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# Electronic signatures in Adobe Sign & 21 CFR Part 11 Compliance

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# Objectives

After this presentation you should better understand:

- When to use Adobe Sign for electronic signatures in clinical research
- What are the 21 CFR Part 11 requirements
- How Adobe Sign meets these requirements with the new Bio-Pharma settings
- How the new settings impact sending a document for signature
- How the new settings impact signing a document

# Electronic Signatures

- Health Canada (GUI-100) states “Electronic signatures are considered acceptable, only if the electronic system is fully validated. The proper controls should be in place to assure that the signature belongs to the user who applied it. Limited access or passwords should be used accordingly.”
- Health Canada does not have its own regulation on electronic signatures, but often references 21 CFR Part 11 standards.
- The University of Calgary expects all **regulated** clinical trials (Health Canada and/or FDA) that choose to use electronic signatures, to utilize 21 CFR Part 11 compliant electronic signatures.
- All clinical researchers who access the University of Calgary Adobe Sign will be provided with the 21 CFR Part 11 version.



# Requesting Adobe Sign

- Request form for Adobe Sign is now available on the [Service Now](#)

The screenshot displays the University of Calgary Information Technologies portal. The header includes the university logo, the text 'Information Technologies', and a search bar. A navigation menu contains links for Home, My Stuff, IT Services, Knowledge Base, News & Updates, Contact & Help, and a Cart icon. Below the header is a search bar for IT services. A left sidebar lists various service categories, with 'Applications and software' selected and highlighted in red. The main content area is titled 'Applications and software' and includes a search bar and a filter section. The filter section shows 'All (25)' selected, along with 'Available for students (5)' and 'Available for faculty/staff (25)'. A grid of service cards is displayed, with the 'Adobe Sign Enterprise' card highlighted in yellow. The other cards include 'Administrative Virtual Private Network (VPN)', 'ArcGIS', 'Citrix', 'Custom Domain validation request', and 'Desire2Learn (D2L) for instructors'.

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Information Technologies

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Services

**Applications and software**

Audio visual (ComMedia)

Collaboration, storage and file shares

Desktop computing

Email and calendar

IT onboarding

IT services for IT

Network and telecom

Printing

Reporting and data analytics

Applications and software

Browse IT Services

Installation, acquisition or renewal of applications and software.

Filter by: **All (25)** • Available for students (5) • Available for faculty/staff (25)

**Administrative Virtual Private Network (VPN)**  
Request access to Admin VPN

**Adobe Sign Enterprise**  
Request for software to collect electronically signed documents

**ArcGIS**  
Request access to ArcGIS products and services.

**Citrix**  
Request for access to a citrix environment

**Custom Domain validation request**  
Request to add a Domain to enable the issuing of SSL certificates

**Desire2Learn (D2L) for instructors**  
D2L (also referred to as Brightspace) is the University's learning management system

# When to use Adobe Sign for clinical research

- ✓ Adobe sign can be used for **study level documents** (protocol signature page, Health Canada submissions, delegation logs, etc)
  
- ✗ Adobe sign should NOT be used for **patient level documents** (labs, consent forms, etc)
  - Health information cannot be shared with Adobe Sign

If your study team is interested in electronic consent, this can be accomplished with the validated instance of REDCap (CRU)

# What is 21 CFR Part 11 Compliance?

21 CFR Part 11 regulatory requirements for **Subpart B – Electronics Records** are:

**1. Sec. 11.10 Controls for closed systems**

- System access is controlled by University of Calgary, who has established processes and procedures to provide access to Adobe Sign, as well as manage electronic records.

**2. Sec. 11.30 Controls for open systems**

- N/A (University of Calgary manages system)

**3. Sec. 11.50 Signature manifestations**

- Adobe Sign signature includes the name of the signer, date and time, as well as reason for the signing.

**4. Sec. 11.70 Signature/record linking**

- Audit report captures the signing history for each document.

**5. Sec. 11.200 Electronic signature components and controls**

- University of Calgary uses a two-step process to authenticate a Signer. The Signer's email address and one-time verification code (OTP) is sent to the Signer email inbox.

**6. Sec. 11.300 Controls for identification codes/passwords**

- University of Calgary sends the one-time verification code (OTP) to the Signer email inbox. Verification code must be inputted into Adobe Sign pop up window prior to accessing the document.

# How to prepare and sign a document with the new settings?

Adopted from University of Calgary  
Adobe Sign 21 CFR Part 11  
Compliance Document Job Aid



## Step 1:

1. Launch [Adobe Acrobat Sign Login — Sign in to your e-signature account \(echosign.com\)](https://secure.na3.echosign.com/public/login) OR manually type below URL address:  
<https://secure.na3.echosign.com/public/login>

2. Sign in using your UCID network id and password. The **Adobe Sign Home** page will display.



Sign In To Your Account

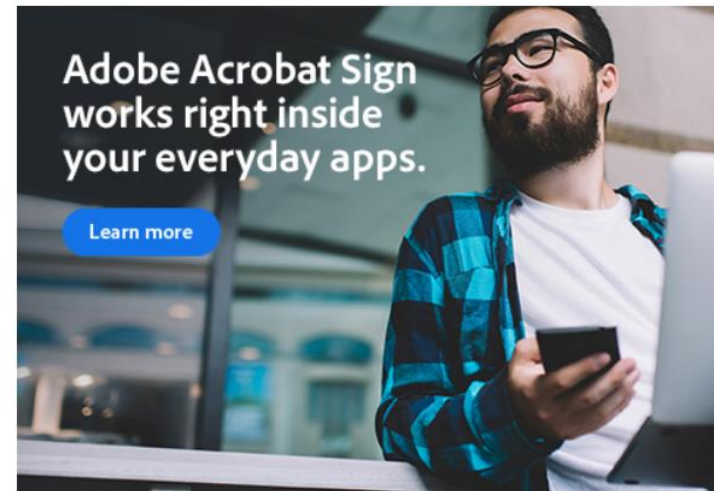
Email:

Password:

Remember Me

[Sign In](#)

[I forgot my password](#)







## Step 2: Click “Send” to prepare an envelope for signature

UNIVERSITY OF CALGARY | Powered by Adobe Acrobat Sign

Home **Send** Manage Workflows Reports Account

Welcome, [blurred name]

0 IN PROGRESS | 0 WAITING FOR YOU | EVENTS AND ALERTS

### Send a document for signature

Request e-signatures on a new agreement, or start from your library of templates and workflows.

[Request e-signatures](#) [Start from library](#)

#### Do more with Acrobat Sign

- Create a reusable template
- Manage and track all agreements
- Enhance your account
- Create a reusable workflow

Send and manage signatures on the go with our mobile app. [Learn More](#)

### Step 3:

Select your department group name from the “Send From” field, click the drop down box



UNIVERSITY OF CALGARY | Powered by Adobe Acrobat Sign | Home | Send | Manage | Workflows | Reports | Account

### Get documents signed

Send an agreement to others for e-signing, approval, or other processing. [Switch to new experience](#)

Send from: **Default Group (Primary Group)** ?

**Recipients\***

Complete In Order  Complete

1	Enter recipient
	Default Group (Primary Group) CCCR CSM Legal - Part 11 Compliance

[Add Me](#) | [Add Recipient Group](#) ?

[Show CC](#)

**Message\***

Agreement Name

Please review and complete this document.

**Files\*** [Add Files](#)

Drag & Drop Files Here

Preview & Add Signature Fields

[Next](#)

**Options** ?

Completion Deadline


Recipients' Language

English: US



## Step 4:

Confirm “*Send From*” field displays the correct department group name before proceeding.




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**Adobe**  
Acrobat Sign

Home Send Manage Workflows Reports Account

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Get documents signed  
Send an agreement to others for e-signing, approval, or other processing.

Send from: **CCCR**  



## Step 5:

### Recipients Section – add Signer’s email address.






Get documents signed [Switch to new experience](#)

Send an agreement to others for e-signing, approval, or other processing.

Send from: **CCCR** ▼ ?

Recipients\*

Complete In Order  Complete In Any Order  [Add Me](#) | [Add Recipient Group](#) | ?


1	 ▼ <input type="text"/>	 ▼ Email OTP	 
2	 ▼ Enter recipient email		

1. Add Recipient email addresses and attached documents for signature.
2. Click “Next” to proceed to the next screen.
3. Assign the Signer’s “Signature” field and the Signer’s “Date” field for each signer.
4. Click “Send” to send the envelope to the signers.



## Step 6:

**Signer Receives Envelope – Signer will receive an email advising there is a document waiting for their signature.**



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██████████ requests your signature on  
**Test - QRG**

**Review and sign**

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Please review and complete Test - QRG.

██████████

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**Don't forward this email:** If you don't want to sign, you can **delegate** to someone else.


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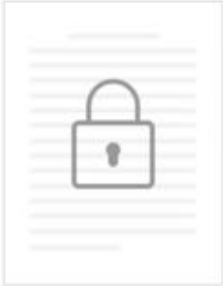
## Step 7:

One Time Verification Code – Signer will click on “*Review and sign*” link and the following screen will display.



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Powered by  
Adobe  
Acrobat Sign



This document requires a one time verification code

After clicking the "Send Code" button you will receive an email sent to [ldforbes@telus.net](mailto:ldforbes@telus.net) with verification code that you must enter to view the document.

If this is not your email, please contact [Laura Forbes](#)


[Send Code](#)





## Step 8

Verification Code Email – Verification code email sent to Signer’s email inbox from Adobe Sign. Signer will input this code into the Verification Code field.

Verification code requested to view agreement: Test - QRG

 Adobe Sign  
To [Redacted]

 Click here to download pictures. To help protect your privacy, Outlook prevented automatic download of some pictures in this message.



Verification code to view Test - QRG

**751597**

Code will expire in 10 mins

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Please return to Acrobat Sign to verify your code and view **Test - QRG** sent by [Redacted]

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Authorized and will open document



## Step 9

### Input Verification Code

1. Signer inputs verification code “751597” and clicks the “Verify” button

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This document requires a one time verification code

Please confirm your identity by entering verification code sent to the following email ldforbes@telus.net

If you encounter any issue receiving the verification code, please reach out to [Laura Forbes](#)

Verification Code

Enter Verification Code ...

Resend Code (00:54)

2. System will verify the verification code and display the document for signature.

3. Signer will sign the document and click “**Finish**”.

**Note:** The verification code will remain active for 10 minutes. After 10 minutes, the Signer will have to click the “**Resend Code**” button (located under the Verification Code field) to generate a new verification code. Signer has five (5) attempts to regenerate a verification code before the link will expire. Once the verification code link expires, the envelope is cancelled and a new envelope will need to be created.



# Contacts

For questions related to Adobe eSignatures please contact

[jldobry@ucalgary.ca](mailto:jldobry@ucalgary.ca)

For questions related to Clinical Trials please contact CCCR

[cccr@ucalgary.ca](mailto:cccr@ucalgary.ca)

# Thank You