Yale eREG Notice re: Standard Operating Procedures (SOPs)

Dear eReg Users,

The eReg Support Staff in the Yale Center for Clinical Investigation (YCCI) have enabled central management of Standard Operating Procedures (SOPs) in eReg. SOPs can be filed and made available at the global level (accessible to all Yale/Yale New Haven Hospital [YNHH] users) or department level (accessible to only those users within a specific department).

SOPs can be added to regular Review Sessions, for sponsor-monitors and auditors to review, and to SOP-only Review Sessions, allowing a group of SOPs to be reviewed outside the context of a protocol.

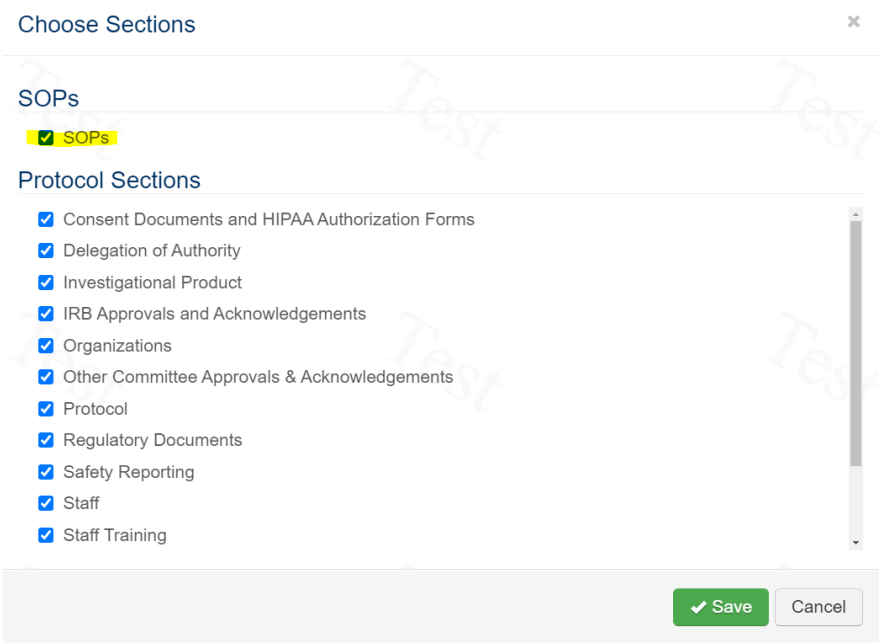
Currently, eReg has SOPs filed for YNHH Investigational Drug Service (IDS) and Yale University Human Research Protection Program (HRPP). These SOPs are accessible to all Yale/YNHH eReg users.

Document Name	Versions	Category
2018 Investigational Drug Service.pdf	1	Investigational Drug Service
2021 YNHHS IDS Investigational Drug Transport SOP.PDF	1	Investigational Drug Service
2021 YNHHS IDS Temperature Monitoring of Storage Locations for Investiga....pdf	1	Investigational Drug Service
2021 YNHHS IDS Verification of Authorized Investigators SOP.PDF	1	Investigational Drug Service
2021 YNHHS IDS Waste and Destruction of Investigational Medications SOP.PDF	1	Investigational Drug Service
Yale HRPP Policies, Procedures, Guidance, and Checklists	1	Yale Human Research Protection Program

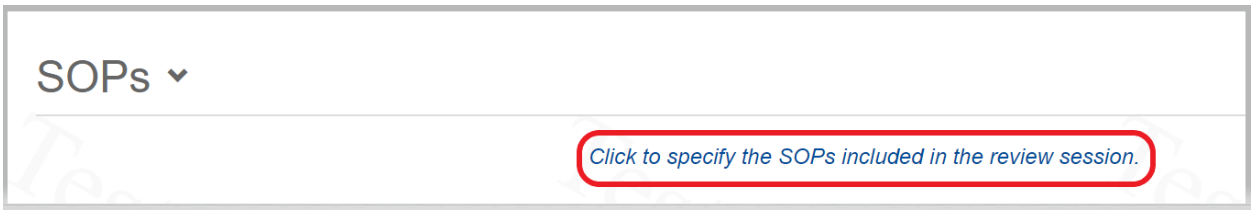
6 Total Records

How do I add SOPs to a Review Session?

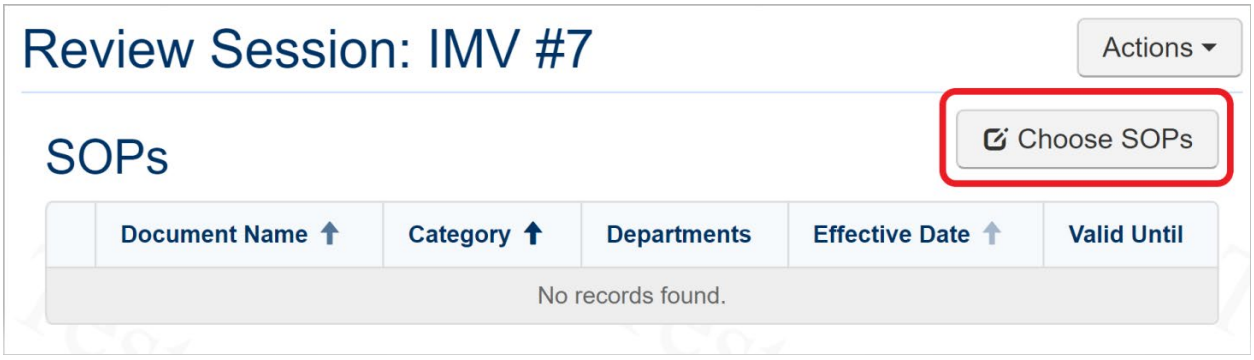
To add SOPs to a Review Session, you must first configure the Review Session to include the SOP section. SOPs are not included in Review Sessions by default, so you will need to manually add the SOP section each time you configure a new Review Session, following the steps below.



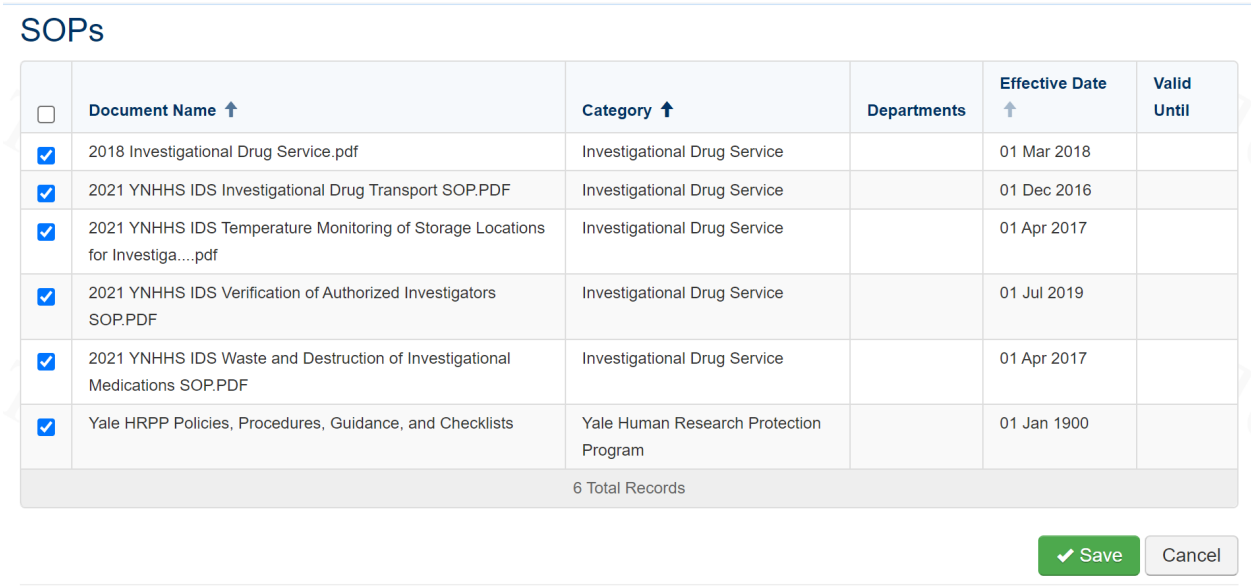
Once the SOP section has been added, you will specify which SOPs you want to include by clicking on the hyperlink within the SOP section.



When you open the hyperlink, you will then click 'Choose SOPs' to pull specific SOPs into the Review Session.



You will then select from the list of SOPs that are available to you. This list will include all SOPs filed at the global level and any department-specific SOPs you have access to.



Once you have added the SOPs to your Review Session, your monitor or auditor will be able to view them. Please note that monitors only have access to view SOPs within eReg. They do not have the ability to download them.

What are SOP-only Review Sessions?

SOP-only Review Sessions are Review Sessions that only contain SOPs and sit outside the context of a protocol. eReg users with the Regulatory Manager and Multi-Site Department roles have access to assign SOP-only Review Sessions to any user needing to review a set of SOPs. For example, if a new staff member joins a department, the Regulatory Manager of that department can assign them an SOP-only Review Session in eReg and include all department-specific SOPs they need to review, aiding in the onboarding process.

What will happen to my existing review sessions?
Existing review sessions will not be impacted.

What do I need to do?
If you have any SOPs that you would like filed in eReg, either at the global or department level, please notify eReg Support (eReg.Support@yale.edu) and we will upload them into the system for you.

Who do I contact with questions?
Please contact eReg Support (eReg.Support@yale.edu) with any questions.