eReg Guidance Document
Investigator Site File Regulatory Templates

Contents

Acronyms

CAP: College of American Pathologists

CAS: Central Authentication Service

CLIA: Clinical Laboratory Improvement Amendments

COLA: Commission on Office Laboratory Accreditation

CRF: Case Report Form

CV: Curriculum Vitae

DoA: Delegation of Authority

EDC: Electronic Data Capture

FDA: Food and Drug Administration

FDF: Financial Disclosure Form

FWA: Federalwide Assurance

GCP: Good Clinical Practice

HIPAA: Health Insurance Portability and Accountability Act

IATA: International Air Transport Association

IB: Investigator's Brochure

IMV: Interim Monitoring Visit

INDSR: Investigational New Drug Safety Report

IP: Investigational Product

IRB: Institutional Review Board

ML: Medical License

NetID: Network Identification

NTF: Note to File

PSP: Protocol Signature Page

SAE: Serious Adverse Event

SOP: Standard Operating Procedure

UADE: Unanticipated Adverse Device Effect

URL: Uniform Resource Locator

YCCI: Yale Center for Clinical Investigation

Regulatory Templates

Investigator Site Files

Investigator Site Files (also known as regulatory binders, investigator binders, study binders, etc.) contain study-specific information and regulatory documentation. Investigator Site Files serve to demonstrate compliance with Good Clinical Practice (GCP) and all applicable regulatory requirements. It organizes essential documents, provides easy access to essential 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.

Investigator Site Files in eReg use a regulatory template that is 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.

A regulatory template is selected when a study is imported into eReg from OnCore. Unless a study does not require an OnCore record, the eReg Support team in the Yale Center for Clinical Investigation (YCCI) will import the protocol from OnCore and assign the appropriate regulatory template. If a study does not require an OnCore record and you would like to maintain a study file directly in eReg, contact eReg Support (eReg.Support@yale.edu).

Once assigned to a protocol, regulatory templates can be edited by regulatory staff at the protocol level, if needed, to fit the needs of the study and/ or sponsor requirements. See below for more information.

The following Investigator Site File regulatory templates are available for use:

- Investigator Site File for Drug Studies
- Investigator Site file for Device Studies
- Investigator Site File for Social/ Behavioral Studies

Investigator Site File for Drug Studies

Section	Requirements
Consent Documents and HIPAA Authorization Forms	❖ IRB-approved Assent Forms ❖ IRB-approved Consent Documents ❖ IRB-approved HIPAA Authorization Forms ❖ IRB-approved Parental Permission Forms ❖ IRB-approved Translated Consent Documents ❖ Short Form Consent Documents ❖ Sponsor Consent Templates ❖ Translated HIPAA Authorization Forms

Section	Requirements
Delegation of Authority (standard section)	N/A – This section contains an integrated delegation of authority log.
Delegation of Authority (Paper)	❖ Delegation of Authority Log
Investigational Product	❖ Investigator's Brochure ❖ Investigator's Brochure Receipt Page ❖ IP Accountability Log ❖ IP Destruction ❖ IP Shipment Records ❖ IP Temperature Log ❖ Other Forms ❖ Package Insert(s) ❖ Pharmacy Manual
IRB Approvals and Acknowledgements	❖ IRB Amendments ❖ IRB Closure* ❖ IRB Communications ❖ IRB Initial Approval* ❖ IRB Prompt Reporting ❖ IRB Renewals
Organizations (standard section)	❖ IRB o IRB Compliance Statement o IRB Federalwide Assurance Number o IRB Registration o IRB Roster ❖ Laboratory o CAP o CLIA o COLA o Lab Director CV o Lab Director Medical License o Normal Range Values o State Certificate This section includes status (Complete or Incomplete) for required documents.
Other Committee Approvals and Acknowledgements	❖ Ancillary Committee Approvals and Acknowledgements

Section	Requirements
	❖ Data and Safety Monitoring Committee/ Board
Protocol	❖ IRB-approved Protocol* ❖ Protocol Signature Page
Regulatory Documents	❖ Financial Disclosure Forms ❖ Form FDA 1572
Safety Reporting	❖ External Safety Reports ❖ Internal Safety Reports and Correspondence ❖ Safety Reporting Log
Staff (standard section)	N/A – This section includes status (Complete or Incomplete) for required credentials. Staff added directly in eReg.
Staff Training (standard section)	❖ EDC Training ❖ Other Protocol Specific or System Training ❖ Protocol Training*
Study Conduct Documents	❖ Case Report Form Completion Guidelines ❖ Case Report Forms* ❖ Eligibility Checklist ❖ Enrollment Form ❖ IRB-approved Patient-Facing Materials ❖ Laboratory Documents ❖ Other Study Conduct Documents ❖ Protocol Deviation Forms ❖ Recruitment Materials ❖ Safety Reporting Forms ❖ Study Contact List ❖ Study Manual of Operations ❖ Study Specific SOPs ❖ Unblinding Procedure
Site Study Correspondence	❖ Meetings ❖ Newsletters and Study Updates ❖ Notes To File (NTF)

Section	Requirements
	❖ Other Study Correspondence ❖ Site Monitoring Reports ❖ Sponsor Correspondence
Study Logs	❖ AE Log ❖ Biospecimen Tracking Log ❖ Equipment Calibration Log ❖ Other Study Logs ❖ Protocol Deviation Log ❖ Screening/ Enrollment Log* ❖ Site Monitoring Visit Log

*Mandatory Requirement

Investigator Site File for Device Studies

Section	Requirements
Consent Documents and HIPAA Authorization Forms	❖ IRB-approved Assent Forms ❖ IRB-approved Consent Documents ❖ IRB-approved HIPAA Authorization Forms ❖ IRB-approved Parental Permission Forms ❖ IRB-approved Translated Consent Documents ❖ Short Form Consent Documents ❖ Sponsor Consent Templates ❖ Translated HIPAA Authorization Forms
Delegation of Authority (standard section)	N/A – This section contains an integrated delegation of authority log.
Delegation of Authority (Paper)	❖ Delegation of Authority Log
Investigational Device	❖ Device Accountability Log ❖ Device Confirmation of Receipt and Review ❖ Device Packing Slips ❖ Instructions for Use
IRB Approvals and Acknowledgements	❖ IRB Amendments ❖ IRB Closure* ❖ IRB Communications ❖ IRB Initial Approval*

Section	Requirements
	❖ IRB Prompt Reporting ❖ IRB Renewals
Organizations (standard section)	❖ IRB ○ IRB Compliance Statement ○ IRB Federalwide Assurance Number ○ IRB Registration ○ IRB Roster ❖ Laboratory ○ CAP ○ CLIA ○ COLA ○ Lab Director CV ○ Lab Director Medical License ○ Normal Range Values ○ State Certificate This section includes status (Complete or Incomplete) for required documents.
Other Committee Approvals and Acknowledgements	❖ Ancillary Committee Approvals and Acknowledgements ❖ Data and Safety Monitoring Committee/ Board
Protocol	❖ IRB-approved Protocol* ❖ Protocol Signature Page
Regulatory Documents	❖ Financial Disclosure Forms ❖ Investigator Agreements
Safety Reporting	❖ External Safety Reports ❖ Internal Safety Reports and Correspondence ❖ Safety Reporting Log
Staff (standard section)	N/A – This section includes status (Complete or Incomplete) for required credentials. Staff added directly in eReg
Staff Training (standard section)	❖ EDC Training ❖ Other Protocol Specific or System Training ❖ Protocol Training*
Study Conduct Documents	❖ Case Report Form Completion Guidelines ❖ Case Report Forms*

Section	Requirements
	❖ Eligibility Checklist ❖ Enrollment Form ❖ IRB-approved Patient-Facing Materials ❖ Laboratory Documents ❖ Other Study Conduct Documents ❖ Protocol Deviation Forms ❖ Recruitment Materials ❖ Safety Reporting Forms ❖ Study Contact List ❖ Study Manual of Operations ❖ Study Specific SOPs ❖ Unblinding Procedure
Site Study Correspondence	❖ Meetings ❖ Newsletters and Study Updates ❖ Notes To File (NTF) ❖ Other Study Correspondence ❖ Site Monitoring Reports ❖ Sponsor Correspondence
Study Logs	❖ AE Log ❖ Biospecimen Tracking Log ❖ Equipment Calibration Log ❖ Other Study Logs ❖ Protocol Deviation Log ❖ Screening/ Enrollment Log* ❖ Site Monitoring Visit Log

*Mandatory Requirement

Investigator Site File for Social/ Behavioral Studies

Section	Requirements
Consent Documents and HIPAA Authorization Forms	❖ IRB-approved Assent Forms ❖ IRB-approved Consent Documents ❖ IRB-approved HIPAA Authorization Forms

Section	Requirements
	❖ IRB-approved Parental Permission Forms ❖ IRB-approved Participant Information Sheets ❖ IRB-approved Translated Consent Documents ❖ Short Form Consent Documents ❖ Sponsor Consent Templates ❖ Translated HIPAA Authorization Forms
Delegation of Authority (standard section)	N/A – This section contains an integrated delegation of authority log.
Delegation of Authority (Paper)	❖ Delegation of Authority Log
IRB Approvals and Acknowledgements	❖ IRB Amendments ❖ IRB Closure* ❖ IRB Communications ❖ IRB Initial Approval* ❖ IRB Prompt Reporting ❖ IRB Renewals
Organizations (standard section)	❖ IRB o IRB Compliance Statement o IRB Federalwide Assurance Number o IRB Registration o IRB Roster ❖ Laboratory o CAP o CLIA o COLA o Lab Director CV o Lab Director Medical License o Normal Range Values o State Certificate This section includes status (Complete or Incomplete) for required documents.
Other Committee Approvals and Acknowledgements	❖ Ancillary Committee Approvals and Acknowledgements ❖ Data and Safety Monitoring Committee/ Board
Protocol	❖ IRB-approved Protocol ❖ Protocol Signature Page

Section	Requirements
Regulatory Documents	❖ Financial Disclosure Forms ❖ Other Regulatory Documents
Safety Reporting	❖ Internal Safety Reports and Correspondence ❖ Safety Reporting Log
Staff (standard section)	N/A – This section includes status (Complete or Incomplete) for required credentials. Staff added directly in eReg
Staff Training (standard section)	❖ EDC Training ❖ Other Protocol Specific or System Training ❖ Protocol Training*
Study Conduct Documents	❖ Case Report Form Completion Guidelines ❖ Case Report Forms* ❖ Eligibility Checklist ❖ Enrollment Form ❖ IRB-approved Patient-Facing Materials ❖ Laboratory Documents ❖ Other Study Conduct Documents ❖ Protocol Deviation Forms ❖ Recruitment Materials ❖ Safety Reporting Forms ❖ Study Contact List ❖ Study Manual of Operations ❖ Study Specific SOPs ❖ Unblinding Procedure
Site Study Correspondence	❖ Meetings ❖ Newsletters and Study Updates ❖ Notes To File (NTF) ❖ Other Study Correspondence ❖ Site Monitoring Reports ❖ Sponsor Correspondence
Study Logs	❖ AE Log ❖ Biospecimen Tracking Log

Section	Requirements
	❖ Equipment Calibration Log ❖ Other Study Logs ❖ Protocol Deviation Log ❖ Screening/ Enrollment Log* ❖ Site Monitoring Visit Log

*Mandatory Requirement

Editing Sections and Requirements

Once assigned to a protocol, regulatory templates can be edited by regulatory staff (User Role: Yale Regulatory Coordinator and Yale Regulatory Manager) at the protocol level, if needed, to fit the needs of the study and/ or sponsor requirements. Editing sections and requirements is done in the Protocol Outline view. To access the Protocol Outline view, choose Protocol Outline from the Actions button menu.

Refer to the eReg Learning Portal for more information on building and managing protocols within eReg.

We recommend removing sections and requirements that are not applicable to your study before the study begins when you are setting up your Investigator Site File. For example, if you are conducting an interventional study for adult subjects, you will remove the requirement for IRB-approved assent forms from the 'Consent Documents and HIPAA Authorization Forms' Section. Or if you intend to use the Delegation of Authority log within eReg, you will remove the section for 'Delegation of Authority Log (Paper)'.

If a requirement may be needed later, we recommend retaining the requirement within your protocol outline. For example, when the study begins to enroll you do not have any non-English language consent documents approved by the IRB as you are not intentionally recruiting from a non-English speaking population. However, should non-English speaking subjects be enrolled later, you would obtain IRB approval for the translated consent documents and would file those documents within your Investigator Site File. You will retain the requirement for 'IRB-approved Translated Consent Documents' within the 'Consent Documents and HIPAA Authorization Forms' Section. If translated documents are required later, you will file them once approved by the IRB of record.

After the sections and/ or requirements have been edited in the Protocol Outline view, you can navigate "Back to Protocol" using the Actions button menu. From the protocol record, you can begin adding

documents and URLs under each requirement. Note: After you've added a requirement to a section and uploaded a document or URL for that requirement, you can no longer remove that requirement from the section nor remove the section from the Protocol Outline. To remove the requirement and/ or section, you must first remove the document or URL for that requirement and file it elsewhere, as needed. If the document has been electronically signed within eReg, you cannot remove it from the system, but you can move it to a new section/requirement by choosing Move Document from the Actions button menu for the requirement version you want to move. A document filed in the Staff Training section can be moved to another requirement within the Staff Training section only (it cannot be moved to another protocol section).

If, at the end of the study, you did not utilize a requirement that you retained, we recommend removing that requirement or placing a note to file within the requirement to indicate it was intentionally left blank. Once either approach is taken, you can proceed with locking the protocol assuming all other steps have been taken preparatory to locking the study in eReg.

Adding Staff to Protocols

Staff members must first be added to the eReg system before they can be added to a protocol. Refer to the *eReg Management System Access Guide* for more information on requesting eReg access for a staff member.

Principal Investigators, Yale Regulatory Managers, Yale Regulatory Coordinators, those with Multi-site Access, and select Administrative roles have the ability to add protocol staff members directly to protocols in eReg.

Please refer to the eReg Learning Portal for more information on adding staff to protocols.

Uploading Documents and URLs

Documents and URLs are managed in three ways in eReg:

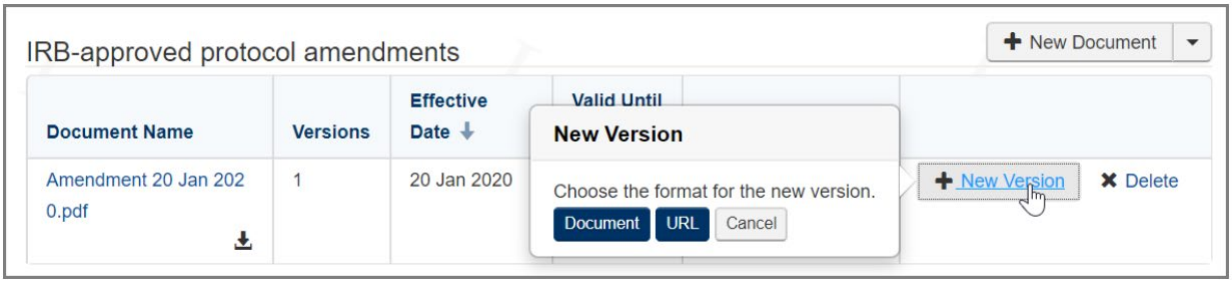
1. Regulatory tracking items – for documents and URLs uploaded to organization records
2. Credentials – for documents and URLs uploaded to contact records (for Yale/YNHH-affiliated staff only)
3. Protocol documents – for documents and URLs uploaded to protocol records

Certain URLs may require credentials or log-in information to be entered before the website can be viewed. Keep this in mind when uploading URLs in eReg, as external monitors who need access to this information will need to request over the shoulder access from a member of the research team or a printed copy of the information directly from the website.

Please refer to the eReg Learning Portal for more information on adding, editing and deleting documents and URLs in eReg. Please refer to the *eReg Guidance – Staff Training Section* for more information on uploading documents and URLs to the standard Staff Training section.

Stacking Versions

When uploading documents and URLs, you can stack new versions over existing versions of a document or URL. To add a new version, access the section that includes the document or URL and click the New Version link. You then need to specify whether the new version is in Document or URL format.



We recommend stacking the following types of documents and URLs:

Document or URL	Document Management Type
IRB-approved consent and assent documents	Protocol Document
IRB-approved HIPAA authorization forms	Protocol Document
Sponsor consent templates	Protocol Document
Delegation of Authority Log (paper)	Protocol Document
IRB-approved Investigator's Brochure(s)	Protocol Document
Investigator's Brochure receipt pages	Protocol Document
IRB-approved Package Insert(s)	Protocol Document
Laboratory certifications	Regulatory Tracking Item
Laboratory reference ranges	Regulatory Tracking Item
IRB Rosters	Regulatory Tracking Item
IRB Registration	Regulatory Tracking Item
IRB Federalwide Assurance (FWA)	Regulatory Tracking Item
IRB-approved protocols	Protocol Document
Protocol Signature pages	Protocol Document
Financial Disclosure Forms (by person)	Protocol Document
Form FDA 1572	Protocol Document
Investigator Agreement	Protocol Document
Curriculum Vitae	Credentials
Medical Licenses	Credentials
GCP Training certificates	Credentials
Other Training certificates (by type, system, etc.)	Credentials and Protocol Document
Study Conduct Documents **Examples:** **Eligibility Checklist** **IRB-approved Patient-Facing Materials** **Study Contact List**	Protocol Document
Study Manuals	Protocol Document
Standard Operating Procedures	Protocol Document
Newsletters and Study Updates	Protocol Document

Document or URL	Document Management Type
Study Logs **Examples:** **Equipment Calibration Log** **Screening/ Enrollment Log** **Site Monitoring Visit Log**	Protocol Document

Related Documents

Related documents can be added to single documents and URLs and should be used to tie documents together. For example, when filing documentation for an IRB approval, file the IRB approval letter as the main file and add the submission documents, approval documents that are not filed elsewhere, and correspondence as related documents.

Note that related documents cannot be routed for electronic signature. A copy of a related document also cannot be sent to the Multi-Site protocol (Trial Master File or Participating Site File) maintained in eReg.

We recommend utilizing the related document feature in the following sections within the investigator site file templates. Please note that the recommendations for main files and associated related documents are not an exhaustive list:

Section	Main File Recommendation	Related Document(s) Recommendation
IRB Approvals and Acknowledgements	❖ IRB Approval Letter	❖ IRB Submission Document(s) ❖ IRB Approval Documents not filed elsewhere ❖ Relevant correspondence related to the submission, such as:

Section	Main File Recommendation	Related Document(s) Recommendation
		○ Team Notification of Approval ○ Sponsor Notification of Approval ○ Sponsor Distribution of Information to be submitted for IRB approval ○ Sponsor Approval of Consent Changes, if applicable ○ IRB Correspondence
IRB Approvals and Acknowledgements	❖ IRB Acknowledgement Letter	❖ IRB Submission Document(s) ❖ IRB Acknowledged Documents not filed elsewhere ❖ Relevant correspondence related to the submission, such as: ○ Team Notification of Acknowledgment ○ Sponsor Notification of Acknowledgement ○ Sponsor Distribution of Information to be submitted for IRB acknowledgement, if applicable ○ IRB Correspondence
Other Committee Approvals and Acknowledgements	❖ Ancillary Committee Approval Letters	❖ Ancillary Committee Submission Document(s) ❖ Ancillary Committee Approval Documents not filed elsewhere ❖ Relevant correspondence related to the submission, such as: ○ Team Notification of Approval ○ Sponsor Notification of Approval ○ Sponsor Distribution of Information to be submitted

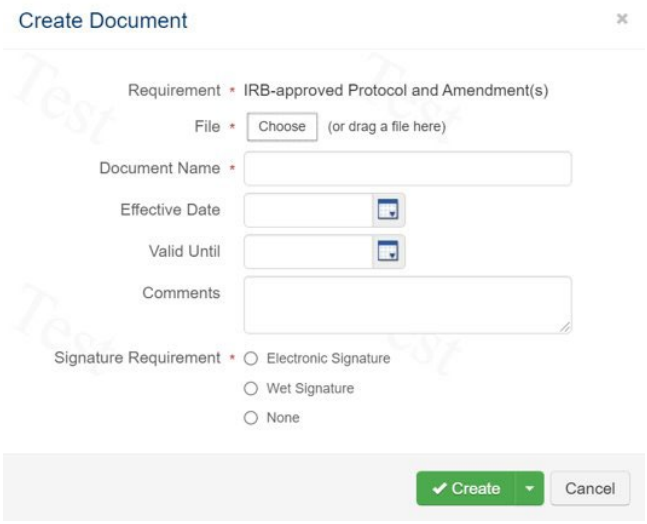
Section	Main File Recommendation	Related Document(s) Recommendation
		for Ancillary Committee approval ○ Sponsor Approval of Consent Changes, if applicable ○ Ancillary Committee Correspondence
Other Committee Approvals and Acknowledgements	❖ Ancillary Committee Acknowledgement Letters	❖ Ancillary Committee Submission Documents ❖ Ancillary Committee Acknowledged Documents not filed elsewhere ❖ Relevant correspondence related to the submission, such as: ○ Team Notification of Acknowledgment ○ Sponsor Notification of Acknowledgement ○ Sponsor Distribution of Information to be submitted for Ancillary Committee acknowledgement, if applicable ○ Ancillary Committee Correspondence
Other Committee Approvals and Acknowledgements	❖ Data Safety Monitoring Board/ Committee Decision Letters	❖ Relevant correspondence to the Data Safety Monitoring Board/ Committee ❖ Relevant correspondence from the Data Safety Monitoring Board/ Committee ❖ Team Notification of Data Safety Monitoring Board/ Committee Decision
Safety Reporting	❖ External Safety Report (i.e., Investigational New Drug Safety Report [INDSR], Unanticipated Adverse Device Effect [UADE] Safety Report, etc.)	❖ Sponsor distribution of safety report ❖ Team communication regarding safety report ❖ Relevant communication regarding safety report

Section	Main File Recommendation	Related Document(s) Recommendation
Safety Reporting	❖ Internal Safety Report (i.e., SAE Reporting Form)	❖ Sponsor notification of safety event ❖ Supporting documentation provided to sponsor (with protected health information redacted) ❖ Team communication regarding safety event ❖ Relevant communication regarding safety event
Site Study Correspondence	❖ Other Study Correspondence	❖ Relevant attachments to communication ❖ Subsequent communication relevant to correspondence
Site Study Correspondence	❖ Site Monitoring Visit Follow-Up Report	❖ Confirmation Letter ❖ Relevant correspondence regarding the scheduling, conduct and/ or follow-up for the visit
Site Study Correspondence	❖ Sponsor Correspondence	❖ Relevant attachments to communication ❖ Subsequent communication relevant to correspondence

Version Control

Version control is important for documents that undergo revision and/ or can be modified electronically by a variety of users, i.e., Principal Investigator, Institutional Review Board, sponsor and/ or their designee, study coordinator, ancillary review boards, etc. Establishing a system for version control at the start of a study will help ensure documents are organized and that the current version is clearly identified by all who revise documents. Version control can also help to keep track of edits made by various users.

eReg includes version control when documents and URLs are uploaded to an organization record, the protocol record and/ or the contact record. The system allows one to enter a document name, the effective date and valid until date. Mandatory fields are marked with an asterisk (*). Either an effective date or valid until date must be entered unless you are adding a URL for a regulatory tracking item in which case the date(s) are not required.



Date ranges in eReg are based on midnight. Effective Dates go into effect at 12:00 AM on the specified date, while the date entered in the Valid Until Date field is when the document is no longer valid or the organization is no longer active on the protocol. For example:

- A document with a Valid Until date of 13 Nov 2018 would be valid until 11:59 PM on 12 Nov 2018. For this reason, valid until dates should be entered as the expiration date + one day, or 13 Nov 2018 + one day = 14 Nov 2018.

In addition to noting effective and/ or valid until dates in eReg, the document should include version control in the naming convention (see Naming Conventions section below) and within the body of the document. Version control will typically include a version number and version date. Oftentimes, the header or footer will be used to document the version number and version date of a document.

We recommend updating a version number when revising a document that was previously approved by the IRB or designated as a final version. For example, the initial consent form submitted to and approved by the IRB was given a version number of 1.0. The sponsor distributes an amendment to the protocol which includes changes to the consent form. The consent form will be revised and the version updated from 1.0 to 2.0. This will be reflected in the document naming convention and within the document.

We recommend updating a version date when a document is revised by any user until such time that the document is approved by the IRB or designated as a final version. For example, the initial consent form submitted to and approved by the IRB was given a version date of 15-Dec-2020. The sponsor distributes an amendment to the protocol which includes changes to the consent form on 22-May-2021. The coordinator revises the consent form and updates the version date from 15-Dec-2020 to 24-May-2021, the date the coordinator made changes to the consent form. The coordinator sends the document to the sponsor for review. The sponsor revises the consent further and updates the version date to 27-May-2021.

Avoid ambiguity in dates by using four digits for the year (ex. 2021) and three letter abbreviations for months (ex. Dec) or the full month name (ex. December). If your sponsor specifies formatting for a date, follow that formatting.

In certain instances, the version date of a document may not align with the effective date in eReg. We recommend using the following effective dates, when applicable:

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*
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

* When uploading a document for electronic signature, use 01 Jan 1900 has a placeholder for the Effective Date. Once the document is signed, confirm that the signature and date appear as expected within the document then update the Effective Date to be the signature date.

Not all documents will include a valid until date. We recommend using the following valid until dates for the below noted document types that typically include valid until dates, when applicable:

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

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. We recommend using 01 Jan 1900 as an effective date for documents without any version control.

Naming Conventions

Standard naming conventions ensure consistency in study files and improve the organization of files. Naming conventions help identify gaps in filing as any omissions are readily identified when a standard naming convention is followed. They allow staff maintaining and reviewing files to be able to find files more quickly and readily.

Advarra eReg does include character limits in document name fields, so it is important that naming conventions be succinct and informative. Standard abbreviations can be used to decrease the character limit if they are consistently applied and prospectively defined.

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.

Below are recommended standard naming conventions for regulatory and essential documents. To ensure chronological sorting of electronic documents by naming convention when they are downloaded from eReg in a review session, we recommend a date format of yyyy.mm.dd. Please note this is not an exhaustive list of regulatory and essential documents:

Document Type	Naming Convention
IRB-approved Assent Forms	Assent Form_[Age Range]_v[#]_yyyy.mm.dd
IRB-approved Consent Documents	Main Consent_v[#]_yyyy.mm.dd
IRB-approved Parental Permission Forms	Parental Permission Form_v[#]_yyyy.mm.dd
IRB-approved Translated Consent Documents	[Language] Consent_v[#]_yyyy.mm.dd
Short Form Consent Documents	[Language] Short Form_v[#]_yyyy.mm.dd
Translated HIPAA Authorization Forms	[Language] HIPAA_v[#]_yyyy.mm.dd
Sponsor Consent Templates	Sponsor Consent Template_v[#]_yyyy.mm.dd
Delegation of Authority Log (Paper)	DoA Log_yyyy.mm.dd
Device Packing Slips	[Device Short Name] Packing Slip_yyyy.mm.dd
Instructions for Use	[Device Short Name] Instructions for Use_v[#]_yyyy.mm.dd
Device Accountability Log	[Device Short Name] Accountability Log_yyyy.mm.dd
Investigator's Brochure	IB for [Drug Short Name]_Ed[#]_yyyy.mm.dd
Investigator's Brochure Receipt Page	IB Receipt for [Drug Short Name]_Ed[#]_yyyy.mm.dd
Package Insert(s)	Package Insert for [Drug Short Name]_v[#]_yyyy.mm.dd
Pharmacy Manual	Pharmacy Manual for [Drug Short Name]_v[#]_yyyy.mm.dd
IP Accountability Log	[Drug Short Name] Accountability Log_yyyy.mm.dd
IP Shipment Records	[Drug Short Name] Shipment_yyyy.mm.dd

Document Type	Naming Convention
IP Temperature Log	Temp Log_[Freezer/ Fridge Identifier]_yyyy.mm.dd
IP Destruction	[Drug Short Name] Destruction_yyyy.mm.dd
IRB Communications	IRB Correspondence_[Topic Description]_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
Ancillary Committee Approvals and Acknowledgements	[Submission Identifier]_[Committee] Approval Ltr_yyyy.mm.dd
Data and Safety Monitoring Committee/ Board	DSMB Decision Ltr_yyyy.mm.dd
IRB-approved Protocol	Protocol_v[#]_yyyy.mm.dd
Protocol Signature Page	PSP for Protocol v[#]_yyyy.mm.dd
Form FDA 1572	Form FDA 1572_yyyy.mm.dd
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
Curriculum Vitae	CV_[Last Name, First Name]_yyyy.mm.dd
Good Clinical Practice Training	GCP Training_[Last Name, First Name]_yyyy.mm.dd
Medical License	ML_[Last Name, First Name]_yyyy.mm.dd
Dangerous Goods Training/IATA	IATA_[Last Name, First Name]_yyyy.mm.dd
Signature Sample	Signature Sample_[Last Name, First Name]_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 Form Completion Guidelines	CRF Guidelines_v[#]_yyyy.mm.dd
Case Report Forms	CRF_[Form Identifer]_v[#]_yyyy.mm.dd
Eligibility Checklist	Eligibility Checklist_Protocol v[#]_yyyy.mm.dd
Enrollment Form	Enrollment Form_v[#]_yyyy.mm.dd
IRB-approved Patient Facing Materials	Subject Diary_v[#]_yyyy.mm.dd
Recruitment Materials	Recruitment Flyer_v[#]_yyyy.mm.dd

Document Type	Naming Convention
Research Laboratory Documents	Lab Manual_ v[#]_yyyy.mm.dd
Safety Reporting Forms	SAE Reporting Form_ v[#]_yyyy.mm.dd
Protocol Deviation Forms	Deviation Reporting Form_ v[#]_yyyy.mm.dd
Study Manual of Operations	Manual of Operations_ v[#]_yyyy.mm.dd
Unblinding Procedure	Unblinding Procedure_ v[#]_yyyy.mm.dd
Study Contact List	Sponsor Contact List_ v[#]_yyyy.mm.dd
Sponsor Correspondence	Sponsor Correspondence_[Topic Description]_yyyy.mm.dd
Newsletters and Study Updates	Newsletter_Ed[#]_yyyy.mm.dd
Other Study Correspondence	Correspondence_[Topic Description]_yyyy.mm.dd
Notes To File (NTF)	NTF_[Brief Description]_yyyy.mm.dd
Study Specific SOPs	SOP_[Brief Description]_yyyy.mm.dd
Enrollment Log	Enrollment Log_yyyy.mm.dd
Screening Log	Screening Log_yyyy.mm.dd
Biospecimen Tracking Log	[Biospecimen Type] Tracking Log_yyyy.mm.dd
Equipment Calibration Log	Calibration Log_[Equipment Identifier]_yyyy.mm.dd
Site Monitoring Visit Log	Site Monitoring Visit Log_yyyy.mm.dd

Additional Resources

- eReg Guidance – Staff Training Section
- eReg Guidance – Delegation of Authority Log
- eReg Management System Access Guide
- eReg Learning Portal
- YCCI eReg website: https://medicine.yale.edu/ycci/researchservices/systems/ereg/