RDCRN

eRegulatory Guidelines

Overview
Provides guidance for management and usage of the Complion eRegulatory Platform.

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Contents

Purpose – The reason for adopting an eRegulatory platform

The Complion eRegulatory platform has been adopted for the Rare Disease Clinical Research (RDCRN) to provide a singular repository for regulatory documentation in response to the growing network of RDCRN facilities across large geographic areas.

Objectives – Actions to achieve the purpose

Regulatory Compliance

Enhanced Audit Preparedness

1. A single, standard, and clearly defined storage system demonstrates RDCRN's commitment to being a collection of well-organized research entities.
2. Clear audit trails of all documentation are included within the system
3. Improves manager tracking of Principal Investigator (PI) oversight, regulatory processes, and incomplete study documentation

Improved Documentation of Principal Investigator (PI) Oversight

1. PIs are able to access regulatory binders and study documentation remotely promoting more frequent and timely access and action
2. FDA-compliant eSignatures are supported by the system and facilitate more timely documentation of oversight for investigators

Users

The roles for users within the system are defined below. They define the permissions that a user has for account setup as well as interactions with binders and documents.

Users are governed by the broadest access they have in the system if they have multiple roles. Study roles cannot be defined on a per study level. Roles have been standardized to align with study responsibilities.

Adding New Internal Users to Complion

All study team members should have access to Complion so that they can complete the necessary documentation needed for a clinical trial. **Admin access is required to create an internal user.**

> **Required information to add a user:**
> Legal Full Name
> Email address
> EPPN (EduPersonPrincipalName) – for SSO setup

1) Click on the Admin key

2) Click the "Create User" button in the upper left

3) Enter account information:

- **EMAIL ADDRESS:** This should be the email from which the new user wishes to receive Complion email correspondence.
- **DISPLAY NAME**: Last Name, First Name, Credentials – this is what will appear as the name of record on audit trails.
- **FIRST NAME:** First name of new user
- **LAST NAME**: Last name of new user
- **GROUPS:** You will need to select at least three groups in order to add a user to Complion: All Users, Consortia and the role assigned to the individual in the system. **Note:** to select more than one role, hold the "CTRL" key
- **LOGIN METHOD:** Users must use their institution's Single Sign On (SSO) configuration.
    - Select "Cincinnati Children's (saml)"
    - Enter the EPPN for the user

4) Click the "Create User" button

5) The new user will be sent a Welcome Email, which will prompt them to log in for the first time. First time login must only occur from the link in the email.

- If you need to RESET a user account:
    - Click on the Admin key

- o Select the Users tab
- o Find the User (use the search feature or scroll through the list)
- o Click on the Quick User Actions Menu on the right of the user's record
- o Choose Account Reset (this will send the user another registration email)

User Roles

Administrator
Administrators have the most access to the Complion System. The number of Administrators is limited and this level of access is determined by consortium leads in collaboration with Complion and the DMCC. May serve as the point of contact for troubleshooting and system access.

Category	Permission	Allowability (Yes/No)
Manage Documents	View PDF	Yes
	Upload Documents	Yes
	View Unfiled Documents	Yes
	File Unfiled Documents	Yes
	Change Document Type	Yes
	Change Document Attributes	Yes
Download Documents	Download PDF	Yes
	Download PDF w/ Signatures and History	Yes
	Download Original Source File	Yes
Tasks and Signatures	Send Document For Signature	Yes
	Sign Documents without Task	Yes
	Manage Tasks	Yes
Binder Management	Edit Binder Details	Yes
	Edit Binder Setup	Yes
	Add External User to Binder	Yes
	Add Internal User to Binder	Yes
Institutional Admin Permissions	Institutional Admin (Create New Users, Assign Users to Group)	Yes
	Create Binder	Yes
	Edit Existing Users	Yes
	Edit Drop Down Menus	Yes

Regulatory

Regulatory has the same permissions as an Administrator except for Institutional Admin Permissions (e.g. creating users, opening binders). However, Regulatory has permission to make changes to the study setup – this allows them to manage assigned researchers, equipment, storage areas, etc. that belong to the study binder.

Category	Permission	Allowability (Yes/No)
Manage Documents	View PDF	Yes
	Upload Documents	Yes
	View Unfiled Documents	Yes
	File Unfiled Documents	Yes
	Change Document Type	Yes
	Change Document Attributes	Yes
Download Documents	Download PDF	Yes
	Download PDF w/ Signatures and History	Yes
	Download Original Source File	Yes
Tasks and Signatures	Send Document For Signature	Yes
	Sign Documents without Task	Yes
	Manage Tasks	Yes
Binder Management	Edit Binder Details	Yes
	Edit Binder Setup	Yes
	Add External User to Binder	Yes
	Add Internal User to Binder	Yes
Institutional Admin Permissions	Institutional Admin (Create New Users, Assign Users to Group)	No
	Create Binder	No
	Edit Existing Users	No
	Edit Drop Down Menus	No

Investigator

Investigators may view, download and complete tasks only.

Category	Permission	Allowability (Yes/No)
Manage Documents	View PDF	Yes
	Upload Documents	No
	View Unfiled Documents	No
	File Unfiled Documents	No
	Change Document Type	No
	Change Document Attributes	No

Download Documents	Download PDF	Yes
	Download PDF w/ Signatures and History	Yes
	Download Original Source File	No
Tasks and Signatures	Send Document For Signature	No
	Sign Documents without Task	No
	Manage Tasks	No
Binder Management	Edit Binder Details	No
	Edit Binder Setup	No
	Add External User to Binder	No
	Add Internal User to Binder	No
Institutional Admin Permissions	Institutional Admin (Create New Users, Assign Users to Group)	No
	Create Binder	No
	Edit Existing Users	No
	Edit Drop Down Menus	No

Coordinator

Coordinators have permissions to view, download, sign and send for signature. Coordinators may not make changes to documents or study setup.

Category	Permission	Allowability (Yes/No)
Manage Documents	View PDF	Yes
	Upload Documents	Yes
	View Unfiled Documents	Yes
	File Unfiled Documents	Yes
	Change Document Type	No
	Change Document Attributes	No
Download Documents	Download PDF	Yes
	Download PDF w/ Signatures and History	Yes
	Download Original Source File	Yes
Tasks and Signatures	Send Document For Signature	Yes
	Sign Documents without Task	Yes
	Manage Tasks	Yes
Binder Management	Edit Binder Details	No
	Edit Binder Setup	No
	Add External User to Binder	No
	Add Internal User to Binder	No
	Institutional Admin (Create New Users, Assign Users to Group)	No
	Create Binder	No

Category	Permission	Allowability (Yes/No)
Institutional Admin Permissions	Edit Existing Users	No
	Edit Drop Down Menus	No

Internal Auditor

Internal Auditors are able to view and download any document within the regulatory binder with the exception of Removed Files.

Category	Permission	Allowability (Yes/No)
Manage Documents	View PDF	Yes
	Upload Documents	No
	View Unfiled Documents	No
	File Unfiled Documents	No
	Change Document Type	No
	Change Document Attributes	No
Download Documents	Download PDF	Yes
	Download PDF w/ Signatures and History	Yes
	Download Original Source File	No
Tasks and Signatures	Send Document For Signature	No
	Sign Documents without Task	No
	Manage Tasks	No
Binder Management	Edit Binder Details	No
	Edit Binder Setup	No
	Add External User to Binder	No
	Add Internal User to Binder	No
Institutional Admin Permissions	Institutional Admin (Create New Users, Assign Users to Group)	No
	Create Binder	No
	Edit Existing Users	No
	Edit Drop Down Menus	No

Other Staff

Staff members who are assigned to the "Other Staff" group do not have system permissions but are able to complete signature tasks as assigned.

In other words, "Other Staff" can only sign documents when a task is sent directly to them.

Category	Permission	Allowability (Yes/No)
	View PDF	No

Manage Documents	Upload Documents	No
	View Unfiled Documents	No
	File Unfiled Documents	No
	Change Document Type	No
	Change Document Attributes	No
Download Documents	Download PDF	No
	Download PDF w/ Signatures and History	No
	Download Original Source File	No
Tasks and Signatures	Send Document For Signature	No
	Sign Documents without Task	No
	Manage Tasks	No
Binder Management	Edit Binder Details	No
	Edit Binder Setup	No
	Add External User to Binder	No
	Add Internal User to Binder	No
Institutional Admin Permissions	Institutional Admin (Create New Users, Assign Users to Group)	No
	Create Binder	No
	Edit Existing Users	No
	Edit Drop Down Menus	No

External Monitors/Auditors

External Auditors can be added by administrators and regulatory staff. They are able to view and download any document within the regulatory binder with the exception of Removed Files. External auditors are automatically assigned to this permission group when granted access to a binder.

Category	Permission	Allowability (Yes/No)
Manage Documents	View PDF	Yes
	Upload Documents	No
	View Unfiled Documents	No
	File Unfiled Documents	No
	Change Document Type	No
	Change Document Attributes	No
Download Documents	Download PDF	Yes
	Download PDF w/ Signatures and History	Yes
	Download Original Source File	No
Tasks and Signatures	Send Document For Signature	No
	Sign Documents without Task	No
	Manage Tasks	No

Binder Management	Edit Binder Details	No
	Edit Binder Setup	No
	Add External User to Binder	No
	Add Internal User to Binder	No
Institutional Admin Permissions	Institutional Admin (Create New Users, Assign Users to Group)	No
	Create Binder	No
	Edit Existing Users	No
	Edit Drop Down Menus	No

External Auditor Access

Monitors/Auditors/CRAs can be given remote access to specific study binders.

1. Select the binder to which you wish to add the monitor/CRA
2. Select the Setup tab at the top of the page (under the Complion logo)
3. Choose External Users
4. Select the Add External User button at the top of the page in orange
5. Enter the desired user's email address in all lowercase letters, their start date, and the duration for which they'll be able to access the system. Hit Save. You will automatically be directed back to the External User page, and the email invitation will send automatically.

If you at any point need to edit the user, select the Actions dropdown to the far right. This is also how you can re-send the registration invitation or remove the user from the binder.

Binder Templates

Each binder template is comprised of a set of document types organized into folders. These templates have different functional purposes: Central Binders hold non-study-specific documents versus the IND and IDE Binder Templates which are intended for study documents.

ACC Central Binder Template

Consortia-level Central Binder Template contains essential credentialing documents for all sites belong to the consortia including documents such as CVs, Trainings, CAP/CLIA, etc.

Site Central Binder Template

Site-level Central Binder Template contains essential credentialing documents for individual sites including documents such as CVs, Trainings, CAP/CLIA, etc.

IND Study Binder Template

Regulatory Binder, applicable for IND studies. This binder type is maintained by the site. It will include all regulatory documents and will also populate staff, lab and site credentials.

IDE Study Binder Template

Regulatory Binder, applicable for IDE studies. This binder type is maintained by the site. It will include all regulatory documents and will also populate staff, lab and site credentials.

Drug/Device Study Binder Template

Regulatory Binder, applicable for trials with both IND and IDE. This binder type is maintained by the site. It will include all regulatory documents and will also populate staff, lab and site credentials.

Drug/Device Study Overview Template

This binder type is used to consolidate all Central IRB documents (study-specific IRB documents, IP documents, recruitment materials, etc.) for a single drug/device protocol.

Observational & Behavioral Binder Template

This regulatory binder type is maintained by the site. It will include all regulatory documents and will also populate staff, lab and site credentials.

Observational & Behavioral Overview Template

This binder type is used to consolidate all Central IRB documents (study-specific IRB documents, recruitment materials, etc.) for a single observational, behavioral, or natural history protocol.

Study Start-Up Binder Template

This binder type is used to begin collection of regulatory documents as a holding place prior to study funding/activation. Any documents filed into a Study Start-Up binder will be pulled into the protocol's regulatory binder when it is opened and will NOT require re-filing.

Expiring Documents Binder Template

Select an upcoming date using this binder template to identify any current document set to expire on or before that date.

Binder Set-Up

Click "Create Binder" to begin the binder set-up process.

Create Study Binder

Any values entered when creating a binder will be viewable on the binder landing page and can be utilized for reports. Only the Binder Template, Title and Description are *required* in order to move to the Binder Set-Up.

Binder Template: Choose the correct template from the drop-down options based on the type of study you are conducting (see Binder Templates for more information)

Title: Binder titles represent how the Binder will be named on the Complion Binder landing page as well as within the binder.

> *Format*: Site – Formal Protocol Name

Description: Enter any desired descriptive information for this required field.

Trial Type: What type of trial is being conducted (e.g. drug, device, observational)

Principal Investigator*: Principal Investigator for this study

IRB Number: Study number assigned by the IRB

Contact: Main point of contact for questions regarding this regulatory binder.

Trial ID*: Protocol Number

Department/Site/Disease Group*: Department primarily responsible for this study

ClinicalTrials.gov Number (if applicable)

Sponsor/CRO*: Sponsor/CRO for this study

Renewal Date: Study renewal date

*Data from these fields will appear across the top of the Delegation of Authority log

Study Binder Setup

Determines which documents are being pulled over from the central binder.

Protocol Number: 4-digit number identifying the study; managed by DMCC

> *Format:* 4-digit number

Site: Name of the site conducting the study

> *Format*: Site Abbreviation (see list)

Name of Researcher: Name of the researcher participating in the study

> *Format:* Consortium Abbreviation – Last Name, First Name

Storage Area: Location of Investigational Product

>*Format:* Storage Area Name – Serial Number

Trial Start Date: Identifies the trial start date defined as the date the PI signed the Delegation of Authority; central documents archived before this date will NOT be included in the binder.

>*Format: DDMMMYYYY (via calendar tool)*

EDC and Version: Identifies which EDCs (if any) will be used on this study; this will pull in assigned researcher's associated EDC training.

>*Format: EDC Name + Version (if applicable)*

Local Lab: Name and Site # (if applicable) for any local lab being used for this study; this will pull in the Lab Director's current CV and Medical License, current CAP and CLIA, Manual and Guidelines.

>*Format:* Consortium Abbrv. - Legal Lab Name - Site # (if applicable)

Central Lab: Name and Site # (if applicable) for any central lab being used for this study; this will pull in the Lab Director's current CV and Medical License, current CAP and CLIA, Manual and Guidelines.

>*Format:* Consortium Abbrv. - Legal Lab Name - Site # (if applicable)

Type of Equipment: Identifies any equipment being used on a study; this will pull in current calibration certificates.

>*Format:* Equipment Name – Serial Number

Standard Operating Procedure: Identifies which SOPs (if any) that should be pulled into the Regulatory Binder. If no SOPs should be pulled into the binder, select the N/A value *Note: NEVER file documents with an N/A value*

>*Format*: SOP: Name of SOP + Version

IRB: Identifies the IRB used for this study; this will pull in the appropriate IRB Rosters

>*Format:* Legal Name of IRB

Other Drop Downs

Outside of the Binder Set-Up page, there are some additional drop downs used when filing documents:

Drug: Identifies the Drug used for the study; this is used to identify certain documents such as the Investigational Brochure and IP Tracking Documents.

>*Format:* Generic Name – Brand Name

Language: Identifies the Language of a translated document; this is used for documents such as Informed Consent and Patient-Facing materials.

Delegation of Authority

There is one standard Delegation of Authority template in the system. Tasks and roles can be added or deleted as needed on a binder-by-binder basis.

Tasks

- Obtain & Review Informed Consent
- Subject Identification/Recruitment
- Confirm Subject Eligibility (Review Inclusion/Exclusion Criteria)
- Obtain Medical History and Concomitant Medications
- Perform Physical Exam
- Perform Medical Assessments
- Evaluate Study-Related Test Results
- Conduct Study Visit Procedure As Outlined In The Protocol
- Collect & Report AEs/SAEs
- Assess AEs/SAEs
- Prepare & Dispense Study Drug/IP
- Maintain and Prepare Study Drug/IP
- Administer Study Drug/IP
- Perform Study Drug/ IP Accountability
- Sample Collection and Processing
- Sample Shipment
- Make Entries/Corrections On (e)CRFs And Query Resolution
- Sign-Off (e)CRFs
- Maintain Regulatory Documents
- Patient Reported Outcome (PRO) Or Questionnaire Review
- Blind/Code Break
- Collection of Vital Signs

Roles

- Principal Investigator
- Sub-Investigator
- Regulatory Staff
- Clinical Research Coordinator
- Pharmacist
- Recruiter
- Rater
- Lab Technician

Delegation Set-Up

1. Click on the "Delegation" tab
2. Click "IMPORT STANDARD TEMPLATE"
3. If necessary, modify the task list and roles to match the requirements on the study. .

Adding Staff
1. Select "ADD STAFF DELEGATION"
2. Select the staff member name from the drop down.

Note: If the staff member does not appear in the drop down, they have not been added as a user to the binder. You need to first grant access for that user to the binder.

Role
1. Select the role of the staff member from the drop down.
2. If the role is not available in the drop down, you may type the new role directly into the "Select Role" field and press "Enter" to create the new role.

Tasks
1. Select the Task drop down
2. Choose "Select All" at the top of the list to select all tasks or click on each appropriate task
3. Click out of the drop down to exit the menu

Start Date
1. Select the start date of the delegation to the staff member.
2. Click "Add Delegation" too add the staff member to the log.

Note: Start dates are to be entered after all required training is completed and not before the study is open to accrual as determined by site.

Modifications
Pre-Acknowledgement/Signature
Line items can only be removed without creating and audit trail prior to being acknowledged by the staff member or signed off by the PI.

Post-Acknowledgement/Signature
Staff ending participation on the study once acknowledged or signed off on can be removed at any time, but with show in the audit trail.

1. Select "Edit".
2. You can change the delegated tasks, start date and end date for that staff member.
3. Select "Save".

End Date
Select the end date of the delegation for the staff member.

1. Click edit for the person you would like to remove.
2. Select calendar icon
3. Identify their end date.
4. Click "Save".

Signatures
1. Copy the hyperlink to the Delegation of Authority page
2. Send link to persons needing to sign off on the document via email
3. User signing will click the link, sign into Complion and enter credentials to sign the log

Export
Click "EXPORT" to create a .pdf version of the delegation log.

Task Management
Send Document for Action
1. Select the document that requires action
2. Select the File Action "Send Document for Action"

- **Title:** This field is treated similar to a subject line of an email
- **Due Date:** Enter an appropriate due date for the requested action.
- **Requested Action:** Select the appropriate action that is required for the document
  - *Approve the contents of the document*
    To be used for documents requiring a signature. Examples include: Confidentiality Disclosures, Contracts, etc.

  - *Review the contents of the document*
    To be used for documents requiring a signature. Examples include: Safety reports, etc.

  - *Train on the contents of the document*
    To be used for documents requiring an individual to review and train on. Examples include: Protocols, protocol amendments, slide decks, etc.

  - *Read the contents of this document – No Signature Requested*
    This only requires someone to open the document and does not require the password to be entered.   Examples include: Newsletters, etc.

- **Description:** Enter a brief description of the task to be completed
- **Users:** Select the Users that are required to complete the task.
  Note: If a task cannot be completed an email, must be sent back to the sender.

Sign Document
Access the document in one of two ways:

- Click the hyperlink either in email OR
- Access the documents via the "Inbox" within Complion

Outstanding Tasks

Daily Digest

The Daily Digest will send an email notification at 6:00am Eastern which includes a link to outstanding tasks.

If a user does not have any outstanding tasks, they will not receive a notification.

Troubleshooting

Questions should first be directed to your consortium project managers (the Complion Administrator at your consortium).

The Regulatory System Coordinator (Stephanie Sullivan at the DMCC) will facilitate the communications as needed between the Consortium Project Managers and Complion.

Complion Support

Our Role
- Solve issues efficiently
- Work with the organization to effectively and proactively communicate
- Collect information, data, and feedback systematically to understand how better to support our users and help make product improvements
- Provide product information and education

Our Staff
Alex Knill - Support Engineer
Jaime Ramos - Support Associate

Contact Us
You may reach out using any of the following tools:
- **Help Tool**
  The Help Tool is the fastest way to connect with the Support Team. It captures application information and allows screen captures when tickets are submitted

- **Email:** support@complion.com

- **Phone:** 800.615.9077 Ext. 2

Support Hours: Monday - Friday, 9:00 AM - 5:00 PM EST

If you have an issue logging in, please use the Support button in the bottom right-hand corner of your screen!

Complion's Help Center
Please follow this link to reach the Help Center. Here, you'll find Part 11 resources, release notes, and Frequently Asked Questions!