



eReg Guidance Document Sending Documents from Investigator Site File to Trial Master File

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Acronyms

GCP: Good Clinical Practice

GMT: Greenwich Mean Time

HIPAA: Health Insurance Portability and Accountability Act

IRB: Institutional Review Board

ISF: Investigator Site File

N/A: Not Applicable

TMF: Trial Master File

URL: Uniform Resource Locator

YCCI: Yale Center for Clinical Investigation

YSM: Yale School of Medicine

Process

[Sending Documents from Investigator Site File to Trial Master File](#)

When a protocol maintained in eReg includes an Investigator Site File (ISF) and a connected Trial Master File (TMF), research team members can send copies of documents and URLs maintained in the ISF, including contact credentials and organizational regulatory tracking items, to the TMF within eReg.

If a member of the Yale Center for Clinical Investigation's (YCCI) monitoring team is designated as the monitor of the study, this individual can also send copies from the ISF to the TMF.

The eReg Multi-Site Access User maintaining the TMF or eReg Support will create the TMF, add the participating sites and invite the ISF staff to connect the ISF to the TMF, when applicable.





The connection between the ISF and TMF can be confirmed by the Multi-Site Protocol Connection tile on the Overview page of the ISF. To view the details about the connection, such as who connected the ISF to the TMF, click the View Multi-Site Protocol Connection button within the tile.

Multi-Site Protocol Connection

Connected To **Yale University**

[➔ View Multi-Site Protocol Connection](#)

Sending Protocol Documents and URLs

When a document or URL is created in eReg, a Regulatory Coordinator, Regulatory Manager, Principal Investigator or YCCI Reviewer can send copies of the document or URL to the connected TMF. Refer to the *eReg Guidance Document for Investigator Site File Regulatory Templates* for more information on adding new documents and URLs to eReg.

To send a copy, (1) navigate to the section and requirement where the document or URL is filed. (2) Click the hyperlink for the document or URL to view details associated with it.

Protocol

IRB-approved Protocol* + New Document ▾

Document Name	Versions	Effective Date ↓	Valid Until ↓	Signature Status	
Protocol_v3.0_2022.01.31.pdf ↓	3	31 Jan 2022		N/A	+ New Version ✕ Delete





When viewing the details for the document or URL, (3) click the “Send Copy” button.

Versions + New Version ▾

Protocol_v3.0_2022.01.31.pdf ✕ Delete

Details Edit

File [Protocol_v3.0_2022.01.31.pdf](#)

Effective Date 31 Jan 2022

Valid Until

Comments

Signature Requirement None

Related Documents (0) > Add Related Document Sent Copies (0) > Send Copy

A pop-up screen will open, confirming the document name and document file to be sent to the connected TMF. (4) Confirm the appropriate document or URL has been selected. Then (5) click Send.

Send Copy ✕

A copy of this document and any signature information will be sent to Yale University for this protocol:

Document Name Protocol_v3.0_2022.01.31.pdf

File Name Protocol_v3.0_2022.01.31.pdf

Send Cancel

The task will appear in the Queued Tasks pop-up window while the transfer is in process and once it is complete. The results of queued tasks are available for a limited time then automatically delete.

The document or URL will land in the Document Inbox of the connected TMF.

[Sending Contact Credentials](#)

When a contact credential is filed in eReg for a staff member on a protocol, a Regulatory Coordinator, Regulatory Manager, Principal Investigator or YCCI Reviewer can send copies of the credentials to the





connected TMF. All filed credentials for a contact can be sent at once or individual credentials can be sent. As new credentials are filed, they will need to be sent to the connected TMF. Refer to the *Electronic Regulatory Management System Access Guide* for more information on adding new staff to eReg.

To send credentials, (1) navigate to the Staff section of the ISF. (2) Click the hyperlink for the staff person to view summary information about them for that protocol.

Select Protocol

Overview
Document Inbox
Summary
Details
Consent Documents and HIPAA Authorization Forms
Delegation of Authority
Investigational Product
IRB Approvals and Acknowledgements
Organizations
Other Committee Approvals & Acknowledgements
Protocol
Regulatory Documents
Safety Reporting
Staff
Staff Training

★ Protocol: YSM-GENERAL Actions

Staff

Choose Columns Export Add Staff

	First Name ↑	Last Name ↑	Start Date	Stop Date	Protocol Staff Roles	Credential Status
	Stephanie	Brogan	16 Feb 2022		Clinical Research Coordinator	Incomplete
	Kacey	Richards	03 Sep 2021	16 Feb 2022	Principal Investigator	Incomplete
	Erica	Rocco	03 Sep 2021		Clinical Research Assistant	Complete
	user1	user1	02 Feb 2022		Clinical Research Coordinator	Incomplete
	user1	user1	01 Feb 2022	01 Feb 2022	Clinical Research Coordinator	Incomplete

5 Total Records

(3) Select or scroll down to credentials to view a list of credentials on file for that staff person. (4) Click Send Copy.

Select staff

Summary
Details
Credentials
Protocol Staff Roles
Delegated Tasks
Sent Copies

Staff: Erica Rocco Actions

Credentials Go to Contact Credentials Send Copy

Credential Type ↑	Status	Valid Until
Good Clinical Practice Training	Complete	14 Jun 2022
Signature Sample	Complete	





A pop-up window will open which will allow you to (5) select the credentials to send to the connected TMF. Once selected, (6) click Send.

Send Copy [Close]

Select credentials to send to Yale University for this protocol. A copy of the document and any signature information will be sent.

Select	Credential Type	File Name	Document Name	Signature Requirement	Signature Status	Effective Date	Valid Until
<input checked="" type="checkbox"/>	Good Clinical Practice Training	GCP Certificate_Rocco, E_exp 2022.06.14.pdf	Rocco, Erica_GCP Training_exp 2022.06.14.pdf	None	N/A	14 Jun 2019	14 Jun 2022
<input checked="" type="checkbox"/>	Signature Sample	Rocco, Erica_Signature Sample_eff 2018.10.01.pdf	Rocco, Erica_Signature Sample_eff 2018.10.01.pdf	Wet Signature	Wet Signed	01 Oct 2018	

[Send] [Cancel]

The task will appear in the Queued Tasks pop-up window while the transfer is in process and once it is complete. The results of queued tasks are available for a limited time, then are automatically deleted.

The credential(s) will land in the inbox of the connected TMF.

Only credential document types indicated as a requirement for the staff person’s Protocol Staff Role will be listed in the credentials section. For example, if Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Training is not listed as a requirement in your protocol outline for the Protocol Staff Role of Clinical Research Coordinator, the HIPAA credential will not be included in the Credential section of the staff person who is listed as a Clinical Research Coordinator on your protocol even if the HIPAA credential is filed in their contact record.





Viewing Previously Sent Documents and URLs in the Investigator Site File

To view documents and URLs previously sent from the ISF to the connected TMF, (1) navigate to the section and requirement where the sent document or URL is filed in the ISF. (2) Click the hyperlink for the document or URL to view details associated with the document or URL. (3) Click the arrow next to Sent Copies to view details associated with any document or URL previously sent to the connected TMF.

The screenshot displays the details for a document titled "Protocol_v3.0_2022.01.31.pdf". At the top right, there is a "Delete" button. Below the title, there is an "Edit" button. The details section includes: File: Protocol_v3.0_2022.01.31.pdf; Effective Date: 31 Jan 2022; Valid Until: (blank); Comments: (blank); Signature Requirement: None. At the bottom, there are two sections: "Related Documents (0)" with an "Add Related Document" button, and "Sent Copies (1)" with a "Send Copy" button. Below the "Sent Copies" section, it states: "Document was sent to Yale University by Stephanie Brogan (ss2762) on 18 Feb 2022 14:11:22 -06:00 GMT".

Please note if the Multi-Site Access User responsible for maintaining the TMF rejects your document, it will still appear in the sent copies section. You will not be notified via eReg if a file that you sent to the connected TMF is rejected. Confirm with the person who is responsible for maintaining the TMF how the rejection of files will be communicated.

Receiving Documents for Trial Master File from Investigator Site File

A document or URL which was sent from the ISF to the TMF will land in the Document Inbox of the connected TMF. The Multi-Site Access User who is responsible for maintaining the TMF will review and file the document or URL or reject it.





Select Protocol ▾

Participating Sites

Document Inbox **1**

Summary

Details

Clinical Study Report (Results)

Committee Approvals and Acknowledgments

Consent Documents and HIPAA Authorization Forms

Investigational Product

★ Multi-Site Protocol: YSM-GENERAL

Actions ▾

This protocol isn't configured to receive documents via email.

Expand All | Collapse All

Yale University (1) ▾

Document Type ↑	Document Name ↑	Received Date ↓	
Protocol Document	Protocol_v3.0_2022.01.31.pdf ↓	18 Feb 2022	✓ Review and File ✗ Reject

A pop-up window will open and allow the file location (Section and Requirement) to be selected and the document name, effective date and valid until date to be updated. Fields will auto-populate with information from the ISF, if applicable, and may be revised before filing in the TMF. Revisions are reflected in the document details within the TMF and will not impact the document details in the ISF. Fields marked with an asterisk are required. (3) Confirm all details are correct, then (4) click File.

Review and File ✕

Section * ✕ ▾

Requirement *

Document Name *

Effective Date

Valid Until





To reject a document, (5) click the reject button.

Select Protocol ▾

Participating Sites

Document Inbox 1

Summary

Details

Clinical Study Report (Results)

Committee Approvals and Acknowledgments

Consent Documents and HIPAA Authorization Forms

Investigational Product

★ Multi-Site Protocol: YSM-GENERAL Actions ▾

This protocol isn't configured to receive documents via email.

Expand All | Collapse All

Yale University (1) ▾

Document Type ↑	Document Name ↑	Received Date ↓	
Protocol Document	Protocol_v3.0_2022.01.31.pdf ↓	18 Feb 2022	✔ Review and File ✖ Reject

A pop-up window will open to warn the user that rejecting the document will cause it to disappear from the inbox and to alert the user that the participating site will not be notified. The participating site will need to be contacted outside of eReg to inform them that the document was rejected, provide a rationale for rejection and request an updated document, if necessary.

Reject Protocol_v3.0_2022.01.31.pdf ✕

! If you reject this document, it will no longer appear in the Inbox, and the participating site will not be notified. Contact the participating site to follow up on the document.

Reject
Cancel

Additional Resources

- eReg Guidance – Investigator Site File Regulatory Templates
- Electronic Regulatory Management System Access Guide
- eReg Learning Portal
- YCCI eReg website: <https://medicine.yale.edu/ycci/researchservices/systems/ereg/>

