

Step 1:

Open the protocol that requires an amendment. On the right side of your screen, there are two important menu items you will need: “Amend” and “Admin Notes & Files.” Start by selecting “Amend,” which also has a little pencil icon and is identified by the pink box in this image:

The screenshot displays the Quali Protocols interface. At the top, there are three tabs: PROTOCOL, ACTIVITY LOG, and ANCILLARY REVIEW. Below the tabs, there is a 'Jump to:' section with three items: Basic Information (checked), Study Personnel (checked), and Resuming In-Person R... (checked). The main content area is titled 'Version: 3 | Initial | Approved' and includes a 'Show Latest Changes' checkbox. The 'Protocol Information' section contains a table with the following data:

Review Type Expedited	Status Approved	Approval Date Mar 25, 2021	Continuing Review Date --
Expiration Date Jul 31, 2023	Initial Approval Date Mar 25, 2021	Initial Review Type Expedited	

Below the table is a 'Feedback' section with a yellow header. It contains an 'Approval Comment' box with the following text:

This Resumption Request is approved. The researchers are approved to move forward with in-person research interactions under the conditions outlined here, and in accordance with the provisions of the Sorenson Center's COVID reopening plans. Please note that some IRB-sanctioned activities do go above and beyond those outlined by the Sorenson Center, and the researchers are expected to follow both sets of plans. Your COVID Info sheets are both in the Admin Notes & Files here, as well as in your original protocol, for use.

On the right sidebar, the 'Amend' button (with a pencil icon) is highlighted in a pink box, and the 'Admin Notes & Files' button has a green notification badge with the number 3.

Step 2:

A new section will appear in your protocol, titled “Amendment.” Review the instructions; they contain information critical to the amendment process. Two items that are often missed that will result in an amendment being denied without further review are:

- 1) The *actual fields within the protocol must be amended*. It is not sufficient to describe your amendment at the top and submit; you must make the changes you are requesting to all fields where the change is relevant.
- 2) If your informed consent documentation requires an update, you *must use the approved versions located in Admin Notes & Files* to request those changes. Using an unapproved version to request changes will result in automatic denial of the amendment.

Once you have described your amendment in the new Amendment section, continue scrolling down to access your approved protocol. All of the fields will be open and editable. Make all of the edits necessary. Please review your protocol for consistency.

Step 3:

If your proposed amendment requires any edits to your informed consent documentation, you must upload a tracked changes version in your Informed Consent uploads. Access your approved documentation in Admin Notes & Files:

The screenshot shows the 'PROTOCOL' management interface. At the top, there are tabs for 'PROTOCOL', 'ACTIVITY LOG', and 'ANCILLARY REVIEW'. Below the tabs, there's a 'Jump to:' section with links for 'Basic Information', 'Study Personnel', and 'Resuming In-Person R...'. The main content area is titled 'Version: 3 | Initial | Approved' and includes a 'Show Latest Changes' checkbox. The 'Protocol Information' section contains a table with the following data:

Review Type	Status	Approval Date	Continuing Review Date
Expedited	Approved	Mar 25, 2021	--

Expiration Date	Initial Approval Date	Initial Review Type
Jul 31, 2023	Mar 25, 2021	Expedited

Below this is a 'Feedback' section with a yellow header and an 'Approval Comment' field. The comment reads: 'This Resumption Request is approved. The researchers are approved to move forward with in-person research interactions under the conditions outlined here, and in accordance with the provisions of the Sorenson Center's COVID reopening plans. Please note that some IRB-sanctioned activities do go above and beyond those outlined by the Sorenson Center, and the researchers are expected to follow both sets of plans. Your COVID Info sheets are both in the Admin Notes & Files here, as well as in your original protocol, for use.'

On the right side, there is a sidebar with various actions: Amend, Renew, Admin Notes & Files (highlighted with a pink box and a '3' badge), Review Assignments, Approval Update, Suspend, Close, Request Close, and Print. A pink arrow points to the 'Admin Notes & Files' option.

The 'Admin Notes & Files' section is shown below the protocol information. It includes a 'Show Archived' button and a '+ Add' button. The main content is a table with the following columns: File, Note, Date Added, Added By, and Actions.

File	Note	Date Added	Added By	Actions
11716 Picardi LOI Final.pdf	This PDF version of your informed consent documentation is intended for use with your participants (the version made available for download). Good luck with your project!	Jan 14, 2021 4:57 PM	Broadstone, Sasha	Edit Archive
11716 Picardi LOI Approved.docx	This Word version of your informed consent documentation is intended to be a formal record of the IRB's approved version of your document. It is locked for tracked changes, which will allow you to later submit amendments to this protocol while allowing our office to track your requests. If you file an amendment to this protocol that requires changes to your informed consent documentation, please use the Word version provided here to request your changes. Upload the new version as an amendment to your informed consent documentation field.	Jan 14, 2021 4:57 PM	Broadstone, Sasha	Edit Archive

A pink arrow points to the '11716 Picardi LOI Approved.docx' file, which is also highlighted with a pink box.

Use that document (which you should already be using!) to make the required changes, and upload it directly into your protocol, in the *Informed Consent* section.

Then, submit your amendment!