Yale University

eRegulatory Training Session
for Regulatory Coordinators and Regulatory Managers

YCCI Yale Center for Clinical Investigation

Training Objective

Provide System Overview

Provide a comprehensive overview of how to electronically maintain regulatory and essential documents for clinical research studies using the Advarra eRegulatory (hereafter referred to as eReg) system.

Discuss System Updates

Discuss recent and upcoming eReg system updates and new features.

Answer Questions

Answer questions related to electronic maintenance of regulatory and essential documents.

Agenda

- eReg System Overview
- Getting Started
  - Importing and setting up a protocol
  - Requesting user access for staff
- Maintaining eReg Binder
  - Adding documents
  - Requesting electronic signatures
  - Documenting staff training
  - Managing the Delegation of Authority Log, including making corrections
  - Locking completed studies
- Setting Up eReg for Use by External Monitors and Auditors
- Closing Statements

eReg System Overview

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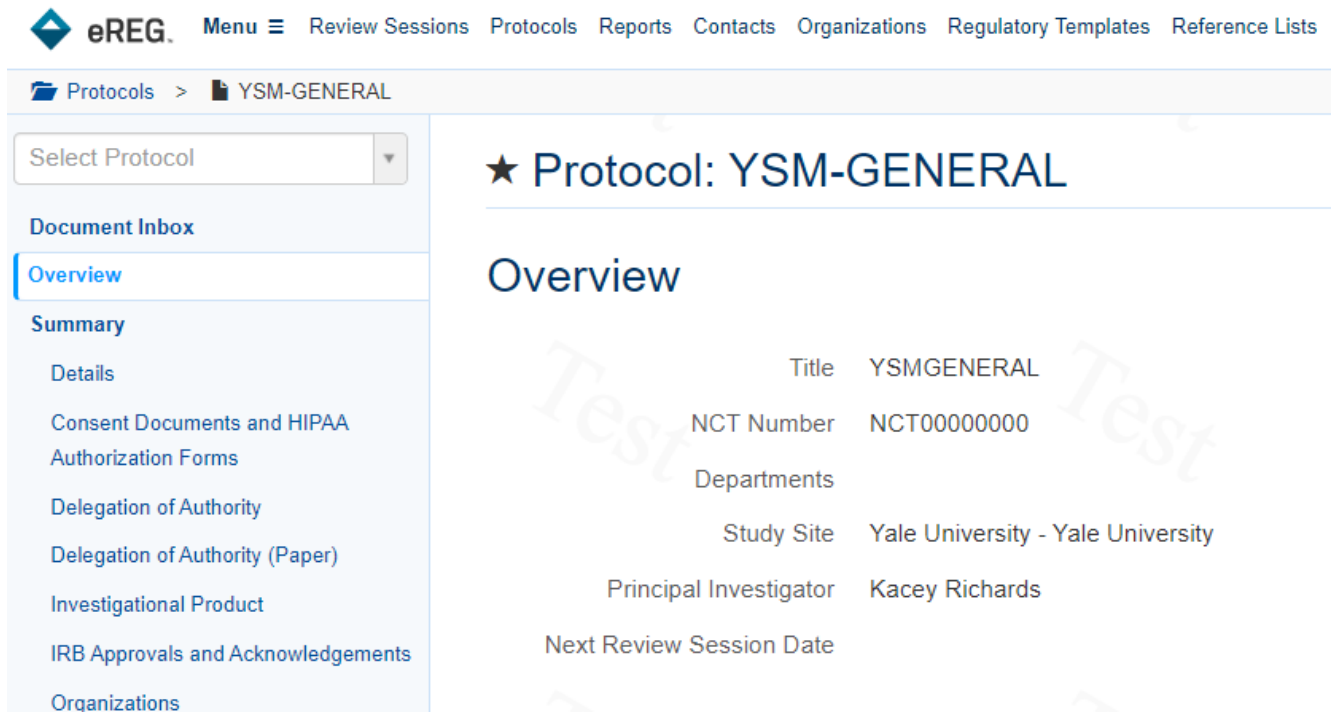
eReg System Overview

- Advarra's eReg system is an electronic regulatory binder management system which is designed to increase regulatory compliance and efficiency
- eReg supports regulatory workflows across the School of Medicine and allows for management of a portfolio of protocols

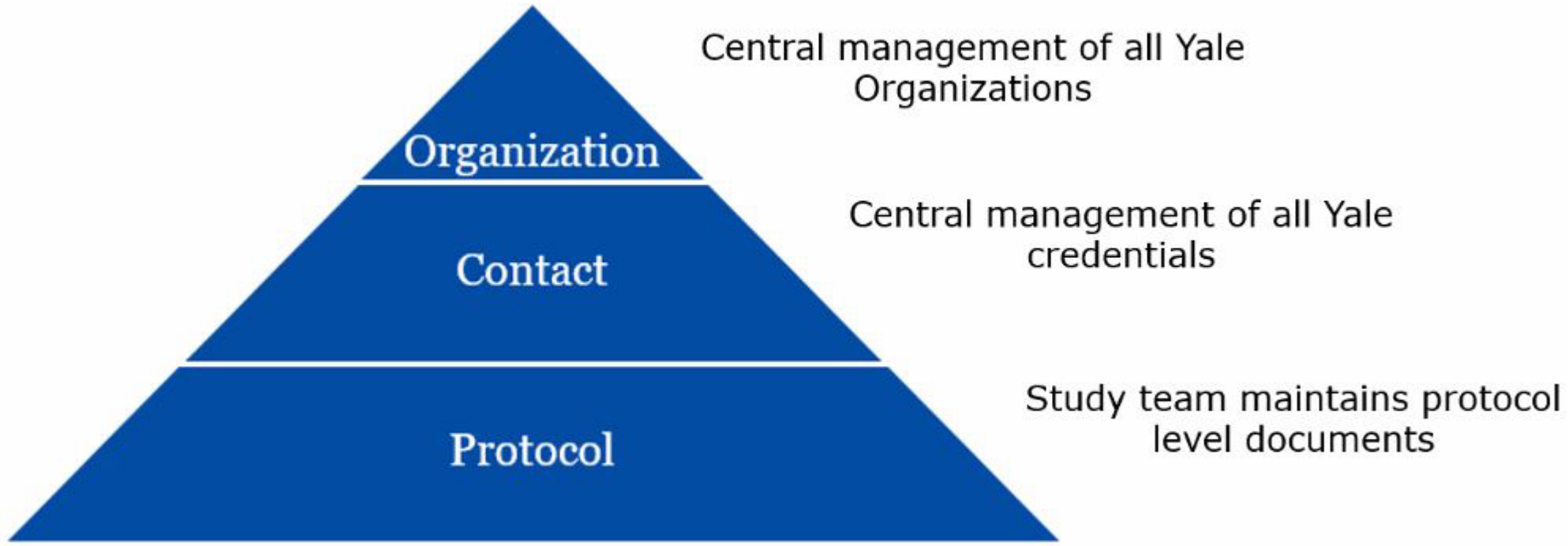


eReg System Overview – Advantages to eReg Binder

- Documents can be compliantly (21 CFR Part 11) routed for electronic signature, eliminating time-consuming administrative tasks and providing the ability for study staff to sign off on regulatory documents at anytime
- Staff credentials and organization (laboratory and Institutional Review Board) documents are maintained in one place and flow to all necessary protocols, allowing for central management
- Increased security, user roles and account permissions allow Yale to control and monitor who sees what and when
- Increased accessibility, allows remote management of essential and regulatory documents and remote reviews by monitors, auditors, and/ or inspectors

eReg System Overview – Document Management

- Documents are maintained in three (3) locations
- Each location contains documents which are essential to maintaining a complete Investigator Site File (ISF)



eReg System Overview – Document Management

Organization

- IRB - Federalwide Assurance Number, Roster, OHRP Registration, Compliance Statement
- Laboratory - Certifications and Accreditations (CAP, CLIA, COLA, State Certifications), Lab Director CV and ML, Normal Range Values

Contact

- CVs, MLs, GCP Training, Signature Sample, additional credentials determined by the department

Protocol

- Form FDA 1572, Financial Disclosure Forms, IRB submissions, approval documents and correspondence, Consents, Assents, Protocols, Investigator's Brochure, Instructions for Use, Case Report Forms, Study Conduct Documents, Study Correspondence, etc.

eReg System Overview – Document Management

YCCI Responsibility (Central Management)

- Yale-affiliated Organization regulatory tracking items
- Contact level staff credentials (GCP, Signature sample, CVs, MLs)

Send these documents to eReg.Credentials@yale.edu for upload into eReg

Study Team Responsibility

- External Organization regulatory tracking items
- Protocol level regulatory and essential documents

If you believe an Organization that is not affiliated with Yale is widely used and could be managed centrally, please submit a request to YCCI (eReg.Credentials@yale.edu).

eReg System Overview – Regulatory Templates

- YCCI has developed regulatory templates to guide study teams and ensure Good Clinical Practice (GCP) and regulatory requirements are met.
  - As future needs arise, additional templates may be developed

	Yale Standard Templates		
Regulatory Templates	**Drug**	**Device**	**Behavioral**
Investigator Site File (ISF)	✓	✓	✓
Participating Site File (PSF)	✓	✓	✓
Trial Master File (TMF)	✓	✓	✓
Trial Master File/Investigator Site File Combination (TMF/ISF)	✓	✓	✓

eReg System Overview – Investigator Site File (ISF)

Contains Study Documents

Investigator Site Files (also known as regulatory binders, investigator binders, study binders, etc.) contain study-specific information and regulatory documentation. This term is applied to files maintained by the site staff.

Facilitates Organization

Organizes regulatory and essential documents, provides easy access to documents by the trial monitor, auditor, Institutional Review Board (IRB), and/or regulatory authorities for review/audit purposes, and allows research team members to reference information and documentation.

Demonstrates Compliance

Investigator Site Files serve to demonstrate compliance with the IRB approved protocol, Good Clinical Practice (GCP) and all applicable regulatory requirements.

eReg System Overview – Trial Master File (TMF)

Contains Sponsor Documents

The Trial Master File contains the essential and regulatory documents required to be maintained by the Sponsor or Sponsor-Investigator. It should be set up at the start of a study and continuously maintained throughout the conduct of the study.

Permits Trial Re-creation

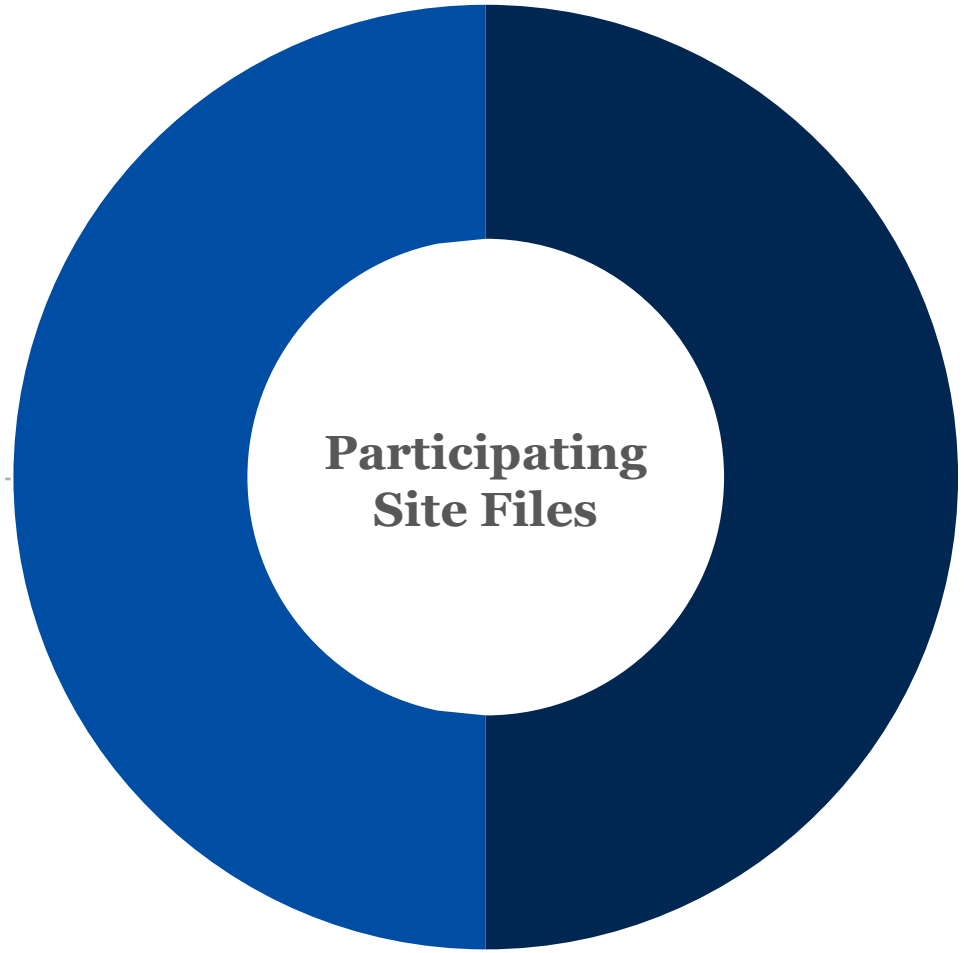
Permits the study to be independently re-created from the filed study records. It is a quality process which includes documentation of the activity that has been performed during the study. This is critical in ensuring study participant rights are protected and that regulators have access to robust, reliable clinical trial documents.

Demonstrates Compliance

Trial Master Files serve to demonstrate compliance with the approved protocol, Good Clinical Practice (GCP) and all applicable regulatory requirements.

eReg System Overview – Participating Site Files

Contains Site-Specific Documents
The Participating Site File contains the essential and regulatory documents required to be maintained by the Sponsor or Sponsor-Investigator for each site that participates in a multi-site trial.



Demonstrates Compliance
Participating Site Files serve to demonstrate compliance with the approved protocol, Good Clinical Practice (GCP) and all applicable regulatory requirements.

Getting Started

Building Protocols

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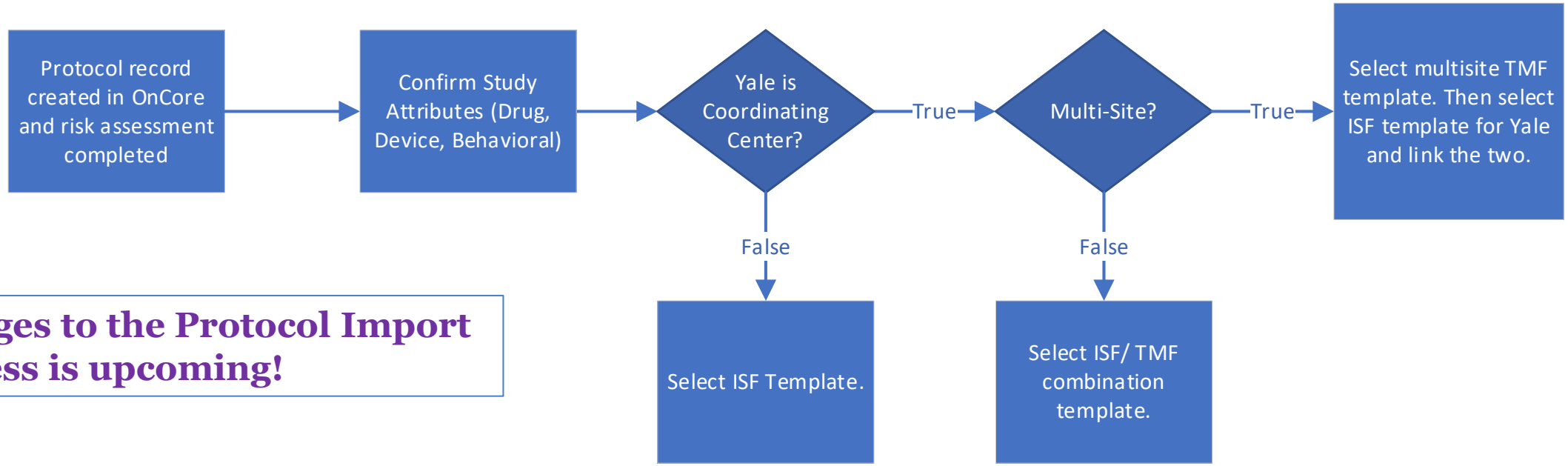
Building Protocols – Protocol Import

- Studies requiring ICH GCP compliance are required to be in eReg for those departments using eReg or for those investigators planning to electronically maintain regulatory files.
- eReg Support will import the record from OnCore and select the appropriate regulatory template based on study attributes and management type. This will be done when YCCI has completed the risk assessment on the study or upon receipt of a request for import.

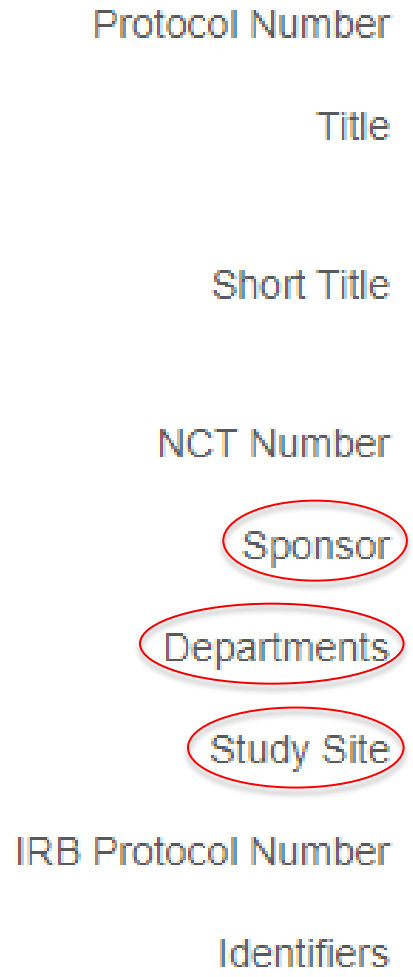


Changes to the Protocol Import Process is upcoming!

Building Protocols – Adding Protocol Details

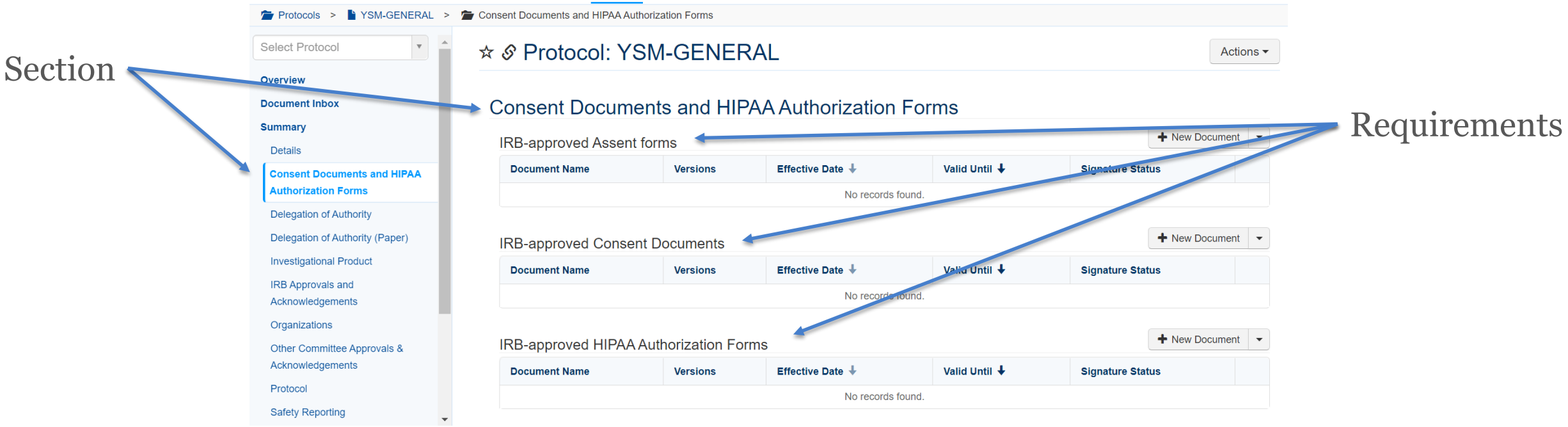
- When a protocol is imported from OnCore, the following details captured in eReg will be imported along with it:
  - Protocol Number
  - Title
  - Short Title
  - NCT Number
  - IRB Protocol Number

- Fields to be completed after import by eReg Support and/or study team:
  - Sponsor
  - Departments (multi-select)
  - Study Site (multi-select)



Building Protocols – Template Section and Requirements

- Regulatory templates are organized into Sections with Requirements found under each Section.
  - A section is similar to a file folder or tab within a physical paper binder
  - A requirement is similar to a document contained within that file folder or tab



Building Protocols – Protocol Outline (Demo)

- Remove sections and requirements that are not applicable to your study before the study begins when you are setting up your Investigator Site File.
  - This does not include sections/requirements in which there is nothing filed yet, however there is a possibility for future use.
- Changes to the sections and requirements are made by accessing the Protocol Outline. To do this, choose Protocol Outline from the Actions button menu.

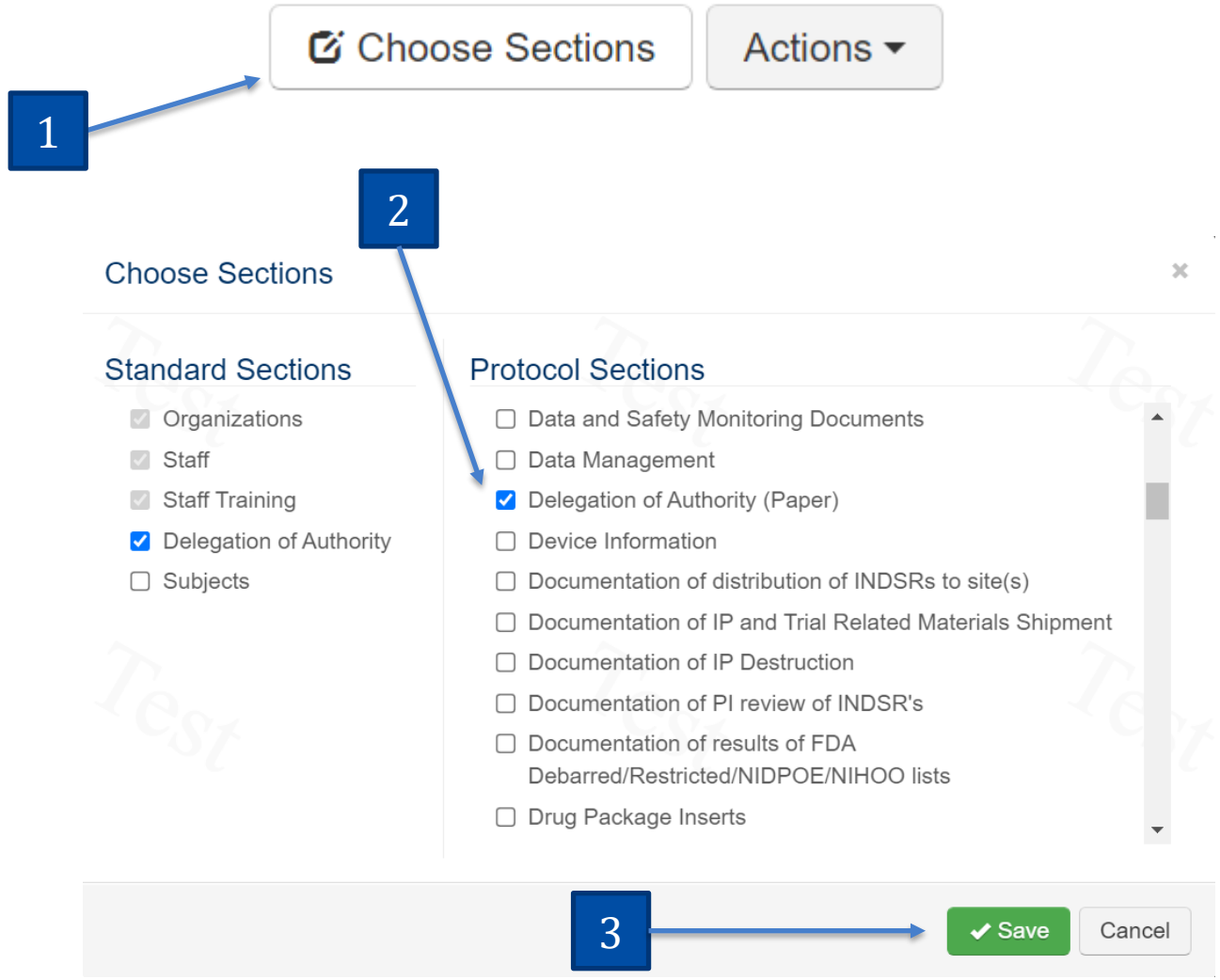
Building Protocols – Protocol Outline (Sections)

- To remove Sections:

1. Navigate to “Choose Sections” within the protocol outline

2. Use the check boxes to select and unselect Protocol Sections

3. Select “Save” when complete

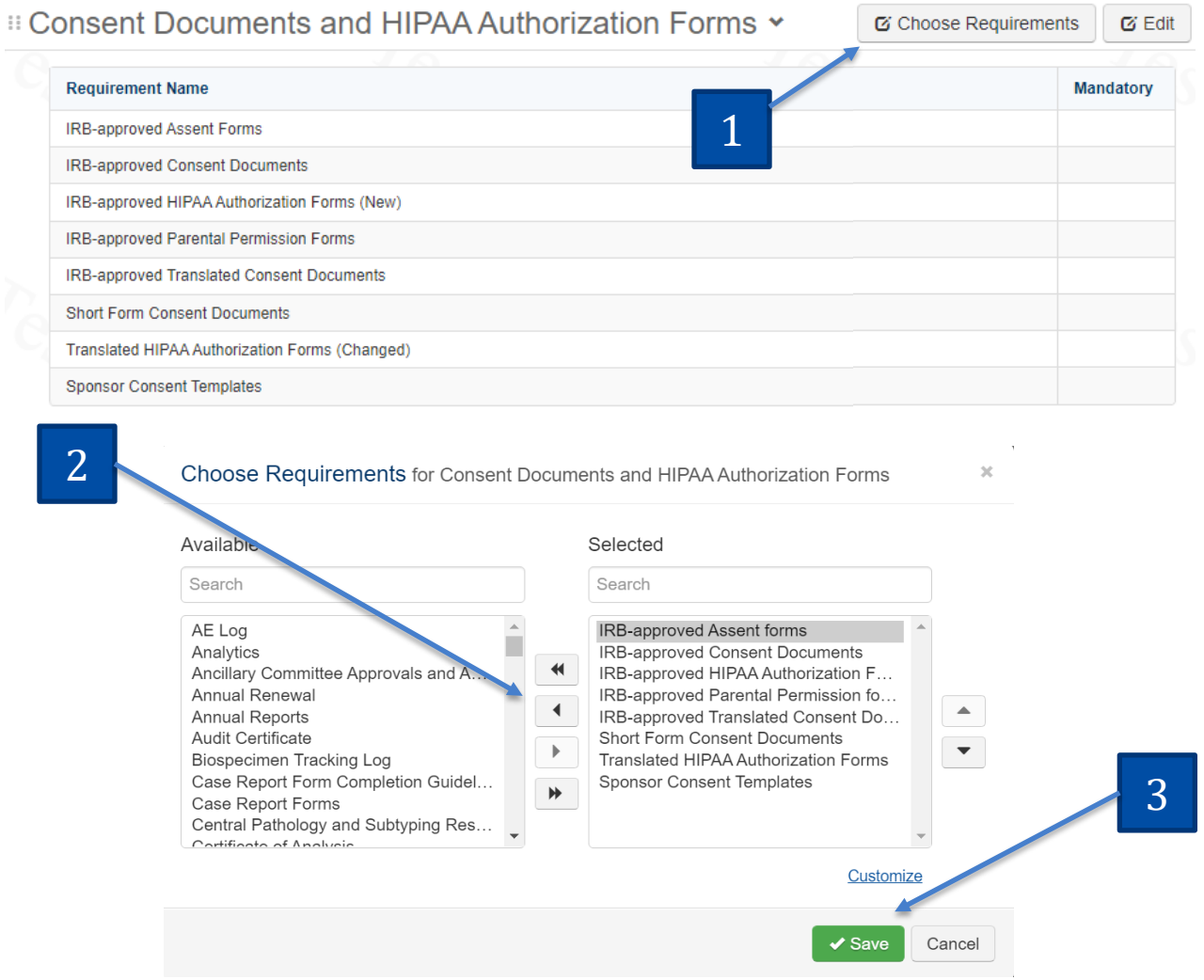


Building Protocols – Protocol Outline (Requirements)

- To remove Requirements:

  1. Select “Choose Requirements”
  2. Use the arrow functions to select and unselect requirements
  3. Select “Save” when complete

*Do not customize Requirements. If you believe you will need a Requirement that is not currently available, consult eReg Support (eReg.Support@yale.edu).



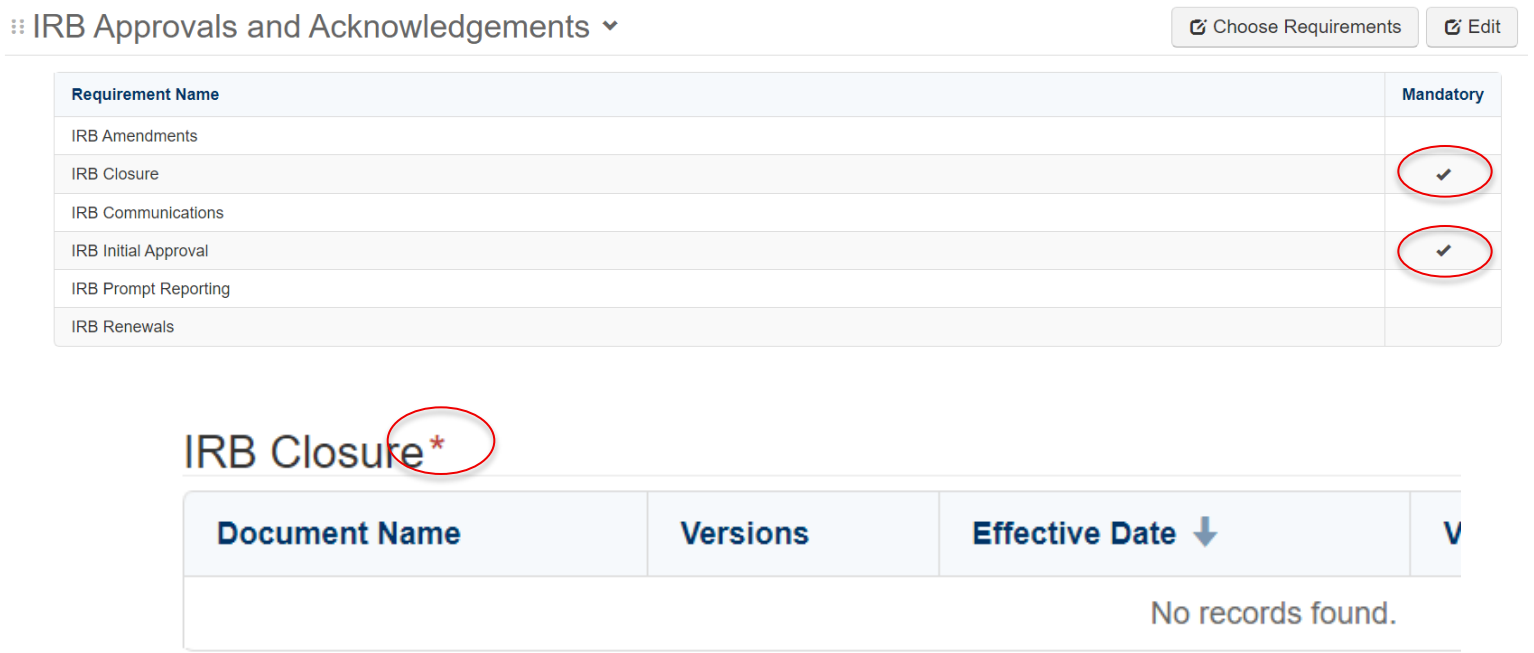
Building Protocols – Protocol Outline Changes

Some Sections and Requirements will not be applicable to every study

If the study…		
	Does not use a paper Delegation of Authority Log	Remove the section “Delegation of Authority (Paper)”
	Is an Open Label study	Remove the requirement “Unblinding Procedure” from the “Study Conduct Documents” section
	Is not a pediatric study	Remove the requirements “IRB-approved Assent Forms” and “IRB-approved Parental Consent Forms” from the “Consent Documents and HIPAA Authorization Forms” section
	Contains reference safety information within an Investigator’s Brochure	Remove the requirement “Package Insert(s)” from the “Investigational Product” section
	Contains reference safety information within a Package Insert	Remove the requirements “Investigator’s Brochure” and “Investigator’s Brochure Receipt Page” from the “Investigational Product” section

Building Protocols – Mandatory Requirements

- Some requirements are marked as mandatory meaning at least one document must be filed within that requirement
- Mandatory requirements are denoted by a checkmark in the Mandatory column in the protocol outline and an asterisk next to the name in the section
- They include:
  - IRB Closure
  - IRB Initial Approval
  - IRB-approved Protocol
  - Protocol Training
  - Case Report Forms
  - Screening/ Enrollment Log



Building Protocols – Adding Organizations (IRBs)

Adding the IRB of Record as an Organization

FDA-regulated IND Studies

- For FDA-regulated investigational new drug (IND) studies, add the IRB noted in BOX 5 of the Form FDA 1572

FDA-regulated IDE Studies

- For FDA-regulated investigational device exemption (IDE) studies, add the IRB noted in the Investigator Agreement or the IRB who approved the study for conduct at the site

Non-FDA-regulated Studies

- For non-FDA-regulated studies or for studies that are FDA-regulated but not conducted under an IND or IDE, add the IRB who approved the study for conduct at the site

Note: If Yale Human Research Protection Program (HRPP) authorizes your study to be reviewed by an external IRB, list the external IRB as the IRB of record.

Building Protocols – Adding Organizations (Laboratories)

Adding Laboratories as an Organization

FDA-regulated IND Studies

- For FDA-regulated investigational new drug (IND) studies, add the laboratory(-ies) noted in Box 4 of the Form FDA 1572

FDA-regulated IDE Studies

- For FDA-regulated investigational device exemption (IDE) studies, add the laboratory(-ies) noted in the Investigator Agreement

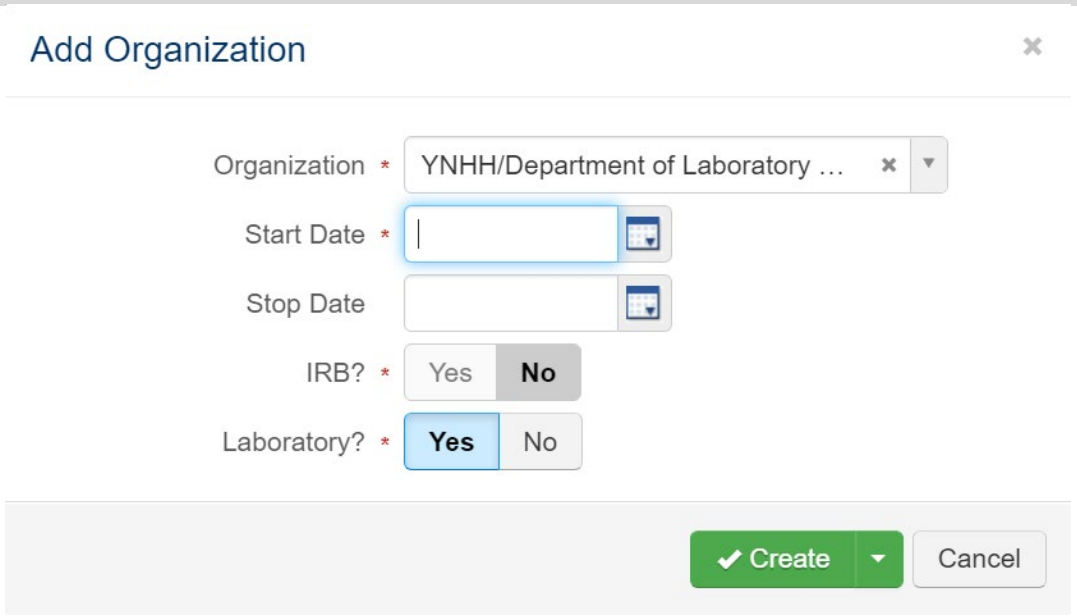
Non-FDA-regulated Studies

- For non-FDA-regulated studies or for studies that are FDA-regulated but not conducted under an IND or IDE, add the clinical laboratory(-ies), testing facilities, analytical labs, and/or laboratories supplying efficacy data

Building Protocols – Adding Organizations

- Yale Regulatory Managers, Yale Regulatory Coordinators, those with Multi-site Access, and select Administrative roles can add Organizations to protocols.
- To add organizations, from the protocol home page select:
  1. Organizations in the left-hand menu
  2. Add Organization

Building Protocols – Adding Organizations



- **Organization:** Select the IRB or Laboratory you want to add.
- **Start Date:** Use the PI signature date found on the Form FDA 1572 or Investigator Agreement, or date when the Organization began being used for the study.
- **Stop Date:** Use the date that the Organization stopped being used for the study.
- **IRB?:** This will automatically populate when the Organization is selected.
- **Laboratory?:** This will automatically populate when the Organization is selected.

Building Protocols – Adding New Staff to eReg

- Study staff members must have a contact record in eReg before they can be added to a protocol and an active user account before they can sign documents in eReg
- The User Access Request Form can be located on the YCCI eReg website

Requesting Access

- Staff member will complete a User Access Request Form with information about their name, role, and typical study tasks

Completing Training

- Staff member will be assigned the appropriate training based on the information provided. This training must be completed, and current credentials filed, before moving on to the next step.

Account Creation

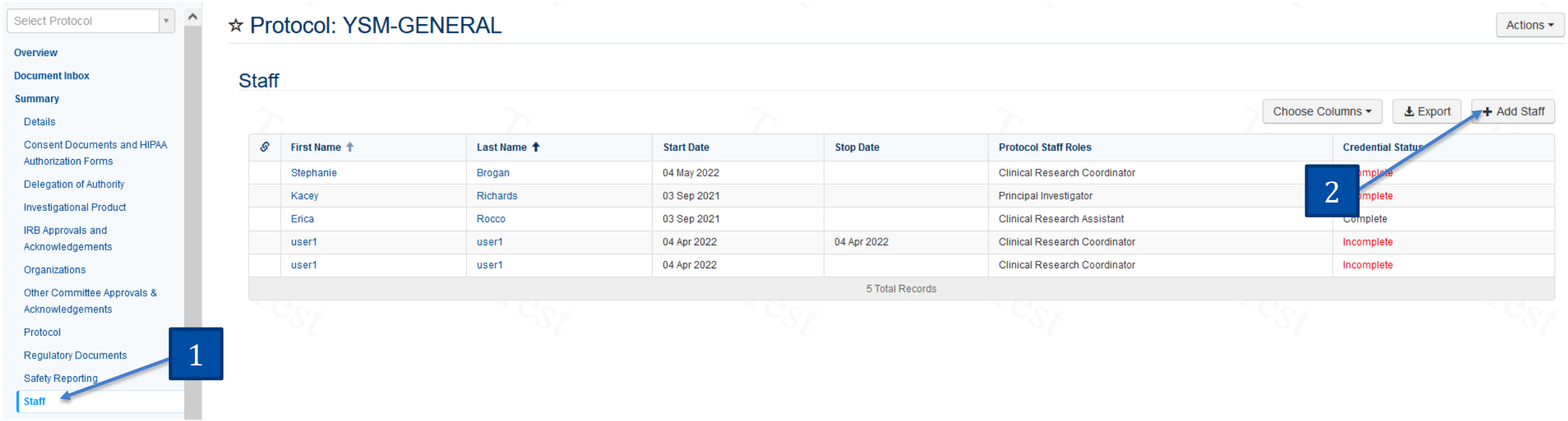
- eReg Support staff will use the information provided to create an account with the correct User Role(s), Staff Role(s), in order to grant the staff member the correct access and permissions.

Adding Staff to Protocols

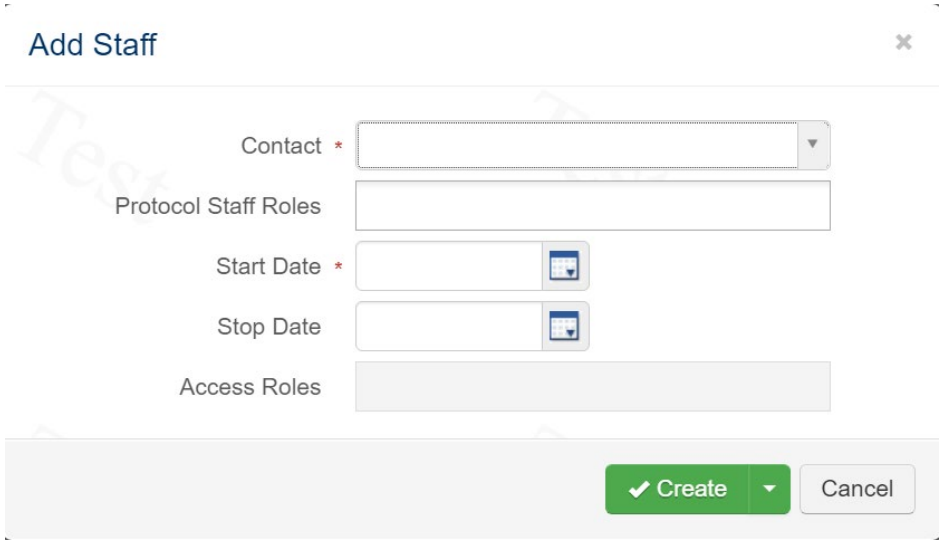
- Staff member will now have an eReg account and can sign documents (ex. Protocol Training) for any protocols with which they are associated.

Building Protocols – Adding Staff to Protocols

- Principal Investigators, Yale Regulatory Managers, Yale Regulatory Coordinators, those with Multi-site Access, and select Administrative roles can add staff members to protocols.
- To add staff, from the protocol home page select:
  1. Staff in the left-hand (Section) menu
  2. Add Staff



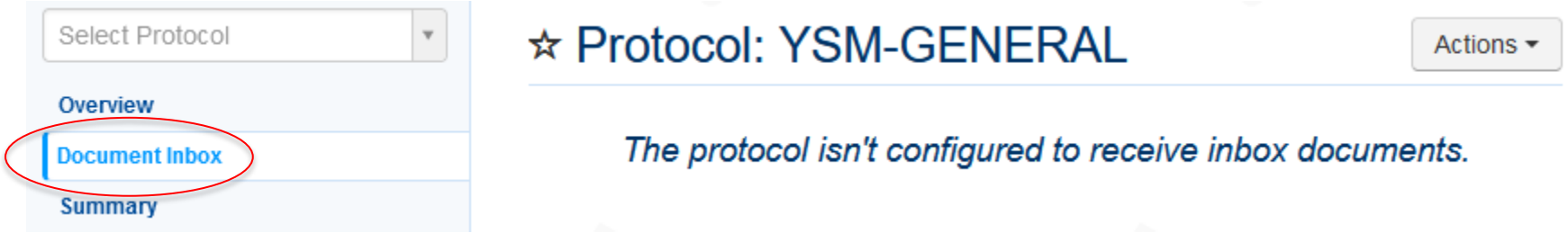
Building Protocols – Adding Staff to Protocols



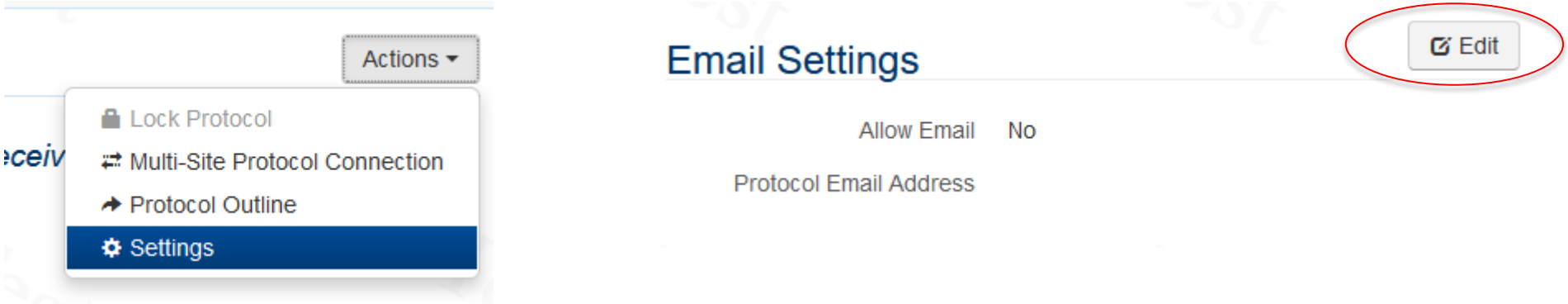
- **Contact:** Select the study staff member you want to add.
- **Protocol Staff Role(s):** Select one of the Protocol Staff Role(s) designated to that individual in their contact record.
- **Start Date:** Enter the date you want this staff person to gain access to the protocol record.
  - **Staff will automatically be added to the delegation of authority log and can be manually removed if they should not be included on the delegation of authority log.**
- **Stop Date:** Enter the date you no longer want this staff person to have access to the protocol record.
- **Access Roles:** Leave blank.

Building Protocols – Email Integration (Demo)

- The Investigator Site File(s) must be configured to receive emails.
- Select the Document Inbox from the Summary Section of the Investigator Site File home page. Before the inbox is configured, you will see a message indicating it is not configured.

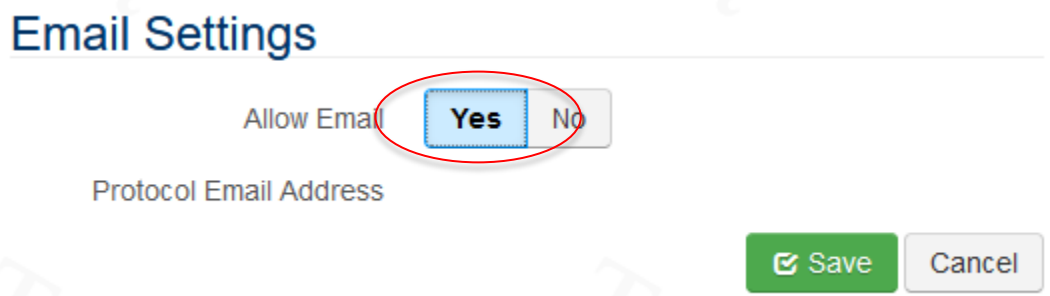


- Select Settings in the Action menu, then click Edit in the Email Settings section.

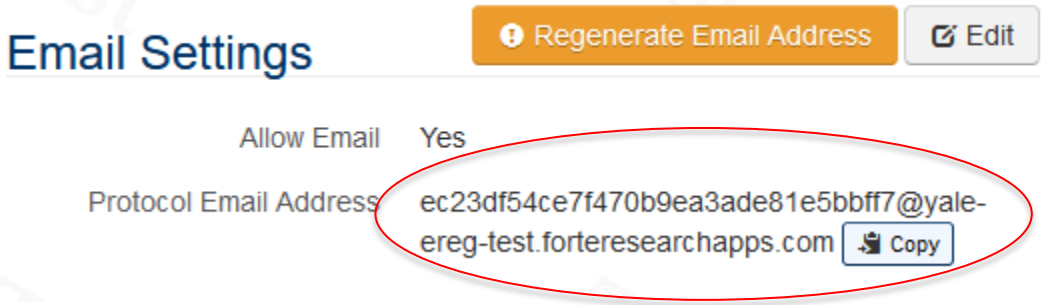


Building Protocols – Email Integration

- Toggle Allow Email setting from No to Yes, then click Save.



- An email address will be generated. Use the Copy button to copy the address and add it to your email contacts (or send it to a user who will be sending documents to the protocol). Only Users who are set up to Send Documents on their contact card can use this feature.



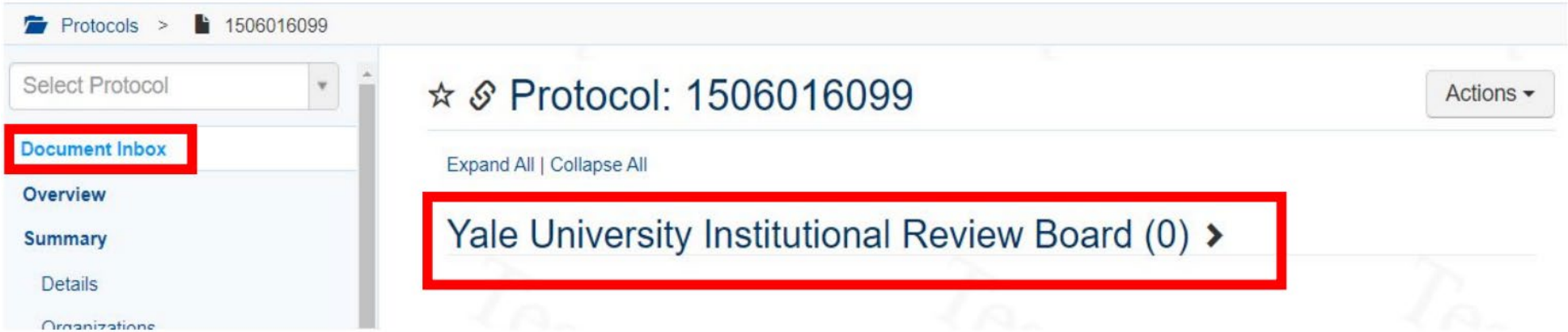
Building Protocols – Yale IRB Integration

Yale University IRB (IRES IRB) is integrated with Advarra eReg, as of April 11, 2024.

IRES IRB → eReg: Protocol Set-Up:

1. eReg Protocol > Details > **IRB Protocol Number field** is populated and correct
2. eReg Protocol > Organizations > Add **Organization**: Yale University Institutional Review Board

New Document Inbox will then appear for Yale IRB:

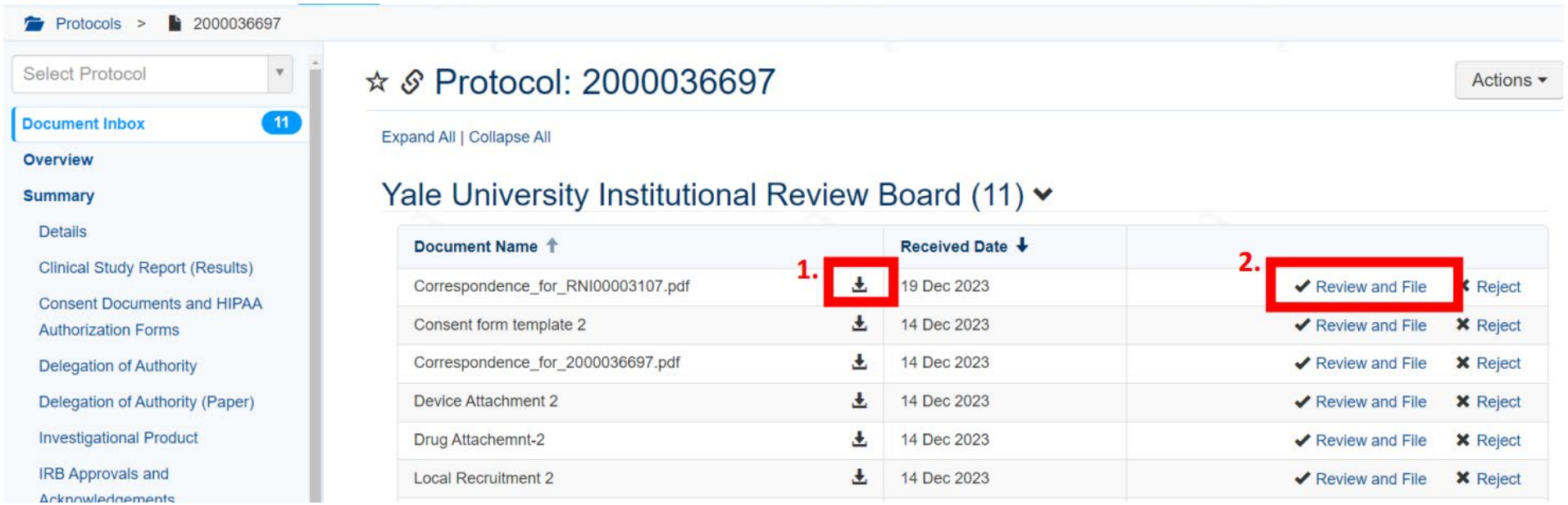


See eReg Guidance - IRES IRB Integration in email messaging for additional details.

Building Protocols – Yale IRB Integration

Documents contained within the following sections in IRES IRB, will flow to eReg upon IRES IRB finalization/approval (may take up to 5min to sync):

- Protocol
- Local Site Documents (Consent Forms, Recruitment Materials and Other Attachments)
- Study-Related Documents (Consent Form Templates, Recruitment Material Templates, Other Attachments)
- Drugs
- Devices



Maintaining eReg Binder

File Management

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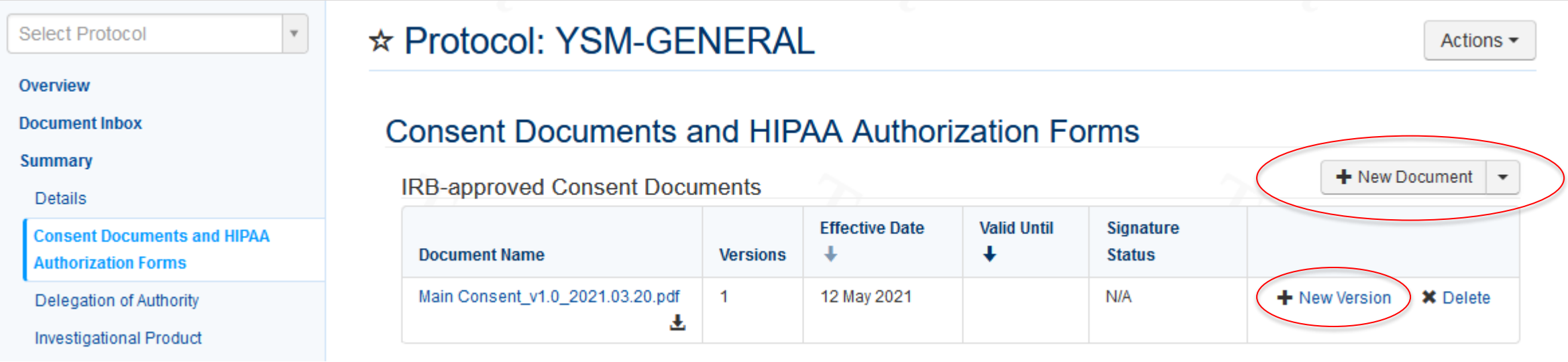
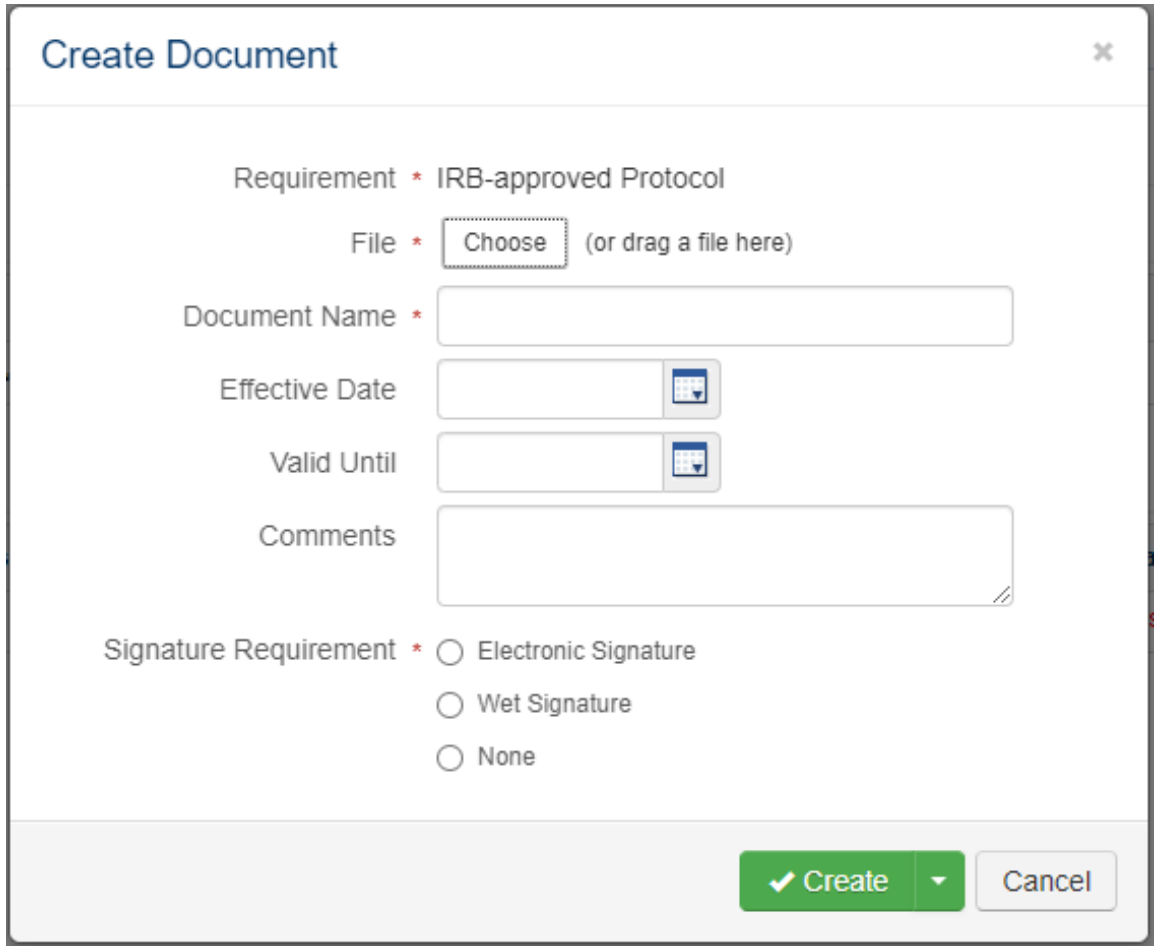
File Management – Adding Documents (Demo)



- To file a protocol document, first navigate to the section and requirement where you would like to upload your document and select “New Document” or “New Version”.
- Note the following:
  - Any document with a file name over 255 characters will become corrupt upon download. Please shorten file name before upload and consider characters within your file name from the file folder location.
  - Limit uploading zip files as they can cause issues during review session downloads due to the character limits outlined above. Zip files cannot be routed for electronic signature.

File Management – Adding Documents

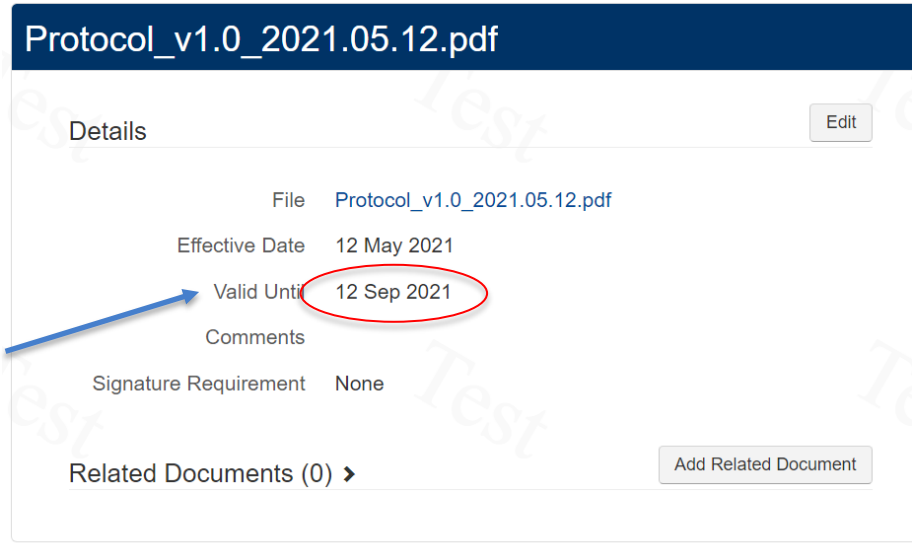
- **Requirement**: Automatically populates
- **File**: Select the file you wish to upload. File name should follow the suggested naming conventions.
- **Document Name**: Automatically populates with the file name. Document name does not need to be modified if file name follows the suggested naming conventions.
- **Effective Date**: Date that the document went into effect
- **Valid Until**: Document expiration date + one day
- **Comments**: Any additional information
- **Signature requirement**:
  - "Electronic Signature" if you wish to route the document within eReg
  - "Wet Signature" if the document is wet ink signed or electronically signed outside of eReg
  - "None" if no signature is needed

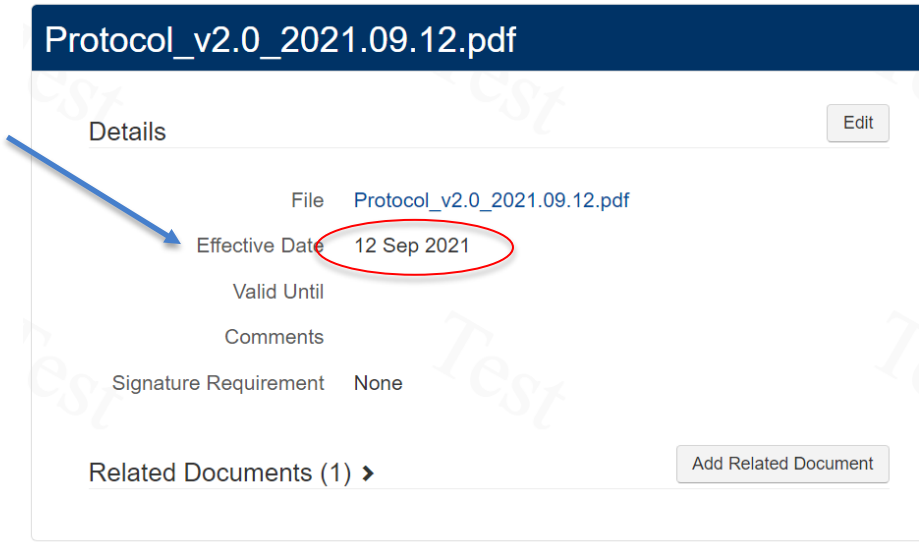


File Management – Adding Documents (Dates)

- Not every document will have an Effective Date
  - If this is the case, use 01 Jan 1900 as the effective date

- Some documents do not have a Valid Until date until the next version of the document is available
  - If this is the case, leave the Valid Until date blank until the new version of the document becomes available. When this occurs, change the Valid Until date for the outdated version of the document to the Effective Date of the new version of the document





File Management – Version Control

- Version control typically includes a version number and version date.
- Update the version number when revising a document that was previously approved by the IRB or designated as a final version.
- Update the version date when a document is revised by any user until such time that the document is approved by the IRB or designated as final.
- Version dates are typically entered as effective dates.
- In certain instances, the version date of a document may not align with the effective date in eReg.
- When the date the document is signed is the effective date and electronically signing in eReg, one will need to edit the details after the document is signed in eReg to update the effective date.

Document Type	Effective Date
Consent Documents and HIPAA Authorization Forms formatted for site use	IRB approval date
Sponsor Consent Templates	Version date of the document
Paper Delegation of Authority Log	Date the study was activated
Documents approved by the IRB such as protocols, Investigator's Brochures, Package Inserts, Instructions for Use, etc.	IRB approval date or IRB acknowledgement date
IRB and Other Committee Approval or Acknowledgement Letters	Date of the letter
Regulatory Documents such as Financial Disclosure Forms, Form FDA 1572s, Investigator Agreements, Protocol Signature Pages, Investigator's Brochure receipt pages, etc.	Date the document is signed
Staff Training	Date the training was conducted/ completed by the staff member
Study Conduct Documents	Version date of the document
Email or Telephone Correspondence	Date of first communication on the specific topic
Notes to File	Version date of the document, or date the document is signed
Site Study Correspondence	Date included on memo, letter, newsletter, etc.
Study Logs	Date the study was activated or date the log was put into effect for use

File Management – Version Control

- Not all documents will include a valid until date.
- If a document does not include an effective date, version date, and valid until date, a date must still be entered in eReg for either effective date or valid until date.
- Use 01 Jan 1900 as an effective date for documents without any version control.

Document Type	Valid Until Date
Consent Documents and HIPAA Authorization Forms formatted for site use	IRB expiration date + one day, if applicable Reminder: Date ranges in eReg are based on midnight
Documents approved by the IRB such as protocols, Investigator's Brochures, Package Inserts, Instructions for Use, etc.	IRB expiration date + one day, if applicable Reminder: Date ranges in eReg are based on midnight
Other documents	Valid until or expiration date + one day noted within the document

File Management – Adding Related Documents

- Related documents can be added to single documents and should be used to tie documents together like a paper clip.
- Example: For IRB and other committee approvals:
  - Main file = Approval Letter
  - Related documents = Submission documents, Acknowledgements of Receipt, Correspondence, Approval documents not filed elsewhere, etc.
    - Note: Related documents cannot be routed for electronic signature. Copies of related documents cannot be sent to a Multi-Site protocol maintained in eReg.

File Management – Adding Related Documents

- Utilize the related documents filing feature for the following document types:
  - IRB approvals letters
  - IRB acknowledgement letters
  - Ancillary committee approval letters
  - Ancillary committee acknowledgement letters
  - Data and Safety Monitoring Board/ Committee decision letters
  - External Safety Reports
  - Internal Safety Reports
  - Study Correspondence
  - Site Monitoring Visit Follow-up Reports
  - Sponsor Correspondence
- Refer to the *eReg Guidance Document for Investigator Site File Regulatory Templates* found on the YCCI eReg website for more information.

File Management – Adding New Versions

- If there is more than one version of the same document, they will be stacked (added as a new version on top of the existing version, not as a new document).

Examples of Documents to Stack

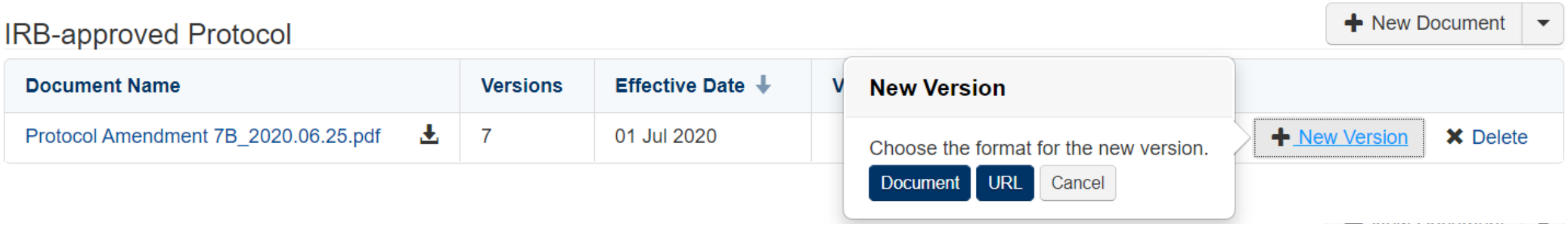
- Protocols
- Investigator's Brochures/ Instructions for Use
- Consent/ Assent Documents
- Financial Disclosure Forms (by person)
- Study Manuals

Examples of Documents to File Separately

- IRB approval and acknowledgement letters
- Correspondence
- Site Monitoring Reports

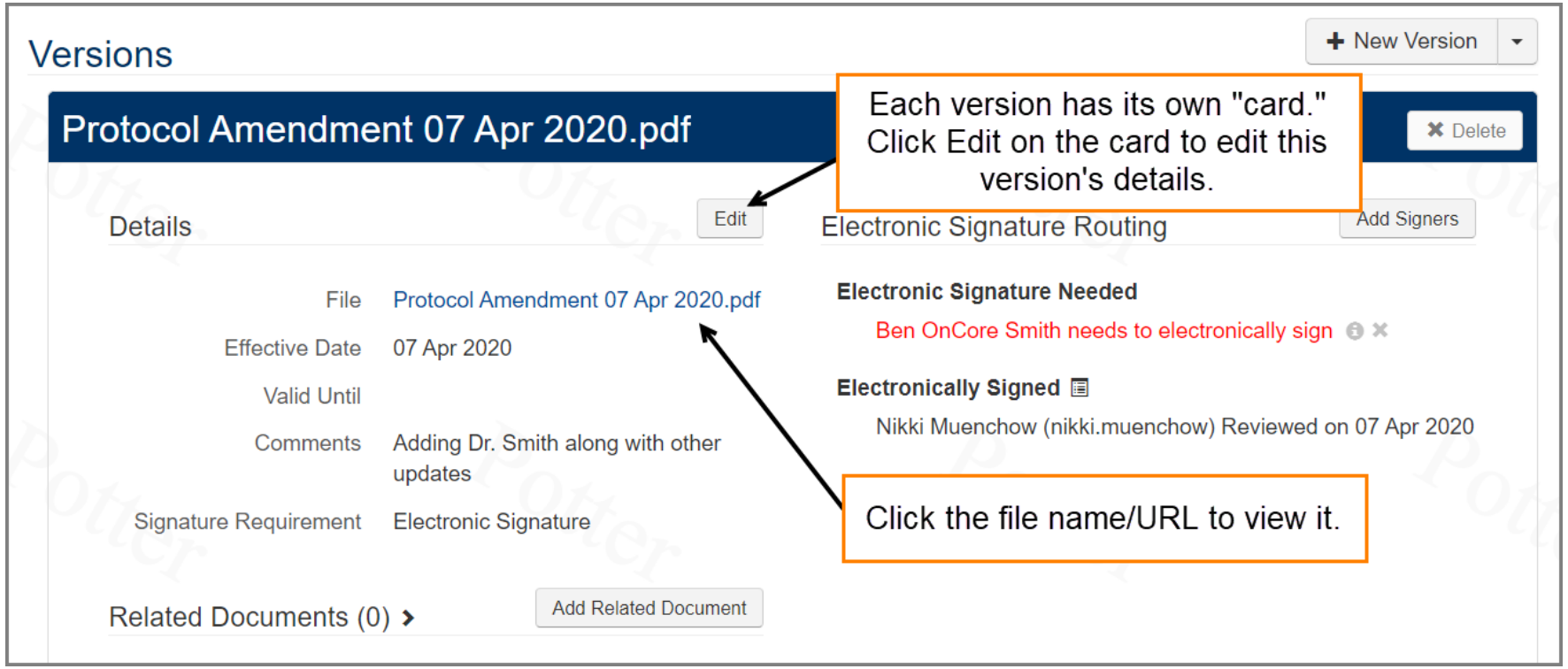
File Management – Adding New Versions

- To stack a document, select “New Version”
- Choose the format for the new version: Document or URL



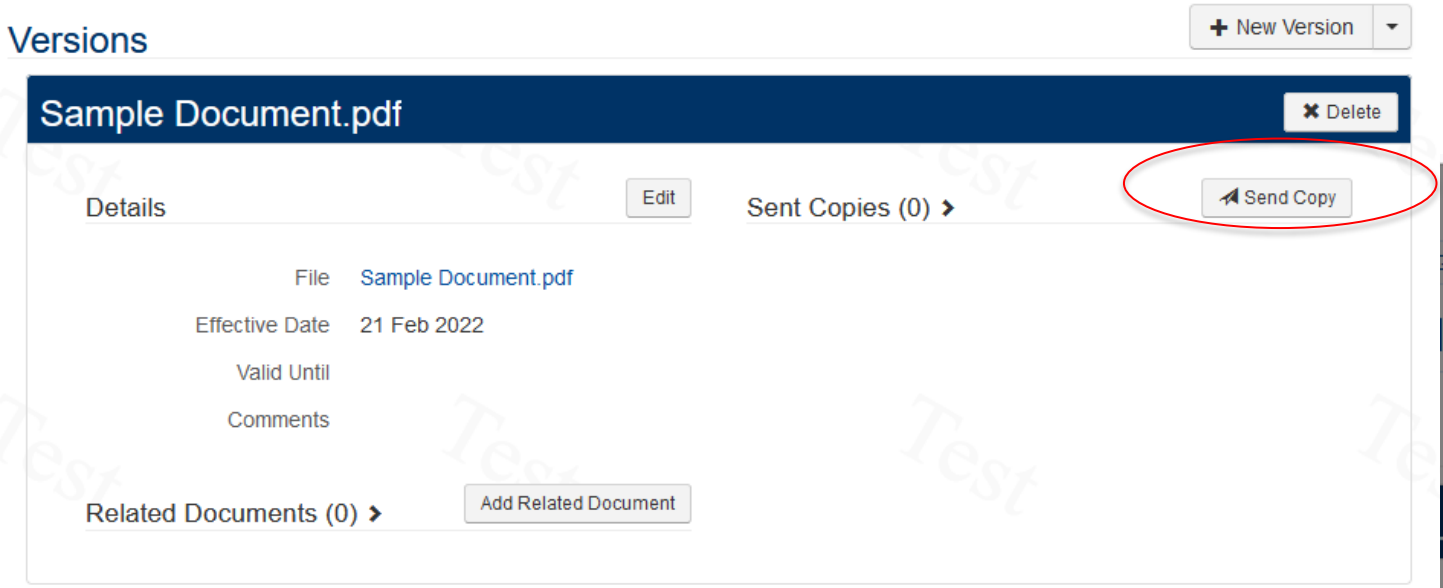
File Management – Adding New Versions

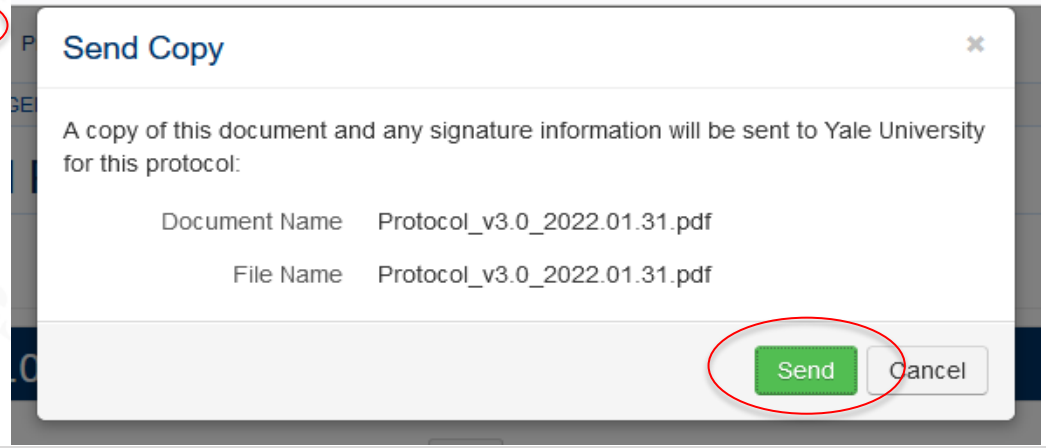
- When viewing a Section, click the link for the Requirement (document) within the Section to see all versions of that Requirement.
- On the Versions page, you can view the details, related documents, signature status and information about sent copies for each stacked version of the requirement.



File Management – Sending Copies

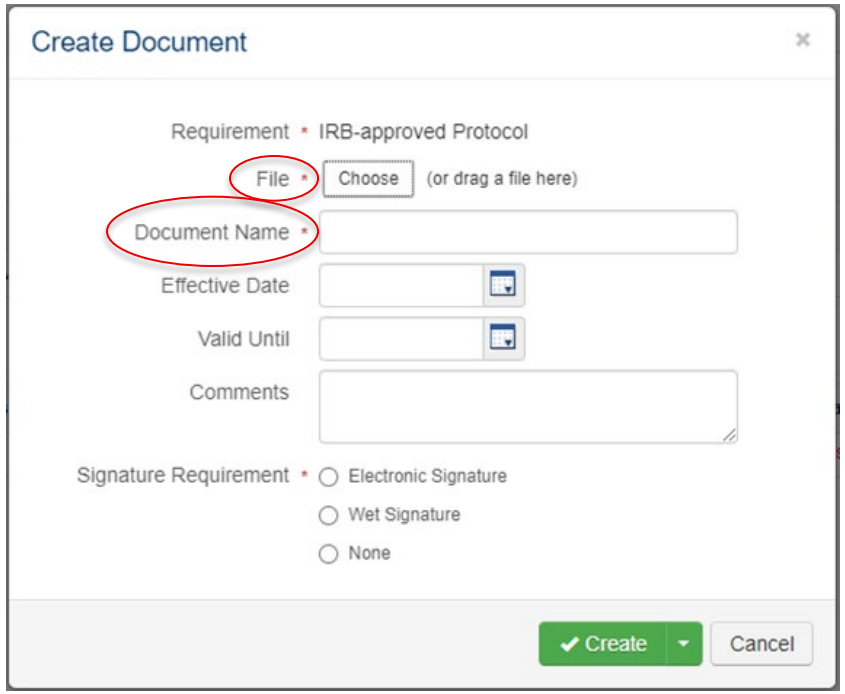
- When the TMF is also maintained in eReg, the Regulatory Coordinator or Regulatory Manager will send copies of regulatory and essential documents from their ISF directly to the TMF within eReg.
- Navigate to the document and click the hyperlink to view the details. Click Send Copy. Confirm details on the pop-up screen then click Send.
- Refer to the *eReg Guidance Document for Sending Document from ISF to TMF* found on the YCCI eReg website for more information.





File Management – Naming Conventions

- Follow naming convention guidelines set forth by YCCI or your department for the File and Document Name. YCCI naming conventions are available in the *eReg Guidance Document for Investigator Site File Regulatory Templates* found on the YCCI eReg website.
- It is best practice to utilize naming conventions which include a brief description of the document, who or what it associates to, and version control to include version number and version date.



File Management – Naming Conventions

- Sample YCCI naming conventions from eReg Guidance Document:

Document Type	Naming Convention
IRB-approved Consent Documents	Main Consent_v[#]_yyyy.mm.dd
Instructions for Use	[Device Short Name] Instructions for Use_v[#]_yyyy.mm.dd
Investigator's Brochure	IB for [Drug Short Name]_Ed[#]_yyyy.mm.dd
IRB Initial Approval	IRB Initial Approval Ltr_yyyy.mm.dd
IRB Amendments	[Amendment Identifier]_IRB Approval Ltr_yyyy.mm.dd
IRB Renewals	[Renewal Identifier]_IRB Approval Ltr_yyyy.mm.dd
IRB Prompt Reporting	[Prompt Report Identifier]_IRB Ack Ltr_yyyy.mm.dd
IRB Closure	IRB Closure Ltr_yyyy.mm.dd
IRB-approved Protocol	Protocol_v[#]_yyyy.mm.dd
Form FDA 1572	Form FDA 1572, v[#]
Investigator Agreement	Inv Agreement_yyyy.mm.dd
Financial Disclosure Forms	FDF_[Last Name, First Name]_yyyy.mm.dd
Internal Safety Reports	SAE_[Subject ID #]_[Event Term]_yyyy.mm.dd
External Safety Reports	INDSR_[Tracking Number]_yyyy.mm.dd
UADE Safety Reports	UADE Safety Report_yyyy.mm.dd
EDC Training Certificates	[EDC System] Training_ [Last Name, First Name]_yyyy.mm.dd
Site Monitoring Reports	IMV [#] FU Report_yyyy.mm.dd
Case Report Forms	CRF_[Form Identifer]_v[#]_yyyy.mm.dd
Sponsor Correspondence	Sponsor Correspondence_[Topic Description]_yyyy.mm.dd
Notes To File (NTF)	NTF_[Brief Description]_yyyy.mm.dd
Enrollment Log	Enrollment Log_yyyy.mm.dd

File Management – Signature Requirements

- Signature requirements apply to contact credential documents and protocol documents.
- URLs and regulatory tracking items cannot be signed.
- eReg includes three signature requirement options:
  - Electronic Signature with three signature meanings:
    - Approved
    - Read and Understood
    - Reviewed
  - Wet Signature
  - None
- Refer to the *eReg Guidance Document for Electronic Signatures* found on the YCCI eReg website for more information.

File Management – Signature Requirements

Signature Requirement	Use	Signature Placement
Electronic Signature	Select for documents to be routed for electronic signature within eReg.	Default Location or Custom Location*
Wet Signature	Select for documents signed in wet ink and/ or electronically signed outside of the eReg system. This requirement may be selected for documents including but not limited to: • Delegation of Authority Log (paper) • Investigational Product/ Device Documents • Financial Disclosure Forms • Other documents that have been digitally signed outside of eReg (using 21 CFR Part 11 compliant software, if necessary)	N/A
None	Select for documents that are not signed and will not be routed for electronic signature within eReg.	N/A

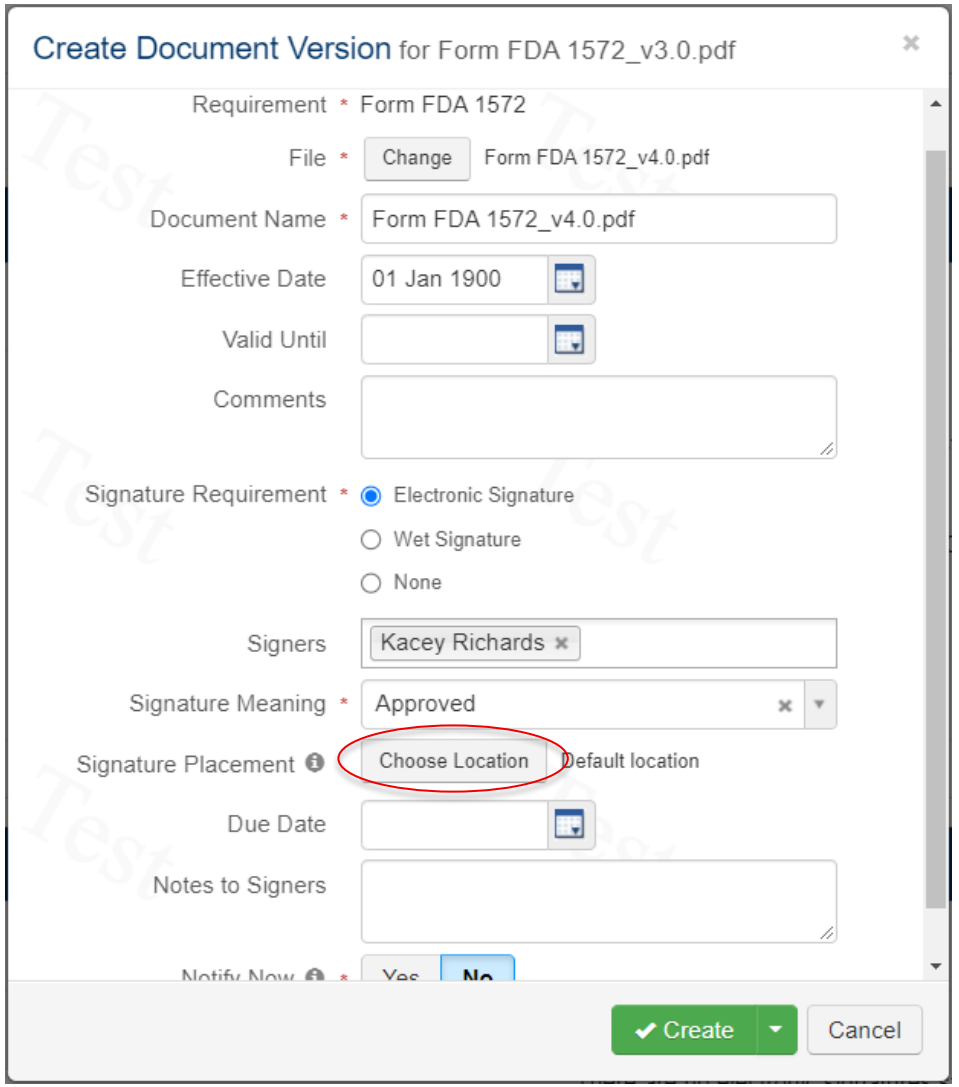
* Default Location (appended to the last page of the document) must be used for all documents requiring multiple signers. The Custom Location can be used if the document requires one signature, such as a protocol signature page.

File Management – Electronic Signature Meaning and Suggested Use

Signature Meaning	Documents	Signature Placement	Due Date
Approved	Curriculum Vitae (CV)	Default location	
	Delegation of Authority Log	N/A	Ensure protocol staff sign-off and PI sign-off on start dates and tasks is obtained before the staff person participates in the conduct of the study.
	Form FDA 1572	Custom location (Box 11 of the Form)	
	Investigator Agreement	Custom location	
	Notes To File (NTF)	Default or Custom location	
	Study Specific Standard Operating Procedures (SOPs)	Default location	
Read and Understood	IRB-approved Protocol	Default location	Ensure protocol training is obtained before the study staff person participates in the conduct of the study.
	Electronic Data Capture (EDC) Training	Default location	Ensure training is documented before the staff person uses the EDC system.
	Other Protocol Specific or System Training	Default location	Ensure training is documented before the staff person uses the system.
Reviewed	Investigator's Brochure Receipt Page	Custom location	Contemporaneous to receipt of the Investigator's Brochure.
	Protocol Signature Page	Custom location	Contemporaneous to the receipt of the protocol.
	IND Safety Reports	Default location	Contemporaneous to notification of the safety event.
	SAE Reports	Default location	Contemporaneous to notification of the safety event.

File Management – Adding Electronic Signatures (Demo)

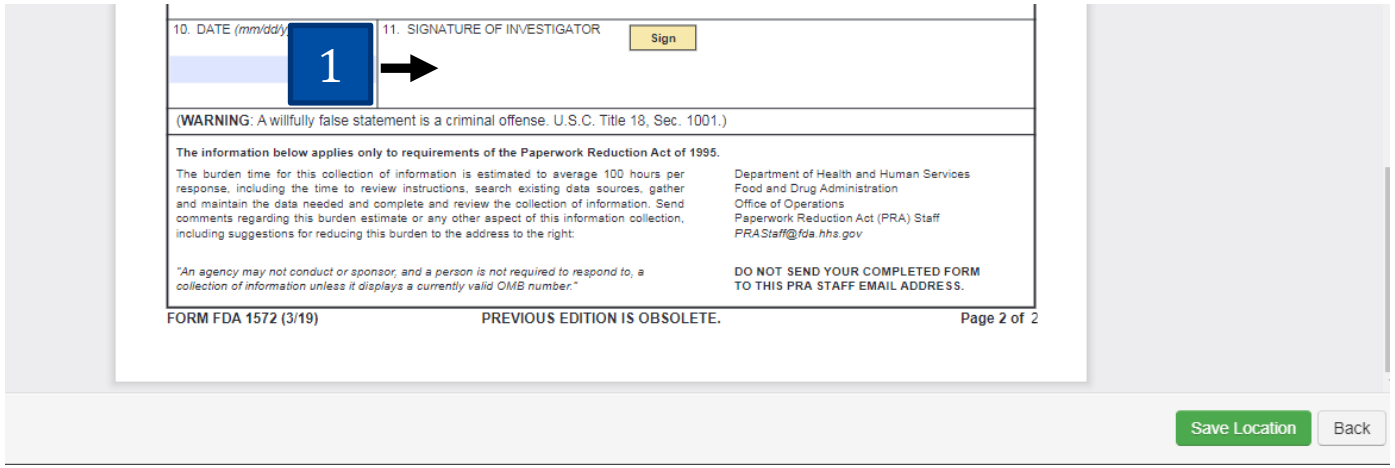
- **Default Location:** Signature manifestation is appended to the end of the document.
- **Choose Location for Signature Placement**: If you want to apply the electronic signature to a designated location on an FDA form, you can choose to place the signature when you set it up for routing.
  - All information must be entered into the FDA form before being uploaded and routed for placed signature.
  - You can choose a signature placement location instead of using the default placement location only when:
    - the document is a PDF,
    - it is being signed electronically,
    - one signer is specified, and
    - a signature meaning has been selected for the document.
  - When these criteria are met, the Choose Location button that was view-only changes to active in the Create Document window.

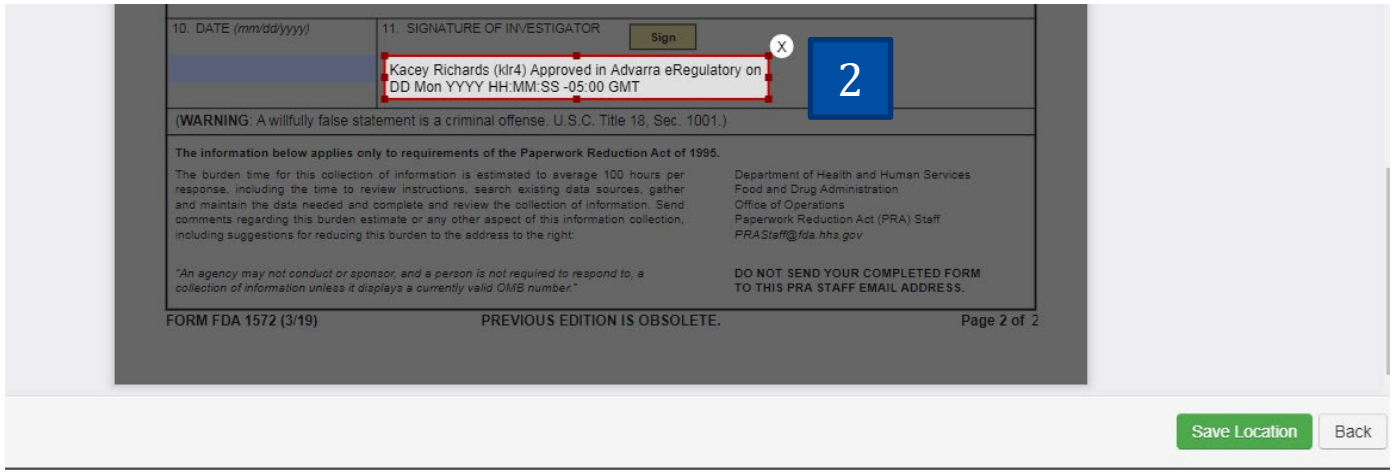


File Management – Adding Electronic Signatures to Custom Location

- To specify the Signature Placement location for a New Document:
  1. Locate the area of the document where you want to place the signature.
  2. Adjust the text box until it appears how you want it. You can move it around in the area and change its height and width.

     If you want to remove the box from where you placed it, click the X to delete it.

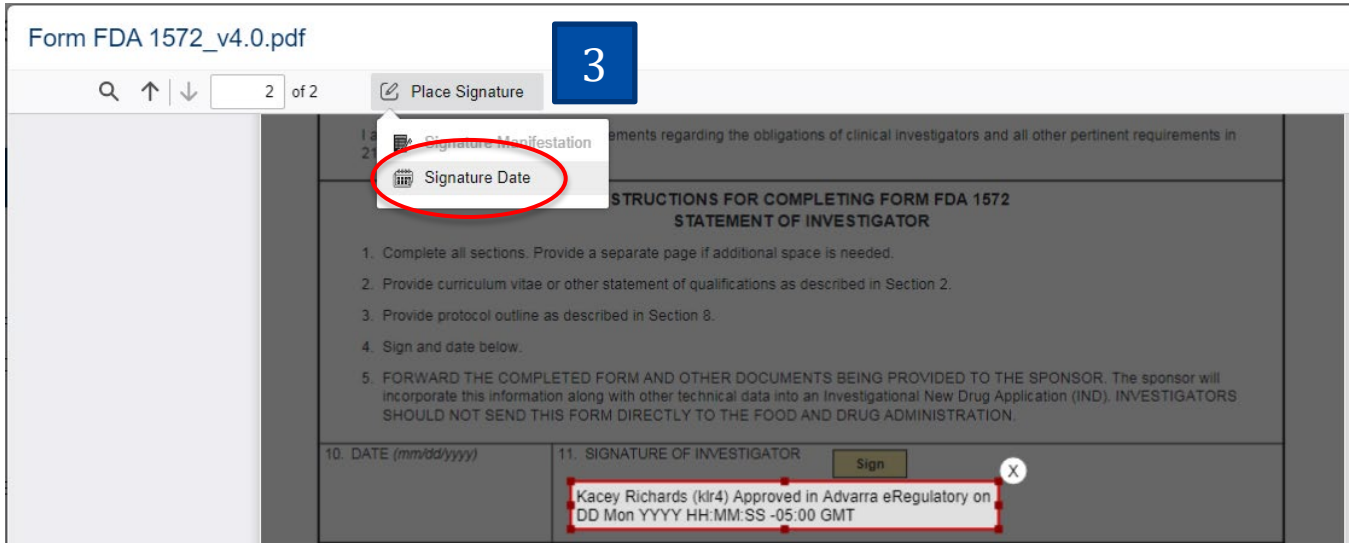


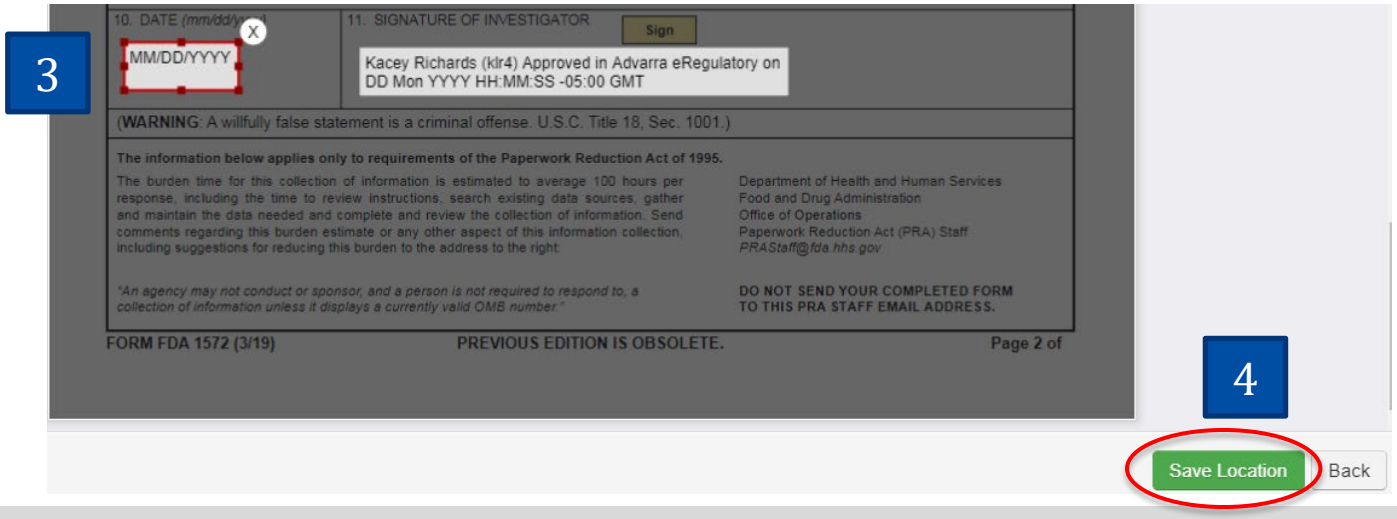


File Management – Adding Electronic Signatures to Custom Location

3. Select Signature Date from the dropdown in the top of the window, to select the area of the document where you want to place the Date. Adjust the text box until it appears how you want it. You can move it around in the area and change its height and width.

   If you want to remove the box from where you placed it, click the X to delete it.

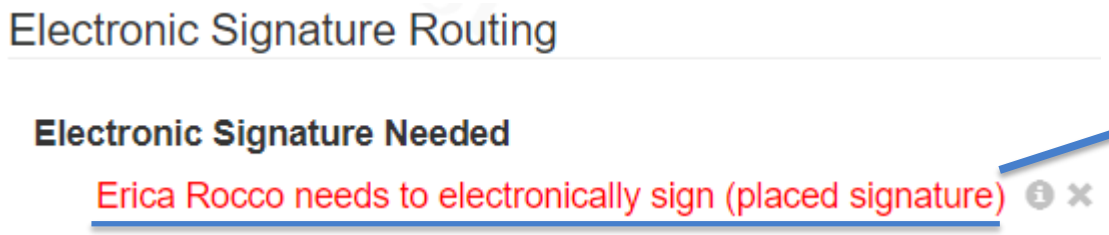




4. When the boxes are where you want them to appear on the signed document, click Save Location to return to the Create Document window.

File Management – Editing Custom Location Electronic Signatures

- How to edit the Location for a Placed Signature on an existing document
  - You can change the location of a placed signature on a protocol document before it is signed. You cannot change the location after the document is signed.
  - View the Versions page for the document. If you've already specified a signature location, you'll see "(placed signature)" in the Electronic Signature Routing section.



  - Click on the link "[Name] needs to electronically sign (placed signature)" to see Electronic Signature Details.
  - Click Choose Location to specify a different location by following the workflow outlined in the Adding Electronic Signatures to Custom Location (previous slide).
  - After you've chosen a new location, click Save.

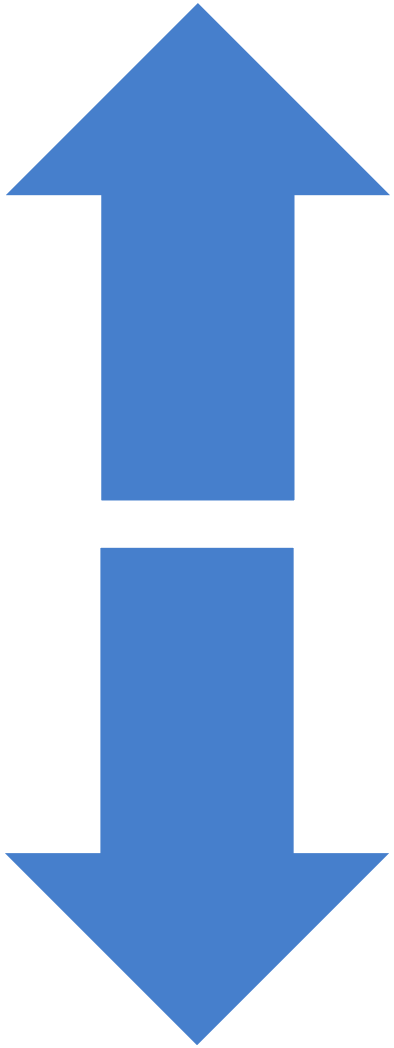
Maintaining eReg Binder

Documenting Staff Training

YCCI Yale Center for Clinical Investigation

Documenting Staff Training – Recommended Use (Demo)

- The Staff Training section is a default section in the regulatory templates.
  - When utilized, departments can review the status of all staff training documents for one or more protocols in order to have a full picture of team training compliance.
- You may upload additional relevant training materials, such as training slides, as related documents to the main file.
  - These related documents cannot be electronically signed.
- If additional training materials require signature, you can either append them as a PDF to the main file or route them for signature separately within the Staff Training Section.



Protocols Section

- Add the IRB-approved Protocol for general filing

Staff Training Section

- Add the IRB-approved Protocol to Protocol Training requirement and route for electronic signature with a meaning of “Read and Understood”

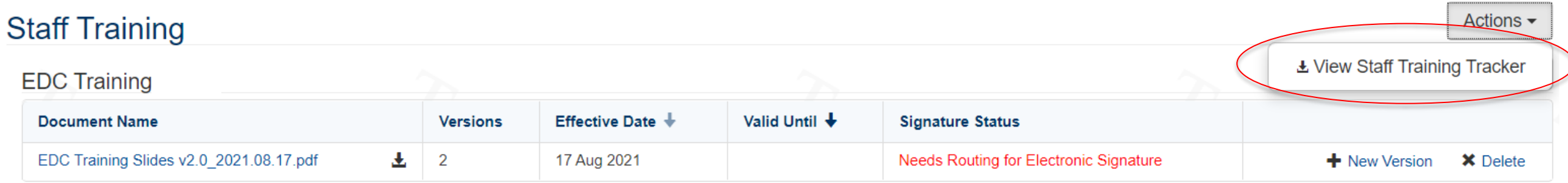
Documenting Staff Training – Recommended Use

- When routing a document for electronic signature in order to document training, you will enter the following information:
  - **Signature Requirement**: Electronic signature
  - **Signers**: All required staff members
  - **Signature meaning**: Read and Understood
  - **Due Date**: Date by which the signatures need to be documented
  - **Note to Signers**: Any information you would like staff to know prior to signing
  - **Notify Now**: Select "Yes" if you would like to send an email to the staff members immediately. Select "No" if you do not want to send an email to the staff immediately. Return here to resend notifications.

  Note: Only one signature requirement method can be selected per document.

Documenting Staff Training – Recommended Use

- A Staff Training Tracker report can be downloaded to view who has signed off on each version of the documents contained in this section.



- In addition to the protocol-level Staff Training Tracker, there is a Staff Training Tracker by Staff Member report (Menu > Reports) that allows you to review the staff training status of a member across one or more protocols.

Name	Description	Report Group	Type
Staff Training Tracker by Protocol	Displays the signature status for a specified protocol's staff training documents. If this report is run for a multi-site protocol, only documents from the coordinating center are included.	Standard Reports	Standard
Staff Training Tracker by Staff Member	Displays the signature status of staff training documents across protocols for specified staff.	Standard Reports	Standard

Documenting Staff Training – Staff Training Tracker

Staff Training Tracker by Protocol

Protocol: YSM-GENERAL - Yale University

PIs: Kacey Richards

First Name	Last Name	Staff Role	Start Date	Stop Date	Protocol v1.0 2021.05.12.pdf 12 May 2021 - 12 Sep 2021	Protocol v2.0 2021.09.12.pdf 12 Sep 2021 - Current
Kacey	Richards	Principal Investigator	03 Sep 2021		01 Jun 2021	16 Dec 2021
Erica	Rocco	Clinical Research Assistant	03 Sep 2021		01 Jun 2021	

For each staff training document, the active dates for that document are listed.

Staff Training Tracker by Staff Member

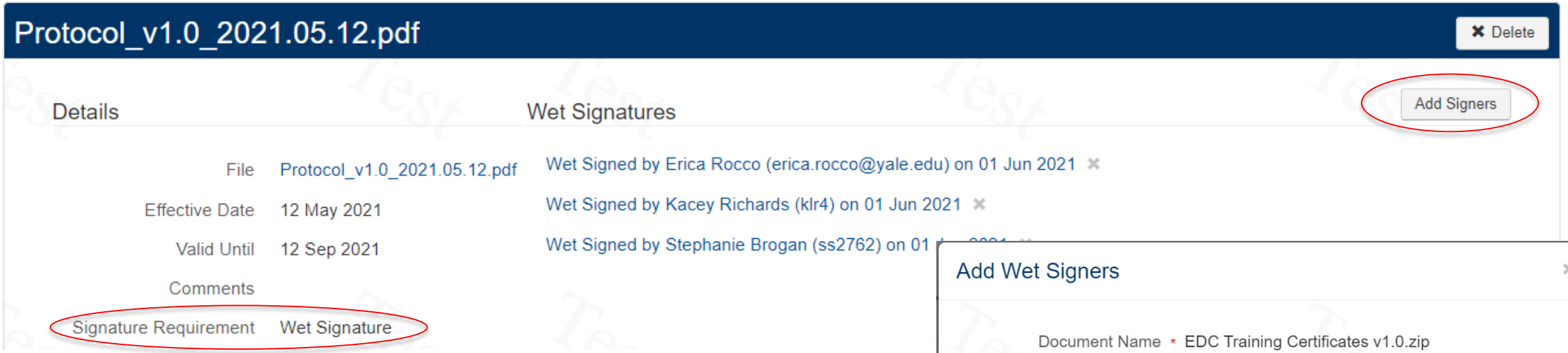
Staff Members: Ann L. Kurtis, Ben R. Jones

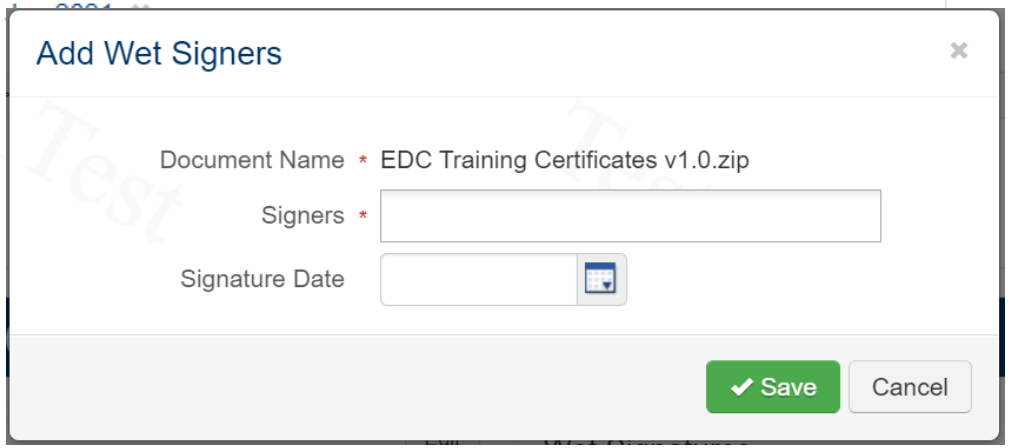
Include Signed Documents: Yes

First Name	Last Name	Protocol	Study Site	Staff Role	Staff Start Date	Staff Stop Date	Staff Training Document Name	Document Effective Date	Document Valid Until Date	Signature Date
Ann	Kurtis	ALK 107921	Multi-Site	Principal Investigator	18 Mar 2020	31 Dec 2020	Training Manual.pdf	19 Mar 2020		01 Apr 2020
Ann	Kurtis	ALK 107921	Multi-Site	Principal Investigator	18 Mar 2020	31 Dec 2020	Protocol Training v3.pdf	19 Mar 2020	29 Apr 2020	01 Apr 2020
Ann	Kurtis	PTL 20200304	East Clinic	Principal Investigator	04 Mar 2020		Clinical Practices.pdf	13 Mar 2020		
Ann	Kurtis	PTL 20200304	East Clinic	Principal Investigator	04 Mar 2020		Training Materials.pdf	13 Mar 2020		29 Apr 2020
Ben	Jones	AAA Demo Protocol	Baylor - East Clinic	Affiliate Principal Investigator	01 Apr 2020		Training Manual.pdf	01 Apr 2020		
Ben	Jones	PTL 20200304	East Clinic	Affiliate Principal Investigator	29 Apr 2020		Training Materials.pdf	13 Mar 2020		29 Apr 2020
Ben	Jones	PTL 20200304	East Clinic	Affiliate Principal Investigator	29 Apr 2020		Training Materials.pdf	13 Mar 2020		

Documenting Staff Training – Additional Uses

- If a document is not being routed for electronic signature, you still have the option to utilize the Staff Training Tracker functionality by adding Wet Signature statuses for everyone who was trained.
- When you upload the document, you can manually enter a wet signature for each staff member based on who signed the document, attended a meeting, etc.



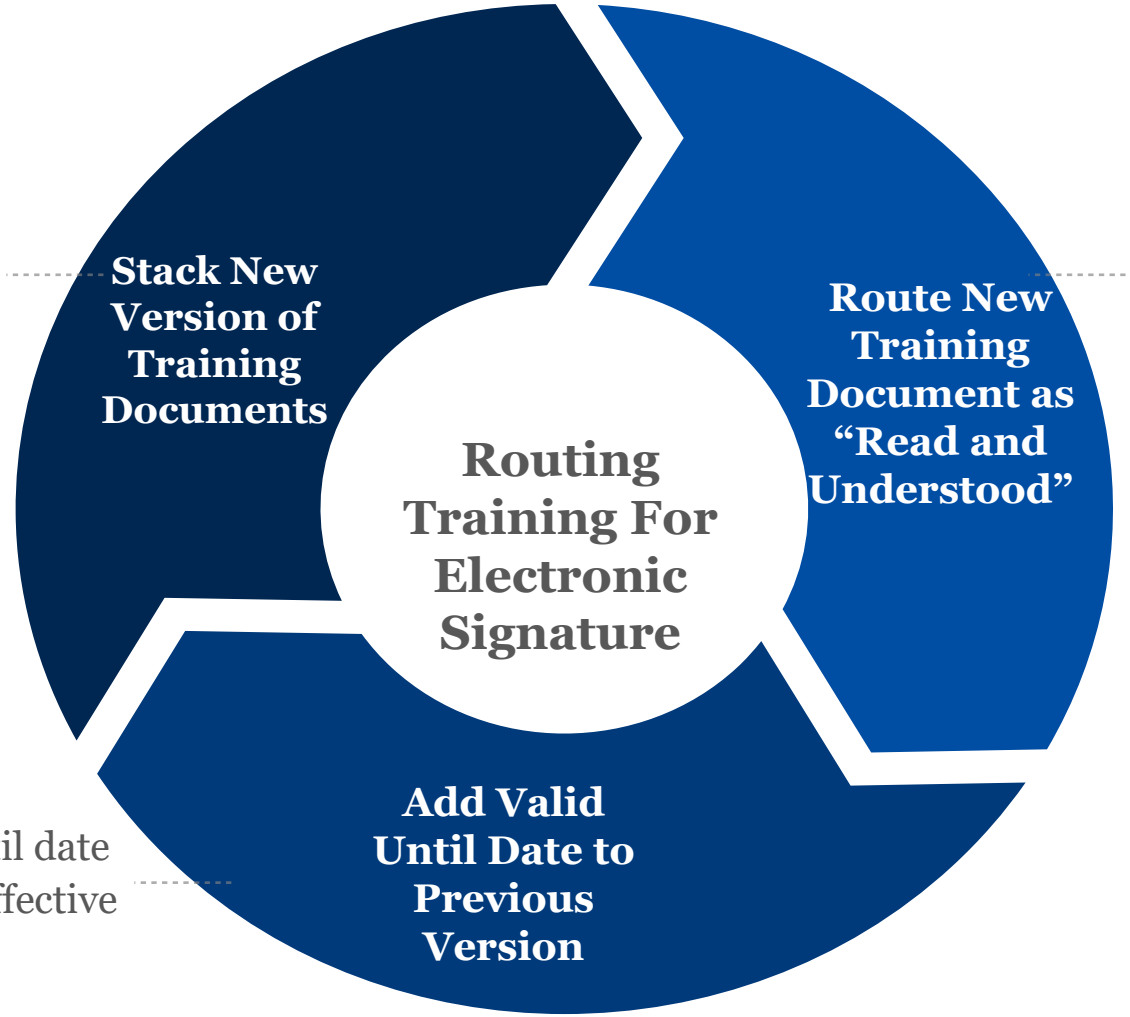


- You will enter the following information:
  - **Signers:** Add Staff member. You must add all signers manually.
  - **Signature Date:** Date of the wet signature.

Documenting Staff Training – Documents to Route

1. Stack

When a new version of a training material is available, stack it on top of the prior version



2. Route for Electronic Signature

Examples of documents to stack and route for training documentation include but are not limited to:

- Electronic Data Capture (EDC) Training Slide Deck
- EDC Training Video Script
- Institutional Review Board (IRB)-approved Protocol
- Corrective and Preventative Action Plan (CAPA)
- Other protocol specific or system training materials

3. Add Valid Until Date

To maximize the utility of the Staff Training Tracker, enter a Valid Until date for the prior version equal to the Effective Date of the current version.

Refer to *eReg Guidance Document for Staff Training Protocol Section* for more information.

Maintaining eReg Binder

Delegation of Authority Log

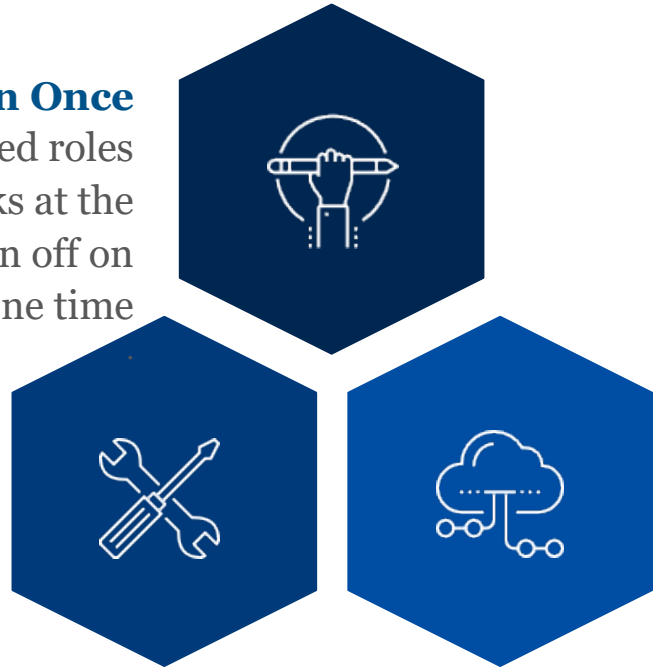
YCCI Yale Center for Clinical Investigation

Delegation of Authority Log – eReg Workflow

- The Master Delegation of Authority allows for increased compliance, a gain in efficiency, and reduced administrative burden

Sign Once
Staff members are assigned roles and associated tasks at the contact level and sign off on those roles/tasks one time

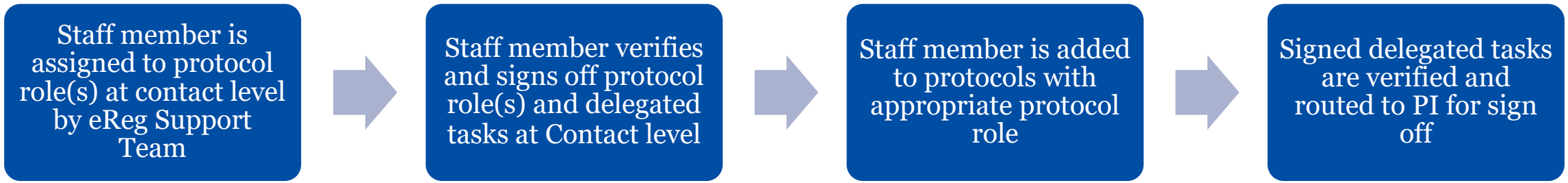
Can be Modified
Tasks can be modified at the protocol level, as needed, to meet the needs of the study and/ or sponsor



Flows to Every Protocol
With this method, the signed tasks are inherited by any protocol with which the staff member is associated

Delegation of Authority Log – eReg Workflow

- eReg Support team will assign a delegated task by staff role which includes Yale standardized delegated tasks typically performed by these roles
  - Additional tasks can be added to specific staff members if they perform those tasks for all or most protocols to which they are assigned
- Staff members electronically sign off on those roles and tasks at the contact-level, one time
- The signed tasks are inherited by any protocol with which the staff member is associated



Delegation of Authority Log – Delegated Tasks by Staff Role

Task	Clinical Research Assistant	Clinical Research Coordinator	Regulatory Coordinator	Research Laboratory	Research Nurse
Conduct informed consent		X			X
CRF/ eCRF - Data entry/ Correction	X	X			X
CRF/ eCRF - Review/ Sign					
CRF/eCRF - Query Response/Resolution	X	X			X
Determine subject eligibility		X			X
IRB/ Ethics Committee - Submission/ Communication		X	X		X
Maintain Investigator Site File/ regulatory documents		X	X		X
Perform study assessments		X			X
Research Biospecimens – Process	X	X		X	X
Research Biospecimens – Ship	X	X		X	X
Safety Event - Assess causality, attribution and severity					
Safety Event - Collect data		X			X
Safety Event – Report	X	X			X

Delegation of Authority Log – Delegated Tasks by Staff Role

Task	Pharmacist	Pharmacy Technician	Principal Investigator	Sub-Investigator
Conduct informed consent			X	X
CRF/ eCRF - Review/ Sign			X	
CRF/eCRF - Query Response/Resolution				
Determine subject eligibility			X	X
Evaluate study assessments			X	X
Investigational Product - Accountability	X	X		
Investigational Product - Destruction/Return	X	X		
Investigational Product - Dispensing	X			
Investigational Product - Preparation	X	X		
Investigational Product - Prescribe			X	X
Investigational Product - Receipt/ Storage	X	X		
Perform physical exams			X	X
Perform study assessments			X	X
Safety Event - Assess causality, attribution and severity			X	X
Safety Event - Collect data			X	X
Safety Event - Report			X	X
Subject recruitment			X	X

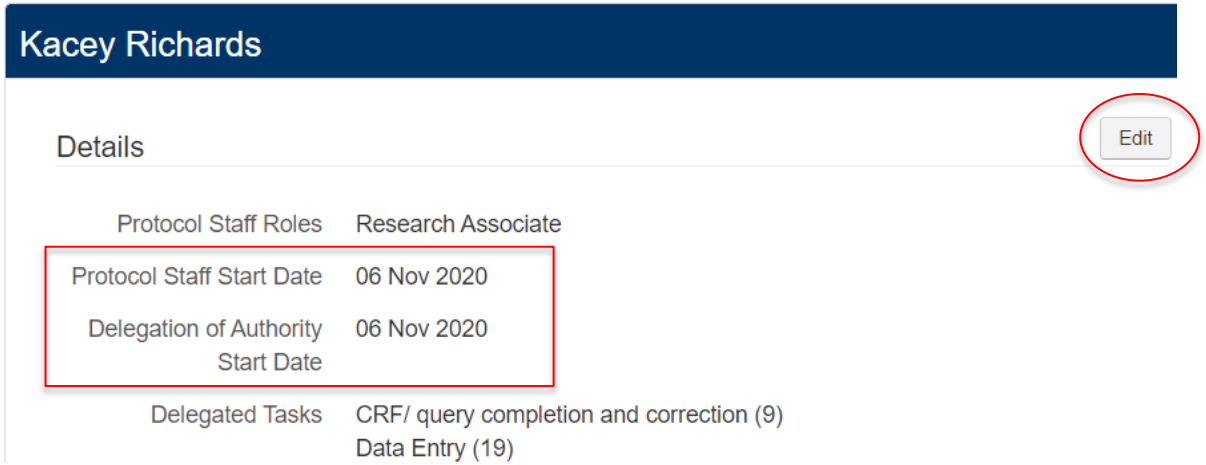
Delegation of Authority Log – Additional Delegated Tasks in eReg

- These additional tasks are available in the Delegated Tasks reference list within eReg.
- These tasks can be selected for a contact record or protocol record, as needed.

Order	Task
14	IVRS/IWRS entry
15	Collect Vital Signs/ECG
16	Emergency Unblinding of Subjects
17	Subject education and/or training
19	Blinded Personnel
20	Unblinded Personnel
21	Apheresis Product - Cryopreservation, sampling, packaging and shipping
29	Research Biospecimens - Collect
32	Investigational Device - Receipt/ Storage
33	Investigational Device - Accountability
34	Investigational Device - Destruction/ Return
35	Investigational Device – Device Use/ Implantation

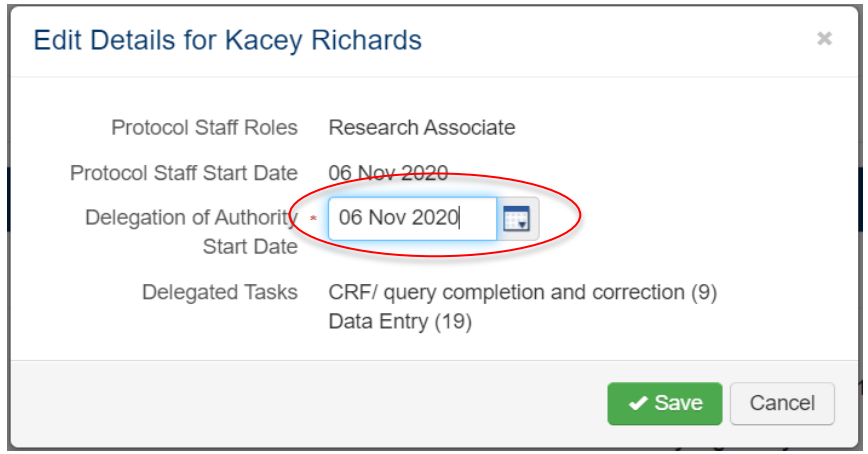
Delegation of Authority Log – Adding Start Dates

- Two start dates appear in the Delegation of Authority section: Protocol Staff Start Date and Delegation of Authority Start Date.
  - Protocol Staff Start Date: The date the staff member has access in eReg to begin viewing and updating the eReg record, and/ or to begin signing documents within the eReg system. Past, current and future dates can be selected. This date must be entered in order to add a Delegation of Authority Start Date.
  - Delegation of Authority Start Date: The date the staff member can begin working on the study. Past, current and future dates can be selected. Consider a staff member's IRB approval status, if applicable, protocol training status and the overall protocol status (i.e., in study start up vs. active) when determining delegation of authority start dates.



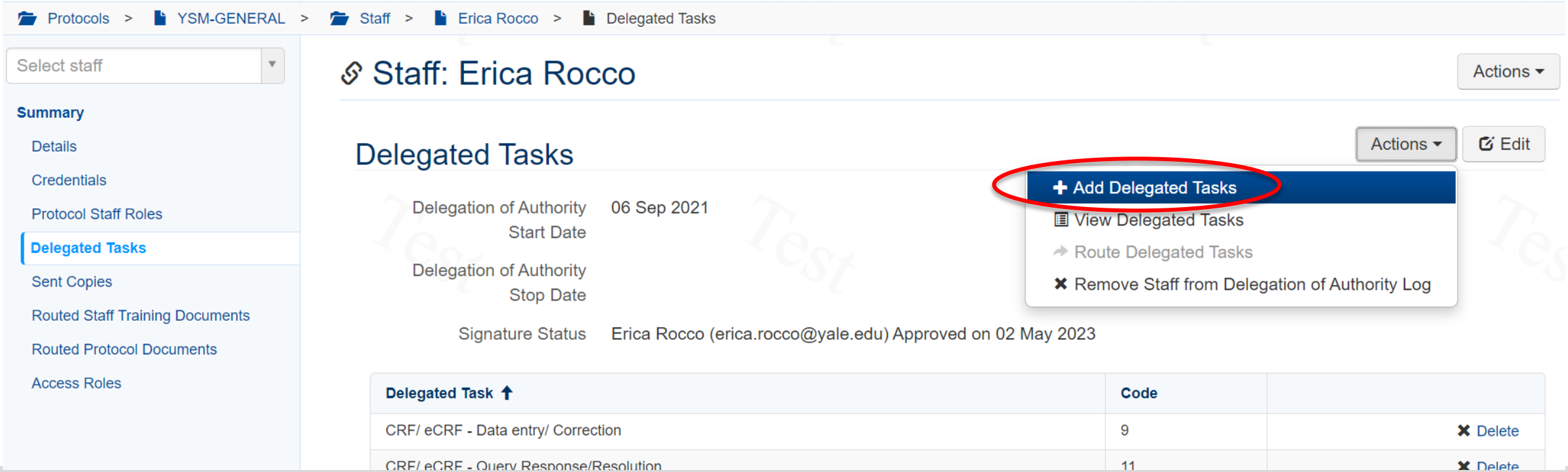
Delegation of Authority Log – Adding Start Dates (Demo)

- The Protocol Staff Start Date and the Delegation of Authority Start Date will default to be the same date.
- Protocol Staff Start Date is entered manually in the Staff section in the eReg binder.
- Delegation of Authority Start Date can be changed prior to PI sign-off by selecting the staff member from the Staff section or from the Delegation of Authority section of a protocol.
  - For an active study, apply a delegation of authority start date that is the latter date of IRB approval and documented protocol training for staff who require IRB approval. The date of documented protocol training should be used for staff who do not require IRB approval.
  - For studies in start up, apply a delegation of authority log start date equal to the date of study activation at the site for all staff who are IRB approved, if applicable, and have documented protocol training.
- Date ranges in eReg are based on midnight. Start Dates go into effect at 12:00 AM on the specified date.



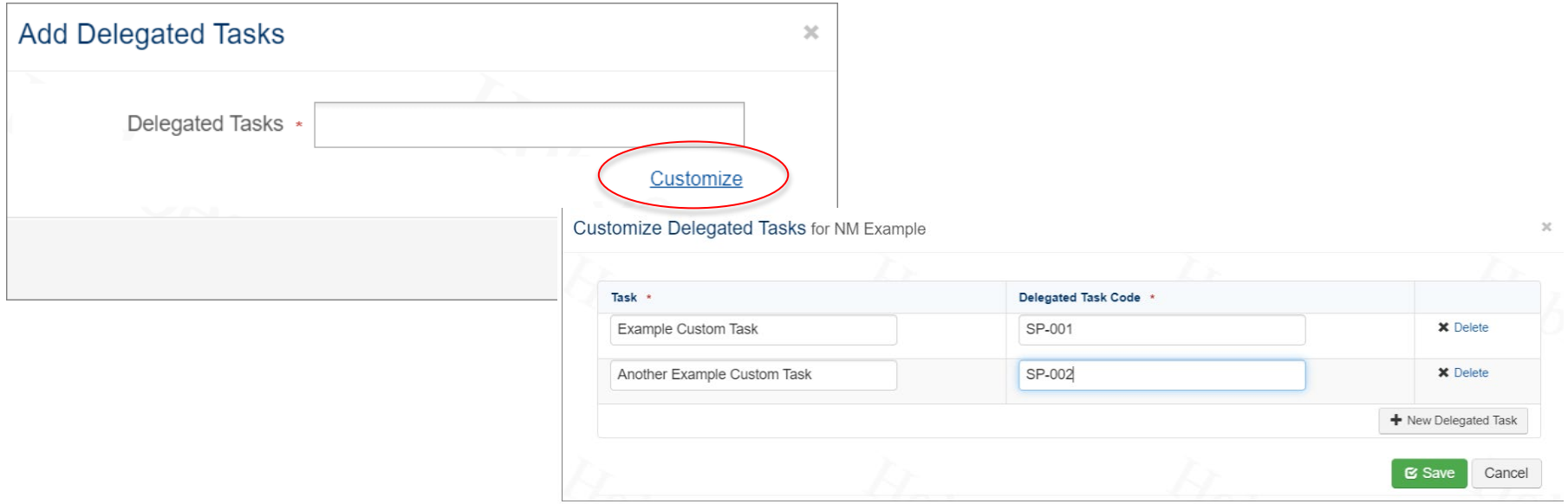
Delegation of Authority Log – eReg Workflow (Protocol Level Changes)

- To add delegated tasks at the protocol level, navigate to Add Delegated Tasks from the Protocol Staff page
- Select all applicable delegated tasks and then route delegated tasks for electronic signature using the signature meaning "Approved"
- Delegated tasks cannot be changed at the protocol level after the PI has signed off on them



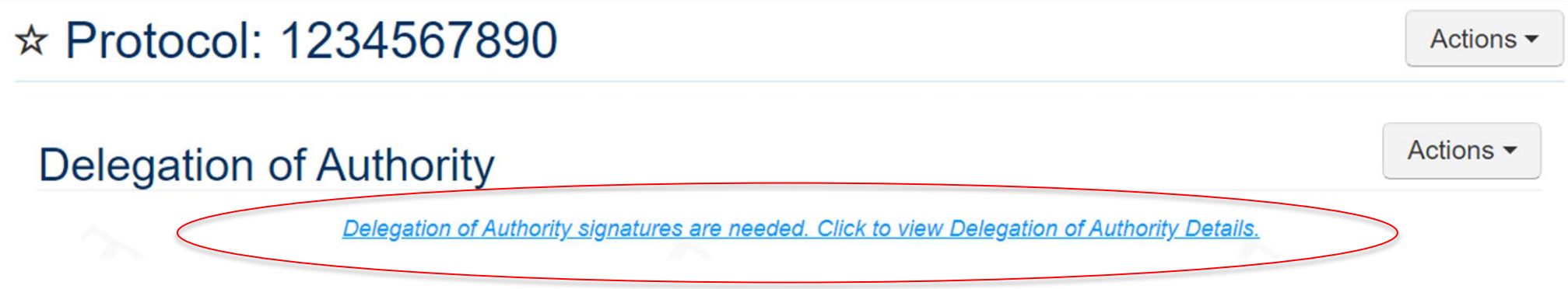
Delegation of Authority Log – Customized Delegated Tasks

- If a protocol requires a staff member perform a specific task that doesn't exist in the list of delegated tasks, a customized delegated task can be added at the protocol level
- Regulatory Managers, Regulatory Coordinators, Administrators, and those with Multi-site access can add customized delegated tasks
- Once changed, the staff member must re-sign the delegated tasks at the protocol level
- If the same task is repeatedly added as a customized task, discuss adding the task to the list in eReg with the YCCI eReg Support team (ereg.support@yale.edu)



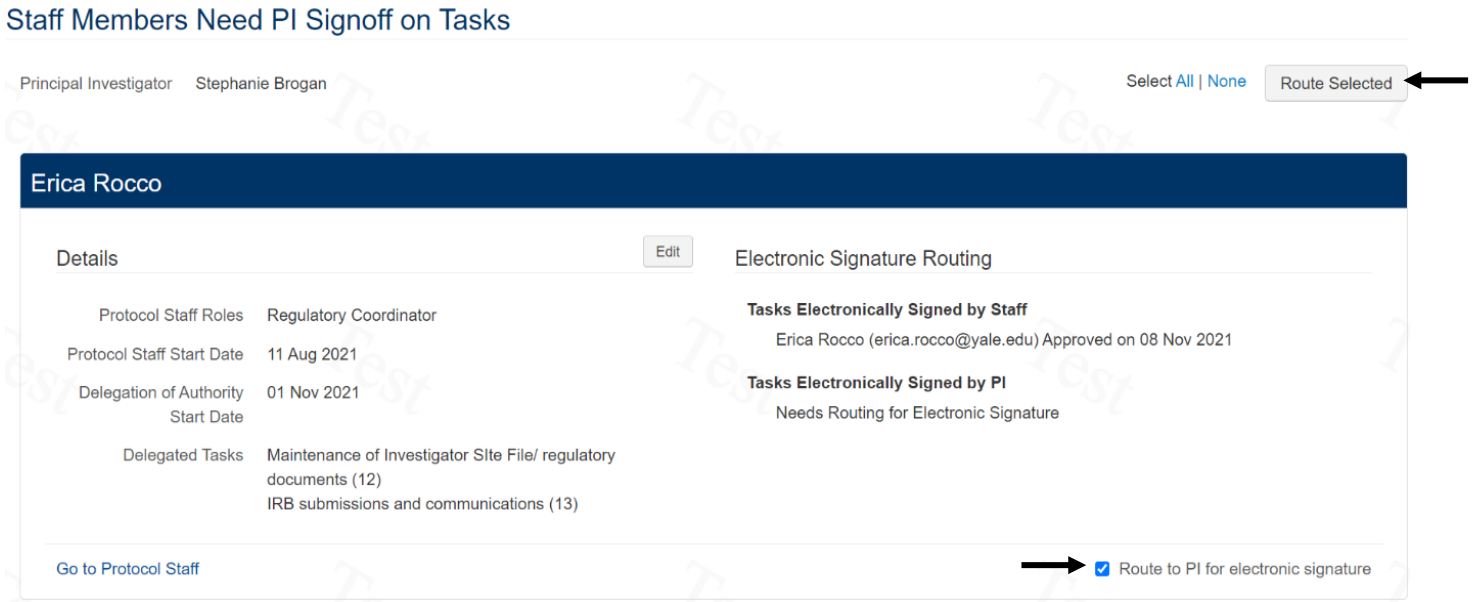
Delegation of Authority Log – Maintenance

- To access detailed information regarding what is needed for your Delegation of Authority, select “Click to view Delegation of Authority Details” in the hyperlink within the Section.



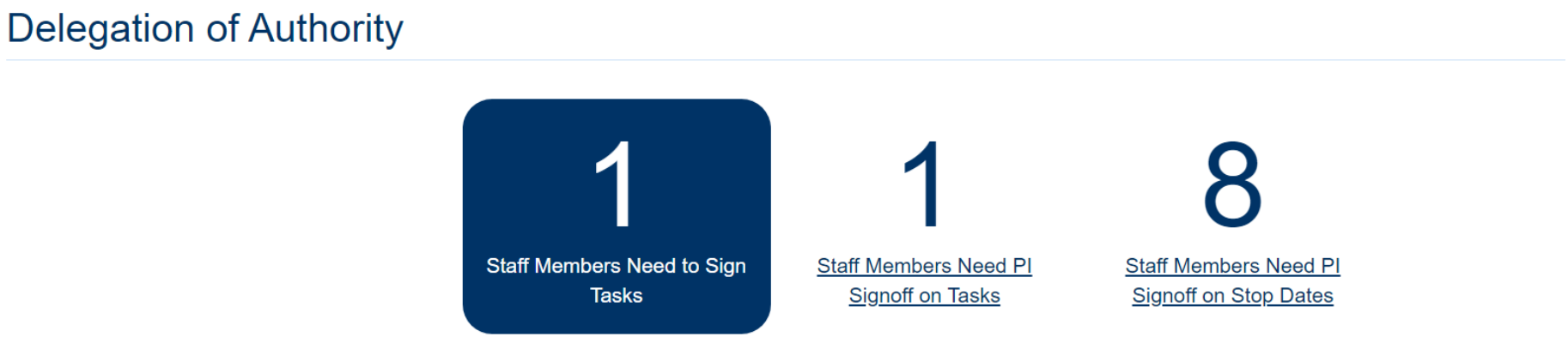
Delegation of Authority Log – Routing Tasks for PI Signoff

- To route study member tasks and start dates to the PI, select the “Route to PI for electronic signature” checkbox. This action is called PI Sign Off on Tasks in eReg and is a sign off of tasks and the start date.
- Click Route Selected.
  - Note that once routed for PI signoff, the staff member’s Delegation of Authority start date, role, and task(s) are read-only unless the routing is undone.



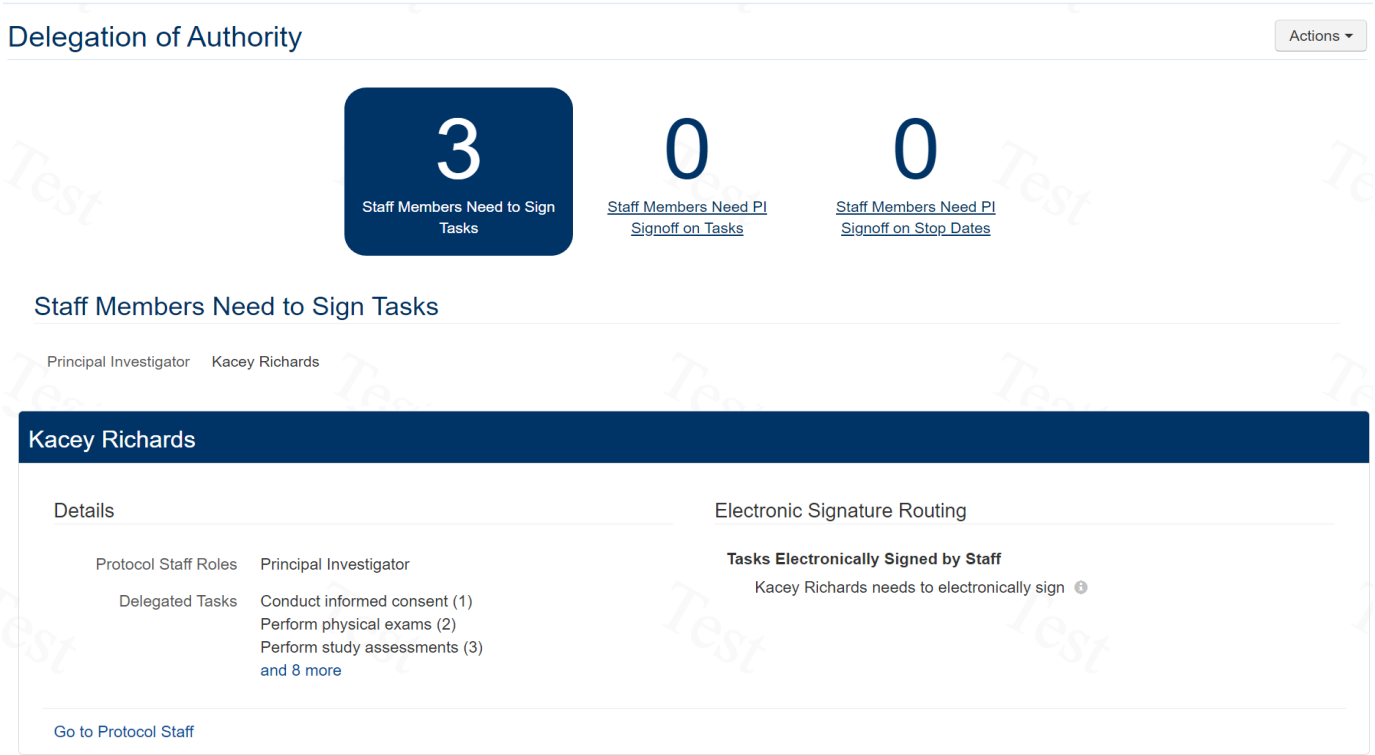
Delegation of Authority Log – Maintenance

- The Delegation of Authority Details page gives you an overview of the DoA signature statuses
  - **Staff Members Need to Sign Tasks**, standard DoA workflow or changes to master DoA tasks
  - **Staff Members Need PI to Signoff on Tasks**, all staff members require PI sign off on tasks and start dates
  - **Staff Members Need PI to Signoff on Stop Dates**, once a stop date is entered, tasks are automatically available for PI sign off; all staff members require PI sign off on stop dates



Delegation of Authority Log – Maintenance

- Clicking the hyperlink associated with each box allows you to:
  - View details for that category
  - Edit details within that category
  - Route staff member tasks for sign off and stop dates for PI sign off



Delegation of Authority Log – Maintenance (Adding Stop Dates)

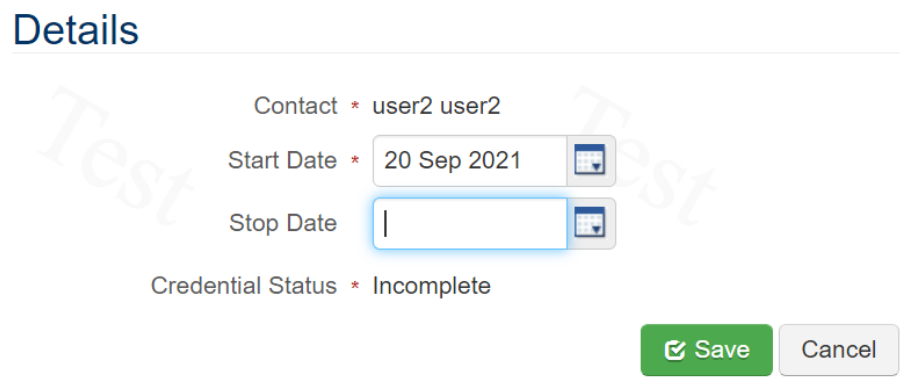
- Two stop dates appear in this section: Protocol Staff Stop Date and Delegation of Authority Stop Date.
  - Protocol Staff Stop Date: The date the study staff member no longer needs access to the eReg record. Past, current and future dates can be selected. This date must be entered in order to add a Delegation of Authority Stop Date.
    - Note: A study staff member requires access to the eReg record in order to route stop dates for PI sign off, to route the DoA for final PI signoff and to lock the protocol. Consider who will be routing stop dates, final PI signoff and locking the protocol when adding protocol staff stop dates.
  - Delegation of Authority Stop Date: The date the study staff member ends their participation in the study. Past, current and future dates can be selected.

Delegation of Authority Log – Maintenance (Adding Stop Dates)

- The Protocol Staff Stop Date and the Delegation of Authority Stop Date will default to be the same date.
- The Protocol Staff Stop Date is entered manually from the Staff Section of the eReg binder.
- Delegation of Authority Stop Date is entered by selecting the staff member from the Staff section or the Delegation of Authority section of a protocol.
  - The delegation of authority stop dates are equal to the date on which a staff member has completed their work on the protocol for the delegated tasks.
- Date ranges in eReg are based on midnight. The date entered in the Stop Date field is when the staff member is no longer active on the protocol. For example:
  - A staff member with a Stop Date of 13 Nov 2018 means that their last active day on the protocol was 12 Nov 2018.

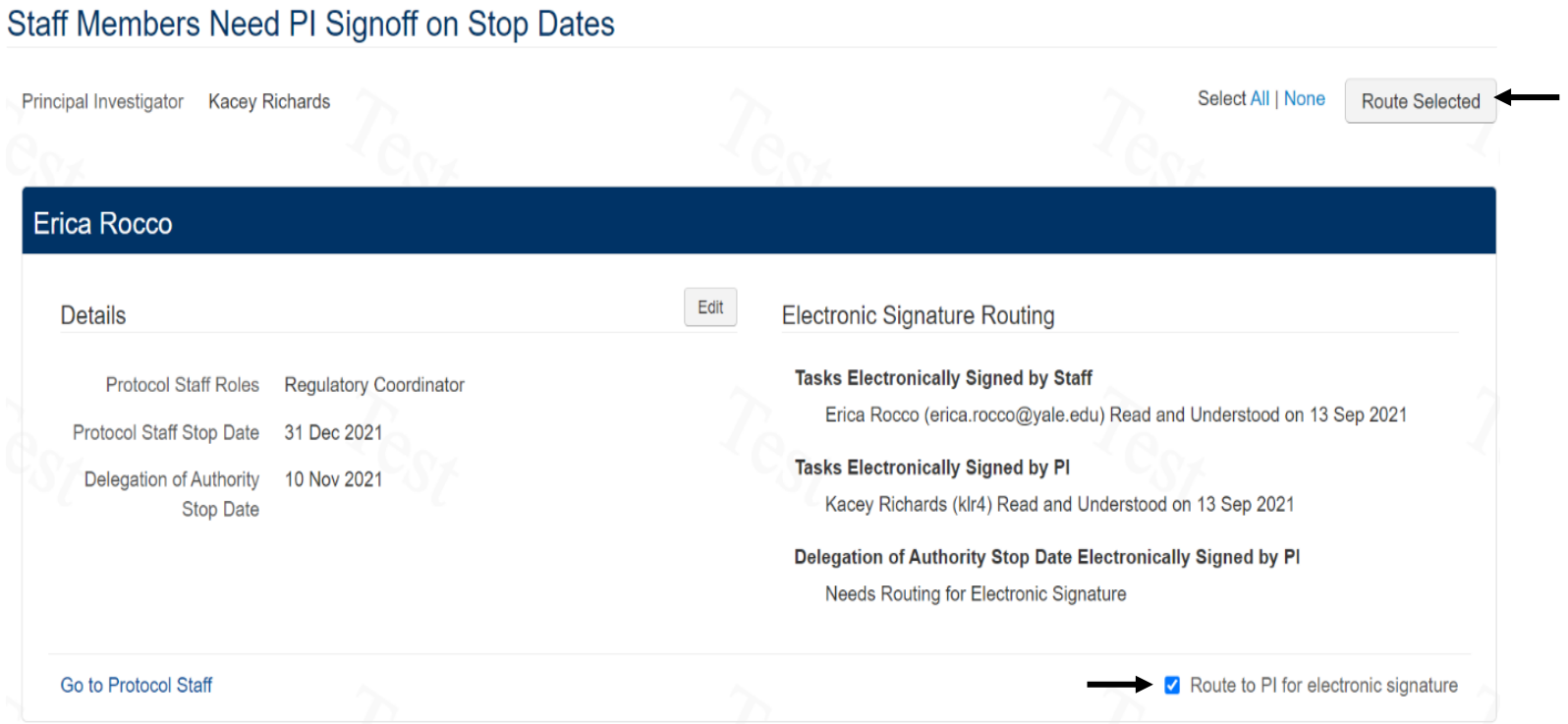
Delegation of Authority Log – Maintenance (Adding Stop Dates)

- When a staff member stops work on a protocol, a stop date must be added to their record on the DoA
  - This may align with IRB removal, date of role change, last day of employment with department or Yale, study closure, etc.
  - Navigate to their protocol staff record, select edit, enter the correct stop date, and select save
  - If the staff member is linked to OnCore, add the stop date in OnCore so that it can flow to eReg
- The stop date should then be routed to the PI for signature
- The staff member cannot complete work on the protocol beyond their stop date



Delegation of Authority Log – Maintenance (Routing to PI for Signature)

- To route study member stop dates to the PI, select the “Route to PI for electronic signature” checkbox.
- Then click Route Selected. Note that after the Delegation of Authority stop date has been routed to the PI, it is view-only unless the routing is undone.

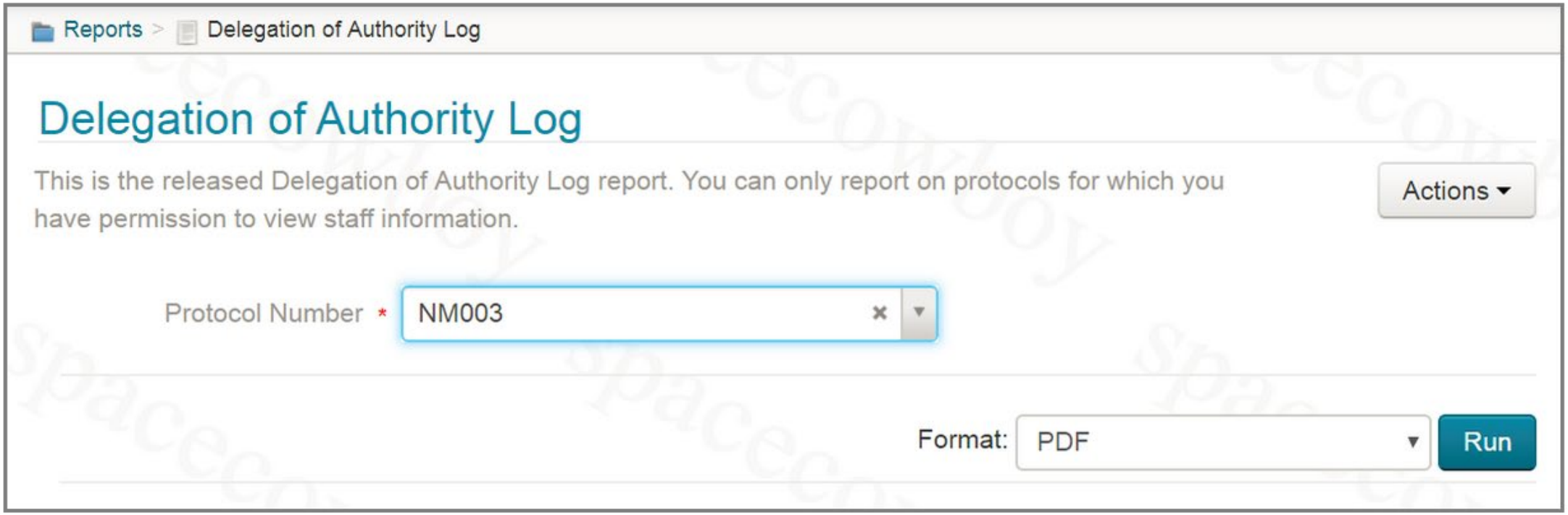


Delegation of Authority Log – Maintenance (View Log)

- You may view the delegation of authority log or create a copy of the current log to provide to monitors, auditors, inspectors, and/ or others in two ways:
  - Option 1: From within the protocol: Navigate to the Delegation of Authority section and choose View Delegation of Authority report from the Actions button menu.

Delegation of Authority Log – Maintenance (View Log)

- You may view the delegation of authority log or create a copy of the current log to provide to monitors, auditors, inspectors, and/ or others in two ways:
  - Option 2: From the Reports menu: Choose your delegation of authority report, specify the protocol for which you want to view it, and click Run.



Delegation of Authority Log – Maintenance (View Log)

Delegation of Authority Log

PI	Kacey Richards
Sponsor	
Protocol Number	DEMO101 - Yale University
IRB Protocol Number	DEMO101
Protocol Title	Demo protocol using new ISF Template for Drug Studies in eReg

Name	Protocol Staff Roles	Delegated Tasks (see key below)	Start Date	Protocol Staff Signoff	PI Signoff - Start Date and Tasks	Stop Date	PI Signoff - Stop Date
Stephanie Brogan	Clinical Research Coordinator	1, 3, 31, 5, 6, 8, 9	01 Jun 2021				
Kacey Richards	Principal Investigator	1, 10, 17, 2, 23, 3, 4, 5, 6, 7, 8	03 Jun 2021	Kacey Richards (klr4) Approved on 04 Oct 2021 07:38:34 -05:00 GMT	Kacey Richards (klr4) Read and Understood on 14 Oct 2021 09:01:56 -05:00 GMT		
Erica Rocco	Regulatory Coordinator	19	10 Sep 2021	Erica Rocco (erica.rocco@yale.edu) Read and Understood on 13 Sep 2021 14:28:55 -05:00 GMT	Kacey Richards (klr4) Read and Understood on 13 Sep 2021 14:41:40 -05:00 GMT		
user2 user2	Regulatory Coordinator		20 Sep 2021				

To be signed upon study completion

PI Signature: _____ Date: _____

Delegated Task Codes

Study personnel are authorized to perform the following study tasks indicated by the codes below as authorized by the Principal Investigator:

Code	Name	Code	Name	Code	Name
1	Conduct informed consent	23	Subject recruitment	6	Safety Event - Collect Data
10	CRF/eCRF - Review/Sign	3	Perform study assessments	7	Safety Event - Assess causality, attribution and severity
17	Investigational Product - Prescribe	31	CRF/eCRF - Query Response/Resolution	8	Safety Event - Report
19	Data Entry	4	Evaluate study assessments	9	CRF/eCRF - Data Entry/Correction
2	Perform physical exams	5	Determine subject eligibility		

Delegation of Authority Log – Unlinked and Linked Staff Records

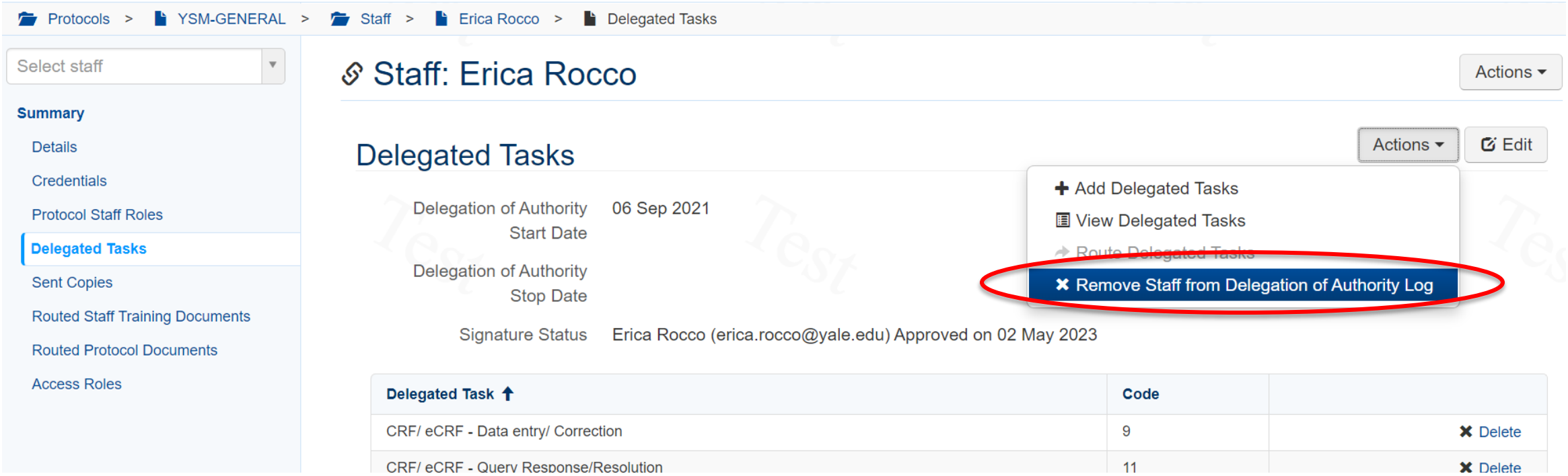
- Unlinked staff records: Effective 18-Oct-2021, protocol staff are no longer being imported from OnCore to eReg and the staff records are no longer linked. Updates to start and stop dates for unlinked staff records are made directly in eReg.

- Linked staff records: Prior to 18-Oct-2021, certain staff records were linked between OnCore and eReg. The start and stop dates for linked staff must be entered in the PC Console of OnCore in the protocol's Staff tab. Dates entered in OnCore flow into eReg and are applied to the delegation of authority log.

- A linked icon appears next to study staff names for any staff records that are linked as shown below.

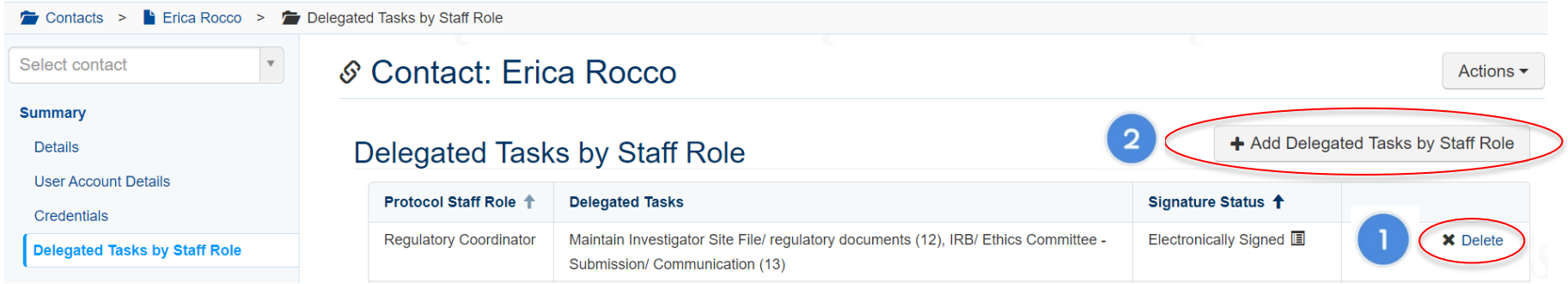
Delegation of Authority Log – Corrections (Removing Staff)

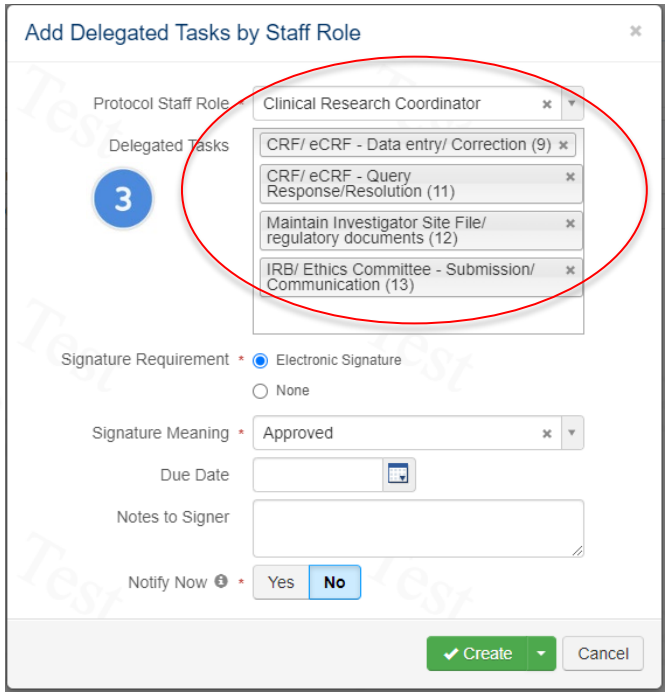
- It is possible to remove a staff member from the delegation of authority log if that staff member's delegated tasks have not yet been routed to the PI (or if you unroute the tasks).
- To remove the staff member from the delegation of authority log, select 'Remove Staff from Delegation of Authority Log' from the Actions button menu in the staff member's record for the protocol.



Delegation of Authority Log – Corrections (Contact Record) (Demo)

- To correct delegated tasks associated with the staff role and/ or delegated tasks assigned in a contact record:
  - (1) Delete the current staff role
  - (2) Add the correct staff role and associated delegated tasks
  - (3) Changes require re-routing for electronic signature within the eReg system, with the signature meaning of "Approved". Changes will not affect protocols that are already signed off and will be applied to new DoA entries.

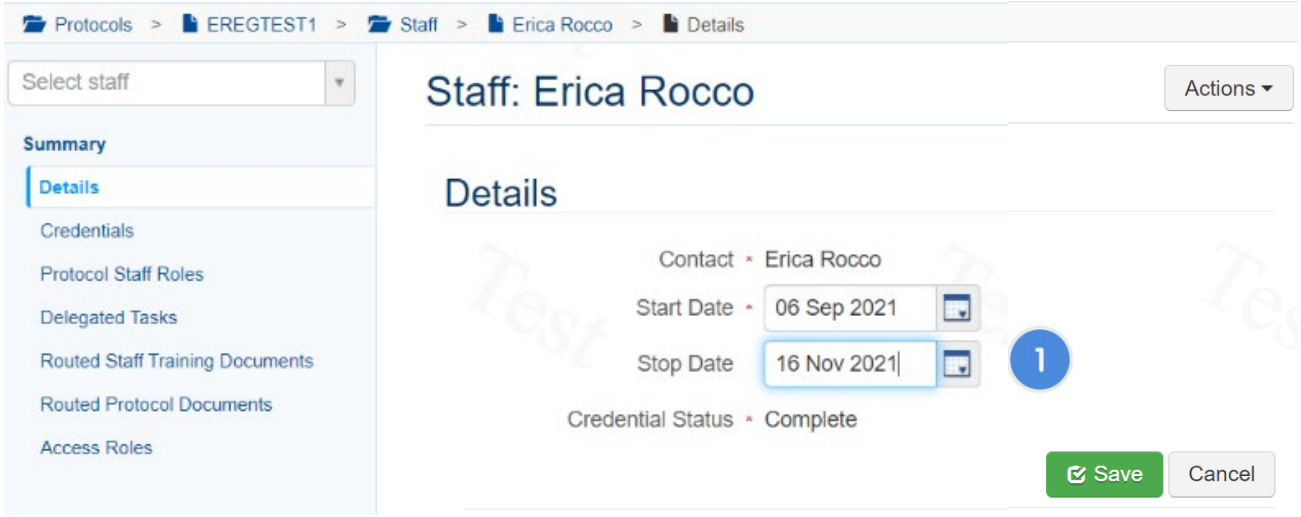


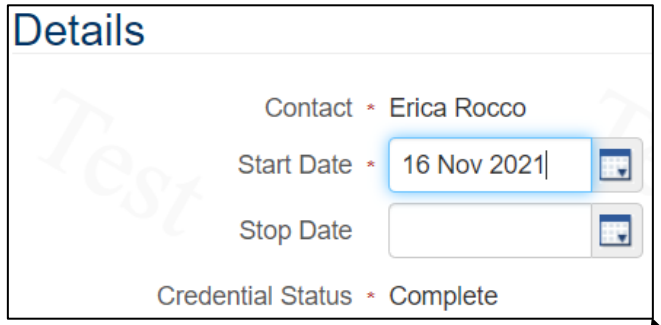


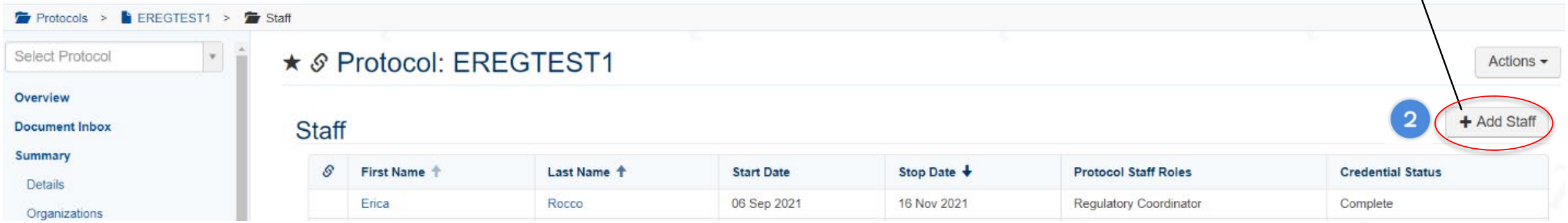
Delegation of Authority Log – Corrections (Protocol Record)

- To correct a staff role, delegated tasks, start dates, and/ or stop dates that have been signed by the PI for a staff member in a protocol record:
  - (1) Enter a Stop Date for the staff member in the Staff-Details tab
  - (2) Re-add the staff member in the Staff tab with a Start Date equal to the Stop Date entered for the original entry or alternative appropriate date. A study team member cannot have more than one active staff role delegated on a protocol at a time
  - (3) Confirm the Delegated Tasks are correct and approved by the staff member for the newly added entry
  - (4) Enter the appropriate Delegation of Authority Start Date
  - (5) Route the corrected entry to the PI for electronic signature
  - (6) If necessary, enter the appropriate Delegation of Authority Stop Date
  - (7) Route the corrected entry to the PI for electronic signature.
    - Note: PI must sign off on tasks and the start date before the stop date can be signed off.

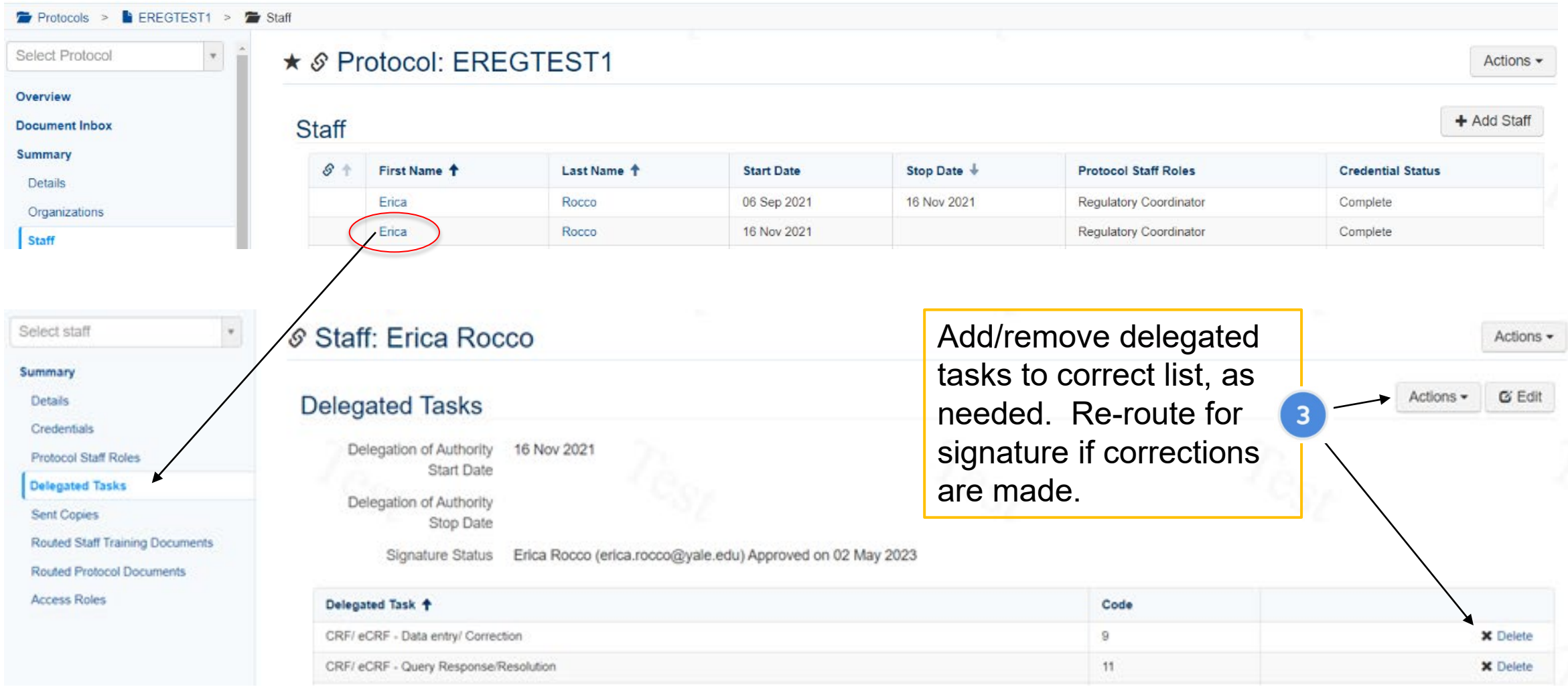
Delegation of Authority Log – Corrections (Protocol Record)



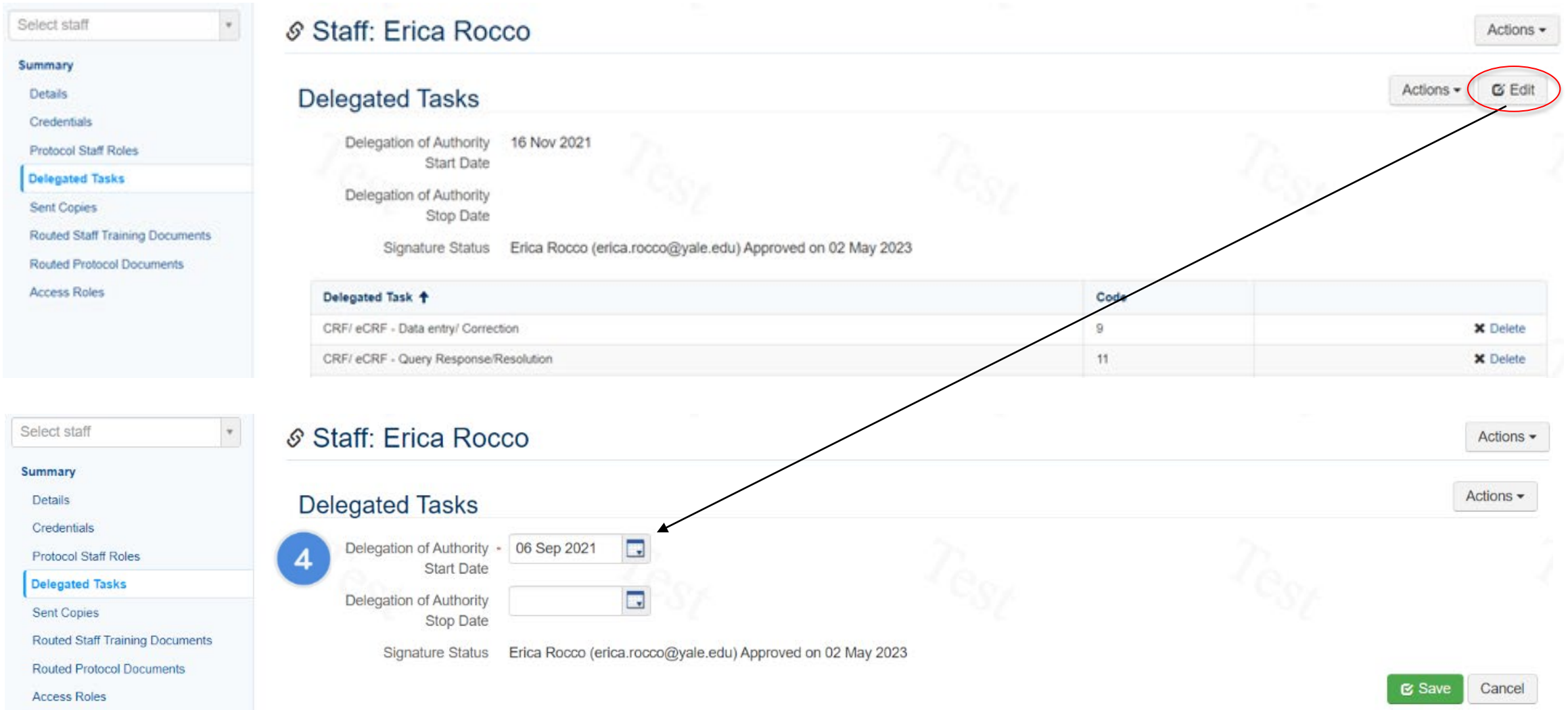




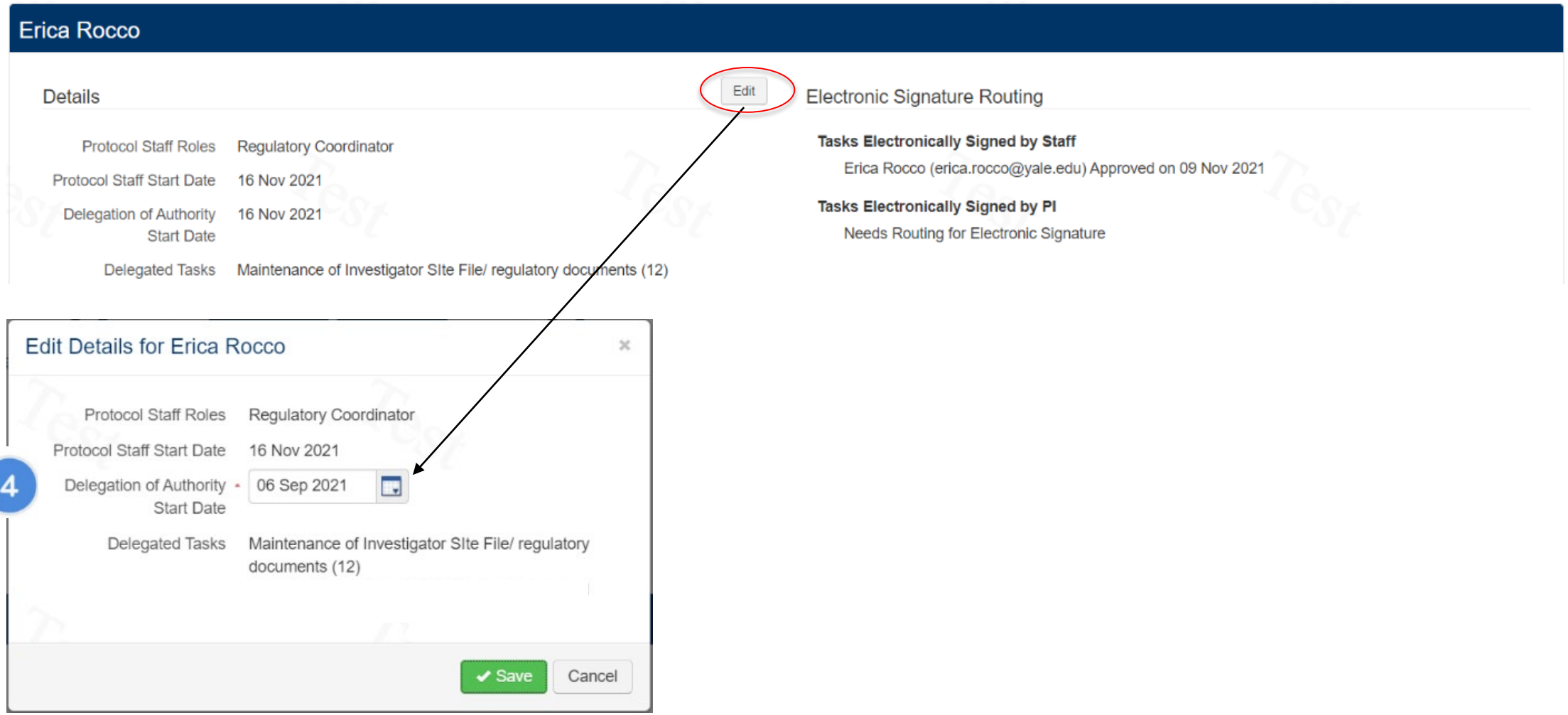
Delegation of Authority Log – Corrections (Protocol Record)



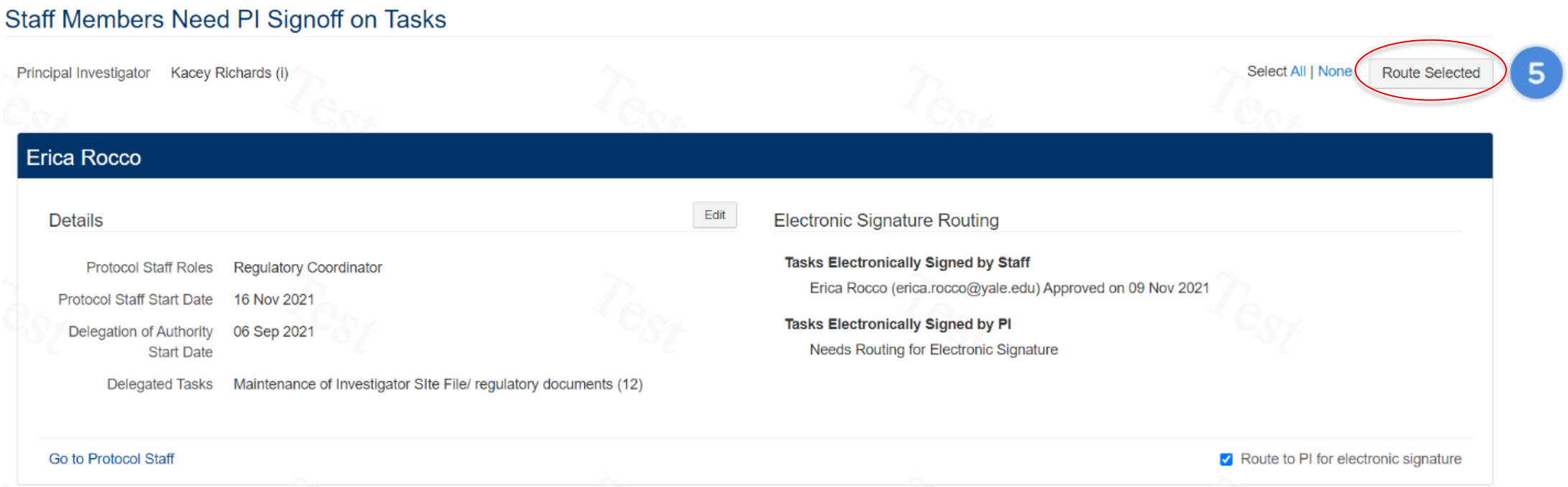
Delegation of Authority Log – Corrections (Protocol Record)



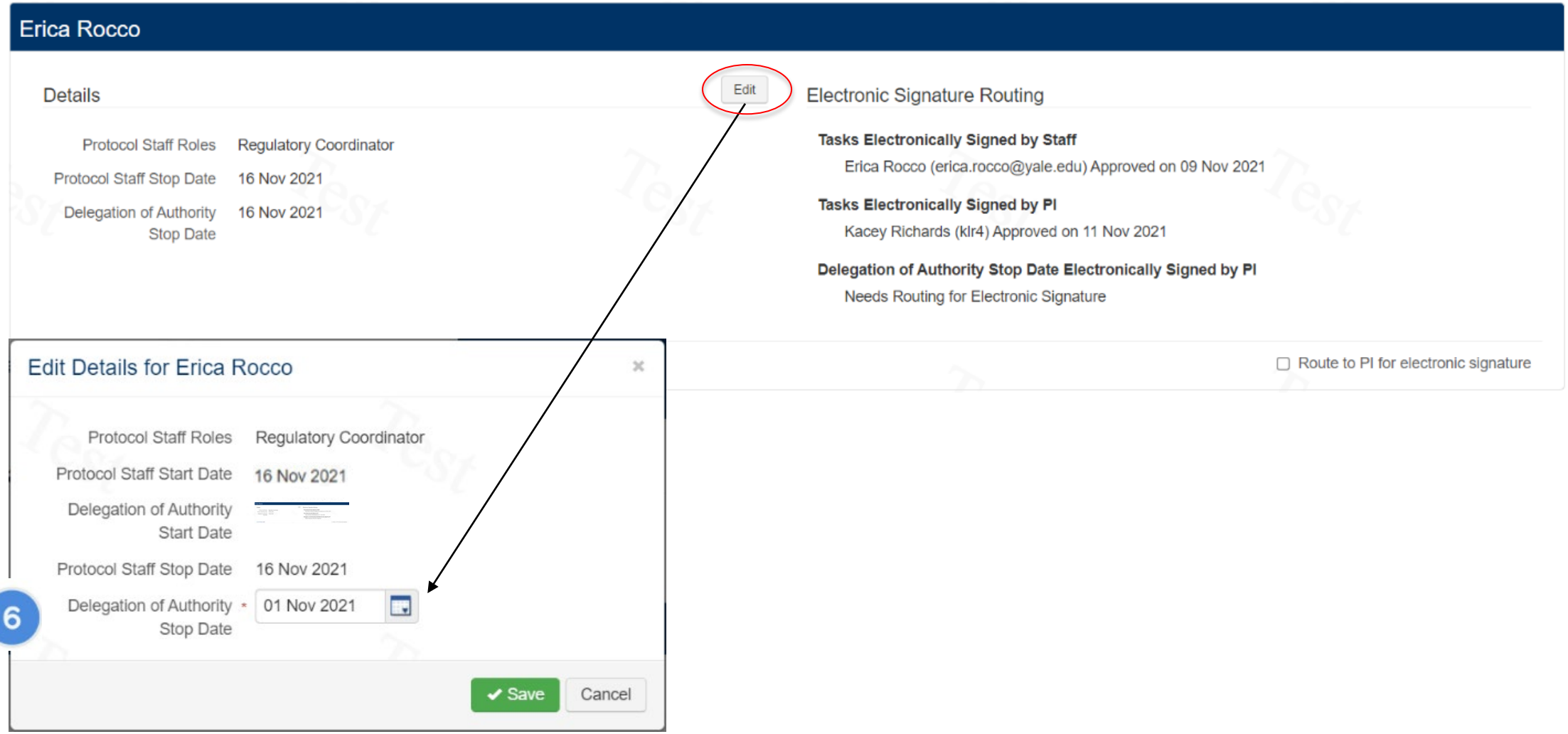
Delegation of Authority Log – Corrections (Protocol Record)



Delegation of Authority Log – Corrections (Protocol Record)



Delegation of Authority Log – Corrections (Protocol Record)



Delegation of Authority Log – Final PI Signoff (Demo)

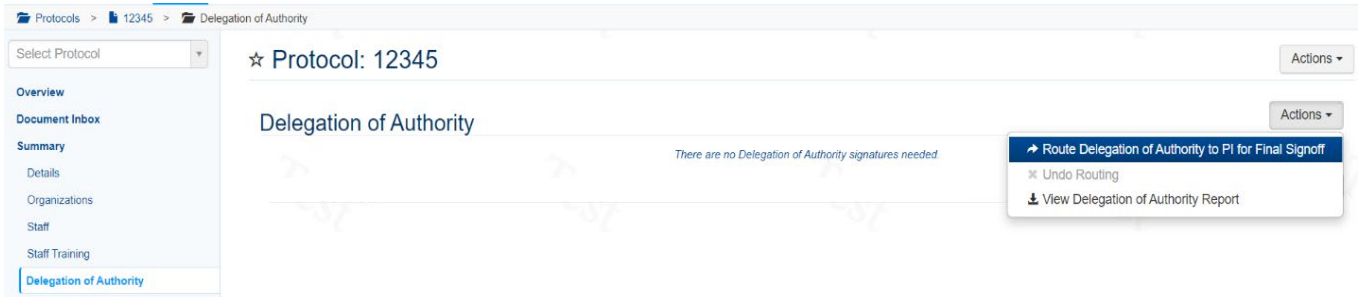
- Routing the Delegation of Authority report for final PI signoff will be done at the time of permanent study closure, oftentimes following a sponsor close out visit or equivalent.

- All staff members must have Delegation of Authority Start and Delegation of Authority Stop Dates entered and signed off in order to route for final signoff by the PI.

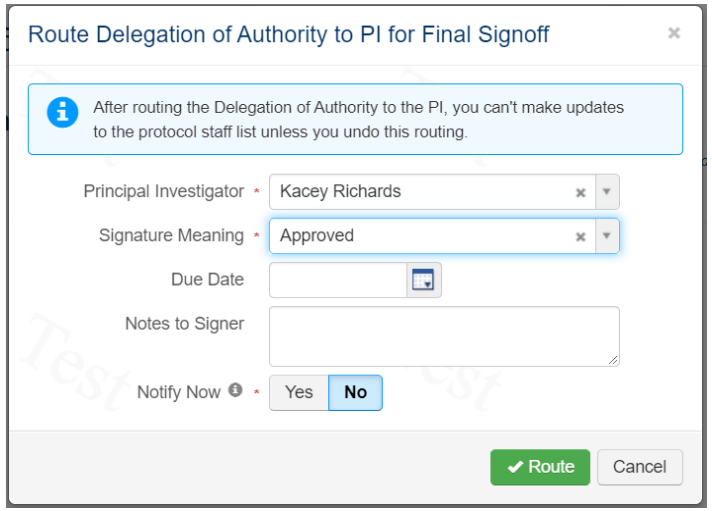
- Once routed for PI final signoff, you can neither add staff members to the protocol nor update the protocol details included in the delegation of authority report (Principal Investigator, Sponsor, Protocol Number, IRB Protocol Number, and Protocol Title) unless the routing is undone.

Delegation of Authority Log – Final PI Signoff

- To route to Delegation of Authority report for final PI signoff, go to the Delegation of Authority section of the protocol.



- Choose 'Route Delegation of Authority to PI for Final Signoff' from the Actions button menu. Use a signature meaning of "Approved".



Delegation of Authority Log – Final PI Signoff

Delegation of Authority Log

PI	Kacey Richards
Sponsor	Pfizer Pharmaceuticals
Protocol Number	2000012345 - Yale University
IRB Protocol Number	2000012345
Protocol Title	DEMO PROTOCOL 3

Name	Protocol Staff Roles	Delegated Tasks (see key below)	Start Date	Protocol Staff Signoff	PI Signoff - Start Date and Tasks	Stop Date	PI Signoff - Stop Date
Kacey Richards	Principal Investigator	1, 10, 11, 12, 13, 14, 15, 16, 2, 3, 4, 5, 6, 7, 8, 9	01 Sep 2021	Kacey Richards (klr4) Approved on 29 Oct 2021 13: 19:27 -06:00 GMT	Kacey Richards (klr4) Approved on 18 Nov 2021 09:45:16 -06:00 GMT	18 Nov 2021	Kacey Richards (klr4) Approved on 18 Nov 2021 09:52:04 -06:00 GMT
Erica Rocco	Regulatory Coordinator	12, 14	01 Oct 2021	Erica Rocco (erica. rocco@yale.edu) Approved on 09 Nov 2021 16:47:34 -06:00 GMT	Kacey Richards (klr4) Approved on 18 Nov 2021 09:48:01 -06:00 GMT	18 Nov 2021	Kacey Richards (klr4) Approved on 18 Nov 2021 09:52:05 -06:00 GMT
user1 user1	Clinical Research Coordinator	1, 11, 3, 5, 6, 8, 9	01 Oct 2021	user1 user1 (user1) Approved on 16 May 2019 13:40:51 -06:00 GMT	Kacey Richards (klr4) Approved on 18 Nov 2021 09:45:16 -06:00 GMT	18 Nov 2021	Kacey Richards (klr4) Approved on 18 Nov 2021 09:52:04 -06:00 GMT

To be signed upon study completion

PI Signature: Kacey Richards (klr4) Approved on 21 Nov 2021 07:45:45 -06:00 GMT

Maintaining eReg Binder

Locking Completed Studies

YCCI Yale Center for Clinical Investigation

Locking Completed Studies – Preparation

Prepare Binder for Closure

- Upon notification that a study is ready for permanent closure at the site:
  - Ensure all regulatory and essential documents are uploaded and in the correct location within eReg including documentation stored elsewhere during the conduct of the study, i.e., pharmacy documents
  - Ensure all signatures are documented within eReg
  - Remove requirements or sections that were not needed for the study or insert notes to file to indicate they were intentionally left blank

Obtain the Final Delegation of Authority Report

- Enter protocol staff stop dates and delegation of authority stop dates for all staff in the protocol staff records
- Route the delegation of authority stop dates for PI signature
- After PI signs off on the stop dates, route the final DoA report for PI signature

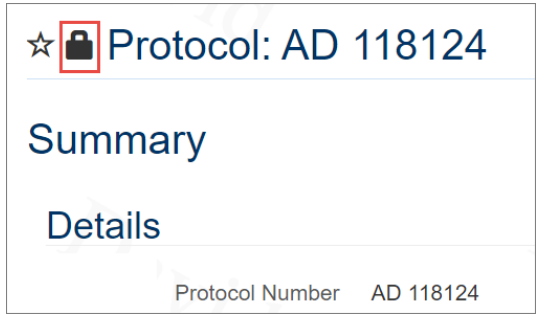
Finalize Closure

- Upon acknowledgement of IRB Closure:
  - Upload all applicable IRB closure documents
  - Consider financial disclosure form requirements post-closure when determining when to lock a study
  - Lock the study so that no further changes can be made

Locking Completed Studies – Process

- To lock a study, Regulatory Managers, Regulatory Coordinators, Administrators, and those with Multi-site access can navigate to the protocol and select “Lock Protocol” from the Actions dropdown.

- After a study has been locked, a lock symbol will appear in the header, indicating that the study cannot be edited. If a study must be unlocked, reach out to the YCCI eReg Support Team with a valid reason (eReg.Support@yale.edu).



Setting Up eReg for Use by External Monitors and Auditors

Review Sessions

YCCI Yale Center for Clinical Investigation

Review Sessions – Access Request (Demo)

Submit eReg Sponsor Account Request Form

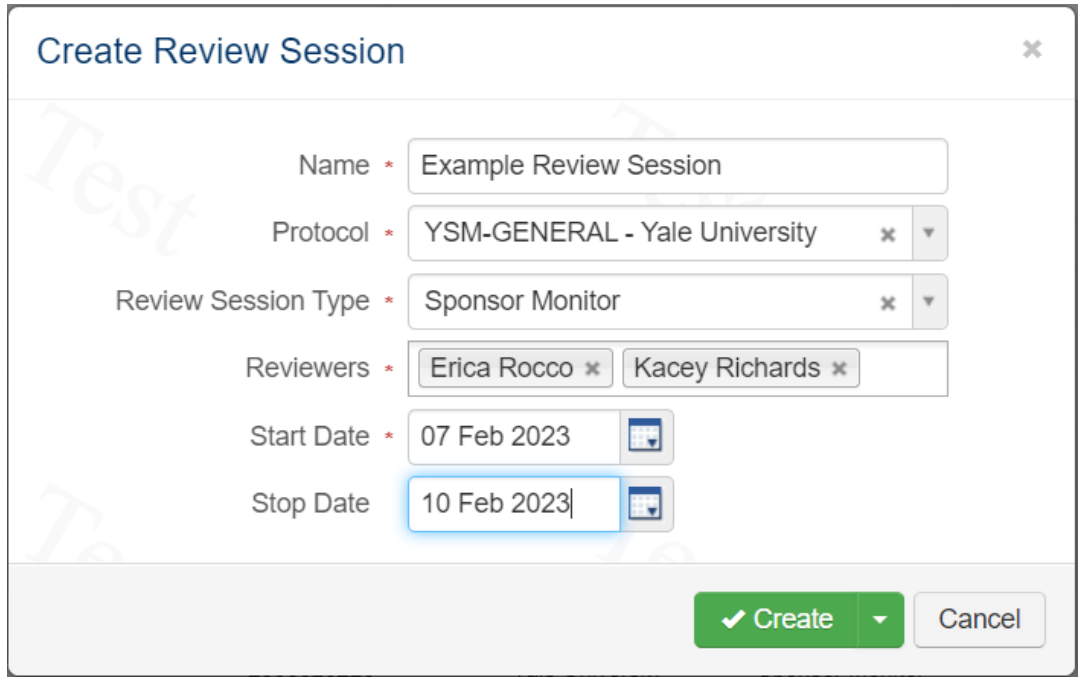
- Monitors, Auditors and Inspectors will be required to take eReg training in Advarra University prior to account activation.
- Ensure YCCI eReg Support staff have sufficient time to coordinate training and access for external reviewers

Set up Review Session

- "+ New Review Session" for one or more reviewers.
- Date ranges in eReg are based on midnight. If a reviewer is granted access September 30 – October 1, the access will terminate at midnight on October 1. To ensure access through October 1, select an end date of October 2.

Review Sessions – Create a Review Session

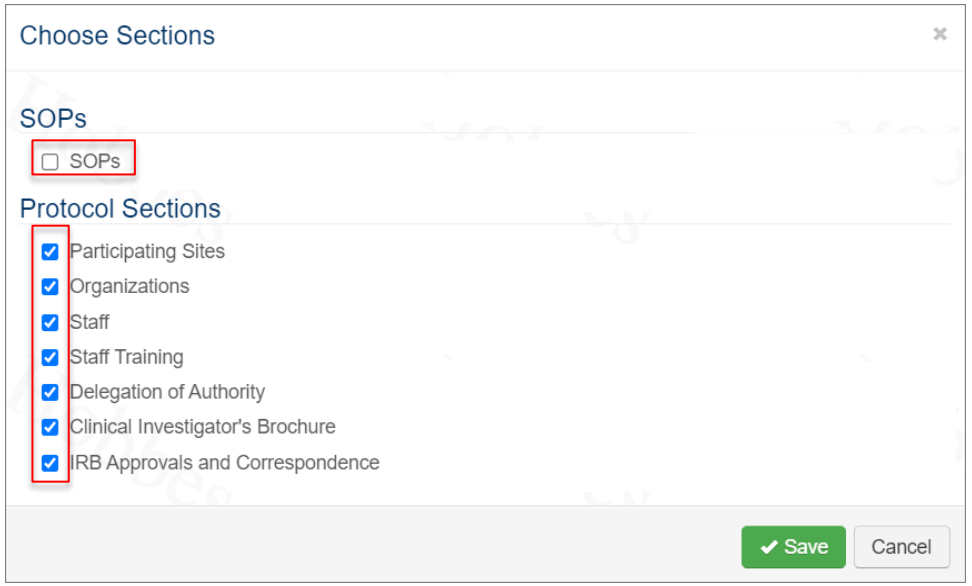
- Refer to the *eReg Guidance Document for Review Sessions* found on the YCCI eReg website for more information
- On the Review Sessions landing page, click New Review Session to open the Create Review Session window.



If both a Start Date and Stop Date are entered for the review session, the values must be unique. A review session can't be set up to start and stop on the same day.

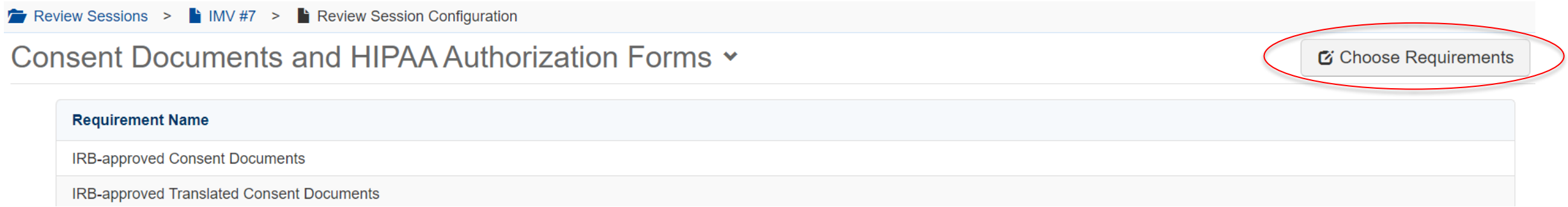
Review Sessions – Customize Review Session

- If the reviewer should only review select documents, you can customize the sections and requirements available for review. If the reviewer needs to review the complete eReg binder, you do not need to customize the review session.
- To customize sections available for review, click the Choose Sections button and clear the checkboxes in front of the sections you do not want the reviewer to see in this review session.
- SOPs can be added to the review session.



Review Sessions – Customize Review Session

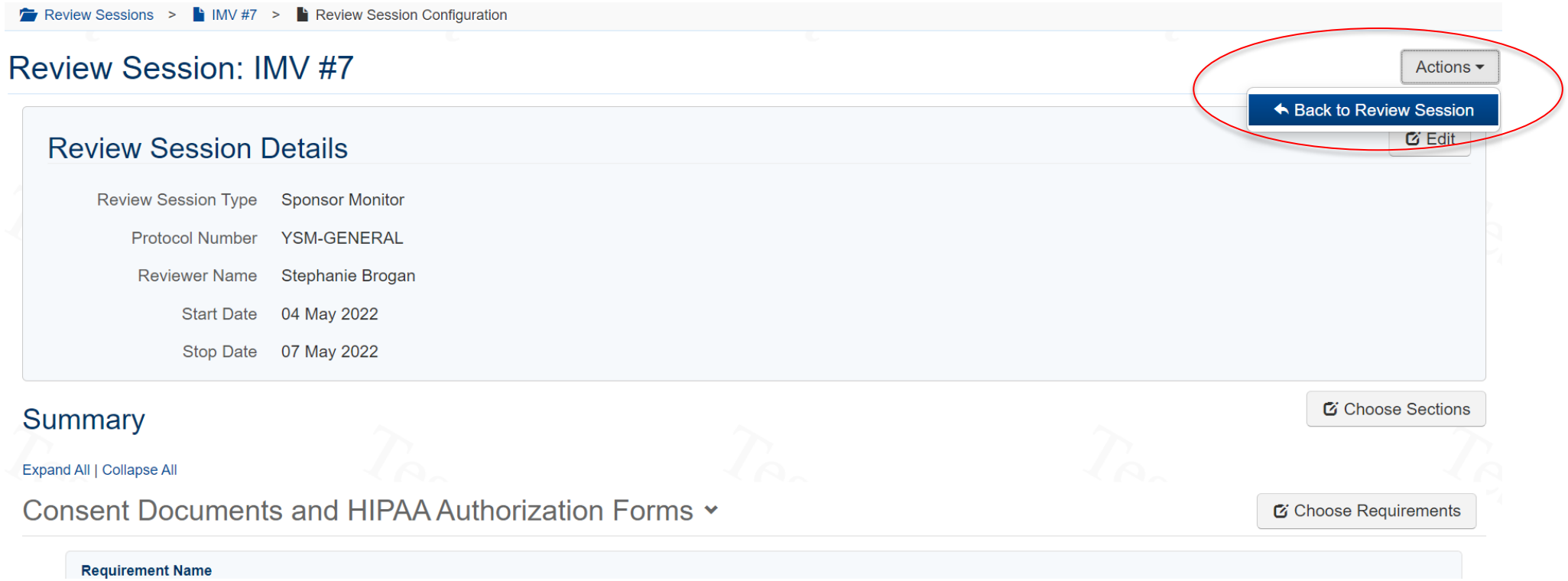
- Click the Choose Requirements button in each section to configure which requirements you want to be visible to the reviewer during the review session.



- All requirements within a section are selected by default to allow the reviewer to see all the regulatory and essential documents housed in the eReg Binder. In most cases, you would grant access to the entire eReg Binder for review sessions.
- To limit the requirements (and therefore the documents) the reviewer has access to, clear the checkboxes next to any requirements that you don't want to appear in the review session. Then, click Save.

Review Sessions – Customize Review Session

- Continue to configure the information and documents available to the reviewer in each section as needed.
- When finished:
  - Choose Back to Review Session from the Actions button menu.



Closing Statements

Closing Statements – Tips for Regulatory Coordinators and Managers

- The eReg system is looking for staff credentials to cover the entire time that staff member has been active on a study as noted by the protocol staff start and stop dates
  - Even if the staff member has a current credential on file, their status will still show incomplete at the protocol level if there are any historical gaps in their credential. eReg Support will insert a NTF to cover the gap in time and remove the incomplete flag.
- Credentials must have an Effective Date that is equivalent or prior to the previous document version's Valid Until date, or a gap will occur
  - Effective Dates go into effect at 12:00AM on the specified date, while the date entered in the Valid Until Date field is when the document is no longer valid
    - Example: A document with a Valid Until date of 13 Nov 2021 would be valid until 11:59 PM on 12 Nov 2021
- Cannot delete staff members from protocol after the PI has electronically signed off on their Delegation of Authority log entry
- Dates must be entered as dd mmm yyyy (some shortcuts can be used, i.e., t = today's date)
- FAQs are available on YCCI eReg website and continuously updated.

Closing Statements – Advarra University/Learning Resources

eReg Learning Resources

Advarra University http://university.advarra.com

Learning Portal in eReg

-From the main page, click on the Rocket Icon or the Help option under your name to find the "Learning Portal"
-Use the Table of Contents or the Search Bar to find topics

Link to YCCI website from eReg

-From the main page, click on the Rocket Icon or the Help option under your name to find the YCCI eReg website link

Guidance documents are available on the YCCI eReg website.

Closing Statements – YCCI eReg Support Staff

- If you have further questions about the eReg system, please reach out to:
  - eReg Support (eReg.Support@yale.edu)

- If you have further questions about the maintenance of Contact Credentials and Organization (IRB & Lab) Regulatory Tracking Items in eReg, please reach out to:
  - eReg Support – Credentials (eReg.Credentials@yale.edu)

- If you have any further questions about maintaining documents, please reach out to:
  - Erica Rocco, Senior Project Manager (erica.rocco@yale.edu)