UT Health San Antonio
Office of the Vice President for Research

Complion Access Guide

Welcome to the Complion Community! Complion is the best-in-class platform that ensures that Clinical Teams follow standard processes and procedures and provides transparency into eRegulatory compliance. Complion has been independently validated for 21 CFR Part 11 compliance as well as meeting HIPAA requirements for the storage of PHI.

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What Is Complion?

The software solution provides greater visibility and efficiency over traditional paper binders. Complion is robust enough to manage the documentation for hundreds of trials across multiple locations – all from any device with an internet connection. With Complion, you will be able to:

- Access eBinders on-site or from a remote location
- Find, view, and download what you need without asking for specific eRegulatory documents
- Review and verify source documents* without relying on over-the-shoulder video calls

Accessing Complion

Any binder you have been granted access to will appear on your Home Screen when you first login to Complion. Access Complion by visiting the website: app.complion.com

CRA Permissions

Access permissions for a study binder are determined by each organization and may vary by study. Generally, CRAs are granted the following access to all essential regulatory documents:

- View PDF and associated metadata
- Download PDF -- including signature and audit history
- View and download original file

Remote source access permission is limited to **View Only.*

Site / Regulatory Binder Organization and Navigation

The Binder Table of Contents is organized to reflect all essential documents. There are two ways to easily navigate the binder.

Side Menu

The menu along the side mirrors what traditionally served as “tabs” in paper binders. Each folder level shows ALL documents in its subfolders. Clicking on each subfolder will filter your document view.

Searching for Documents

A search bar appears at the top of each binder. This searches all document information including the type of document (e.g., use 1572 to find the FDA 1572) as well as its metadata (e.g., use a study team member’s name to find all of his/her credentials).

Search Term Glossary

You can also use the search bar to quickly locate what you need. Below is a list of some common search terms used to locate key documents.

Search Terms	Key Documents
1572	FDA 1572
Adverse	Serious Adverse Event, Adverse Event (source binder only)
Investigator Brochure	Investigator Brochure, Package Insert, Addendum Letter, Summary of Changes
Central Lab	Lab Director CV, Lab Director Medical License, Reference or Normal Ranges, Guidelines, Manual, CAP, CLIA, COLA
Correspondence	All Correspondence Types
CRF or Case Report Form	Case Report Form -- Blank, Case Report Form Template
Delegation	Delegation of Authority, Delegation of Responsibility
Deviation	Protocol Deviation Log (Source Binder)
DSMB	Agenda, Letter, Minutes, Submission
EDC	Training, Manual
Financial Disclosure or FDF	Financial Disclosure Form
Informed Consent or ICF	Informed Consent Form, Informed Consent Certificate of Translation
IRB	Submission, Approval, Acknowledgement,

	Roster, FWA
License	Lab Director Medical License, Medical License, Other
Local Lab	Lab Director CV, Lab Director Medical License, Reference or Normal Ranges, Guidelines, Manual, CAP, CLIA, COLA
Package	Package Insert
Signature Page	Protocol Signature Page, Investigator Brochure Signature Page

Download + Document Collection Instructions

The Complion platform uses intuitive technology making it easy to find and download the documents you need.

Once you have navigated to the desired document, click the “File Actions” button to download the PDF.

For further instructions, please use this brief online tutorial. [link here]

https://training.complion.com/modules/role-specific/investigator-with-certificate/story.html

Remote Source Access*

CROs or External Monitors will have remote access to source documents for review and verification. These documents are kept in a SEPARATE subject’s binder with completed eCRFs rather than with the Regulatory documents.

Access to source documents is limited to “View” permissions only. CROs and External Monitors will not be able to print or download these documents from Complion.

21 CFR Part 11 Validation

Complion publishes its own 21 CFR Part 11 validation documentation. UT Health San Antonio finds these validation processes to be acceptable.

Every Complion client has a binder for storing documents related to 21 CFR Part 11. To view these documents email your department administrator or vpr-it@uthscsa.edu to request access to the Validation Binder.

For additional support, please contact support@complion.com.

Technical Whitelisting and Safe Emails

Your internal firewalls and browser permissions may impede your ability to access the system. If this occurs, please contact us at support@complion.com.

You may also contact vpr-it@uthscsa.edu and report the following list of URLs that should be identified as safe or “whitelisted”.

app.complion.com	The main Complion application. This is the URL you go to in your browser.

training.complion.com	Complion Training Center
complion.zendesk.com	Complion Support Center

Please note: *Your VPN may prohibit your ability to access the system. It would be better to logout out of the VPN prior to accessing Complion*.

The following is a list of the email addresses that are from the Complion platform:

no-reply@complion.com	Used for registration
noreply@app.complion.com	Used for correspondence related notifications
support@complion.com	Used to submit and received responses for support tickets

General Support

Helpful tips, articles, and videos can be found in the Support Center located on the upper right-hand side of the screen. *For general questions or inquiries feel free to contact support at* support@complion.com.

FAQs

- **How do I get access to a Study Binder?**

  To get access to a Complion electronic binder, email vpr-it@uthscsa.edu

- **How do I reset my password?**

  To reset your password, go to the Login screen and enter your email address. When prompted for your password, click “Forgot Password?” You will be prompted to send a password reset email where you can create a new password.

  If the issue persists, contact support@complion.com.