



NAVIGATING IRB MENTOR

SJSU INVESTIGATORS WHO WISH TO RELY ON AN EXTERNAL IRB APPROVAL

Preliminary Steps and Information

You must first contact the reviewing IRB to determine whether they are willing to engage in a reliance agreement with SJSU to allow us to rely on their review or exemption determination for the study. It will save you time to take the preliminary step of confirming that the reviewing IRB is willing to engage in a reliance agreement.

If the reviewing IRB is not willing to engage in a reliance agreement

You will proceed with the standard application submission that all SJSU investigators fill out, as described in our [User Guide for Initial Submissions](#). Only activities that SJSU investigators are involved in should be described in the submission, as our review does not extend to external investigators who are covered under their own IRB approval.

If the reviewing IRB is willing to engage in a reliance agreement

You must ask the reviewing IRB if they have any site-specific forms that they would like our office to fill out as well as if they prefer to use their own reliance agreement form, typically referred to as an Institutional Authorization Agreement (IAA). These additional documents can be added under the Other Institutions section of application, as noted later in this document.

If the reviewing IRB contacts our office first to engage in a reliance agreement

You are still responsible for filling out the application in Mentor, as described below, and attaching all required documents. Our office will move forward with signatures on a reliance agreement only after you submit the required documentation in IRB Mentor even if the reviewing IRB contacts our office and provides some of the documentation.

Required documentation

You are responsible for conducting the preliminary step of compiling the required documents outlined below. The IRB office will not gather documents on your behalf. You may need to contact the principal investigator at the reviewing institution to obtain some of the required documents.

Please have the following information and documents ready before you create a protocol in Mentor:

1. The name, title, and contact details of the reviewing IRB.
2. The name, title, and contact details of the signatory official for the reviewing institution.
3. The FWA number of the reviewing IRB.
4. The tracking number assigned to the protocol by the reviewing IRB.
5. A study approval letter from the reviewing IRB. If the external IRB is not willing to approve a protocol until a reliance agreement is established, you are responsible for submitting all other documents except for the approval notification. Please note this in the free-text message field on the create new protocol form.
6. The IRB application, outlining the methods and procedures of the study, which lists you as part of the study personnel.
7. Consent documents, if applicable.
8. Data instruments, if applicable.
9. Any site-specific forms required by the reviewing IRB and/or the reliance agreement form that the external IRB wishes to use. The reliance agreement form is typically referred to as an Institutional Authorization Agreement (IAA). If the reviewing IRB does not supply a form, we will provide our own.
10. Be prepared to explain how SJSU is involved in the study, whether subjects will be recruited on campus (if so, provide the recruitment materials), whether data will be collected on campus, and what kind of information will be shared with external team members.

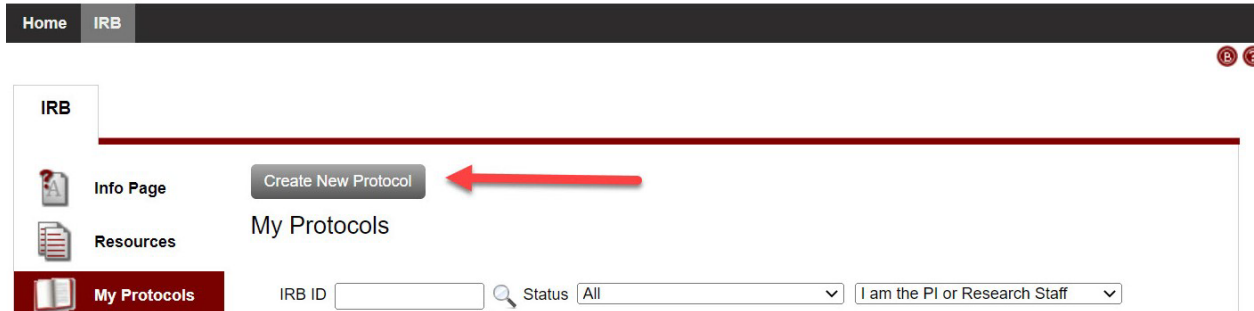
In addition to the above documentation, you may also need to obtain ancillary agreements depending on the type of data or materials shared between institutions. Agreements such as Data Use Agreements (DUAs) and Material Transfer Agreements (MTAs) are handled by the [SJSU Research Foundation](#). The IRB office may direct you to the Research Foundation when applicable, though the IRB reliance agreement process between institutions can be pursued separately from any additional agreements that may be required.

Identification of study personnel

Although you may be collaborator on a study where there is an external principal investigator, for the purpose of managing the SJSU IRB application in Mentor, you are identified as the PI. You can identify other external study personnel in the Study Personnel section of the application.

Steps for Initiating a Reliance Agreement Process in IRB Mentor

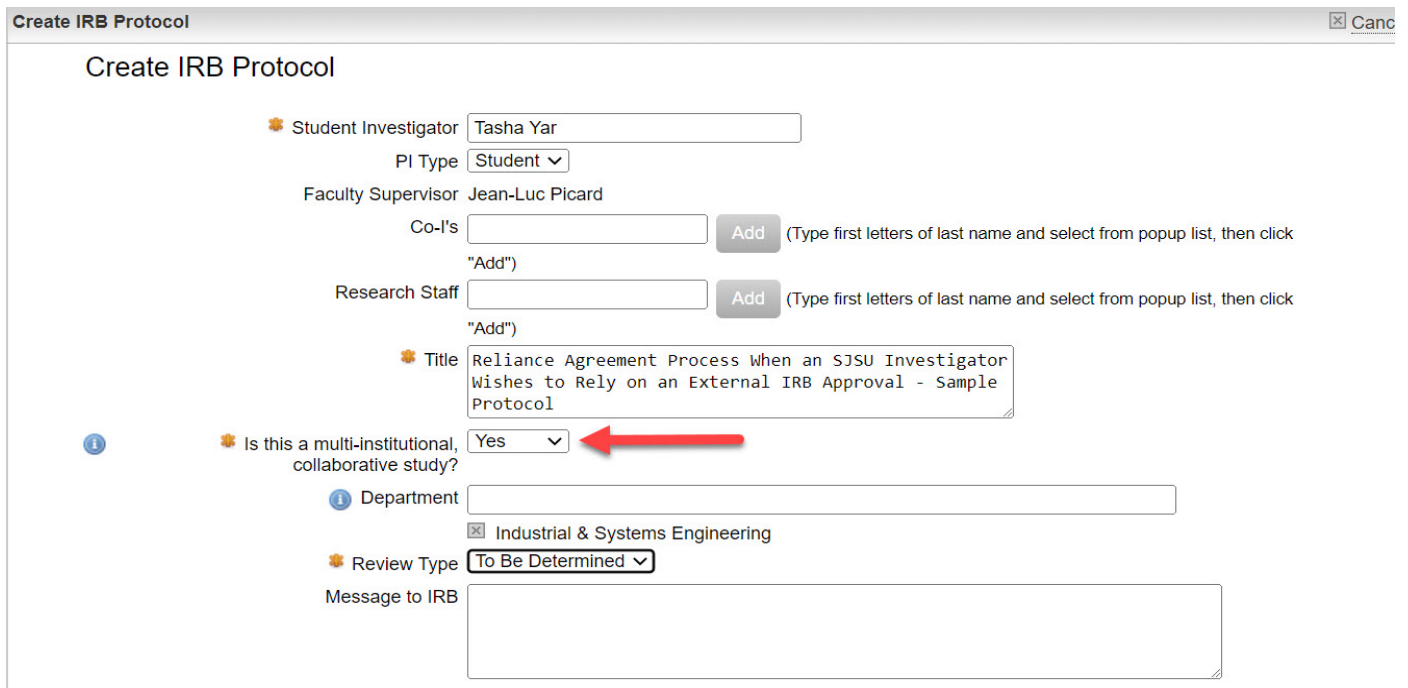
STEP 1: Create a new protocol by going to the My Protocols page, and clicking the Create New Protocol button at the top of the My Protocols page.



Fill out the information in subsequent the pop-up window about the study.

Make sure that you answer **Yes** to the question: “Is this a multi-institutional collaborative study?” Answering Yes will open the relevant section of the application where you will be providing the information that the SJSU IRB office needs in order to sign off on a reliance agreement.

Note that you cannot add external personnel in the Co-I and Research Staff fields on this form, as external personnel are not users in the Mentor system. You will be able to identify external personnel in the Study Personnel section of the application.



Click the save button to navigate to the protocol information page.

STEP 2: Fill out the application sections by clicking the Application Sections link on the protocol information page.

IRB

Application Sections [View Protocol Page](#)

Reliance Agreement Process When an SJSU Investigator Wishes to Rely on an External IRB Approval - Sample Protocol

PI: Tasha Yar
Faculty Supervisor: Jean-Luc Picard

Expand All Sections

» STUDY PERSONNEL Required Questions Unanswered: 2
» STUDY TIMING AND FUNDING Required Questions Unanswered: 2
» OTHER INSTITUTIONS Required Questions Unanswered: 3
» STUDY LOCATION Required Questions Unanswered: 1
» FINANCIAL CONFLICTS OF INTEREST Required Questions Unanswered: 1
» OTHER ISSUES - OPTIONAL FREE-TEXT SECTION

Under the Study Personnel Section

You are listed as the SJSU Principal Investigator even if the study has an external PI. Identify the external PI or Co-I(s) under the External Personnel question in this section. If there is an external PI, please also include their email address and phone number. You do not need to submit training certificates of external personnel unless the IRB office specifically requests it.

External Study Personnel

List the names, affiliations, and roles of any external study personnel.

Answer



If you have human subjects research training certificates for external personnel, please upload the document(s) here.

Answer:

Edit Answer


Under the Other Institutions Section

This section is where you will provide the details and documents related to the external IRB's review. Fill out the required, highlighted questions.

- Make sure to answer **Yes** to the question: "Besides SJSU, do any of the participating institutions listed have their own IRB committee?"

- Make sure to answer **No, an external IRB will be the IRB of record/reviewing IRB** to the question “Is the PI requesting that SJSU serve as the IRB of record/reviewing IRB for one or more of the participating institutions?”

* Besides SJSU, do any of the participating institutions listed have their own IRB committee?

Answer: Yes 
 No


List the names of the participating institutions which have their own IRB.

Starfleet Academy

Edit Answer

Add/Edit Answers

* Is the PI requesting that SJSU serve as the IRB of record/reviewing IRB for one or more of the participating institutions?

Answer: Yes
 No, each institution will conduct its own IRB review.
 No, an external IRB will be the IRB of record/reviewing IRB. 

In order to register an external IRB approval with the SJSU IRB, the SJSU investigator must:

1. Be named in the protocol application reviewed by the external IRB or in the approval letter.
2. Confirm with the reviewing IRB office that the reviewing IRB has a valid and active **federalwide assurance**.
3. Confirm with the reviewing IRB office that it is willing to engage in a reliance agreement with SJSU to allow us to rely on their review. The reliance agreement will be initiated by the SJSU IRB analyst upon evaluation of the below information and attachments.

Fill out the remaining questions related to SJSU’s Involvement in the study and the reviewing IRB’s information. Attach all relevant documents for each of the specific file upload questions.

NOTE: Although the file upload questions are not flagged as required, you must upload all requested files as outlined earlier in this document. No action will be taken by the SJSU IRB office if you do not submit the required documents.

* Provide information on whether and how SJSU will be involved as a campus in this multi-institutional, collaborative study (e.g., as a source of recruitment for subjects, as a source of secondary data, as a source of research personnel).

Answer:

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Reader Comments

Request Revisions

Edit Answer

* Provide the name of the external IRB that will be the IRB of record.

Reader Comments

Request Revisions

Answer Required

Answer


* Provide the name, title, email address, and phone number of the contact person in the external IRB office or the contact person who handles reliance agreements.

Reader Comments

Request Revisions

Answer Required

Answer

*  Provide the name and title of the Signatory or Institutional Official (IO) of the reviewing IRB.

Reader Comments

Request Revisions

Answer Required

Answer

*  Provide the Federalwide Assurance number (FWA) for the IRB of record.

Reader Comments

Request Revisions

Answer Required

Answer

Provide the tracking number assigned by the reviewing IRB to the study protocol.

Reader Comments

Request Revisions

Answer

External IRB Approval Letter Attachment

Use the Other External Documents Attachment file upload question to upload any documents the external IRB wishes our office to fill out, such as a site-specific local context form or the reliance agreement/IAA form that the reviewing IRB wishes to use. If no reliance agreement form is provided, we will use our own form which will be sent to the reviewing IRB with the SJSU Institutional Official's signature.

Other Application Sections

Fill out the remaining application sections – Study Timing and Funding, Study Location, and Financial Conflicts of Interest. The Optional Free Text Section may be used if the SJSU IRB Office requests further information that does not fit into any of the other sections.

STEP 3: Submit the protocol to the IRB Office.

Navigate to the protocol information page after you have completed filling out all application sections. In order to submit the protocol for review, you need to electronically sign an assurance. The button appears next to your name on the protocol information page.

The screenshot shows the IRB application interface. On the left is a navigation menu with options: Info Page, Resources, My Protocols (highlighted), (1) Pending Signatures, Protocol Reports, Research Coordinators, and CITI Training Certs. The main content area shows the protocol title: "Reliance Agreement Process When an SJSU Investigator Wishes to Rely on an External IRB Approval - Sample Protocol". There are buttons for "Edit", "Research Coordinators", and "Print / Zip". A yellow warning banner states: "Electronic Signature(s) Required of Tasha Yar: • New Protocol Signature Required as PI". Below this, it says "1 Signatures Missing" and a button "Submit Protocol to Faculty Supervisor" is disabled. A blue information banner reads: "Required signatures missing. Submit button will be enabled after all required signatures are present." The tracking status is "Tracking Status: No Status Recorded". At the bottom, a table lists protocol details:

Admin	
Protocol ID	49
Panel	No Panel Assigned
Student Investigator	Tasha Yar (CITI Certificates) Sign Electronically
PI Type	Student
Faculty Supervisor	Jean-Luc Picard (CITI Certificates) 02/19/2023
Faculty Supervisor Acceptance Status	Not Yet Accepted

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 office.

STEP 4: Await confirmation of finalized reliance agreement.

You will receive an initial confirmation message once the submission has been screened by the IRB Office that the reliance agreement is either underway or that the IRB Office requires more information. You will also be copied to any emails with the reviewing IRB as our office attempts to obtain the required signatures. Once the reliance agreement is signed by both institutions, it will be added to your protocol in IRB mentor by the SJSU IRB analyst, and you will receive a final

email confirmation that the reliance agreement has been established and that you may proceed with your part in the study.

Your involvement in study activities that include human subjects may not begin until our office has either sent you a confirmation that a fully executed reliance agreement has been established or you have received your own IRB approval via SJSU IRB review after submitting an application using our forms. If the reviewing external IRB does not respond to our request, it is your responsibility to follow-up with the external IRB or study PI or to submit your own protocol to the SJSU IRB. Due to the high volume of submissions we receive, our office is unable to engage in repeated follow-up requests in the event that the external IRB does not respond to our request for a reliance agreement or does not return a fully executed agreement.