SJSU SAN JOSÉ STATE UNIVERSITY

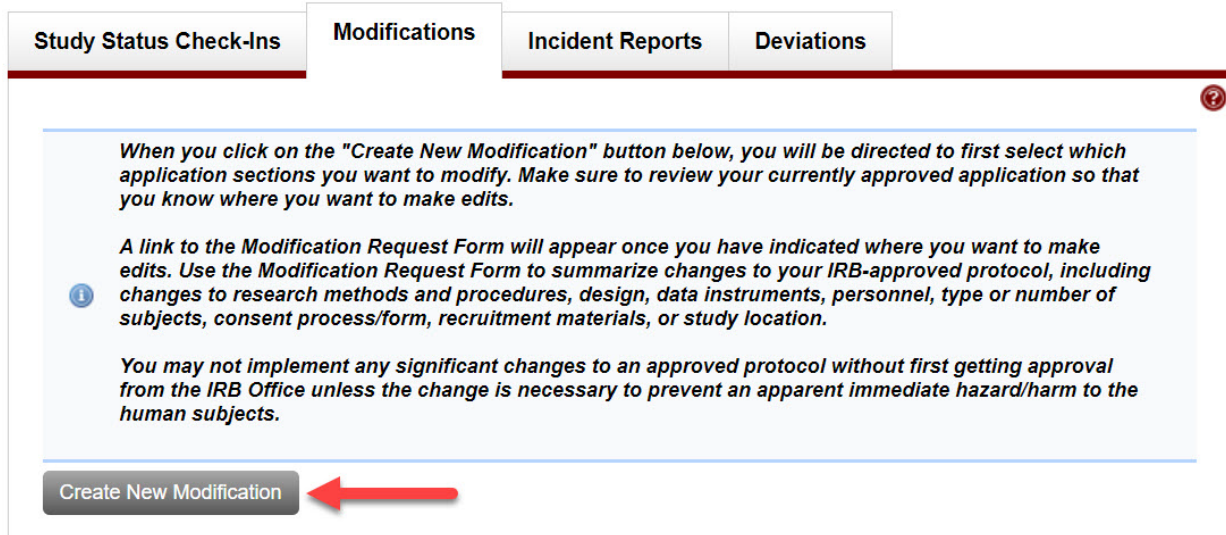# NAVIGATING IRB MENTOR: POST-APPROVAL REPORTING

Table of Contents

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 Create 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 Your ability to create new modifications will be locked until your current modification is approved or withdrawn.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.

	Status	Status Date
📄 1 02/02/2023	New - Not Yet Submitted	

Submit

Edit Application Sections ← 1.   Print   Messages (0)

Modification Request Form (Required) ← 2.

Required Questions Not Answered
Required Modification Electronic Signatures

📄 Consent Document(s)
  Upload
📄 Data Instruments
📄 Intervention Materials
📄 Other Modification Documents
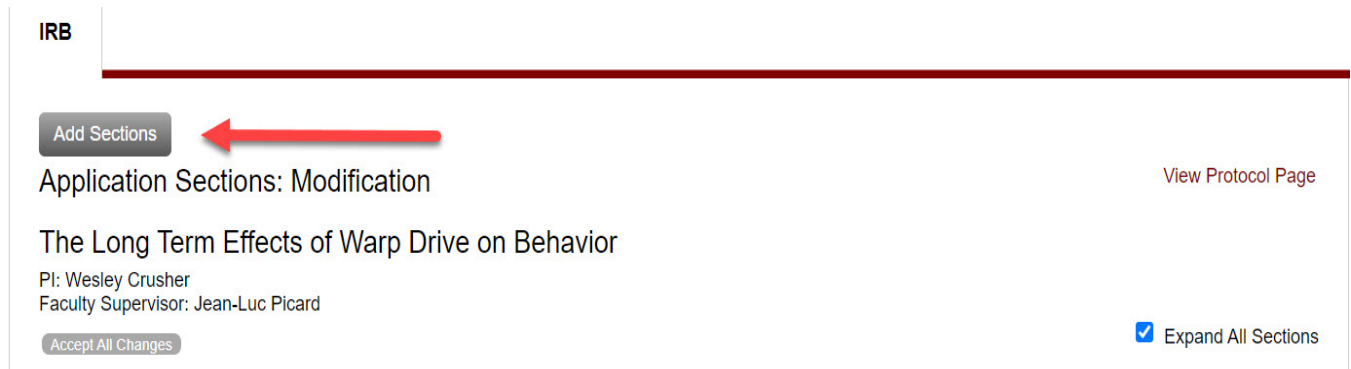📄 Recruitment Materials
📄 Translation Verification Form

Request Signatures ←   4. If you are a student

- PI: Wesley Crusher Sign Electronically ←   3.
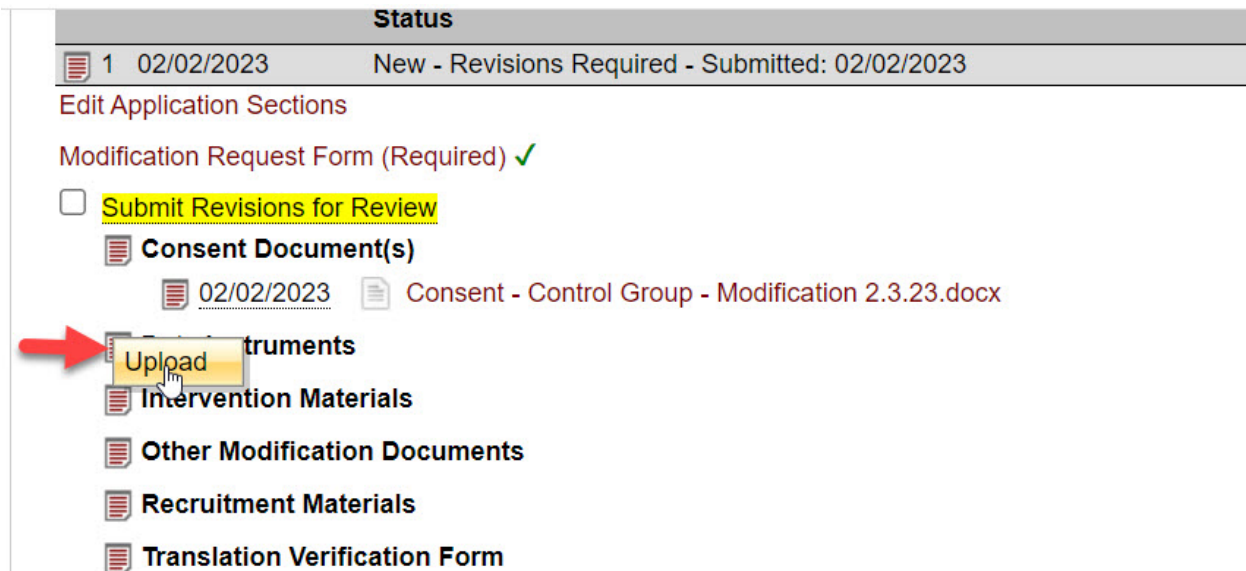- Faculty Supervisor: Jean-Luc Picard

3

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 at the top of application sections page.

IRB

Add Sections ←

Application Sections: Modification

View Protocol Page

The Long Term Effects of Warp Drive on Behavior
PI: Wesley Crusher
Faculty Supervisor: Jean-Luc Picard

Accept All Changes

☑ Expand All Sections

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 Edit Answer button to upload a new file):

	Status
📄 1 02/02/2023	New - Revisions Required - Submitted: 02/02/2023

Edit Application Sections

Modification Request Form (Required) ✓

☐ Submit Revisions for Review

📄 **Consent Document(s)**

📄 02/02/2023 📄 Consent - Control Group - Modification 2.3.23.docx

→ Upload truments

📄 **Intervention Materials**

📄 **Other Modification Documents**

📄 **Recruitment Materials**

📄 **Translation Verification Form**

To replace an IRB-approved file with a newer, edited version, upload the new file and, in the resulting pop-up window, use the Link 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.

Answer:

Choose File | Attachment.docx

Rename File to | Consent - Control Group - Modification 2.3.23

Leave blank to use original file name

Link File to Existing Protocol File | Do Not Link ⌄

Do Not Link

Approved Consent Documents

Consent-Experimental Group-1.21.23.pdf Approved 02/02/2023

Consent-Control Group-1.23.23.pdf Approved 02/02/2023

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 next to 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 02/02/2023 4:14 PM PST   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 that highlights where they need to sign.

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.

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.

	Status	Status Date
1 02/02/2023	New - Not Yet Submitted	

Submit

Edit Application Sections   Messages (0)

Modification Request Form (Required) ✓
Required Modification Electronic Signatures
  Consent Document(s)
    02/02/2023   Consent - Control Group - Modification 2.3.23.docx
  Data Instruments
  Intervention Materials
  Other Modification Documents
  Recruitment Materials
  Translation Verification Form

Request Signatures

  ✓ PI: Wesley Crusher   Signed 02/02/2023 4:14 PM PST
  • Faculty Supervisor: Jean-Luc Picard   Sign Electronically   Requested 02/02/2023 4:24 PM PST

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 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 red text where revisions are required.

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.

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.

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.

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

STEP 3. Electronically sign the incident report by clicking the button next to 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.

	Event / Date	Status / Comments / Files	Submitted By
📄 1.	02/16/2023	New Adverse Event - Not Yet Submitted	

Incident Report Questionnaire ✓   Print   Messages (0)

	02/16/2023	New Adverse Event Reported	Jean-Luc Picard
	02/16/2023	New Adverse Event - Not Yet Submitted	Jean-Luc Picard

[Approve Documents]

📄 **Additional Documentation**

[Submit Incident Report] [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 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
📄 1	02/16/2023	New Adverse Event Reported	

| View |
| Upload Docs | Print   Messages (0)
| Upload Additional Docs | New Adverse Event Reported   Jean-Luc Picard
| Delete | New Adverse Event - Not Yet Submitted Jean-Luc Picard
| Send Receipt Confirmation 🖱 | New Adverse Event Reported   Wesley Crusher   ←

📄 **Additional Documentation**

✓ PI: Wesley Crusher Signed 02/16/2023 1:37 PM PST
✓ Faculty Supervisor: Jean-Luc Picard Signed 02/16/2023 1:33 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 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.

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

A protocol deviation/violation is a departure from the approved protocol procedures made without prior IRB approval. Some examples include: enrolling participants who do not meet the inclusion criteria or enrolling more participants than what was approved; additional or modified research procedures; subjects signing an incorrect consent form.

Use this form to report a study 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

| Status | Deviations File/Comments | Submitted By |

No Deviations Found

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

STEP 3. Electronically sign the deviation report by clicking the button next to 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 ✓
    02/16/2023

Print Messages (0)

📄 **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

Ty Edit Deviation

D Upload Additional Docs   Print Messages (0)

Send Receipt Confirmation ←

Delete ntation

✓ 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.