SJSU SAN JOSÉ STATE UNIVERSITY

NAVIGATING IRB MENTOR: FACULTY SUPERVISORS OF STUDENT RESEARCH

Preliminary Information

Read through the User Guide for Initial Submissions to understand the overall workflow for submissions. Your students are expected to read the initial submissions user guide so that they understand how to create a protocol, navigate within the IRB Mentor system, and utilize the file management and organization features of IRB Mentor.

Training Requirement

Make sure you have a training certificate for human subjects research completed with the last 5 years on file within the IRB Mentor system. For information on how to access training and which courses fulfill the requirement for human subjects research, please see the Researcher Training Information page on our website. 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. To check whether you have a current training certificate in IRB mentor, log into your IRB Mentor account and navigate to the IRB tab. Click on the CITI Certs page in the left-hand column.

Options for Creating a Student Submission

OPTION 1: Because faculty supervisors are considered Principal Investigators on student-led research, you may choose to fill out an IRB submission on behalf of a student or group of students you are supervising. To do so, please consult the User Guide for Initial Submissions, and identify student team members as Co-Investigators in the study personnel section of the application (you may choose to grant edit rights to Co-Investigators by clicking the Allow Edit checkbox next to their name within the personnel section of the application).

OPTION 2: If you prefer to have a student prepare the submission, you will receive an email notification once the student has completed and signed the submission asking you to review it. Students are required to identify their faculty supervisor as part of their submission workflow. To review your student's protocol or to check on the tracking status of your students' submissions, log into your IRB Mentor account and navigate to the My Student Protocols page under the IRB tab.

Click on the title of the study to navigate to the protocol information page. If you want to navigate to any student protocol that you have supervised, make sure to set the Acceptance Status filter on the My Student Protocols page to "show all statuses."

Reviewing a Student Submission

This guidance document is written with the assumption that you have directed the student to prepare the protocol submission.

You can ensure a smooth and efficient process by reviewing the common application problems posted on our website. Faculty Supervisors/PIs are responsible for confirming that submissions are free from these common application problems.

STEP 1. Log into your IRB Mentor account and navigate to the My Student Protocols page. Make sure that the Acceptance Status Filter is set to show all statuses if you do not see your student's protocol.

STEP 2. After clicking on the protocol title and navigating to the information page for the student protocol, read through the application sections and associated attachments. Application sections can be accessed by clicking the Application Sections link on the protocol information page. Attachments can be accessed either on the protocol information page or within the application sections where a file upload question prompted the user to add an attachment. You can click the context menu next to a file to view a document, replace a document with a revised version, and compare to prior iterations of a file, as shown in the image below.

STEP 3. You can either make edits to student answers within the application sections yourself by clicking the Edit Answer button for a question, or you can compile revisions for the student to make prior to accepting the submission for delivery to the IRB. We recommend that you edit answers and attachments yourself to save time.

To make edits to the content of an attached document convert it to Word if it is in some other format (see the context menu option Convert to Word in the above image) or ask the student to provide you with an editable copy, download the converted document to your computer, make edits to the content, and then upload the revised document by selecting the Replace option from the file context menu, as in the image above. Make sure to follow established naming and formatting conventions for files in our User Guide for File Requirements.

If you would like to have the student make the revisions you require before accepting their submission, you will need to compile your revision requests to be inserted into an email

template designed for requesting revisions from your student (see Step 4 below). We recommend that you keep a blank Word document open for compiling comments as you move along through the application sections and attachments for the student protocol.

Clicking the Request Revisions checkbox under a specific question flags the section with red text to alert the student to the area within the application where you would like to see revisions. However, you will need to type up a description of the revisions separately to copy and paste into the email template provided by IRB Mentor for registering your decision.

Request revisions checkbox before it is checked:

Flagged revisions sections after request revisions checkbox is checked:
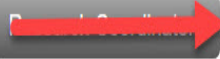

STEP 4. To make a decision about whether you want to accept the student's submission for delivery to the IRB or request edits for your student to address, select the Faculty Supervisor Action Button at the top of the protocol information page.

IRB

Info Page

Resources

Edit | ~~Research Compliance~~ | Faculty Supervisor Action | Print / Zip

The Long Term Effects of Warp Drive on Behavior

On the resulting pop-up window, read through the assurance statement and select which action you want to take from the drop-down menu under the assurance statement.

- **Faculty Supervisor Revisions Required** means that you would first like to like to see revisions to the submission before it is delivered to the IRB office. An applicable email template will load once you click the Update Status button where you will be able to insert your compiled comments. The student will be sent a notification and will need to log into their IRB Mentor account to make the revisions. The steps noted in this user guide are repeated until you accept the submission.

- **Accepted** means that the protocol is delivered to the IRB office once you click the Update Status button. An automated message will be sent to the student alerting them to your acceptance and to the fact that the submission has been delivered to the IRB office. You can track the status of the IRB process by going to the protocol information page under My Student Protocols.

Info Page

Resources

My Protocols

Protocol Reports

My Student Protocols

Faculty Supervisor Action | Print / Zip

The Long Term Effects of Warp Drive on Behavior

All Electronic Signatures Recorded

Tracking Status: Submitted to the IRB

Admin
Protocol ID | 23-001
Panel | No Panel Assigned
Student Investigator | Wesley Crusher (CITI Certificates) Signed 01/22/2023 3:59 PM PST

- **Rejected** means that you not willing to serve as the faculty supervisor on the submission. An applicable email template will load once you click the Update Status button where you will be able to insert your explanation to be delivered to the student. Do not select this option if you just want the student to make revisions. This option is strictly to communicate to the student that you are not willing to serve as the faculty supervisor on the protocol.

Faculty Supervisor Action

Assurance

I understand and accept my responsibilities as the Faculty Supervisor/PI for this study. I hereby assure the following:

1. I have consulted the Exclusion Worksheet on the IRB website and determined that the work meets the regulatory definition of human subjects research requiring submission of an IRB application.
2. I have no significant financial conflict of interest in this project or have disclosed a conflict per institutional policies and federal requirements.
3. All experiments and procedures involving human subjects will be performed under the Faculty PI's supervision or that of another qualified professional listed in the IRB application, and all research personnel are adequately trained.
4. Faculty and staff PIs and Co-Is have completed the training requirement for the protection of human research subjects as outlined on the SJSU IRB website.
5. Responsibility for compliance of any external personnel listed in the application rests with the SJSU Faculty PI.
6. The study will be conducted according to the protocol approved by the IRB, and no changes in the design, conduct, or key personnel of this research will be implemented without prior SJSU IRB review and approval, unless the changes are necessary to eliminate an apparent immediate hazard to participants. Changes made to eliminate hazards to participants will be reported to the IRB promptly.
7. If any study subject experiences an unanticipated problem and/or serious adverse event, the IRB will be informed promptly within no more than one week (7 calendar days).
8. Participants' complaints or requests for information about the study will be addressed appropriately.
9. I will promptly and completely comply with an SJSU IRB or an Institutional Official (IO) decision to suspend or withdraw approval for the study.
10. I will apply all relevant professional standards.
11. The protocol is clearly written for a general audience and all documents have been proof-read.
12. The information provided in the protocol application is accurate and complete to the best of my knowledge.
13. I understand that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

I have read and agree to the above assurance.

Acceptance Status: **Not Yet Accepted** ⌄

- Not Yet Accepted
- Faculty Supervisor Revisions Required
- Accepted
- Rejected

Notes on Requesting Revisions

- If you require revisions from the student, they will need to notify you via a separate message when they are done. There is no action button within mentor to allow a student to alert their faculty supervisor to the fact that they have made the revisions requested. Students and faculty supervisors can use the protocol messaging system within IRB Mentor, as described in the User Guide for Initial Submissions to communicate with one another. Please do not copy the IRB administrator or chair to your messages – we do not need to be informed of your correspondence with the student. You can also monitor a student's progress on their protocol revisions by logging into Mentor and going to the My Student Protocols page.

- Revisions are noted by track changes with green highlights. You can also see if a student made changes elsewhere in the protocol where you did not request revisions by checking for green highlights.

- To continue requesting revisions for a question, uncheck the Revisions Submitted checkbox to return the submission to its native state and check the box again to Request Revisions (which results in flagging the section in red text noting that revisions are required).

Uncheck Revisions Submitted box (before):

Study Purpose
Provide an explanation of the purpose of the proposed research, written for a general audience. Include a concise statement of your research questions or hypotheses.
Answer:
I am editing this answer for my faculty supervisor.
Versions 01/23/2023 3:57 PM PST

☑ Revisions Submitted ⬅

Then check the Request Revisions box if you want more revisions:

Study Purpose
Provide an explanation of the purpose of the proposed research, written for a general audience. Include a concise statement of your research questions or hypotheses.
Answer:
I am editing this answer for my faculty supervisor.
Versions 01/23/2023 3:57 PM PST

🔲 Request Revisions ⬅

The checkboxes are there to help faculty supervisors and students flag where they require revisions and where they have made revisions respectively. Make sure that you uncheck the Revisions Submitted checkbox when you are ready to accept the submission for delivery to the IRB, so that the IRB office receives a clean copy of the application with no flagged sections.
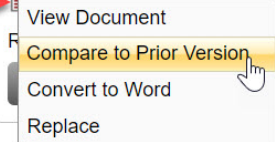
Notes on Navigating Attachments

- If the student followed instructions on the [User Guide for Initial Submissions](#), then a revised document that is intended to replace a previous document will be listed both within the relevant section of the application and on the protocol information page, and the previous version will be hidden under a superscript. To view each version or compare documents, select the context menu for the file and select which action you want to take.

Answer:
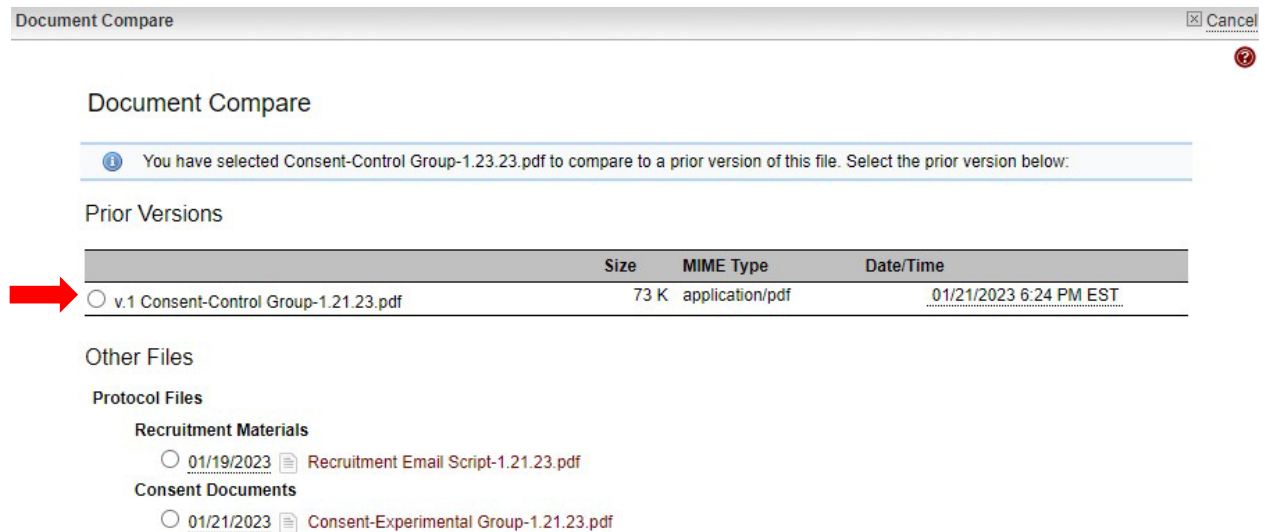📄 Consent-Experimental Group-1.21.23.pdf 01/21/2023 (Consent Documents) Edit
📄 Consent-Control Group-1.23.23.pdf 01/23/2023 [1] (Consent Documents) Edit

➡ | View Document |
| **Compare to Prior Version** |
| Convert to Word |
| Replace |

- 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 previous version of a file that matches the same file type listed at the top.

Post-IRB Review

Once you accept a student's submission, it will automatically be delivered to the IRB Office. If the IRB requires changes, you may be required to review and approve the student's revisions again unless the revisions are minor in nature. The IRB office enables or disables the routing of a student protocol to the faculty supervisor when revisions are requested from the IRB according to need. Faculty supervisors are notified automatically on all emails to the student. For substantial revisions or cases where a student has attempted multiple iterations without resulting in approval, the IRB office may require that you take over the revisions and submission process for the student. This will either be noted in an email notification when revisions are requested or as a separate protocol message from the IRB. The IRB office may also choose to withdraw the student application and require a new submission by the faculty supervisor.

Post-IRB Approval

For information on approval durations, please see our User Guide for Study Status Check-ins and Continuing Reviews.

NOTE: 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.

Post-Approval Reporting

A separate guidance document has been prepared for investigators who need to submit modification requests, report incidents that adversely affect participants, or to report study

deviations. Refer to our User Guide for Post-Approval Reporting for information on how to navigate these types of reporting mechanisms within IRB Mentor.

A similar faculty supervisor approval process as described here is required for students who submit a modification to their approved protocol. However, we require that the faculty supervisor take charge of incident and deviation reports on behalf of the student.