Kuali Protocols - IRB User Guide

The Kuali Research module streamlines the development of protocols and facilitates best practices in protocol management throughout the research lifecycle. Kuali facilitates fast, clear, and specific communication between the IRB, researchers, and the Human Research Protection Office, to ensure efficiency and compliance. Kuali is designed to be intuitive – the simple interface design should allow researchers to quickly create and manage protocols. Some key features of the Kuali 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 Net ID and password for integration with the human subjects training CITI records, integration with the grants and proposal management Kuali modules, and future integration with conflict of interest Kuali module

- **Submit Amend/Renew actions** at the same time (rather than having to submit them as separate actions)

- **Newly revised Reportable Events section** (Unanticipated Problems, Serious Adverse Events, Incidental Findings)
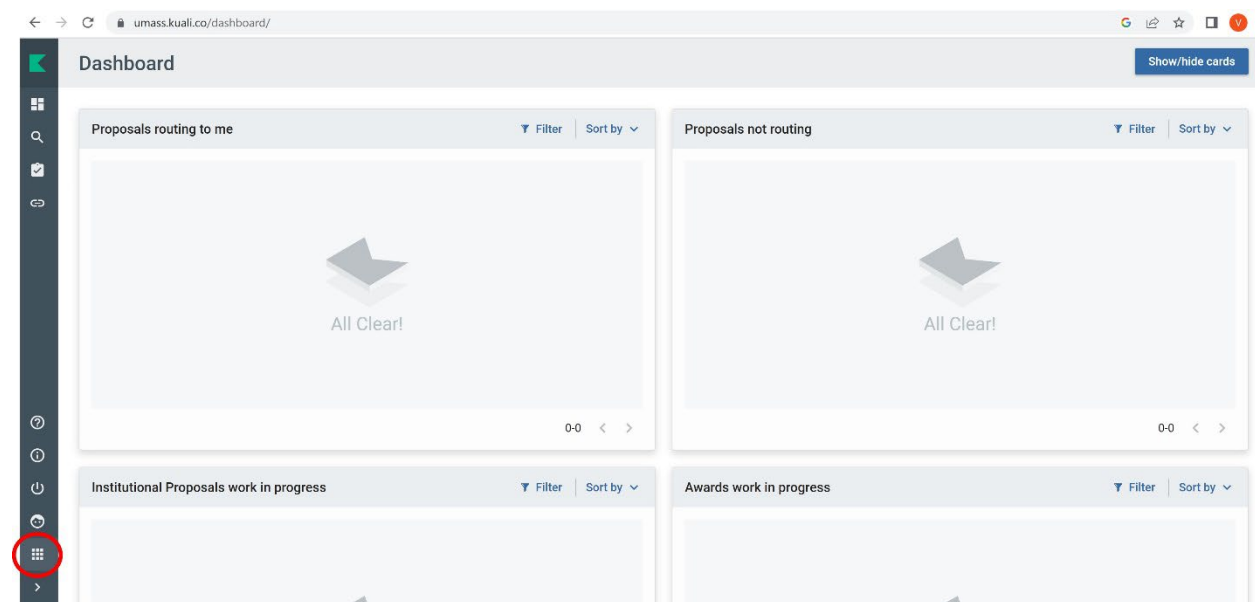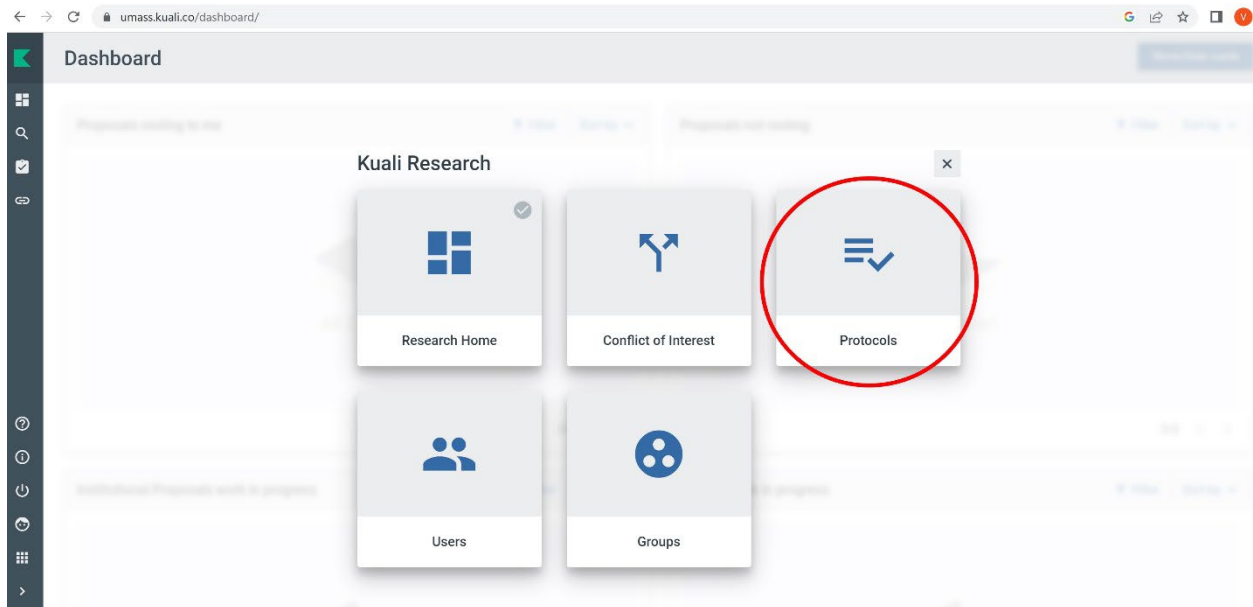
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Creating a New IRB Protocol

1. Log into Kuali (www.umass.edu/research/kuali) using your NetID and password.
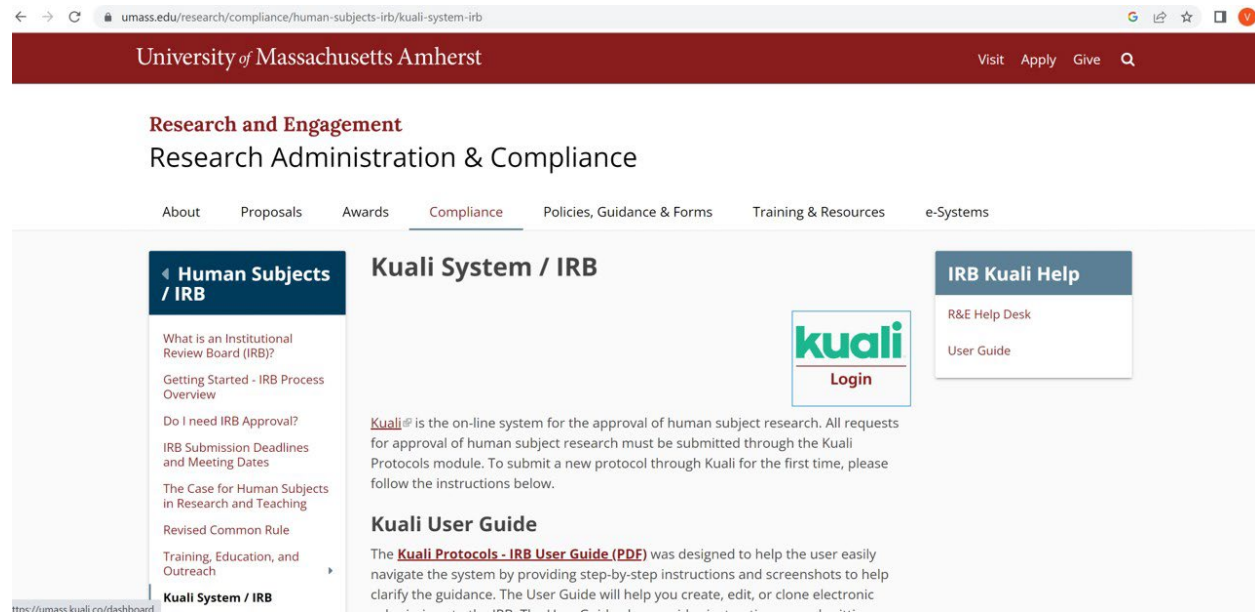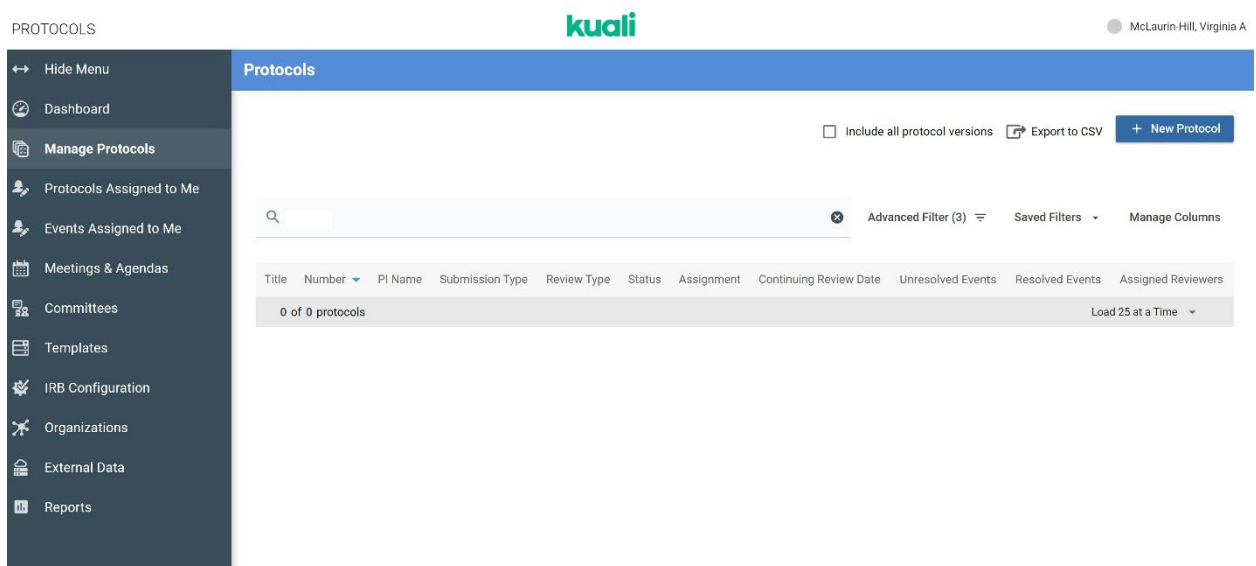

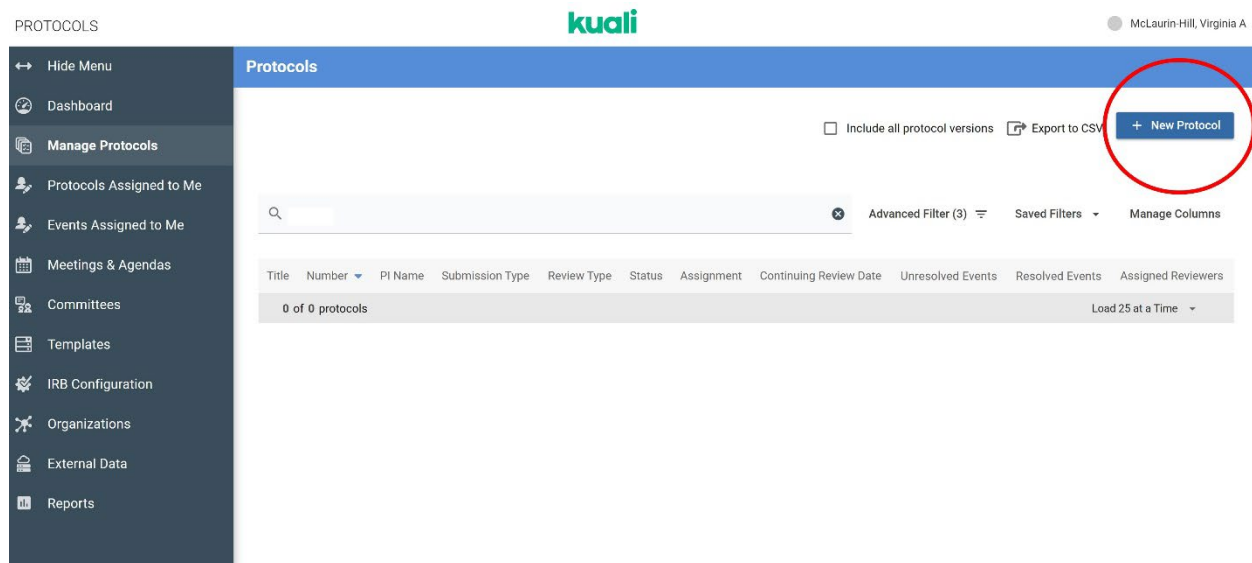2.   Select Switch Apps on the lower left margin.
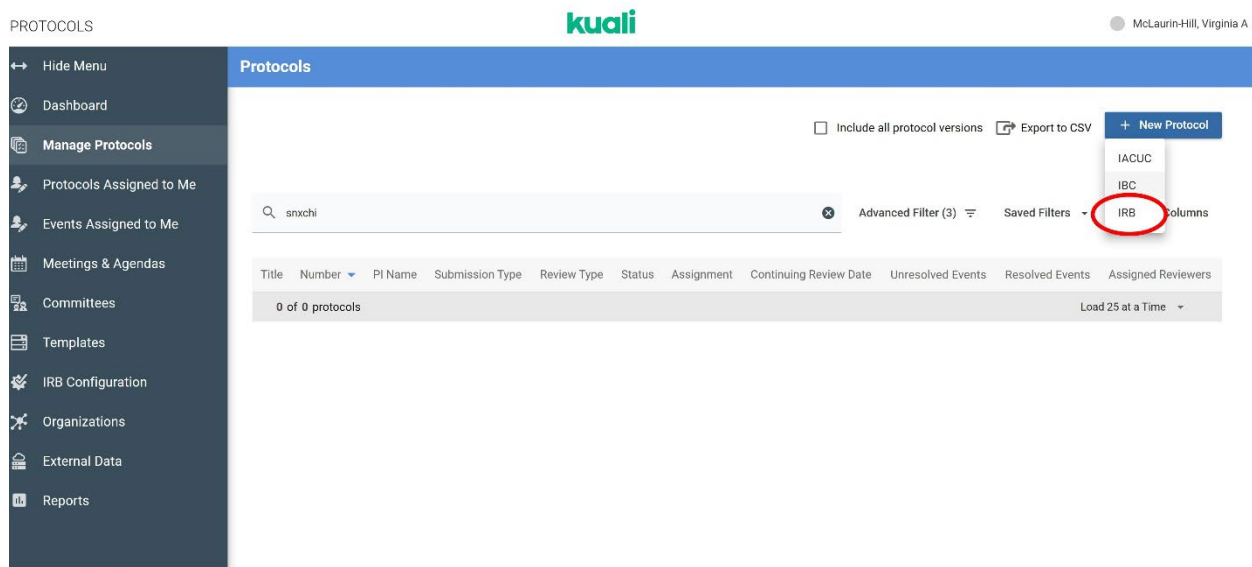
3.	Select the tile called Protocols.

4.	You will see a dashboard that looks like this:

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

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

7.   Enter the name of the Principal Investigator/Protocol Director. This is the researcher (undergraduates and graduate students should enter their own name for their research projects). As you type in your name, it will automatically populate, and when you select your name from the drop-down box, the department (Lead Unit) will automatically fill in as well. Then, enter the Title of the protocol. This title will not have to be the one you use for future publications; ideally, it is descriptive enough so that you can quickly identify what protocol it refers to if you have several in the Kuali system at once.

8.   After entering the required information, click on Next.

9. The Kuali system will then proceed to ask a couple of administrative questions. When you see the question "Are you seeking to determine whether or not your project requires IRB review?" please select "no" if you know that you will be filling out a full protocol, and "yes" if you are unsure if your project will require a full protocol; this will start a determination request to our office. See page 41 of this guide for more information on submitting a determination request.

10.   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.

kuali

McLaurin-Hill, Virginia A

← Back | **Manage Protocols → IRB: #4671 Sample Protocol**

Protocol   Activity Log   ⬤ Ancillary Review   Permissions

Jump to:

General Information

Study Personnel

General Questionnaire

Protocol Details

Study Details

Attachments

Researcher Comments

sidebar navigation

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 action of the Protocol.

Principal Investigator *

McLaurin-Hill, Virginia A ⊗

Department *

Dept: Research Compliance ⊗

Protocol Title *

Sample Protocol

Study Personnel
2 REQUIRED REMAINING

Is the PI a student? *

◯ Yes

📎 Admin Notes & Files

⊗ Abandon

⬆ Submit

🖨 Print

scrolling

Adding Study Personnel, Locations, and Funding

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

Adding UMass Personnel:

Adding Non-UMass Personnel:

2.   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.

3. Next, please enter all study locations by clicking the **+Add Line** button. Note that for online studies, there is an "online" location option, and general geographical areas can also be noted.

If your study is supported by a grant or any funding, please select the appropriate box and answer the prompts that appear. For example, clicking on External Funding will trigger two follow-up statements and either an Institutional Proposal Lookup (see the example highlighted in yellow below) or an Award Lookup. For a detailed guide on adding funding, see Page 17 of this user guide.

Body of the Protocol: Tips and Suggestions

1. Under Study Details, in the Background section, please provide scholarly sources that provide a context and background for the research being conducted - these may be sources on the topic, the methodology, etc.

2. In Recruitment and Screening, note that we will want to see samples of any outreach materials, whether they are flyers posted around campus, online jpeg flyers, emails, Prolific/MTurk "HIT" descriptions, verbal scripts, etc. There is a section where you can upload documents such as flyers or documents related to your recruitment. Clicking on either **+Add Info** or **+Add Line** will cause the Recruitment Attachments section to expand. You can drag the recruitment file directly onto this section or bring up a navigation window and search for the file on your computer. You can add as many recruitment attachments as necessary by repeating the process. (Note that other sections of the protocol will also have this built-in logic. Depending on your answer to a specific question, a follow-up question or pop-up may be triggered.)

3. If you are screening participants, note that screeners are generally not meant to ask for personal or identifiable information, and should contain only questions that determine if a person could potentially participate in the research.

4. Under Compensation, include in this section any proration that takes place, as well as anything that would result in failure to be compensated (such as failing "attention check" questions in surveys).

5. Under Benefits, note that for the majority of projects, there is likely no direct benefit to participants that can be guaranteed. Most projects will state this and then list any potential benefits.

6. In the Confidentiality section, note that OneDrive is the preferred method of storing information, and be aware that audio and video, phone numbers, and emails do count as identifiable data.

7. In the Informed Consent section, please hit **+Add Line** or **+Add Info**.

A pop-up box will emerge. There will be questions about how you will get consent. The answer to the first question, "Are you requesting a waiver of consent?" will likely be no. For the second question, "Are you requesting a waiver of documentation of consent?", select "yes" if you are doing an online form where participants click 'I agree/I don't agree' or any consent process where there is no signature. Select "no" if participants will sign a consent form either in person or online (such as by typing their name).

Then, upload the consent form within this pop-up box. If you have multiple consent forms for different aspects of your study, you can add additional lines. If you have indicated that children are in your study, additional sections will populate for parental permission forms and for assent forms. Templates for all of these forms can be found here.

8. The Attachments section at the bottom of the protocol is where you can upload additional documents related to what your participants will be doing. These may be sample interview questions, the survey you are administering, an outline of the physical activity participants will be doing, etc.

9. Answer all relevant aspects of the protocol and upload documents such as recruitment materials, consent forms, grant write-ups, letters of support, etc. The last section of the protocol is the Researcher Comments, in this section the researcher can provide comments to the IRB reviewer that may provide context, special instructions, or circumstances that have not been captured in the body of the protocol.

Submitting a Protocol

1.   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).

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 Add Funding

If your project is being funded by an external source, especially a federal agency, it is important it is reflected in the protocol. By entering the "Institutional Proposal Number" all relevant aspects of your funded protocol should populate and your IRB proposal will be linked to that grant. To find the "Institutional Proposal Number" please follow these instructions:

1.   Select Grants/Contracts for the "funding type" in the Protocol. This will expand that portion of the Funding section.

You will need to know whether your grant is in a Pre-Award or Post-Award stage. If Pre-Award, you will want to link the Institutional Proposal (submitted proposal, not yet awarded). If PostAward, you will want to link the Award – please follow the steps below for each of these.

2.   On the left-hand side of the Kuali Dashboard, you should see some icons. Click on the icon shaped like a paperclip (see below). Clicking on that icon should take you to a page listed "All Links."
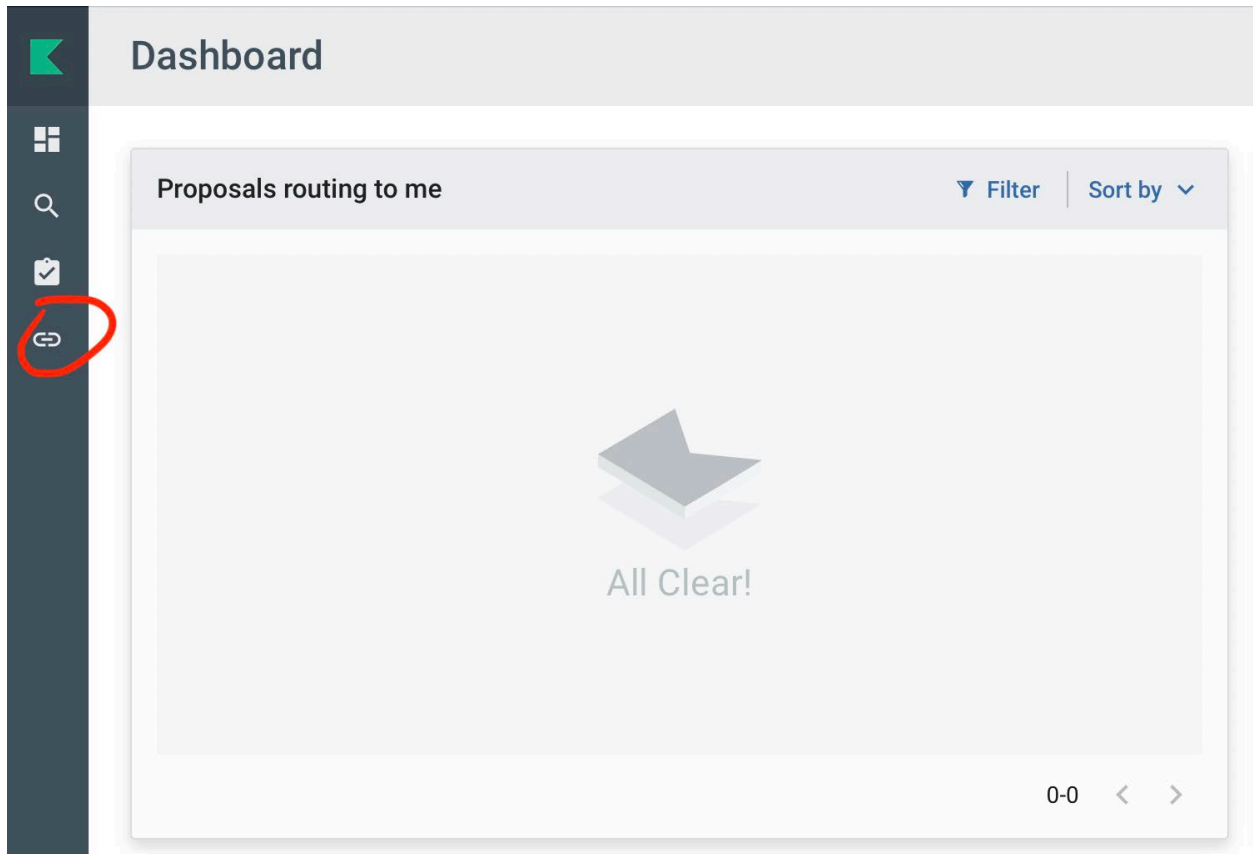
3.   From the "All Links" page you should see a heading called "Awards" and a hyperlink below it called "All My Awards."

For Institutional Proposals

1.   You will be brought to the Institutional Proposal Lookup screen.

You will need to pick one or more criteria to search by. Title or Proposal Person work best.

2.   To search by Proposal Person (personnel listed), start by clicking the Magnifying Glass to the right of the Proposal Person field.

3.   This brings you to the Institutional Proposal Person Lookup. Search for your last name in the Full Name field WITH an asterisk/wildcard character (*) before and after and click Search.

You may see your name listed many times in the search results; this is normal. Click "return value" next to one with your name. This will bring you back to the Institutional Proposal Lookup screen with your full name as Kuali has it listed in the Proposal Person field. Click Search to pull up the list of Institutional Proposals.

4.   Kuali Institutional Proposal numbers have the format of 8 numbers, either starting with zeros (migrated from SmartGrant) or 200 (Kuali submitted proposals). This 8 digit number is what you will enter into the Protocol Funding field with Institutional Proposal selected. Click "Find and add" once you enter the number.

5.   You will now see the Institutional Proposal linked in your main protocol.
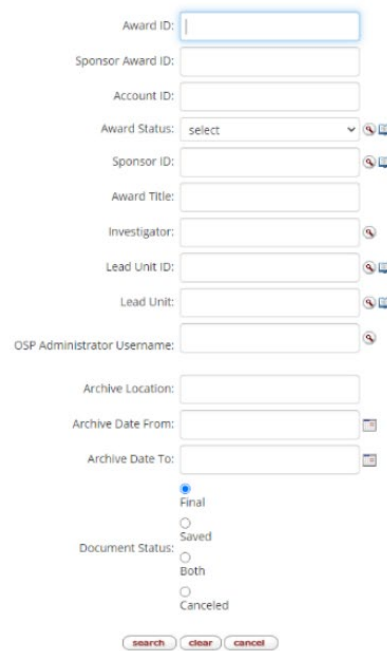
For Awards

1.   You will be brought to the Award Lookup screen.

You will need to pick one or more criteria to search by. Title or Investigator work best.

2.   To search by Investigator, start by clicking the Magnifying Glass next to the Investigator field.

3.   This will bring you to the Person Lookup screen. Start by typing in your first and last names in the appropriate fields WITH an asterisk/wildcard character (*) before and after. Click Search.

Click "return value" next to your name in the results. This will insert your full name as Kuali has it into the Investigator field back on the Award Lookup screen

4.   Click on the Award Status drop-down field and select "Active."

5.   Click Search and find the correct Award in the list. Kuali Award numbers have the format of ######-##### (015999-00001) and will either start with 00 (Legacy Awards from SmartGrant) or with 015 (Kuali Awards). This will be the number you will enter into the Protocol Funding field with Award selected. Click "Find and add" once you enter the number.

6.   You will now see the Award linked in your main protocol.

How to Access Your Approval Letter

1.   Log in to your Kuali IRB Dashboard and click on the title of the approved protocol for which you want to access the Approval Letter.

2.   Once you've opened the protocol, click on the **Admin Notes & Files** button on the right side of the screen.

3.   Clicking Admin Notes & Files make a pop-up appear which should list documents added by our office such as the Approval Letter, any stamped informed consents (for Expedited or Full Board level studies), any external approval documents, agreements, etc. Find the document with the description IRB Approval Letter (red circle below) and click on the corresponding hyperlink to its left (red arrow below).
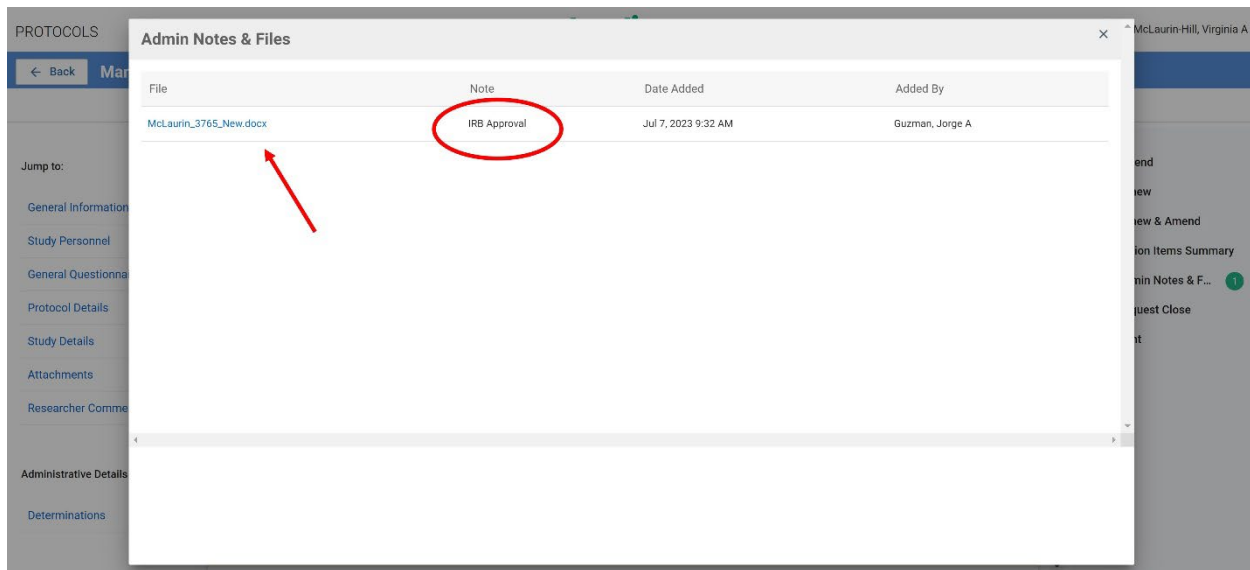
4.   Another pop-up screen will appear which looks like the following:
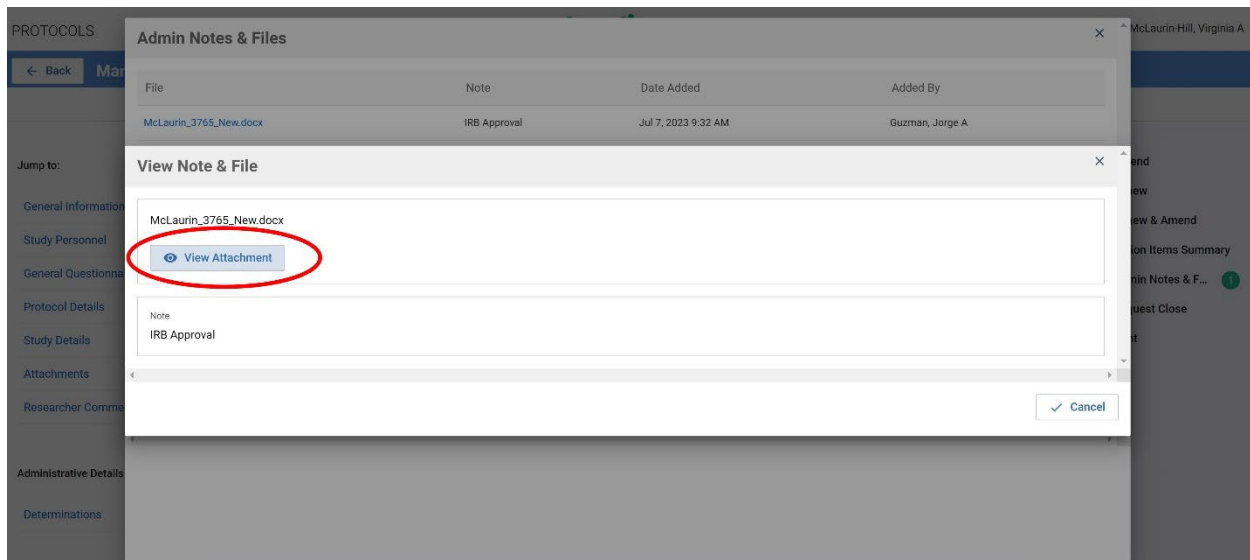
5. Be sure to click the View Attachment button to view your Approval Letter.
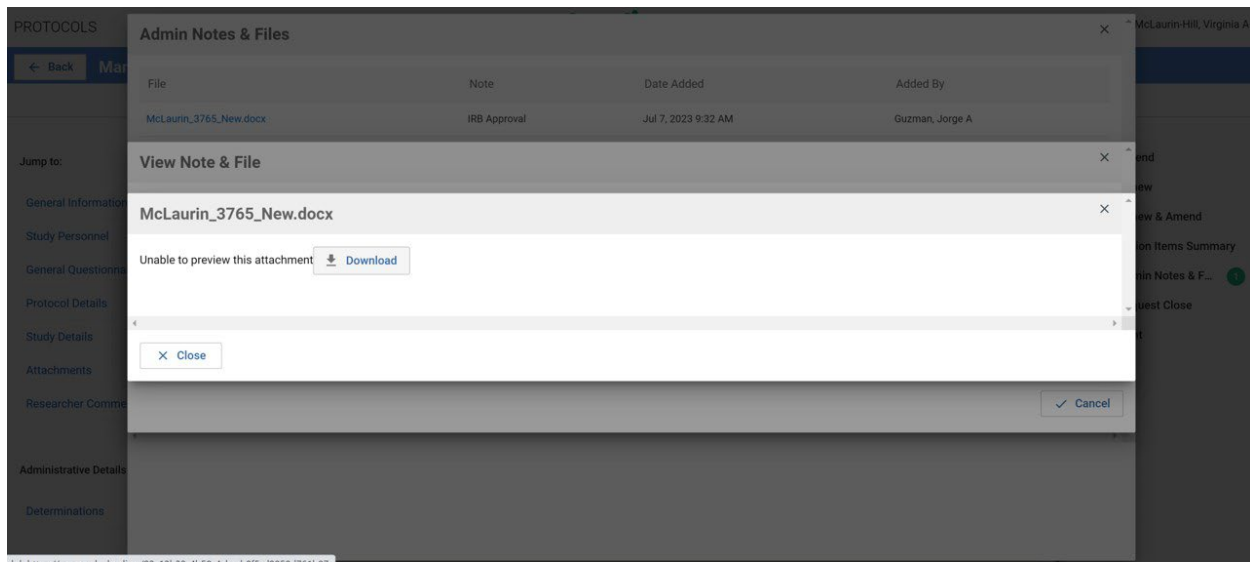
6. You may be able to view pdf and jpeg files in the Kuali system. However, for .doc and .docx files, you will be asked to download the files to your computer to view them.

Sample Approval Letter:
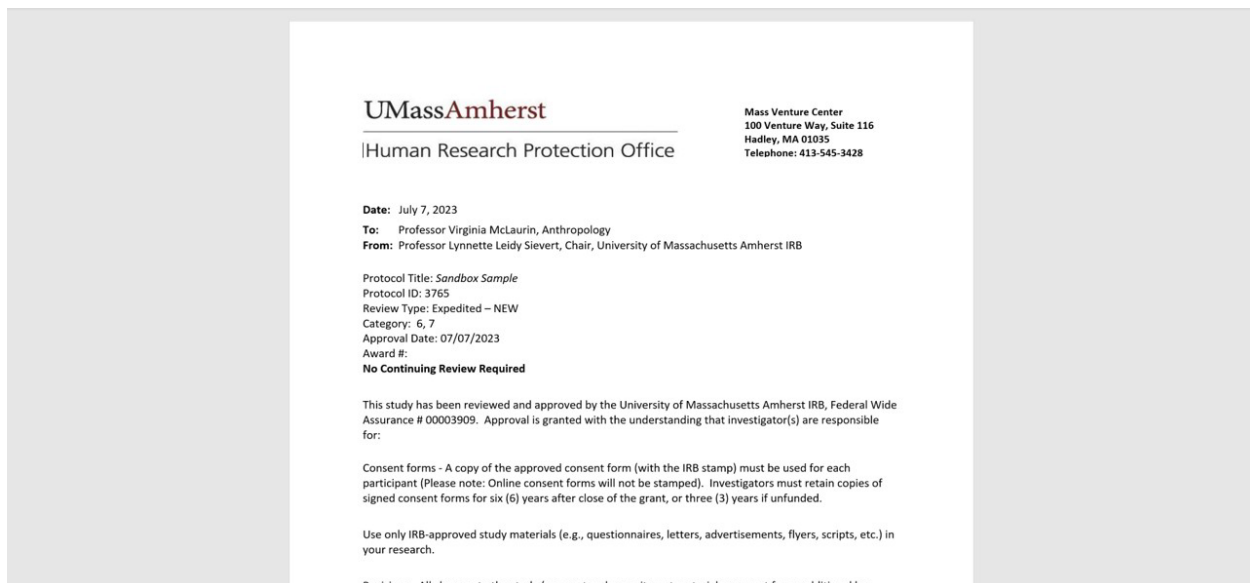
How to "Amend," "Renew," or "Renew & Amend" Your Protocol

1.   After your protocol is approved, any changes you wish to make must be reviewed by the IRB. In certain cases, a Renewal submission to the IRB may be necessary (your Protocol Approval letter will indicate whether a "Renewal" or "Annual Check-In" submission is required). Previously, researchers could only submit an Amendment or a Renewal separately. The Kuali system now allows researchers to submit a combined Renew & Amend request. This feature aims to alleviate administrative burdens for both researchers and the IRB by reducing the number of actions needed to amend and renew a protocol.

2.   Log in to your Kuali IRB Dashboard and click on the title of the protocol you want to Amend, Renew, or Renew & Amend.

3.   The right sidebar will provide you several options (see red circle below). In this example, we will be selecting Amend, but the other options will work very similarly.

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

5. 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 requesting. 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 should be included in the body of the protocol.

Example of Proposed Change:

Example of Corresponding Change in Participant Number in Protocol Main Body:

Example of Corresponding Addition of New Flyer:

6. 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.

Submitting a Reportable Event

1.   Log in to your Kuali 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 our guidance on Adverse Events Reporting. Click on Reportable Event at the top of the screen to open this form.

2.   The Reportable Event 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.

3.   The Report Event page has a drop-down menu, select the type of event you want to report. In this example, we will be submitting an "Unanticipated Adverse Event."

4.   Answer all the prompts regarding the reportable event. Although Kuali auto-saves your work, please click the Save button on the right side of the screen often to save your work as a precaution.

Once you've completed the form, please click the Submit for Review button on the right side of the screen.

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

How to Close Your Protocol

1.   Log in to your Kuali 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. If you have any questions regarding what closing out a protocol means for your study, please review this guidance or contact our office.

2.   Once you open the desired protocol, the sidebar on the far-right side will provide you available actions. Click on **Request Close** (in the past this action was called Final Report) to initiate this action.

3. 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 the researcher 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.

4. 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.

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

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

kuali

← Back   **Manage Protocols → IRB: #3765 Sandbox Sample**

Protocol   Reportable Events   Activity Log   Permissions

Close Request

Jump to:

Close Request ✓

General Information ✓

Study Personnel ✓

General Questionnaire ✓

Protocol Details ✓

Study Details

Attachments ✓

Researcher Comments

Administrative Details

Determinations

○ No

Number of reportable protocol deviations/violations since the start of the study.

(sample text)

Describe all Reportable Protocol Deviations/Violations since the start of the study.

(sample text)

Did you have any Serious Adverse Events since the last approval date?
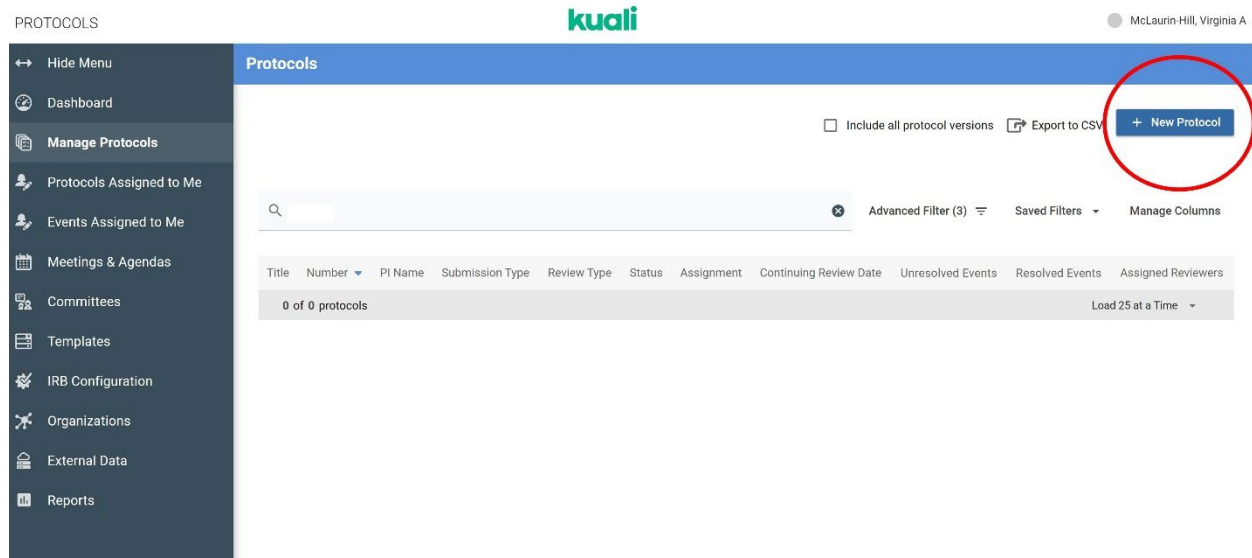
○ Yes

◉ No

Section 4
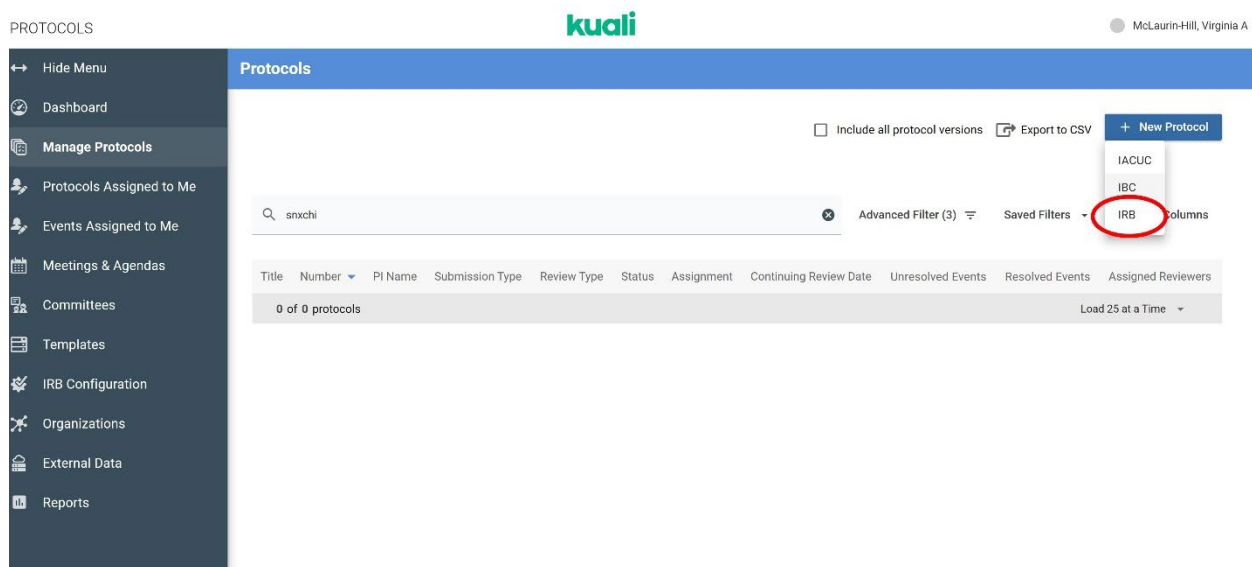
⊗ Abandon

⬆ Submit

🖶 Print
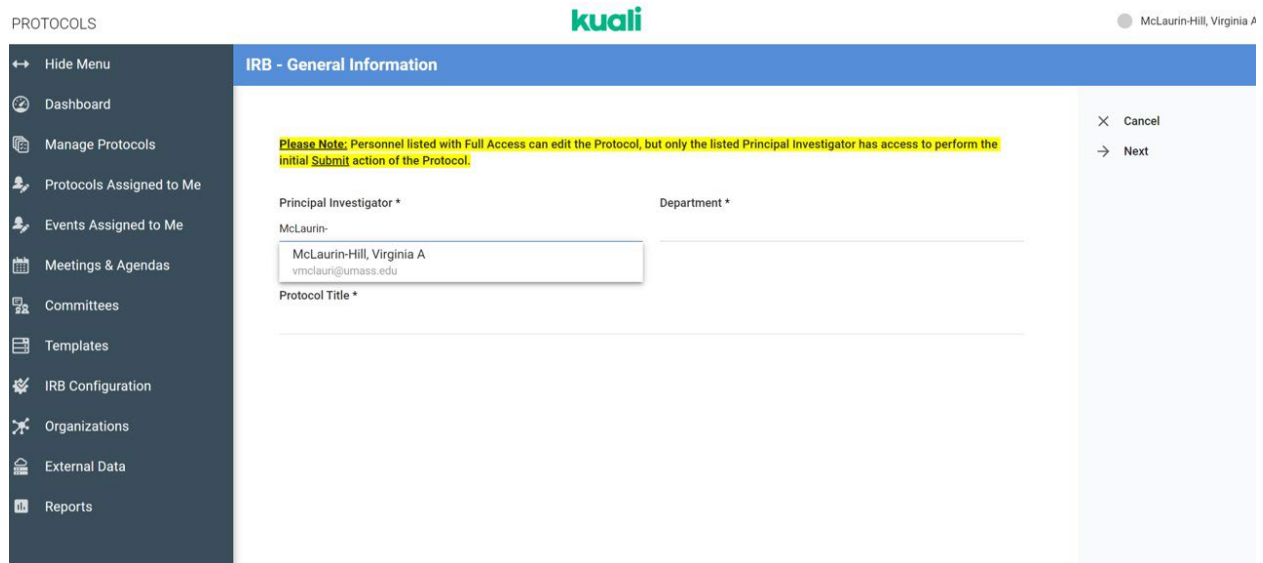
How to Submit a Determination

1.   Log in to the Kuali IRB Dashboard and click the **+New Protocol** button located on the upper right-hand side of the screen.
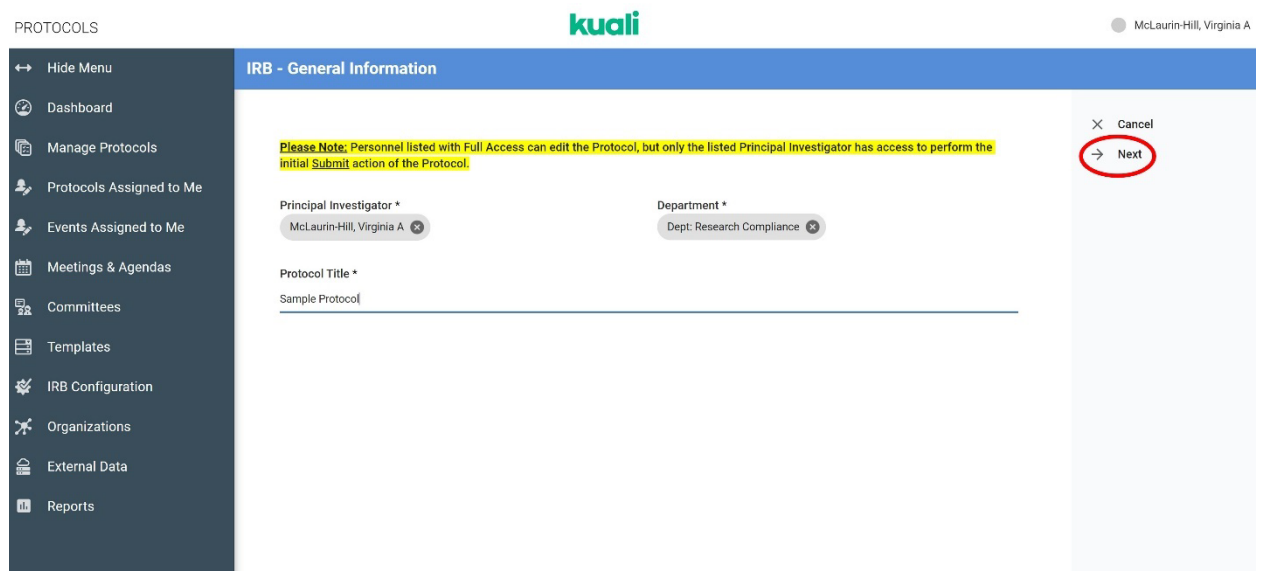

2.   Select "IRB" from the drop-down menu that will appear.

3.   Complete the General Information fields (Principal Investigator, Department, and Protocol Title)

4.   Click "Next" on the right-hand side of the screen.

5.   Complete the questions regarding project type (Biomedical or Social Behavioral) and Community Engagement.

6.	The final question on this page will be "Are you seeking to determine whether or not your project requires IRB review?" Answering "YES" to this question and clicking "Next" on the right-hand side of the screen will open the Determination form. This will trigger an abbreviated form that only requests essential information for our office to decide whether your project needs IRB review or whether it falls outside the federal regulations. After filling it out, hit "Submit" on the right hand side, and our office will reach out with our determination or follow-up questions.