

NAVIGATING IRB MENTOR: POST-APPROVAL REPORTING

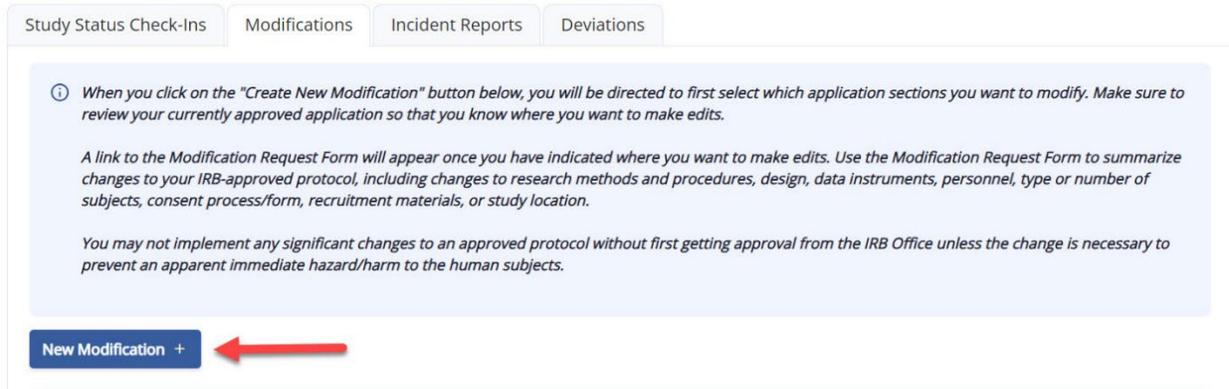
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All post-approval activities related to your approved protocol are completed under the relevant tab at the bottom of the protocol information page.

Modifications

Navigate to the Modifications tab at the bottom of the protocol information page for the study. Click on the New Modification button. Your ability to create new modifications will be locked until your current modification is approved or withdrawn.



Select the sections of the original protocol application that you want to revise in the subsequent pop-up window and click on the Create Modification button. The modification process only displays the specific sections of the application you wish to edit. After the modification is approved, those edits will get copied to the Approved Application Sections file type under the files section of the protocol information page. This is where you can download the most current iteration of your full protocol.

Protocol Title The Long Term Effects of Warp Drive...

Select Application Sections you wish to revise

- STUDY PERSONNEL
- STUDY TIMING AND FUNDING
- OTHER INSTITUTIONS
- STUDY LOCATION
- STUDY DESIGN
- SUBJECT POPULATION
- RECRUITMENT
- CONSENT
- ASSENT
- STUDY PROCEDURES
- DATA INSTRUMENTS AND RECORDING DEVICES
- MEDICAL DEVICES
- SUBJECT IDENTIFIERS
- DATA MANAGEMENT PLAN
- RISKS AND BENEFITS
- FINANCIAL CONFLICTS OF INTEREST
- OTHER STUDY ATTACHMENTS

Create Modification

Cancel

Complete the following steps to deliver your modification request to the IRB office.

#	Date	Status	Status Date
4	03/25/2024	New - Not Yet Submitted	

Submit (0) Tracking Status: No Status Recorded

Edit Application Sections **1.**

Modification Request Form (Required) ✓ **2.**

Required Modification Electronic Signatures

Upload ↕

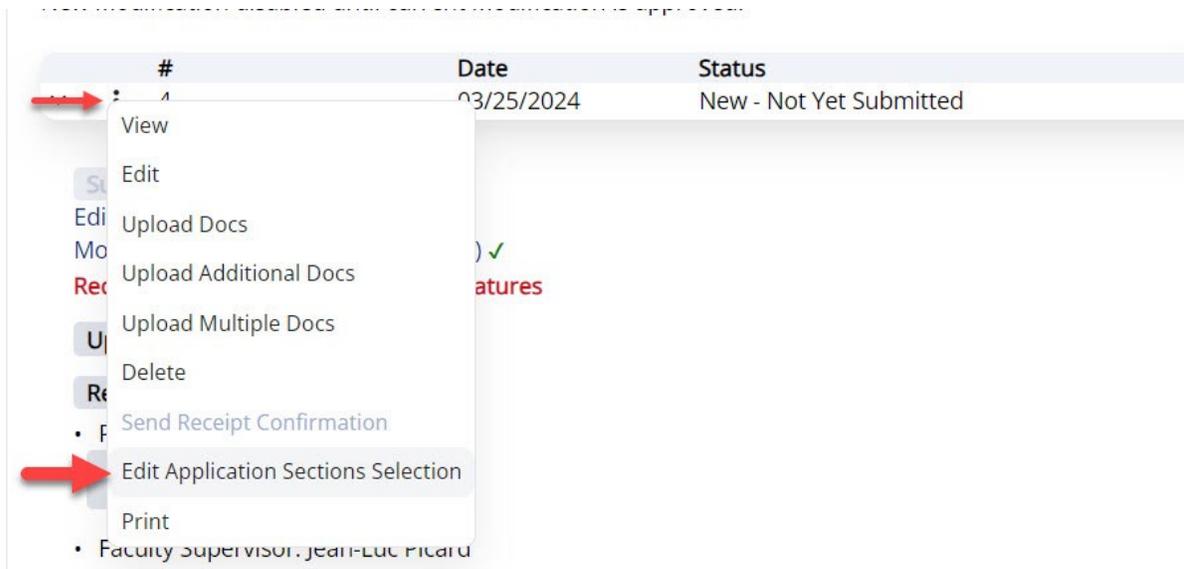
Request Signatures **4. If you are a student**

- PI: Wesley Crusher

Sign Electronically **3.**

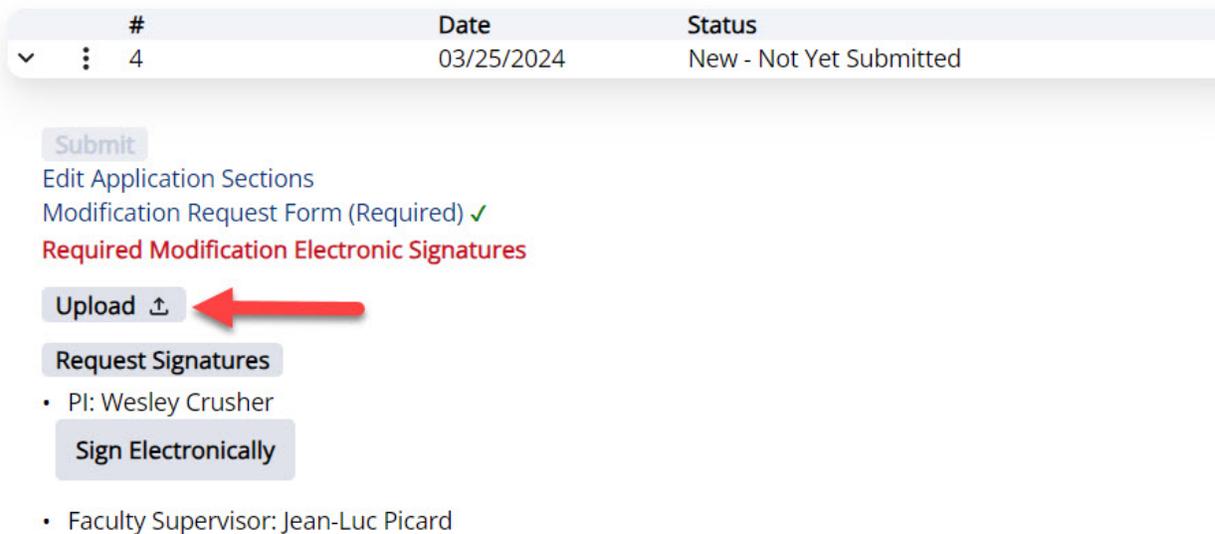
- Faculty Supervisor: Jean-Luc Picard

STEP 1. Click the Edit Application Sections link on the modification information page and make the changes to the specific areas of the protocol that you wish to modify. You can always add more sections to edit by clicking on the context menu at the top of the modification (three vertical dots) and selecting Edit Application Sections Selection from the menu.



You can upload a new file within the application section under the relevant file upload question or on the modification information page, as shown in the screen capture below.

Uploading a new file (if you are doing this within the application sections you would click on the Answer button to upload a new file):



To replace an IRB-approved file with a newer, edited version, upload the new file by selecting Choose File and use the Link File to Existing Protocol File menu. Select the file that will be replaced with the new version. If you are adding a new file and not replacing an existing file, leave the menu set to the Do Not Link option.

Upload Modification Document

Consent Document(s)

Choose File Consent Form - Control Group - Modification 3.25.24.docx

Allowed Extensions: doc, docx, pdf, rtf

Rename File to

Leave blank to use original file name

Link File to Existing Protocol File	Do Not Link <input type="button" value="v"/>
	Do Not Link
	Approved Consent Documents
	Consent-Control Group-1.23.23.pdf Approved 03/18/2024
	Consent - Experimental Group - Modification 2.9.23... Approved 03/18/2024

Allowed Extensions: doc, docx, pdf, rtf

STEP 2. Fill out the Modification Request Form by clicking on the link on the modification information page. The required form is intended to capture a summary of the modifications you wish to make.

STEP 3. Electronically sign your modification by clicking the button under your name on the modification request information page. If the protocol was not created by a student, clicking this button will result in delivery of the modification request to the IRB office. If you are a student, you must complete step 4 below. Alternatively, if you are a faculty supervisor who is completing the modification request on behalf of a student, you must complete step 4 below.

STEP 4. If you are a student, you must click the Request Signatures button to have your faculty supervisor sign off on the modification before it is delivered to the IRB. The button will be enabled only after you have completed steps 1-3. The protocol will not be delivered to the IRB office until both you and your faculty supervisor have signed off on the submission, so do not forget this step. Alternatively, if you are a faculty supervisor submitting a modification on behalf of a student, you will need to click the Request Signatures button after you have signed to have your student electronically sign the submission before it is delivered to the IRB office.

Request Signatures



✓ PI: Wesley Crusher Signed 03/25/2024 3:10 PM PDT

Cancel Signature ⊗

- Faculty Supervisor: Jean-Luc Picard

Faculty Supervisor Role for Modifications

Faculty supervisors will get an email with a link directly to the modification section of the protocol information page. After checking the request, click the Sign Electronically button under your name if you have no revisions to make to deliver the request to the IRB office.

#	Date	Status	Status Date
4	03/25/2024	New - Not Yet Submitted	

Submit (0) Tracking Status: No Status Recorded

Edit Application Sections
Modification Request Form (Required) ✓
Required Modification Electronic Signatures

Upload

✓ PI: Wesley Crusher Signed 03/25/2024 3:10 PM PDT

- Faculty Supervisor: Jean-Luc Picard

Sign Electronically

It is expected that if you are signing off on the modification request as the faculty supervisor, you have read the revised application sections, any new attachments, and the Modification Request Form summarizing the changes, and you have no issues with the submission.

If, as the faculty supervisor, you need to make edits to the student's submission, you will not be able to do so when clicking the free-view link in the email requesting your electronic signature. In order to make edits to a student modification submission, you would need to log into your Mentor account using [SJSU single sign-on](#) (SSO), navigate to the pending signatures page, and select the student's protocol from the menu.

IRB

IRB

Info Page
Resources
My Protocols
(2) Pending Signatures
Protocol Reports

Pending Signatures

IRB #	Title	PI	Status
23-001	The Long Term Effects of Warp Drive...	Wesley Crusher	Full Board Review Approved
23-010	Hobbits in Space	Tasha Yar	Full Board Review Approved

You would then scroll down to the modification tab for the protocol. An alert at the top of the protocol information page regarding the need for your signature will also get you the correct location.

Accessing the application via SSO allows you to make edits to the modification submission – STEPS 1 and 2 described earlier. If you wish for the student to make the revisions you can use the Messages link that accompanies the modification section to communicate your requests to the student. However, it is easier for the faculty supervisor to make the edits themselves. Faculty supervisors can also submit a modification on behalf of the student.

#	Date	Status	Status Date
4	03/25/2024	New - Not Yet Submitted	

[Submit](#) ✉ (0) Tracking Status: No Status Recorded
[Edit Application Sections](#)
[Modification Request Form \(Required\) ✓](#)
[Required Modification Electronic Signatures](#)
[Upload ↕](#)
 ✓ PI: Wesley Crusher Signed 03/25/2024 3:10 PM PDT
 • Faculty Supervisor: Jean-Luc Picard
[Sign Electronically](#)

Once the faculty supervisor and student have both electronically signed the modification request it is delivered to the IRB Office.

Confirmation of Delivery of Modification Request

There is no email confirmation that is sent to investigators or faculty supervisors about submission of the modification, though you will receive an email if revisions are requested and when the modification is approved. You can check on the status of a modification by logging into your Mentor Account, navigating to the Protocol Reports page in the left column, and selecting Modifications from the filter menu. The status of the protocol reports will appear under the title of the study.

If you would like a confirmation of the submission, you can request that an automated version be sent by selecting it from the context menu (three vertical dots) for the specific modification request.

Making Requested Revisions to Modifications

After receiving the email notification for requested revisions, proceed to make the edits within either the application sections selected or on the modification summary form, depending on what was requested. It's a good idea to scan the Modification Request Form, as reader comments/revision requests are not automatically flagged in the email notification. The application sections, however, will be flagged with text where revisions are required.

Application Sections: Modification

[View Protocol Page](#)

23-001. The Long Term Effects of Warp Drive on Behavior

PI: Wesley Crusher

Faculty Supervisor: Jean-Luc Picard

Show Hidden Sections

Expand All Sections

Revisions Required Questions

Close Comments

Show Unresolved Comments Only

Highlight Comments Entered Since

Search

> STUDY DESIGN

Revisions Required: 1 Comments: 1 01/23/2023 4:03 PM PST

> CONSENT

Revisions Required: 1 Comments: 1 02/06/2023 12:45 PM PST

[View Protocol Page](#)

Use the same process for making revisions as was outlined in the [User Guide for Initial Submissions](#).

Use the same options for adding or replacing files via the context menu for a file as noted earlier.

When you are ready to submit the revisions to the IRB office click the highlighted “Submit Revisions for Review” button on the information page for the modification.

#	Date	Status	Status Date
4	03/25/2024	New - Revisions Required - Submitted: 03/25/2024	

(0) Tracking Status: Revisions Requested

Edit Application Sections
Modification Request Form (Required) ✓

Submit Revisions for Review

Notifications

03/25/2024 [SJSU IRB - Modification - Revisions Required - 23-...](#) by Alena Filip

Modification Approvals

You will be sent an email notification once your modification has been approved. Approved modifications to the application sections are copied to the Approved Application Sections file type under the files section of the protocol information page. This is where you can download the most current iteration of your full protocol. As well, new files that were added as part of the modification request will appear under the appropriate file type in this section of the protocol

information page. Files that were flagged to replace existing files will now be listed on the protocol information page.

> Reviewers

Protocol Fields

Submitted By Wesley Crusher	Department Aerospace Engineering	College College of Engineering	Legacy Import
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Multi-institutional?
Yes

> Files [Click carrot to expand files section and see approved files](#)

Study Status Check-Ins | Modifications | Incident Reports | Deviations

- Approved Application Sections
 - 03/25/2024 Approved Application Sections.pdf ⁴
 - 03/25/2024 Approved Application Sections - admin.pdf ¹
- Approved Consent Documents
 - 02/06/2023 Consent - Control Group - Modification 2.3.23.pdf ⁵ Approved - 03/18/2024 M #1
 - 02/09/2023 Consent - Experimental Group - Modification 2.9.23... ⁴ Approved - 03/18/2024 M #2
- Notifications
 - 01/23/2023 SJSU IRB: Faculty Supervisor Requested Revisions -...
 - 01/30/2023 SJSU IRB: Revisions Required - 23-001.pdf
 - 02/02/2023 SJSU IRB: Protocol Submission Approved - 23-001.pd...

Study Status Check-Ins | Modifications | Incident Reports | Deviations

Incident Reports

Incidents are any problematic or unanticipated events that may adversely impact the study participants or the conduct of the study.

Incidents that involve unanticipated problems, adverse events, or injuries to human subjects must be reported within 7 calendar days. Only faculty and staff principal investigators may submit incident reports. Faculty supervisors must submit an incident report on behalf of a student investigator.

STEP 1. To submit an incident report, go to the Incident Reports tab at the bottom of the protocol information page and click on the New Incident Report button.

> Files

Study Status Check-Ins

Modifications

Incident Reports

Deviations

 Incidents are any problematic or unanticipated events that adversely impact the study participants or the conduct of the study.

Any incidents which include unanticipated problems, adverse events, or injuries to human subjects during the course of research must be reported to the IRB Office within 7 calendar days by the primary investigator upon discovery of the incident. If this incident report concerns a student protocol, it should be filled out by the faculty supervisor.

New Incident Report +



STEP 2. Fill out the Incident Report Form in the subsequent window.

STEP 3. Electronically sign the incident report by clicking the button under your name on the incident report information page. If the protocol was not created by a student, clicking this button will result in delivery of the incident report to the IRB office. If you are a faculty supervisor completing the incident report on behalf of a student, you must also request a signature from the student by clicking the Request Signatures button. The report will be delivered to the IRB office once both the student and faculty supervisor have signed.

New Incident Report +

Event / Date	Status / Comments / Files	Submitted By
4. 03/25/2024	New Adverse Event - Not Yet Submitted	Jean-Luc Picard
Incident Report Questionnaire ✓		
03/25/2024	New Adverse Event Reported	Jean-Luc Picard
03/25/2024	New Adverse Event - Not Yet Submitted	Jean-Luc Picard
Additional Documentation		
Submit Incident Report		
Request Signatures  		
• PI: Wesley Crusher		
• Faculty Supervisor: Jean-Luc Picard		
Sign Electronically  		

No Panel Assigned Tracking Status: No Status Recorded

Confirmation of Delivery of Incident Report

There is no email confirmation that is sent to investigators or supervisors about submission of the incident report. If you would like a confirmation of the submission, you can request that an automated version be sent by selecting it from the context menu for the specific incident report.

New Incident Report +		
Event / Date	Status / Comments / Files	Submitted By
4. 03/25/2024	New Adverse Event Reported	Jean-Luc Picard
View	✓	Print Message
Upload Docs	Adverse Event Reported	Jean-Luc Picard
Upload Additional Docs	Adverse Event - Not Yet Submitted	Jean-Luc Picard
Delete	Adverse Event Reported	Wesley Crusher
Send Receipt Confirmation	Confirmation	
	03/25/2024 4:05 PM PDT	
Cancel Signature ⊗		
✓ Faculty Supervisor: Jean-Luc Picard Signed 03/25/2024 4:04 PM PDT		
No Panel Assigned		
Tracking Status: Submitted to t		

Your report will be triaged by the IRB office, and you will either receive an acknowledgement or further instructions/action plan, depending on the nature of the incident.

Deviation Reports

A protocol deviation/violation is a departure from the approved protocol procedures made without prior IRB approval. A study deviation should be reported as soon as it is discovered. Note that frequent deviations may result in the study being suspended by the IRB if the deviations represent continuing non-compliance by the study team.

Only faculty and staff principal investigators may submit deviation reports. Faculty supervisors must submit a deviation report on behalf of a student investigator.

STEP 1. To submit a deviation report, go to the Deviation Reports tab at the bottom of the protocol information page and click on the New Deviation button.

> Files

Study Status Check-Ins Modifications Incident Reports Deviations

A protocol deviation is an unplanned instance of non-compliance from the approved protocol procedures made without prior IRB approval. Some examples include: failure to do a required screening procedure, enrolling a participant who did not meet all the inclusion/exclusion criteria, not conducting all required procedures, or performing additional or modified research procedures that are not part of the approved protocol.

Use this form to report a protocol deviation as soon as it is discovered. This form should not be used to report incidents or adverse events that subjects have experienced. Please use the Incident Report process for reporting any problematic or unanticipated events that may adversely impact the study participants or the conduct of the study.

New Deviation +

STEP 2. Fill out the Deviation Report Form in the subsequent window.

STEP 3. Electronically sign the deviation report by clicking the button under your name on the deviation report information page. If the protocol was not created by a student, clicking this

button will result in delivery of the deviation report to the IRB office. If you are a faculty supervisor completing the deviation report on behalf of a student, you must also request a signature from the student by clicking the Request Signatures button. The report will be delivered to the IRB office once the student has signed.

Status	Deviations File/Comments	Submitted By
1. New 02/16/2023	No file	Jean-Luc Picard

Type: Deviation

[Submit Deviation](#) **Required Signatures Missing**

Deviation Survey Print Messages (0)
02/16/2023

Additional Documentation

[Request Signatures](#) **B**

- PI: Wesley Crusher
- Faculty Supervisor: Jean-Luc Picard [Sign Electronically](#) **A**

No Panel Assigned Tracking Status: No Status Recorded

Confirmation of Delivery of Deviation Report

There is no email confirmation that is sent to investigators or supervisors about submission of the deviation report. If you would like a confirmation of the submission, you can request that an automated version be sent by selecting it from the context menu for the specific deviation report.

Status	Deviations File/Comments	Submitted By
1.	No file	Jean-Luc Picard

View

Edit Deviation

Upload Additional Docs

Send Receipt Confirmation

Delete

Print Messages (0)

PI: Wesley Crusher Signed 02/16/2023 3:55 PM PST

Faculty Supervisor: Jean-Luc Picard Signed 02/16/2023 3:53 PM PST [Cancel Signature](#)

No Panel Assigned Tracking Status: Submitted to the IRB

Your report will be triaged by the IRB office, and you will either receive an acknowledgement or further instructions/action plan, depending on the nature of the deviation.