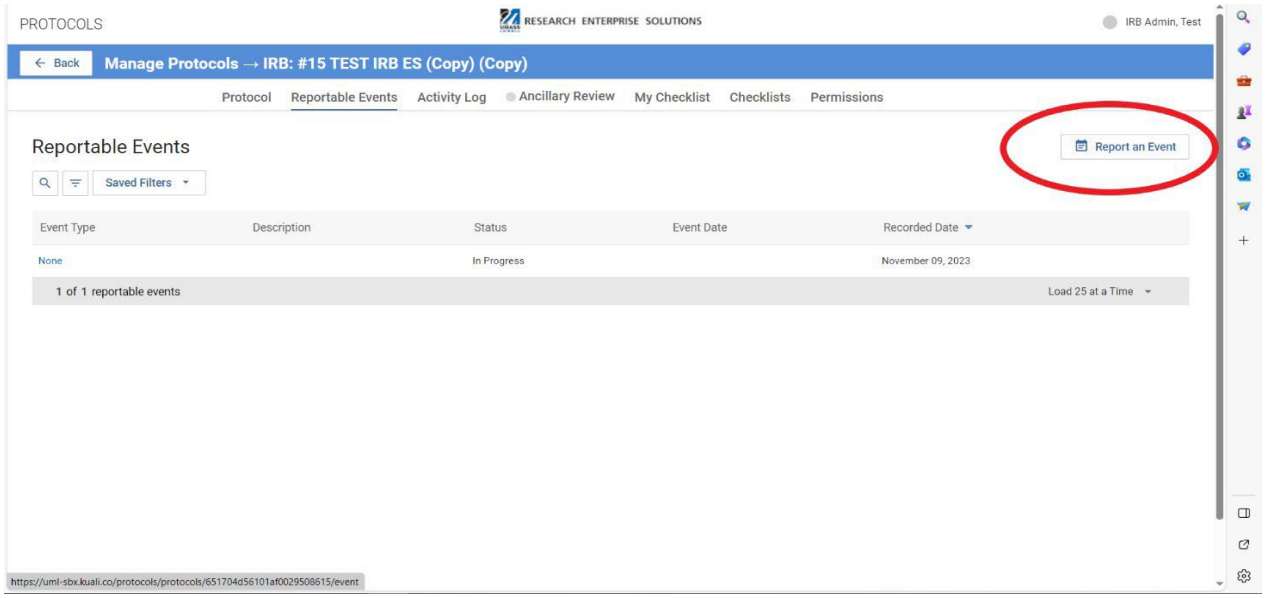
In the event you are able to click "Yes" or "N/A", you will need to "Abandon" the submission on the right side bar, click confirm in the box-up box, and instead you will need to "Request to Close". This topic is covered in next section.

How to Submit a Reportable Event

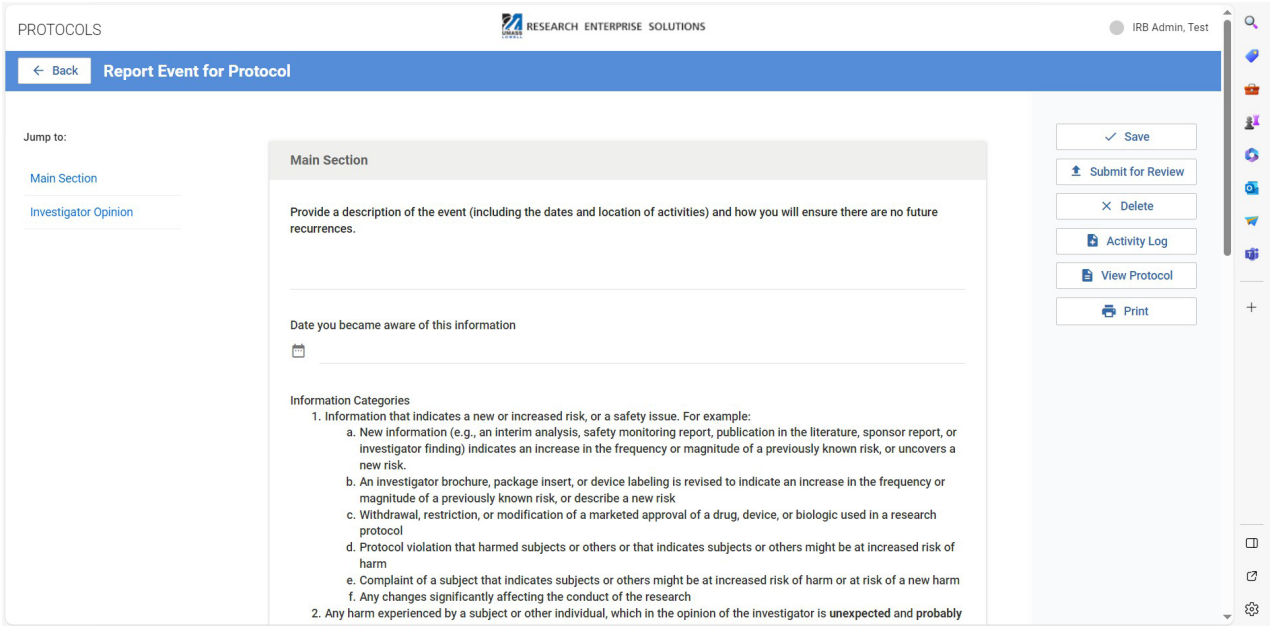
Log in to your RES IRB Dashboard and click on the title of the protocol for which you want to submit a Reportable Event – this may be an adverse event or an unanticipated problem. For information on what constitutes a Reportable Event please review the HRP-071 Policy – Prompt Reporting Requirements. Click on Reportable Events at the top of the screen to open this form.



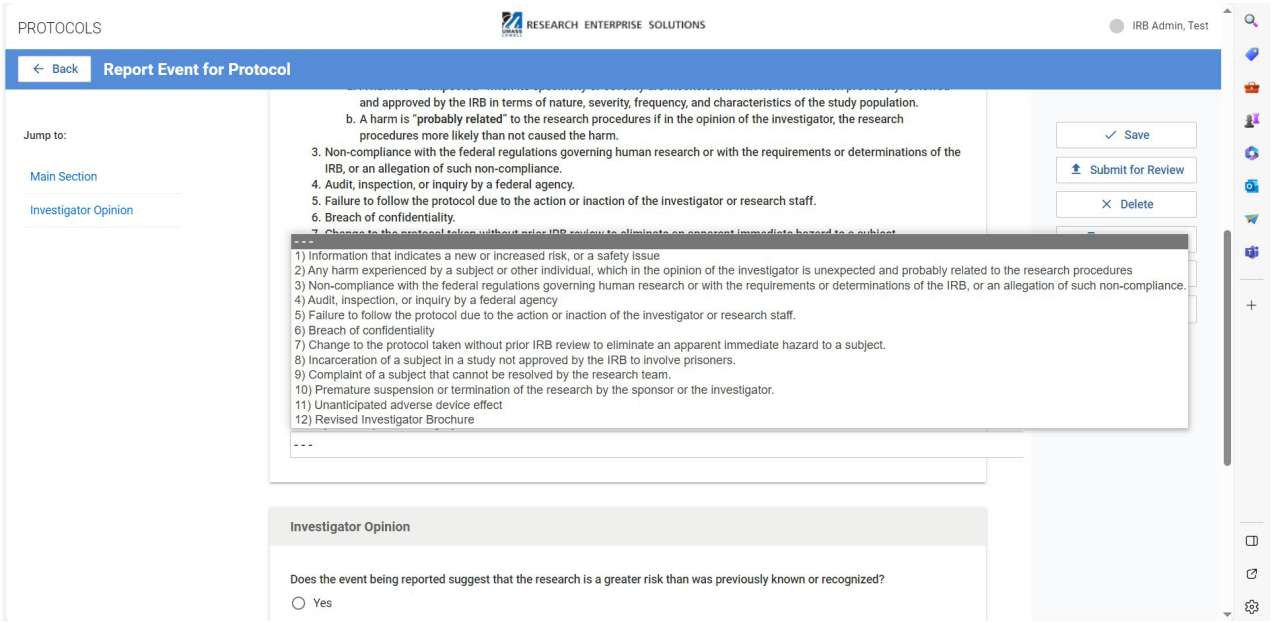
The Reportable Events page will show previously submitted events submitted to the IRB. To submit a new Reportable Event, click on the "Report an Event" button on the right side of the screen.


PROTOCOLS
RESEARCH ENTERPRISE SOLUTIONS
IRB Admin, Test
Back
Manage Protocols → IRB: #15 TEST IRB ES (Copy) (Copy)
Protocol
Reportable Events
Activity Log
Ancillary Review
My Checklist
Checklists
Permissions
Reportable Events
Report an Event
Saved Filters
Event Type
Description
Status
Event Date
Recorded Date
None
In Progress
November 09, 2023
1 of 1 reportable events
Load 25 at a Time
https://uml-sbx.kuali.co/protocols/protocols/651704d56101af0029508615/event

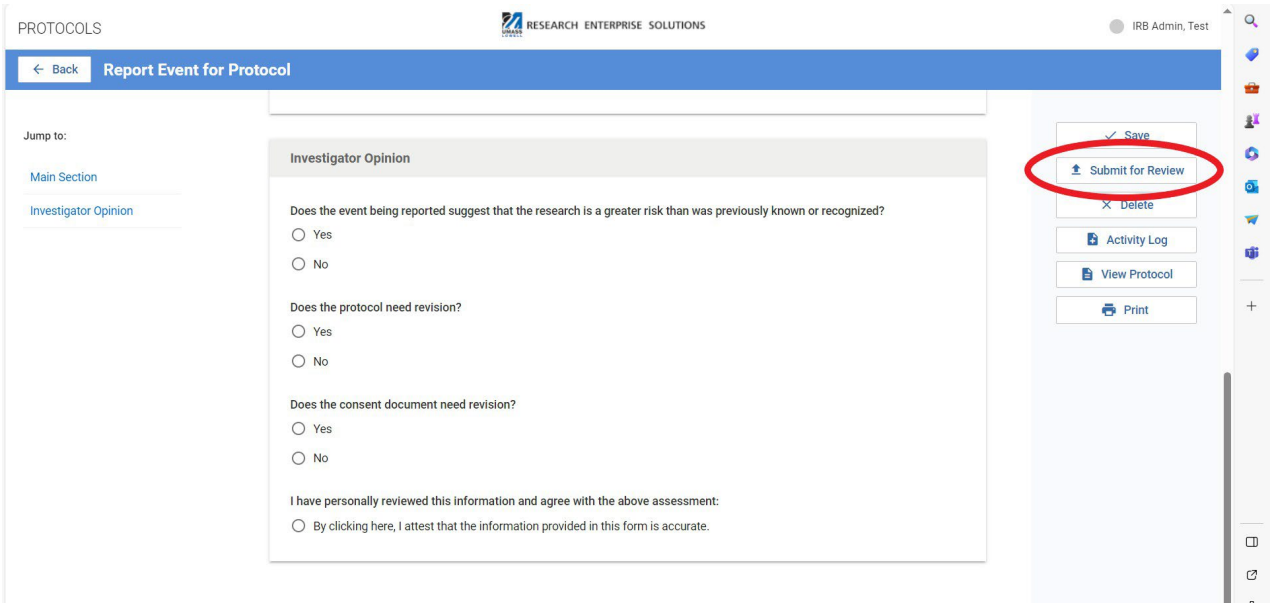
The Report Event page will have a “Main Section” which will ask for a description of the event and the date the researcher became aware of the information.



After answering the first 2 question, the next section are examples, “Information Categories”. Make a selection from the options provided above.



Once you've made a selection you will be asked a few questions regarding the event. When all questions are answered, click the "Submit for Review" Button on the right hand side.



Once you click the Submit for Review button all the other buttons disappear except for Activity Log, View Protocol and Print buttons. You've successfully submitted your Reportable Event.

How to Request to Close a Protocol

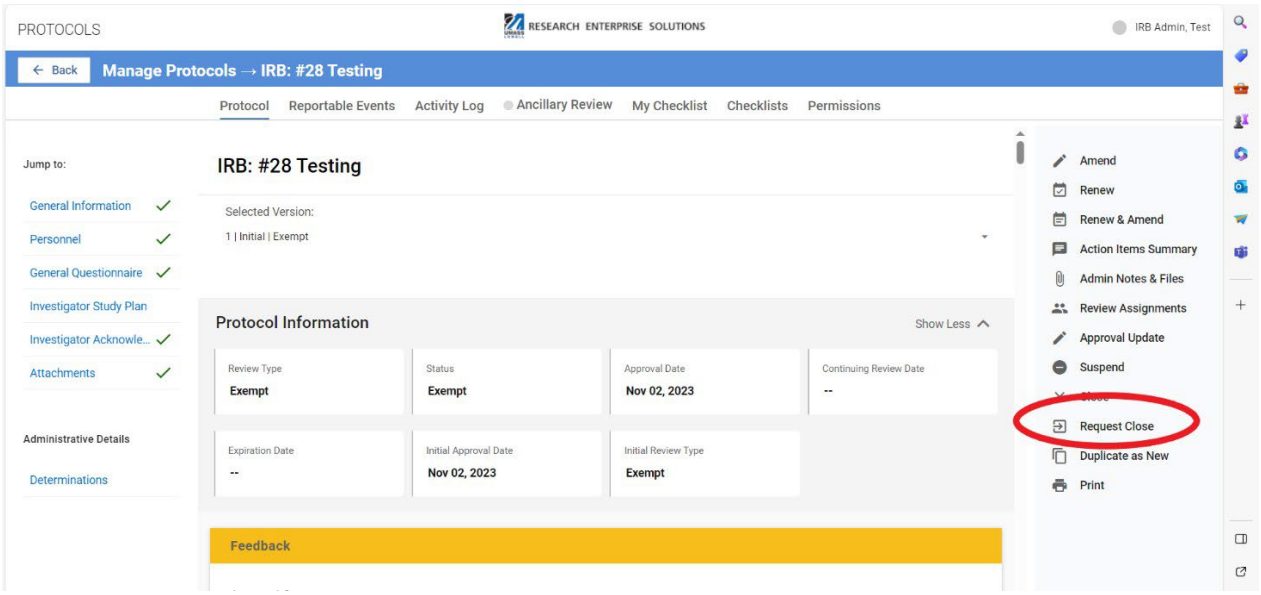
Log in to your RES IRB Dashboard and click on the title of the protocol you want to close. If there are any outstanding actions such as a pending Amendment or Renewal, you will not be able to close the protocol until that action is resolved. Please be aware that once you close the protocol you will not be able to clone it or re-open it.

Studies would be considered eligible for closure once the following is complete:

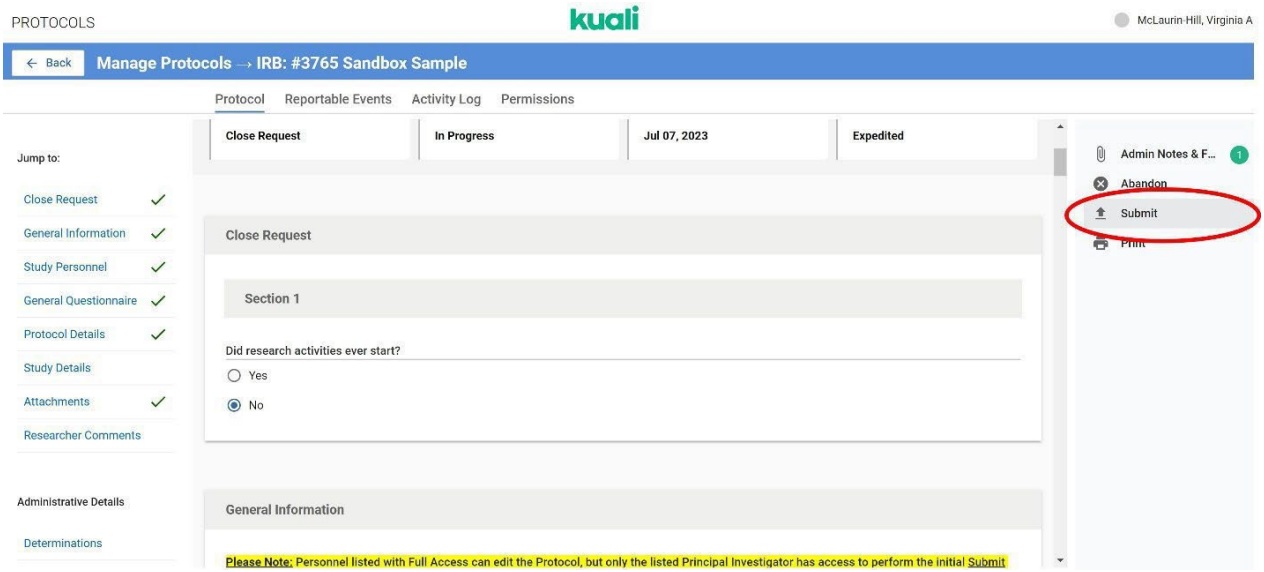
- enrollment of subjects is closed, and subjects have completed all research-related interventions, and
- data collection is complete, and
- data are de-identified*, for example data are being maintained in such a way that identifiers are separated from the coding system, or data is in a secure location, and
- there is no additional research beyond the original intent planned for these data.

*For the purposes of submitting the IRB close request, the study will be considered complete if only data analysis using de-identified data remains.

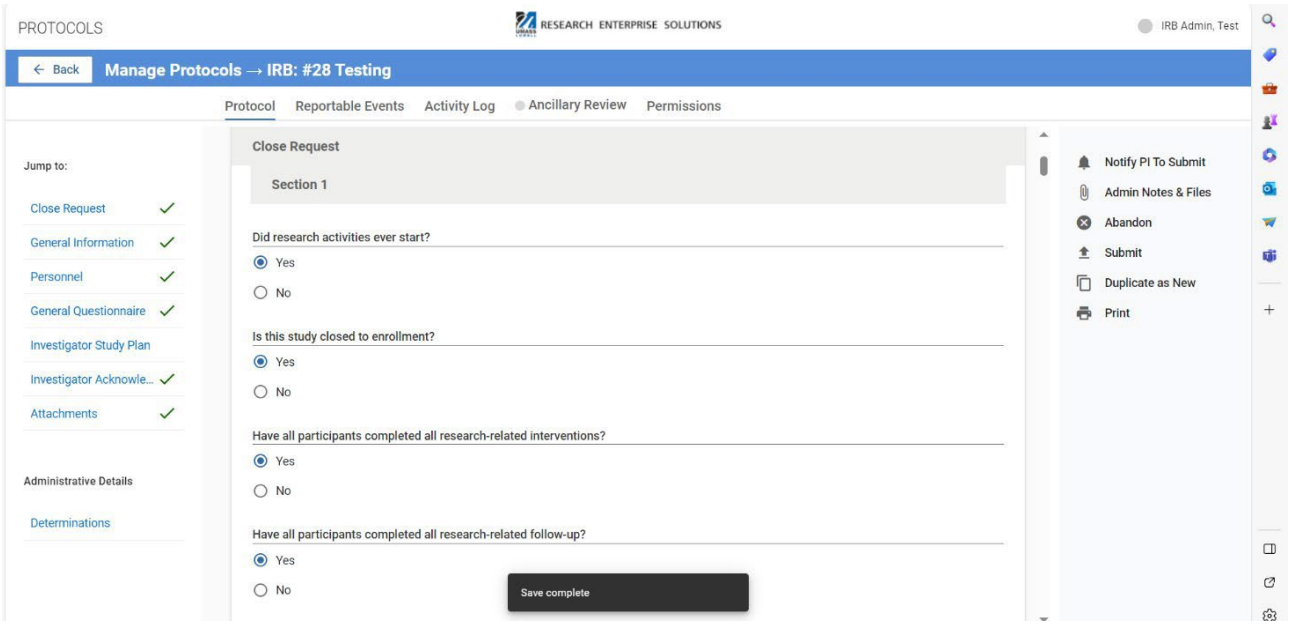
Once you open the desired protocol, the sidebar on the far-right side will provide you available actions. Click on "**Request Close"** to initiate this action.



Clicking on Request Close will open the request along with a copy of the entirety of the approved protocol. Section 1 of the Close Request will ask you whether the research activities described in the approved protocol ever occurred. If the researcher chooses “No” then the researcher can then immediately submit the Close Request.



On the other hand, if the answer is “Yes,” the form will display relevant questions (pictured below) that should be answered before submission of the Close Request.



Once all the questions have been answered you will be able to submit the Close Request. Clicking Submit will cause the RES system to validate that all the required questions have been answered. If there are unanswered questions, the system will alert you.

If the Close Request passes the validation, the request will be submitted for IRB review.