



## **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 or what kind of data external team members will share with you.

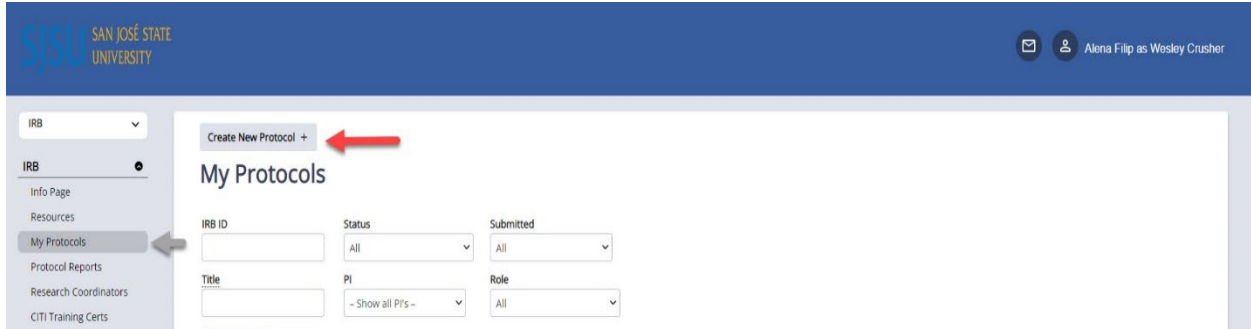
In addition to the above documentation, you may also need to obtain ancillary agreements depending on the type of data or materials shared between institutions. Agreements such as Data Use Agreements (DUAs) and Material Transfer Agreements (MTAs) are handled by the [SJSU Research Foundation](#). The 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.

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.**

Submit Protocol for Review Edit More (0) Tracking Status: No Status Recorded

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

24-118

Required Questions Not Answered  
1 Signature Missing

PI	Approval Status	Created	04/18/2024	Approved	Set Date
Jean-Luc Picard	To Be Determined	Received		Final Approval	Set Date
Staff , Professor - Faculty	To Be Determined	Date of Completion	Set Date	Date Closed	Set Date
	<a href="#">Withdraw Protocol from Review</a>				

[Application Sections](#)

Required Questions Unanswered: 9

Personnel

[Add/Edit personnel](#)

[View Protocol Page](#)

### Application Sections

## 24-118. Reliance Agreement Process When an SJSU Investigator Wishes to Rely on an External IRB - Sample Protocol

PI: Jean-Luc Picard

- Show Hidden Sections  
 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.

Note that you cannot add external personnel by clicking the Add Personnel button, 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.


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 in addition to their role. For all other external personnel, indicate their affiliation and role in the research. You do not need to submit training certificates of external personnel unless the IRB office specifically requests it.

Answer 



#### External Study Personnel

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

Answer 

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

Do not submit training certificates for SJSU personnel under this question - this question relates to external personnel.

*Note: SJSU does not provide access to its CITI training subscription to external investigators.*

## 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?"

Answer 


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

Yes 

No

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


Starfleet Academy

Answer 

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

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.**

Answer 

\* 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 Required

Answer 

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

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.

Answer Required

Answer 

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

Answer Required

Answer 

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

Answer Required

Answer 

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

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 the reviewing IRB wishes to use. If no reliance agreement form is provided, we will use our 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. To submit the protocol for review, you need to sign an assurance electronically. The button appears next to your name on the protocol information page.

**IRB**

- Info Page
- Resources
- My Protocols**
- (2) Pending Signatures
- Protocol Reports
- My Student Protocols
- Research Coordinators
- Reviewer
- CITI Training Certs

## Reliance Agreement Process When an SJSU Investigator Wishes to Rely on an External IRB - Sample Protocol 24-118

⚠️ Electronic Signature(s) Required of Jean-Luc Picard:  
New Protocol Signature Required as PI

⚠️ 1 Signature Missing

PI	Approval Status	Created	04/18/2024	Approved	Set Date
Jean-Luc Picard	To Be Determined	Received	Set Date	Final Approval	Set Date
Staff, Professor - Faculty	To Be Determined	Date of Completion	Set Date	Date Closed	Set Date

[Withdraw Protocol from Review](#)

[Application Sections](#)

Personnel

[Add/Edit personnel](#)

PI	Name	CITI Status	Signed Date	Date Added
	Jean-Luc Picard			04/18/2024

[Sign Electronically](#)

Protocol Fields

Submitted By	Department	College	Legacy Import
Jean-Luc Picard	Aerospace Engineering	College of Engineering	

If you are a student, submitting an electronic signature means that the protocol first gets routed to your faculty supervisor, who must review the submission and accept it before it gets delivered to the IRB office.

#### **STEP 4: Await confirmation of the finalized reliance agreement.**

You will receive an initial confirmation message once the IRB Office has screened the submission 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 both institutions sign the reliance agreement, 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.