



## **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 Institutional Section of Application** if the reviewing IRB is willing 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

## Steps for Initiating a Reliance Agreement Process in IRB Mentor

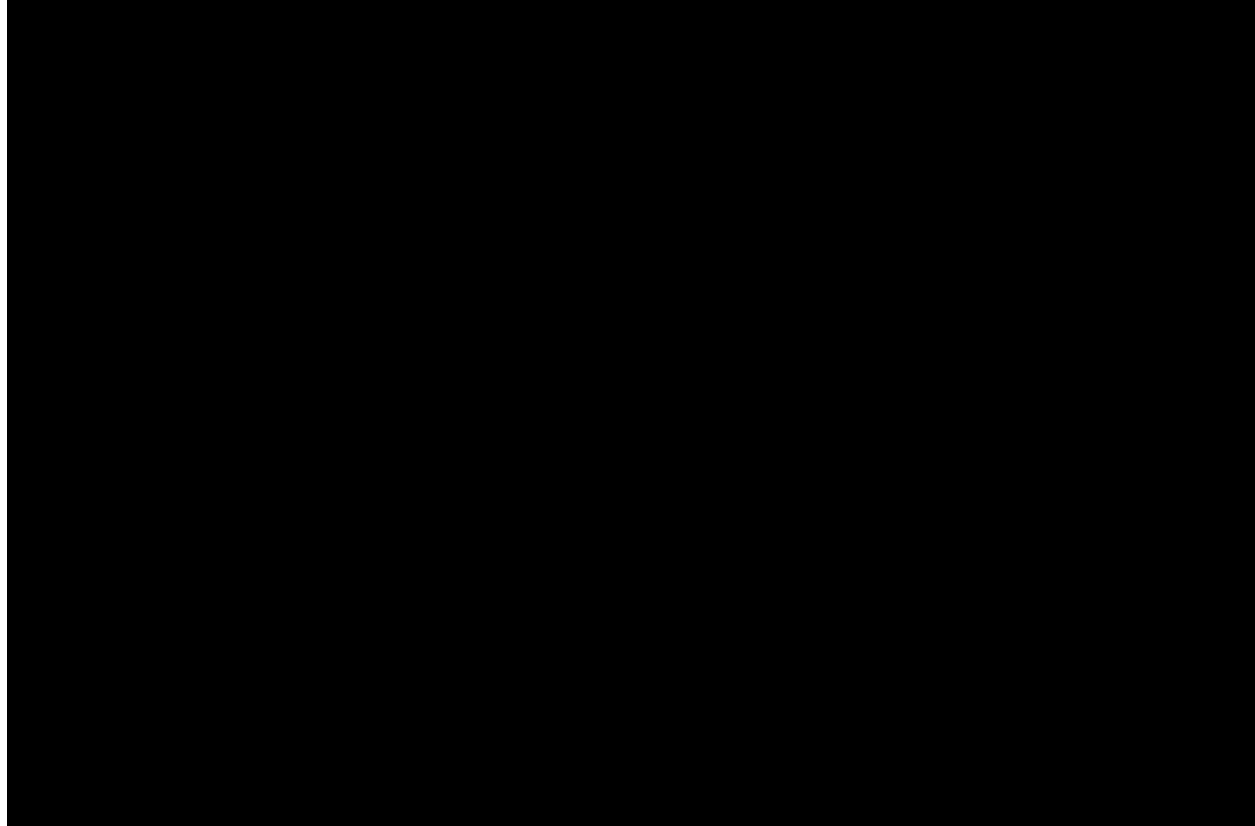
**STEP 2: Fill out the application sections by clicking the Application Sections link on the protocol information page.**

### **Under the Study Personnel Section**

You are listed as the SJSU

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.

## **Under the Other Institutions Section**



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.

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.

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

attached to your protocol and included in the IRB file for review. If you have any questions, please contact the IRB Office at (616) 487-1111.