Communication to Share Reference List Changes in eReg for Enterprise

Dear eReg Users,

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

- Staff Training Requirement Name
- Section Name
- Requirement Name

New requirements have been added to each reference list, and a number of requirement names have been modified. These changes are in preparation for implementing new Regulatory Templates in the coming weeks.

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 on 03-Sep-2021. New requirements will be available for use on 03-Sep-2021, 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.

The major change to Section Names is that the section previously named "Committee Approvals and Acknowledgments" is being changed to "IRB Approvals and Acknowledgements." Therefore, you may need to migrate non-IRB approvals, acknowledgements, correspondences, etc. to a new "Committee Approvals and Acknowledgements" section. IRB-related approvals, acknowledgements, correspondences, etc. will not need to be re-filed.

Who do I contact with questions?

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

Reference List - Staff Training Requirement Name

Prior Requirement	New Requirement
N/A	EDC Training
N/A	Other Protocol Specific or System Training
N/A	Other Training

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Reference List - Section Name

Prior Requirement	New Requirement
Committee Approvals and Acknowledgments	IRB Approvals and Acknowledgements
Correspondence, Other Regulatory Authorities	Study Correspondence
Delegation of Authority Log	Delegation of Authority (Paper)
Investigator's Brochure and/ or Package Inserts	Investigational Product
N/A	Committee Approvals and Acknowledgments

Reference List - Requirement Name

Prior Requirement	New Requirement
Ancillary Review Approvals	Ancillary Committee Approvals and Acknowledgements
Certificate of Analysis of IP Shipped	Certificate of Analysis
Correspondence	Other Study Correspondence
CV's Licenses Investigator	CVs & Medical Licenses
Data and Safety Monitoring Committee	Data and Safety Monitoring Committee/ Board
Data Management Oversight	Data Management
Documentation of distribution of INDSRs to site(s)	INDSR Distribution
Documentation of IP Destruction	IP Destruction
DSMC/DSMB Reports	DSMC/DSMB Documents
FDA Form 1572	Form FDA 1572
Investigational New Drug Safety Reports	External Safety Reports
IP Shipment Log	IP Shipment Records
Master SAE Log	SAE Log
Notes to File	Notes To File (NTF)
Pharmacy Documents	Pharmacy Manual
Recruitment Flyers/Posters	Recruitment Materials
SAE Reporting Forms	Safety Reporting Forms
Sample of labels attached to investigational product containers	Sample of Label(s) for Investigational Product
Serious Adverse Event Reports	Internal Safety Reports and Correspondence
Specimen Tracking Log	Biospecimen Tracking Log
Unmasking procedures for blinded trials	Decoding Procedures for Blinded Trials
N/A	Contracted Services/Vendors
N/A	CVs
N/A	Documentation of PI Review of Safety Events
N/A	DSMC/DSMB Meetings
N/A	Good Clinical Practice (GCP) Training
N/A	HIPAA Privacy and Security Training
N/A	Human Subjects Protection Training

N/A	IP Temperature Log
N/A	IRB Amendments
N/A	IRB Closure
N/A	IRB Personnel Amendments
N/A	IRB Prompt Reporting
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