The University of Texas Rio Grande Valley

WELCOME

TO THE NEW IRB ELECTRONIC SYSTEM

Tick@lab

Amendments (Modifications) 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

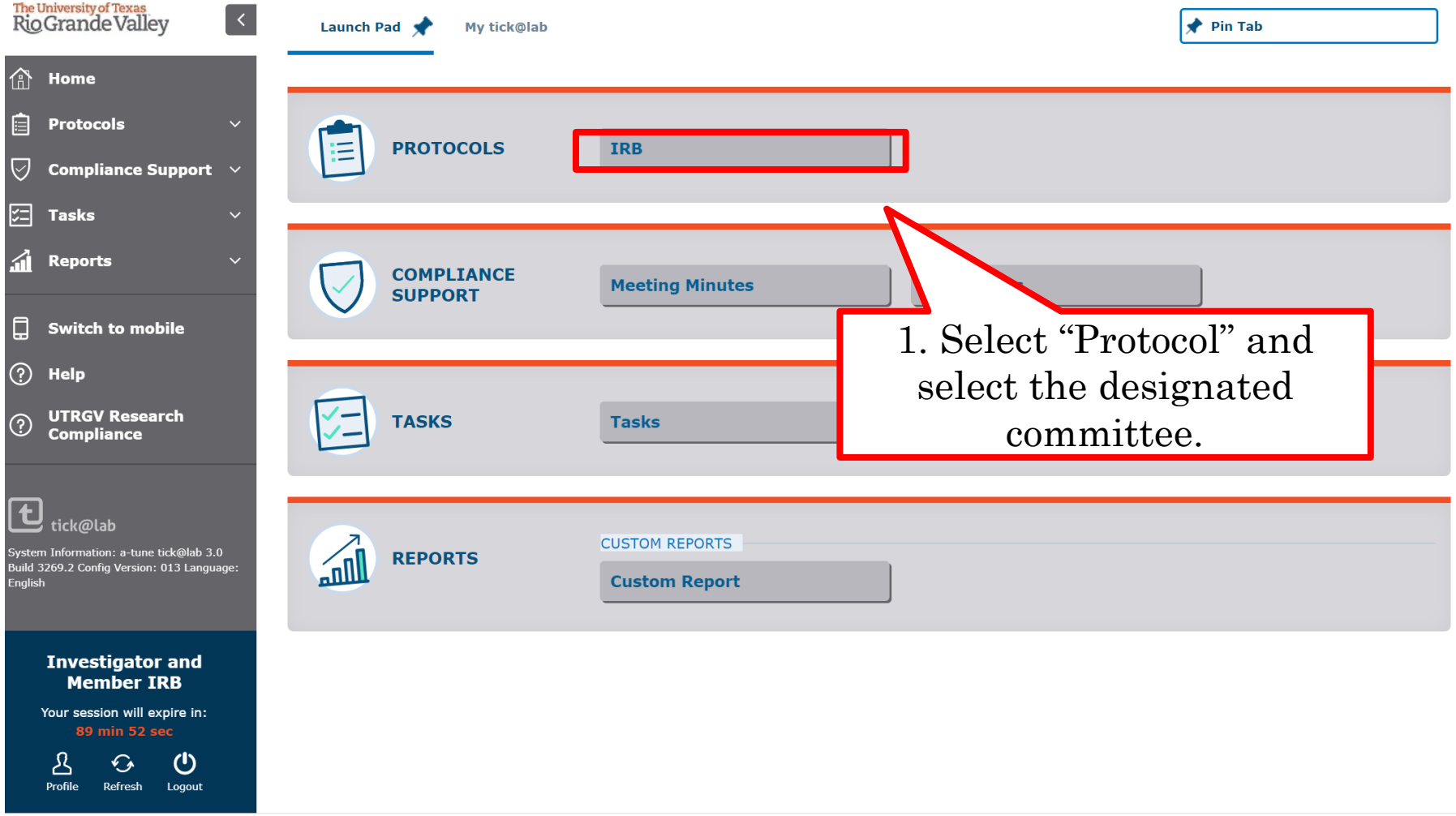
https://lar.utrgv.edu/tickatlab/default.aspx

Log in with your UTRGV Credentials

If you are unable to log in 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.

After Login in to Tick@lab,



How to Submit an Amendment (Modification) Request

Submission Steps

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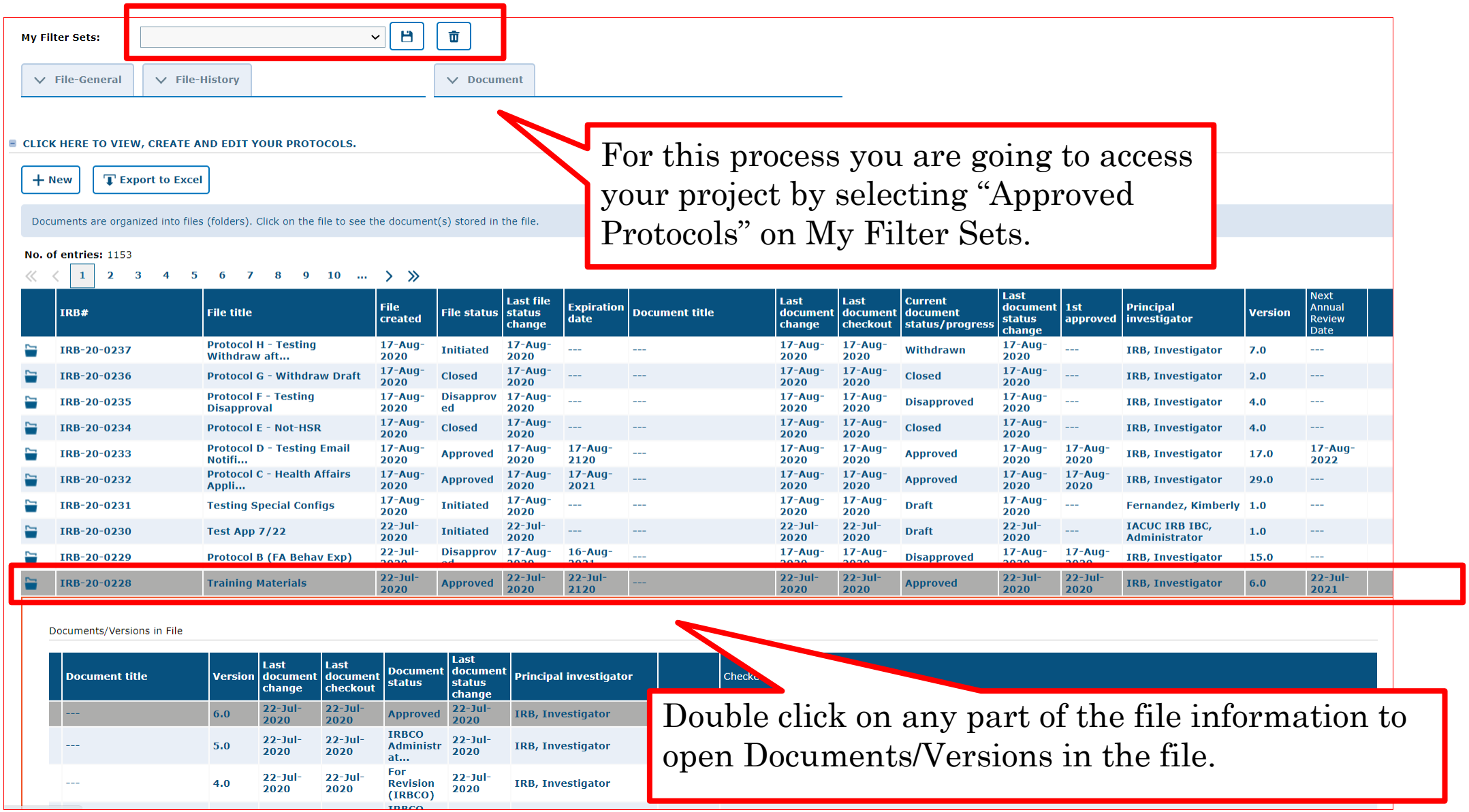
Please note: The PI or Co-Investigators can amend (modify) an approved protocol.



For this process you are going to access your project by selecting “Approved Protocols” on My Filter Sets.

Double click on any part of the file information to open Documents/Versions in the file.

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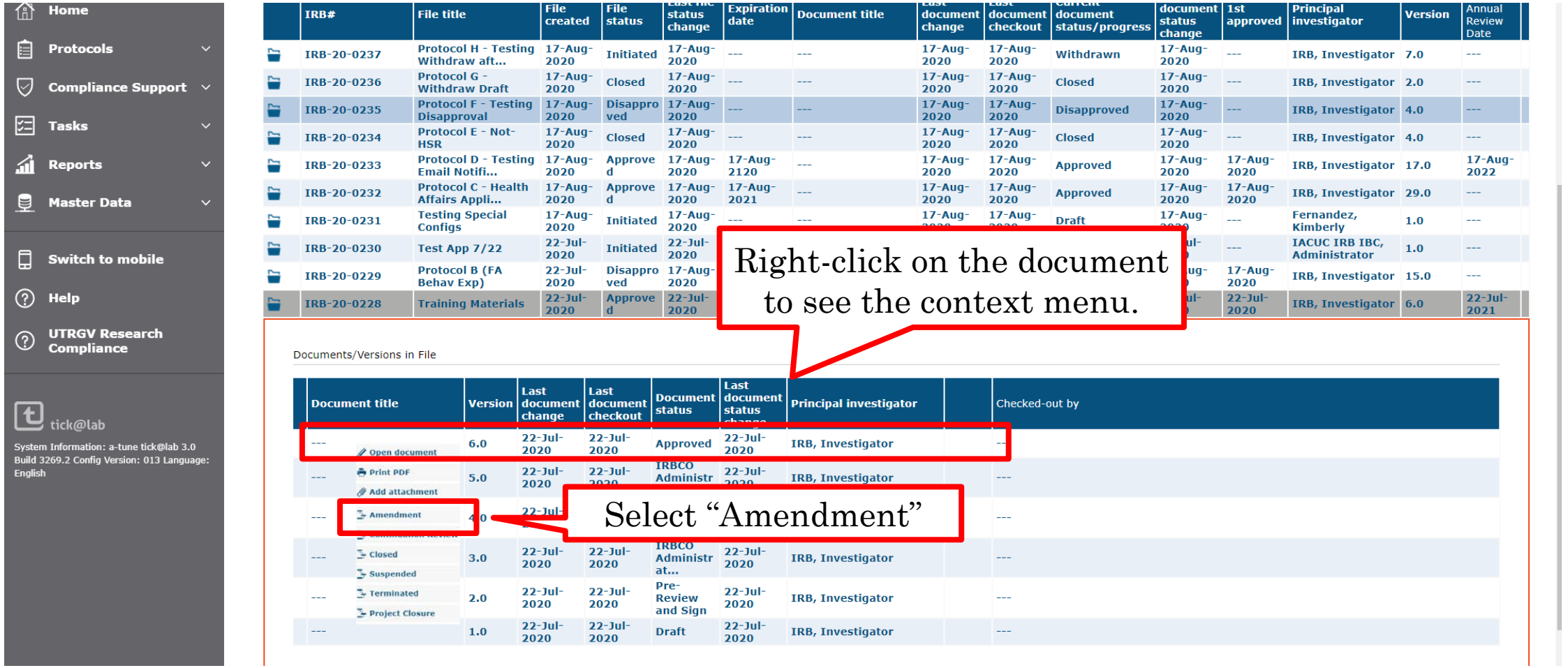
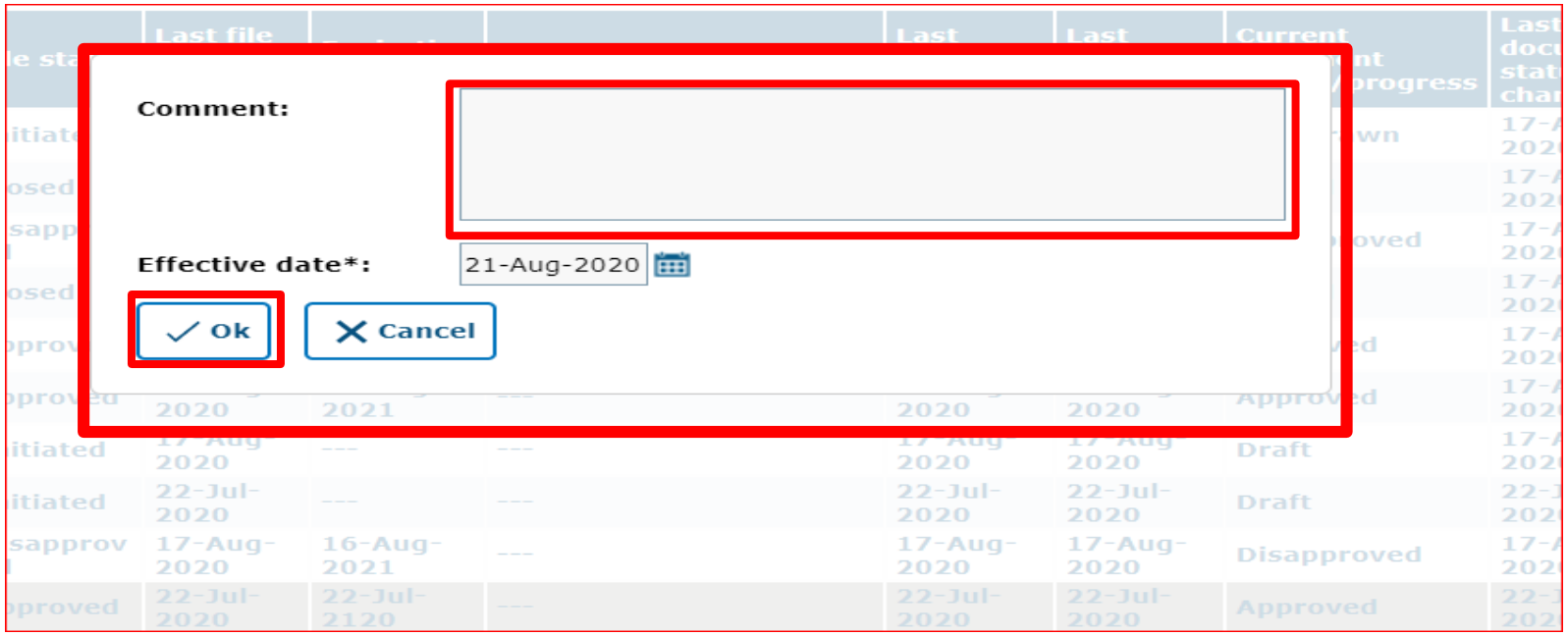
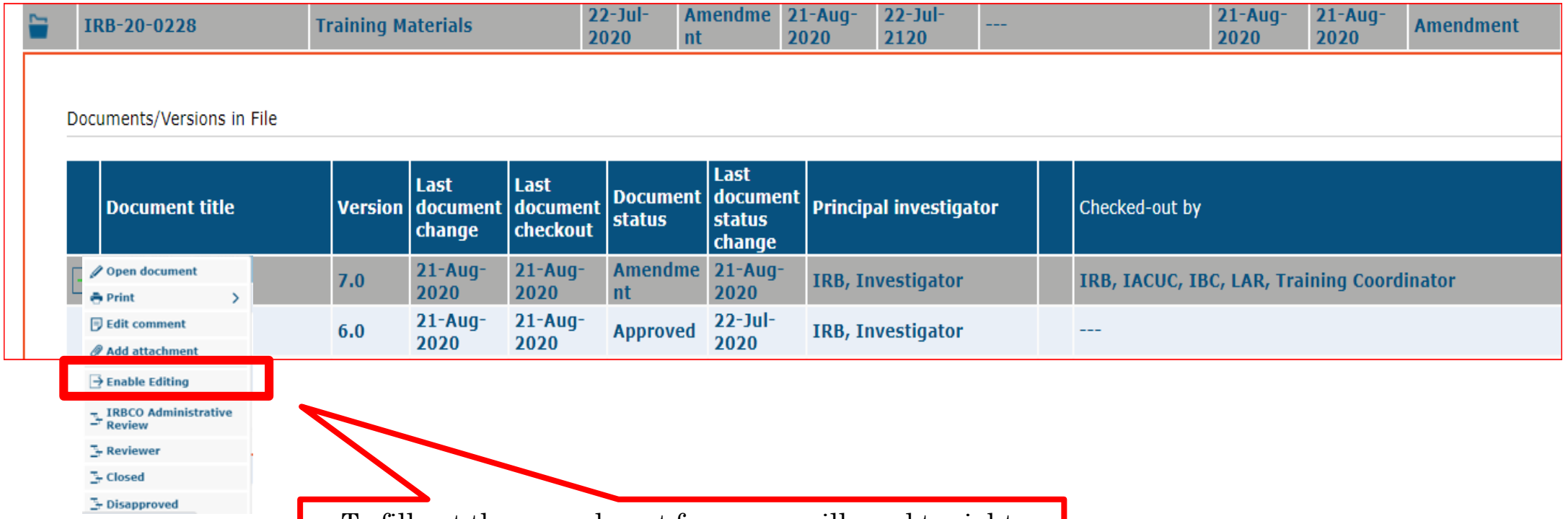
The Document/Version file contains a collection of documents related to the same study protocol, including your approved version of the initial protocol.



Please provide a brief description of the amendment and click “Ok.”



Now you will see that an additional document version is created.

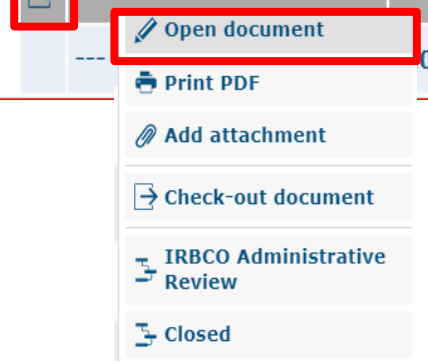


To fill out the amendment form, you will need to right-click on the new version and select "Enable Editing."

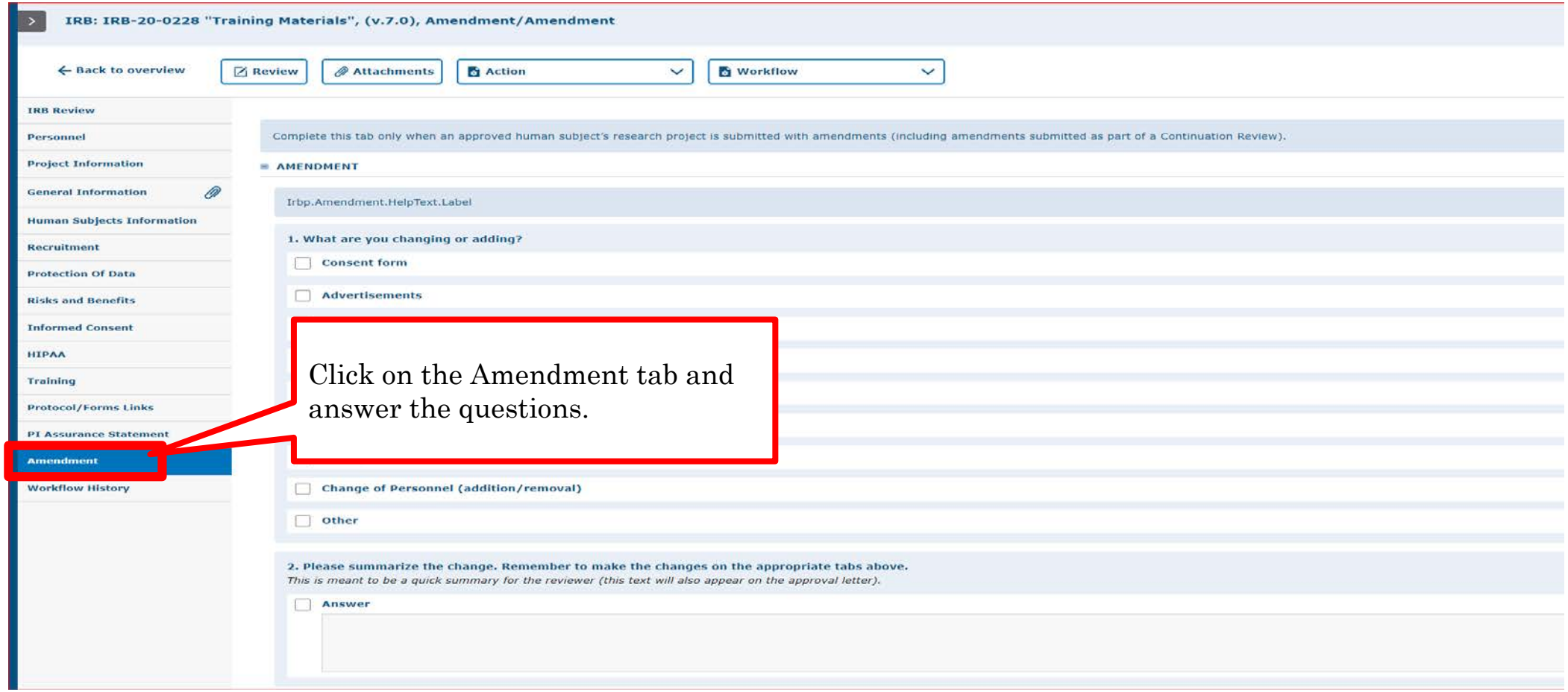
	IRB-20-0228	Training Materials	22-Jul-2020	Amendment	21-Aug-2020	22-Jul-2120	---	21-Aug-2020	21-Aug-2020	Amendment

Documents/Versions in File

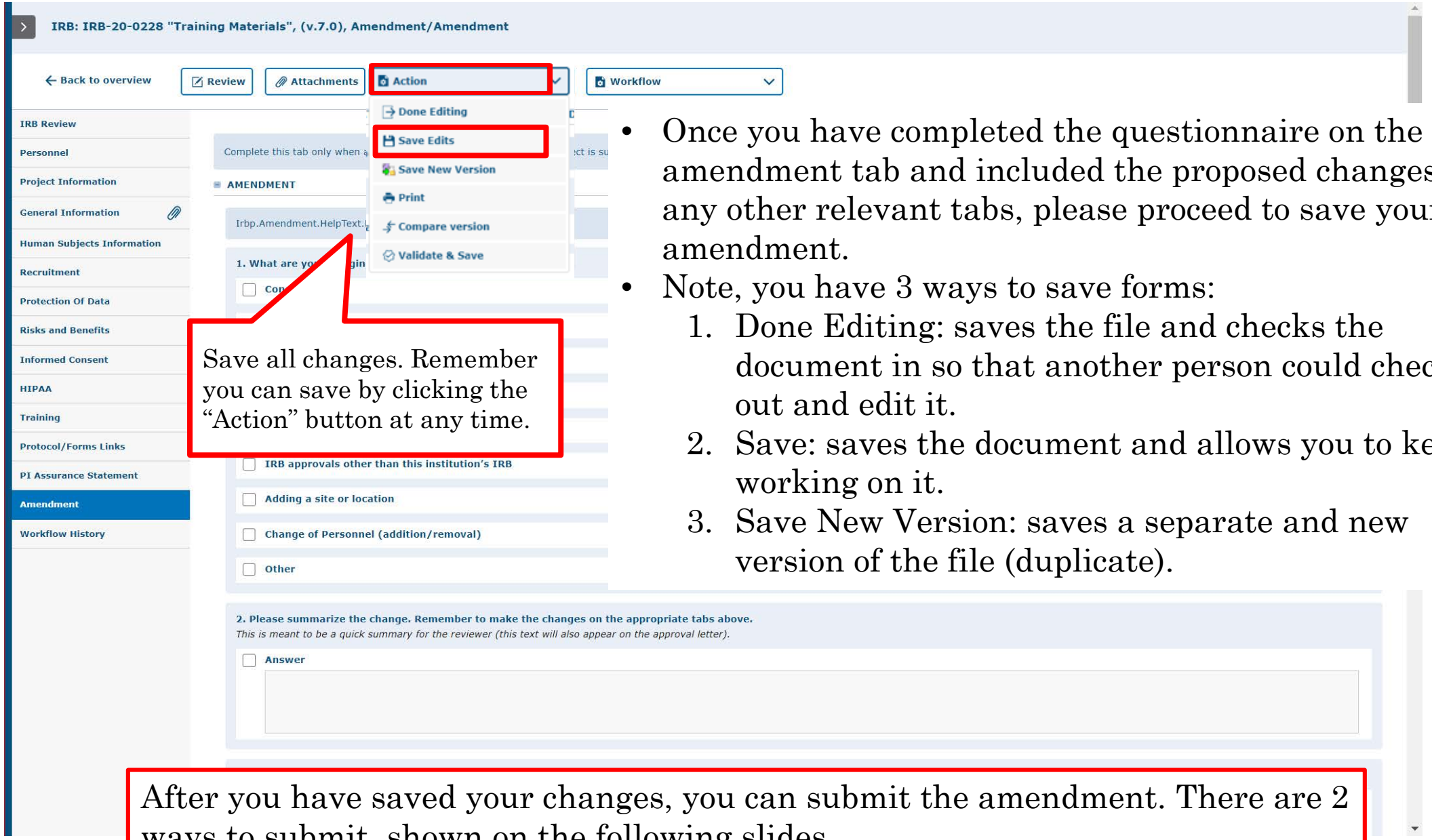
	Document title	Version	Last document change	Last document checkout	Document status	Last document status change	Principal investigator		Checked-out by
	---	7.0	21-Aug-2020	21-Aug-2020	Amendment	21-Aug-2020	IRB, Investigator		IRB, IACUC, IBC, LAR, Training Coordinator
	---	0	21-Aug-2020	21-Aug-2020	Approved	22-Jul-2020	IRB, Investigator		---



After enable editing on the document, please right click and select “Open document.”



Certain questions will ask if your proposed changes were also captured in the appropriate tabs. If your approved application was generated in Tick@lab, you will see the original information you entered on the tabs to the left. If that is the case, all you need to do is modify the text on any relevant tabs. If your approved protocol was processed originally using IRBNet or prior to IRBNet, your approved protocol was uploaded into Tick@lab as an attachment on the General Information tab. However, to process this amendment you will need to enter the proposed changes on each of the relevant tabs.

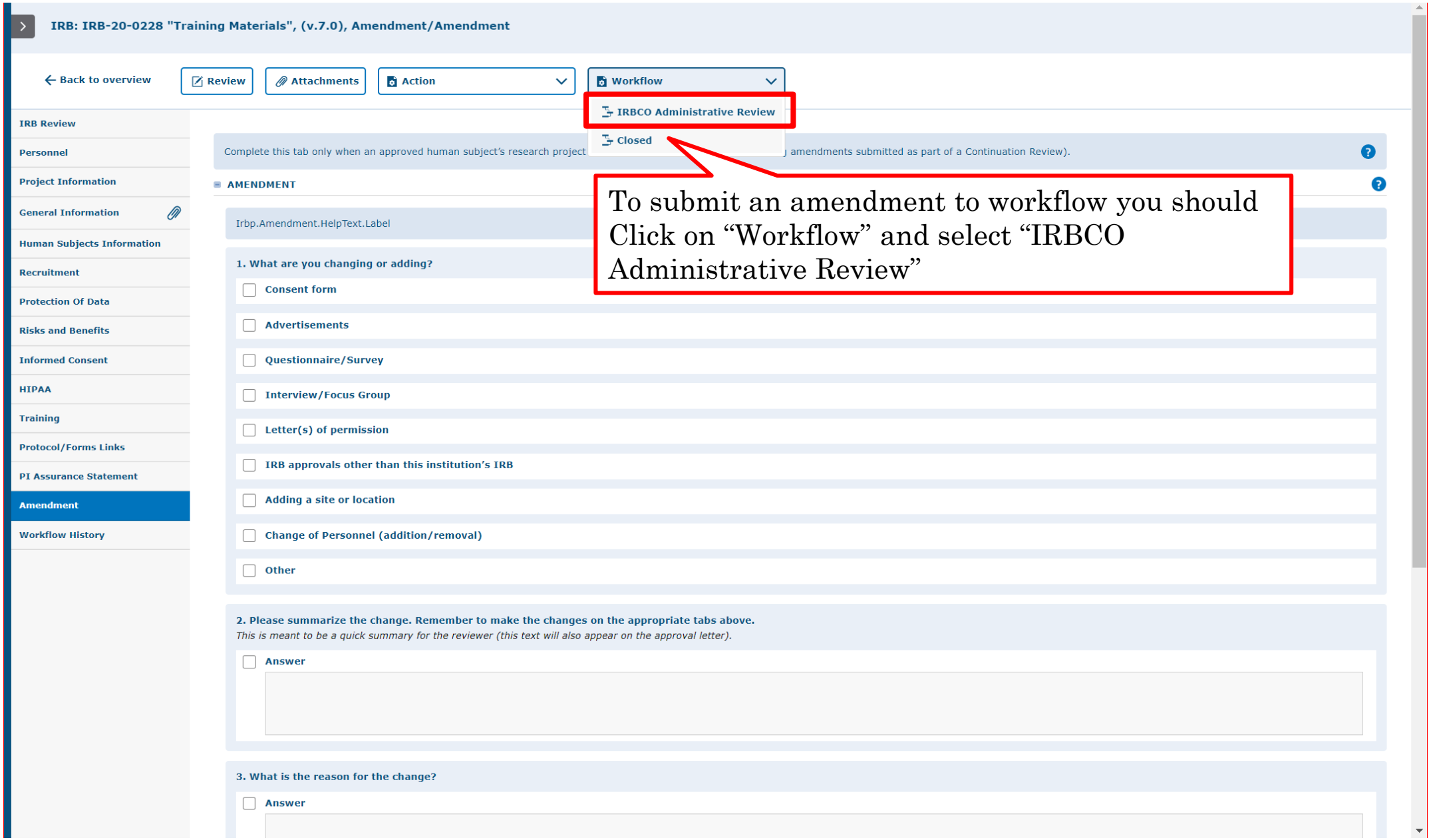


Save all changes. Remember you can save by clicking the "Action" button at any time.

- Once you have completed the questionnaire on the amendment tab and included the proposed changes on any other relevant tabs, please proceed to save your amendment.
- 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.
  2. Save: 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).

After you have saved your changes, you can submit the amendment. There are 2 ways to submit, shown on the following slides.

1st way to submit – within the application:



To submit an amendment to workflow you should Click on "Workflow" and select "IRBCO Administrative Review"

2nd way to submit – from the protocols page:

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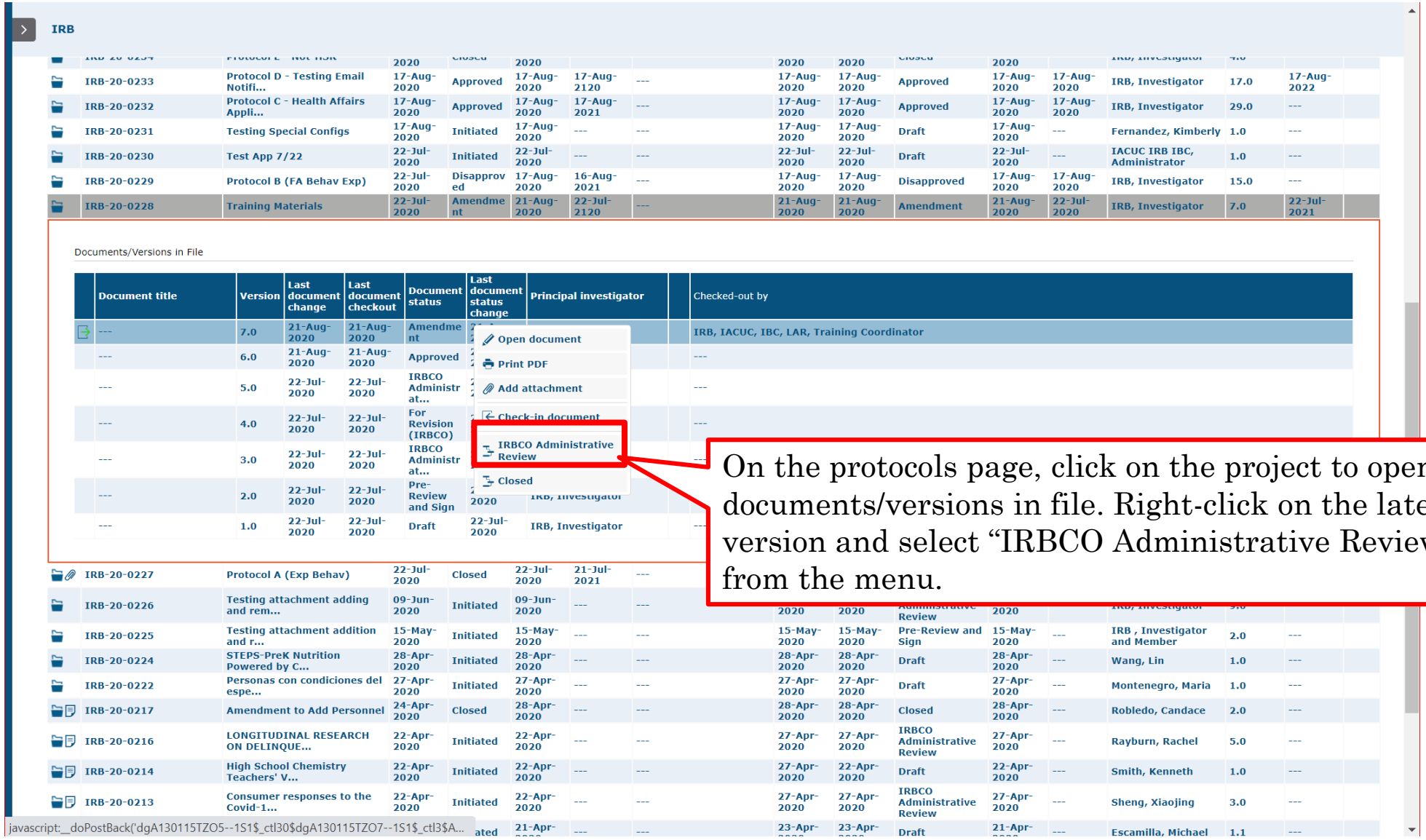
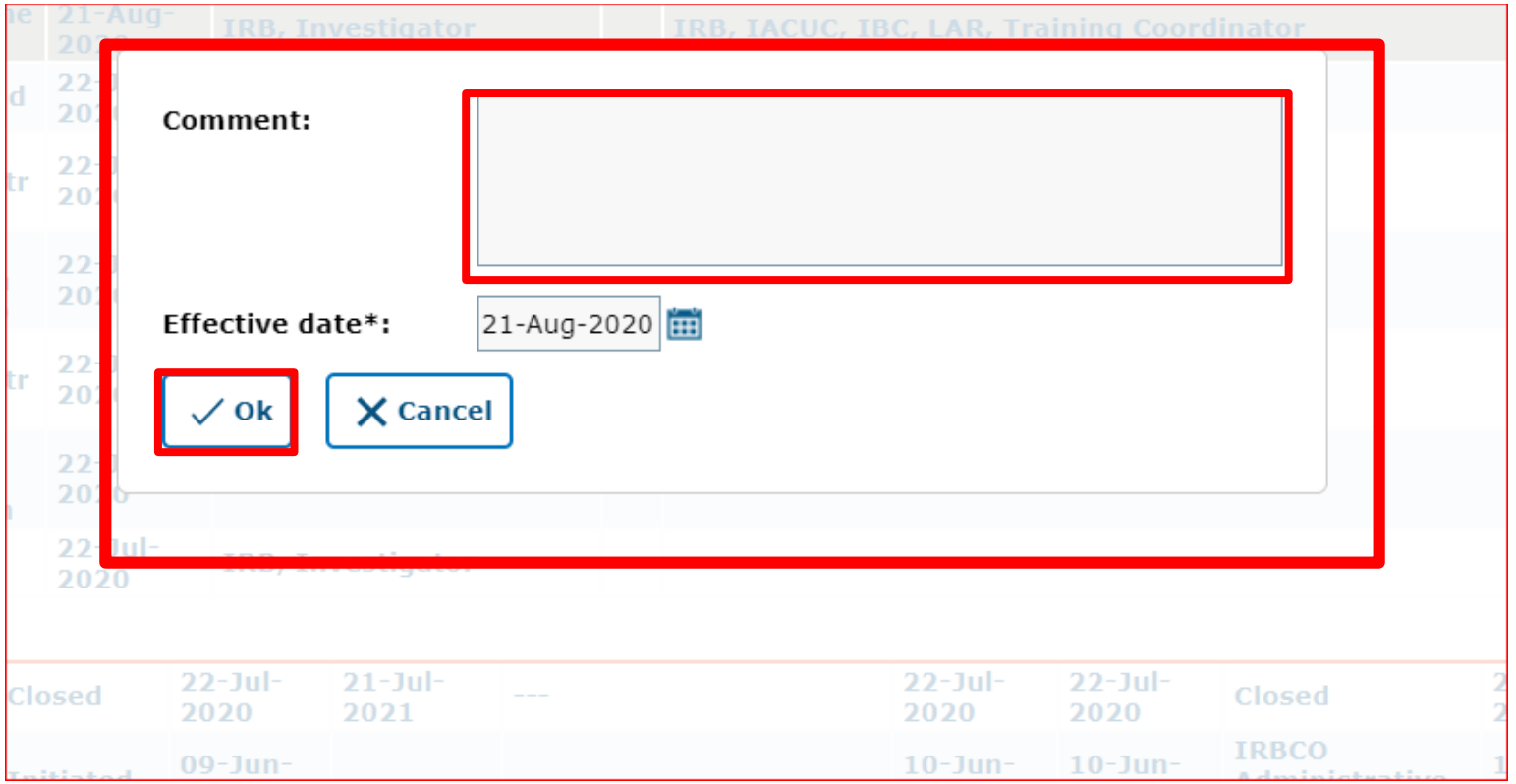
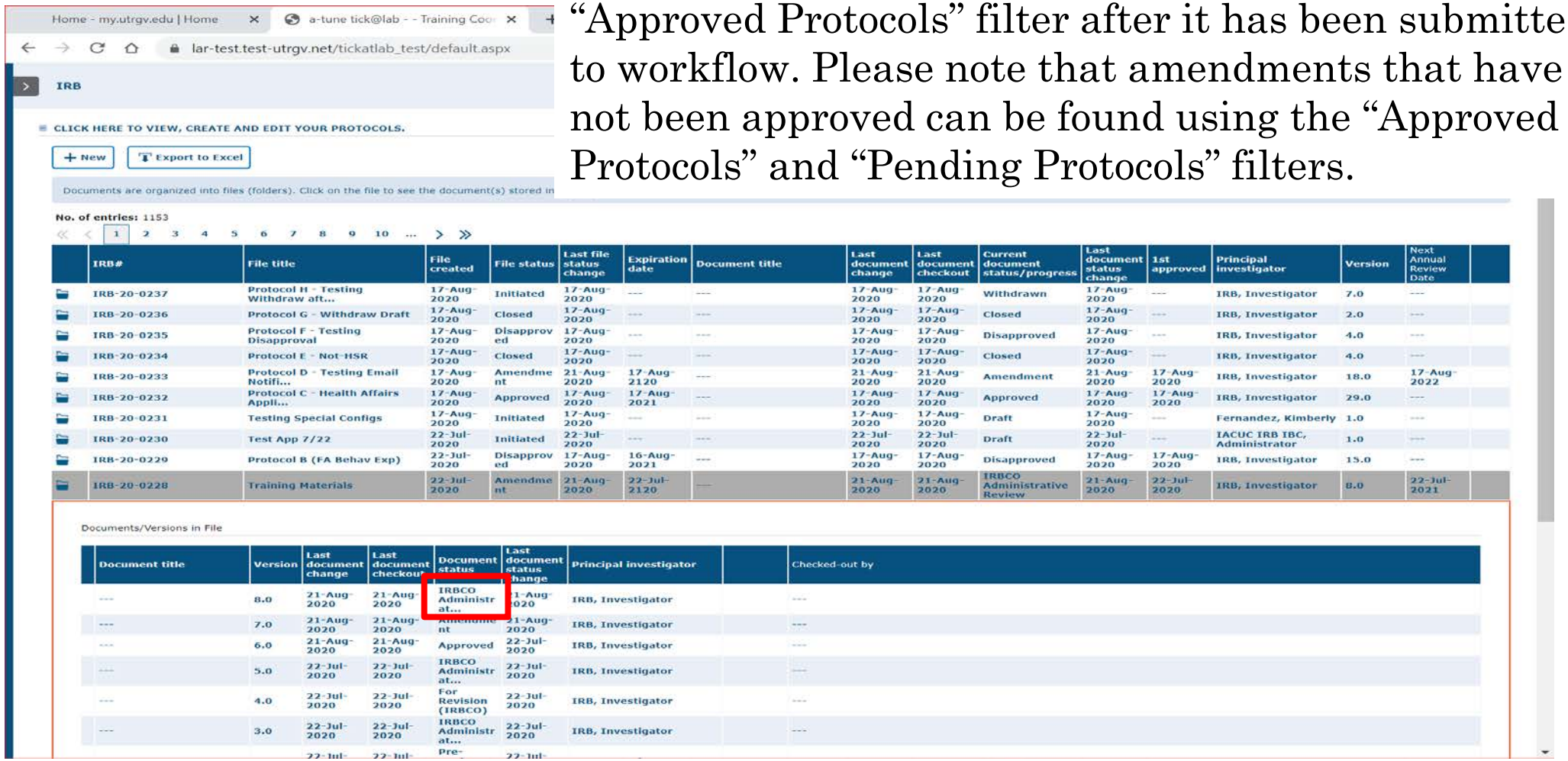


On the protocols page, click on the project to open the documents/versions in file. Right-click on the latest version and select "IRBCO Administrative Review" from the menu.



Please include a comment that briefly summarizes proposed changes (E.g., add personnel, modify recruitment or data collection procedures, etc.) and click “Ok.”

This is how your amendment will look like in your "Approved Protocols" filter after it has been submitted to workflow. Please note that amendments that have not been approved can be found using the "Approved Protocols" and "Pending Protocols" filters.



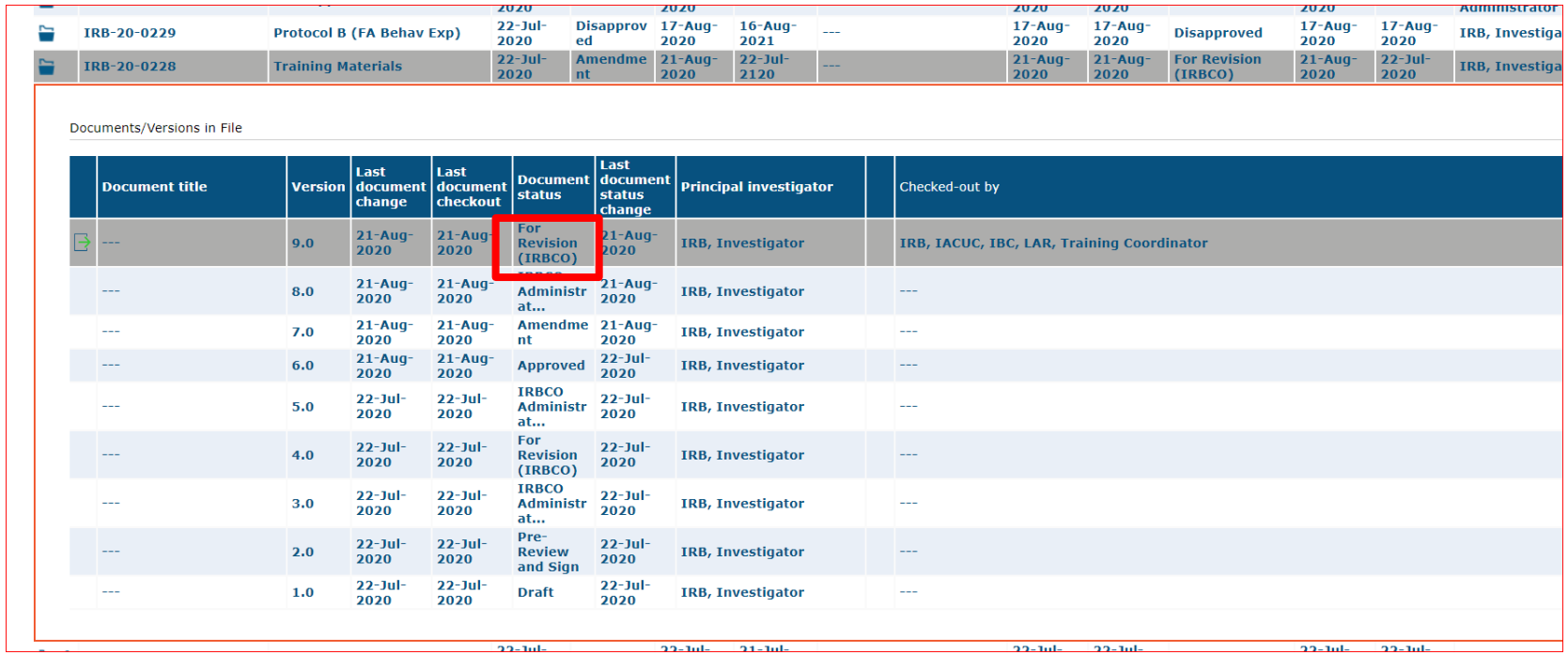
Your Amendment has been submitted to workflow for IRB Review

How to Revise a Submitted Amendment

Returned to you for Revision

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

- Approved by the IRBCO
- Referred to a Reviewer IRB Member for review
- Referred to the Full Board
- Returned to you For Revisions.



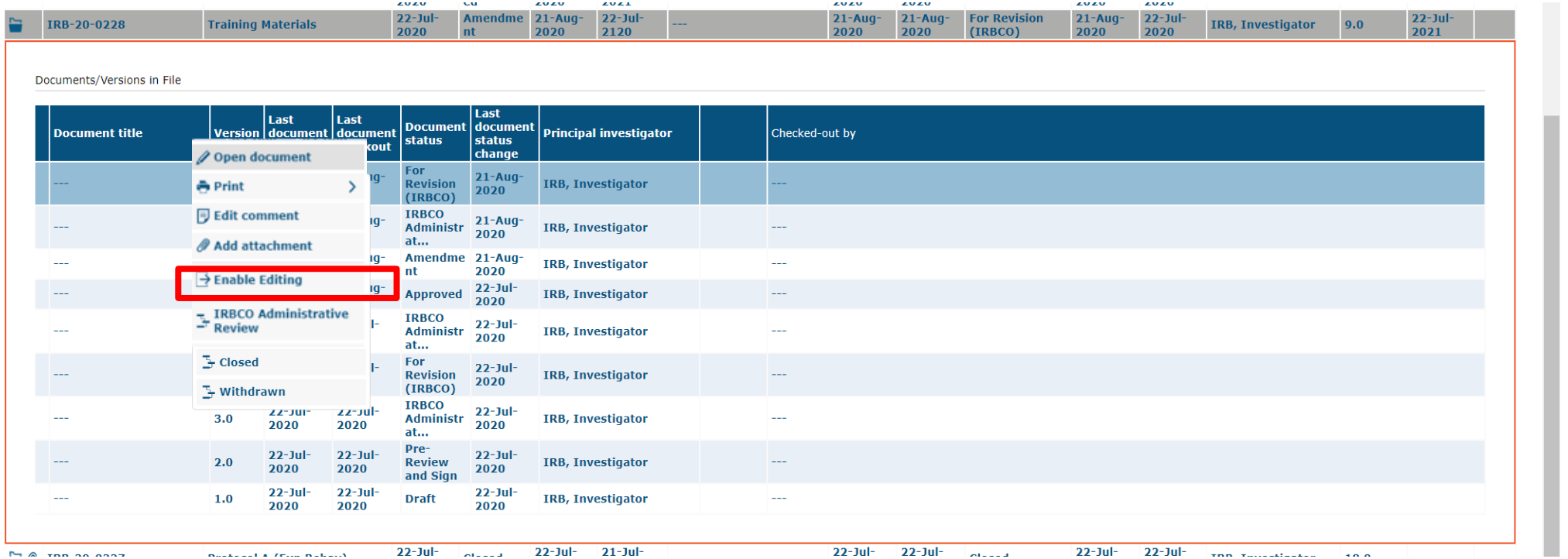
IRB-20-0229	Protocol B (FA Behav Exp)	22-Jul-2020	Disapproved	17-Aug-2020	16-Aug-2021	---	17-Aug-2020	17-Aug-2020	Disapproved	17-Aug-2020	17-Aug-2020	IRB, Investiga
IRB-20-0228	Training Materials	22-Jul-2020	Amendment	21-Aug-2020	22-Jul-2120	---	21-Aug-2020	21-Aug-2020	For Revision (IRBCO)	21-Aug-2020	22-Jul-2020	IRB, Investiga

Documents/Versions in File

	Document title	Version	Last document change	Last document checkout	Document status	Last document status change	Principal investigator		Checked-out by
	---	9.0	21-Aug-2020	21-Aug-2020	For Revision (IRBCO)	21-Aug-2020	IRB, Investigator		IRB, IACUC, IBC, LAR, Training Coordinator
	---	8.0	21-Aug-2020	21-Aug-2020	Administrat...	21-Aug-2020	IRB, Investigator		---
	---	7.0	21-Aug-2020	21-Aug-2020	Amendment	21-Aug-2020	IRB, Investigator		---
	---	6.0	21-Aug-2020	21-Aug-2020	Approved	22-Jul-2020	IRB, Investigator		---
	---	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		---

If your amendment application gets returned to you for revisions:

- You will get an email that Review comments need to be addressed and the amendment 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 of the document first. During the time of enable editing, no other person can edit your document.
- Right-click on the document and select “enable editing.”

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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		---

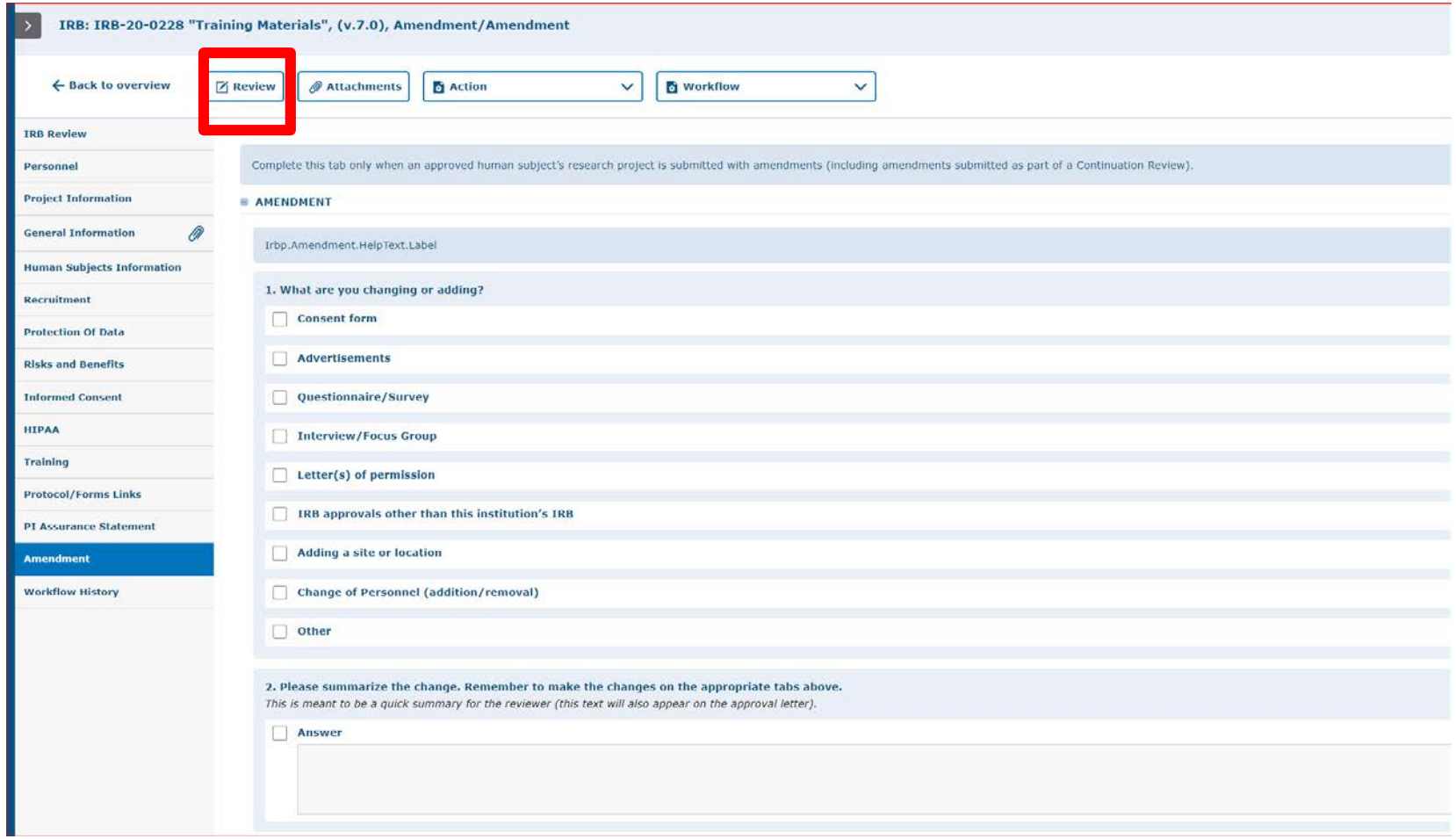
Enable Editing (read-only mode): Means someone is working on the document.

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

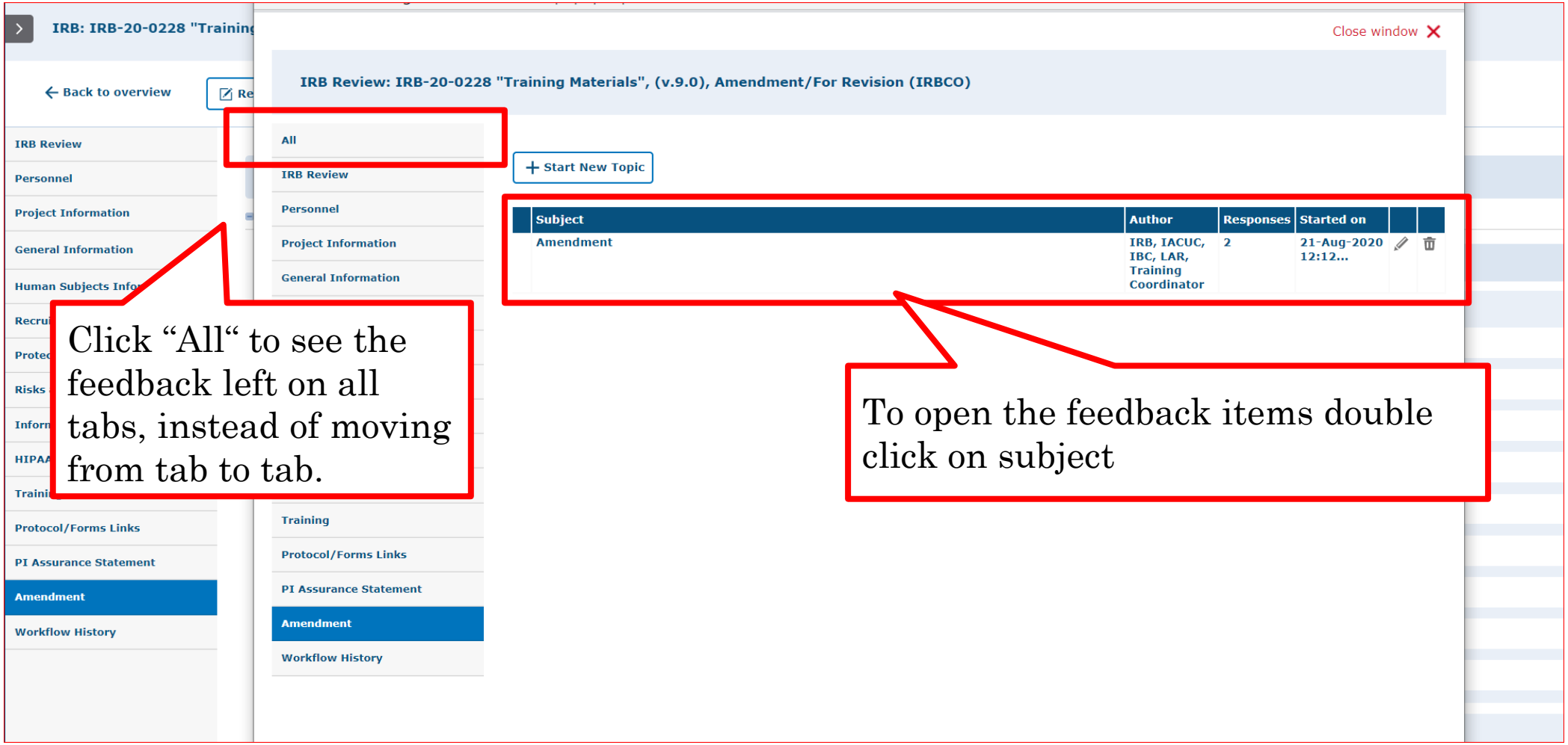
Documents/Versions in File

	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		---

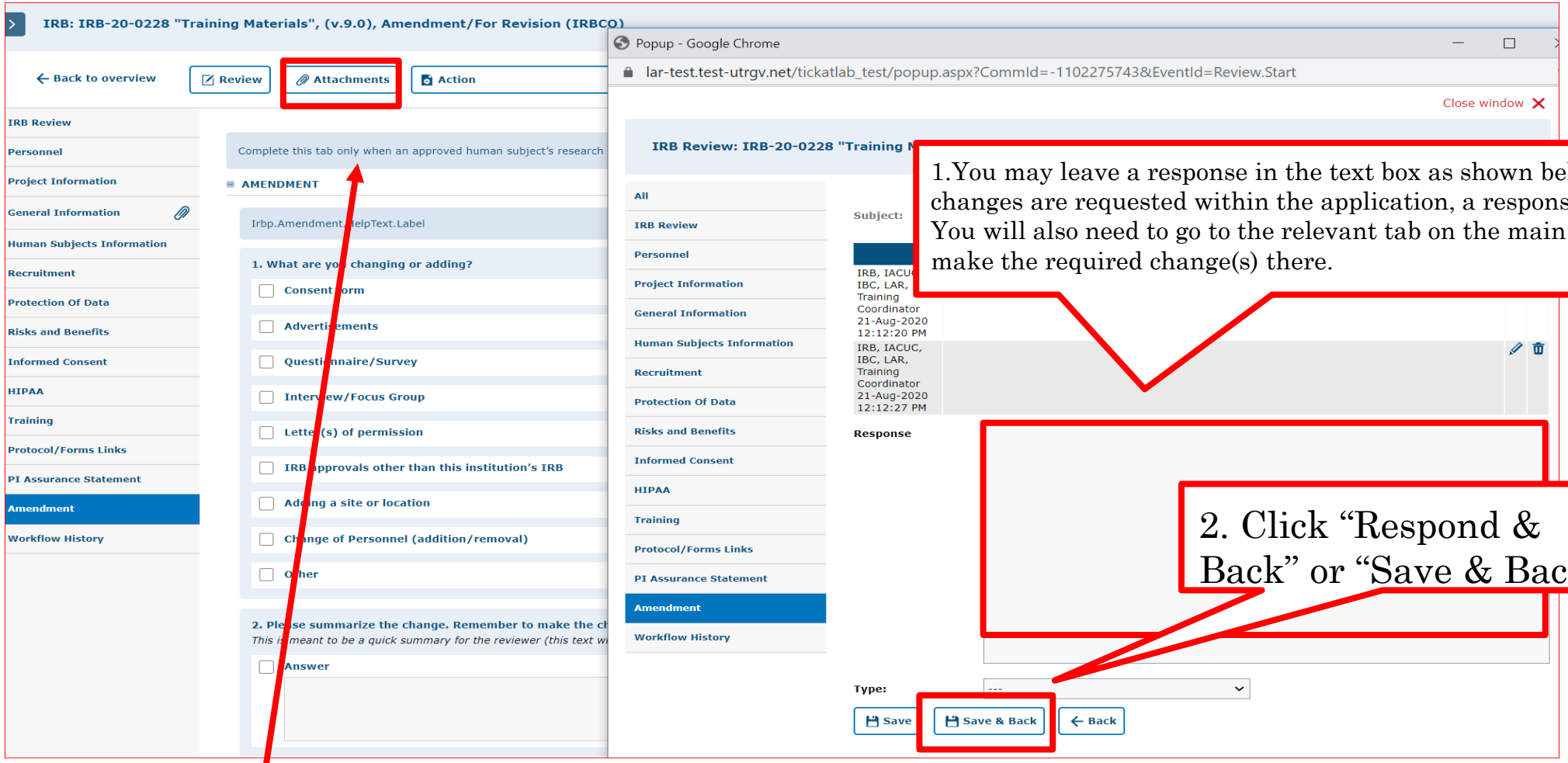
Once you have enable editingthe Amendment application, then you can navigate through all the revisions requested by using the Review button



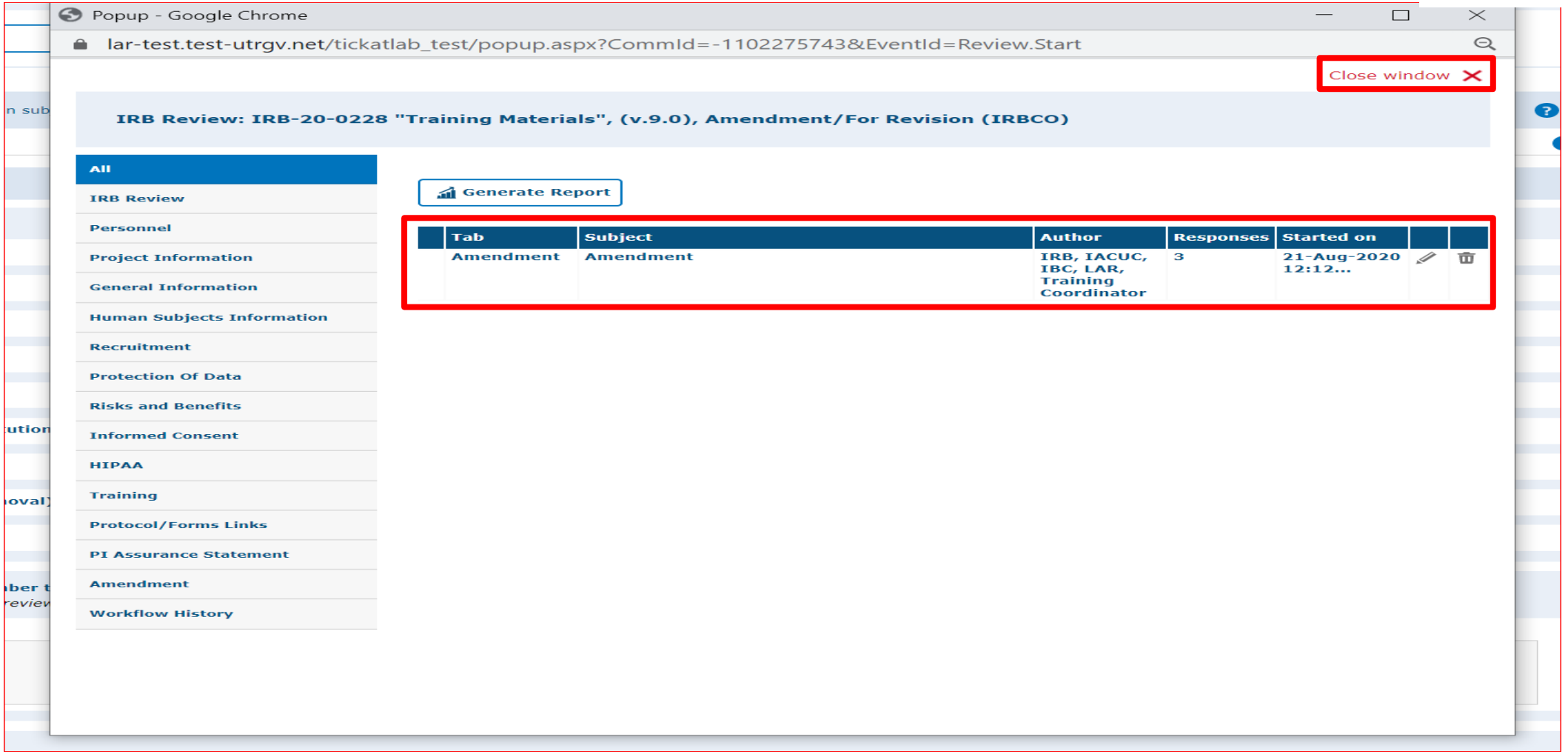
Click on the "Review" button to see all feedback from the reviewer.



- As illustrated in the red box above, you will find a list of items requested by reviewers for the amendment and you may see other comments throughout the protocol if applicable.
- Please click on each topic under the "Subject" column to view the comments.



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.



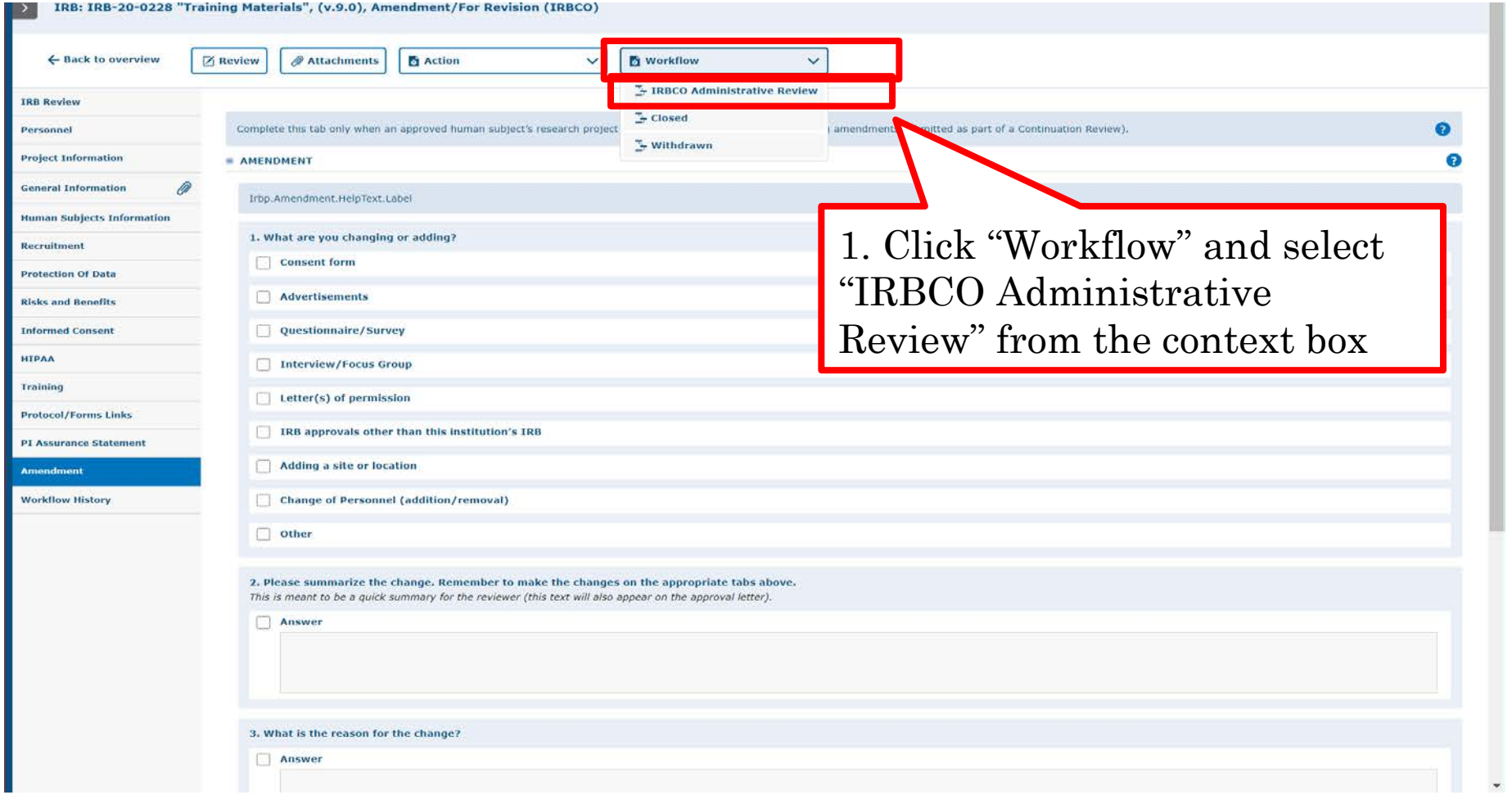
- After reviewing and addressing all items, click “close window”.
- Every time a researcher makes modification to a form a new version is activated in the system. The creation of versions allows the IRB Coordinator and Board Members to streamline the review by conducting automatic comparisons among versions.

Resubmitting an Amendment

Submitting back to Workflow, after making required revisions

You have two options to submit your Revised Amendment back to Workflow.

Option #1 - Within the Application:



Please use this box to communicate with the next Workflow user.

Option #2 - from the Protocols page:

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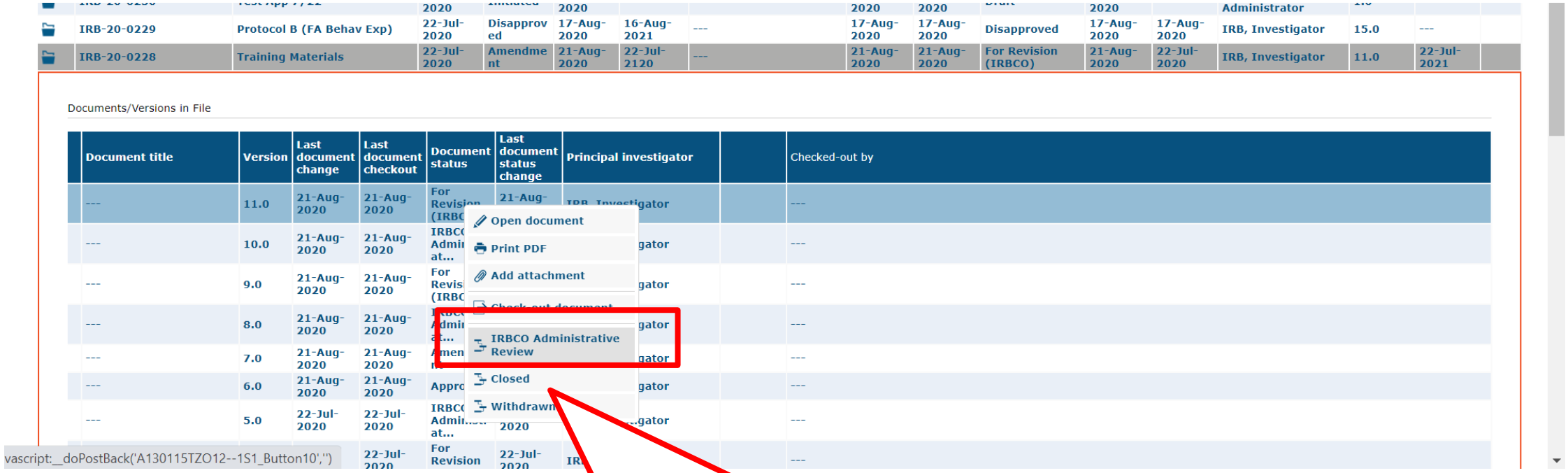
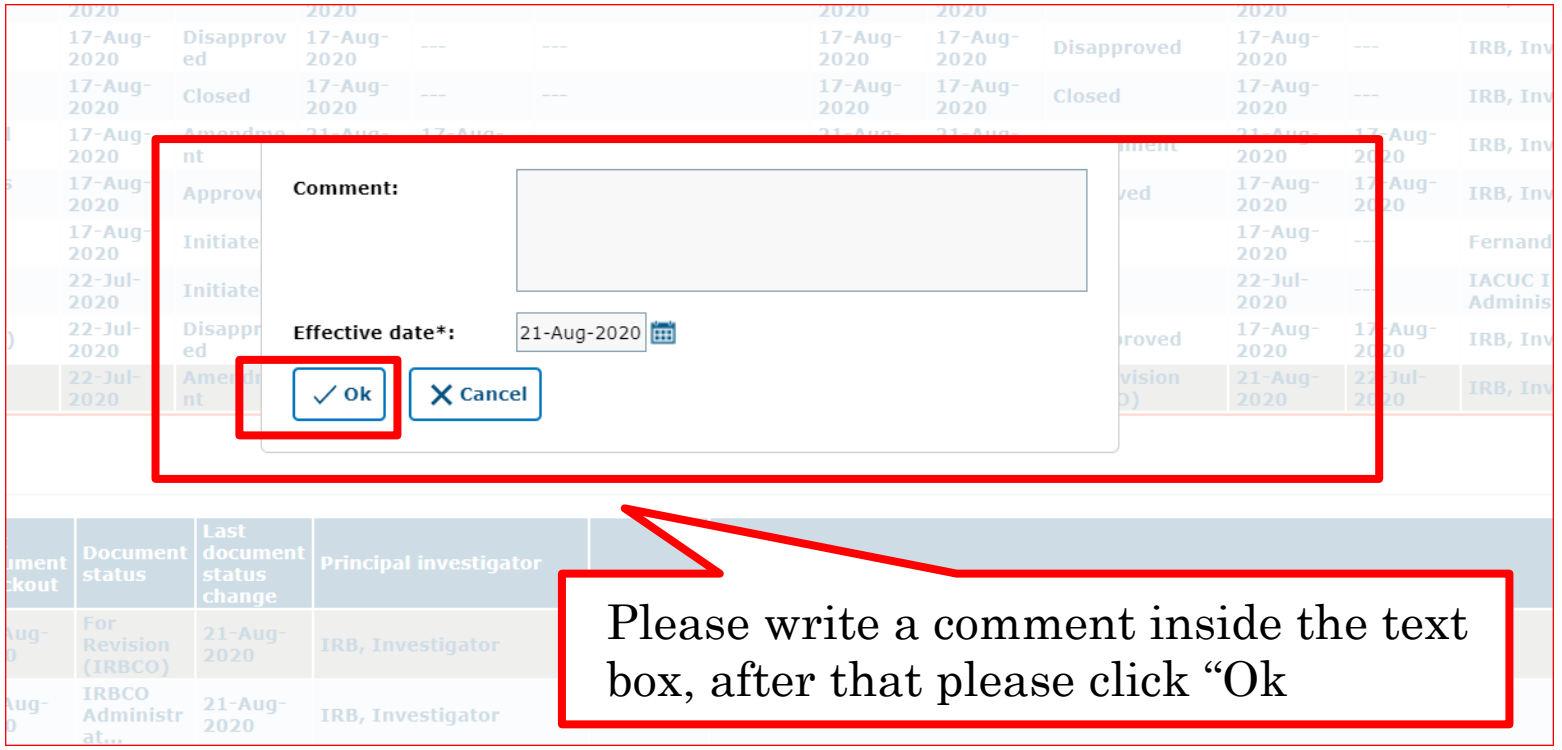
Open the amendment by clicking on the text in the gray row as shown below. This will open the document level shown below in the red box.

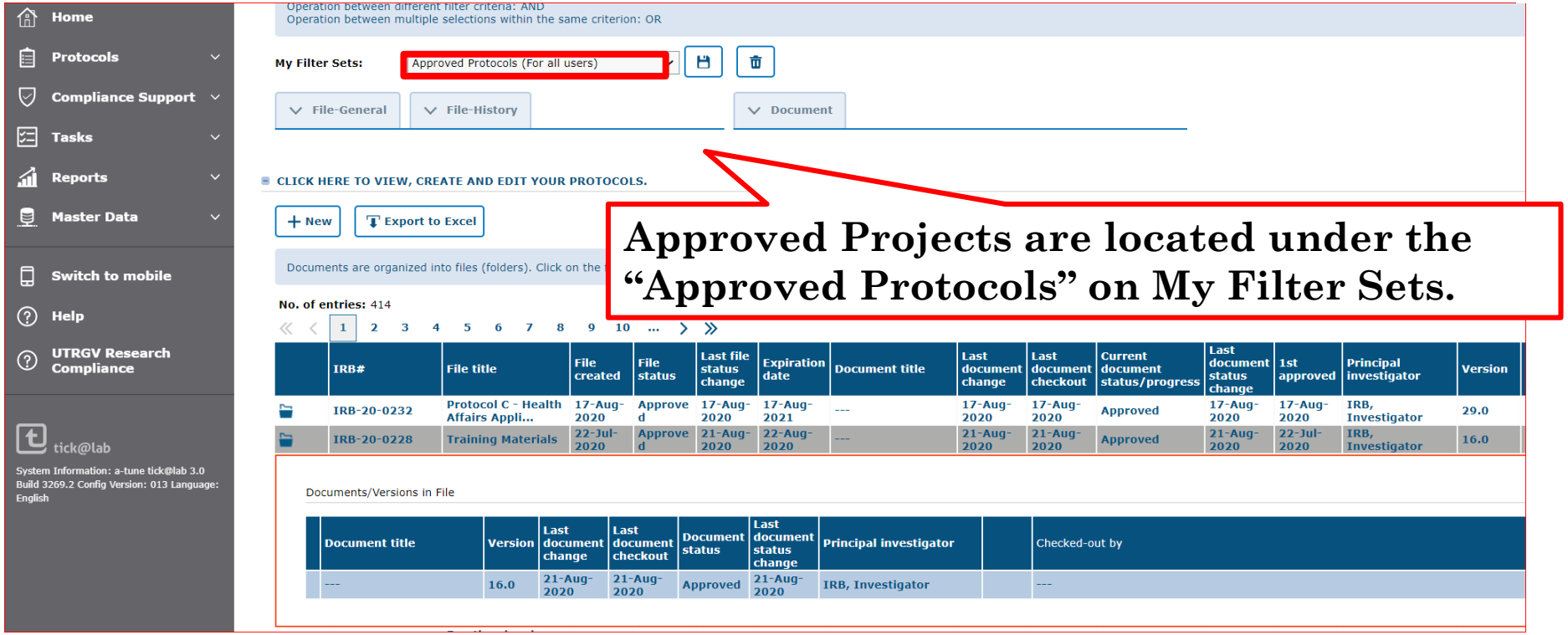


Right click on document and select “IRBCO Administrative Review”.



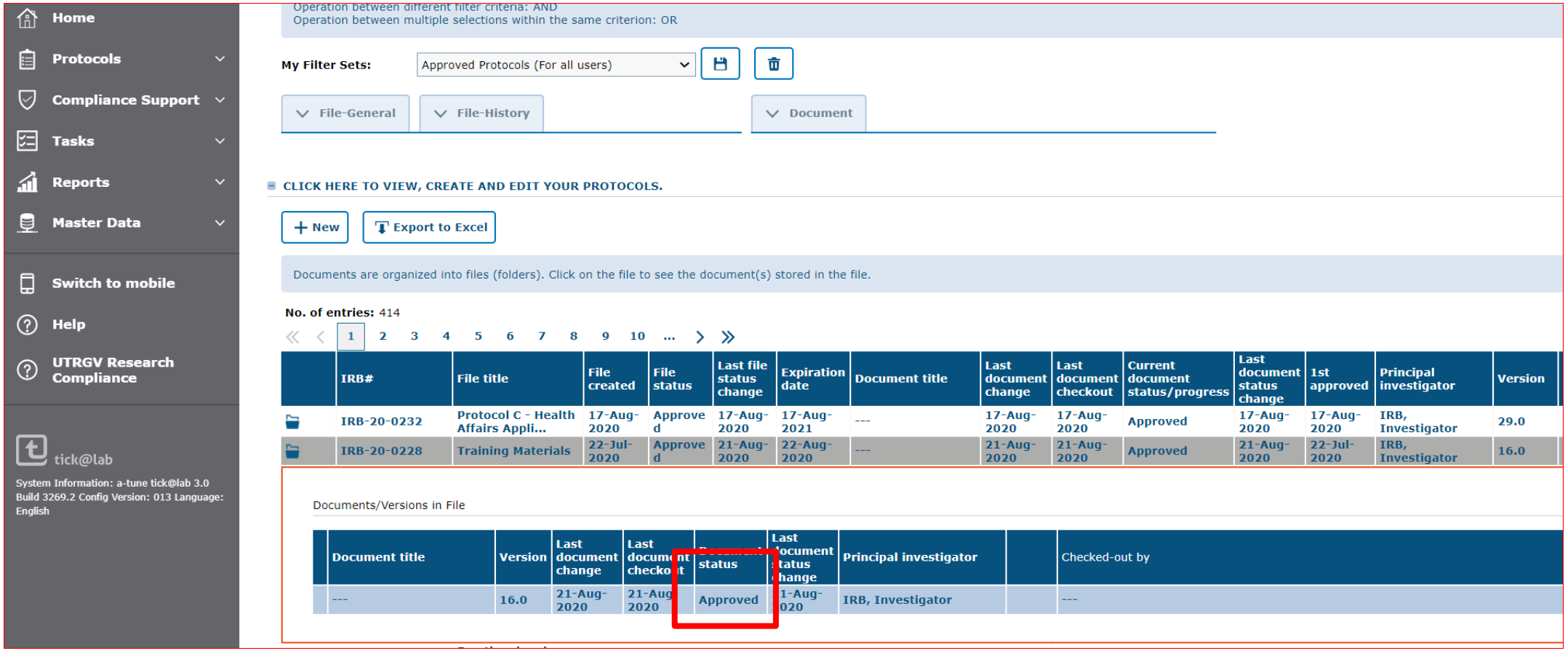
Please use this box to communicate with the next Workflow user

Once your revisions are completed and received, your submission will be revisited. It 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.



Once approved, you will receive an email notification and your amendment will disappear from the ‘Pending Protocols’ list.

This is how your approved amendment will look like on Tick@lab, Approved Protocols filter



*****Amendment has been APPROVED*****