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DocuSign: How to Sign a DocuSign Part 11 Document

When someone sends you a DocuSign document for your electronic signature, you first receive an email from DocuSign sent on behalf of the sender. For FDA regulated studies, you will receive an email that has the notation **Part 11 Module Enabled** (as shown in the following example), then there are some special requirements when signing the documents.
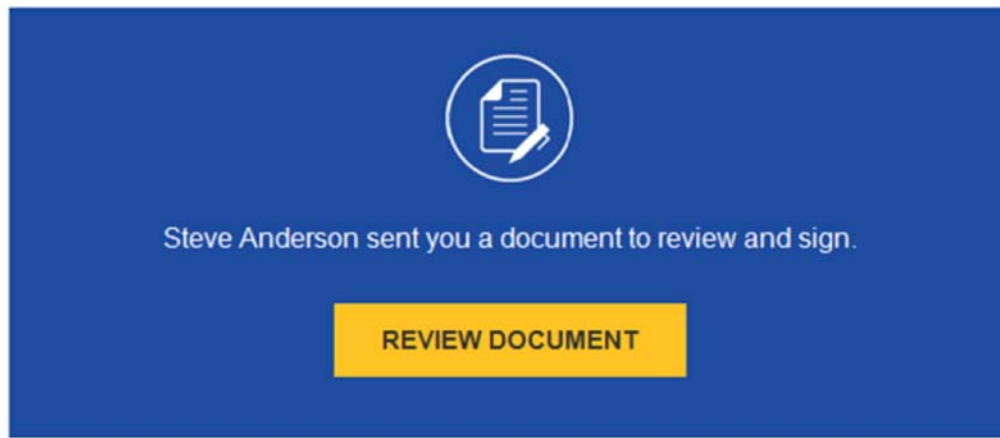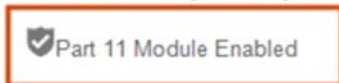
Note: With the CFR Part 11 method, the signer is prompted to authenticate upon opening the envelope and upon finishing the signing session.

1. **Review the DocuSign email**: After opening the email, click **REVIEW DOCUMENT** to begin the signing process.

2. **Signer Authentication:** You might be asked to verify your identity before signing using a passcode

   Follow the on-screen instructions to complete this step. The following example shows authentication through an access code received by phone or SMS:

Please enter the access code to view the document

Paul Allen
paul.allen_tally_demo

The sender has requested you enter a secret access code prior to reviewing the document. You should have received an access code in a separate communication. Please enter the code and validate it in order to proceed to viewing the document.

Access Code

[••••••••••]   VALIDATE   I NEVER RECEIVED AN ACCESS CODE

Show Text

3. **Agree to sign electronically**: Review the disclosure and select the check box for agreeing to use Electronic Records and Signatures, then select **CONTINUE** to begin the signing process.

Important!   To view and sign the documents, you must agree to conduct business electronically.
Note: To view additional options, click **OTHER ACTIONS**.

4. **Start the signing process**: Select the **Next Page** tag on the left to begin the signing process. As you are scrolling through the document, please take action on the tags requiring your action. Please enter any required information. Select the **SIGN** tag.
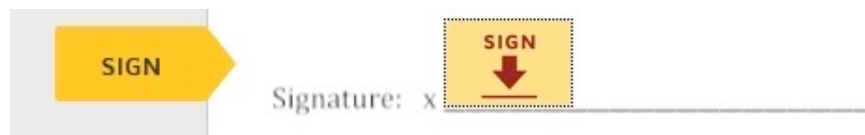
You may be asked to **Adopt Your Signature**. Verify that your name and initials are correct. If not, change them as needed. Select **ADOPT AND SIGN** to adopt and save your signature information and return to the document.

5. **Confirm signing**: When you finish clicking all signature tags in the document, confirm signing by selecting **FINISH**.

6. Select a **Signing Reason** from the list, then click **SIGN** to continue.
   You cannot continue until the signing reason is selected.

7. After adding a signing reason, you are asked to authenticate your signature by entering your DocuSign password on a secure login page. Click **CONTINUE** and enter your password
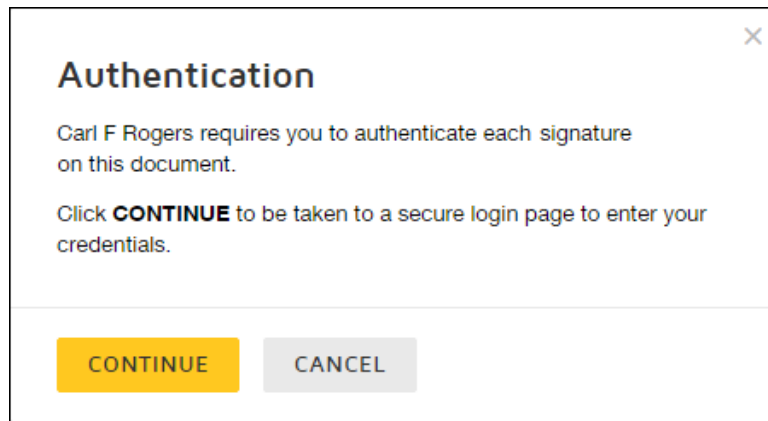
Note: The password authentication is only required once per document. You have five chances to correctly enter your password. If the correct password is not entered, you are locked out of DocuSign.

Each time you select a signature or initials field, the process of selecting a reason and authenticating is repeated.

8. When you have finished adding all information and signatures to the documents, you can review the documents and then select **FINISH** at the bottom of the browser window to complete signing.

A message appears stating that you have completed your document. You can now download a PDF copy or print a copy of the document. The sender receives an email with the signed document attached, and the signed document appears in their DocuSign account.