

Yale eREG Notice Regarding Reference List Changes (CORRECTION)

Dear eReg Users,

The eReg Support Staff in the Yale Center for Clinical Investigation (YCCI) have made additional changes to the following Reference Lists in the eReg system:

- Section Name
- Requirement Name

The tables below indicate which requirements have been modified (prior and new requirement names are listed) and which are new (prior requirement is N/A).

What will happen on my existing studies?

You will see the prior requirement names updated to the new requirement names within your existing protocol records. New requirements are currently available for use, and they will be incorporated into the new regulatory templates. eReg Support will send a separate communication when the new templates are available for use.

What do I need to do?

The Requirement Name changes do not impact the documents that are expected to be filed under each requirement; therefore, you should not need to re-file documents that are already filed in those requirements.

Who do I contact with questions?

Please contact eReg Support (eReg.Support@yale.edu) with any questions.

Reference List - Section Name

Prior Requirement	New Requirement
Protocol and Amendments	Protocol

Reference List - Requirement Name

Prior Requirement	New Requirement
IRB-approved Protocol and Amendment(s)	IRB-approved Protocol
Short Form HIPAA Authorizations	Translated HIPAA Authorization Forms

N/A	IP Temperature Log
N/A	IRB Amendments
N/A	IRB Closure
N/A	IRB Prompt Reporting
N/A	IRB-approved HIPAA Authorization Forms
N/A	Other Forms
N/A	Other Study Logs
N/A	SAE Report Templates
N/A	SAE Reports
N/A	Safety Information
N/A	Safety Management Plan
N/A	Signature Log
N/A	Site Monitoring Reports
N/A	Site Monitoring Visit Log
N/A	Transfer of Regulatory Obligations
N/A	Trial Insurance (Policy and Certificate)
N/A	Trial Registry