eReg Guidance Document
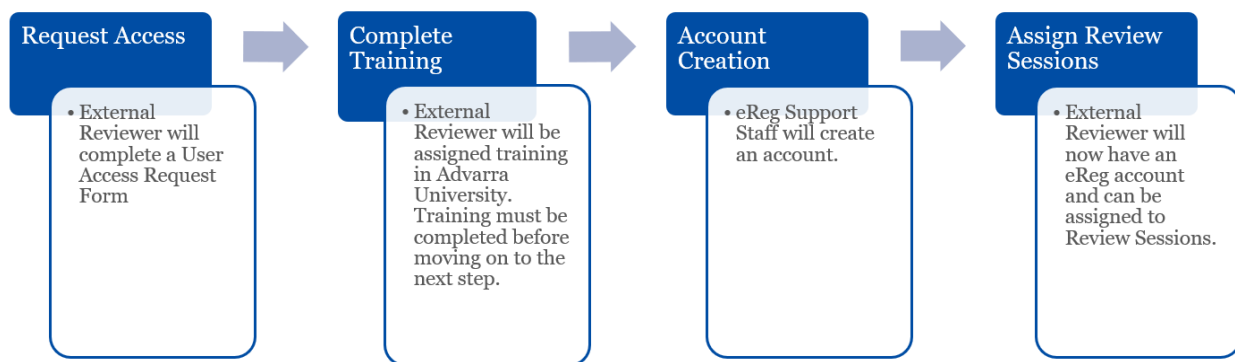# Review Sessions

Contents

Acronyms

GCP: Good Clinical Practice

HRPP: Human Research Protection Program

IDS: Investigational Drug Service

IMV: Interim Monitoring Visit

SOP: Standard Operating Procedure

YCCI: Yale Center for Clinical Investigation

YNHHS: Yale New Haven Health System

Review Sessions

Review Sessions are used to provide External Reviewers, such as Monitors, Auditors and Inspectors, electronic access to regulatory and essential documents and/ or Standard Operating Procedures (SOPs) to conduct a review. Review Sessions can also be used to provide internal reviewers, such as site staff, access to regulatory and essential documents and/ or SOPs.

eReg Access for External Reviewers

External Reviewers such as Monitors, Auditors and Inspectors must have an active eReg User Account to be assigned and conduct a review session. External Reviewers will complete the User Access Request Form located on the Yale Center for Clinical Investigation (YCCI) eReg website. External Reviewers are required to complete eReg training in Advarra University prior to account activation. Ensure YCCI eReg Support staff have sufficient time (approximately one week) to coordinate training and access for External Reviewers.

Request Access	Complete Training	Account Creation	Assign Review Sessions
• External Reviewer will complete a User Access Request Form	• External Reviewer will be assigned training in Advarra University. Training must be completed before moving on to the next step.	• eReg Support Staff will create an account.	• External Reviewer will now have an eReg account and can be assigned to Review Sessions.

The User Access Request Form requires a date of request, full name, email address, job title, relationship to Yale/ Yale New Haven Hospital, Sponsor/ Home Organization and Role Requested. External Reviewers will indicate they are External to Yale/ Yale New Haven Hospital on the request form. They will then select a role of Monitor, Auditor or Inspector, as appropriate.

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The form must be completed by the External Reviewer as it includes an attestation. The attestation indicates they have read and understand Yale University's [Information Technology Appropriate Use Policy](#). Site Staff who create review sessions should share this policy with their External Reviewers prior to requesting they complete the User Access Request Form. External Reviewers must attest that they will complete the role-appropriate eReg training prior to being granted access to the system. External Reviewers must agree to use eReg only for work-related business, to not share their eReg password with anyone and to not let anyone use eReg while logged into their account. External Reviewers must also agree to only share the information obtained within eReg with personnel who have a legitimate work-related need for the information.

Once an account is created, the External Reviewer will retain access to the system until eReg Support Staff receives a request to inactivate the External Reviewer's account or after 200 days of not logging into eReg, whichever comes first. Should more than 200 days elapse between Review Sessions for an External Reviewer or if the External Reviewer forgets their password, the account can be reactivated by contacting eReg Support (eReg.Support@yale.edu). Site Staff or the External Reviewer may make this request directly.

Should an External Reviewer's eReg access need to be terminated immediately for any reason, please contact eReg Support (eReg.Support@yale.edu) for assistance. Site Staff who create the Review Session can revoke access to regulatory and essential documents and/ or SOPs immediately by deleting the Review Session. Refer to the Deleting a Review Session section below for more information on how to delete a Review Session.

Creating a Review Session

On the Review Sessions landing page, click + New Review Session to open the Create Review Session pop-up window.
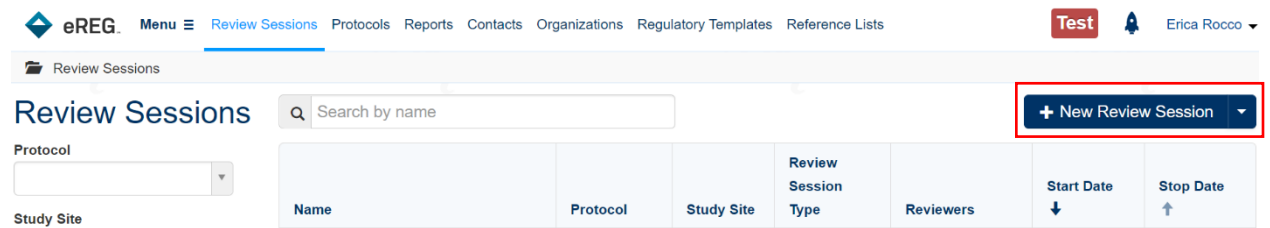
In the Create Review Session pop-up window, complete the required fields which are marked with an asterisk. Please note the Name of the session must be unique. We suggest including the review type and a protocol identifier for the Name such as 'Interim Monitoring Visit #[X] for [Protocol Identifier]', 'Site Initiation Visit for [Protocol Identifier] or 'Sponsor Audit for [Protocol Identifier]'.

A Stop Date for the Review Session is not required; however, we recommend entering a Stop Date so that the Reviewer(s) does not have continuous access to the regulatory and essential documents for that protocol and any SOPs included in the Review Session. If both a Start Date and Stop Date are entered for the Review Session, the dates must be unique. A Review Session cannot be set up to start and stop on the same day.

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.

Create Review Session   ✕

Name *	
Protocol *	▾
Review Session Type *	▾
Reviewer Name *	▾
Start Date *	📅
Stop Date	📅

✔ Create ▾   Cancel

Multiple reviewers can be assigned to one Review Session. After all fields are completed, click Create. The action menu under the Create button will allow you to Create the existing entry and start a new entry.

Configuring a Review Session

After the Review Session is created, you will be brought to the Review Session configuration page. By default, all sections and requirements (including any related documents) within the protocol are included in the review session. If the reviewer(s) should only review select documents, you may customize the sections and requirements available for review. If the reviewer(s) needs to review the complete eReg binder, you do not need to customize the review session. In most cases, you would grant access to the entire eReg Binder for Review Sessions. If the review session is being created for a multi-site protocol, all participating sites are selected by default.

Choosing Sections

To customize Sections available for review, click the Choose Sections button.

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Review Session: IMV #1 for Test Protocol

Actions ▾

Review Session Details

Edit

Review Session Type	Sponsor Monitor
Protocol Number	YSM-GENERAL
Reviewer Name	Stephanie Brogan
Start Date	08 Mar 2022
Stop Date	10 Mar 2022

Summary

Choose Sections

The Choose Sections pop-up window will open. Clear the checkboxes in front of the Protocol Sections you do not want the reviewer to see in this Review Session. Then click Save.

Choose Sections ✕

SOPs

☐ SOPs

Protocol Sections

☑ 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

✔ Save   Cancel

Short Form Consent Documents

Choosing Requirements

Within each Section, you may choose the Requirements you want the reviewer(s) to see in the Review Session. When a Requirement is included in a Review Session, its associated documents (as well as any related documents) are available to the reviewer. All Requirements within a Section are selected by default to allow the reviewer to see all the regulatory and essential documents associated with that Section.

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To customize Requirements available for review, click the Choose Requirements button in each Section.

The Choose Requirements pop-up window will open. To limit the requirements (and therefore the documents) the reviewer(s) has access to, clear the checkboxes next to any Requirements that you do not want to appear in the review session. Then, click Save.

Continue to configure the information and documents available to the reviewer in each section as needed.

Choosing Participating Sites

If a Review Session is created for a multi-site protocol, you may choose the Participating Site files to include in the Review Session.

To choose the Participating Sites to include, click Choose Participating Sites.

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To limit the Participating Sites the Reviewer has access to, clear the checkboxes next to any Participating Sites that you do not want to appear in the Review Session. Then, click Save.

When finished choosing Sections, Requirements and/ or Participating Sites, click Back to Review Session from the Actions button menu to preview the Review Session configured for the Reviewer.

Credentials and Regulatory Tracking Items

The credentials and regulatory tracking items that are included in the Review Session are based on the protocol requirements and the documents' valid date ranges. If a credential or regulatory tracking item's valid range does not overlap with when the staff member or organization was active on the protocol, that document will not be included in the Review Session. Likewise, if a credential is not listed as a requirement in the protocol outline, it will not appear in the Review Session regardless of the valid date range.

Deleting a Review Session

Review Sessions can be deleted. On the Review Sessions landing page, select the Review Session that you wish to delete. Under the actions menu, select Delete.

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When Delete is clicked, you will be asked to confirm the delete. Click Delete to proceed with deleting the Review Session. Click Cancel to retain the Review Session.

SOP Review Sessions

SOPs can be added to a Review Session created for a protocol. You can also create SOP-only Review Sessions which allow a group of SOPs to be reviewed outside the context of a protocol.

Adding SOPs to Protocol Review Sessions

When configuring the Sections for your protocol Review Session, click the checkbox in front of SOPs to add SOPs to the Review Session. Then click Save.

Once the SOP section has been added, you will specify which SOPs you want to include by clicking on the hyperlink within the SOP section.

When you open the hyperlink, click Choose SOPs to include specific SOPs in the Review Session.

Select from the list of SOPs available to you. This list will include all SOPs filed at the global level and any department-specific SOPs to which you have access. Click Save.

SOPs

	Document Name ↑	Category ↑	Departments	Effective Date ↑	Valid Until
☐	2018 Investigational Drug Service.pdf	Investigational Drug Service		01 Mar 2018	
☐	2021 YNHHS IDS Investigational Drug Transport SOP.PDF	Investigational Drug Service		01 Dec 2016	
☐	2021 YNHHS IDS Temperature Monitoring of Storage Locations for Investiga....pdf	Investigational Drug Service		01 Apr 2017	
☐	2021 YNHHS IDS Verification of Authorized Investigators SOP.PDF	Investigational Drug Service		01 Jul 2019	
☐	2021 YNHHS IDS Waste and Destruction of Investigational Medications SOP.PDF	Investigational Drug Service		01 Apr 2017	
☐	Yale HRPP Policies, Procedures, Guidance, and Checklists	Yale Human Research Protection Program		01 Jan 1900	
	6 Total Records				

✔ Save   Cancel

Once added, the Reviewer(s) will be able to view the SOPs. Please note that Reviewers' access to SOPs is limited to view-only. Reviewers do not have the ability to download SOPs. If the Reviewer requires a copy of an SOP, you will need to provide it outside of eReg.
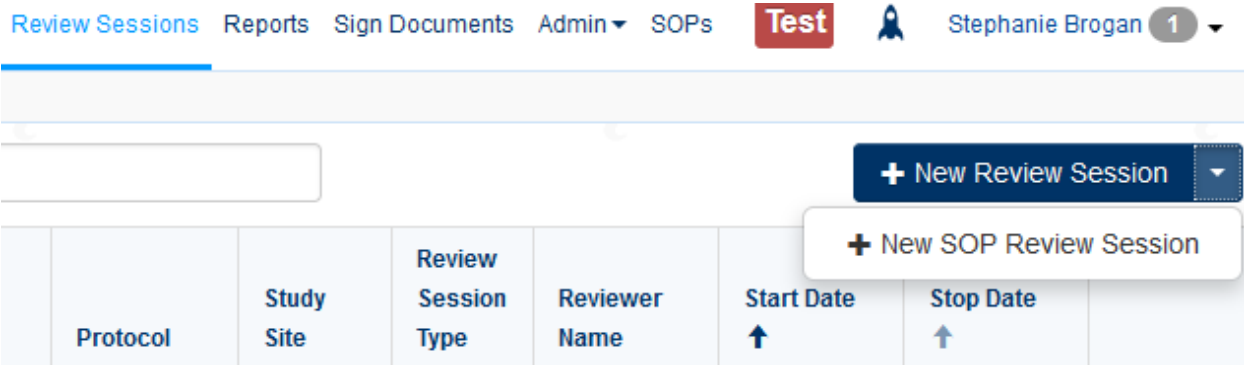
SOP Review Sessions

SOP Review Sessions are Review Sessions that only contain SOPs and are reviewed outside the context of a protocol review. eReg users with a Regulatory Manager and/ or Multi-Site Department user role can assign SOP Review Sessions to any eReg user (internal or external). For example, when a new staff member joins the department, a Regulatory Manager in the department can assign them an SOP Review Session in eReg and include all department-specific SOPs they need to review, aiding in the onboarding process. Or, when a Sponsor Auditor is performing a Good Clinical Practice audit and needs to review SOPs as part of the audit, the Regulatory Manager can assign them an SOP Review Session in eReg to facilitate review of organizational and/ or departmental SOPs.

Creating an SOP Review Session

On the Review Sessions landing page, click the down arrow next to + New Review Session to select + New SOP Review Session and open the Create SOP Review Session pop-up window.

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In the Create SOP Review Session pop-up window, complete the required fields which are marked with an asterisk. Please note the Name of the session must be unique. We suggest including the review type and relevant unique identifiers in the Name such as 'SOP Review for GCP Audit for [Protocol Identifier]' or 'SOP Review for [First and Last Name] Onboarding'. Select a Review Session Type of SOP Only.

A Stop Date for the SOP Review Session is not required; however, we recommend entering a Stop Date so that the Reviewer(s) does not have continuous access to the SOPs included in the Review Session. If both a Start Date and Stop Date are entered for the SOP Review Session, the dates must be unique. An SOP Review Session cannot be set up to start and stop on the same day.

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.

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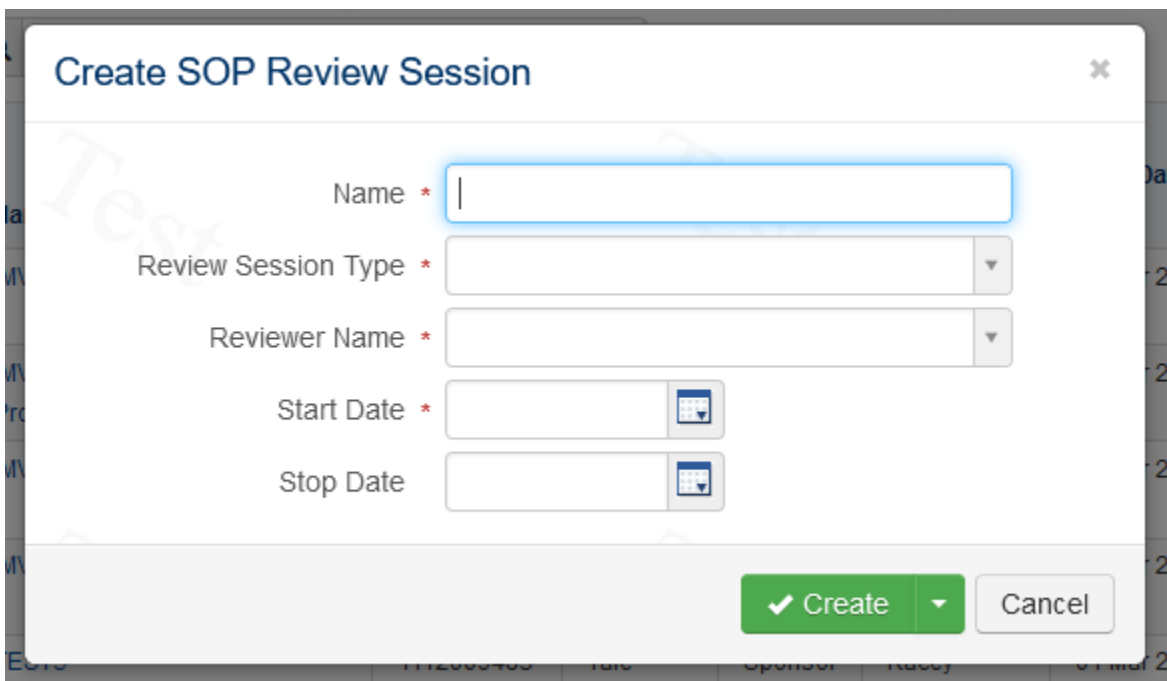
Multiple reviewers can be assigned to one SOP Review Session. After all fields are completed, click Create. The action menu under the Create button will allow you to Create the existing entry and start a new entry.

Configuring an SOP Review Session

After the SOP Review Session is created, you will be routed to the SOP Review Session configuration page. Click Choose SOPs to select the SOPs to be included in the SOP Review Session.

Select from the list of SOPs available to you. This list will include all SOPs filed at the global level and any department-specific SOPs to which you have access. Click Save.

Once added, the Reviewer(s) will be able to view the SOPs. Please note that Reviewers' access to SOPs is limited to view only. Reviewers do not have the ability to download SOPs. If the Reviewer requires a copy of an SOP, you will need to provide it outside of eReg.

When finished choosing SOPs, click Back to Review Session from the Actions button menu to preview the SOP Review Session configured for the Reviewer.

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Deleting an SOP Review Session

SOP Review Sessions can be deleted. On the Review Sessions landing page, select the SOP Review Session that you wish to delete. Under the actions menu, select Delete.

When Delete is clicked, you will be asked to confirm the delete. Click Delete to proceed with deleting the SOP Review Session. Click Cancel to retain the SOP Review Session.
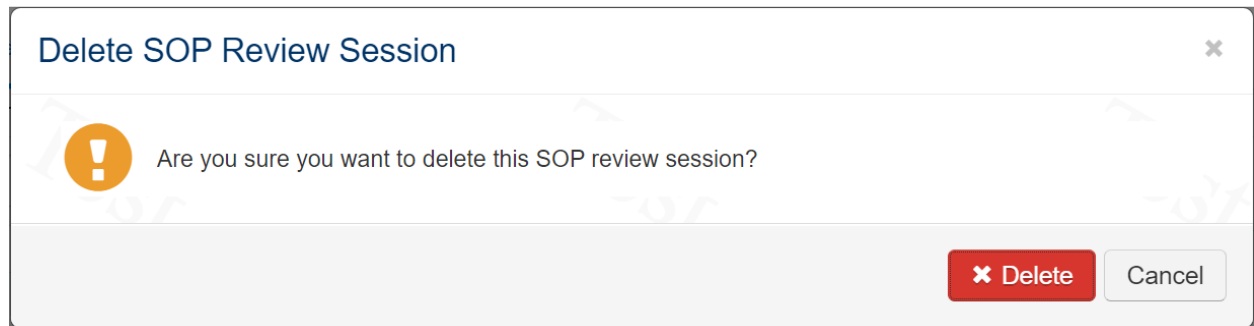
Viewing and Downloading Review Session Documents

Within a Review Session, the Reviewer can view and download protocol documents, view signature information for documents that were electronically signed within eReg, and view SOPs if included in the Review Session.

To download documents into a file folder for review outside of eReg, click Download Documents from the Actions button menu. Sections will display as main folders and Requirements as sub-folders within the relevant Section. If the delegation of authority log is maintained within eReg, a current version of the log will populate and be filed within the Delegation of Authority folder. Folders and sub-folders will not be created for any Sections and Requirements that are blank, i.e., no documents filed within that Section or Requirement or for Sections that are view-only within eReg, i.e., SOPs.

Review Session: Test Review Session

Actions ▾

➡ Configure Review Session
✖ Delete
⬇ Download Documents

Summary

Review Session Details

If new protocol documents are uploaded to the Sections and Requirements included in a Review Session, the Review Session will reflect the new documents in real time. However, the downloaded documents are representative of what was available for review in the eReg binder at the time of download.

Additional Resources

- Electronic Regulatory Management System Access Guide
- eReg Learning Portal
- YCCI eReg website: https://medicine.yale.edu/ycci/researchservices/systems/ereg/

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