

Joining an Existing Study with Schulman IRB

1. Complete ePTF and notify ORA of intention to join a study approved by Schulman IRB.
2. Follow the standard process for creating a new study record in JeffTrial.
3. In the JeffTrial Portal, at the “Create an IRB Application” dropdown menu, select “Schulman” and upload an OHR-1. (Be sure to check off “Schulman IRB” at top of OHR-1.) This is the only document you will upload in the Portal. There is no paper submission.
4. If OHR authorizes the submission to Schulman IRB, OHR will issue to Schulman the Authorization Form for the specific study. This will help Schulman prepare and keep an eye out for your submission.
5. Submitting to Schulman IRB:
 - a. Register/Login to Schulman eTools at [eTools](#)
 - b. Choose eSubmission to submit to Schulman.
 - c. Then choose “Initial Submission: eSubmission 2.0 SmartForm”

Initial Submission: eSubmission™ 2.0 SmartForm

Submit or retrieve new study and new site initial submission forms using our intuitive SmartForms.

- d. To submit a new form, scroll to the middle of the menu on the left side and click “Initial Submission” in the “Start New Form” section.



- e. The SmartForm will ask 4 questions to help customize the submission questions for TJU researchers. Select your responses as indicated in the screenshot below. If you are submitting a left-over specimen study, change question #4 to yes.

[Start](#) > [New Submission Form](#)

In order to direct you to the correct Initial Submission Form, please answer a few questions:

1. I am a:

2. Which do you wish to submit?

3. Please select a statement from the following list:

4. Does your site/study involve only the testing of an in vitro diagnostic device using leftover specimens that are not individually identifiable?

- f. Complete the form, upload attachments and submit.
- g. You will receive an automated email notification confirming Schulman has successfully received your submission.
- h. Schulman's administrative staff will be in touch via email with any questions or requests for clarification (as applicable).

Notes on using Schulman's eSubmission SmartForm:

- The Form Requirements page includes a link to preview the entire submission form. Please note that this is provided for reference only, and the preview PDF is not a valid submission form.

3. Preview entire form content before starting the form:

 [Research Site Form Content Preview](#)

- If you need to save your incomplete form and come back to it later, click save prior to exiting form. Go to "Started Forms" in the "My Forms" section to access your saved form and return to where you left off with your submission.

My Forms

- ▶ Initial Submission Templates (0)
- ▶ Started Forms (20)
- ▶ Submitted Forms (0)

Additional Information and Tips

Maria Stivers is your primary point of contact.

mstivers@sairb.com
513-794-5743

Ashley Carpenter is another great contact.

acarpenter@sairb.com
513-761-4100

1. If PI/Sub-I is working with Schulman for the first time, please submit a CV signed and dated within the last two years.
2. During the IRB review process, you may receive emails from different Schulman staff members who are working on your submission.
3. Schulman can insert your TJU-specific ICF language, which has been approved by OHR and is already on file with Schulman. You may also submit the ICF with TJU-specific language already inserted.
4. You can develop a template in eSubmission to use with multiple Schulman submissions.
5. You can share documents with other users via eSubmission.
6. SiteAccess is Schulman's tracking and approval document access system. Please contact Maria or Ashley if you have any questions about using SiteAccess.
7. You may receive an automated email indicating there are study-related documents to review and revise on SiteAccess.
8. Once your submission has been approved by the IRB, you will receive an email notification informing you of the approval. The email will include a direct link to access the approval documents. You can also access your approval documents by signing in to Schulman's [eTools](#) and choosing "SiteAccess."