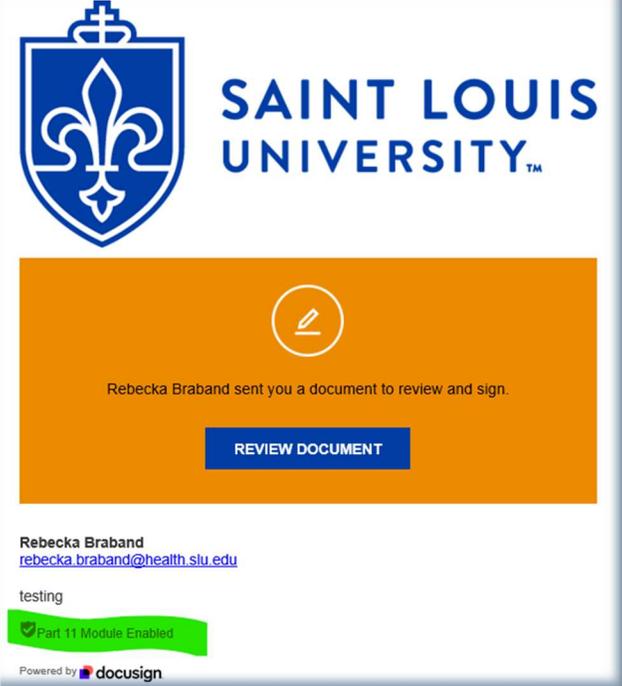
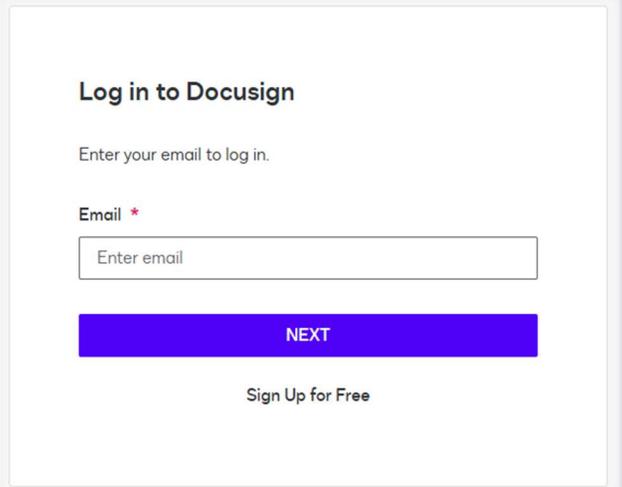


## **DocuSign Part 11 Fundamentals Training Guide for SLU Research Services Staff**

21 CFR Part 11 is an FDA regulation that relates to research. SLU School of Medicine has a separate instance that has additional policies and regulations in place to meet the 21 CFR Part 11 Guidelines.

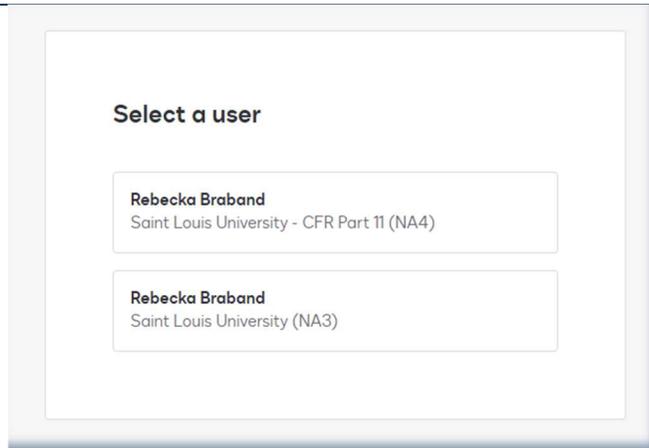
Signing a 21 CFR Part 11 compliant document is a slightly different process than signing a normal envelope. Please see the steps outlined below.

<b>Step</b>	<b>Screenshot</b>
<p>1. When a user receives a Part 11 compliant document, they will need to have a DocuSign account to sign it. Upon receiving a Part 11 envelope, the user(s) will know that it requires authentication with DocuSign because it states that the Part 11 module is enabled.</p>	
<p>2. After selecting “Review Document”, signers will be routed to the DocuSign login page. If the signer does not already have a DocuSign account, they will be prompted to create one and set up a password.</p>	

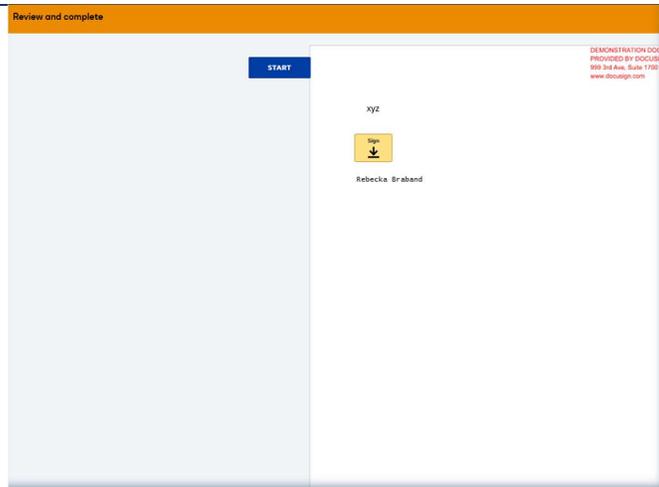
3. SLU users should utilize SSO to sign into DocuSign (if the tile is not visible on your “SLU My Apps Dashboard”, you will need to [request an account](#) with the CTO).

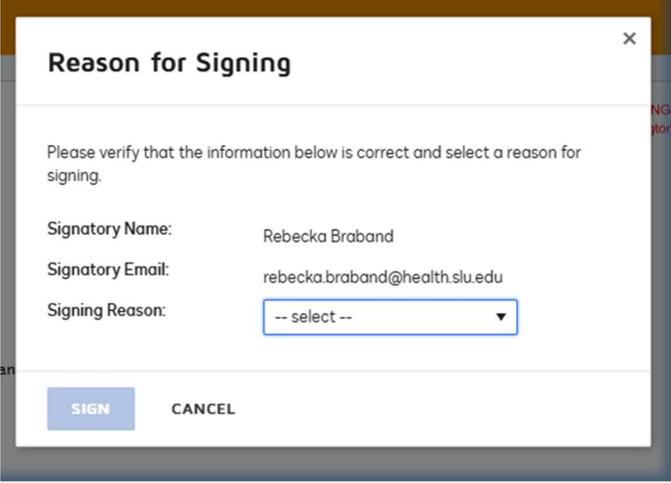
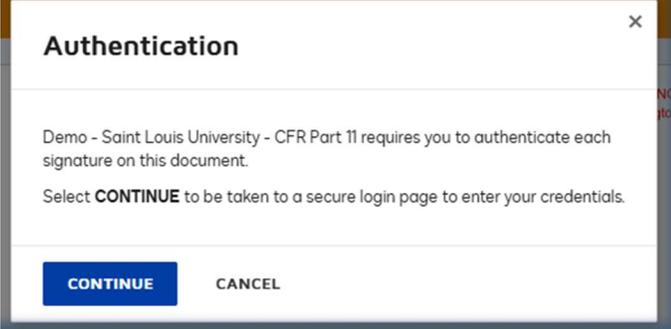


4. You will then be prompted to select which instance you would like to sign into. Choose the CFR Part 11 instance.



5. Once the signer has clicked on the signing field, shown here, they will be directed to the following screen to select their reason for signing.



<p>6. In the dropdown, select a reason for signing. In most cases, the signer will select “I approve this document” and click sign.</p>	
<p>7. This pop-up should appear. The signer will click “continue” and then be redirected back to the login page where they will have to authenticate again. They will also need to re-authenticate for each initials field.</p>	
<p>CFR Part 11 signature with signing reason, date and timestamp.</p>	

Video on signing a 21 CFR Part 11 DocuSign Envelope:

<https://support.docusign.com/en/videos/Sign-a-CFR-Part-11>