TEXAS ★ STATE ®

**Research Integrity and Compliance
Office of Research and Sponsored Programs**

Kuali Protocol Training Exercises

IRB Researcher

Exercise 1 – Logging In

Step No.	Instructions
1	Navigate to: https://txstate.kuali.co/protocols
2	**Username**: <enter your Net ID> **Password**: <enter your password>

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Login to Kuali Protocols

NetID

> Forgot your password?

> Activate your NetID

Password

Login

Kuali Software as a Service
Use of computer and network facilities owned or operated by Texas State University requires prior authorization. Unauthorized access is prohibited. Usage may be subject to security testing and monitoring, and affords no privacy guarantees or expectations except as otherwise provided by applicable privacy laws. Abuse is subject to criminal prosecution. Use of these facilities implies agreement to comply with the policies of Texas State University.
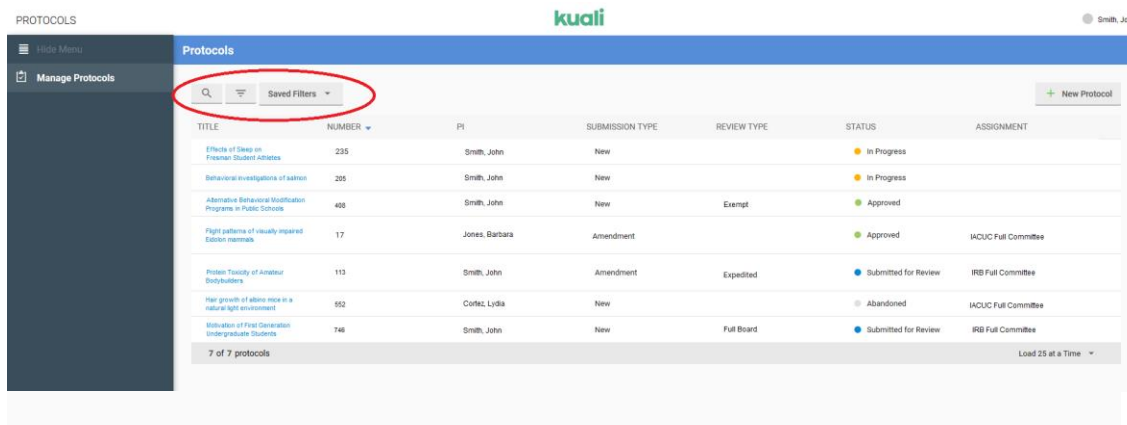
Exercise 2 – Researcher Portal

As a researcher, student, or administrator acting on behalf of a researcher, you can prepare and manage your IRB protocols throughout their life cycle to ensure compliance with regulations and policies.

Upon logging into Kuali Protocols, the researcher will see all current protocols for that given individual Protocol Type. This list allows researchers to track all past, present, and in progress protocols so they are aware of their status and can ensure compliance.

The **Filter** [icon] functionality can be used to hone down the list to your desired results or views. These filters can also be saved for future use. To access the filters, click on the arrow at the top of the page.

Also, within the **Filter** section, you can configure the **'Table Column Visibility'**. This allows you to configure the columns that suits your needs.
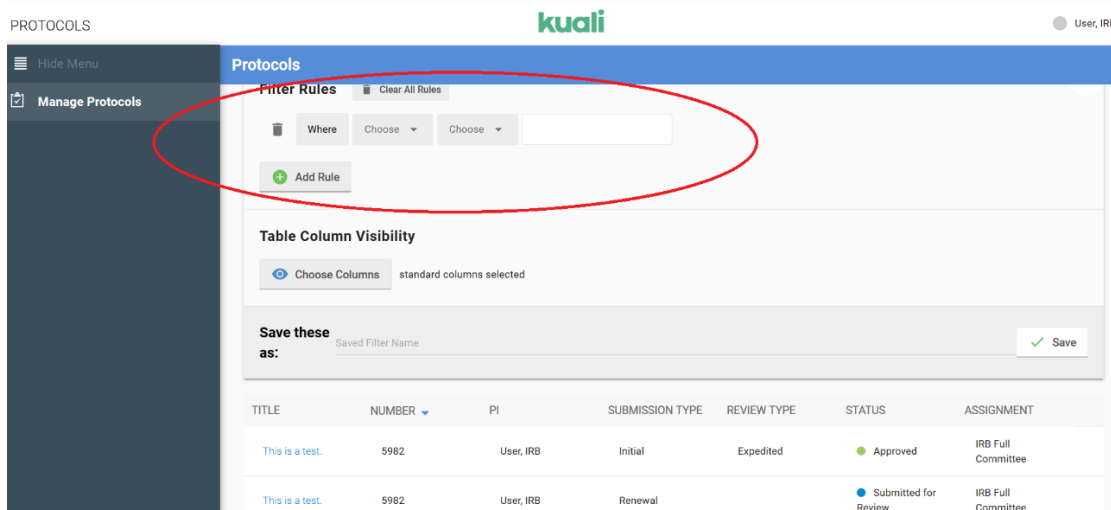
Exercise 3 – Creating a Protocol

Step No.	Instructions
	Navigate to the **Manage Protocols** section.
1	To start a new protocol simply click the **'New Protocol'** button in the top right-hand corner of the Manage Protocols screen and select **IRB**.
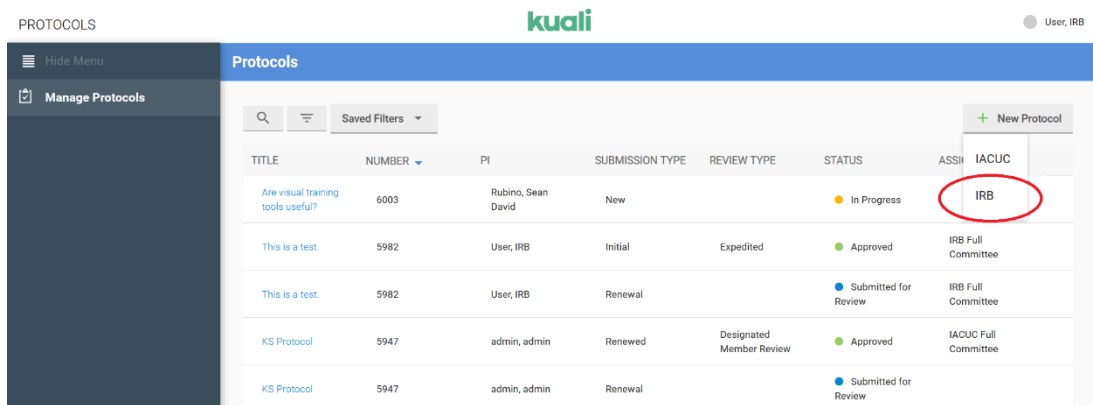
2	Once initiated the system will guide you through the protocol creation starting with **Researcher Information**.
	In the **Researcher Information** section complete the following:
	• Are you a Research Integrity and Compliance staff member? **ANSWER as NO**
	• Answer the proceeding questions regarding the researcher.

Click below the heading and begin to type the last name of the **Principal Investigator**. A drop down menu will appear. Highlight and click the **last name** of the Principal Investigator. Only faculty and staff are eligible to be Principal Investigator.
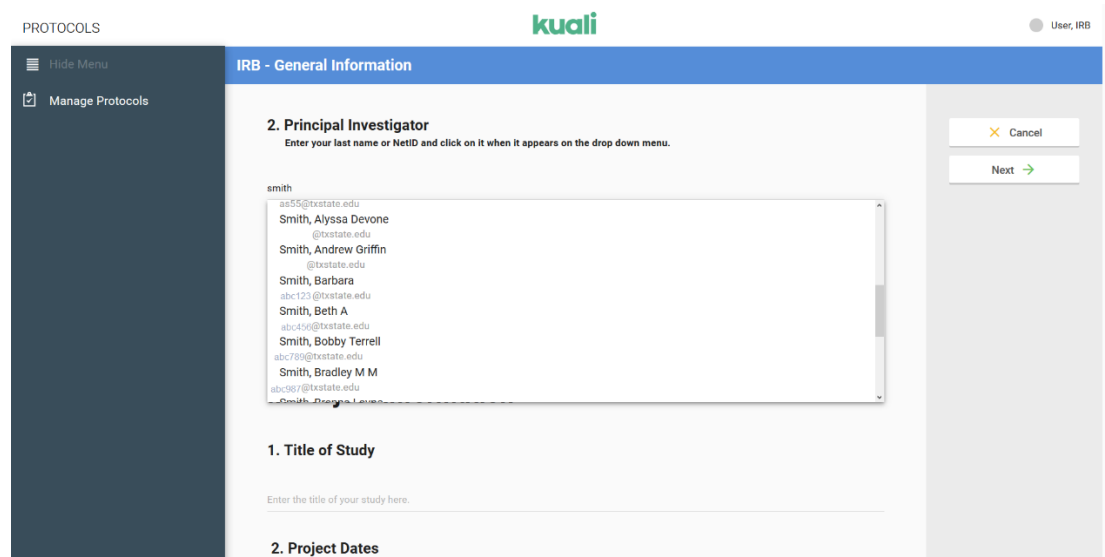
3

Click below the heading. A drop down menu containing department names. Highlight and click the appropriate department.
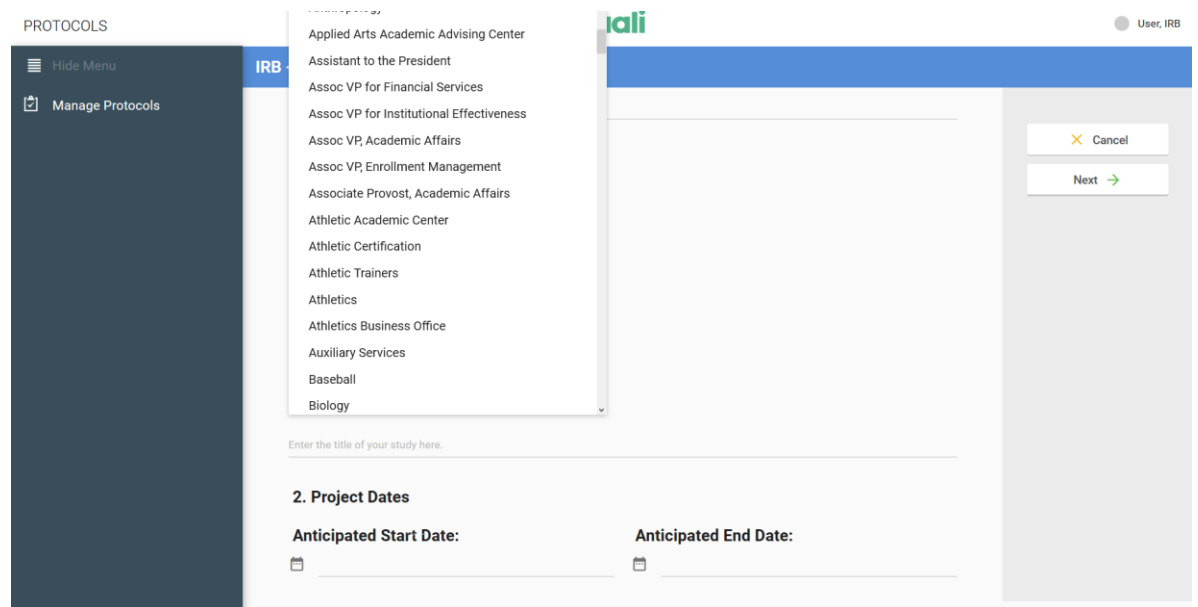
4   Answer the remaining questions as they appear and click the '**Next**' button on the right of the screen.

5   The next section is the **Risk Review**. Answer the questions as they appear. The **Risk Review** section is designed to assess the protocol's review level and type and inform the researcher. Click the **'Next'** button when the Risk Review is complete.

6   After the initial information is collected, the system will provide you with an entire protocol view.

Complete the remaining sections.

During this portion, you may provide the names of co-investigators and other key personnel associated with the protocol, study objectives, and other protocol relevant information.

The Jump to... area on the left side of the screen allows users to easily navigate to the desired sections in the protocol. This quick navigation allows you to move freely throughout the multiple sections of the application.
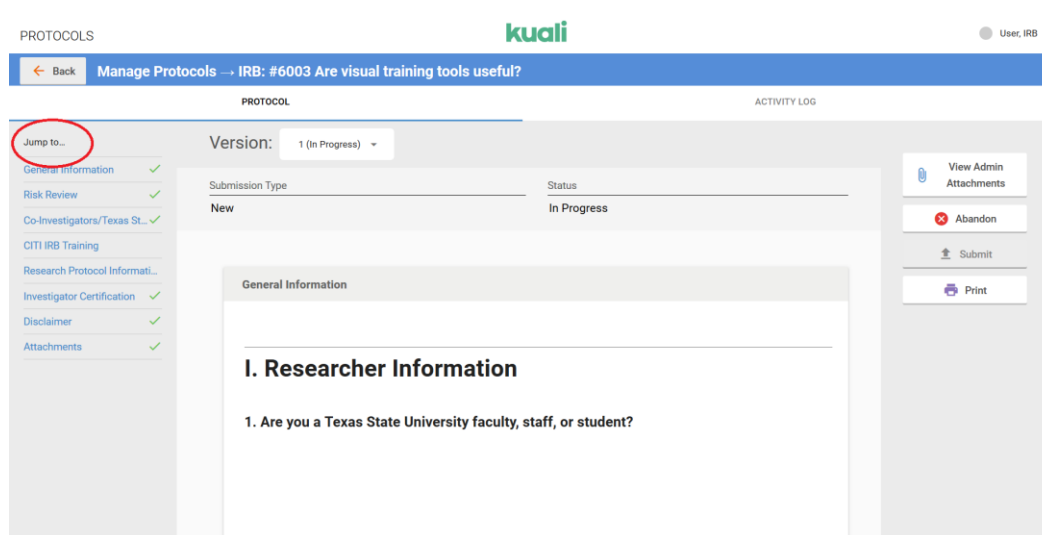
Protocol Personnel

Scroll down or click on the section titled '**Protocol Personnel**'. This section allows you to add co-investigators and key personnel and assign their protocol role and access to the protocol in Kuali. The principal investigator will click on the + Add Line button to add individuals to the protocol.

7   Once you click the button, the following box will appear. Provide the names, roles, contact and training information of the individuals working on the research protocol.

Add   ✕

Person   Enter the last name of the individual. Like in the Principal Investigator section, the names of Texas State employees will automatically populate. The names of students and non-employees will need to be inserted manually.

Department   Click on the arrow and identify the applicable department of the individual. If none of the names are applicable, then choose N/A.

Email Address   Manually insert the individual's email address.

Phone   Manually insert the individual's phone number.

Protocol Role   Click the Action button to assign the individual's protocol role. Only the roles of Principal Investigator, Co-Investigator, or Key Person can be assigned. Only one individual is able to be assigned the role of Principal Investigator.
  + Add

Contact Roles   Click the Action button to assign the Contact Role of the indivual. The individual may be assigned the role of Admin, Department Admin or Department Contact.
  + Add

Protocol Access Permissions

☐ Full Access (able to view and edit this protocol)   Indicate the level of Kuali Protocol access the individual will have to the protocol. Full Access will allow the individual to freely change and edit the protocol.

☐ Read-Only (able to view this protocol)

People Attachments   👁 Columns   + Add Line

ATTACHMENT	NAME	ATTACHMENT TYPE	
		+ Add Info	Click on '+Add Info' to upload protocol required training documents, professional certifications, or other pertinent personnel documents.

✕ Cancel   ✓ Done

Exercise 4 – Submitting a Protocol

Step No.	Instructions

Upon completion of your protocol the following actions are available:

1

- The option to **View Admin Attachments** is available. If you have been working with RIC while developing your Protocol there may be attachments in this section for you to review. In most cases this section will be empty until the Protocol has been submitted for review.
- As the initiator, you can **Abandon** this Protocol until it is submitted for review if you decide not to proceed with this document.
- You can submit for review using the appropriate '**Submit**' action button on the right-hand corner.
- There is a '**Print**' option available that allows you to print the entirety of your protocol to PDF for your review or for physical printout of you desire.

To submit the protocol to the appropriate protocol administrator for review, click the **'Submit'** button.

2
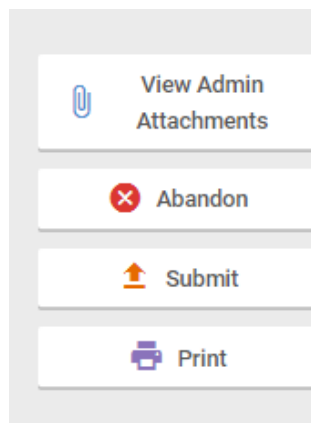
3	After you click the 'Submit' button, the following actions will be available in the h right corner of the protocol: • The **'View Admin Attachments'** will be available for the life of the protocol. • A **'Withdraw'** option allows you to pull the protocol from review if you need to make additional edits prior to review. • Once RIC assigns your protocol to a committee, the **'Withdraw'** action is no longer available. • The **'Print'** option will be available for the life of the protocol.
4	After submission you can track the progress of your protocol in the researcher **Manage Protocols** portal which will display the current Status, Assignment, Assigned Reviewers, Approval Date, Expiration Date, etc.

TITLE	NUMBER ▼	PI	SUBMISSION TYPE	STATUS	⚙
Research Protocol Title	41	McGregor, Geoff	New	● Submitted for Review	

Exercise 5 – Returned Protocols Requiring Action

Upon review of a given protocol, RIC may send it back to the principal investigator for additional information or other requested changes. When a protocol is returned, the status of the protocol will be either **'Returned to PI'** or **'Requires Revision'** in your researcher portal. Protocols are returned to the PI when they are incomplete or not ready for review or when they have been reviewed but need some sort of edit or additional information prior to approval.

Step No.   Instructions

1	Click on the protocol title to open a returned protocol.
2	Upon opening the protocol you will see either general comments or section specific comments highlighted with orange text boxes. Click on the **'General Comment'** or **'Comment'** icons to review comments and specific items requiring action.

If needed, click the **'Show Latest Changes'** checkbox to see any changes that have occurred on the protocol since the last version. This helps better identify items that have changed since the last submission.

3

Also, when a protocol is returned, the top section provides a history of the versions and a summary of the current protocol status and information.

The **'Version'** dropdown allows you to view prior version information, and the **'View Activity Log'** gives you a history of the series of actions that have taken place on this protocol.
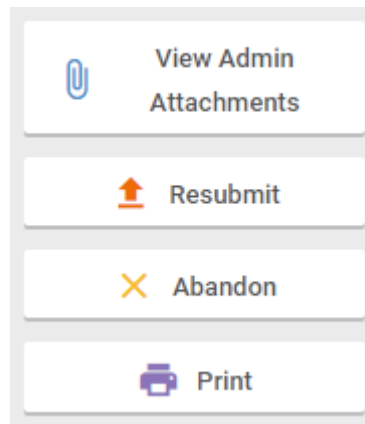
4

5   Once the commented items have been addressed and you have applied changes where appropriate you can resubmit the protocol back to the IRB administrator using the **'Resubmit'** action button in the right-hand corner.

Also, if you decided to cancel or permanently discard this protocol for any reason you can utilize the **'Abandon'** action button.

Exercise 6 – Amending or Renewing (Continuation) an Approved Protocol

Once a protocol is approved, the PI (if granted full access on the protocol) or Admin can initiate an Amendment or Renewal on the protocol if needed.

Within these actions, you can update information and attach necessary updated documents for review.

When an Amendment or Renewal is initiated, a separate request under the same protocol number is created and, once approved, the changes merge back into the original protocol.

Please note, only one outstanding action can be taken on a given protocol. If an amendment or renewal has already been initiated on a protocol, the **'Amend'** and **'Renew'** buttons will be greyed out in the existing approved protocol.

Amending an Approved Protocol
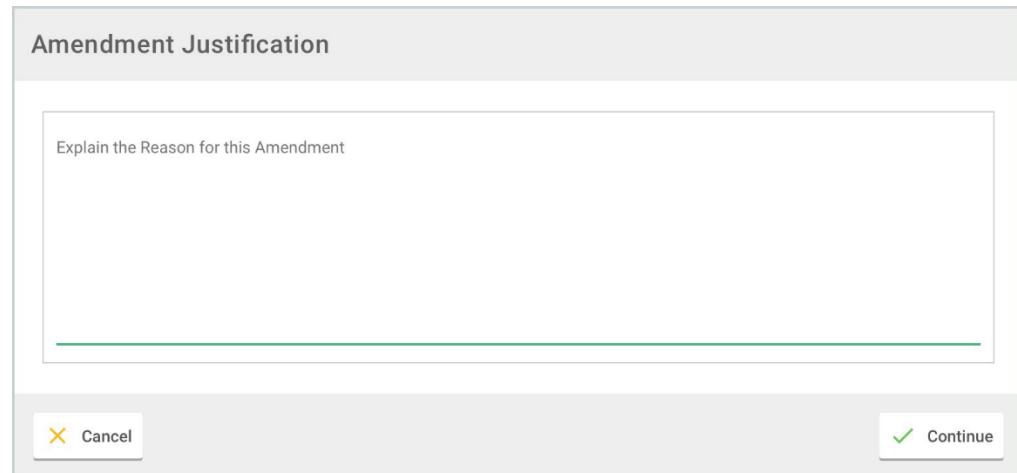
Step No.	Instructions
1	On an approved protocol the **'Amend'** button will be available if you need to make a change, modification, or addition to something on the protocol. This button will only be available to those granted full access to the protocol or an admin can initiate.
2	Upon clicking the **'Amend'** you will be required to fill out more detail on the reason for the Amendment. Once you complete and click **'Continue'** it will initiate an amendment on the protocol in which you will need to fill out the necessary information.
3	You may scroll down or click the name of the section on the menu that requires amending. Click the ✎ Edit button and insert the appropriate information.

Renewing an Approved Protocol

Step No.	Instructions
1	On an approved protocol the **'Renew'** button will be available if you need to submit a continuing review request. This button will only be available to those granted full access to the protocol or an admin can initiate.
2	Upon clicking the **'Renew'** button you will be required to fill out/complete the necessary information as applicable. 🗓✓ Renew
3	Once complete you can submit the protocol for review/approval and the same available actions and functionality are available as when you initially submitted your protocol.

Other Actions

In addition to the **'Amend'** and **'Renew'** buttons, the **'View Admin Attachments'** and **'Print'** buttons are available to the right. The **'View Admin Attachments'** allows you to see the attachments associated with the protocol for review. The **'Print'** button opens the protocol in new browser window so it can be easily saved and printed from your computer.