The University of Texas Rio Grande Valley

WELCOME

TO THE IRB ELECTRONIC SYSTEM

Tick@lab

New Protocol Submission Training

IMPORTANT NOTE: Remember to Allow Pop-Ups in your web browser.

If you do not allow pop-ups, the system will not work properly.

Tick@lab URL

https://lar.utrgv.edu/tickatlab/default.aspx

Log in with your UTRGV Credentials

If you are unable to log in with your UTRGV credentials please contact the Office of Research Compliance at (956) 665-2093/ (956) 665-2889/ (956) 665-3598 / (956) 882-7743. Or, you may also email the IRB to irb@utrgv.edu

We will check on your account to see if updating is required. If no account is found, you will have to complete a web form to request access.

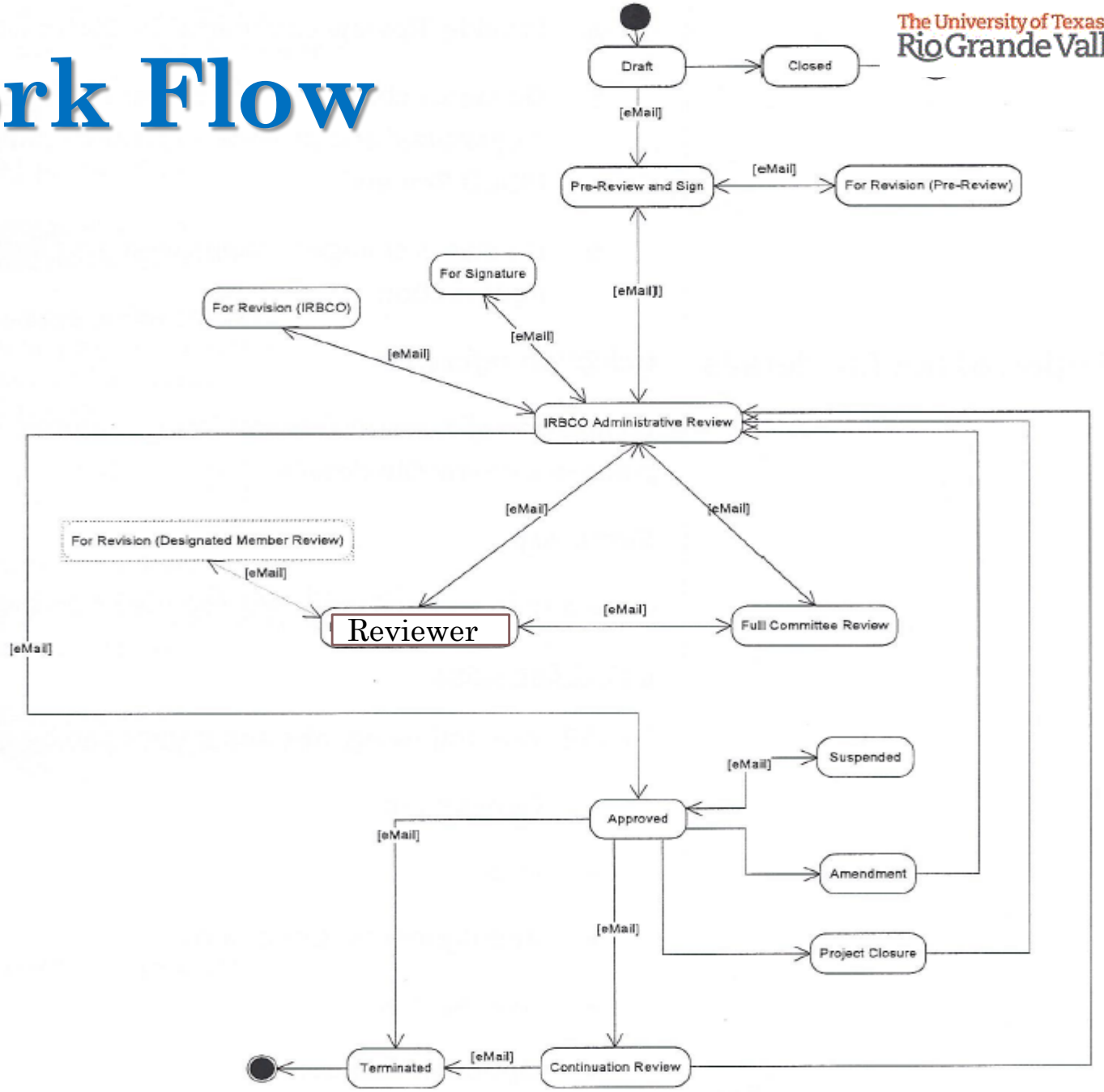
Workflow

Guide

Tick@Lab Work Flow

- **New Protocol**

- PI or research team will create a draft protocol.
- PI should assign personnel to the protocol with their applicable roles (Personnel Tab). Note, the PI must be assigned as a Reviewer and Signer at the bottom. As well as the Faculty Advisor if applicable.
- PI Assurance must be completed before moving to Pre-Review and Sign.
- PI should do a status change by selecting **Pre-Review and Sign**.
- PI, and Faculty Advisors (*if applicable*) must sign the protocol.
- Once signed by all Reviewers and Signers, the protocol is automatically forwarded to the IRBCO (Coordinators).
- *Exempt protocols are reviewed and approved by IRBCO.*
- *Expedited and Full Review protocols are administratively screened before being assigned to a member.*



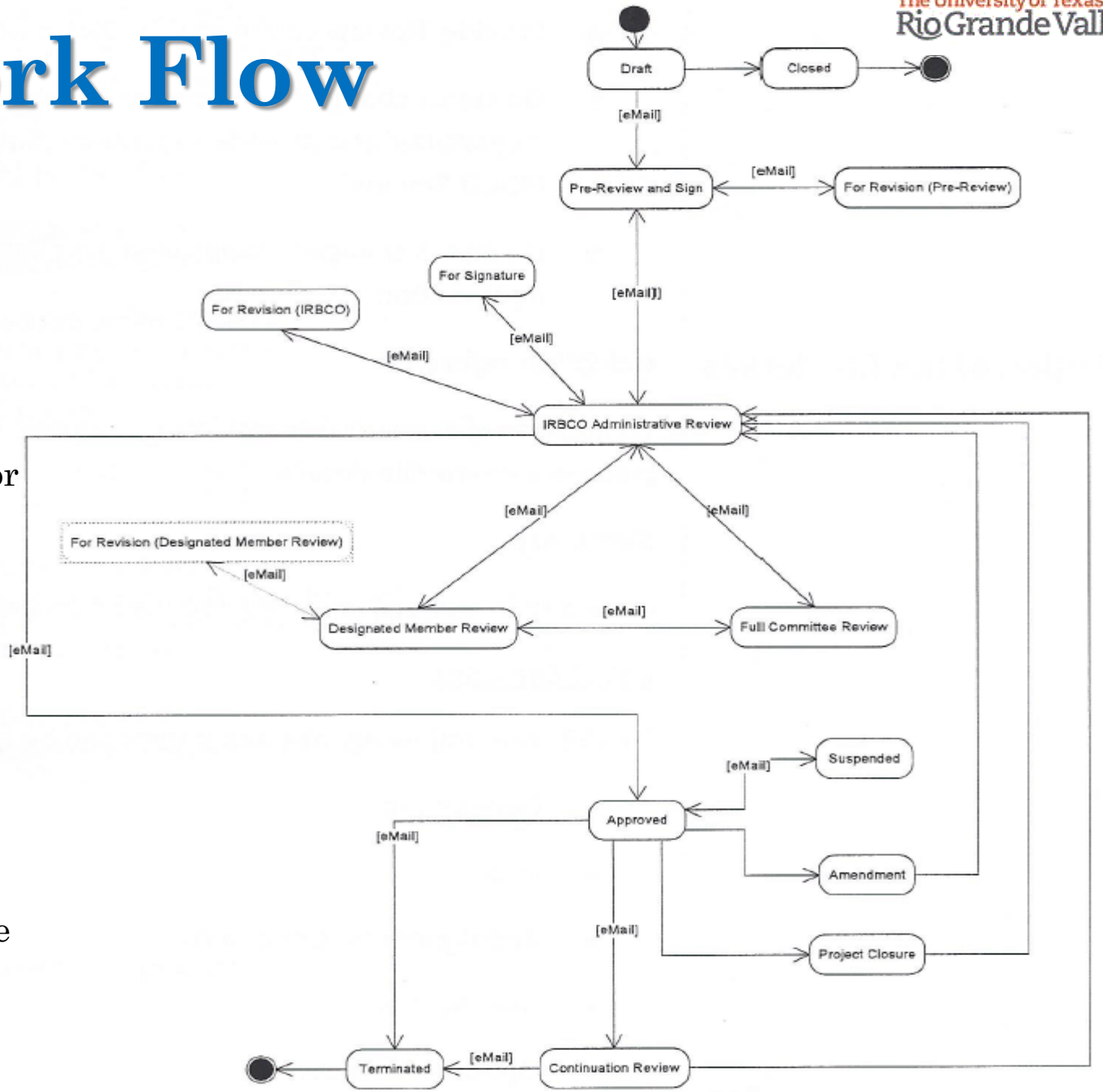
Tick@Lab Work Flow

- If no pertinent documents or information is missing the protocol is assigned to Reviewer (Board Member) for review.
- If during administrative screening any pertinent documents or information is missing, the IRBCO will send the protocol back to you for revision.

Administrative review and Reviewer - Review comments will be provided within the protocol, located on the respective tab. The protocol will be pushed back to you For Revision.

Amendments and Continuations

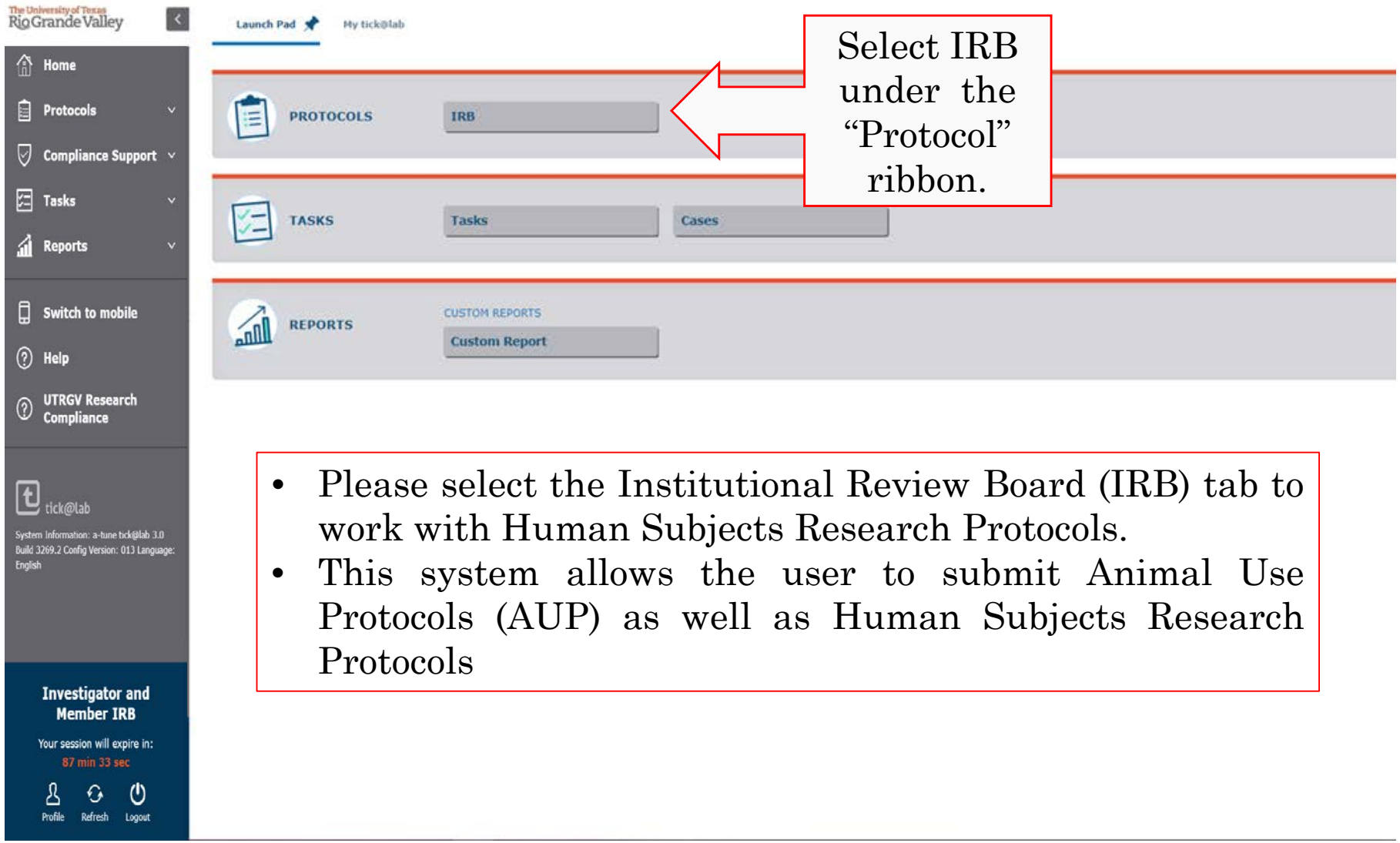
After a protocol has been approved, the PI may draft and submit an Amendment or Continuation.



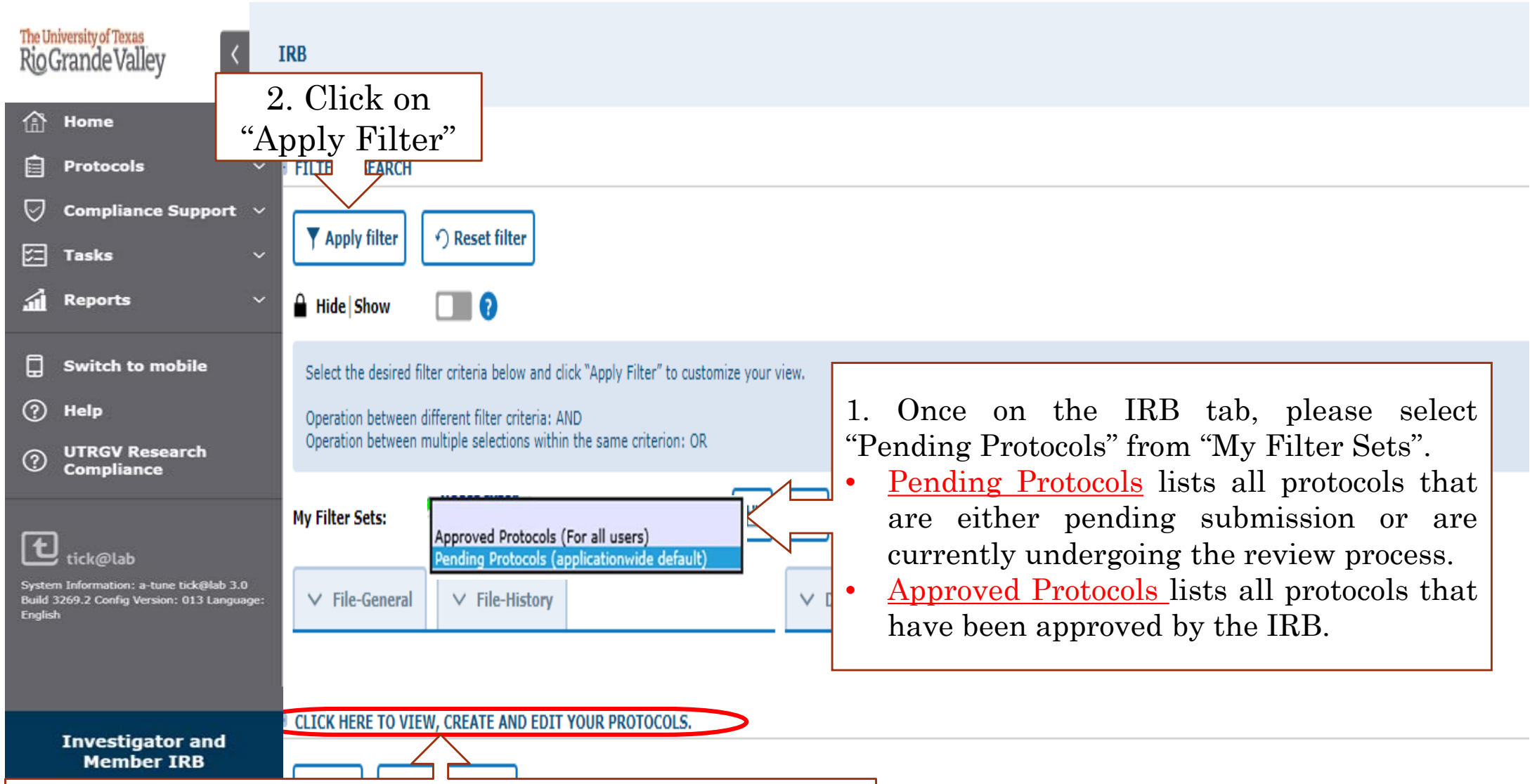
Document Status Types

- **Draft** – This means your submission is in Draft Mode and is not yet submitted.
- **Pre-Review & Sign** – This means your submission is in the pre-review stage, all reviewers and signers *(as designated by you on the Personnel tab)* must review before signing.
- **Signatures** – This means your submission is in the signing stage, all reviewers and signers *(as designated by you on the Personnel tab)* must sign the protocol.
- **IRBCO Administrative Review** – This means your submission is being reviewed by IRB Coordinators
- **For Revision** – This means your submission is being sent back to you for revisions *(may be based on feedback from Coordinators, a Designated Member, or the Full Committee)*
- **Reviewer** – This means that your submission has been assigned to a designated IRB Member for review, and is currently under review by them.
- **Full Committee Review** – This means that your submission has been pushed for Full Review by either the Coordinators or a Designated IRB Member. Note, in this stage the project will be added to a meeting agenda and will be visited by the board at a convened meeting.
- **Approved** – This means your submission has been approved. An approval memo will be published at the file level.

Steps on how to submit an IRB application.

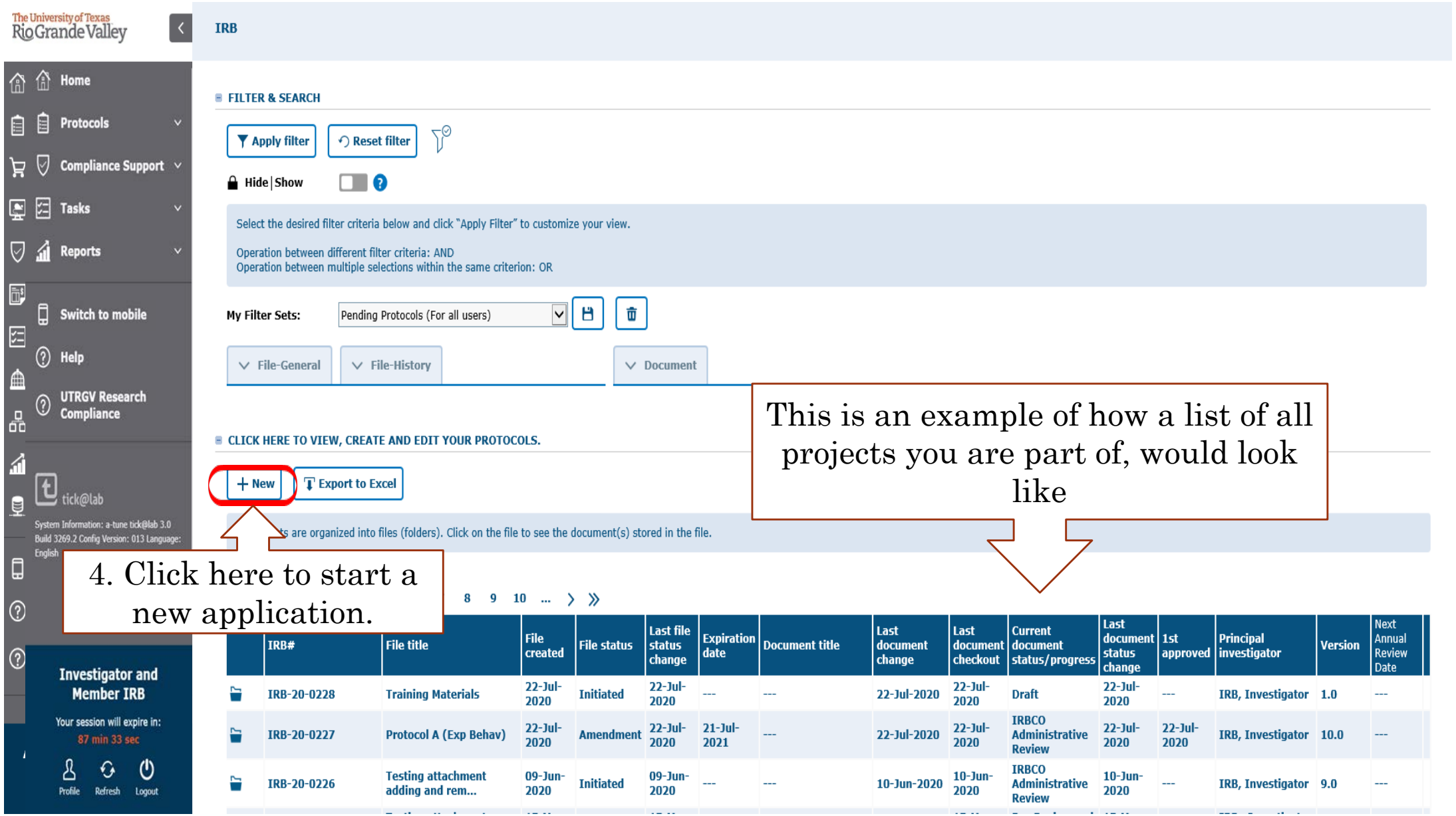


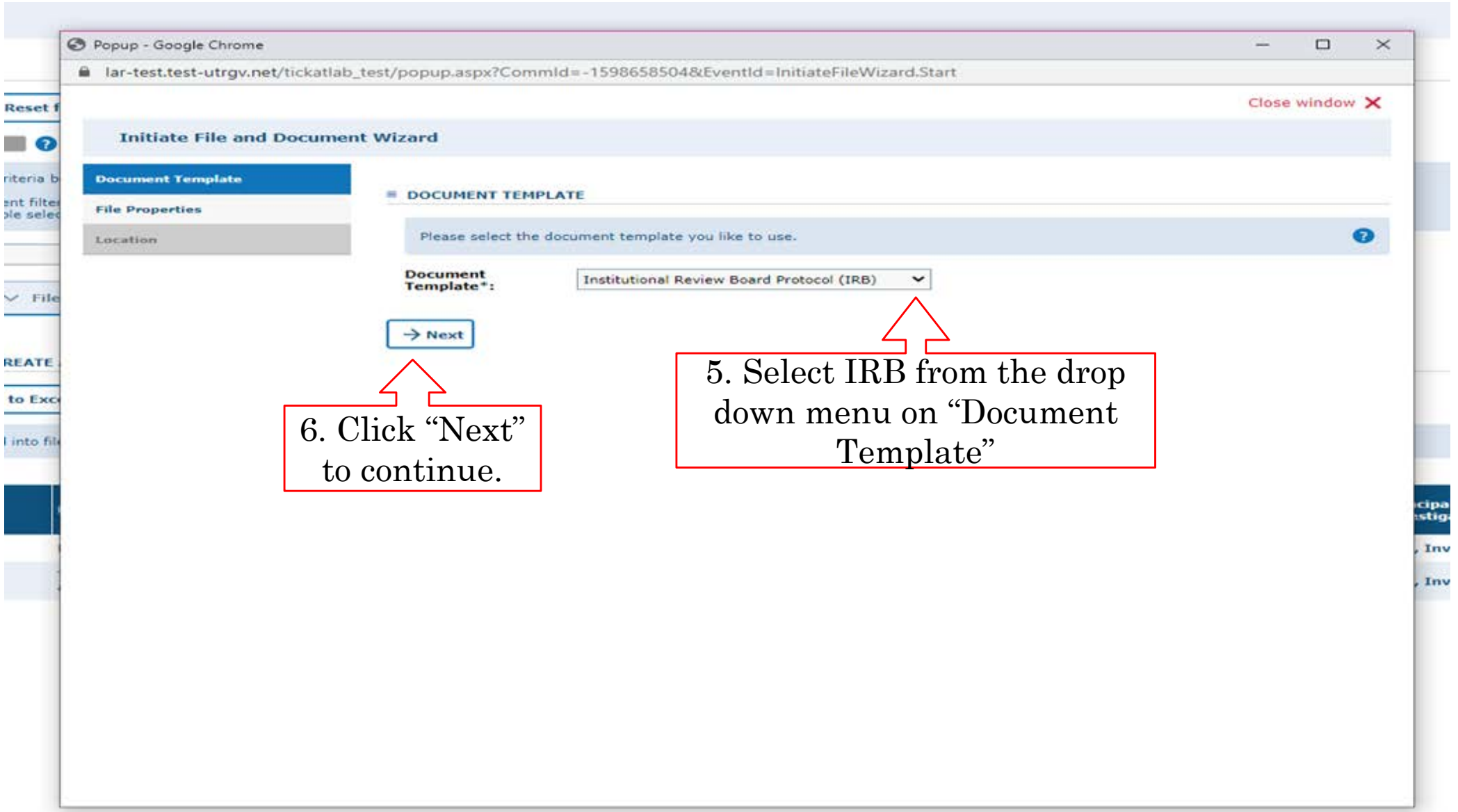
- Please select the Institutional Review Board (IRB) tab to work with Human Subjects Research Protocols.
- This system allows the user to submit Animal Use Protocols (AUP) as well as Human Subjects Research Protocols

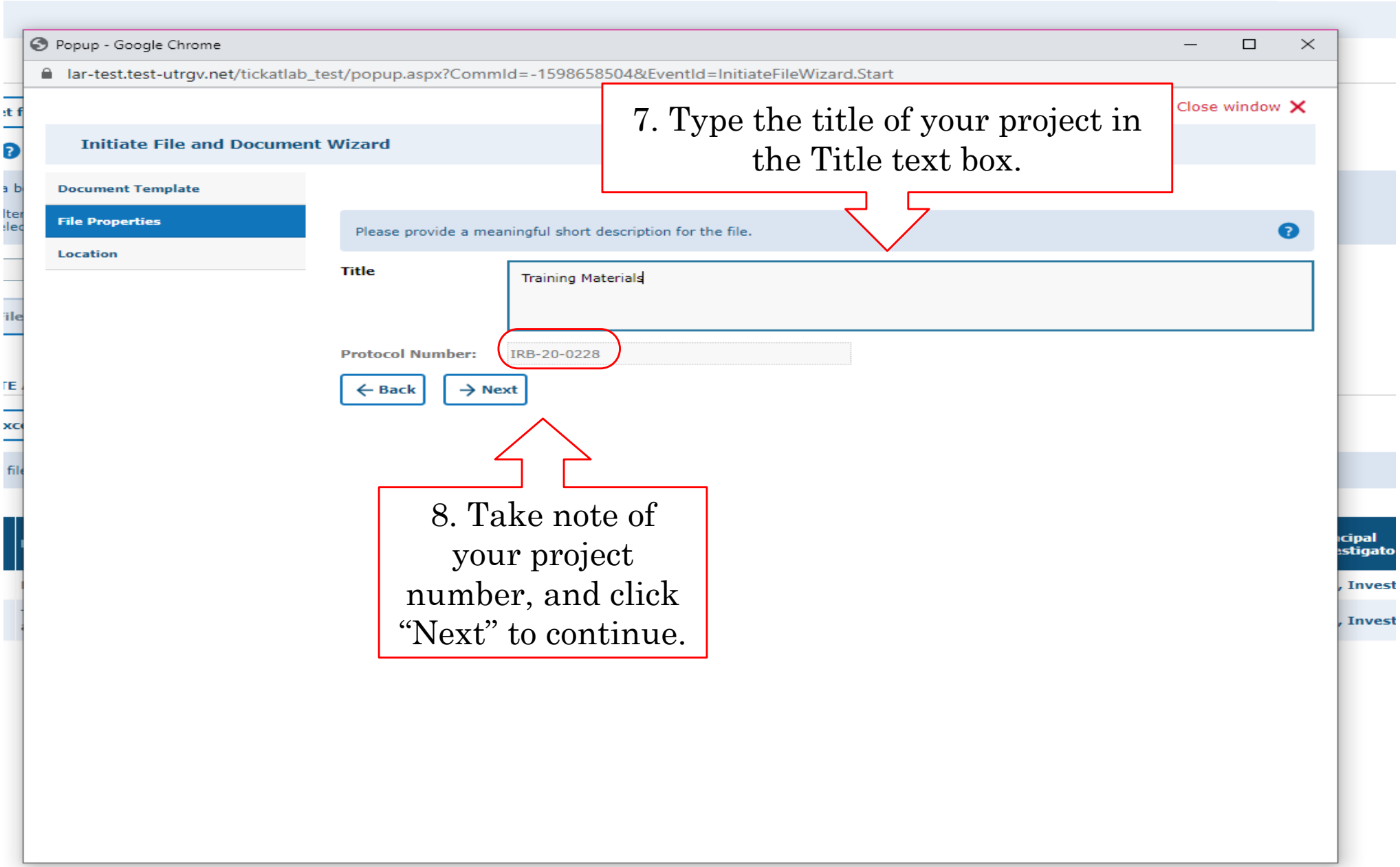


1. Once on the IRB tab, please select "Pending Protocols" from "My Filter Sets".
- Pending Protocols lists all protocols that are either pending submission or are currently undergoing the review process.
- Approved Protocols lists all protocols that have been approved by the IRB.

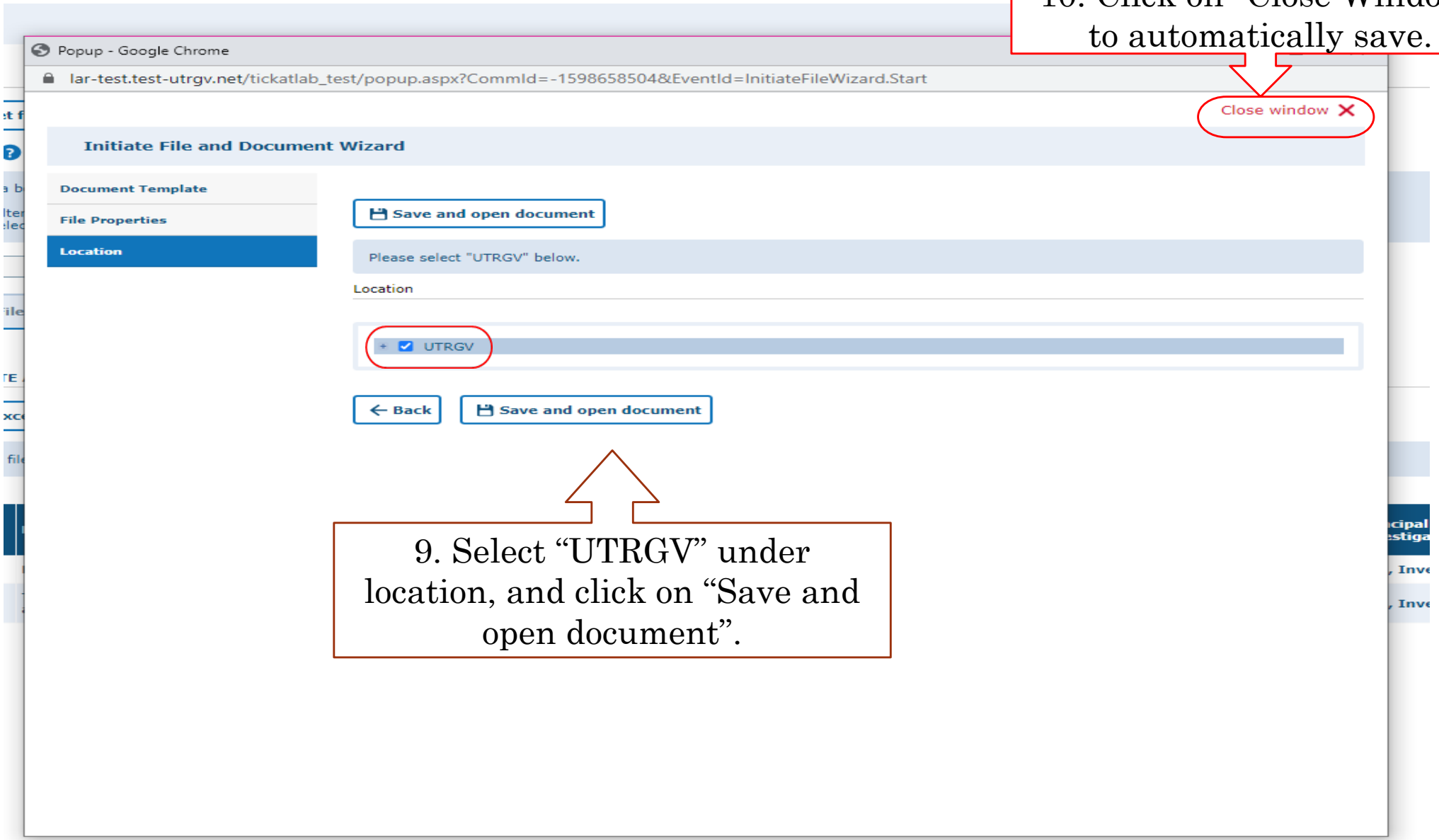
3. Click here to Expand Files. By default Tick@lab collapses all files. You need to expand files in order to see the folders that contain your protocol.


The University of Texas Rio Grande Valley
IRB
Home
Protocols
Compliance Support
Tasks
Reports
Switch to mobile
Help
UTRGV Research Compliance
tick@lab
System Information: a-tune tick@lab 3.0
Build 3269.2 Config Version: 013 Language:
English
Investigator and Member IRB
Your session will expire in:
87 min 33 sec
Profile
Refresh
Logout
FILTER & SEARCH
Apply filter
Reset filter
Hide | Show
Select the desired filter criteria below and click "Apply Filter" to customize your view.
Operation between different filter criteria: AND
Operation between multiple selections within the same criterion: OR
My Filter Sets:
Pending Protocols (For all users)
File-General
File-History
Document
CLICK HERE TO VIEW, CREATE AND EDIT YOUR PROTOCOLS.
+ New
Export to Excel
s are organized into files (folders). Click on the file to see the document(s) stored in the file.
8 9 10 ... › »
IRB# | File title | File created | File status | Last file status change | Expiration date | Document title | Last document change | Last document checkout | Current document status/progress | Last document status change | 1st approved | Principal investigator | Version | Next Annual Review Date
IRB-20-0228 | Training Materials | 22-Jul-2020 | Initiated | 22-Jul-2020 | --- | --- | 22-Jul-2020 | 22-Jul-2020 | Draft | 22-Jul-2020 | --- | IRB, Investigator | 1.0 | ---
IRB-20-0227 | Protocol A (Exp Behav) | 22-Jul-2020 | Amendment | 22-Jul-2020 | 21-Jul-2021 | --- | 22-Jul-2020 | 22-Jul-2020 | IRBCO Administrative Review | 22-Jul-2020 | 22-Jul-2020 | IRB, Investigator | 10.0 | ---
IRB-20-0226 | Testing attachment adding and rem... | 09-Jun-2020 | Initiated | 09-Jun-2020 | --- | --- | 10-Jun-2020 | 10-Jun-2020 | IRBCO Administrative Review | 10-Jun-2020 | --- | IRB, Investigator | 9.0 | ---
4. Click here to start a new application.
This is an example of how a list of all projects you are part of, would look like


Popup - Google Chrome
lar-test.test-utrgv.net/tickatlab_test/popup.aspx?CommId=-1598658504&EventId=InitiateFileWizard.Start
Close window
Initiate File and Document Wizard
Document Template
File Properties
Location
DOCUMENT TEMPLATE
Please select the document template you like to use.
Document Template*:
Institutional Review Board Protocol (IRB)
Next
5. Select IRB from the drop down menu on "Document Template"
6. Click "Next" to continue.

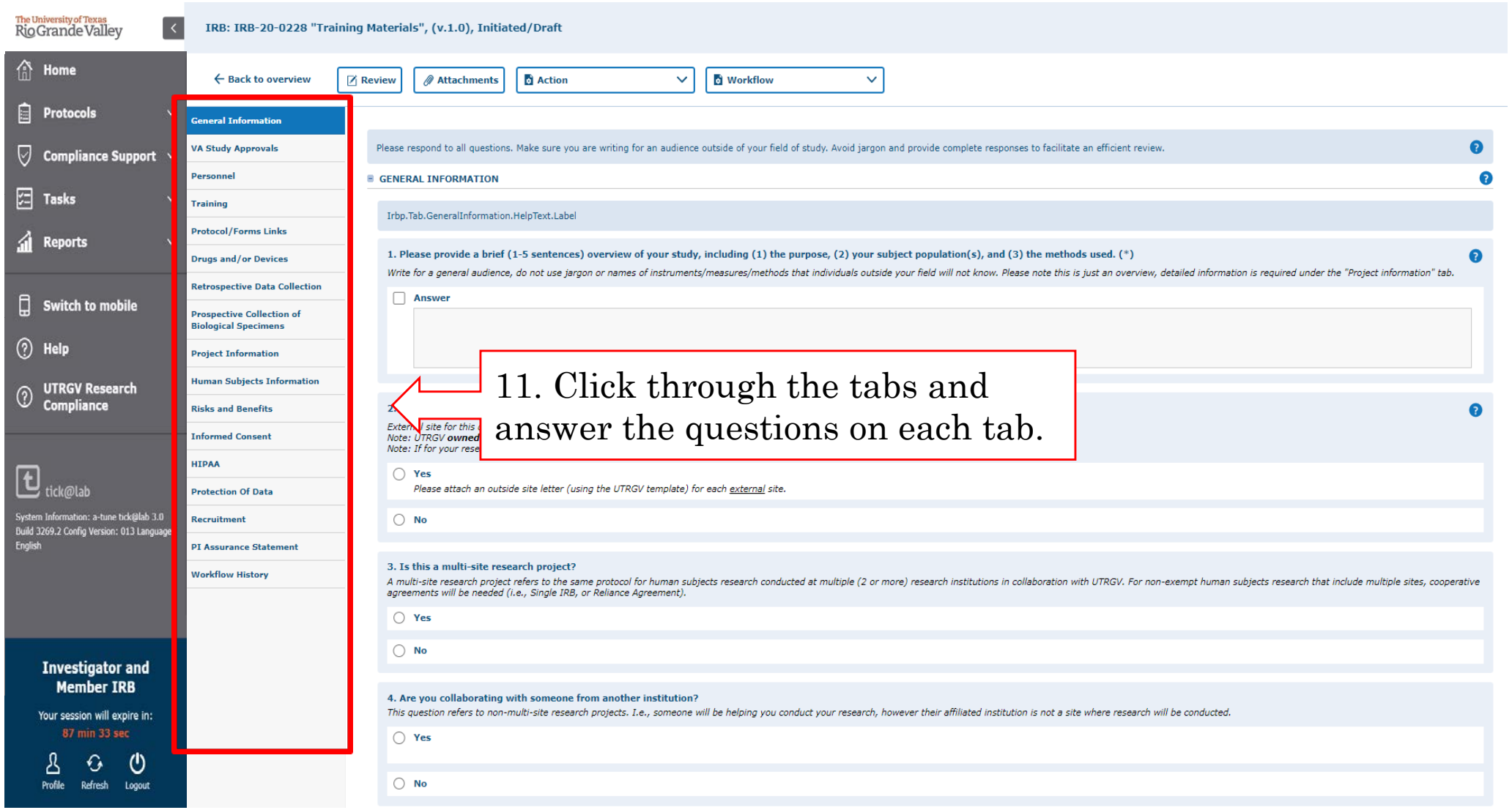

Popup - Google Chrome
lar-test.test-utrgv.net/tickatlab_test/popup.aspx?CommId=-1598658504&EventId=InitiateFileWizard.Start
Close window
Initiate File and Document Wizard
Document Template
File Properties
Location
7. Type the title of your project in the Title text box.
Please provide a meaningful short description for the file.
Title
Training Materials
Protocol Number:
IRB-20-0228
Back
Next
8. Take note of your project number, and click "Next" to continue.

10. Click on “Close Window” to automatically save.



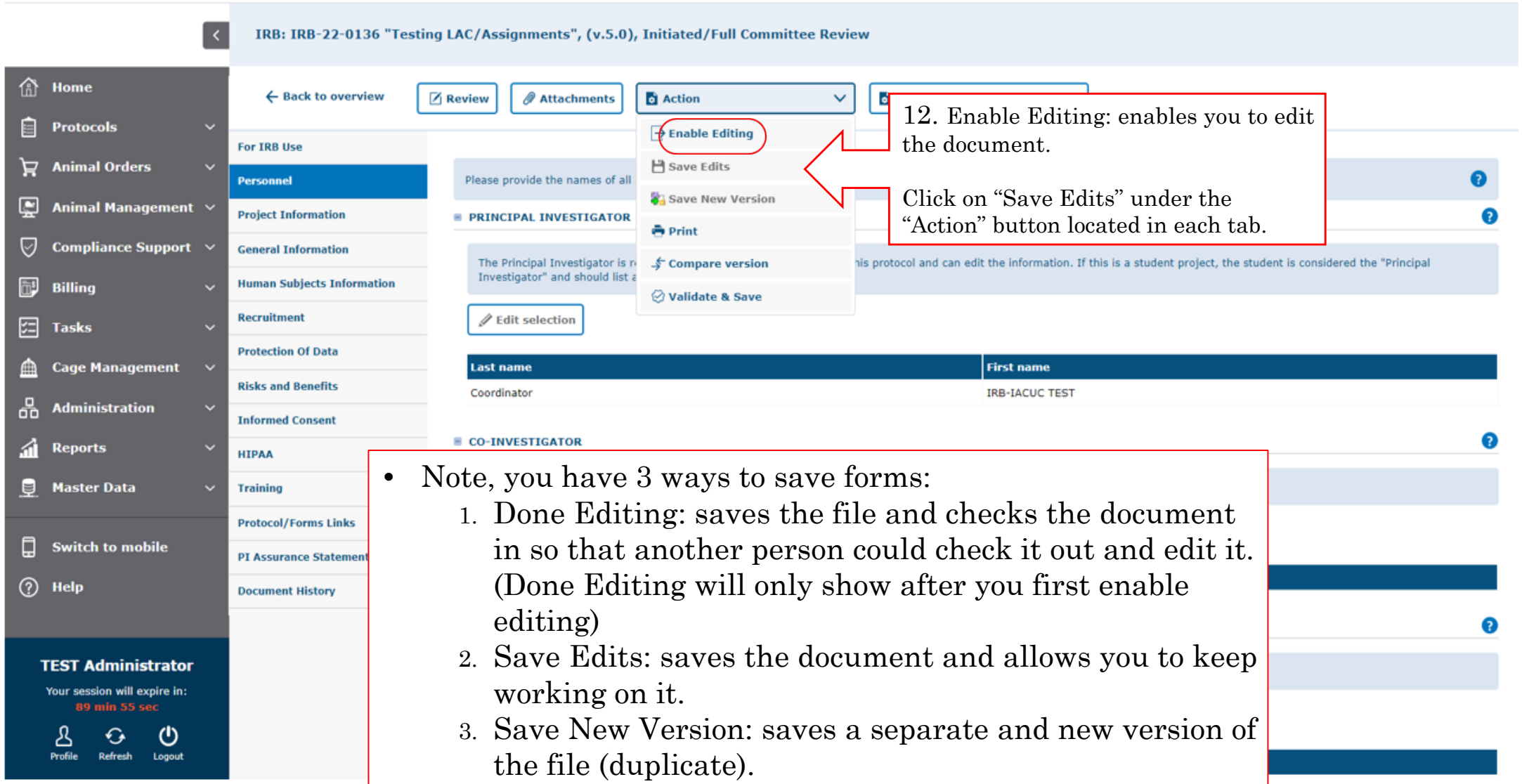
9. Select “UTRGV” under location, and click on “Save and open document”.

- This is how the application for a new project will look like.
- The questions on the application are organized by topics on the left side of the form.



11. Click through the tabs and answer the questions on each tab.

Save Often, Tick@lab does not save information automatically. Make sure you save information after completing each tab.



12. Enable Editing: enables you to edit the document.

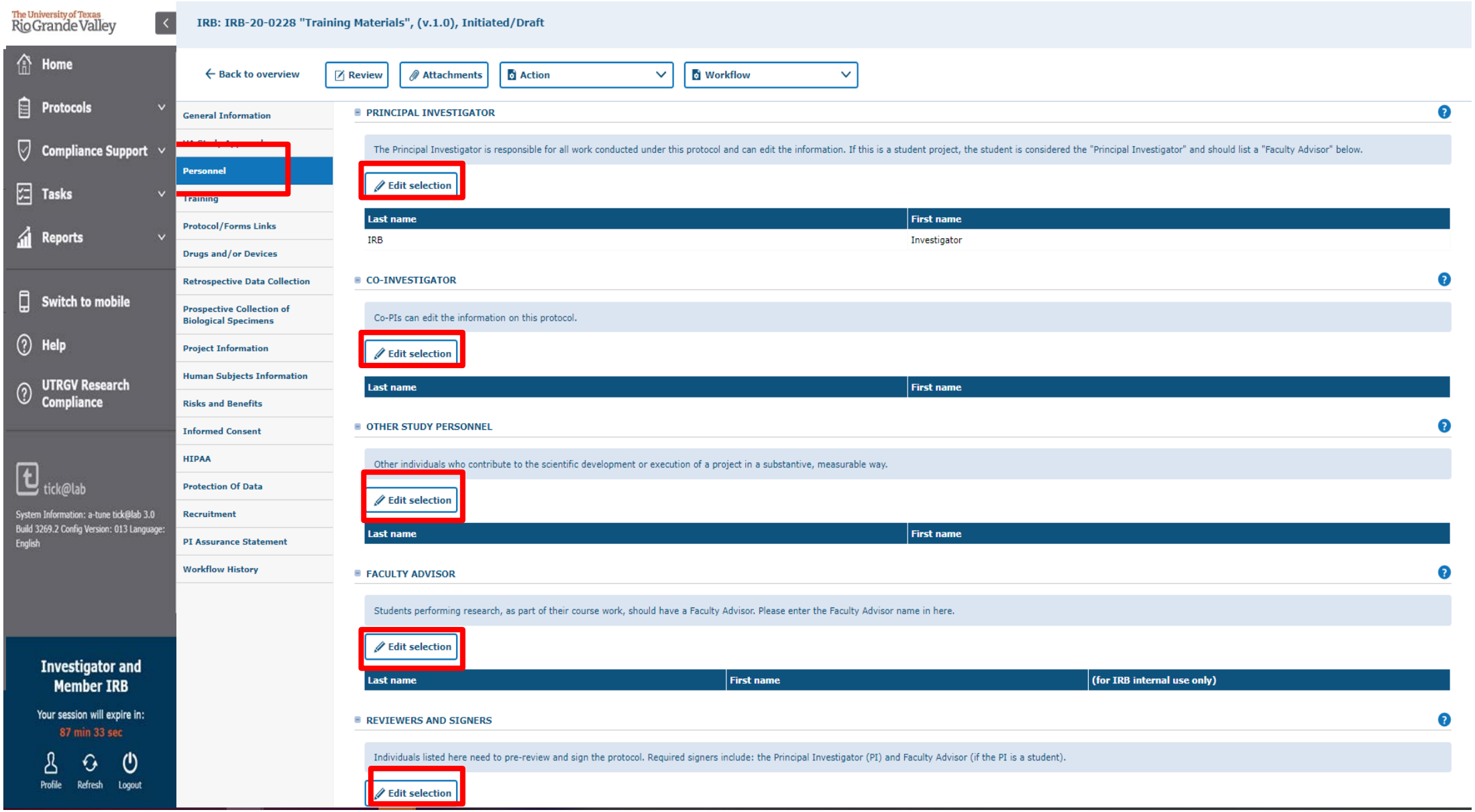
Click on "Save Edits" under the "Action" button located in each tab.

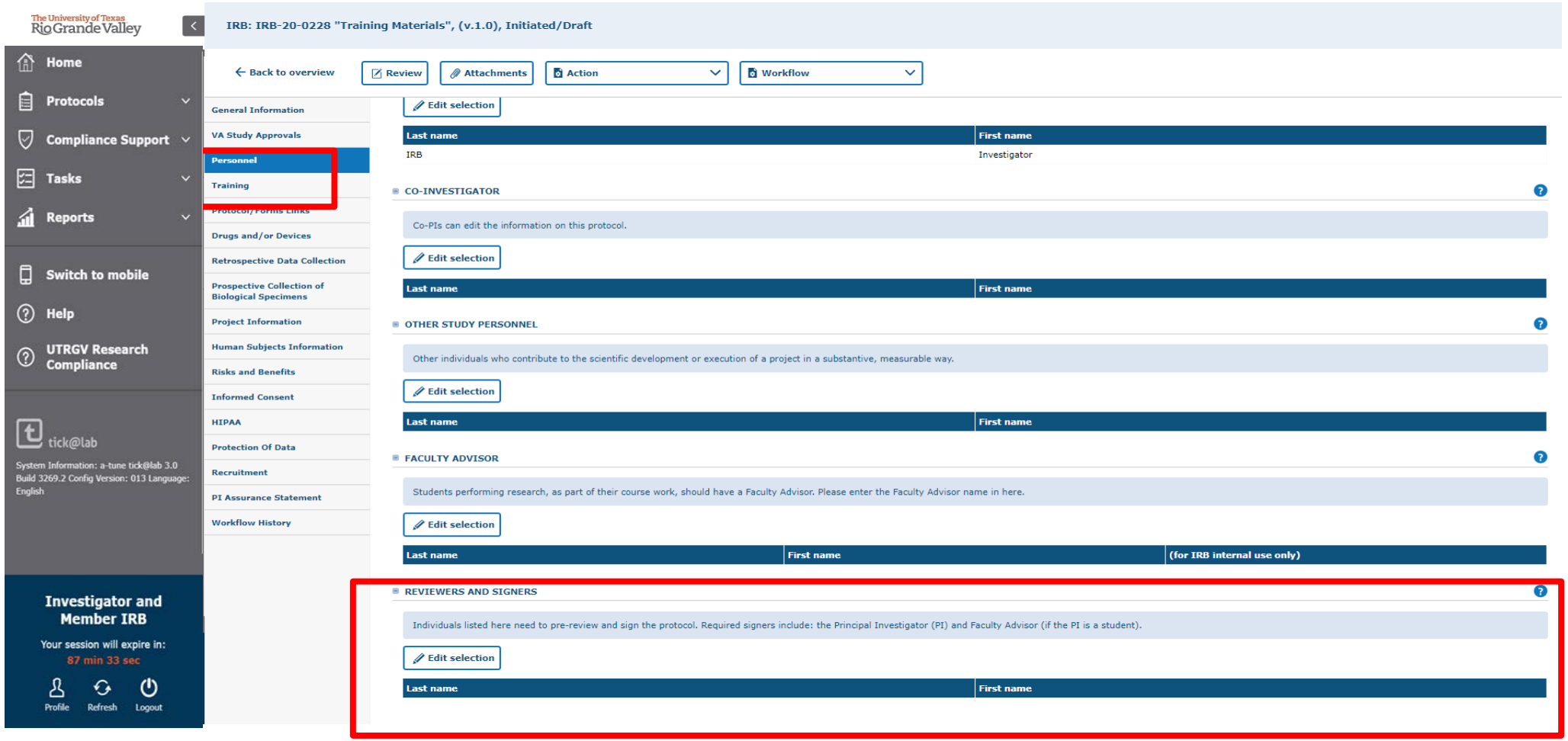
- Note, you have 3 ways to save forms:
  1. Done Editing: saves the file and checks the document in so that another person could check it out and edit it. (Done Editing will only show after you first enable editing)
  2. Save Edits: saves the document and allows you to keep working on it.
  3. Save New Version: saves a separate and new version of the file (duplicate).

Personnel

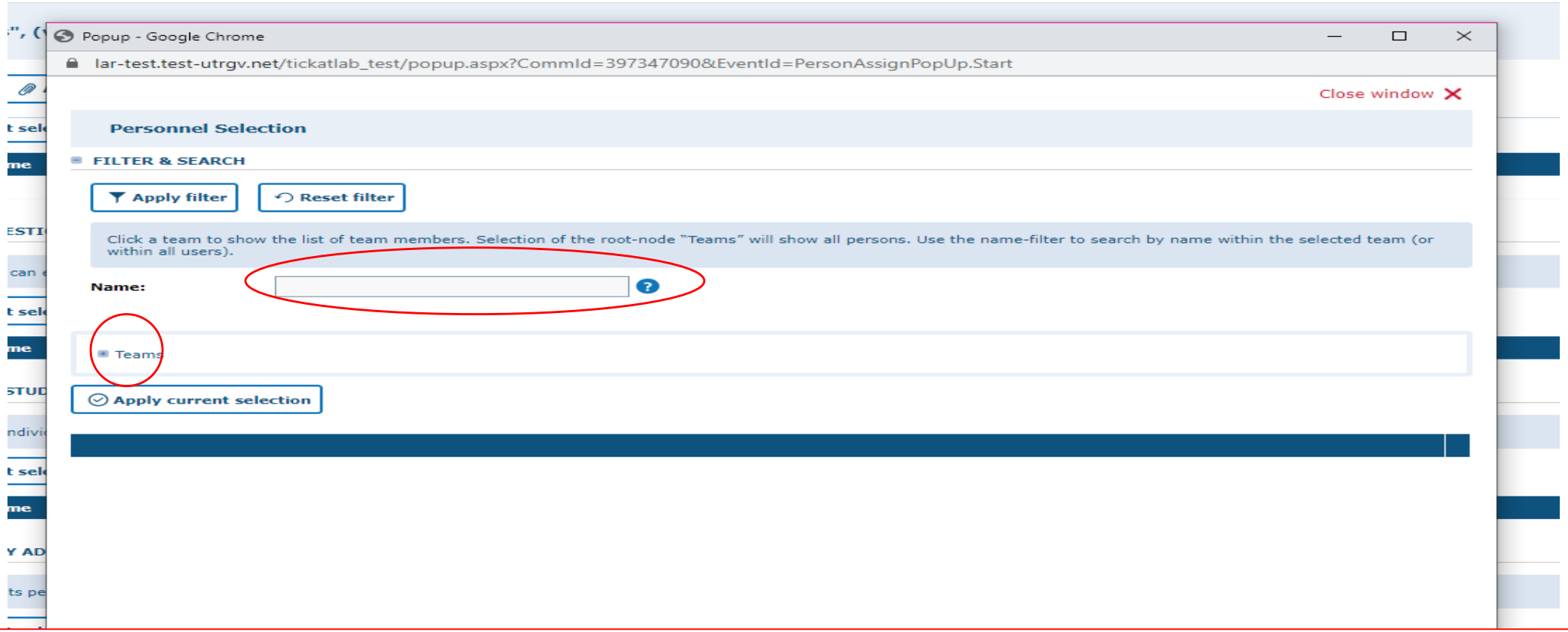
How to add project team members to your protocol

From the “Personnel” Tab on the left, go into each of the questions and click “Edit selection” to assign personnel as Co-Investigators, Key Personnel, Faculty Advisor and Reviewer and Signers from the Pop-up window.





- If the PI is a student, a Faculty Advisor must be assigned in the Faculty Advisor section. Advisors are also required to pre-review and sign the application. Therefore, it is also important to ensure the advisor is assigned as a Reviewer and Signer.
- If the PI is <u>not</u> a student, only the PI needs to be assigned as a Reviewer and Signer to complete the pre-review and sign process.



1. Type the Name of the person you want to add (first or last name only, not both) then click on "Apply filter", or
2. You can click on Teams to select from the list, then click on "Apply current selection"

Note 1: You can add as many personnel as you want.

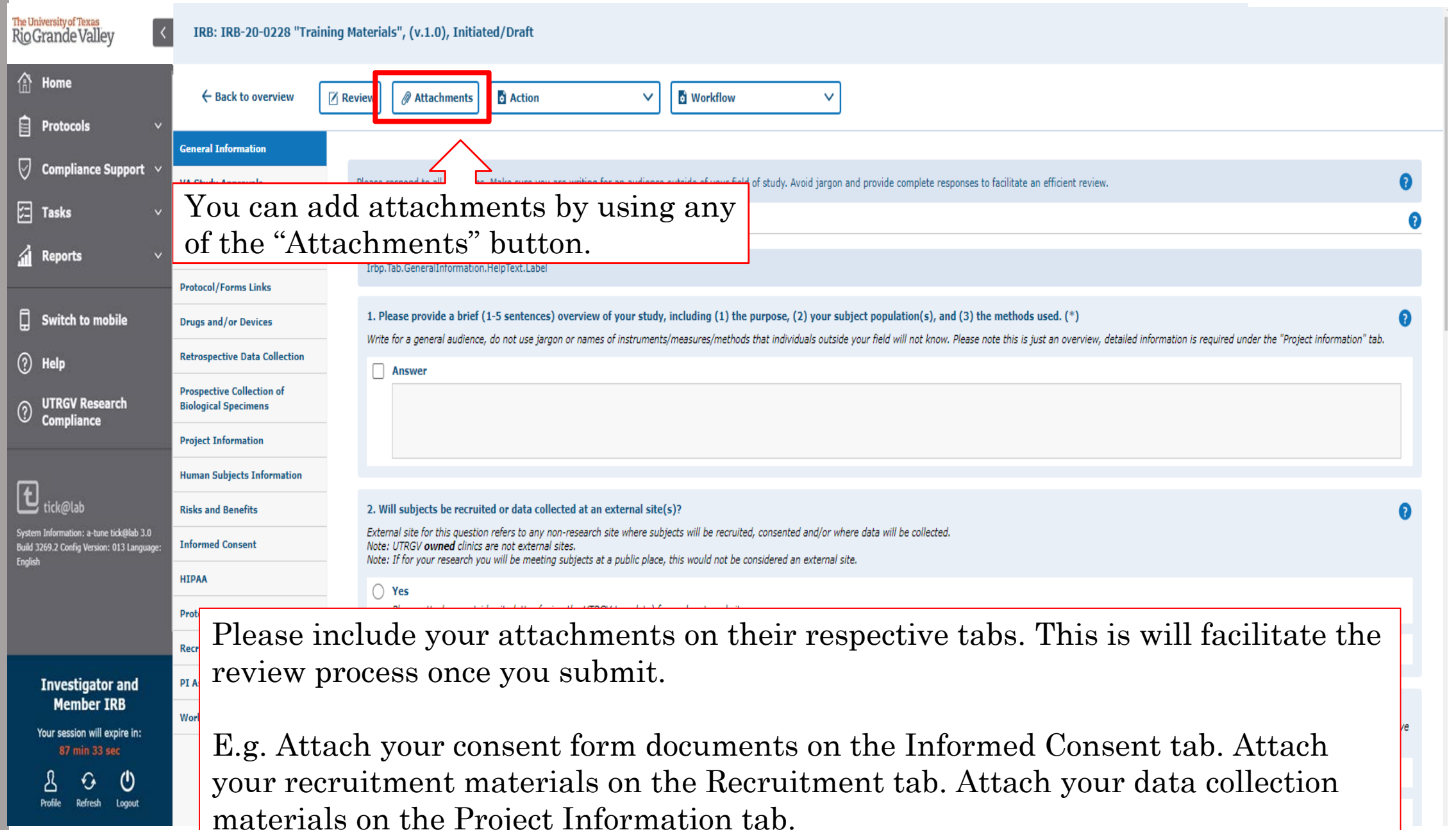
Note 2: If you cannot find a researcher from the list, there is a slight possibility that the researcher does not have access to Tick@Lab and will need to submit an Access Request to get an account created.

Personnel Notes

- Only Reviewers and Signers may view the project and documents.
- Only Reviewers and Signers who are also listed as the PI or Co-I's can modify protocol content.
- The PI on the project should always be designated as a Reviewer and Signer.
- Other personnel such as research assistants or coordinators do not have write access.
- All Reviewers and Signers must sign the document before you submit to the IRB Coordinators (IRBCO).

Attachments

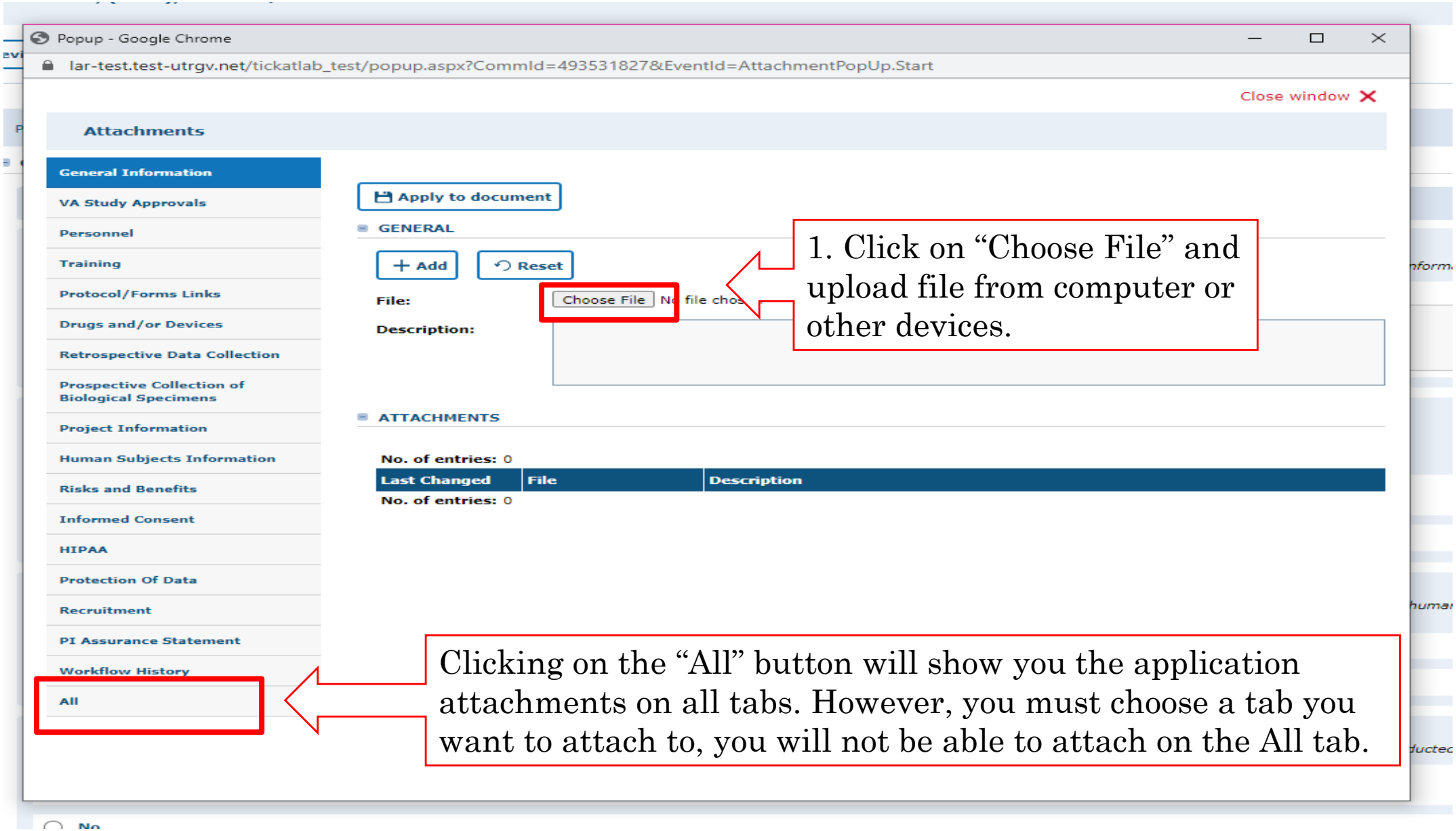
How to add attachment to your protocol

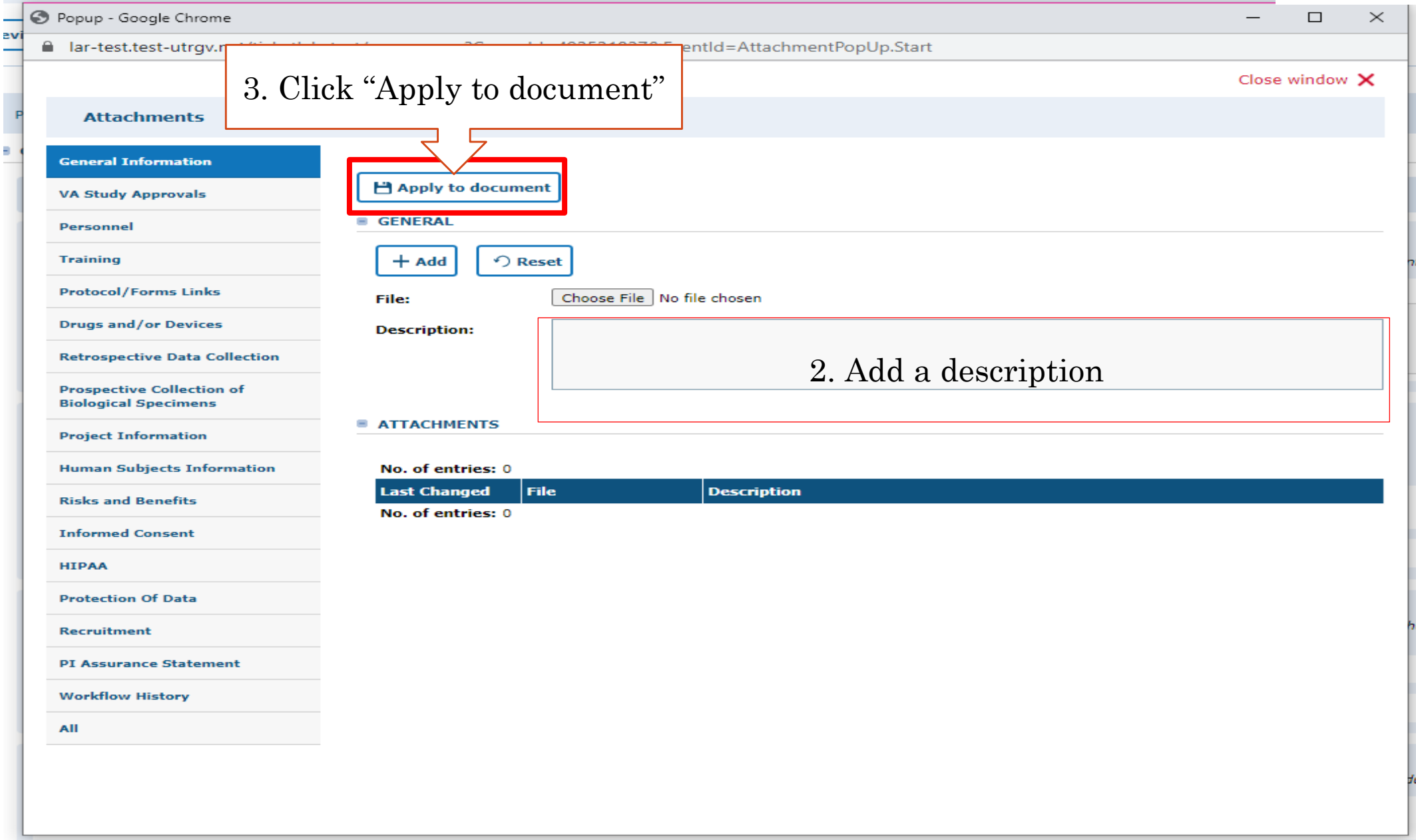


You can add attachments by using any of the "Attachments" button.

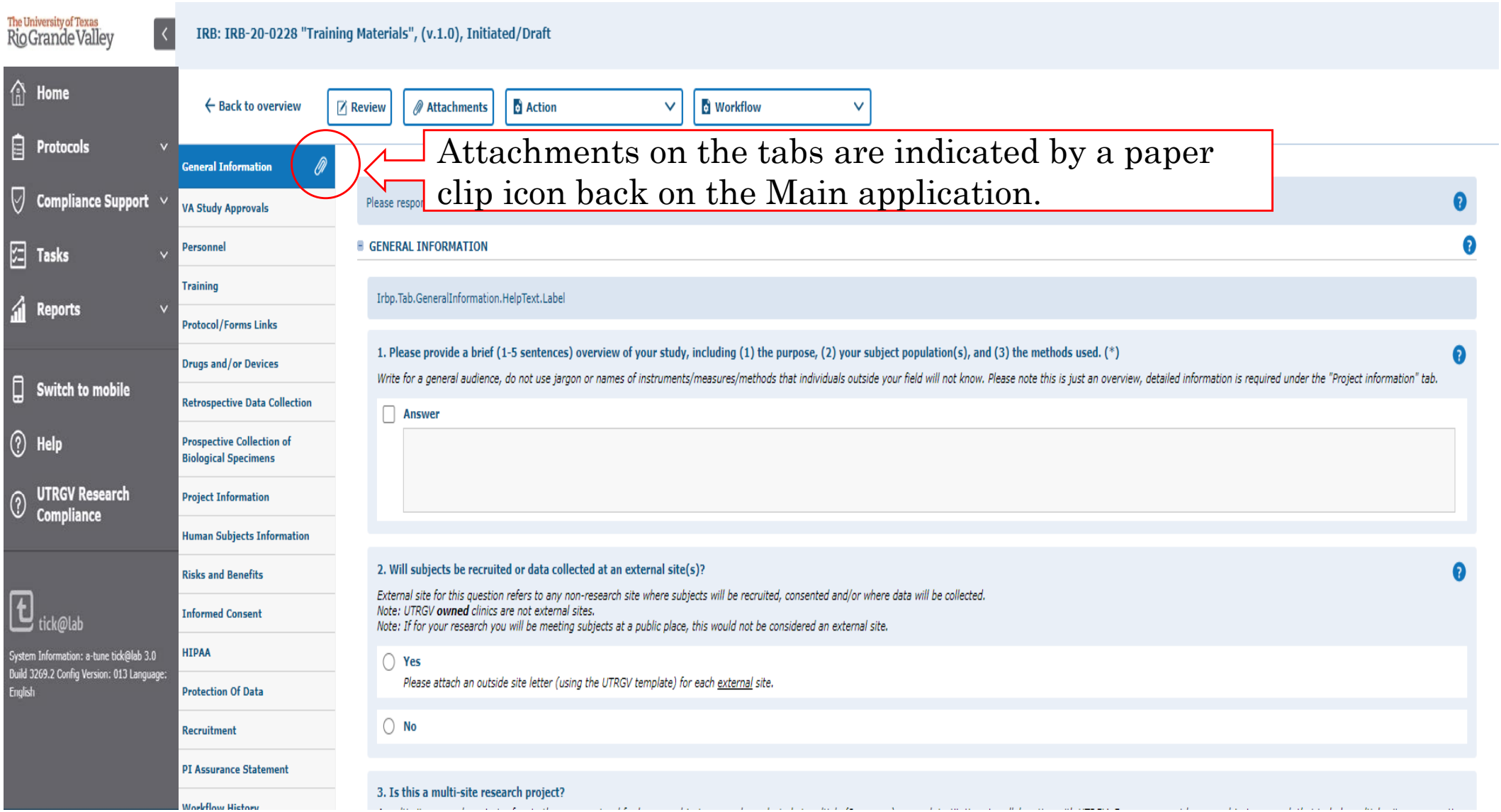
Please include your attachments on their respective tabs. This is will facilitate the review process once you submit.

E.g. Attach your consent form documents on the Informed Consent tab. Attach your recruitment materials on the Recruitment tab. Attach your data collection materials on the Project Information tab.

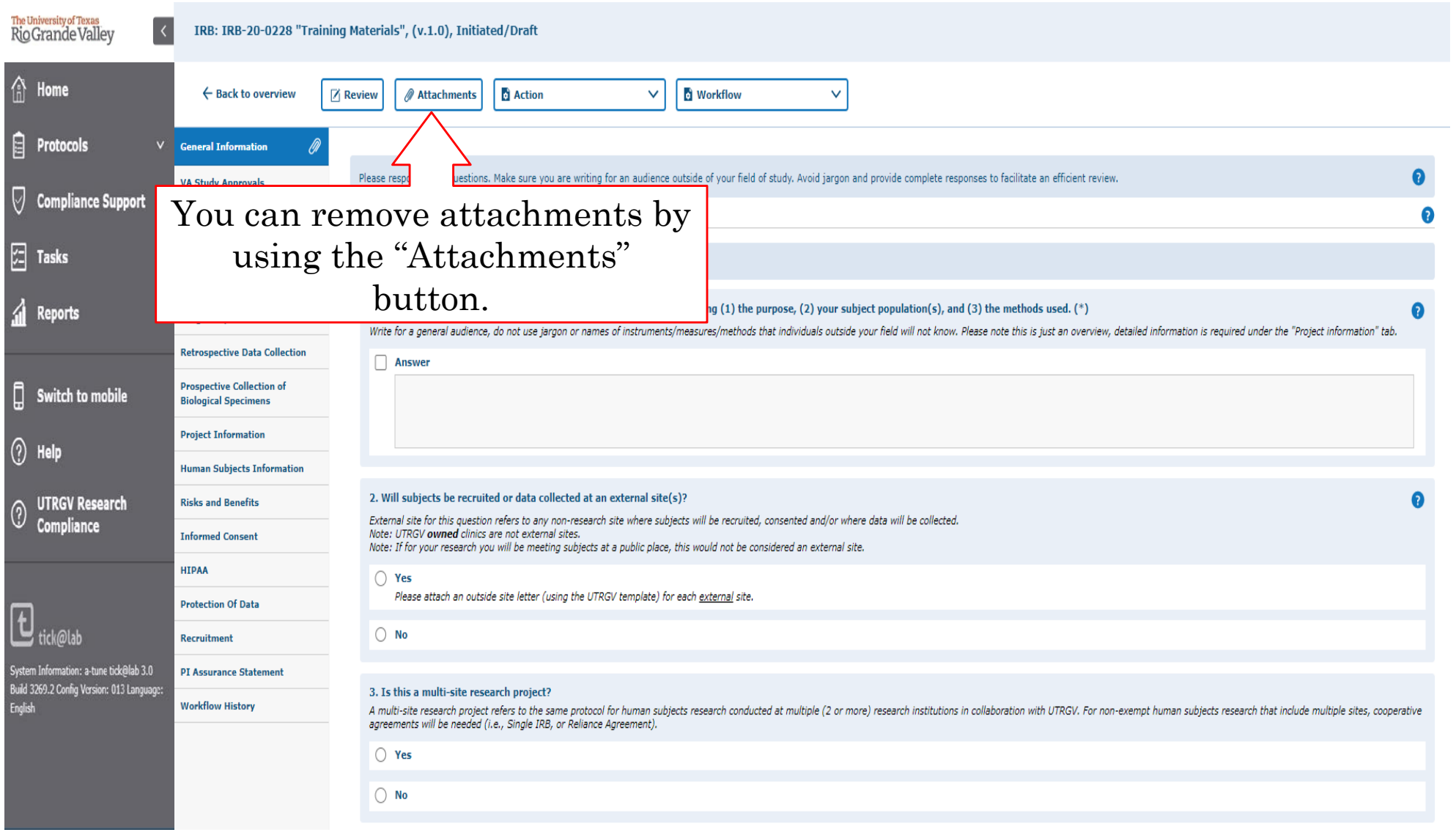

Popup - Google Chrome
lar-test.test-utrgv.net/tickatlab_test/popup.aspx?CommId=493531827&EventId=AttachmentPopUp.Start
Close window
Attachments
General Information
VA Study Approvals
Personnel
Training
Protocol/Forms Links
Drugs and/or Devices
Retrospective Data Collection
Prospective Collection of Biological Specimens
Project Information
Human Subjects Information
Risks and Benefits
Informed Consent
HIPAA
Protection Of Data
Recruitment
PI Assurance Statement
Workflow History
All
Apply to document
GENERAL
Add
Reset
File:
Choose File
Description:
ATTACHMENTS
No. of entries: 0
Last Changed
File
Description
No. of entries: 0
1. Click on "Choose File" and upload file from computer or other devices.
Clicking on the "All" button will show you the application attachments on all tabs. However, you must choose a tab you want to attach to, you will not be able to attach on the All tab.

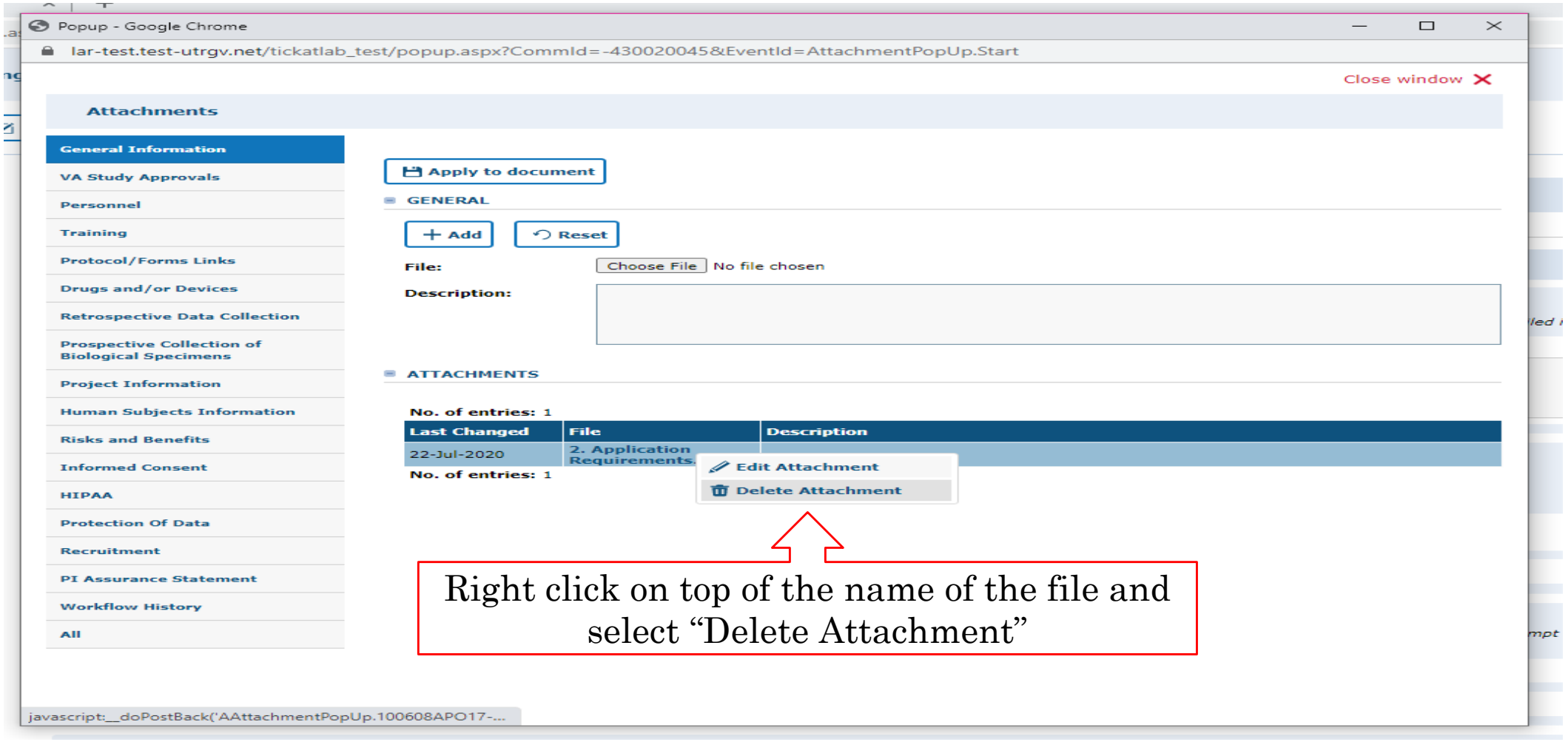

Popup - Google Chrome
lar-test.test-utrgv.
entId=AttachmentPopUp.Start
3. Click “Apply to document”
Close window
Attachments
General Information
VA Study Approvals
Personnel
Training
Protocol/Forms Links
Drugs and/or Devices
Retrospective Data Collection
Prospective Collection of Biological Specimens
Project Information
Human Subjects Information
Risks and Benefits
Informed Consent
HIPAA
Protection Of Data
Recruitment
PI Assurance Statement
Workflow History
All
Apply to document
GENERAL
Add
Reset
File:
Choose File
No file chosen
Description:
2. Add a description
ATTACHMENTS
No. of entries: 0
Last Changed
File
Description
No. of entries: 0

How to locate an attachment…



How to remove attachments…

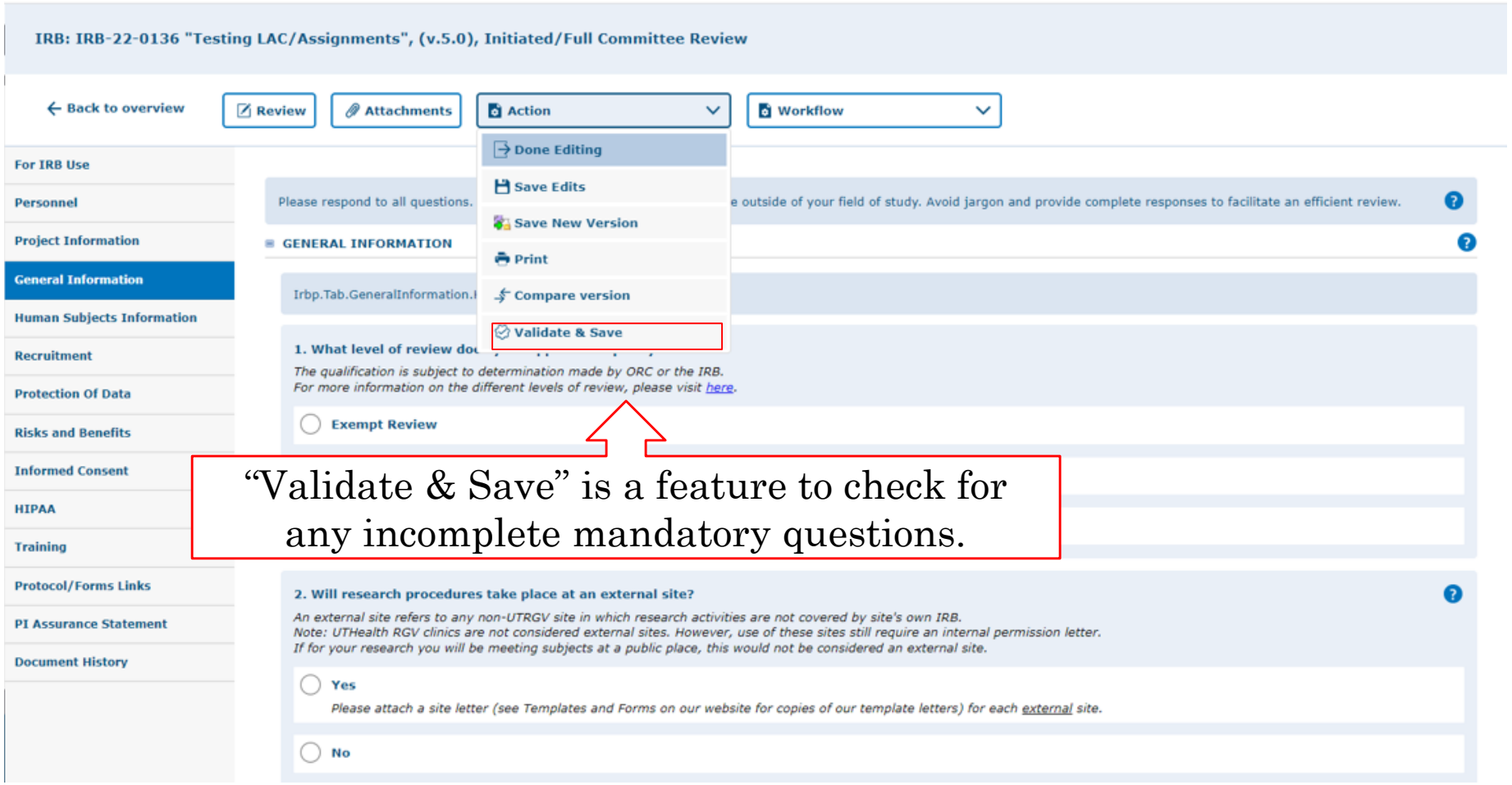




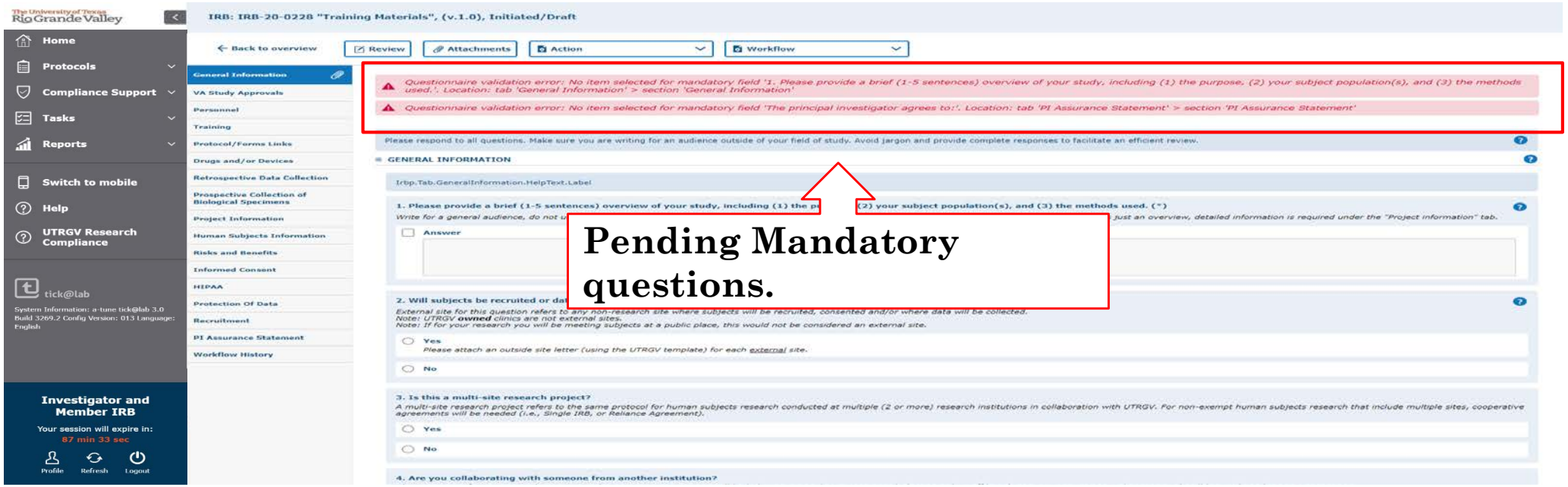
Note: by changing the workflow, the attachments will be locked and can no longer be deleted. I.e., while in draft mode and pre-review revision mode you may delete any attachments that you do not need. However, once you submit to the IRBCO Administrative Review attachments will be locked.

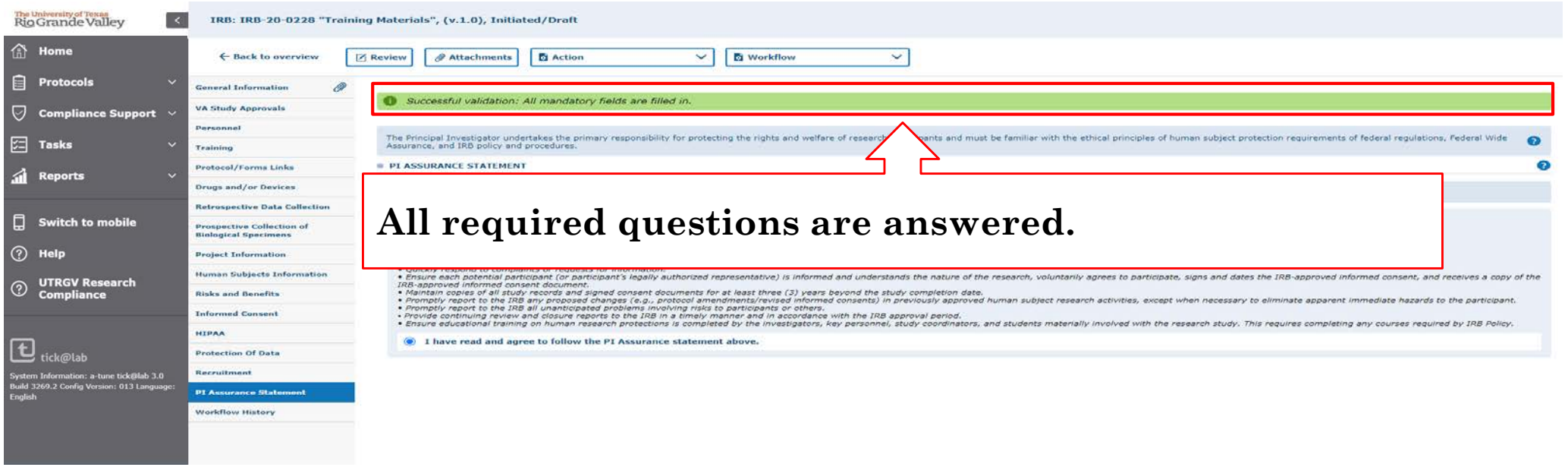
Validating and Saving

- Once you have completed the application, then you need to Validate and Save your application.
- Mandatory questions are marked with (*) at the end of the questions.



Application Validation…





Pre-Review, Signatures and Submission

Submitting the protocol into Workflow

Important Notes before Moving Forward with Signatures

Please keep these notes in mind:

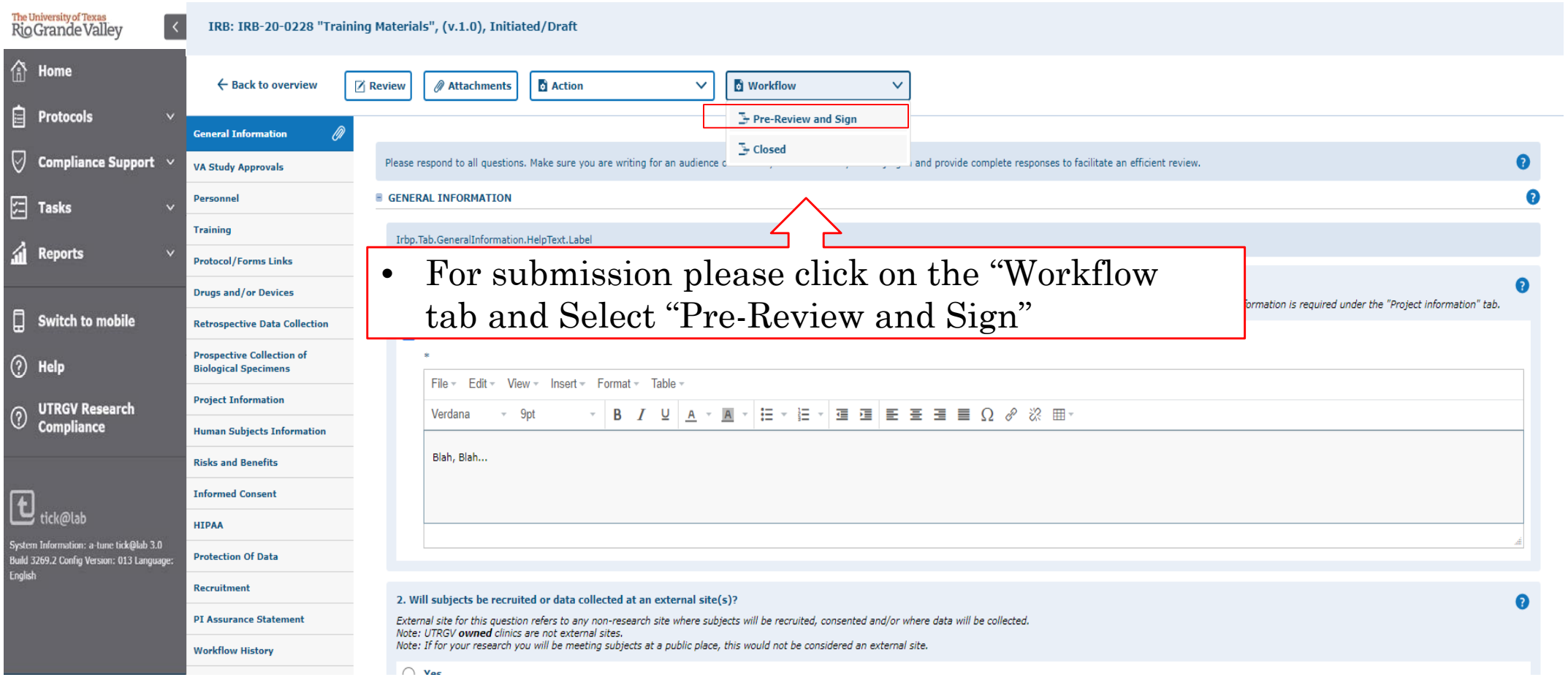
- Pre-Review and Sign is not IRB review, the project is not yet submitted.
- All Reviewers and Signers which you have designated on the Personnel tab must sign.
- Once a person signs, the next signer can view and sign the application but will not be able to edit it.
- If edits are required after someone has signed, the reviewer requesting such revisions must select “For Revision (Pre-Review)” from the workflow button and leave their comments. However, this will erase all previously obtained signatures.
- After edits have been made, the protocol must submitted to ‘Pre-Review and Sign’ and everyone who is listed as a Reviewer and Signer must sign again using the ‘Signatures’ option on the Workflow button.

Pre-Review and Signature Steps

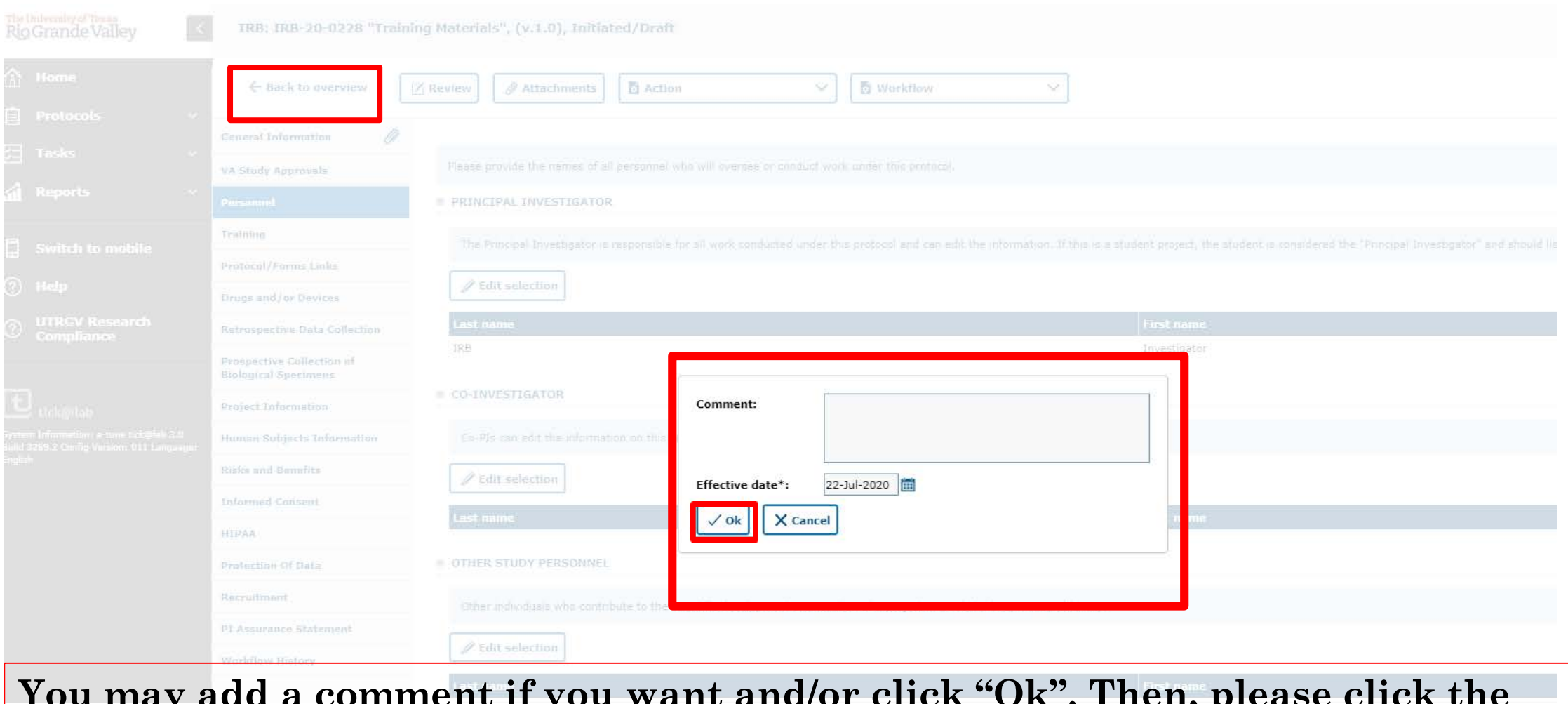
1. Designate Reviewers and Signers on the Personnel tab
2. Push for 'Pre-Review and Sign' using the Workflow button at the top.
3. Click on 'Signatures' using either the Workflow button at the top. Or, right click on the document and select 'Signatures' from the context menu.
4. Sign by entering your password, and click on close window at the top of the pop-up window.

This will leave the document available for others to sign. Once all signatures have been obtained the protocol will automatically be submitted to the IRB Coordinators (IRBCO). When this happens you will see the status change from 'Pre-Review and Sign' to 'IRBCO Administrative Review'. **That is your confirmation that the project has been successfully submitted.**

- Once you have validated your application then you need to submit the application to workflow for Pre-review and Signature. A copy of the workflow process has been included at the end of this presentation.



- For submission please click on the “Workflow tab and Select “Pre-Review and Sign”



You may add a comment if you want and/or click "Ok". Then, please click the "Back to overview" button. This button will take you back to the protocols page where projects are listed.

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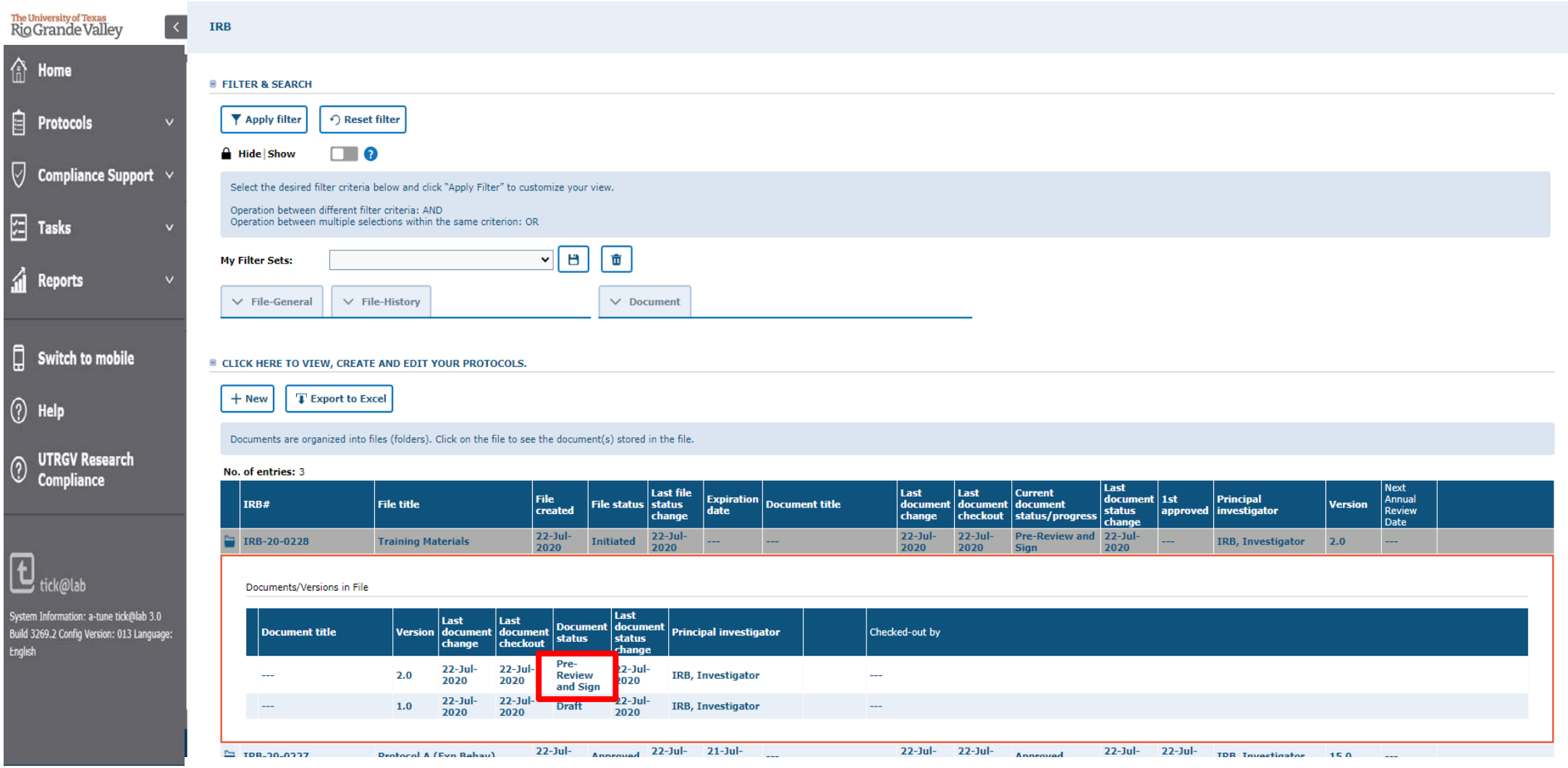
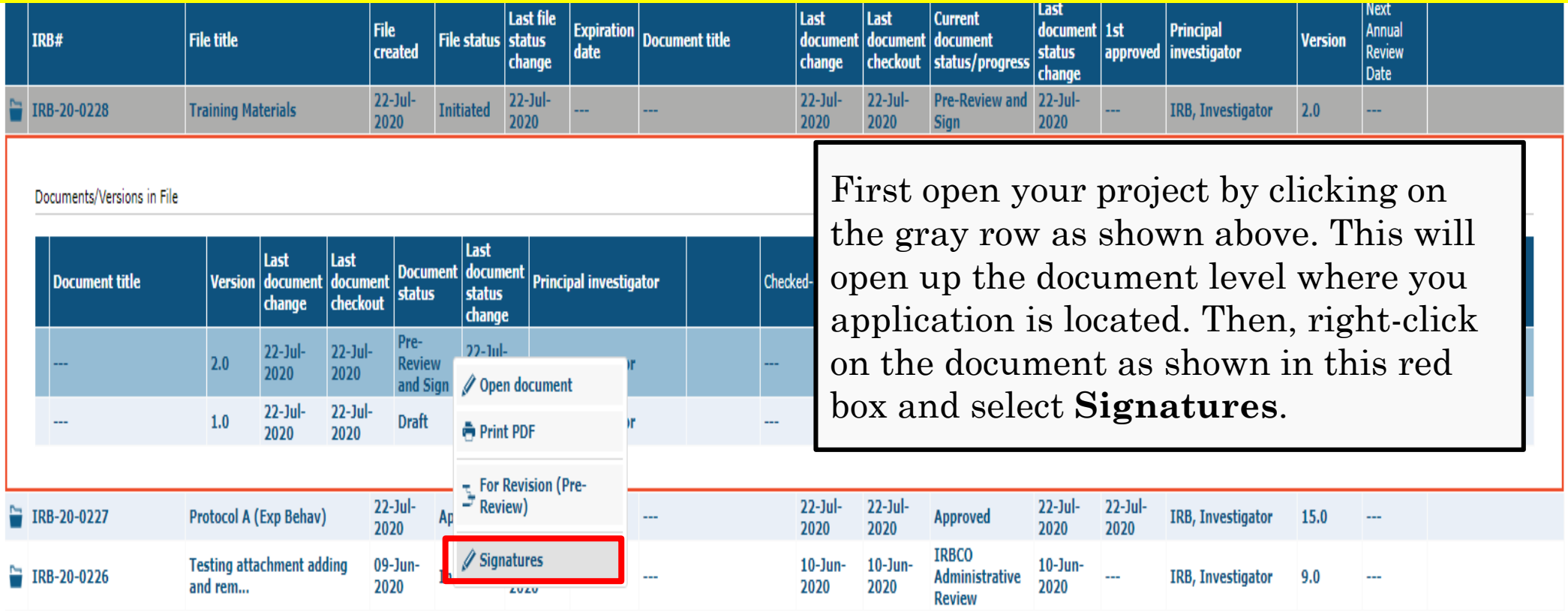
This is how your application will look like in your "Pending Protocols" files after it has been sent for Pre-Review and Signature.



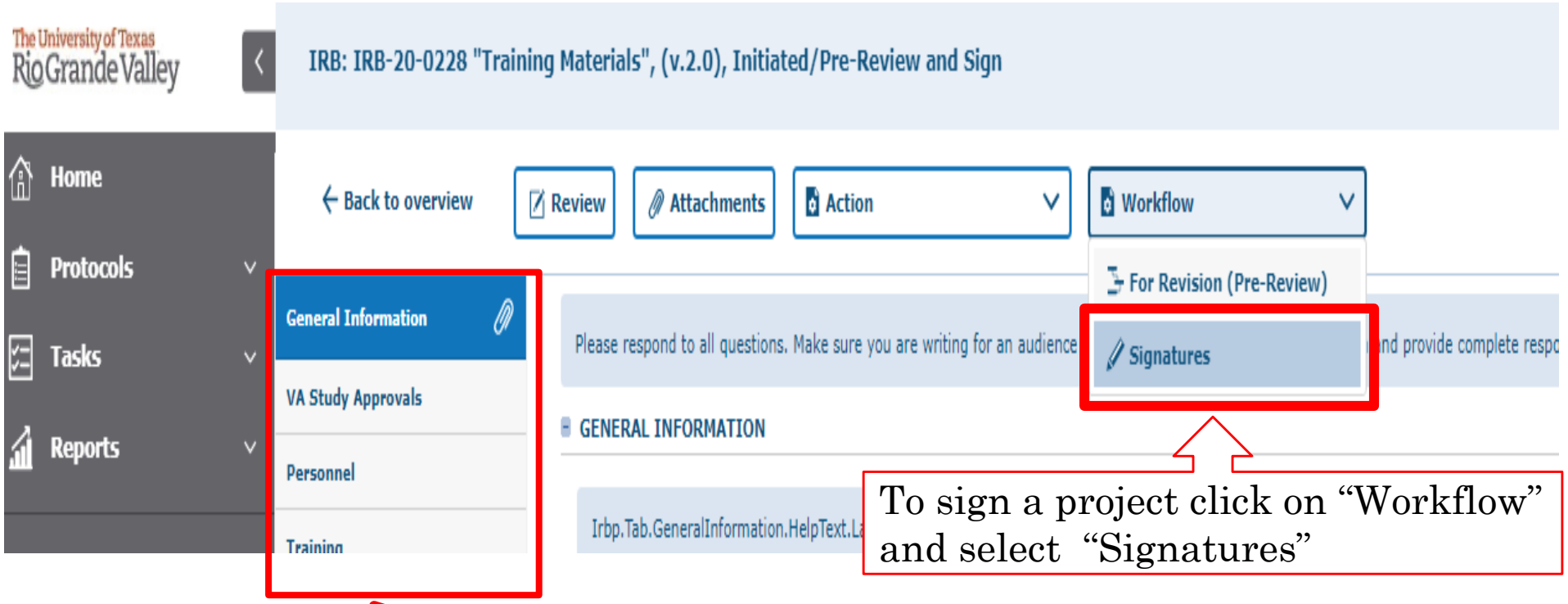
1st way to access the Signatures function: Protocols Page



First open your project by clicking on the gray row as shown above. This will open up the document level where you application is located. Then, right-click on the document as shown in this red box and select **Signatures**.

- All pre-reviewers and signers listed on the protocol must sign in order to move on to the next step in the workflow. They may all use this step, or the next to sign.
- For PIs who <u>are</u> students, the pre-review and signature process will be completed once both the student PI and the Faculty Advisor have signed.

2nd way to access the Signatures function: Within the application



If you are a Faculty Advisor you can sign the project after reviewing all tabs, then by clicking on "Workflow" and select "Signatures".

How to Sign

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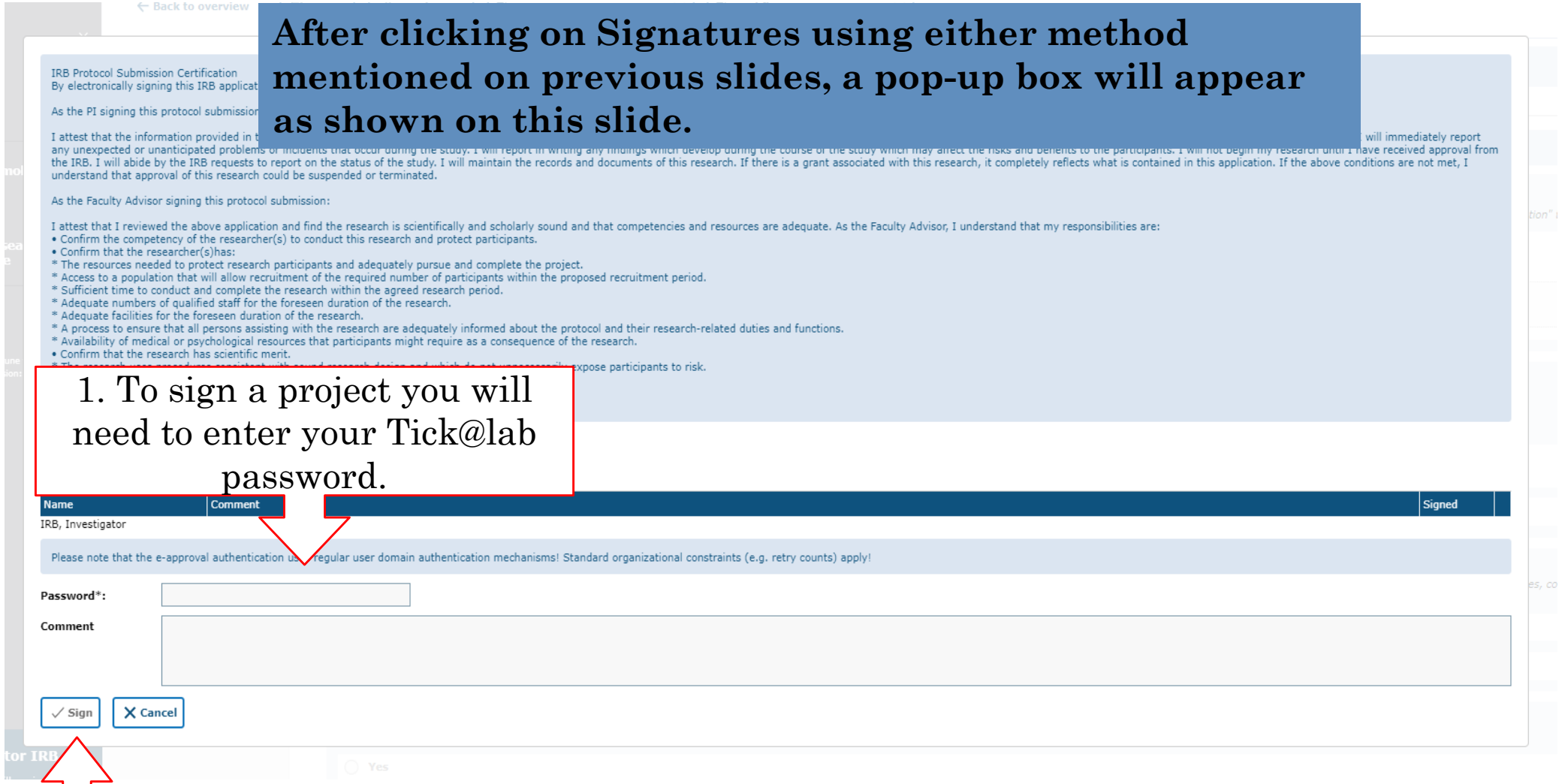
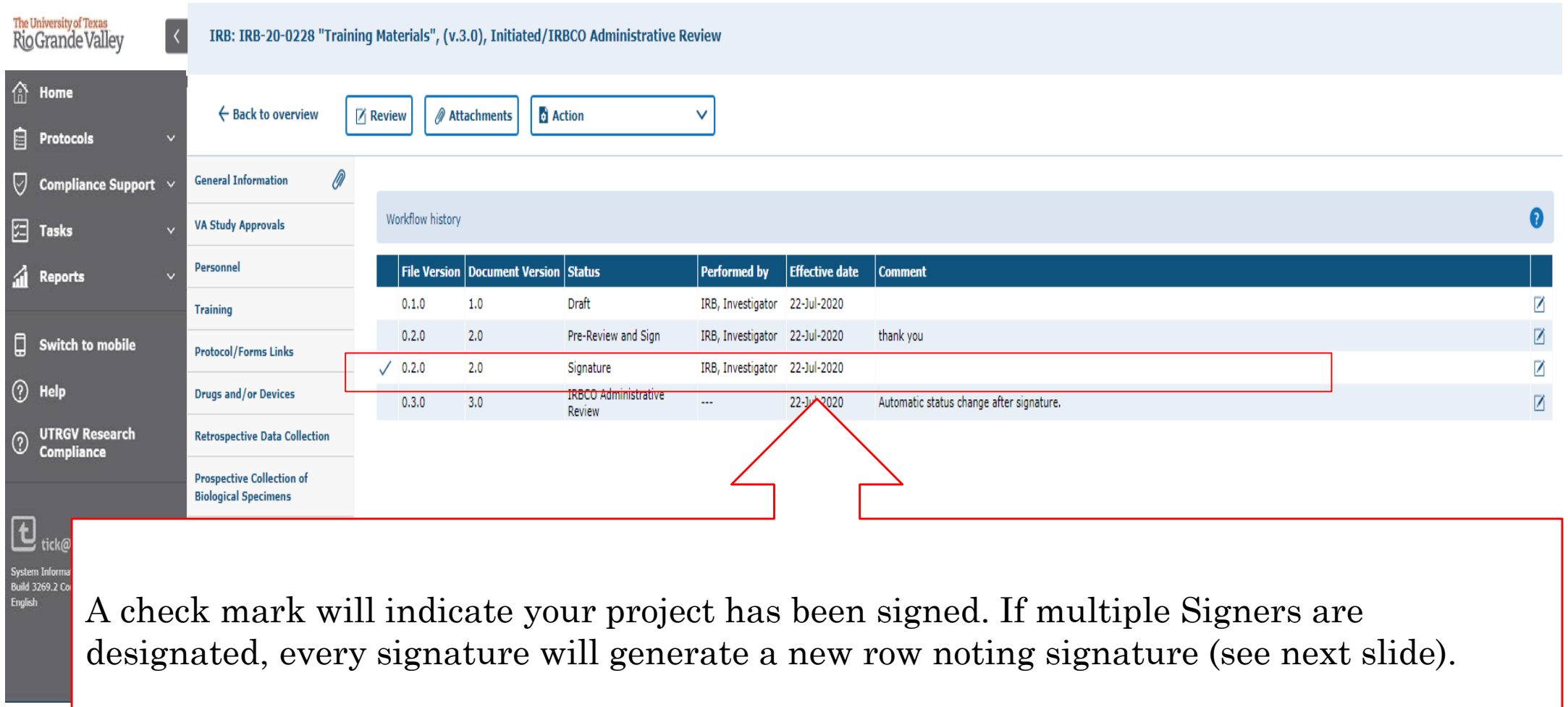
After clicking on Signatures using either method mentioned on previous slides, a pop-up box will appear as shown on this slide.

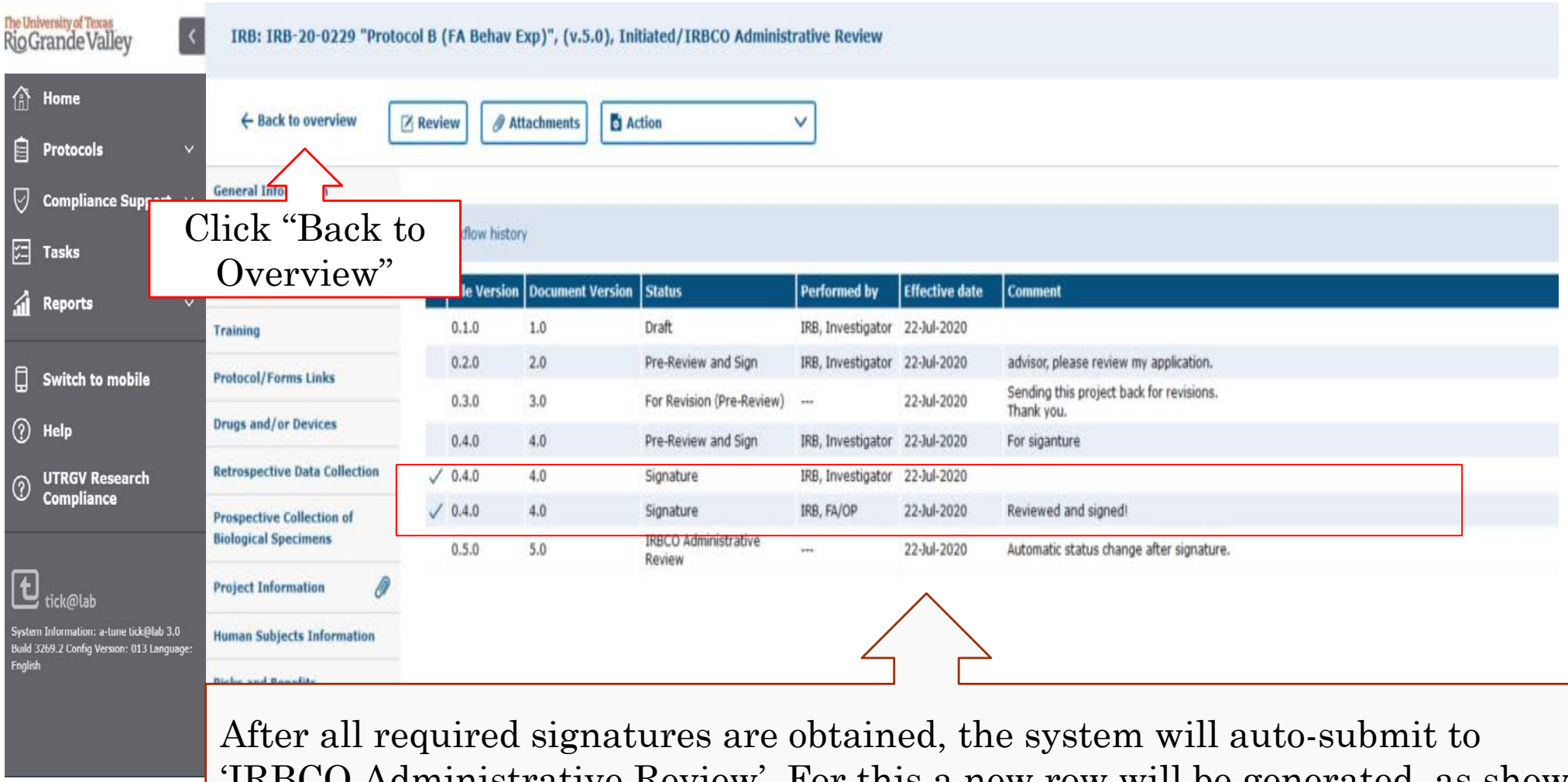


This is how a signed protocol will look like



A check mark will indicate your project has been signed. If multiple Signers are designated, every signature will generate a new row noting signature (see next slide).

This is how a protocol signed by a faculty advisor would look like.



After all required signatures are obtained, the system will auto-submit to 'IRBCO Administrative Review'. For this a new row will be generated, as shown above noted as file version 5.0.

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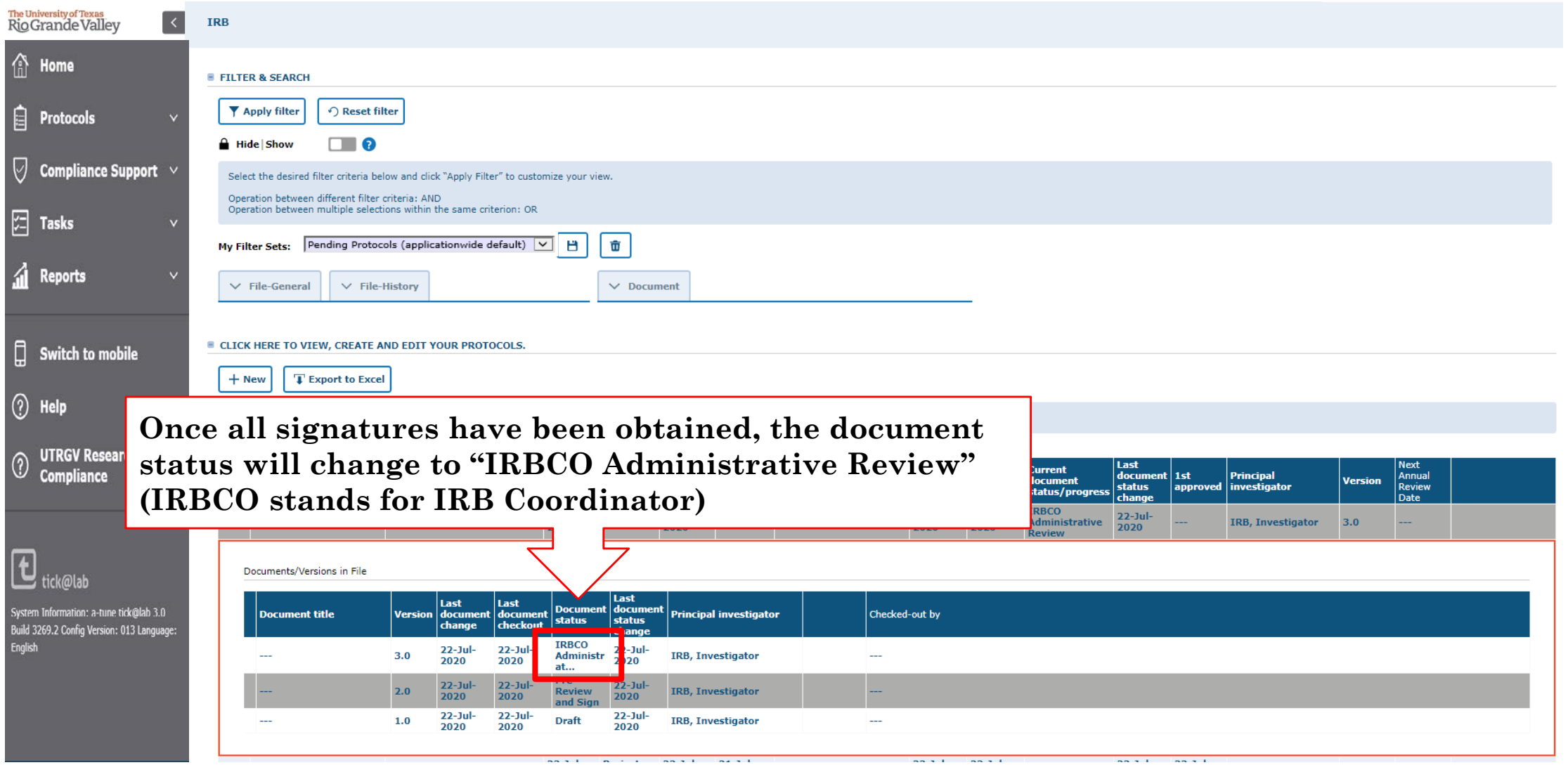


Once all signatures have been obtained, the document status will change to "IRBCO Administrative Review" (IRBCO stands for IRB Coordinator)

- **You will get an email that the application has been submitted for review, but you may also verify proper submission here.**

How to Revise a Submitted Protocol

Returned to your for Revision

Once your application goes to the IRBCO for review, one of the following will happen:

- Approved by IRBCO (aka IRB Coordinators)
- Referred to a IRB Member for review – aka (Reviewer)
- Referred to the Full Committee Review
- Returned to you For Revisions

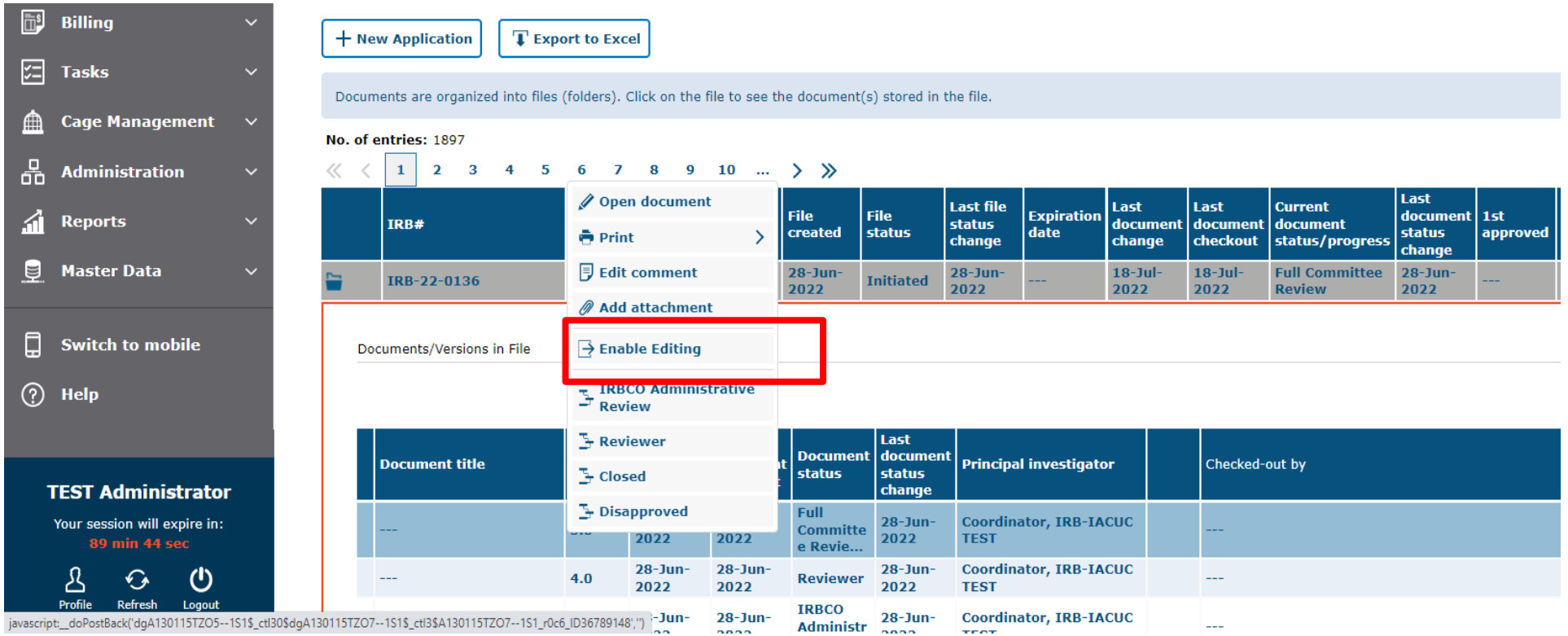
	IRB-20-0228	Training Materials	22-Jul-2020	Initiated	22-Jul-2020	---	---	22-Jul-2020	22-Jul-2020	For Revision (IRBCO)	22-Jul-2020	---	IRB, Investigator	4.0	---	

Documents/Versions in File

Document title	Version	Last document change	Last document checkou	Document status	Last document status change	Principal investigator		Checked-out by
---	4.0	22-Jul-2020	22-Jul-2020	For Revision (IRBCO)	22-Jul-2020	IRB, Investigator		---
---	3.0	22-Jul-2020	22-Jul-2020	IRBCO Administrat...	22-Jul-2020	IRB, Investigator		---
---	2.0	22-Jul-2020	22-Jul-2020	Pre-Review and Sign	22-Jul-2020	IRB, Investigator		---
---	1.0	22-Jul-2020	22-Jul-2020	Draft	22-Jul-2020	IRB, Investigator		---

If your protocol application gets returned to you for revisions:

- You will get an email that reviewer comments need to be addressed and the protocol needs to be revised.
- Requested revisions, approval notices, and renewal reminders will also be sent by email to you as PI.



- In order to make changes to a document in Tick@lab you need to enable editing the document first. During the time a document is enable editing, no other person can edit your document.
- Right-click on the document and select “enable editing document.”

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Remember, only one person at a time can work on an application.

- **Others can view in read-only mode, while the document is during enable editing mode.**

Done Editing (operational mode): Means it is available to edit.

Documents/Versions in File

	Document title	Version	Last document change	Last document checkout	Document status	Last document status change	Principal investigator		Checked-out by
	---	4.0	22-Jul-2020	22-Jul-2020	For Revision (IRBCO)	22-Jul-2020	IRB, Investigator		IRB, Investigator
	---	3.0	22-Jul-2020	22-Jul-2020	IRBCO Administrat...	22-Jul-2020	IRB, Investigator		---
	---	2.0	22-Jul-2020	22-Jul-2020	Pre-Review and Sign	22-Jul-2020	IRB, Investigator		---
	---	1.0	22-Jul-2020	22-Jul-2020	Draft	22-Jul-2020	IRB, Investigator		---

Enable Editing (read-only mode): Means someone is working on the document.

	IRB-20-0228	Training Materials	22-Jul-2020	Initiated	22-Jul-2020	---	---	22-Jul-2020	22-Jul-2020	For Revision (IRBCO)	22-Jul-2020	---

Documents/Versions in File

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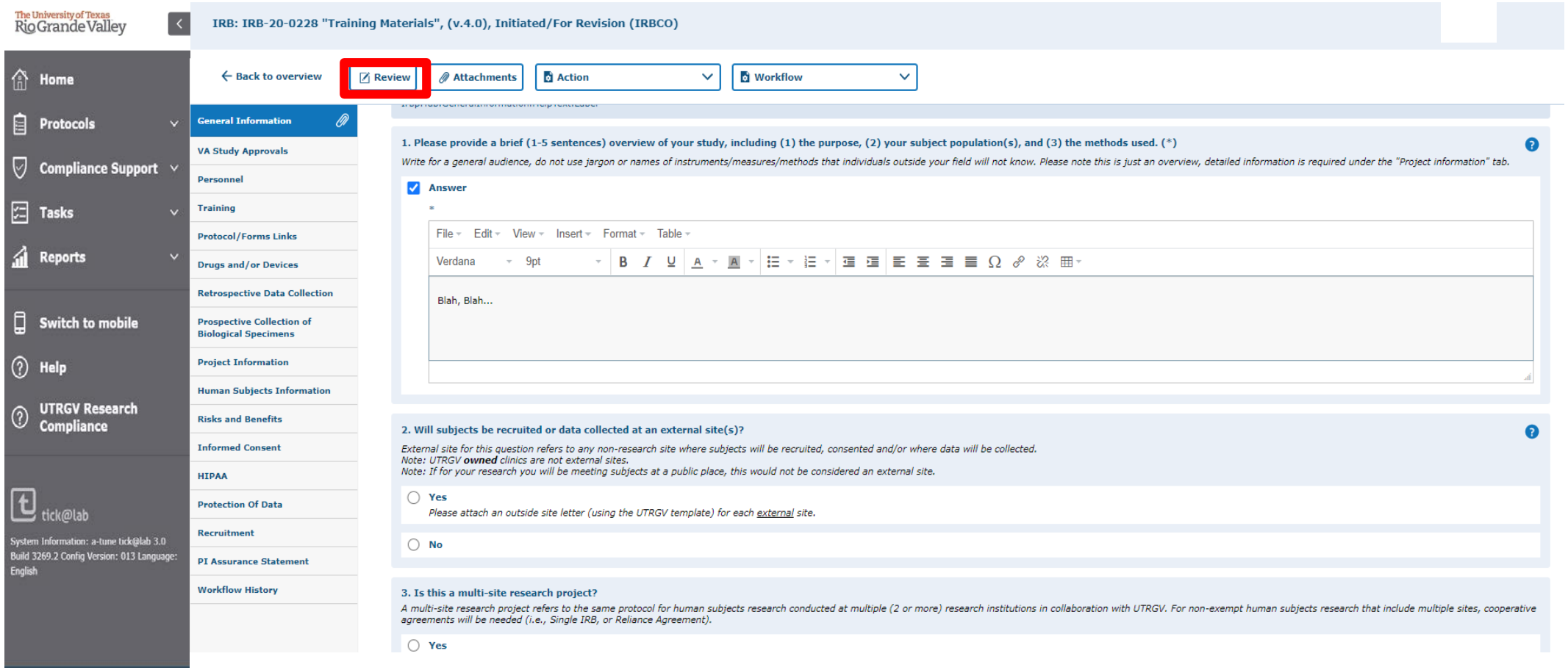
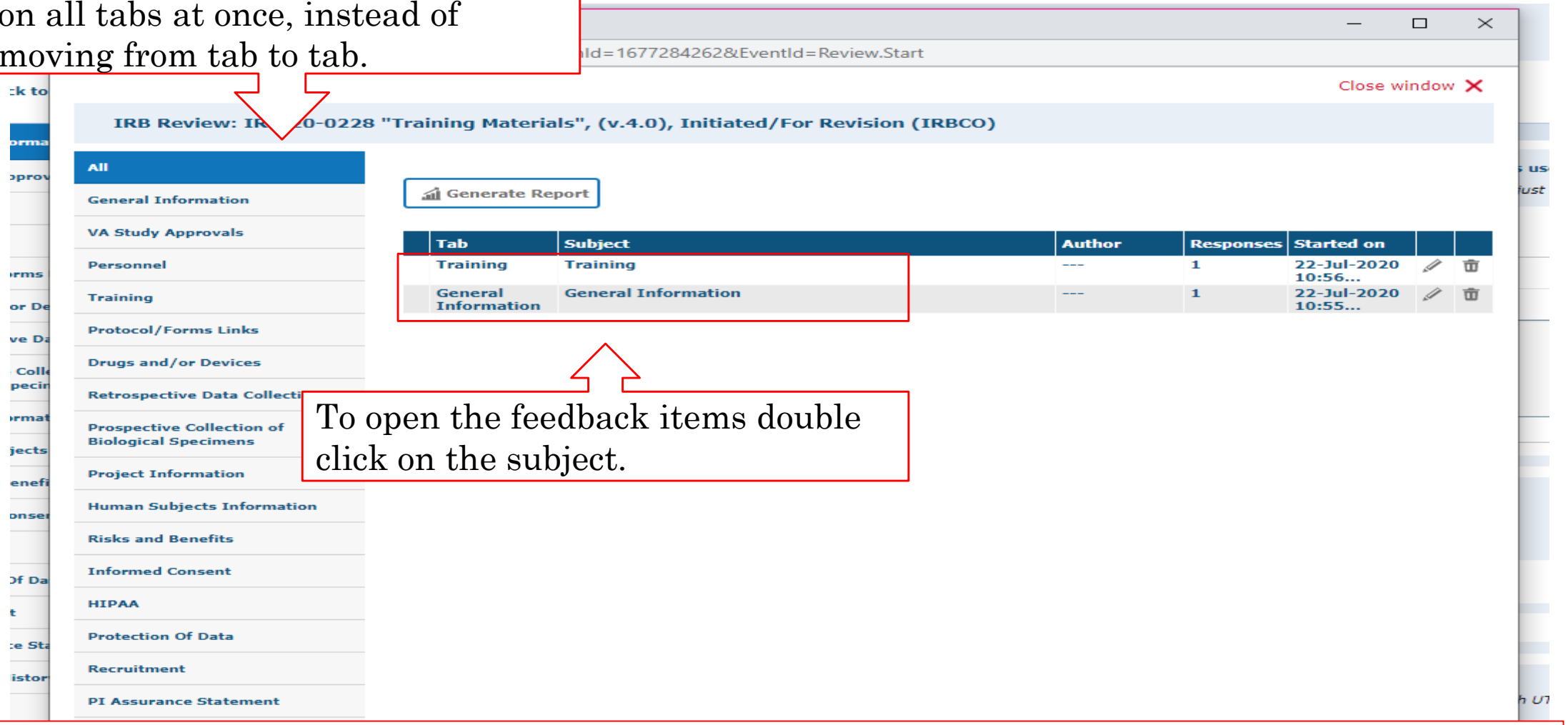
	---	4.0	22-Jul-2020	22-Jul-2020	For Revision (IRBCO)	22-Jul-2020	IRB, Investigator		IRB, Investigator
	---	3.0	22-Jul-2020	22-Jul-2020	IRBCO Administrat...	22-Jul-2020	IRB, Investigator		---
	---	2.0	22-Jul-2020	22-Jul-2020	Pre-Review and Sign	22-Jul-2020	IRB, Investigator		---
	---	1.0	22-Jul-2020	22-Jul-2020	Draft	22-Jul-2020	IRB, Investigator		---

Once you have enable editing on the document, then you can navigate through all the revisions requested by using the review button.



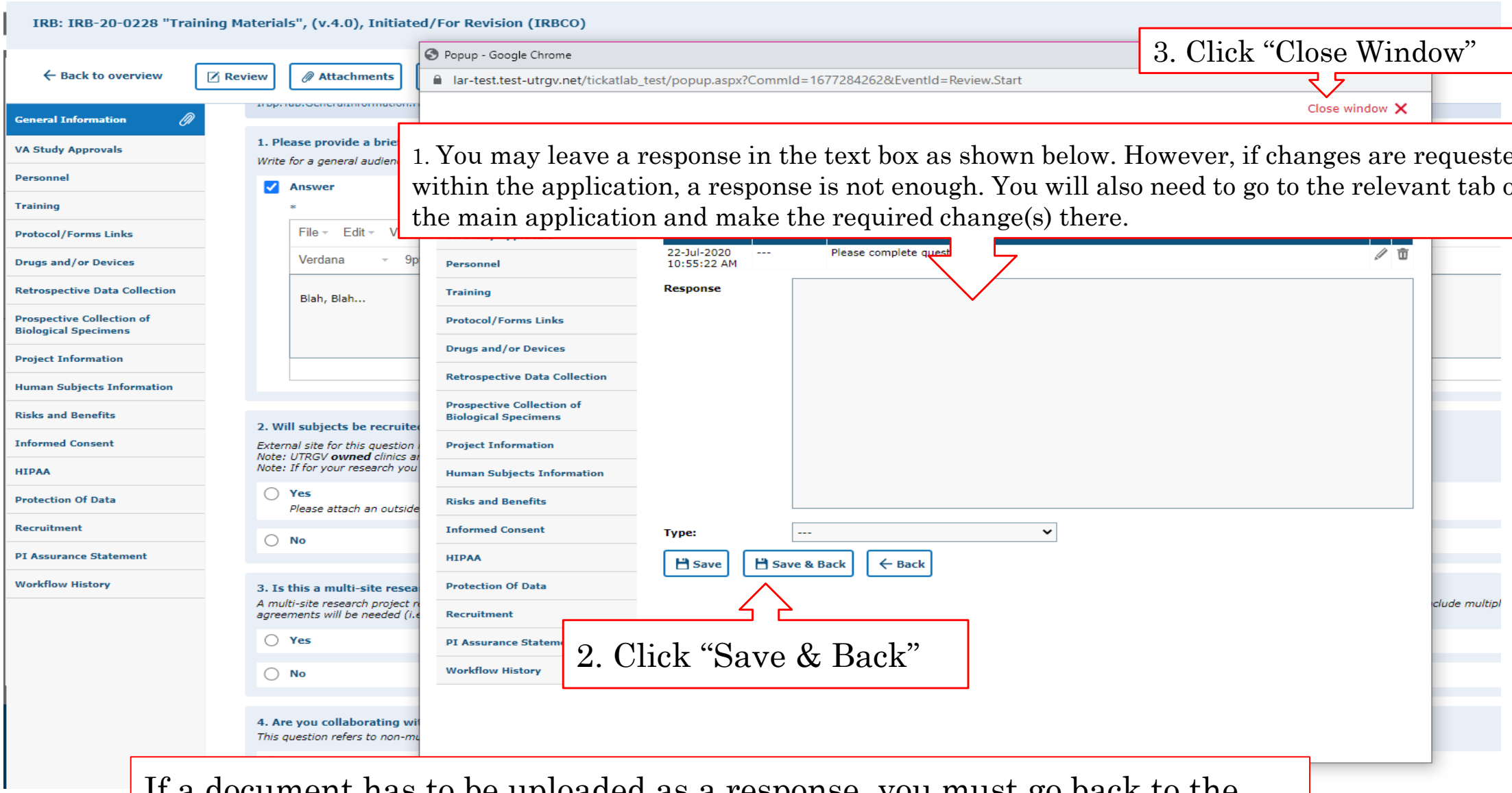
Click on "Review" button to see all feedback from the reviewer.

Click “All“ to see the feedback left on all tabs at once, instead of moving from tab to tab.

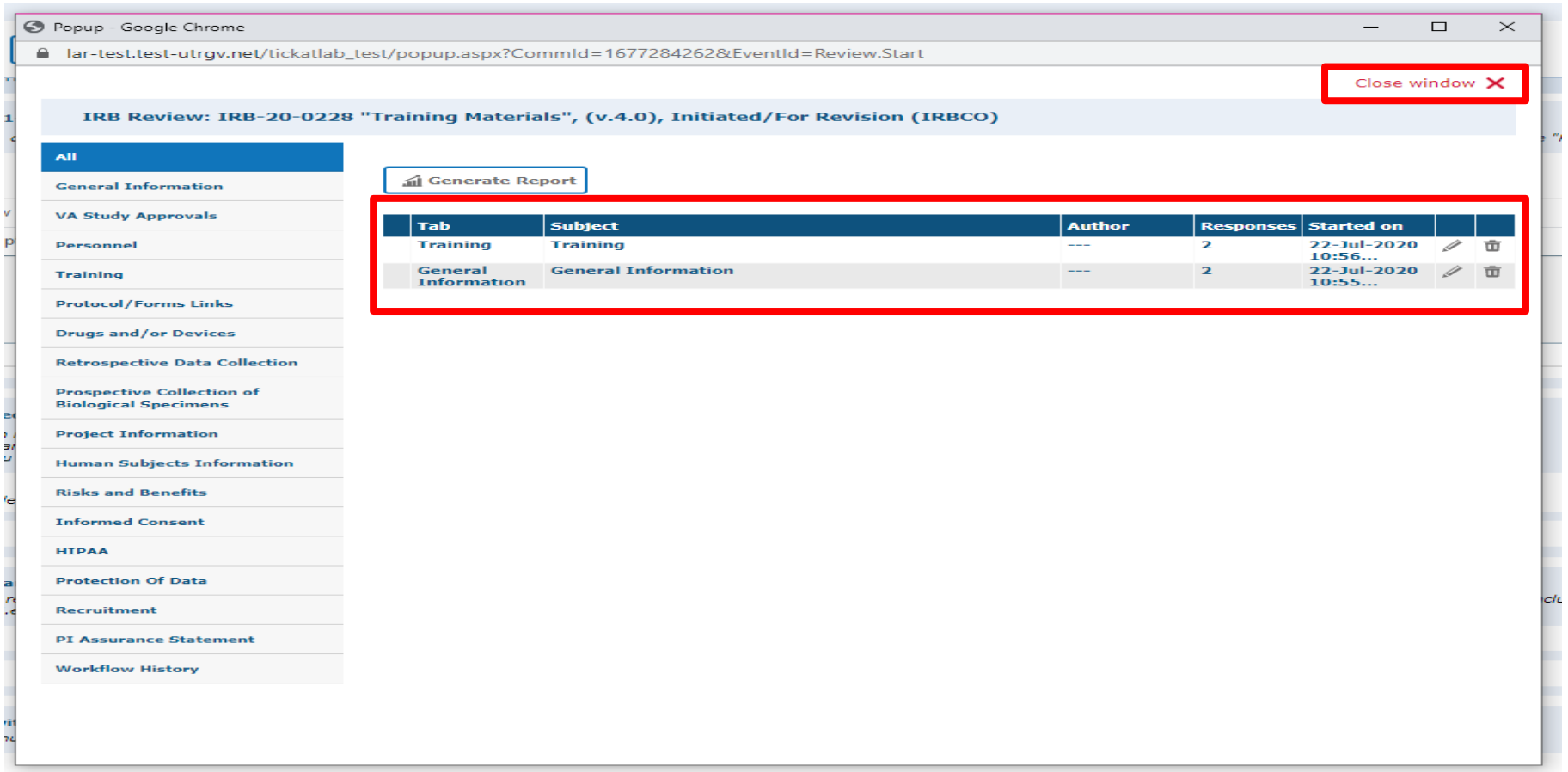


To open the feedback items double click on the subject.

- As illustrated in the red box above, you will find a list of items requested by reviewers for the entire protocol.
- To view the feedback, please click on each topic under the “Subject” column to open the message.

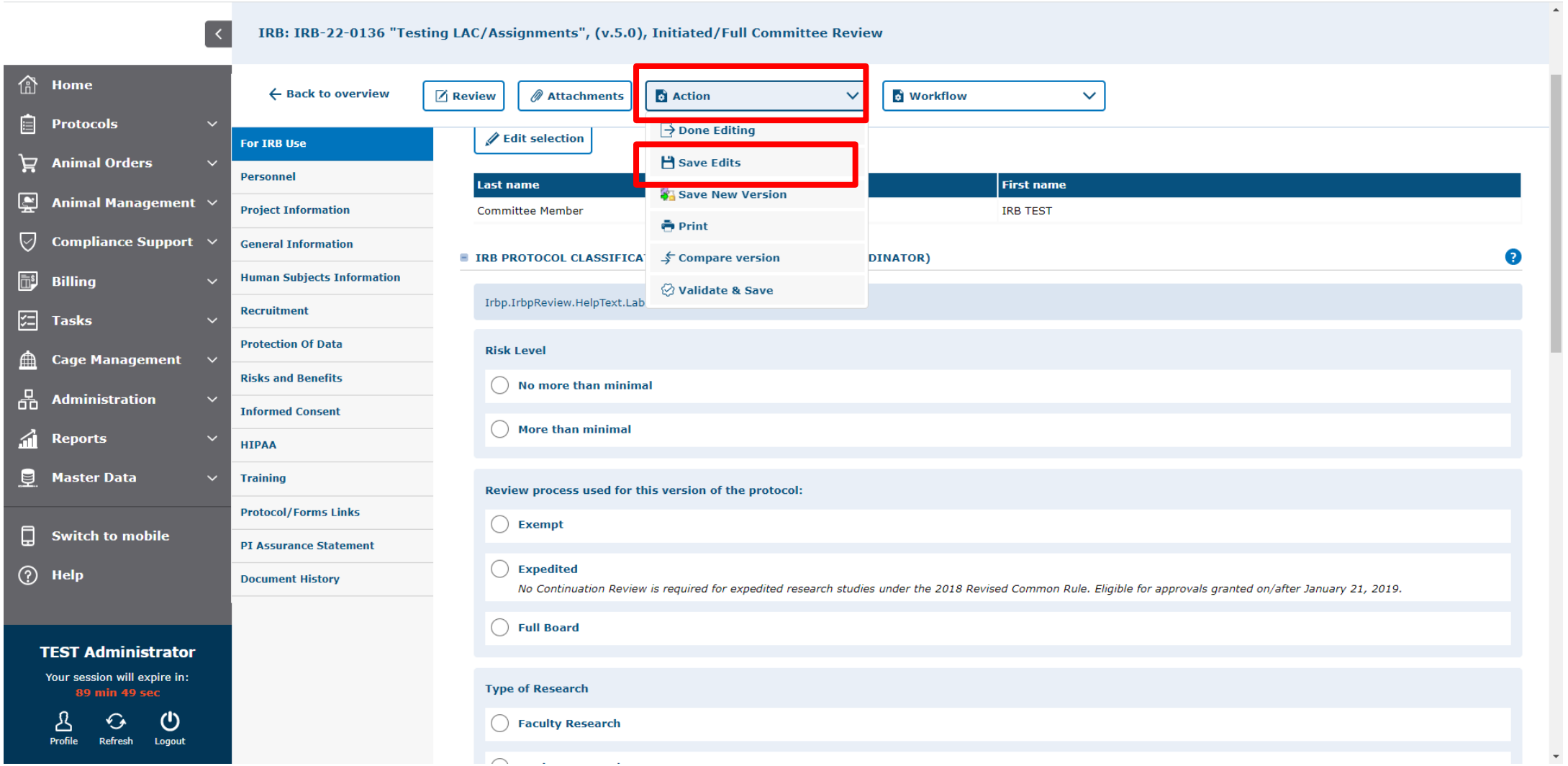


If a document has to be uploaded as a response, you must go back to the "attachments" tab and upload the document in the respective section.



- After reviewing and addressing all items, click “close window”.
- Every time a researcher makes modification to a form a new version is activated in the system. The creation of versions allows the IRB Coordinators and Board Members to streamline the review process by conducting automatic comparisons among versions.

Don’t forget to save your changes before submitting!

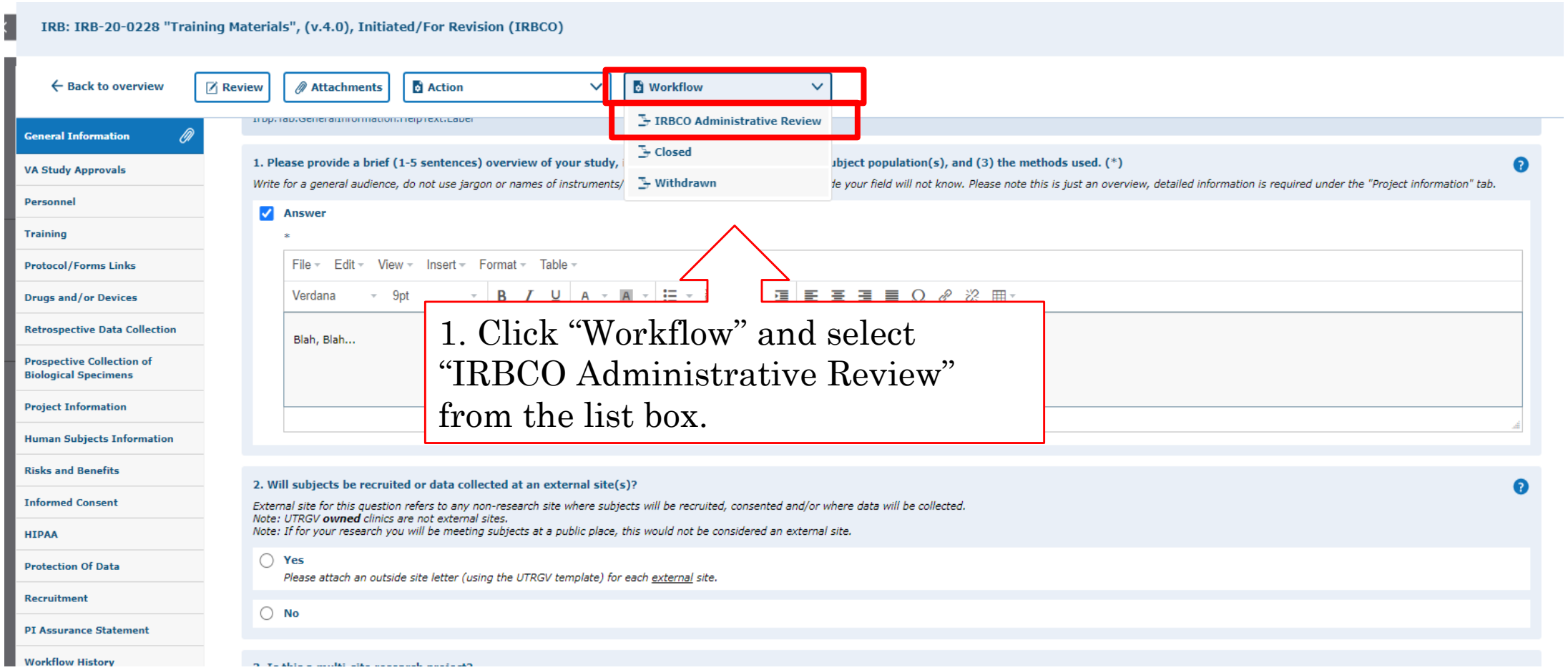


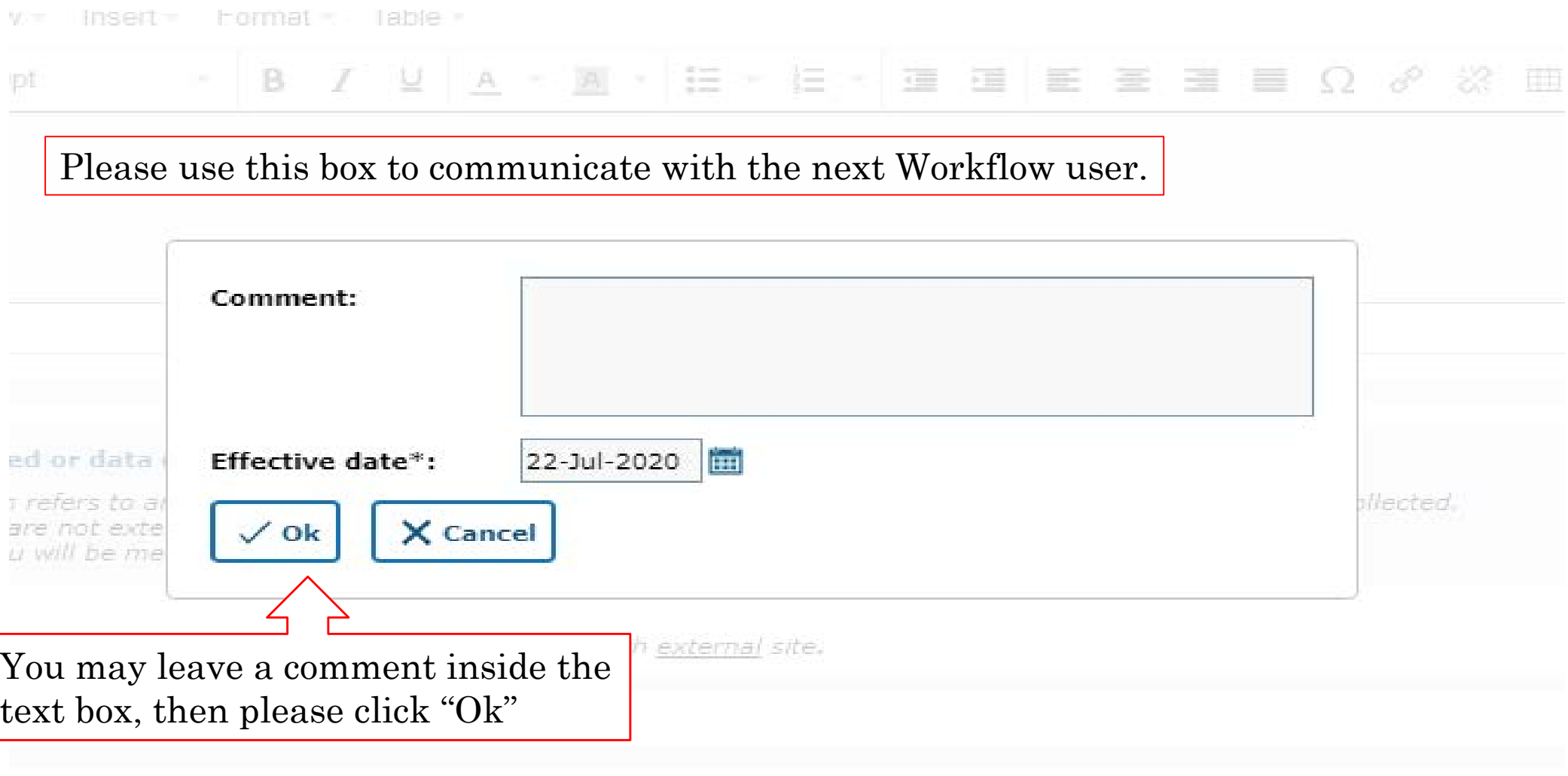
Resubmitting a Protocol

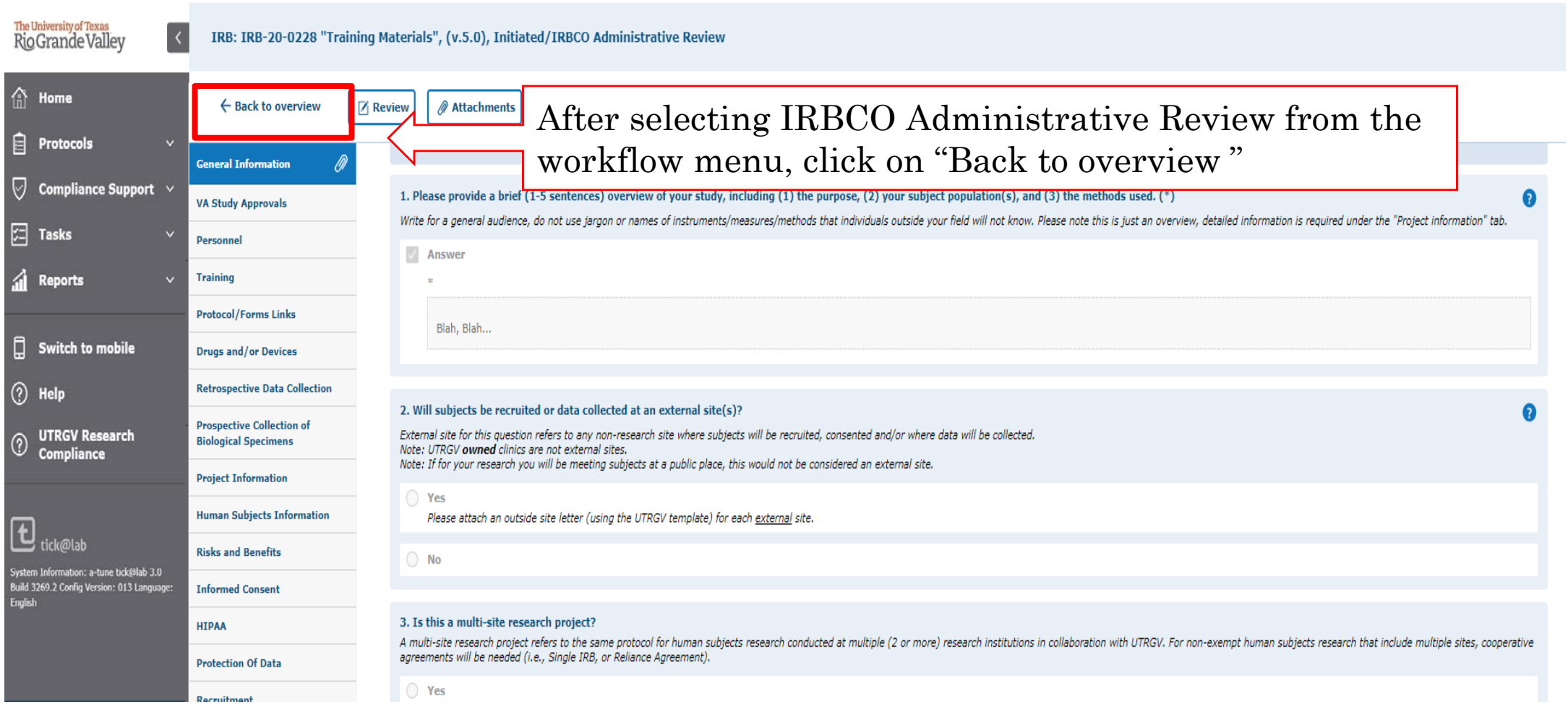
Submitting back to Workflow, after making required revisions

You have two options to submit your revised protocol back to Workflow.

Option #1: Within the application




Please use this box to communicate with the next Workflow user.
Comment:
Effective date*:
22-Jul-2020
Ok
Cancel
You may leave a comment inside the text box, then please click “Ok”



After selecting IRBCO Administrative Review from the workflow menu, click on “Back to overview ”

Option #2: From the Protocols page

Open the project by clicking on the text in the gray row as shown below. This will open up the document level shown in the red box.

	IRB-20-0228	Training Materials	22-Jul-2020	Initiated	22-Jul-2020	---	---	22-Jul-2020	22-Jul-2020	For Revision (IRBCO)	22-Jul-2020	---	IRB, Investigator	4.0	---	

Documents/Versions in File

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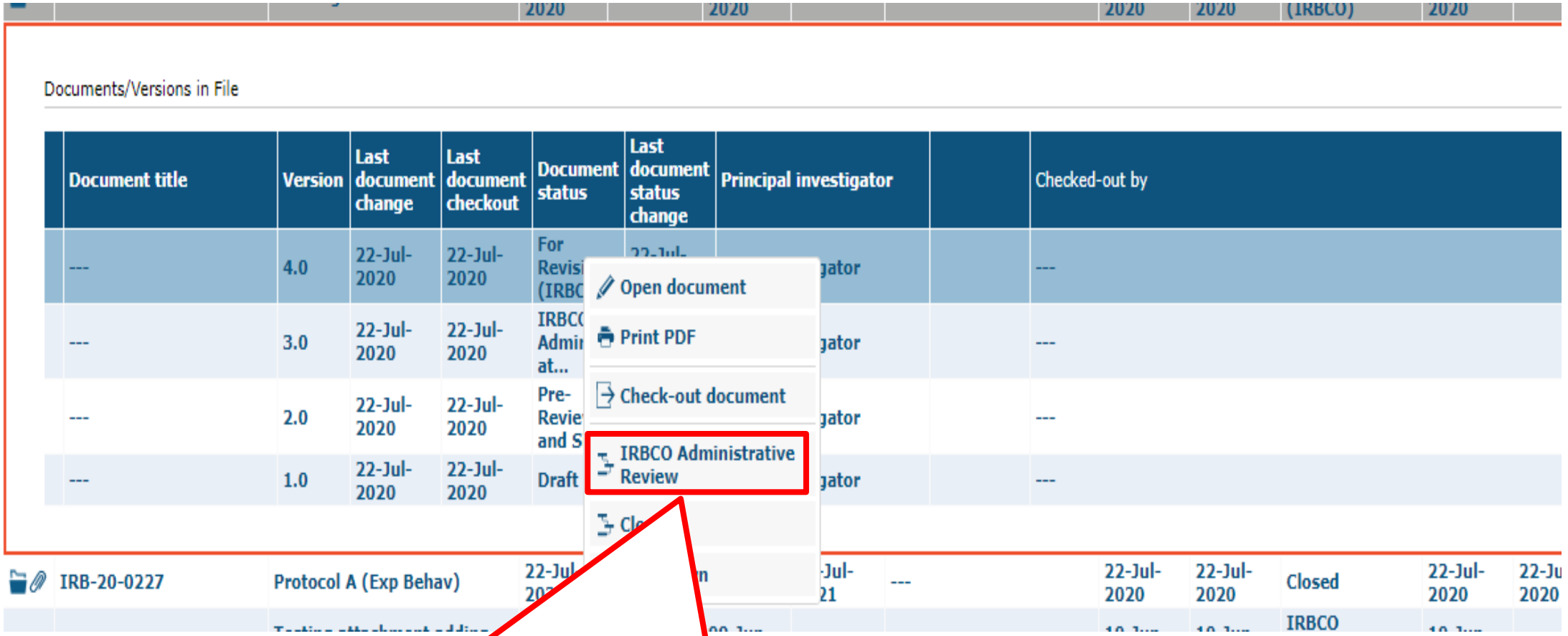
	---	4.0	22-Jul-2020	22-Jul-2020	For Revision (IRBCO)	22-Jul-2020	IRB, Investigator		---
	---	3.0	22-Jul-2020	22-Jul-2020	IRBCO Administr at...	22-Jul-2020	IRB, Investigator		---
	---	2.0	22-Jul-2020	22-Jul-2020	Pre-Review and Sign	22-Jul-2020	IRB, Investigator		---
	---	1.0	22-Jul-2020	22-Jul-2020	Draft	22-Jul-2020	IRB, Investigator		---

Next, at the document level right-click on the latest version of your application. From the menu select “IRBCO Administrative Review”.



Right click on document and select “IRBCO Administrative Review”.

	IRB-20-0228	Training Materials	22-Jul-2020	Initiated	22-Jul-2020	---	---	22-Jul-2020	22-Jul-2020	IRBCO Administrative Review	22-Jul-2020	---	I

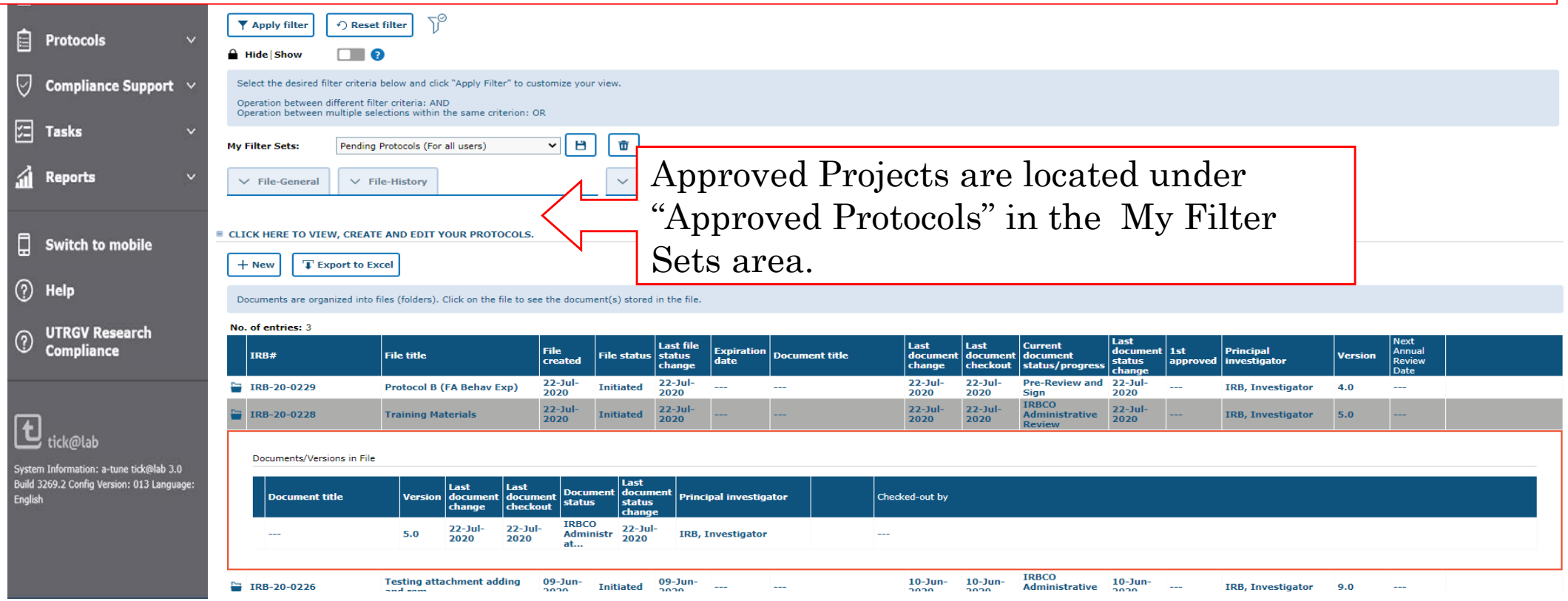
Documents/Versions in File

	Document title	Version	Last document change	Last document checkout	Document status	Last document status change	Principal investigator		Checked-out by
	---	5.0	22-Jul-2020	22-Jul-2020	IRBCO Administrat...	22-Jul-2020	IRB, Investigator		---
	---	4.0	22-Jul-2020	22-Jul-2020	For Revision (IRBCO)	22-Jul-2020	IRB, Investigator		---
	---	3.0	22-Jul-2020	22-Jul-2020	IRBCO Administrat...	22-Jul-2020	IRB, Investigator		---
	---	2.0	22-Jul-2020	22-Jul-2020	Pre-Review and Sign	22-Jul-2020	IRB, Investigator		---
	---	1.0	22-Jul-2020	22-Jul-2020	Draft	22-Jul-2020	IRB, Investigator		---

	IRB-20-0227	Protocol A (Exp Behav)	22-Jul-	Closed	22-Jul-	21-Jul-	---	22-Jul-	22-Jul-	Closed	22-Jul-	22-Jul-	I

You may verify that your project was submitted by looking at the document status column. The status should show “IRBCO Administrative Review”.

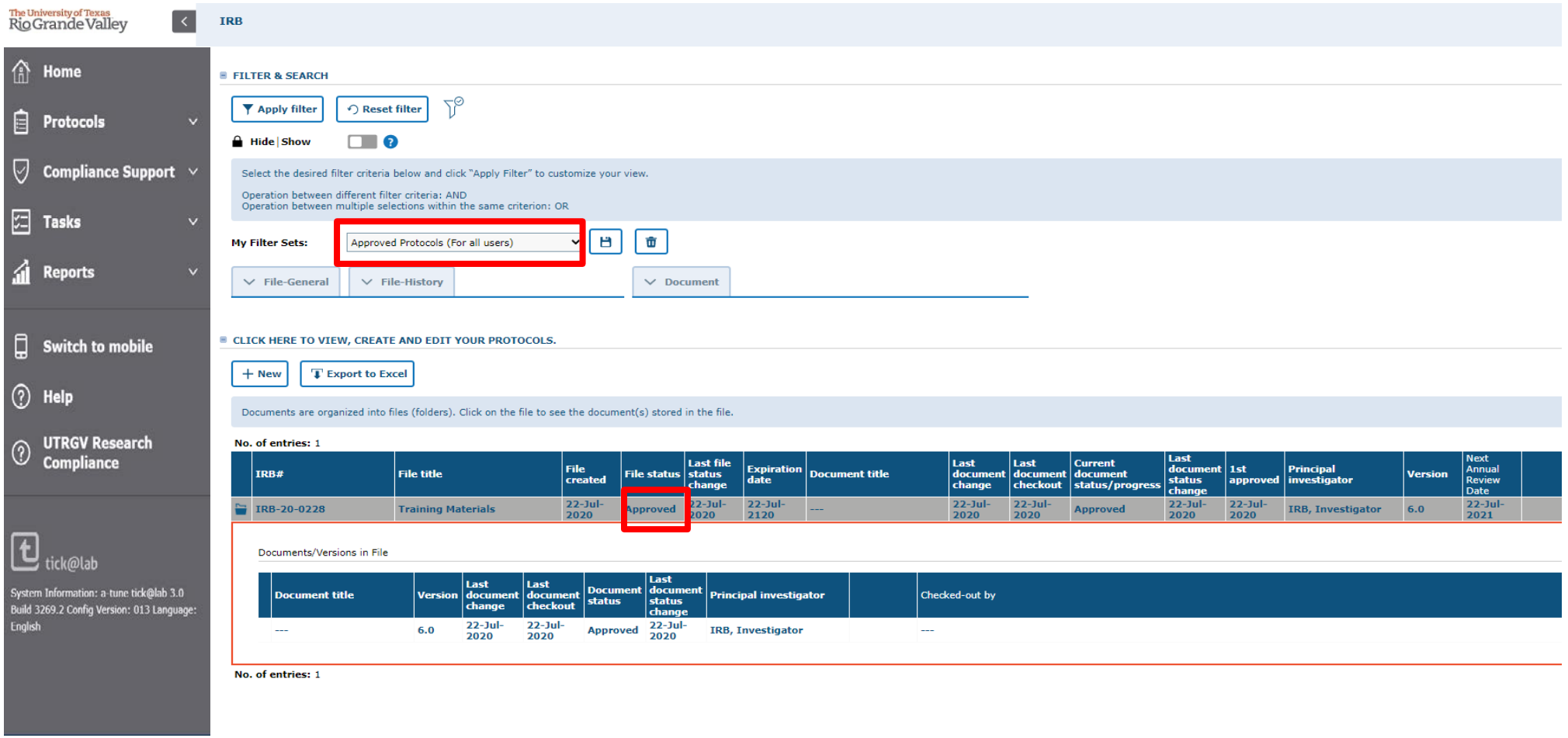
Once your revisions are completed and received, your project will be revisited. Your project may be approved after that, depending on where it is in the workflow. If your revisions are not sufficient or something was missed, the protocol will be pushed back to you for revision.



Approved Projects are located under "Approved Protocols" in the My Filter Sets area.

Once approved, you will receive an email notification and your application will disappear from the 'Pending Protocols' list.

This is how your approved protocol will appear on the IRB tab 'Approved Protocols' filter



Your project has been APPROVED