

## NAVIGATING IRB MENTOR: INITIAL SUBMISSION

### Table of Contents

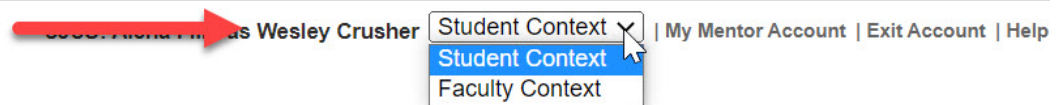
<b>The IRB Mentor Dashboard .....</b>	<b>2</b>
<b>Creating a Protocol.....</b>	<b>3</b>
<b>The IRB Application .....</b>	<b>6</b>
<b>Navigation and Responding to Questions .....</b>	<b>7</b>
<b>Notes on Uploading Documents and Attachments.....</b>	<b>7</b>
<b>Notes on the Personnel Section.....</b>	<b>8</b>
<b>Notes on the Other Institutions Section.....</b>	<b>8</b>
<b>Additional Submission Notes for Students.....</b>	<b>10</b>
<b>Faculty Supervisor Instructions.....</b>	<b>11</b>
<b>Addressing Requests for Revisions .....</b>	<b>11</b>
<b>File Management When Revisions to Attachments Are Required .....</b>	<b>14</b>
<b>Summary of Steps for Submitting Your Revised Protocol .....</b>	<b>16</b>
<b>Approval Duration.....</b>	<b>17</b>
<b>Exempt or Expedited Reviews .....</b>	<b>17</b>
<b>Continuing Reviews.....</b>	<b>18</b>
<b>Post-Approval Reporting.....</b>	<b>20</b>

**IMPORTANT NOTE:** The Mentor system is set up to send notifications to the email address that you identified as your preferred email address in Peoplesoft. If you do not receive communication from us when expected, please check your preferred email address or spam folder.

## The IRB Mentor Dashboard

When you sign in, you will land on our home page, which contains links to all our compliance committees that are using the system. Click on the IRB link to navigate to the IRB Mentor dashboard.

**User roles:** Notice if there is a roles context menu at the top right of the dashboard. If you are a student submitting an IRB protocol as part of your academic work for a degree *and* you happen to also be an SJSU employee, you must select the student context in the drop-down menu at the top right of the IRB Mentor page. For faculty, staff, and students who only have one role, you will not see this menu.



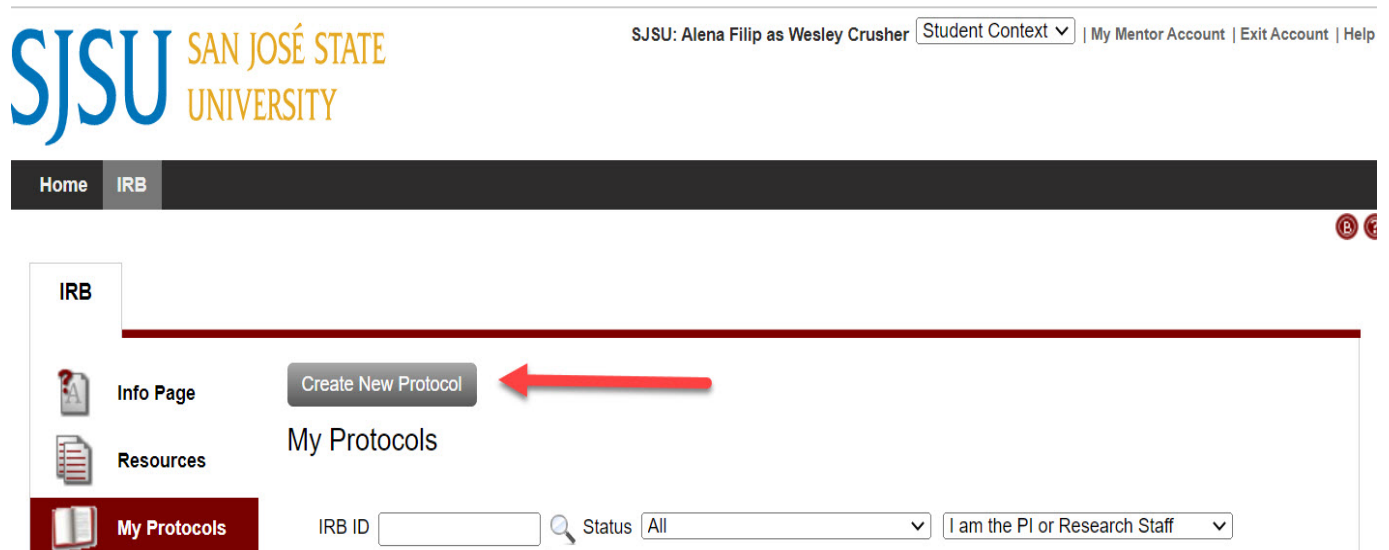
**Research coordinators:** The research coordinators page is for investigators who want to use research coordinators. These are staff who you designate to create or have edit rights to a submission but who are not co-investigators (to whom you can assign edit rights within the application submission) or Research Associates (who have read-only access). You first need to identify the names of your research coordinators before they can create a specific study on your behalf or before they can be added to the study personnel section of the IRB application. The research coordinators page is the place to do that.

**Training certificates:** Faculty PIs, Co-Is, and Supervisors of student research must have a current CITI training certificate in their IRB Mentor account. Your training certificate will be valid until it expires (every 5 years) and will be attached to all protocol submissions where you are part of the research personnel. SJSU has integrated CITI training certificates into our online IRB submission system; however, you must be prepared to upload your training certificate if it is not accessible by the IRB office when requested.

For more information on how to access CITI and which courses fulfill the human subjects research requirement visit the [training page on our website](#).

## Creating a Protocol

**STEP 1: To create a new protocol, go to the My Protocols page, and click the Create New Protocol button at the top of the My Protocols page.**



The screenshot displays the SJSU IRB My Protocols page. At the top, the SJSU logo and name are visible, along with the user's name 'Alena Filip as Wesley Crusher' and a 'Student Context' dropdown menu. Below the header is a navigation bar with 'Home' and 'IRB' tabs. The main content area is divided into a sidebar and a main panel. The sidebar contains links for 'Info Page', 'Resources', and 'My Protocols'. The main panel shows the 'My Protocols' section with a 'Create New Protocol' button highlighted by a red arrow. Below this button are search fields for 'IRB ID', a 'Status' dropdown menu set to 'All', and a 'I am the PI or Research Staff' dropdown menu.

- The pop-up window will ask for basic information that will then be populated on the protocol information page which serves as a kind of cover sheet for the protocol.
- Be aware that all name fields are based on last name lookup. Do not type the first name of the person you are searching for. If you're unable to find someone in the look-up fields, please contact the IRB office. Do not forget to click the Add button after selecting the person you want to add to the study.
- Co-I's are research personnel to whom you can grant edit rights to the submission by clicking the Allow Edit checkbox. Research associates are individuals who have read only access to the submission and are not able to make edits.
- The review type is always determined by the IRB office. SJSU does not use different applications for different review types. Instead, different sections and questions are made visible based on how you respond to questions as you move along in the application.

## Create IRB Protocol

Next Meeting

Deadline for Submission

\* Student Investigator

PI Type

Faculty Supervisor Jean-Luc Picard


Co-I's   (Type first letters of last name and select from popup list, then click "Add")

Tasha Yar  Allow Edit

Research Staff   (Type first letters of last name and select from popup list, then click "Add")

\* Title

\* Is this a multi-institutional, collaborative study?

 Collaborative studies are those in which each of the institutions involved are significantly engaged in the research, usually by means of local investigators carrying out research activities at each study site. If the study does not entail employees of external institutions collecting data from participants, obtaining informed consent, or being involved as members of the research team, then the work is probably not a collaborative study. Likewise, if study personnel will be asking employees at other institutions to pass along recruitment information to prospective participants this, alone, does not constitute a collaborative study.

When you click on the "Save" button below, you will be provided with the required IRB Application Forms. Once completed, you will be asked to electronically sign an assurance statement. If you are a student, your faculty supervisor will be sent a link notifying them that they must review your submission before it is delivered to the IRB office. Once all signatures are complete, an e-mail will automatically be sent to the IRB Analyst informing them of the submission of a new protocol. The IRB Analyst will contact you after screening the submission and deciding how best to proceed in its review.

*Notice the tooltips that are scattered throughout the protocol application to provide clarifications and definitions.*

- Once you fill out this initial questionnaire and click the save button, you will be directed to the protocol information page. The protocol information page lists status and tracking information that is populated as you move along in the review process. This page will also eventually include access to your approval notification, correspondence, and uploaded files. This is the “homepage” or dashboard for your protocol.
- Most items on the protocol information page are locked until you fill out the application sections. After you respond to all required questions, you can return to this page to electronically sign the submission, which will submit the protocol for review. If you are a student, the system will first send a link to your faculty supervisor after you have signed the

protocol alerting them that they need to review and accept the protocol before it can be delivered to the IRB office.

**STEP 2: To go to the IRB application, click the link labeled Application Sections on the protocol information page and fill out the required sections.**

Info Page   Edit   Research Coordinators   Print / Zip   Messages (0) | Back

Resources

**My Protocols**

Protocol Reports   **1 Signatures Missing**

Research Coordinators   **Required Questions Not Answered**

CITI Training Certs   Submit Protocol to Faculty Supervisor

Meetings   **Required signatures missing. Submit button will be enabled after all required signatures are present.**

IRB Members   Tracking Status: No Status Recorded

Admin

Protocol ID   42

Panel   No Panel Assigned

Student Investigator   Wesley Crusher (CITI Certificates)   Sign Electronically

PI Type   Student

Faculty Supervisor   Jean-Luc Picard (CITI Certificates) 01/18/2023

Faculty Supervisor Acceptance Status   Not Yet Accepted

Department

PI Institution

Co-I's   Tasha Yar (CITI Certificates) 01/18/2023 (Can Edit)

Review Type   To Be Determined

Approval Status   To Be Determined   Withdraw Protocol from Review

Submitted By   Wesley Crusher

Date Received

Date of Completion

Date Approved

Final Approval Date

Date Closed

Is this a multi-institutional, collaborative study?   Yes

➔ **Application Sections** ←

Modifications   Incident Reports   Deviations

?

## The IRB Application

Not all application sections are visible when you first open the IRB application. This is because new sections will open up depending on how you respond to questions. Each section will have a flag in red text indicating what you have not done yet – these will disappear as you respond to questions. You will not be able to submit your protocol until all flagged items are cleared.

IRB

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Application Sections [View Protocol Page](#)

The Long Term Effects of Warp Drive on Behavior

PI: Wesley Crusher  
Faculty Supervisor: Jean-Luc Picard

Expand All Sections

» STUDY PERSONNEL	
» STUDY TIMING AND FUNDING	Date Last Updated: 01/19/2023 2:52 PM PST
» OTHER INSTITUTIONS	Date Last Updated: 01/19/2023 2:54 PM PST
» STUDY LOCATION	Date Last Updated: 01/19/2023 3:01 PM PST
» STUDY DESIGN	Date Last Updated: 01/19/2023 3:06 PM PST
» SUBJECT POPULATION	Date Last Updated: 01/19/2023 3:14 PM PST
» RECRUITMENT	Date Last Updated: 01/19/2023 3:17 PM PST
» CONSENT	Required Questions Unanswered: 1
» ASSENT	Required Questions Unanswered: 1
» STUDY PROCEDURES	Required Questions Unanswered: 1
» SUBJECT IDENTIFIERS	Required Questions Unanswered: 2
» RISKS AND BENEFITS	Required Questions Unanswered: 3
» FINANCIAL CONFLICTS OF INTEREST	Required Questions Unanswered: 1
» OTHER STUDY ATTACHMENTS	

## Navigation and Responding to Questions

1. Click on a section heading to open it. Notice instructions that may appear at the top of some sections. You also may have instructions for each individual question. Make sure to read everything carefully, as some questions may be tied to conditional logic, and the instructions also provide useful information on how to respond for different circumstances.
2. To respond to a question(s), click the Answer or Edit Answer button. This will open a pop-up window with response fields. Note that some questions will be batched in a group. Required questions that all applicants must fill out are flagged with a red asterisk and with highlighted text indicating that the question is required. However, you should not ignore questions simply because they are not flagged as required. If it applies to your research, you are required to fill out the question.
3. To expand or hide a section, click on the chevron button next to the section heading.

## Notes on Uploading Documents and Attachments

[Review our User Guide for File Requirements](#) before you begin on your submission in IRB Mentor.

Documents that are typically required, such as consent documents, are requested via file upload questions within the relevant application sections. If you have multiple documents of a certain type (e.g., consent forms for different groups of participants), they should be submitted as separate attachments. This helps the IRB office to better compare revisions with original documents. Separating consent attachments also enables the IRB office to stamp each approved consent document at the end of the approval process in those cases where a stamp is needed.

- Use the Multiple File Upload link in the top right corner of the file upload question pop-up window to attach more than one document.

ADD/EDIT ANSWERS

**\* Consent Document Attachment(s) Important Instructions**

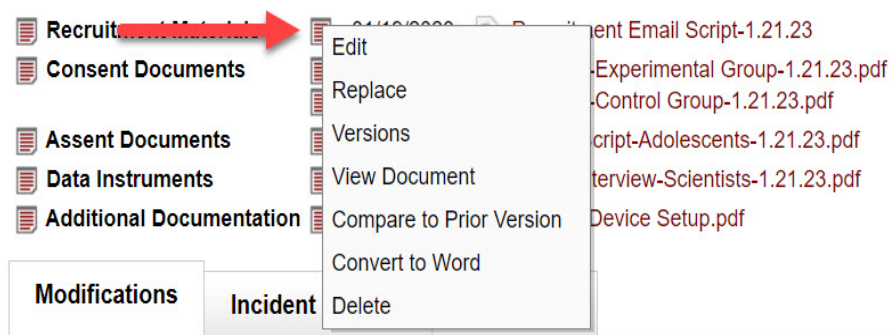
- For studies that include multiple consent documents, you will need to label the attachment file so that it is clear what the document is. Please follow this simple naming convention as applicable: file type-subject type-language-date. For example, a Spanish consent form for parents of minors submitted on Jan 1, 2023 would be labeled as: Consent-Parents-Spanish-1.1.23.
- Include translated consent documents here, as well as the *translation verification form*, if applicable.

Upload Multiple Files



- Once you have completed all application sections, go back to the protocol page. Notice that all your file uploads are now listed on the protocol information page and organized by file type. You can take various actions related to the files, such as replacing them or comparing versions, by clicking on the context menu for each file both on the protocol information page and within application sections.

### ➔ Application Sections



NOTE: If you save a file without a file extension such as in the first file listed in the image above, you will get an error message when trying to compare to a prior version.

### Notes on the Personnel Section

- Students should not list all of their thesis/dissertation committee members as co-Is unless they have a role in carrying out the human subjects research. Otherwise, all co-Is (with the exception of students) will need to have a current training certificate in the system, and you will not get approval to proceed with your study until the training certificate of each person has been accepted by the system admin (evident by a green checkbox next to the certificate listing); the more people you add to the study, the longer it will take to get approval if they haven't completed their training.
- Students are not required to complete the training but it is highly recommended.
- Training certificates for external personnel are not required unless specifically requested by the IRB office. SJSU does not provide access to our CITI training subscription for external personnel

### Notes on the Other Institutions Section

The Other Institutions section is hidden unless you indicate that the work involves a multi-institutional collaborative study. [A separate guidance document has been prepared for investigators who intend to rely on an external IRB approval for their research.](#)



You can also refer to our [Collaborative and External Studies webpage](#) for preliminary information so that you understand what is required to establish a reliance agreement between SJSU and the external reviewing IRB before initiating the process in IRB mentor.

### Submitting a Completed Protocol

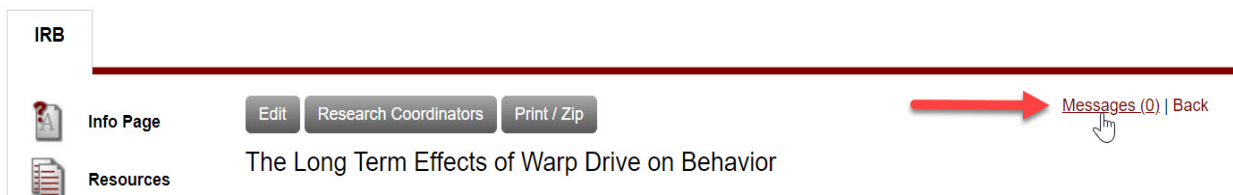
Navigate to the protocol information page after you have completed filling out all application sections. In order to submit the protocol for review or notify your faculty supervisor that your protocol is ready for their evaluation, you need to electronically sign an assurance. The button appears next to your name on the protocol information page.

- Once your protocol is delivered to the IRB, it is locked from editing and will be unlocked only if the IRB requests revisions.
- Although you will receive an email confirmation upon initial submission of your protocol to the IRB office, you will not receive a confirmation email from the IRB office when you submit revisions or if/when your protocol has been assigned to a reviewer. You can view the tracking status of your protocol at any time by going to the protocol information page. Information on [review timelines for different review types is posted on our website](#).

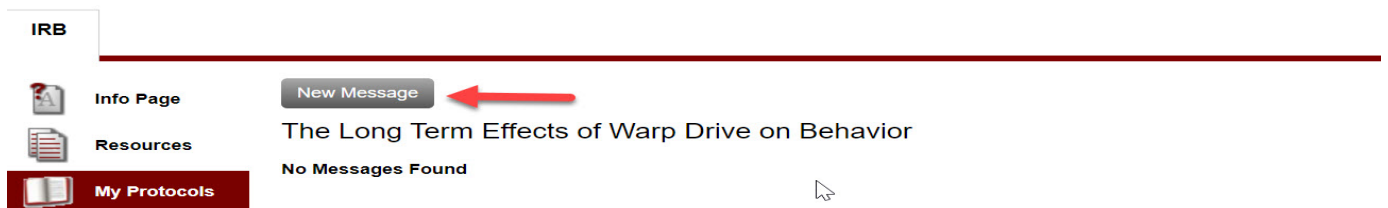
## Additional Submission Notes for Students

- If you are a student, submitting an electronic signature means that the protocol first gets routed to your faculty supervisor, who is required to review the submission and accept it before it gets delivered to the IRB. Make sure that you click the electronic signature button next to your name on the protocol information page. If you communicate with your faculty supervisor outside of the system and they begin reviewing your submission or making edits before you have electronically signed the submission, your protocol will not be delivered to the IRB even in your faculty supervisor accepts the submission. The faculty supervisor may choose to either make revisions directly or they may choose to ask you to make revisions. The Mentor system enables them to send a notification explaining what revisions they want you to make and to flag the sections in the protocol where you need to make revisions.
- If your faculty supervisor requests revisions, follow the instructions they provide to you in their email notification and then send them a separate email when you are done. There is no action button within Mentor to alert your faculty supervisor to the fact that you have made revisions that they have requested. If you do not let them know you have completed the revisions they requested, your protocol will not move forward and will not be submitted to the IRB. However, you can use the protocol messaging option at the top right of the protocol information page to communicate with your faculty supervisor. Protocol messages automatically append your name and the study title to the message. The email address that you identified as your preferred email address in PeopleSoft (MyJSU) is the default address in the Mentor system to which protocol messages as well as correspondence from the IRB office will be sent.

### Protocol message link:



### Create a new message:



**Make sure to select the correct recipients (e.g., your faculty supervisor if you are a student):**

New Protocol Message

The Long Term Effects of Warp Drive on Behavior


Message

Hello Dr. Picard,  
I have made the revisions requested. Please let me know if they are acceptable.

I

Send Notification(s) to PI(s)

- Wesley Crusher (PI)
- Jean-Luc Picard (Faculty Supervisor)
- Tasha Yar (Co-I's)



Please do not include the IRB chair, IRB analyst, or the SJSU IRB on internal communications between you, your faculty supervisor, or other study team members. If you have a question and need to send a protocol message to the IRB, please select SJSU IRB from the recipient list. If you have no need to contact the IRB, please do not copy us to your correspondence.

## Faculty Supervisor Instructions

A separate guidance document has been prepared for faculty who are supervising student research. Refer to the [User Guide for Faculty Supervisors](#) for information on how to navigate your evaluation of student submissions within IRB Mentor.

## Addressing Requests for Revisions

If revisions are requested to your submission from the IRB office, you will receive an email that will list the section questions which were flagged for revisions along with the reviewer comments to your answer. You may also receive general comments provided by the reviewer.

- After navigating to the application sections, notice that sections where reviewer comments appear are highlighted with green text. Sometimes the IRB may make a comment where no revisions are required. Revisions that are required will additionally be highlighted in red text that states “Revisions Required” for each application section, indicating that this is not optional and must be addressed.

» STUDY PERSONNEL	
» STUDY TIMING AND FUNDING	Date Last Updated: 01/
» OTHER INSTITUTIONS	Date Last Updated: 01/
» STUDY LOCATION Revisions Required: 2 Questions with Comments: 2	Date Last Updated: 01/
» STUDY DESIGN Revisions Submitted: 1 Questions with Comments: 1	Date Last Updated: 01/
» SUBJECT POPULATION Revisions Required: 1 Questions with Comments: 2	Date Last Updated: 01/
» RECRUITMENT	Date Last Updated: 01/

- Because all the revisions you make will be preserved in track changes (highlighted in green), you can delete or add text as needed within your previous answer by clicking the Add/Edit Answers button.

Add/Edit Answers

\* List the study location(s).

Answer:

This is a resubmission of a test submission to illustrate how track changes appear within previously existing text

Versions 01/30/2023 4:29 PM PST

» Reader Comments

**Anonymous** 01/30/2023 3:53 PM PST

This is a required revision.

Please do x, y, z.

- After saving your edits/revisions to an answer, the system will automatically flag the revision as having been addressed. However, this may not be the case for certain types of questions, such as file upload questions. In order to allow the IRB to see that you have made the edits and to clear flagged items, make sure to check the Submit Revisions for Review checkbox (if it appears) for each individual question where the checkbox is highlighted in yellow.

**\* Consent Document Attachment(s) Important Instructions**

- For studies that include multiple consent documents, you will need to label the attachment file so that it is clear what the document is. Please follow this simple naming convention as applicable: file type-subject type-language-date. For example, a Spanish consent form for parents of minors submitted on Jan 1, 2023 would be labeled as: Consent-Parents-Spanish-1.1.23.
- Include translated consent documents here, as well as the *translation verification form*, if applicable.
- It's best to provide each consent document as a separate attachment to make revision comparison easier and to allow the IRB office to stamp each approved consent document.

Please note that even if you have a web link to a consent document, the SJSU IRB still requires that you attach all consent documents to your application here.

**Answer:**

- Consent-Experimental Group-1.21.23.pdf 01/21/2023 (Consent Documents)
- Consent-Control Group-1.23.23.pdf 01/23/2023 <sup>1</sup> (Consent Documents)

**Reader Comments**

01/30/2023 11:50 AM PST

Reviewer is making a comment on the file upload question for a consent form because they want to see some revisions as follows:

1. The purpose of the study needs to align with what is stated in the purpose section of the application: "Space, the final frontier. These are the voyages of the starship Enterprise. Its 5-year mission: to explore strange new worlds, to seek out new life and new civilizations, to boldly go where no one has gone before."
2. Remove all jargon and technical language so that the consent form is accessible to a general audience.

**Submit Revisions for Review** Check this box after you have revised your answer to this question to indicate that the question is ready for review. Check the Reader Comments for instructions on how to revise the answer.

- Once you have submitted your revisions for each question, notice that the highlighted alert disappears and is replaced with text that says "Revisions Submitted."

**Reader Comments**

Revisions Submitted

Be aware, however, that this does not mean your revised protocol has been delivered to the IRB. There is an additional checkbox at the top of the application sections page that enables you to deliver your protocol to the IRB or to your faculty supervisor if the IRB office requires faculty supervision for revisions/resubmits. See the section "Summary of Steps for Submitting Your Revised Protocol" later in this guide for a screen capture of this final step.

Notice also, that once you address all revisions for each question where revisions were required, the application section headings are now flagged with text that says "Revisions

Submitted” instead of revisions required.

» STUDY LOCATION Revisions Submitted: 2 Questions with Comments: 2	Date Last Updated: 0
» STUDY DESIGN Revisions Submitted: 1 Questions with Comments: 1	Date Last Updated: 0
» SUBJECT POPULATION Revisions Submitted: 1 Questions with Comments: 2	Date Last Updated: 0
» RECRUITMENT	Date Last Updated: 0
» CONSENT Revisions Submitted: 1 Questions with Comments: 1	Date Last Updated: 0

## File Management When Revisions to Attachments Are Required

- If you need to add new files, click on the Edit Answer button on the appropriate file upload question and add a new attachment.
- If you are replacing one file with another, do not delete the previous attachment. You also do not need to highlight or enable track changes in a revised file unless this is requested by the IRB. The document comparison feature in Mentor will allow users to see what has changed across iterations of the same file for pdf documents. Always submit a clean, final PDF version with no track changes or highlights, especially when submitting files that participants will see.
- To replace a file with a new version, click on the context menu next to the file name of the document you want to replace after you have made your edits. You can click on the context menu either within the application sections or on the protocol information page. Then select the Replace option. A pop-up window will appear asking you to upload the new file.

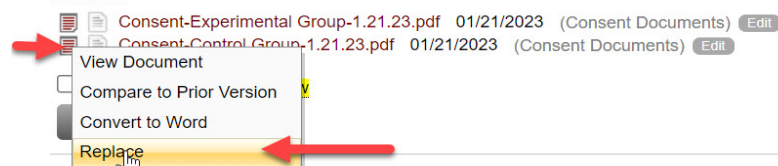
### **Replace option for replacing a file with an edited version:**

#### \* Consent Document Attachment(s) Important Instructions

- For studies that include multiple consent documents, you will need to label the attachment file so that it is clear what the document is. Please follow this simple naming convention as applicable: file type-subject type-language-date. For example, a Spanish consent form for parents of minors submitted on Jan 1, 2023 would be labeled as: Consent-Parents-Spanish-1.1.23.
- Include translated consent documents here, as well as the *translation verification form*, if applicable.
- It's best to provide each consent document as a separate attachment to make revision comparison easier and to allow the IRB office to stamp each approved consent document.

Please note that even if you have a web link to a consent document, the SJSU IRB still requires that you attach all consent documents to your application here.

Answer:



After clicking on the Replace button and uploading the revised file in the pop-up window, your new file will be listed under the relevant file type and the old file will be hidden under a superscript.



**Files with multiple versions have a superscript:**

Answer:

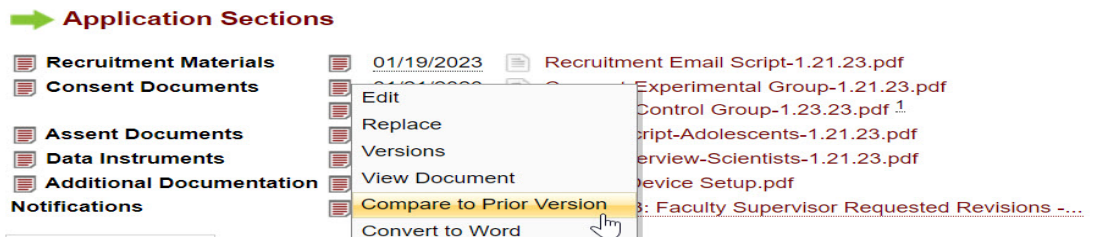
- Consent-Experimental Group-1.21.23.pdf 01/21/2023 (Consent Documents) Edit
- Consent-Control Group-1.23.23.pdf 01/23/2023 <sup>1</sup> (Consent Documents) Edit

[Submit Revisions for Review](#)

[Edit Answer](#)

You can always view the old file or compare two versions of a file by clicking the context menu for the file on the protocol information page and selecting the Versions or Compare to Prior Versions options respectively.

**To view prior versions or to do a side-by-side comparison of prior versions of files select the appropriate option after clicking the context menu on the protocol information page:**



The resulting pop-up window when selecting the Compare to Prior Version option will ask you to select which prior version you want to compare the new document to, with the most recent file matching the same file type listed at the top.

Document Compare Cancel

Document Compare

*i* You have selected Consent-Control Group-1.23.23.pdf to compare to a prior version of this file. Select the prior version below.

Prior Versions

	Size	MIME Type	Date/Time
<input type="radio"/> v.1 Consent-Control Group-1.21.23.pdf	73 K	application/pdf	01/21/2023 6:24 PM EST

Other Files

Protocol Files

**Recruitment Materials**

- 01/19/2023 Recruitment Email Script-1.21.23.pdf


**Consent Documents**

- 01/21/2023 Consent-Experimental Group-1.21.23.pdf



## Summary of Steps for Submitting Your Revised Protocol

1. Make the revisions, whether by editing text directly in the application or by uploading revised attachments using the replace feature in the context menu for an existing file.
2. Mark the highlighted “Submit Revisions for Review” checkbox under each question where revisions were made if this is not automatically done by the system.


 **Reader Comments**

01/30/2023 11:50 AM PST

Reviewer is making a comment on the file upload question for a consent form because they want to see some revisions as follows:

1. The purpose of the study needs to align with what is stated in the purpose section of the application: "Space, the final frontier. These are the voyages of the starship Enterprise. Its 5-year mission: to explore strange new worlds, to seek out new life and new civilizations, to boldly go where no one has gone before."
2. Remove all jargon and technical language so that the consent form is accessible to a general audience.

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  **Submit Revisions for Review** Check this box after you have revised your answer to this question to indicate that the question is ready for review. Check the Reader Comments for instructions on how to revise the answer.

3. Select the “Submit Revisions for Review” at the top of the application sections page to submit to the IRB office. If the IRB office requires faculty supervision for student revisions/resubmits, the text will read “Submit Revisions to Faculty Supervisor,” and your faculty supervisor will be notified by email that your revisions are awaiting their review and approval after you click this final checkbox.


IRB

Application Sections

[View Protocol Page](#)

The Long Term Effects of Warp Drive on Behavior

PI: Wesley Crusher  
Faculty Supervisor: Jean-Luc Picard

**Submit Revisions to Faculty Supervisor** 

Highlight Comments Entered Since

- Expand All Sections
- Revisions Required Questions
- Revisions Submitted Questions

**DON'T FORGET TO COMPLETE STEP 3!!!** If you do not mark this checkbox, your revised protocol will not be delivered to the IRB Office or Faculty Supervisor.

- If more revisions are requested by the IRB, the same cycle (Steps 1-3 above) continues. In the event that a student continues to submit iterations that do not address IRB comments, the faculty supervisor will be notified that they must make the edits themselves or submit a new protocol on behalf of the student.
- Once your protocol is approved, you will get an email with the approval notification and approved consent document(s); these items will also appear on the protocol information

page. You can access approved files by expanding the chevron button next to the files heading. Approved documents are denoted with a green checkbox.

**Application Sections**

**Files**

<b>Recruitment Materials</b>	01/19/2023	Recruitment Email Script-1.21.23.pdf ✓ 02/02/2023	<b>Green Check = Approved Document</b>
<b>Consent Documents</b>	01/21/2023	Consent-Experimental Group-1.21.23.pdf	
	01/23/2023	Consent-Control Group-1.23.23.pdf	
<b>Assent Documents</b>	01/21/2023	Assent Script-Adolescents-1.21.23.pdf	
	02/02/2023	Assent Script-Adolescents-1.21.23.pdf ✓ 02/02/2023	
<b>Data Instruments</b>	01/21/2023	Group Interview-Scientists-1.21.23.pdf ✓ 02/02/2023	
<b>Additional Documentation</b>	01/21/2023	Medical Device Setup.pdf ✓ 02/02/2023	
<b>Approved Application Sections</b>	02/02/2023	Approved Application Sections.pdf	
<b>Approved Consent Documents</b>	02/02/2023	Consent-Control Group-1.23.23.pdf ✓ 02/02/2023	
	02/02/2023	Consent-Experimental Group-1.21.23.pdf ✓ 02/02/2023	
<b>Notifications</b>	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...	

- Approved consent forms may be stamped at the bottom of each form. You must use the stamped version(s) of your approved consent documents. It is your responsibility to ensure that the formatting of your consent document(s) allows enough room for the stamp.

If you are doing an online survey where the consent information is embedded into the text preceding the survey, you may use an unstamped version so long as you: 1) include a link to the stamped version that participants can print/download, and 2) the text on the version preceding the survey does not deviate in any way from the stamped version.

Deviations from approved stamped consent documents are protocol violations. It is your responsibility to ensure consistency even if the IRB did not catch a discrepancy. If you wish to modify an approved consent document, submit a modification request to the IRB (see the Post-Approval Reporting section in this document).

## Approval Duration

The IRB office will determine whether and when your protocol approval expires. This information will be noted on the protocol information page.

## Exempt or Expedited Reviews

For most minimal risk research that went through either an exempt or expedited review, there will be a check-in requirement within 1-3 years (by default it is 3 years). Although this may be characterized as an “expiration date,” the purpose of the check-in is to ensure that the IRB office has accurate information regarding active studies in the SJSU research portfolio. The approval for most research that undergoes exempt and expedited review does not actually expire. You will be sent an automated email reminder to log into IRB Mentor and report the

status of your protocol. This is done via the post-approval reporting tab at the bottom of the protocol information page, which will not appear until your protocol is approved.

- After receiving the automated alert that your status check-in is due, click on the form under the Study Status Check-in tab and report whether or not the study is complete or is still ongoing. If it is ongoing, the IRB office will re-stamp your consent document if you were provided with a stamped version.
- If you complete the study before the check-in date, you can click on the Study Status Check-in Submission Form at any time, and select the Close Study option from the drop-down menu.

### Study Status Check-In

IRB ID 23-001  
 Protocol Title The Long Term Effects of Warp Drive on Behavior  
 Year Number 1

Continuation Status

An email will Cont Review.  Message

- Faculty supervisors are responsible for filing study status check-ins to close the study for students who have graduated and who have not closed their study within the system; automated alerts and reminders are copied to faculty supervisors of student research.

### Continuing Reviews

If your protocol went through a full-convened committee review, the tab at the bottom of the protocol information page will say “Continuing Review” once your study is approved.



- Your protocol will be placed on the next meeting agenda closest to your approval expiration date. If the meeting is scheduled after the approval expires, the system will automatically send you an expiration email alert even if the continuing review is upcoming. Once the approval expires, all study activities must stop until the IRB has reviewed the study and provided a renewal approval.
- You must file a continuing review request one last time when all study activities have been completed to notify the IRB of the completion of the study.
- Faculty supervisors are responsible for filing a final continuing review form to close the study for students who have graduated and who have not closed their study within the system; automated alerts and reminders are copied to faculty supervisors of student research.

## Post-Approval Reporting

A separate guidance document has been prepared for investigators who need to submit modification requests, report incidents and unanticipated problems, and to report study deviations/protocol violations. Refer to the [User Guide for Post-Approval Reporting](#) for information on how to navigate these types of reporting mechanisms within IRB Mentor.