## 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.

Step	Screenshot	
1. When a user receives compliant document need to have a Docus account to sign it. Up receiving a Part 11 en the user(s) will know	a Part 11 they will ign on relope, hat it n with	
DocuSign because it that the Part 11 modu enabled.	Rebecka Braband rebecka Braband	
2. After selecting "Revie Document", signers w routed to the DocuSig page. If the signer doe already have a DocuS account, they will be to create one and set password.	V ill be n login s not gn prompted up a Log in to Docusign Enter your email to log in. Email * Inter email NEXT Sign Up for Free	

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 <u>request an account</u> with the CTO).	DocuSign DocuSign
4. You will then be prompted to select which instance you would like to sign into. Choose the CFR Part 11 instance.	Select a user         Rebecka Braband         Saint Louis University - CFR Part 11 (NA4)         Rebecka Braband         Saint Louis University (NA3)
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.	Review and complete  STAT  STAT STAT STAT  STAT

<ol> <li>In the dropdown, select a reason for signing. In most cases, the signer will select "I approve this document" and click sign.</li> </ol>	Reason for Signing       NG         Please verify that the information below is correct and select a reason for signing.       NG         Signatory Name:       Rebecka Braband         Signatory Email:       rebecka.braband@health.slu.edu         Signing Reason:       select         An
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.	Authentication Demo - Saint Louis University - CFR Part 11 requires you to authenticate each signature on this document. Select CONTINUE to be taken to a secure login page to enter your credentials. CONTINUE CANCEL
CFR Part 11 signature with signing reason, date and timestamp.	Signed by: Kurcke Evaluated. Signing Reason: Laprove this document Signing Time: 124/2024   12:58:40 PM PST B197BE84C08240E0B18F376D11569412

Video on signing a 21 CFR Part 11 DocuSign Envelope: https://support.docusign.com/en/videos/Sign-a-CFR-Part-11