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## **Research Enterprise Solutions (RES) - IRB User Guide**

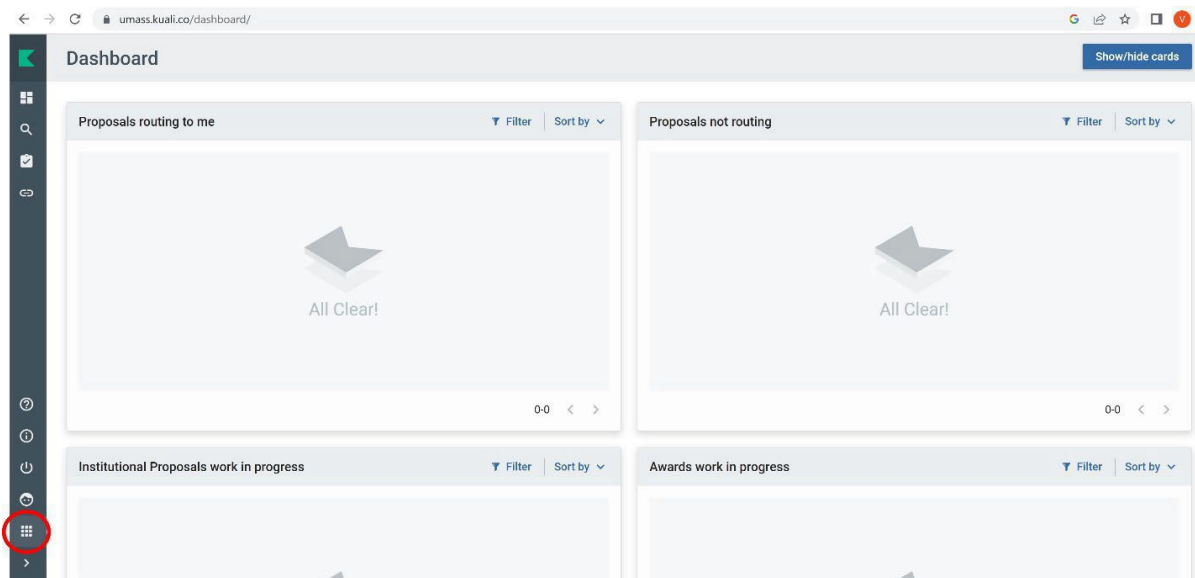
The Research Enterprise Solutions (RES) IRB module streamlines the development of protocols and facilitates best practices in protocol management throughout the research lifecycle. RES facilitates fast, clear, and specific communication between the IRB, researchers, and the Human Research Protection 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)

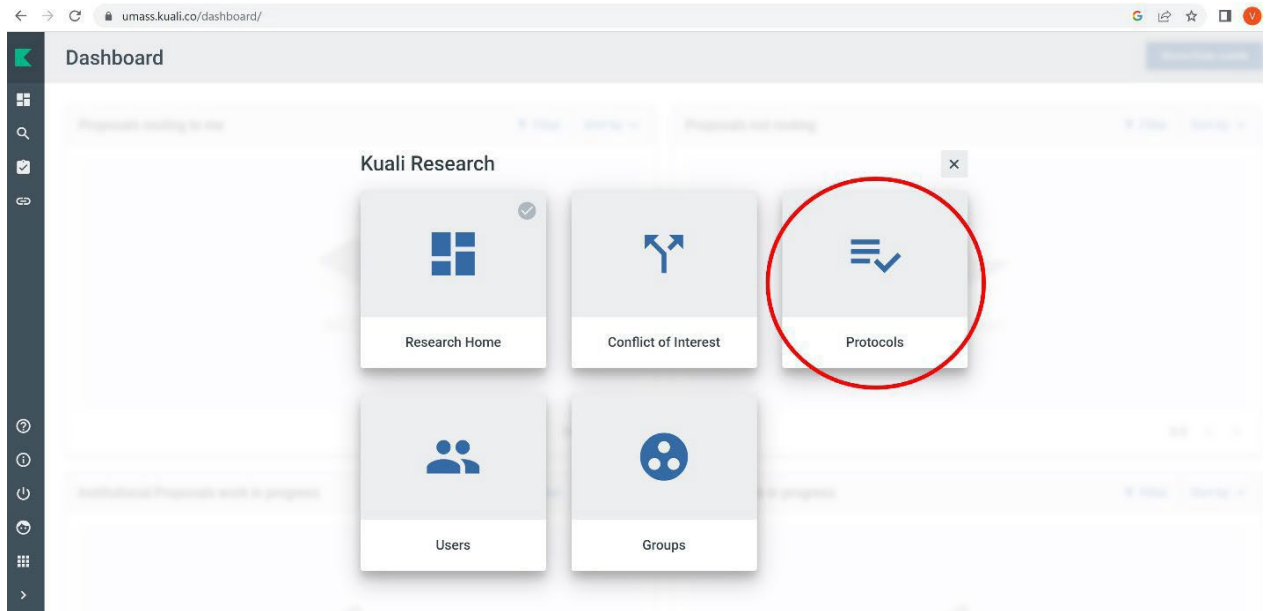
## Creating a New IRB Protocol

Log into [Research Enterprise Solutions](#) using your RES ID and password.

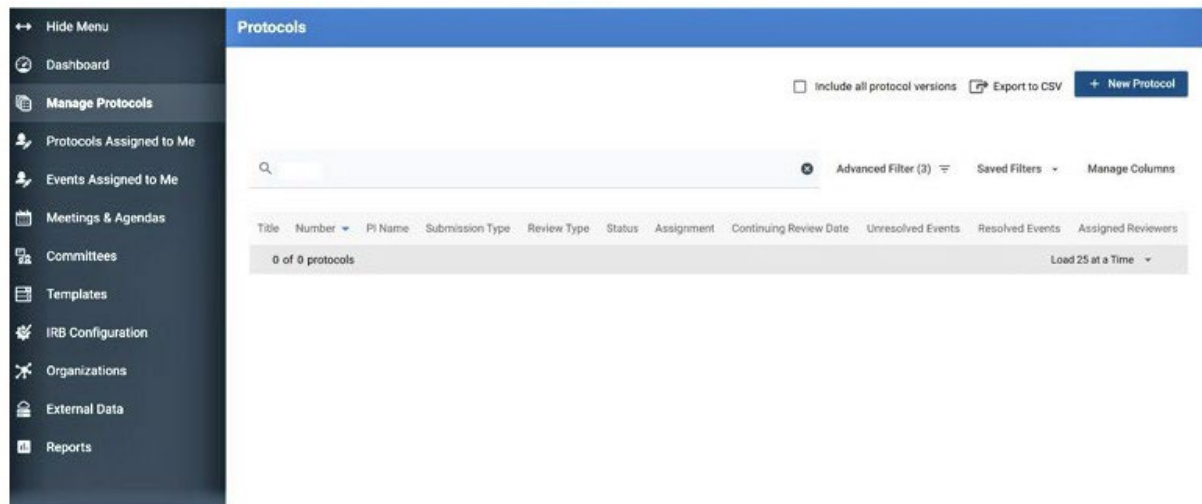
Once logged in, Select Switch Apps on the lower left margin.



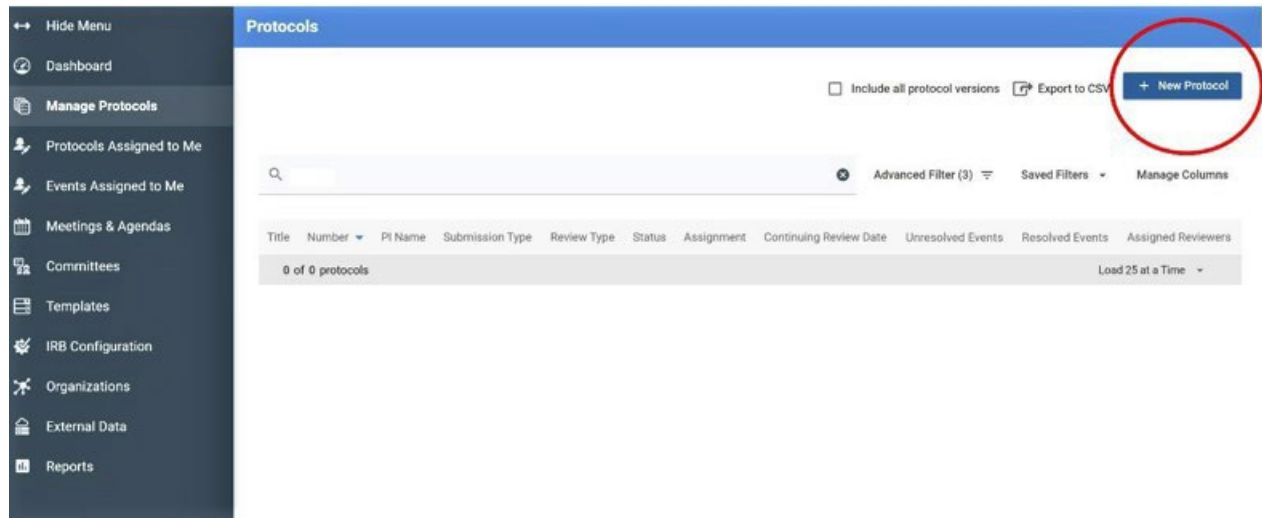
Select the tile called Protocols.



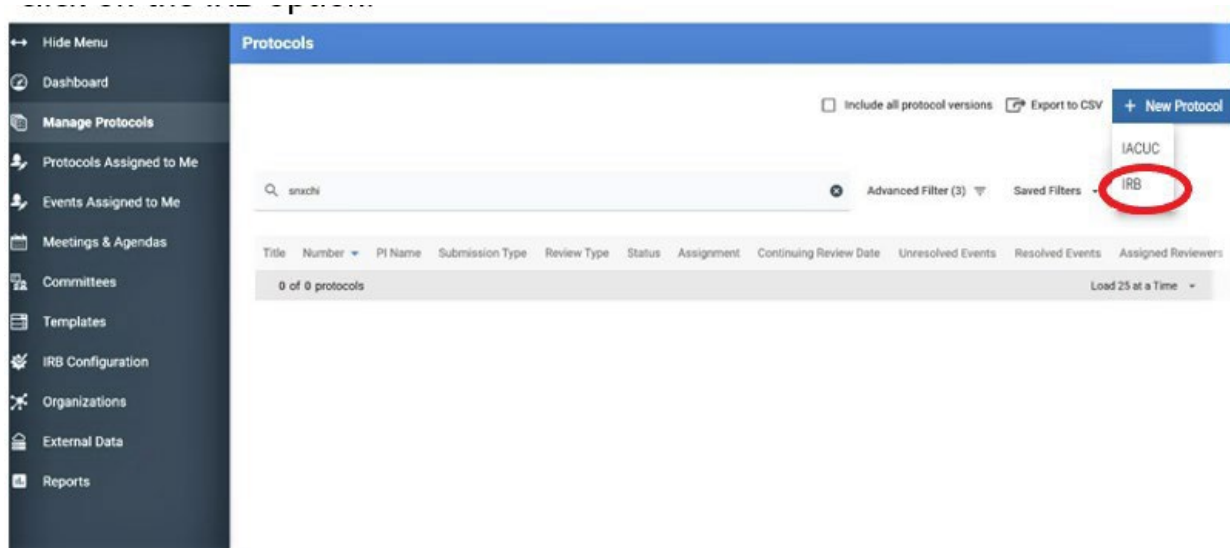
You will see a dashboard that looks like this:



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

The screenshot shows the 'IRB - General Information' form in the Research Enterprise Solutions (RES) system. The form is titled 'IRB - General Information' and is part of the 'RESEARCH ENTERPRISE SOLUTIONS' interface. It contains three main sections for data entry: 'Study Nickname', 'Principal Investigator', and 'Study Title'. Each section has a text input field with a placeholder 'Click Here to Add Text'. To the right of the form, there are two buttons: 'Cancel' and 'Next'. The 'Next' button is highlighted, indicating it is the next step in the process. The user's name 'IRB Admin, Test' is visible in the top right corner.

“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.

The screenshot shows the 'Manage Protocols' form in the Research Enterprise Solutions (RES) system. The form is titled 'Manage Protocols' and is part of the 'RESEARCH ENTERPRISE SOLUTIONS' interface. It contains three main sections for data entry: 'UML Location(s) where subjects/participants will be seen.', 'Does this study have funding external to UML?', and 'Is this research required to be registered on ClinicalTrials.gov?'. Each section has a text input field with a placeholder 'Click Here to Add Text'. To the right of the form, there are two buttons: 'Cancel' and 'Next'. The 'Next' button is highlighted, indicating it is the next step in the process. The user's name 'Sousa, Emily' is visible in the top right corner.

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.

PROTOCOLS

RESEARCH ENTERPRISE SOLUTIONS

IRB Admin, Test

← Back Manage Protocols → IRB: #30 Testing (Copy)

Protocol Activity Log Ancillary Review Permissions

Jump to:

- General Information ✓
- Personnel ✓
- General Questionnaire ✓
- Investigator Study Plan ✓
- Investigator Acknowledge... ✓
- Attachments ✓
- Determinations

IRB: #30 Testing (Copy)

Selected Version:  
1 | New | In Progress

Protocol Information

Submission Type <b>New</b>	Status <b>In Progress</b>
-------------------------------	------------------------------

General Information

Study Nickname  
Testing 123

Jump to:

- Notify PI To Submit
- Admin Notes & Files
- Abandon
- Submit
- Duplicate as New
- Print

## 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>

The screenshot shows the 'PROTOCOLS' interface for 'Manage Protocols → IRB: #30 Testing (Copy)'. The 'Personnel' section is active, displaying a table of study personnel. The table has columns for PERSON, COI DISCLOSURE, RESEARCHER ROLE, and TRAININGS. A red circle highlights the '+ Add Line' button in the top right corner of the table. Below the table, there is a question: 'Does this protocol include any researchers from another institution?' with 'Yes' selected. A red error message states 'At least one role is required'.

PERSON	COI DISCLOSURE	RESEARCHER ROLE	TRAININGS
IRB Admin, Test	Status: Not Disclosed Disposition: No Disposition	At least one role is required	Test IRB Admin has no training courses on file.

Adding UMass Personnel:

Adding Non-UMass Personnel:



PROTOCOLS

RESEARCH ENTERPRISE SOLUTIONS

IRB Admin, Test

Manage Protocols → IRB: #30 Testing (Copy)

Protocol Activity Log Ancillary Review Permissions

Jump to:

General Information

Personnel

General Questionnaire

Investigator Study Plan

Investigator Acknowledge

Attachments

Administrative Details

Determinations

Personnel

Does this protocol include any researchers from another institution?

Yes

No

External Personnel

Add Non-UML Personnel

Columns + Add Line

NAME	INSTITUTION/ORGANIZATION/COMPANY	RESEARCHER ROLE	OTHER RESEARCHER ROLE
David Svintradze	The New Vision University	Co-Investigator	

Additional Departments involved in the study.

Columns + Add Line

ADDITIONAL UML UNIT

+ Add Info

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.

PROTOCOLS

RESEARCH ENTERPRISE SOLUTIONS

IRB Admin, Test

Manage Protocols → IRB: #30 Testing (Copy)

Protocol Activity Log Ancillary Review Permissions

Jump to:

General Information

Personnel

General Questionnaire

Investigator Study Plan

Investigator Acknowledge

Attachments

Administrative Details

Determinations

Personnel

Does this protocol include any researchers from another institution?

Yes

No

External Personnel

Add Non-UML Personnel

Columns + Add Line

NAME	INSTITUTION/ORGANIZATION/COMPANY	RESEARCHER ROLE	OTHER RESEARCHER ROLE
David Svintradze	The New Vision University	Co-Investigator	

Additional Departments involved in the study.

Columns + Add Line

ADDITIONAL UML UNIT

+ Add Info

Edit

Person

Required Field

COI Disclosure

Status: Not Disclosed

Disposition: No Disposition

Home Unit

Email Address

Click Here to Add Text

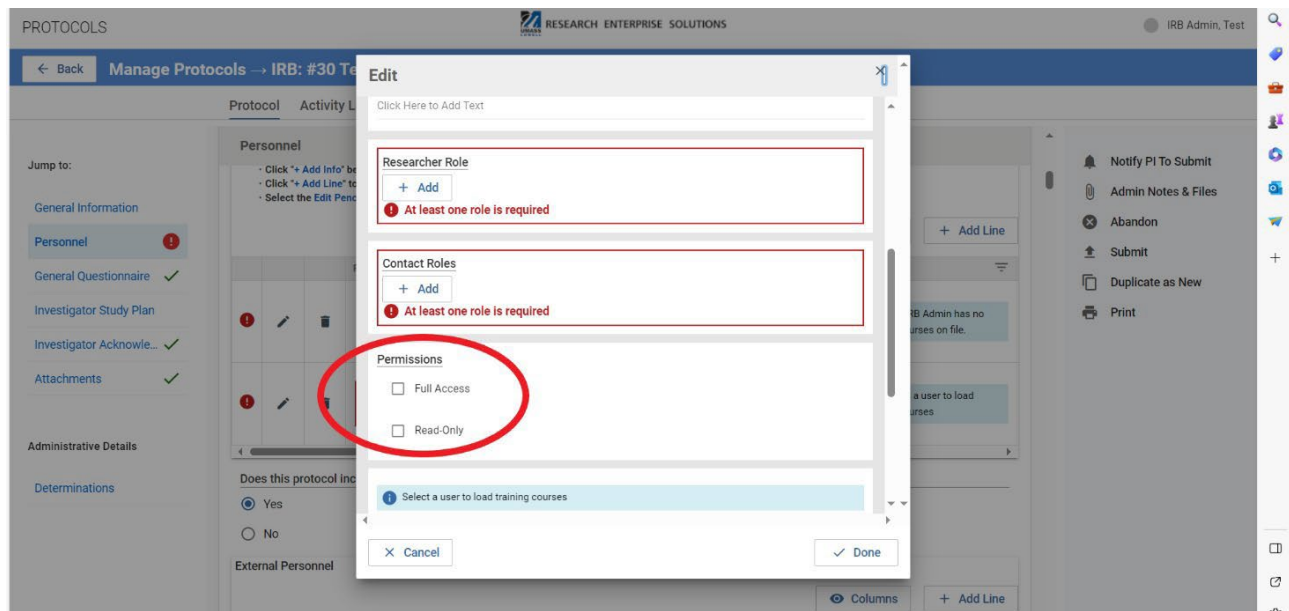
Phone

Click Here to Add Text

Cancel Done

Save complete

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.

PROTOCOLS

RESEARCH ENTERPRISE SOLUTIONS

IRB Admin, Test

← Back Manage Protocols → IRB: #30 Testing (Copy)

Protocol Activity Log Ancillary Review Permissions

Jump to:

- General Information
- Personnel
- General Questionnaire ✓
- External Funding**
- Investigator Study Plan
- Investigator Acknowledge ✓
- Attachments ✓

Administrative Details

Determinations

**General Questionnaire**

☒ No, UML is the only institution involved in this study.

"Only select "Yes" if you have already contacted the IRB@uml.edu to verify that UML IRB has agreed to serve as the single IRB or has agreed to cede IRB review to another institution. UML serving as the lead IRB is determined on a case-by-case basis."

**External Funding** ← This section will appear if "Yes" is selected in the General Questionnaire

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.

Enter a funding source number

☒ Award ☐ Institutional Proposal ☐ Proposal Development

**Find and add**

**Investigator Study Plan**

**INSTRUCTIONS:**

Notify PI To Submit

Admin Notes & Files

Abandon

Submit

Duplicate as New

Print

## 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

The first screenshot shows the 'Manage Protocols' page for 'IRB: #30 Testing (Copy)'. The 'Attachments' section is active, displaying a table with three rows, each containing a file named 'Kuali test attachment.pdf' and a 'Replace' button. A dropdown menu titled 'Options for Attachment Types' is open, listing various document types such as 'Consent form(s)', 'Assent forms(s)', 'Fact sheet(s)', 'Surveys, measures, instruments, etc.', 'Data collection sheets, case report forms, etc.', 'Recruitment materials such as flyers, brochures, posters, scripts of radio ads, etc.', 'Written approvals from ancillary reviews (COI, IBC, RSC,)', 'Adverse event log', 'Approval order for Humanitarian Use Device', 'Certificates of translation or translator attestations/Fact sheet(s)', 'Compensation log/Assent forms(s)', 'Data safety monitoring plan', 'Data use agreements, memoranda of understanding, Multi-site communication plan', 'DMC or DSMB charter', 'Documentation of data/specimen anonymity (i.e., provider will never break the code)', 'Study staff training plan', 'HIPAA authorization', 'HIPAA waiver', and 'ND or IDE documentation'. The second screenshot shows the same page with the 'Attachments' table expanded to show the 'ATTACHMENT TYPE' column. The first row is set to 'Consent form(s)', the second to 'Recruitment materials such as flyers, brochures, posters, scripts of radio ads, etc.', and the third to 'Data collection sheets, case report forms, etc.'. The 'Replace' buttons are still visible next to each file name.

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.**

The screenshot displays the 'Manage Protocols' interface for 'IRB: #30 Testing (Copy)'. The left sidebar lists sections: General Information, Personnel, General Questionnaire, External Funding, Investigator Study Plan, Investigator Acknowledgment, Attachments, Administrative Details, and Determinations. Red exclamation point icons are present next to General Information, Personnel, External Funding, Investigator Study Plan, and Attachments. A yellow oval highlights these icons. The main content area shows the 'Investigator Study Plan' section with a red border and a message: 'Sections with a red exclamation point require review.' A yellow arrow points to this message. Above this, a red box contains the text 'Incomplete' and '10 fields have validation errors.' Below the message, there is a 'Required' section with a question about radiation-emitting devices and materials, with 'Yes' selected. At the bottom, there is a 'Radiation Approval Attachment' section with a 'Drag & Drop a File or + Choose' button. The right sidebar contains action buttons: Notify PI To Submit, Admin Notes & Files, Abandon, Submit, Duplicate as New, and Print.

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.

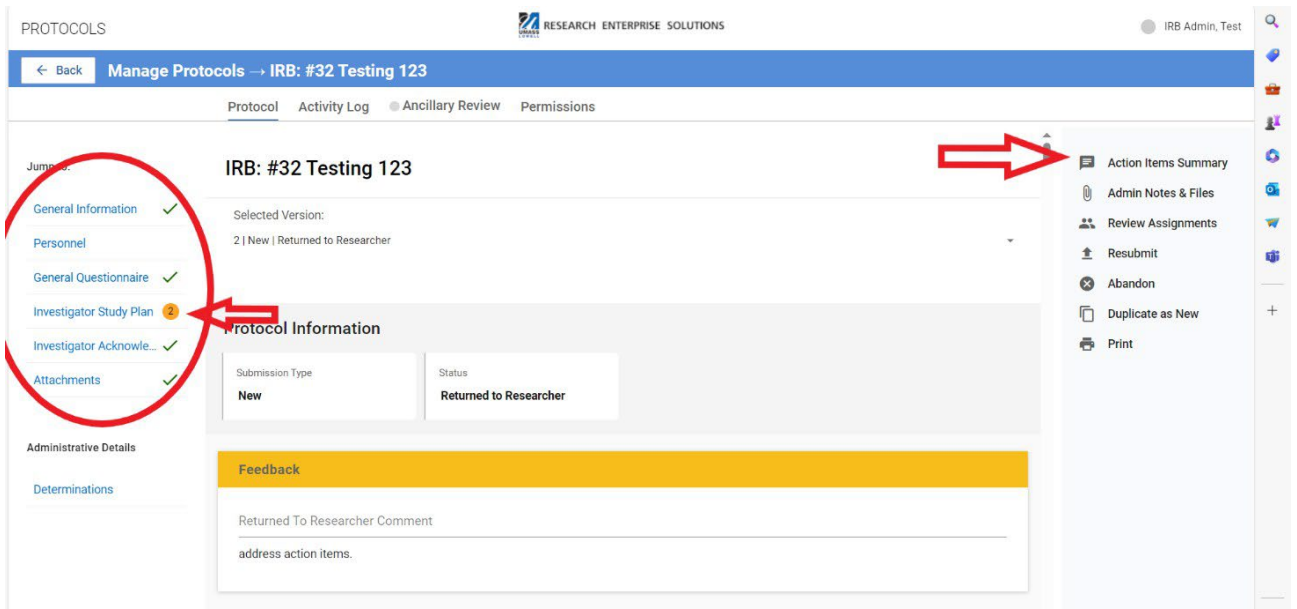
**Important:** Study Personnel permissions must be set to "Full Access" only. Please make sure to un-check the system default of "Read Only".

The screenshot shows a mobile application interface for adding a user. The 'Add' dialog box is open, showing the following fields and options:

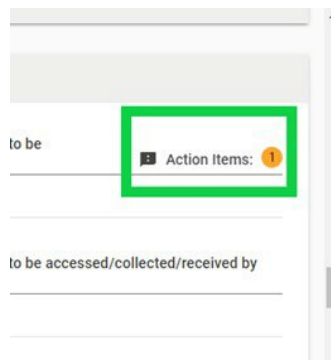
- Person:** A tag labeled 'GERRITY, CHRISTOPHER' with a remove icon.
- Home Unit:** An empty text input field.
- Researcher Role:** A tag labeled 'Co-Investigator' with a remove icon.
- Permissions:** Two radio button options: 'Full Access' (selected) and 'Read-Only' (unselected). A large green checkmark is overlaid on this section.

At the bottom of the dialog are two buttons: 'Cancel' and 'Done'.

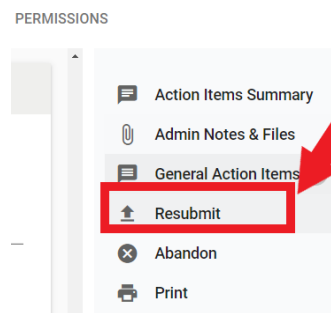
Once you’ve logged in and accessed the protocol requiring revisions on the screen you may have a “Feedback” comment and you will see one or more yellow circles with a number on sections in the navigation column on the left hand side of the screen (Red Box below). These are the sections that require revisions. 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):



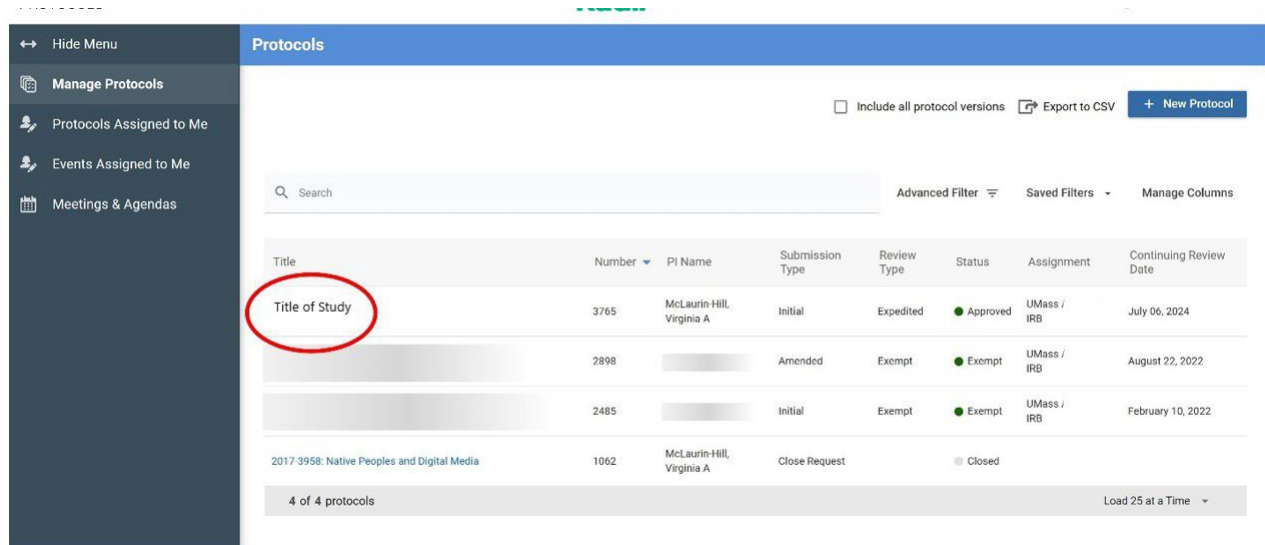
After responding to all “Action Items” or “General Action Items” and performing all requested updates, changes or corrections you can Resubmit your application by clicking the button in the top right (Red Box & Arrow below).





## How to Access Your Approval Letter and Approved Documents

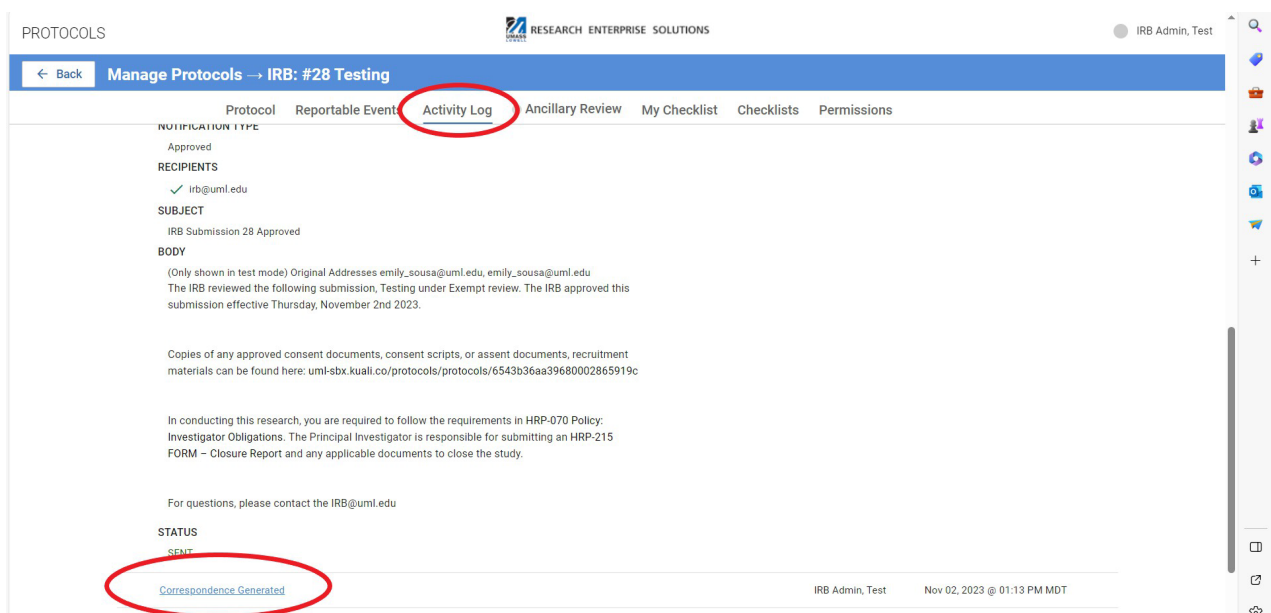
Log in to your RES IRB via the email notification received or via the IRB Res Dashboard and click on the title of the approved protocol for which you want to access the Approval Letter.



Title	Number	PI Name	Submission Type	Review Type	Status	Assignment	Continuing Review Date
Title of Study	3765	McLaurin-Hill, Virginia A	Initial	Expedited	Approved	UMass / IRB	July 06, 2024
	2898		Amended	Exempt	Exempt	UMass / IRB	August 22, 2022
	2485		Initial	Exempt	Exempt	UMass / IRB	February 10, 2022
2017-3958: Native Peoples and Digital Media	1062	McLaurin-Hill, Virginia A	Close Request		Closed		

4 of 4 protocols

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.



PROTOCOLS

RESEARCH ENTERPRISE SOLUTIONS

IRB Admin, Test

Manage Protocols → IRB: #28 Testing

Protocol Reportable Event **Activity Log** Ancillary Review My Checklist Checklists Permissions

NOTIFICATION TYPE  
Approved

RECIPIENTS  
✓ irb@uml.edu

SUBJECT  
IRB Submission 28 Approved

BODY  
(Only shown in test mode) Original Addresses emily\_sousa@uml.edu, emily\_sousa@uml.edu  
The IRB reviewed the following submission, Testing under Exempt review. The IRB approved this submission effective Thursday, November 2nd 2023.

Copies of any approved consent documents, consent scripts, or assent documents, recruitment materials can be found here: uml-sbx.kuali.co/protocols/protocols/6543b36aa3968002865919c

In conducting this research, you are required to follow the requirements in HRP-070 Policy: Investigator Obligations. The Principal Investigator is responsible for submitting an HRP-215 FORM – Closure Report and any applicable documents to close the study.

For questions, please contact the IRB@uml.edu

STATUS  
SENT

[Correspondence Generated](#)

IRB Admin, Test Nov 02, 2023 @ 01:13 PM MDT

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.

Protocol Reportable Events Activity Log Permissions

Jump to:

- Renewal Progress Rep... ✓
- General Information ✓
- Personnel ✓
- General Questionnaire ✓
- Investigator Study Plan
- Investigator Acknowledge ✓
- Attachments ✓**
- Administrative Details
- Determinations

**Attachments**

Download All Columns

	ATTACHMENT	ATTACHMENT TYPE	COMMENTS
No Action Items	<a href="#">Kuali test attachment.pdf</a>	Consent form(s)	
No Action Items	<a href="#">Kuali test attachment.pdf</a>	Recruitment materials such as flyers, brochures, posters, scripts of radio ads, etc.	

**IRB Attachment Checklist**

This checklist is provided for your convenience and is not a requirement for review.

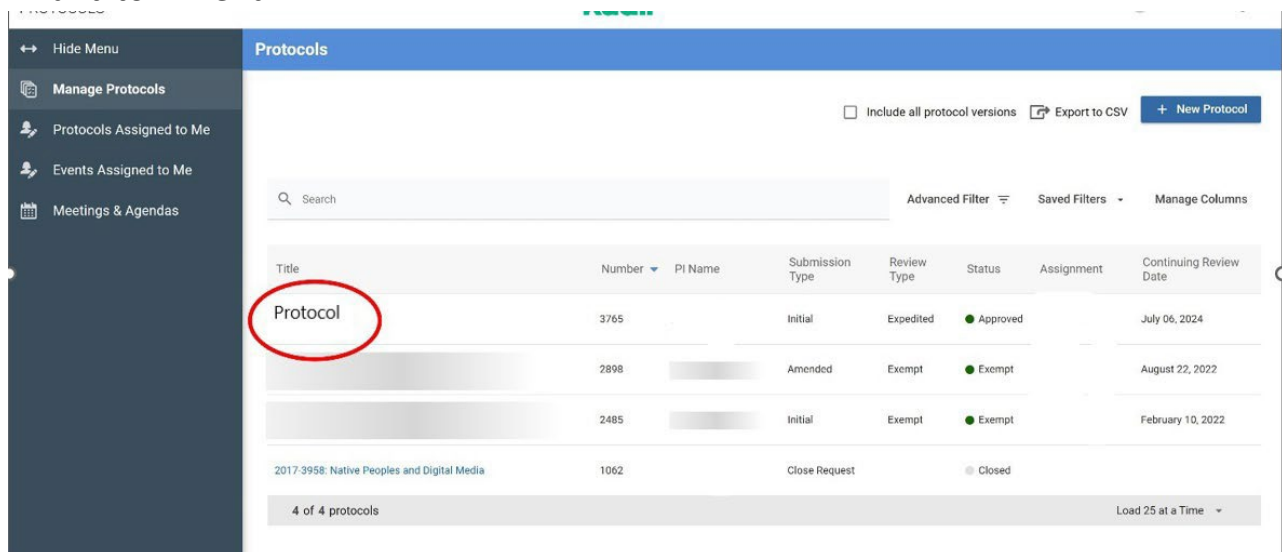
- Consent form(s)
- Assent forms(s)
- Fact sheet(s)
- Surveys, measures, instruments, etc.
- Data collection sheets, case report forms, etc.

Amend  
Renew  
Renew & Amend  
Action Items Summary  
Admin Notes & Files  
Request Close  
Duplicate as New  
Print

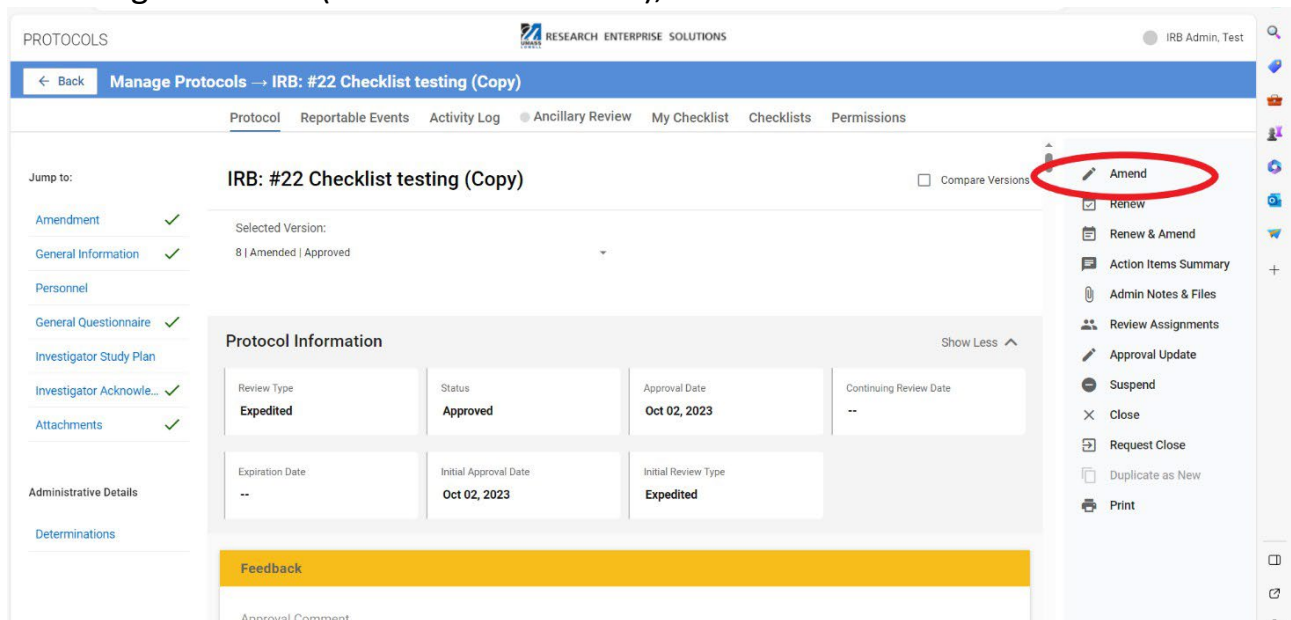
## How to “Amend” Your Protocol

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](mailto: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 screenshot shows the 'Amendment' form within the 'PROTOCOLS' system. The header includes 'Manage Protocols → IRB: #22 Checklist testing (Copy)'. The left sidebar has a 'Jump to:' section with links for 'Amendment', 'General Information', 'Personnel', 'General Questionnaire', 'Investigator Study Plan', 'Investigator Acknowledge...', and 'Attachments'. The main content area is titled 'Amendment' and contains two sections: 'Section 1' and 'Section 2'. Section 1 includes prompts to 'Summarize the proposed changes to the protocol (including personnel changes) in lay terms.' and 'Provide justification/explanation for the proposed changes.', each with a 'Click Here to Add Text' link. Section 2 asks 'Is the proposed change congruent with the current purpose and objectives of the study?' with radio buttons for 'Yes' and 'No'. A right sidebar contains action buttons: 'Notify PI To Submit', 'Admin Notes & Files', 'Abandon', 'Submit', 'Duplicate as New', and 'Print'.

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

The screenshot shows the 'Attachments' form within the 'PROTOCOLS' system. The header includes 'Manage Protocols → IRB: #15 TEST IRB ES (Copy) (Copy)'. The left sidebar has a 'Jump to:' section with links for 'Amendment', 'General Information', 'Personnel', 'General Questionnaire', 'Investigator Study Plan', 'Investigator Acknowledge...', and 'Attachments'. The main content area is titled 'Attachments' and includes instructions to 'add or update attachment'. It features a table with columns for 'ATTACHMENT', 'ATTACHMENT TYPE', and 'COMMENTS'. The first row shows 'Kuali test attachment.docx' with a 'Replace' button and 'Consent form(s)' as the attachment type. Below the table is an 'IRB Attachment Checklist' section. A right sidebar contains action buttons: 'Notify PI To Submit', 'Admin Notes & Files', 'Abandon', 'Submit', and 'Print'. The 'Submit' button is circled in red.

ATTACHMENT	ATTACHMENT TYPE	COMMENTS
Kuali test attachment.docx	Consent form(s)	Click Here to Add Text

**IRB Attachment Checklist**  
This checklist is provided for your convenience and is not a requirement for review.

Consent form(s)  
Assent form(s)  
Fact sheet(s)  
Surveys, measures, instruments, etc.  
Data collection sheets, case report forms, etc.  
Recruitment materials such as flyers, brochures, posters, scripts of radio ads, etc.  
Written approvals from *ancillary reviews* (COI, IBC, RSC). (MAY REPLACE WITH ANCILLARY REVIEW FUNCTIONALITY)

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.

The screenshot displays the 'Annual Check In Form' interface. On the left, a sidebar lists navigation options: 'Jump to:' followed by 'Renewal Progress Report', 'General Information' (with a green checkmark), 'Personnel', 'General Questionnaire' (with a green checkmark), 'Investigator Study Plan', 'Investigator Acknowledge...' (with a green checkmark), 'Attachments' (with a green checkmark), 'Administrative Details', and 'Determinations'. The main content area contains four questions, each with radio button options:

- Question 1: "Is the protocol is permanently closed to enrollment of new participants?" with options "Yes" and "No".
- Question 2: "Have all participant completed all protocol interventions and interactions?" with options "Yes" and "No".
- Question 3: "Is collection of identifiable private information about the participants complete?" with options "Yes" and "No".
- Question 4: "Is analysis of private identifiable information and identifiable biospecimens is completed." with options "Yes", "No", and "N/A".

Below the questions, a note states: "NOTE: If you answered 'Yes' or 'N/A' to all questions, please complete the 'Request Close' to close the study." On the right side of the form, there is a vertical sidebar with icons and labels: a bell icon for 'Notify PI To Submit', a document icon for 'Admin Notes & F...' (with a green circle containing the number 1), a trash icon for 'Abandon', a checkmark icon for 'Submit', a document icon for 'Duplicate as New', and a printer icon for 'Print'.

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 screenshot displays the RES IRB Dashboard interface. At the top, the 'PROTOCOLS' header is visible, followed by the 'Manage Protocols' breadcrumb and the protocol title 'IRB: #15 TEST IRB ES (Copy) (Copy)'. A red circle highlights the 'Reportable Events' tab in the navigation bar, which also includes 'Protocol', 'Activity Log', 'Ancillary Review', 'My Checklist', 'Checklists', and 'Permissions'. On the left, a 'Jump to:' sidebar lists various sections with checkmarks: Amendment, General Information, Personnel, General Questionnaire, Investigator Study Plan, Investigator Acknowledge, Attachments, Administrative Details, and Determinations. The main content area shows the 'Protocol Information' for the selected protocol, including a table with fields like Review Type (Expedited), Status (Approved), Approval Date (Sep 29, 2023), Continuing Review Date, Expiration Date, Initial Approval Date (Sep 27, 2023), and Initial Review Type (Expedited). A 'Feedback' bar is at the bottom. On the right, a vertical menu lists actions: Amend, Renew, Renew & Amend, Action Items Summary, Admin Notes & Files, Review Assignments, Approval Update, Suspend, Close, Request Close, Duplicate as New, and Print.

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

Saved Filters

Report an Event

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/651704d56101a0029508615/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.

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IRB Admin, Test

← Back Report Event for Protocol

Jump to:

- Main Section
- Investigator Opinion

**Main Section**

Provide a description of the event (including the dates and location of activities) and how you will ensure there are no future recurrences.

Date you became aware of this information

Information Categories

1. Information that indicates a new or increased risk, or a safety issue. For example:
  - a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
  - b. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk
  - c. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
  - d. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
  - e. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
  - f. Any changes significantly affecting the conduct of the research
2. Any harm experienced by a subject or other individual, which in the opinion of the investigator is unexpected and probably

Save

Submit for Review

Delete

Activity Log

View Protocol

Print

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

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← Back Report Event for Protocol

Jump to:

- Main Section
- Investigator Opinion

**Investigator Opinion**

Does the event being reported suggest that the research is a greater risk than was previously known or recognized?

Yes

Information Categories

- 1) Information that indicates a new or increased risk, or a safety issue
- 2) Any harm experienced by a subject or other individual, which in the opinion of the investigator is unexpected and probably related to the research procedures
- 3) Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
- 4) Audit, inspection, or inquiry by a federal agency
- 5) Failure to follow the protocol due to the action or inaction of the investigator or research staff.
- 6) Breach of confidentiality
- 7) Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
- 8) Incarceration of a subject in a study not approved by the IRB to involve prisoners.
- 9) Complaint of a subject that cannot be resolved by the research team.
- 10) Premature suspension or termination of the research by the sponsor or the investigator.
- 11) Unanticipated adverse device effect
- 12) Revised Investigator Brochure

Save

Submit for Review

Delete



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.

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← Back Report Event for Protocol

Jump to:

- Main Section
- Investigator Opinion

Investigator Opinion

Does the event being reported suggest that the research is a greater risk than was previously known or recognized?

☐ Yes

☐ No

Does the protocol need revision?

☐ Yes

☐ No

Does the consent document need revision?

☐ Yes

☐ No

I have personally reviewed this information and agree with the above assessment:

☐ By clicking here, I attest that the information provided in this form is accurate.

Save

Submit for Review

Delete

Activity Log

View Protocol

Print

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.

The screenshot displays the RES IRB Dashboard interface. At the top, the header includes 'PROTOCOLS', the 'RESEARCH ENTERPRISE SOLUTIONS' logo, and a user profile 'IRB Admin, Test'. Below the header, a blue navigation bar shows 'Manage Protocols → IRB: #28 Testing'. A secondary navigation bar contains tabs: 'Protocol', 'Reportable Events', 'Activity Log', 'Ancillary Review', 'My Checklist', 'Checklists', and 'Permissions'. The main content area is titled 'IRB: #28 Testing' and includes a 'Jump to:' section with links for 'General Information', 'Personnel', 'General Questionnaire', 'Investigator Study Plan', 'Investigator Acknowledge...', 'Attachments', 'Administrative Details', and 'Determinations'. The 'Protocol Information' section displays a table with the following data:

Review Type	Status	Approval Date	Continuing Review Date
Exempt	Exempt	Nov 02, 2023	--

Below this, another table shows 'Expiration Date' as '--', 'Initial Approval Date' as 'Nov 02, 2023', and 'Initial Review Type' as 'Exempt'. A 'Feedback' bar is at the bottom. On the right, a sidebar lists actions: 'Amend', 'Renew', 'Renew & Amend', 'Action Items Summary', 'Admin Notes & Files', 'Review Assignments', 'Approval Update', 'Suspend', 'Request Close' (circled in red), 'Duplicate as New', and 'Print'.

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.

PROTOCOLS **kuali** McLaurin Hill, Virginia A

← Back Manage Protocols → IRB: #3765 Sandbox Sample

Protocol Reportable Events Activity Log Permissions

Close Request In Progress Jul 07, 2023 Expedited

Jump to:

- Close Request ✓
- General Information ✓
- Study Personnel ✓
- General Questionnaire ✓
- Protocol Details ✓
- Study Details
- Attachments ✓
- Researcher Comments

Administrative Details

Determinations

Close Request

Section 1

Did research activities ever start?

☐ Yes

☒ No

General Information

Please Note: Personnel listed with Full Access can edit the Protocol, but only the listed Principal Investigator has access to perform the initial Submit

Admin Notes & F... 1

Abandon

Submit

Print

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.

PROTOCOLS

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← Back Manage Protocols → IRB: #28 Testing

Protocol Reportable Events Activity Log Ancillary Review Permissions

Jump to:

- Close Request ✓
- General Information ✓
- Personnel ✓
- General Questionnaire ✓
- Investigator Study Plan
- Investigator Acknowledge... ✓
- Attachments ✓

Administrative Details

Determinations

Close Request

Section 1

Did research activities ever start?

☒ Yes

☐ No

Is this study closed to enrollment?

☒ Yes

☐ No

Have all participants completed all research-related interventions?

☒ Yes

☐ No

Have all participants completed all research-related follow-up?

☒ Yes

☐ No

Save complete

Notify PI To Submit

Admin Notes & Files

Abandon

Submit

Duplicate as New

Print

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.