**SJSU** SAN JOSÉ STATE UNIVERSITY

# NAVIGATING IRB MENTOR: INITIAL SUBMISSION

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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 SJSU Institutional Review Board 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.
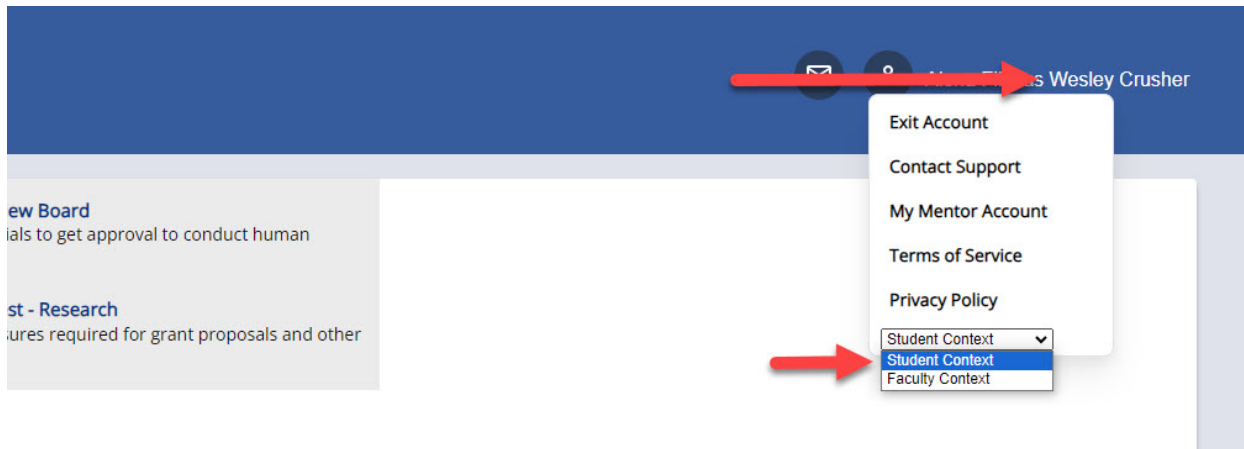


**Research coordinators:** The research coordinators page is for investigators who want to use research coordinators. These are staff who you designate to create or have edit rights to a submission but who are not co-investigators (to whom you can assign edit rights within the application submission) or Research Staff (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. Faculty supervisors do not need to be designated as research coordinators, as they have full access and edit on student protocols.

**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, select the My Protocols page from the left menu, and click the Create New Protocol button at the top of the My Protocols page.**



- 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 are unable to find someone in the look-up fields, please contact the IRB office. If you are a student, please contact your faculty supervisor to inquire about their official name in the SJSU system if you are not able to locate your faculty supervisor.

- 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.

*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.

- You can go back and edit the Create IRB Protocol page by clicking the Edit button at the top of the protocol information dashboard.

- You may add study personnel to the protocol from the protocol information dashboard or within the Application Sections. If you add personnel on the protocol information dashboard, you will be prompted to provide additional information about each member of the research team within the application sections. Remember that all name fields are based on **last name** lookup. Make sure to click the add button after you have looked up the individual:

- Co-I's are research personnel to whom you can grant edit rights to the submission by clicking the Allow Edit checkbox. Research staff are individuals who have read only access to the submission and are not able to make edits.

- 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.**



## 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.



## 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 <u>carefully</u>, 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 an asterisk and with highlighted text indicating that the question is required. However, <u>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.</u>

3. To expand or hide a section, click on the arrow 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 <u>separate</u> 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. Otherwise, to upload a single file at a time, click the Choose File button.



- 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 (three vertical dots) for each file both on the protocol information page and within application sections.

  NOTE: In order to compare versions of files, <u>the IRB office does not enable file deletion for investigators</u>. Please use the **replace** option in the context menu for the file to replace an older iteration of a file with a new version. If you accidently upload the wrong file, rename it

to "delete" by clicking the edit option, and the IRB office will delete the file when we receive the protocol submission.
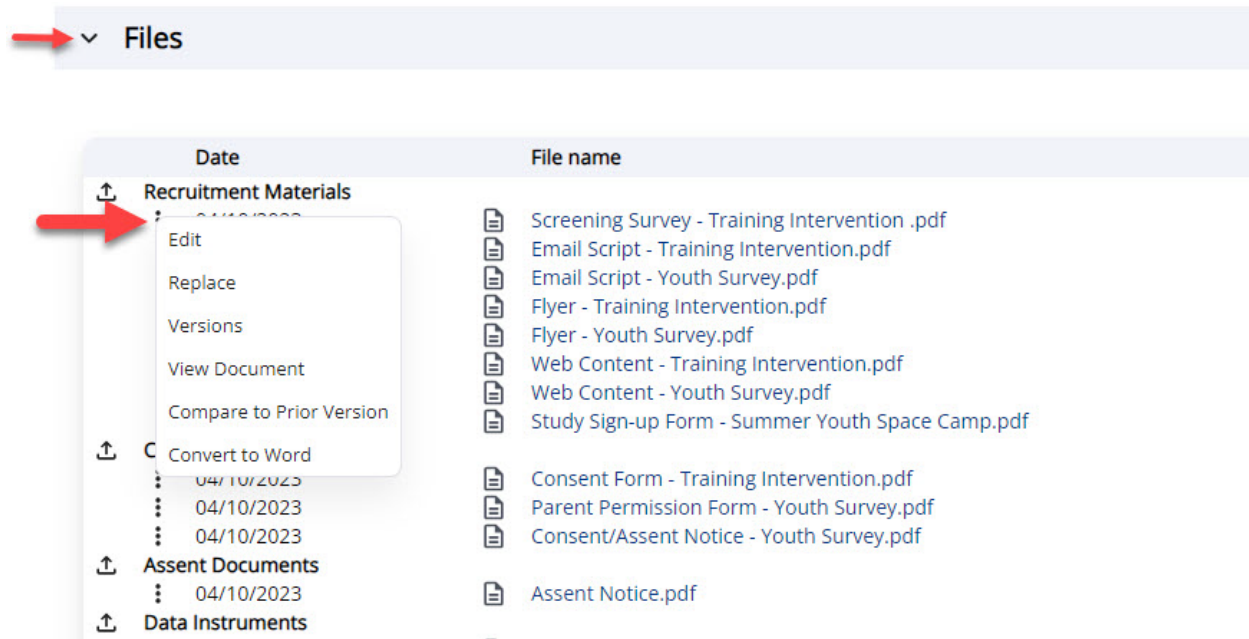


NOTE: If you save a file without a file extension, you will get an error message when trying to compare to a prior version.

## 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.

- Regardless of the labeling in Mentor, students who submit their protocol are not considered Principal Investigators (PIs) for their studies. Students must always identify a faculty supervisor as part of the study team. Faculty supervisors have unlimited access and edit rights to the student protocols that they oversee. Please disregard any Mentor labeling that identifies the student as "PI." The IRB office understands that faculty supervisors are PIs and no communication with the IRB office is needed about the Mentor labeling.

- 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 under the Personnel section 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.
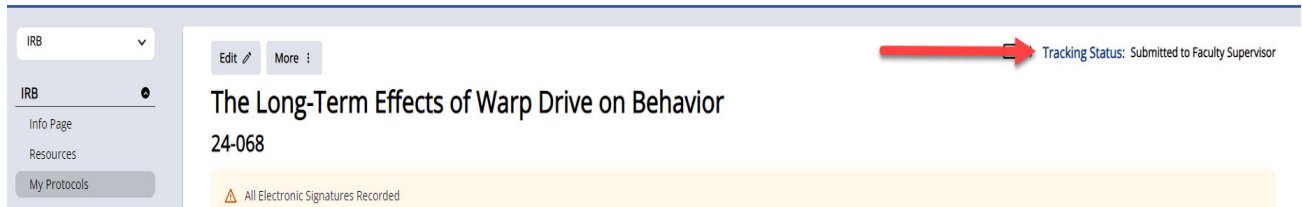


## Additional Submission Notes for Students

- 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 (MySJSU) 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:*
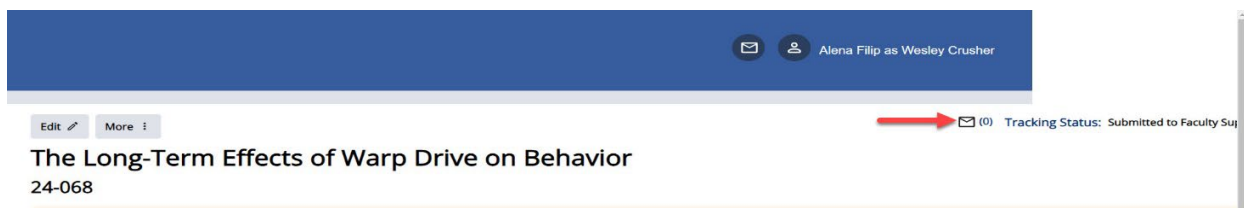
*Create a new message:*



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



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 yellow text that states "Revisions Required" for each application section, indicating that this is not optional and must be addressed.

| | | |
|---|---|---|
| > STUDY DESIGN | | 03/04/2024 10:09 AM PST |
| > SUBJECT POPULATION | | 03/04/2024 9:55 AM PST |
| > RECRUITMENT | Revisions Required: 1   Comments: 1 | 02/29/2024 11:44 AM PST |
| > CONSENT | Revisions Required: 1   Comments: 1 | 03/04/2024 11:02 AM PST |

- 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.

Name the external study location(s) where recruitment/enrollment, data collection, and other study procedures will take place.

This is a resubmission of a sample test submission to illustrate how track changes appear within existing text. Track changes are highlighted in green. Deleted text is crossed out.

˅ Comments   ⓘ Versions   03/18/2024 1:52 PM PDT

Anonymous   01/30/2023 3:53 PM PST
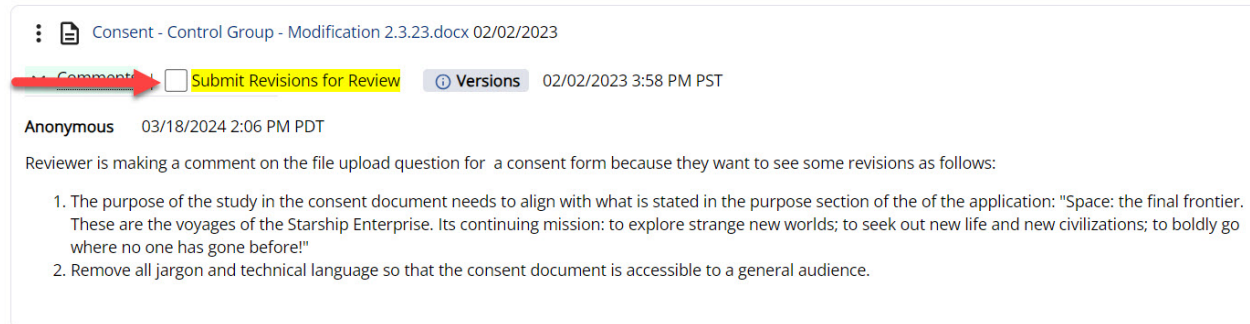
This is a required revision.

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)**

Review our user guide for file requirements before you upload any files. This is required reading if you will be uploading an attachment.

Make sure that your consent document(s) are each submitted as separate attachments; that they meet the requirements for stamping by the IRB office; and that they a presented in their final form as participants will see them (no highlights or track changes).

⋮ 📄 Consent - Control Group - Modification 2.3.23.docx 02/02/2023
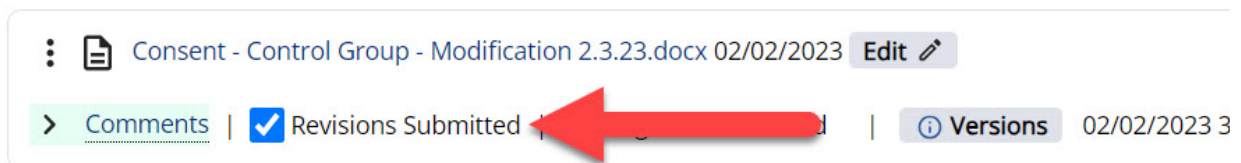
└ Comment | ☐ Submit Revisions for Review   ⓘ Versions   02/02/2023 3:58 PM PST

Anonymous     03/18/2024 2:06 PM PDT

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 in the consent document needs to align with what is stated in the purpose section of the of the application: "Space: the final frontier. These are the voyages of the Starship Enterprise. Its continuing 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 document is accessible to a general audience.

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

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

› Comments | ☑ Revisions Submitted      |   ⓘ Versions   02/02/2023 3

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 revisions, the application section headings are now flagged accordingly.

| › STUDY LOCATION | (Revisions Submitted: 2) (Comments: 3) 03/18/2024 1:52 PM PDT |
|---|---|
| › STUDY DESIGN | (Revisions Submitted: 2) (Comments: 1) 01/23/2023 4:03 PM PST |
| › SUBJECT POPULATION | (Revisions Required: 1) (Revisions Submitted: 1) (Comments: 2) 01/30/2023 4:39 PM PST |
| › RECRUITMENT | (Revisions Required: 1) 01/19/2023 3:17 PM PST |
| › CONSENT | (Revisions Submitted: 1) (Comments: 3) Modification 1  02/06/2023 |

## File Management When Revisions to Attachments Are Required

- If you need to add new files, click on the Answer button on the appropriate file upload question and add a new attachment.

- If you are replacing one file with another, you will not be able to delete the previous attachment. Use the **Replace File** option shown in the screen capture below. 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. <u>Always submit a clean, final PDF version with no track changes or highlights, especially when submitting files that participants will see.</u>

- To replace a file with a new version, click on the context menu (three vertical dots) 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:***
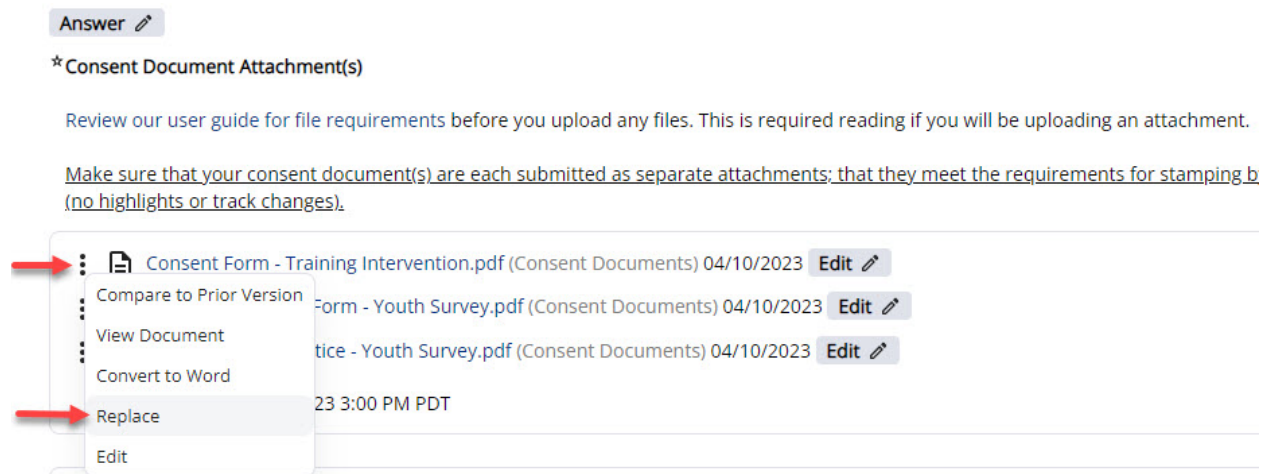


After clicking on the Replace button and uploading the revised file in the pop-up window, your new file will be listed under the relevant file type and the old file will be hidden under a superscript.

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

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:***
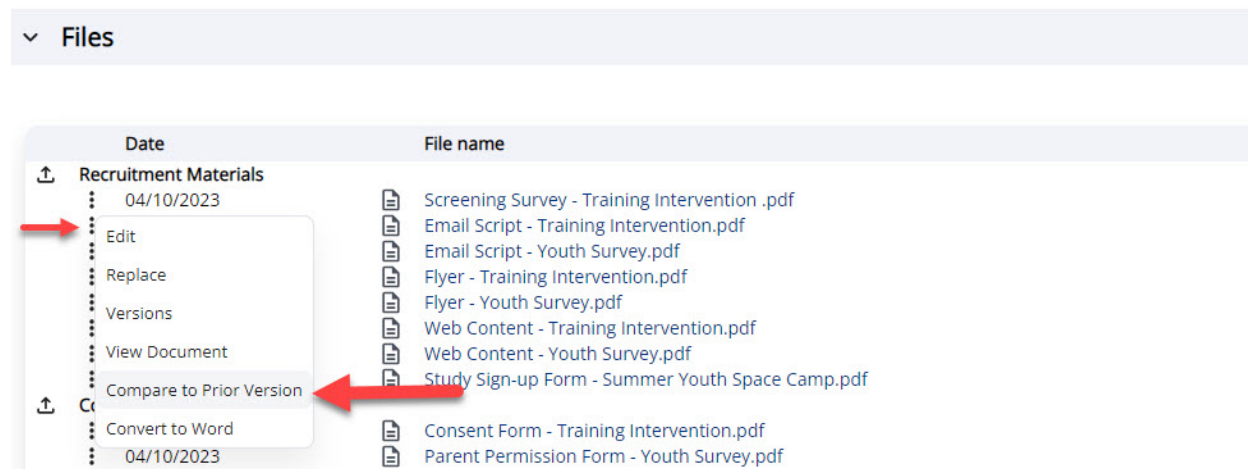


The resulting pop-up window when selecting the Compare to Prior Version option will ask you to select which prior version you want to compare the new document to, with the most recent file matching the same file type listed at the top.
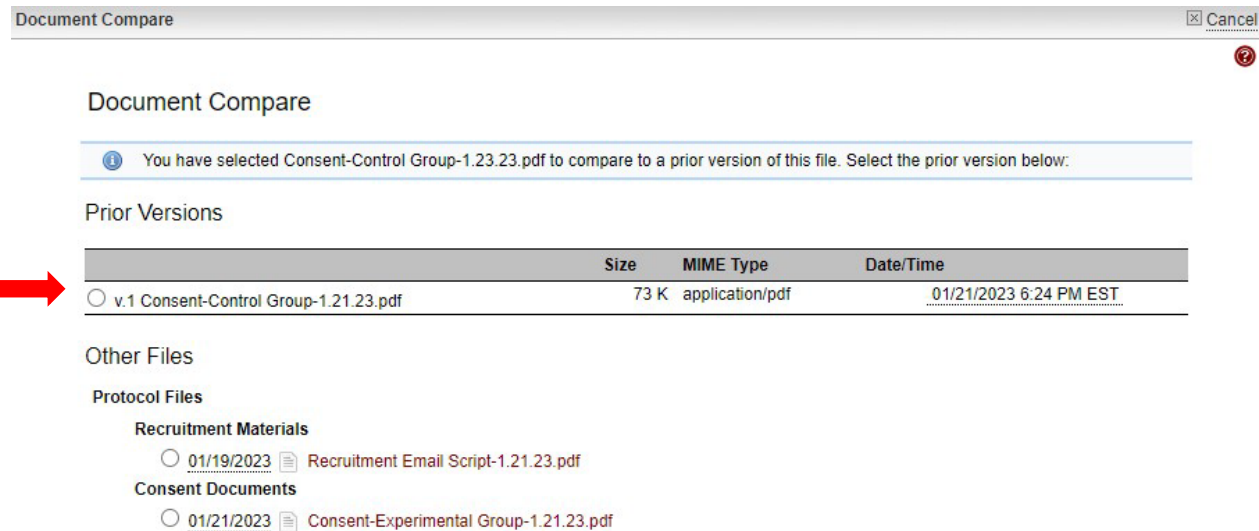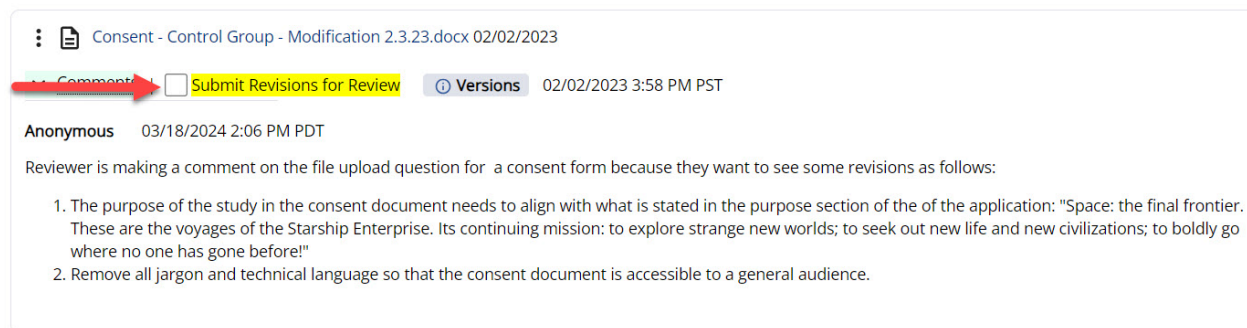
## Summary of Steps for Submitting Your Revised Protocol

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 <u>each question</u> where revisions were made if this is not automatically done by the system.

Consent Document Attachment(s)

Review our user guide for file requirements before you upload any files. This is required reading if you will be uploading an attachment.

Make sure that your consent document(s) are each submitted as separate attachments; that they meet the requirements for stamping by the IRB office; and that they a presented in their final form as participants will see them (no highlights or track changes).

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

Comment [ ] Submit Revisions for Review    ⓘ Versions    02/02/2023 3:58 PM PST

Anonymous    03/18/2024 2:06 PM PDT

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

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2. Remove all jargon and technical language so that the consent document is accessible to a general audience.

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.

## Application Sections

## 24-068. The Long-Term Effects of Warp Drive on Behavior

PI: Wesley Crusher
Faculty Supervisor: Jean-Luc Picard

[ ] Submit Revisions to Faculty Supervisor

◯ Show Hidden Sections
◯ Expand All Sections

<u>DON'T FORGET TO COMPLETE STEP 3!!!</u>  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 flagged with green text; previous iterations of a document will not be flagged in green, making it clear which IRB-approved documents must be used.



In addition, two new file types will appear upon approval: 1) Approved Application Sections, which will be the final, approved protocol, and 2) Approved Consent Documents, where your approved consent documents are listed. When any subsequent post-approval modifications are approved, these files will be updated on the protocol information page.

- 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 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**                                                   Cancel ✕

**IRB ID**
23-001

**Protocol Title**
The Long Term Effects of Warp Drive on Behavior

**Year Number**
1

**Continuation Status**

– Select Continuation ...  ▾

| |
|---|
| **– Select Continuation Status –** |
| Continue Study |
| Close Study |
| Administrative Closure |

nt to the IRB Chair and Administrator upon successful upload of your
send any message along in that email, please use the text box below.

**Save** ✓    **Cancel** ⊗

- 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.

Approvals for continuing review protocols typically expire after one year, unless the IRB has decided on a shorter approval period (one year is the maximum duration of approval for protocols that undergo a full review).

- After receiving the automated alert that your continuing review is due, fill out the two forms under the Continuing Review Tab on the protocol information page: Study Status Form and Continuing Review Form.

- To submit the continuing review request to the IRB, click the sign electronically button next to your name.



If the protocol was a student submission, the faculty supervisor will be required to sign as well. Click the Request Signatures button if you are a student to send the continuing review submission to your faculty supervisor for approval after you have signed it.

- 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.