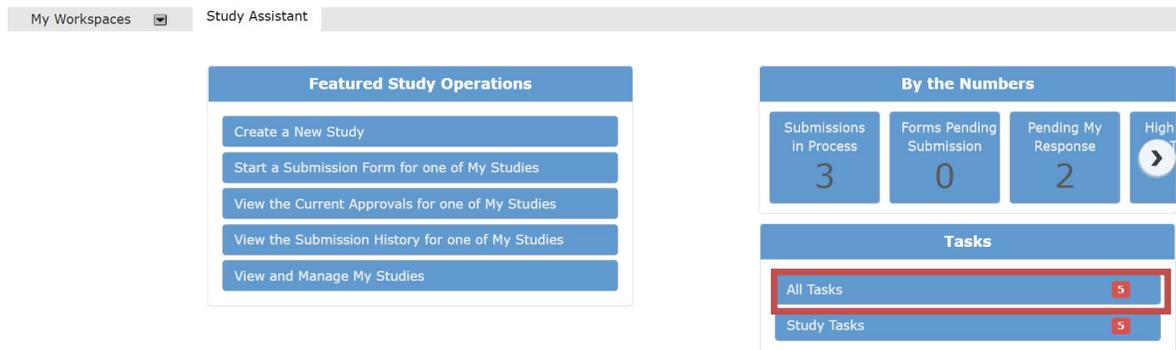


User Guide: *How to Respond to a Study Signoff Denial*

| | |
|--------------------------|--|
| Last Update | November 7th, 2022 |
| Intended Audience | Principal Investigator/Researcher |
| Purpose | To provide the user with step-by-step instructions on how to respond to a study signoff denial. |

Follow the steps below to respond to a study denial and resubmit the denied application:

- STEP 1.** Close all open web browsers.
- STEP 2.** Open a new browser and go to: <https://carilionclinic.imedris.net/>
- STEP 3.** Login using your Carilion ID and password.
- STEP 4.** Ensure you are in the Study Assistant dashboard by hovering the pointer over “My Workspaces” on the left of the page and clicking on “Study Assistant” if necessary.
- STEP 5.** Click on the button under Task: “**View All Tasks**”.



- **STEP 6.** Find the Task Type "Submission Signoff Denied" and click the pencil and paper icon under "Click to Open".

The screenshot shows a dashboard with tabs for 'All Tasks' and 'Study Tasks'. The 'Outstanding' tab is selected. A dropdown menu shows 'Task List: Submission Signoff Denied' and 'Filter By: --none--'. Below, a table lists one task:

| Click to open | Task Type | Date Received | Description | Priority | Complete By |
|---------------|---------------------------|----------------------------|---------------------|-------------|----------------------|
| | Submission Signoff Denied | 11/04/2022 11:07:28 AM EDT | Submission rejected | No Priority | <input type="text"/> |

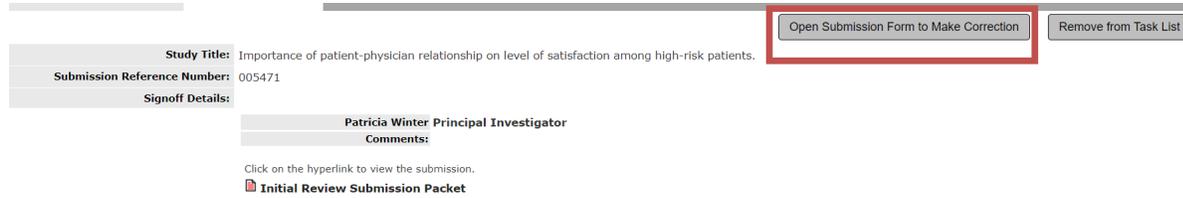
STEP 7. Check the comments to determine why the signoff was denied or contact the PI for more information about why the signoff was denied and decide whether you will proceed with revising the application for re-review.

The screenshot shows submission details for 'Importance of patient-physician relationship on level of satisfaction among high-risk patients.' (Submission Reference Number: 005471). The Principal Investigator is Patricia Winter. A red box highlights the 'Comments' section, with a red arrow pointing to it from a text box that says 'Check here for comments'. Buttons for 'Open Submission Form to Make Correction' and 'Remove from Task List' are visible at the top right.

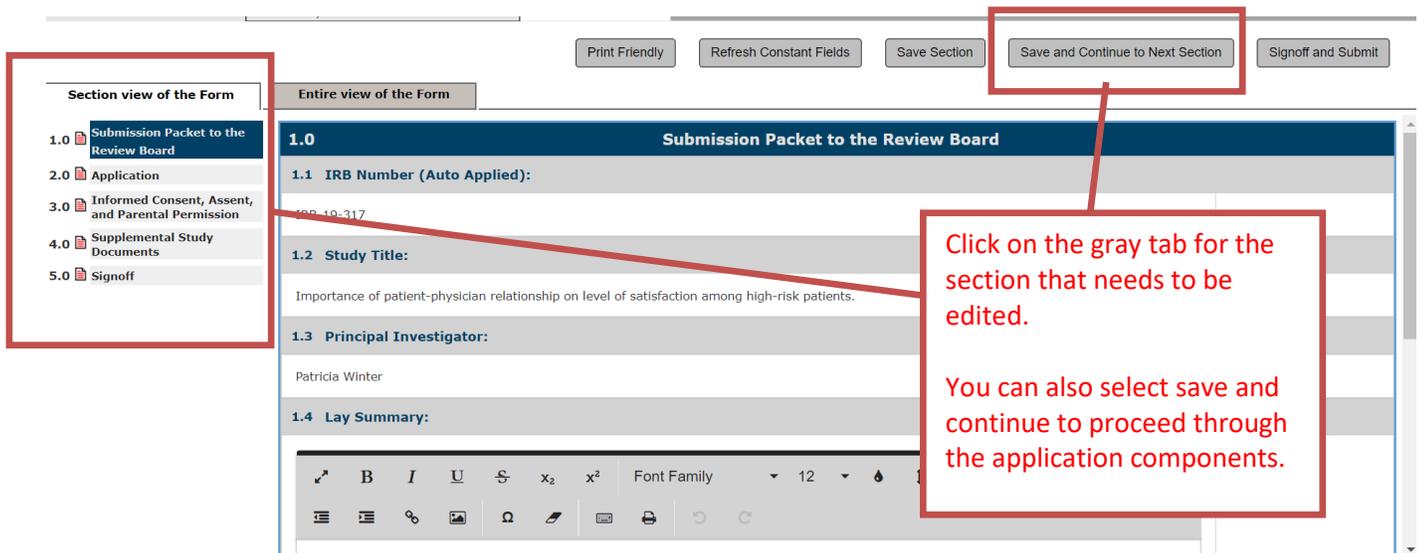
If you will be proceeding with the revision and resubmission, go to **Step 8**.
 If you will not be proceeding with revising the application for resubmission, click "Remove from Task List". You can then delete the study from your dashboard.
 You have completed the actions for this denial.

This is a duplicate of the submission details screenshot above. A red box highlights the 'Remove from Task List' button at the top right.

STEP 8. In order to revise application and respond to the reason for the denial, click the "**Open Submission Form to Make Correction**" button on the top right of the page.



STEP 9. Navigate to the component of the application that needs revision. For example, if it is the IRB Application that needs revision, click the **gray tab** on the left for Section 2.0 Application.



To revise IRB Application:

- You must make a revision of the application by clicking the icon under **Revise/Attach**.
- The system will give you a prompt stating a new revision will be created. Select "**OK**".
- You will then make your edits to the new version. Make changes to the application as necessary, then proceed through the ENTIRE application by clicking **Save and Continue to Next Section**. It is necessary to proceed through the entire application from start to finish, as your responses may change the sections or questions required.
- Ensure you have completed the application then save the new version. You should note the new version number in the application title.

Section view of the Form

- 1.0 Submission Packet to the Review Board
- 2.0 **Application**
- 3.0 Informed Consent, Assent, and Parental Permission
- 4.0 Supplemental Study Documents
- 5.0 Signoff

Entire view of the Form

2.0 Application

2.1 * Attach / Review your completed application for this study:

| Deattach | Revise/ Attach | Edit/ View | Title |
|----------|----------------|------------|--|
| (X) | | | Carillon IRB Application (Version 1.0) |

To revise Informed Consent, Assent, Parental Permission:

- Navigate to the Gray tab on the left for section 3.0.
- To attach a new Consent, Assent, or Parental Permission, click **“Add a New Consent”**.
- To revise an already attached document, click **“Select or Revise Existing”**
- Select the document you wish to revise by clicking on the icon under **“Create Revision”** for that document.
- Click **“Check-out Document”** and the document will open on your computer. You may have to choose “enable editing.”
- You will then make your revisions. Once you have made your revisions be sure to save them on your computer, then you can select **“Check-in Document.”**
- A pop up window will appear that will allow you to upload the revised document from your desktop and Save the Selected Document.
- Upload the revised document and click **“Save Consent”**, and you can also update the version document of the new document.
- Once complete and verified that the correct version is uploaded, click “Save and Continue to Next Section.”

Section view of the Form

- 1.0 Submission Packet to the Review Board
- 2.0 Application
- 3.0 **Informed Consent, Assent, and Parental Permission**
- 4.0 Supplemental Study Documents
- 5.0 Signoff

Entire view of the Form

3.0 Informed Consent, Assent, and Parental Permission

3.1 * Attach the Inform Consent Document(s), including Parental Permission and Assent, for this study:

| Detach | Version | Title | Category | Language | Expiration Date | Consent Outcome | Checked Out | View Document |
|--------|---------|---|----------|----------|-----------------|-----------------|-------------|---------------|
| (X) | 1.1 | Research Subject Information Sheet_Patient-Doctor Relationships | | English | | | | 20.87 KB |

Select Existing or Create Revised Study Consent

Select Category: --none--
 Version #:
 Version Date: between
 Consent Outcome: --none--

Title:
 Search level: Top All
 Expiration Date: between

Add a New Consent Filter Documents

1 result(s) found...

| Select | Show all Versions | Edit | Delete | Version | Version Date | Title | Language | Expiration Date | Consent Outcome | Checked Out By | View Document | Create Revision |
|--------|-------------------|------|--------|---------|--------------|---|----------|-----------------|-----------------|----------------|---------------|-----------------|
| | | | | 1.1 | 04/01/2019 | Research Subject Information Sheet_Patient-Doctor Relationships | English | | | | 20.87 KB | |
| | | | | 1.0 | 04/01/2019 | Research Subject Information Sheet_Patient-Doctor Relationships | English | | | | 24.10 KB | |

Be sure to revise the correct version of any forms or documents in the system.

Study Consent Revision

*Consent Title:

*Version Number: .

*Version Date:

Category: --none--

* Language: English

Description:

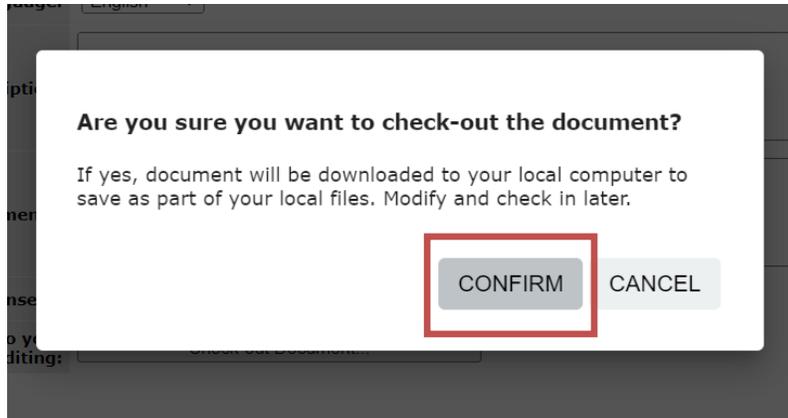
Comments:

Download Consent:

Check-out the Document to your workstation for editing:

View Document

Close, don't save any changes Save Consent



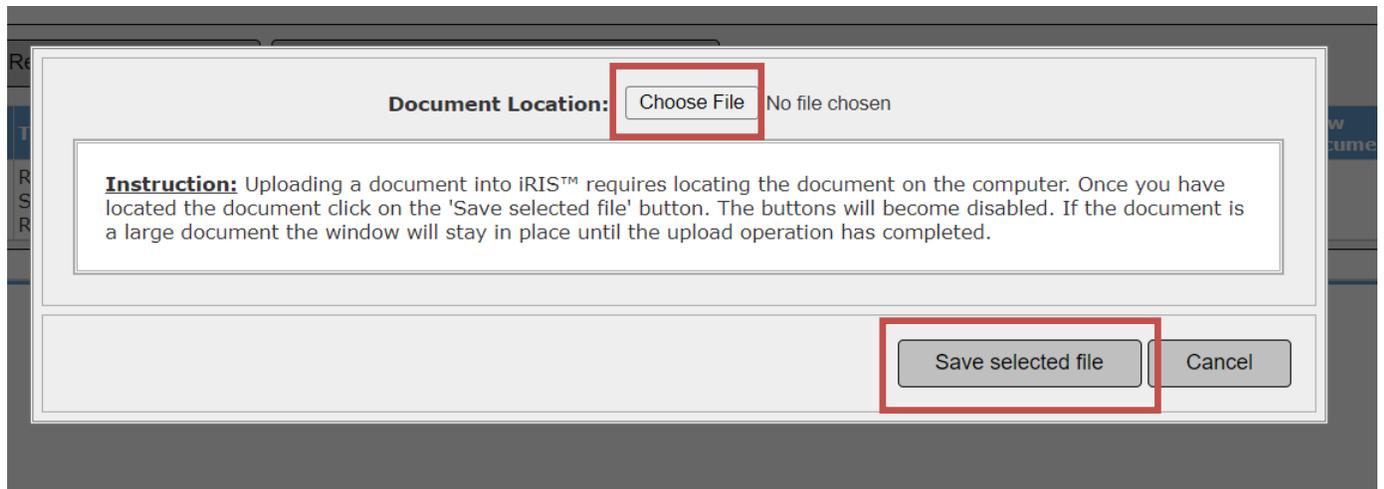
Study Consent Revision

| | |
|--|---|
| *Consent Title: | Research Subject Information Sheet_Patient-Doctor Relationships |
| *Version Number: | 1 .2 |
| *Version Date: | 04/01/2019 |
| Category: | --none-- |
| * Language: | English |
| Description: | <input type="text"/> |
| Comments: | <input type="text"/> |
| Download Consent: | Download |
| This document is currently checked out by.. | Patricia Winter at 11/04/2022 01:48:02 PM |
| Check-in when you are done editing upload the document back into IRIS. | <input type="button" value="Check-in Document..."/> |
| Revert to the document stored in IRIS. | <input type="button" value="Undo Check-out Document..."/> |

View Document

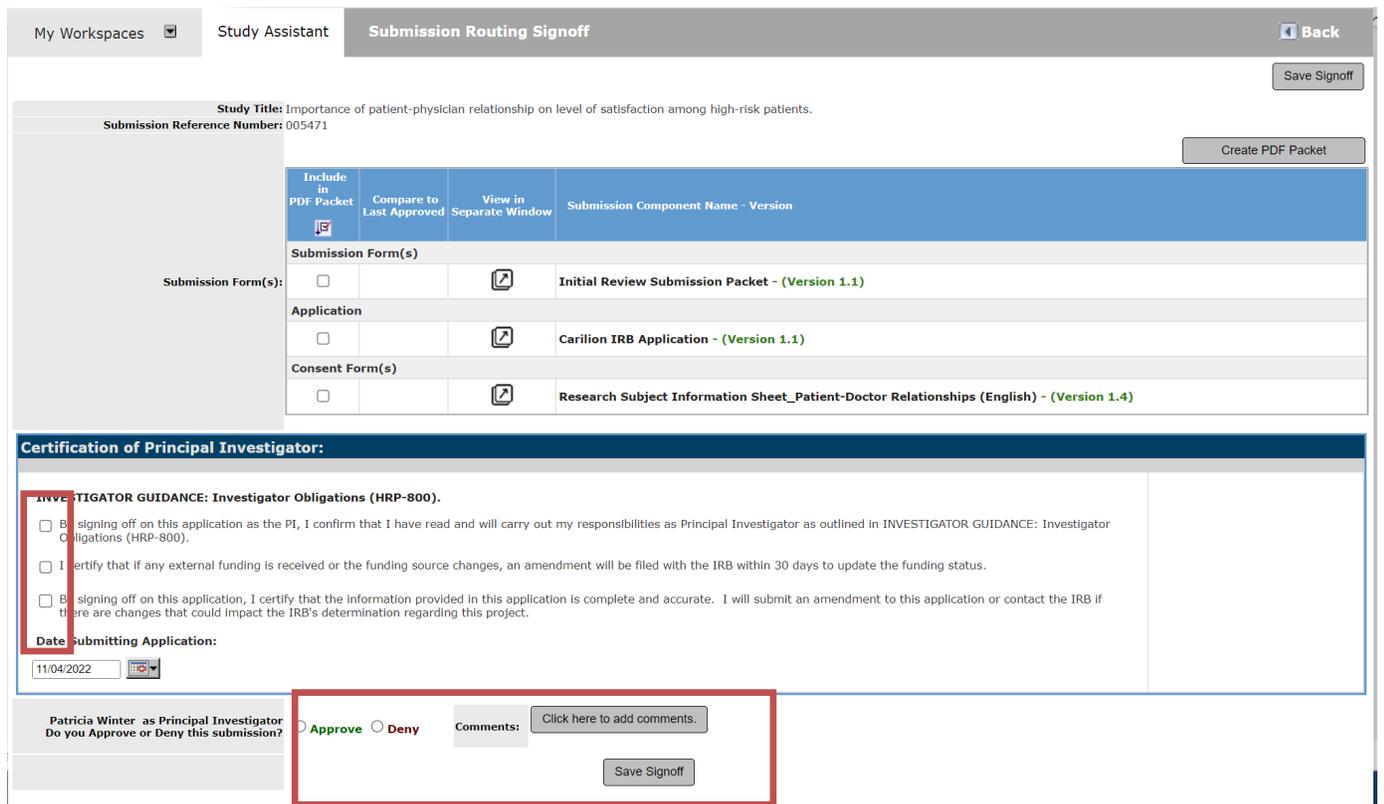
Can review document to make sure it's accurate. And update title and version date.

Close, don't save any changes



To revise Supplemental Study documents, follow same steps as described for the Consent documents above.

STEP 10. Once all revisions have been made, complete the PI signoff for the application and route the application to the PI for signoff.



- If your signoff is accepted, you will be taken to your main Tasks menu where you can track the routing of the submission. The application has now been routed to the Department signoff.
- If you have questions, please email the IRB at irb@carilionclinic.org.

NOTE: If the study is not ready for PI signoff, you can always proceed back to continue with the revisions from the main study dashboard by clicking the **Initial Review Submission Packet** link, then following the steps above.

The screenshot shows a dashboard with a search bar and filters. Below the filters, there are 4 results found. The table below shows the details of the first result.

| Click to open Study Dashboard | Study Status | Review Board | Project Number RB Number | RB Expiration | Study Title Study Alias | Principal Investigator | Actions |
|-------------------------------|--|---------------------|-----------------------------|---------------|--|------------------------|--|
| | Pending - Submitted for Initial Review | Carilion Clinic IRB | IRB-19-317 | | Importance of patient-physician relationship on level of satisfaction among hig... Patient-Physician Relationship & Level of Satisfaction | Winter, Patricia | Applications Documents Forms Hide Exempt Copy Delete Correspond |

Click here to return to the study dashboard to review the submission history and to track your study through the process.

| | | |
|---|--------------------------------|--|
| Study Status: Pending - Submitted for Initial Review | IRB Number : IRB-19-317 | Study Title : Importance of patient-physician relationship on level of satisfaction among high-risk patients. |
|---|--------------------------------|--|

Protocol Items

- Study Application
- Informed Consents ▶
- Other Study Documents ▶

Post-Approval Forms

- Annual Check-In Form (for Minimal Risk studies approved with Annual Check-In after 1/20/19)
- Carilion Clinic - Conclusion Form
- Carilion Clinic - Continuing Review Form
- Carilion Clinic - Promptly Reportable Information Form
- Carilion Clinic - Research Change / Update Form

Initial

- Initial Review Submission Packet

| Submissions History | | | |
|---|------------|---|--------------------|
| Study Correspondence | | | |
| Outstanding Submission(s) | | | |
| Track | Ref number | Request Type | Process Submission |
|  | 05471 | Click on the hyperlink to edit/view the submission. Initial Review Submission Packet | Retract Submission |

You can retract the submission up to the time the IRB is reviewing the application.