



eReg Frequently Asked Questions (FAQs)

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Acronyms

- CFR:** Code of Federal Regulations
- FDA:** U.S. Food and Drug Administration
- FDF:** Financial Disclosure Form
- HIC:** Human Investigation Committee
- HRPP:** Human Research Protection Program
- IDS:** Investigational Drug Services
- IRB:** Institutional Review Board
- NCT:** National Clinical Trial
- NTF:** Note to File
- PI:** Principal Investigator
- YCCI:** Yale Center for Clinical Investigation

Delegation of Authority

1. Where are wet-ink signatures and initials documented if not on a paper Delegation of Authority Log?

Hand-written printed name, signature, initials, and numbers 0-9 are documented on the Signature Sample form for each study staff member and submitted to ereg.credentials@yale.edu. The document is uploaded in the user's Credential record, with the Credential Type: Signature Sample.

New internal eReg users are required to submit the Signature Sample document prior to being granted access to the system.

2. How do I know which tasks to assign to each study team member?

The eReg Guidance Document – Delegation of Authority includes a table of tasks that are assigned by staff role and are signed off at the contact level. At the protocol level, a staff member's delegated tasks can be revised (including addition of custom, study-specific tasks as needed), until the PI signs off.

3. Can I route the Delegation of Authority Log for final sign-off by the Principal Investigator (PI) at the time of IRB study closure if the PI has already been Stop Dated?

Yes, you can route the final Delegation of Authority Log for PI sign-off after the PI is stop dated in the Staff section and on the Delegation of Authority Log. The PI will need to sign-off on his/her Stop Date on the Delegation of Authority Log before the Log can be routed for final signature upon IRB study closure.





4. Why does the Delegation of Authority log show that study staff signed off on their delegated tasks well before their Start Date?

Yale is utilizing the Master Delegation of Authority workflow in eReg. Therefore, study team members are asked to sign off on their typically delegated tasks at the contact level when they are first added to the eReg system. Their signed, delegated tasks then populate into the studies for which they are on the Delegation of Authority Log. The Protocol Staff Signoff date on the Delegation of Authority Log is the date they initially signed off on their tasks. The Start Date is when they started performing those tasks on the specific protocol.

5. When using the Master Delegation of Authority workflow, will staff members who are assigned additional delegated tasks by role need to re-sign off on tasks at the protocol level?

Yes. If additional or custom delegated tasks are added to a staff member after they have signed off on the Master delegated tasks or a staff member is assigned an additional role, the staff member will need to re-sign off on their tasks.

6. What is the difference between the Protocol Staff Start/Stop Dates and the Delegation of Authority Start/Stop Dates?

The Protocol Staff Start and Stop Dates reflect when the staff member needs access to the eReg protocol record in order to manage files, view documents, and/or electronically sign protocol documents. The Delegation of Authority Start and Stop Dates reflect when the staff member is trained (and IRB approved, if required) and able to participate in the research study. A Protocol Start Date must be entered when adding an eReg user to a protocol. The Delegation of Authority Start Date will automatically default to be the Protocol Staff Start Date. However, the Delegation of Authority Start Date can and should be corrected to reflect when the staff member is trained and able to work on the protocol (see Adding Start Dates section in the eReg Guidance Document – Delegation of Authority).

7. Why is my Credential Status 'Incomplete' even though my credentials are filed in eReg and cover the time I was delegated on the protocol?

eReg looks for credentials effective starting from your Protocol Staff Start Date listed in the Staff section of the protocol record. If you do not have a Protocol Staff Stop Date, eReg is looking at credentials effective through today. Protocol-required contact credentials must cover the period from Protocol Staff Start Date through present, or through Protocol Staff Stop Date once entered, regardless of start and stop dates on the Delegation of Authority Log.

The credential status displayed in the protocol record will show 'Incomplete' if there is a gap in a credential's valid period. For example, if a User's GCP Training expired on 01-Jan-2022 and they completed training on 01-Feb-2022, there will be a gap from 01-Jan through 31-Jan-2022.



A Note to File (NTF) is uploaded by eReg Support to close a gap in a credential’s validation period.

YSM-GENERAL > Staff > user2 user2

Staff: user2 user2

Summary

Details

Contact user2 user2

Start Date 15 Jan 2022

Stop Date 04 Apr 2022

Credential Status Incomplete

Credentials

Credential Type ↑	Status	Valid Until
Good Clinical Practice Training	Incomplete	01 Feb 2025

[Go to Contact Credentials](#)

Credential Type ↑	Versions	Document Name	Effective Date ↑	Valid Until ↑
Good Clinical Practice Training	1	GCP Training_User2, User2_2022.02.01	01 Feb 2022	01 Feb 2025

Electronic Signatures in eReg

1. How can I use eReg to collect regulatory documents during study activation?

Once a new protocol is imported from OnCore into eReg by eReg Support, the regulatory designee can begin adding staff members and regulatory documents requiring signature during start-up. Documents can be routed for signature to staff members who have active user accounts. See the eReg Guidance Document – Electronic Signatures for further recommendations for when to use electronic signatures on various regulatory documents.

If the site protocol (Investigator Site File) is linked to a multi-site protocol (Trial Master File), the site can “Send a Copy” of each signed document to the coordinating center in eReg. A Review Session can also be set up during study activation to share regulatory documents with the study start-up contact. A document that has been signed in eReg can be downloaded showing the electronic signature.

2. Can I route Financial Disclosure Forms (FDFs) for signature in eReg?

Most FDFs require that the signer check Yes/No boxes to complete the form prior to signing. Since eReg does not currently have a tool to allow checking boxes prior to placing a signature, FDFs must be completed in wet-ink or signed with a 21 CFR Part 11 compliant system outside of eReg that allows completing the Yes/No boxes when signing.

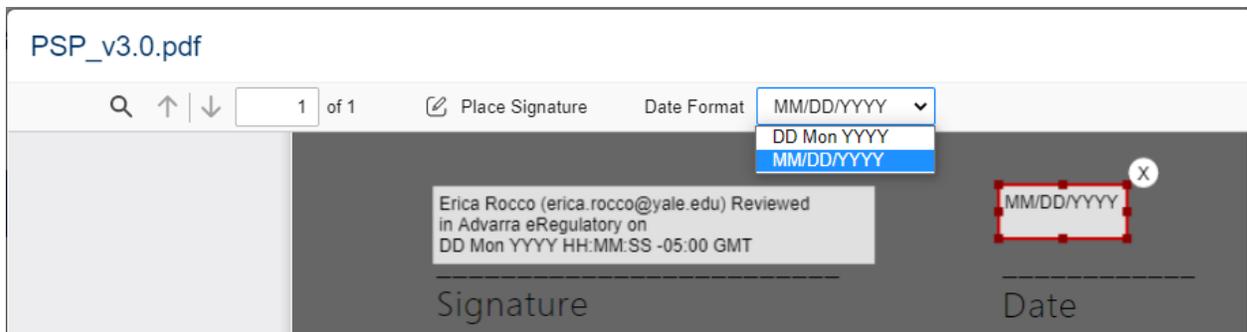
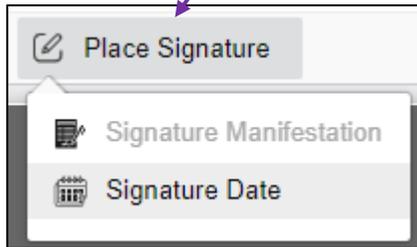
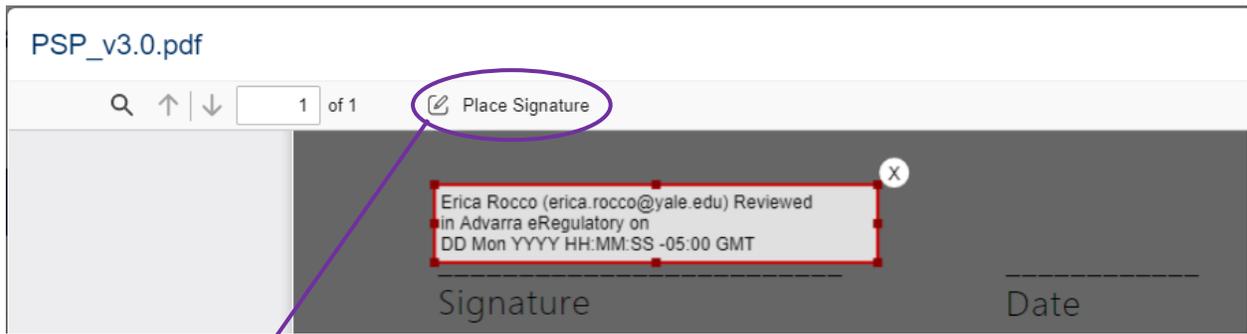
3. When should I use the Default location vs. Custom location for electronic signature placement?

Default Location (appended to the last page of the document) must be used for all documents that will be electronically signed by multiple staff. The Custom Location can be used if the document requires one signature, such as a protocol signature page and Form FDA 1572. Note: if the PDF has



been rotated prior to being saved to your computer, the Custom Location tool may not work as expected. If you must rotate the PDF page(s) prior to uploading, use the Default Location.

All information must be entered in the PDF by the individual preparing the document before being uploaded to eReg and routed for signature. When placing a signature in a custom location, the signature date can be placed in a second location when needed:



4. What date should I use as the Effective Date when routing a document for electronic signature?

When uploading a document for electronic signature, use 01 Jan 1900 as 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.

5. Why can't I see the electronic signature on my document when eReg says it was electronically signed?

Electronic signatures are viewed by selecting the icon next to the "Electronically Signed" status:





Electronic Signature Routing

Electronic Signatures Needed

There are no electronic signatures still needed.

Electronically Signed

[View the signed document](#)

Kacey Richards (klr4) Reviewed on 16 Dec 2021

If you used the Custom Location tool, check that the signature/date appears as expected. Note: if the PDF had been rotated prior to being uploaded, the placed signature may not appear. If the signature/date is not visible on the signed document, you must re-upload the document as a New Version and route for electronic signature using the Default Location. It is recommended to create and upload a Note to File (NTF) to account for the duplicate document and delay in signature.

6. Why can't I route a document or delegated tasks to a protocol team member who is listed in the staff section of my protocol?

In order to route documents and/or tasks to protocol staff members in eReg, the staff member must have an active eReg User Account. All protocol staff members listed in eReg have a contact record; however, not all of those people will have a user account.

Please note, staff members can be added to protocols without having an active user account. You can check their eReg contact record to determine if they have an active user account by searching their name in the contacts search bar and looking to see what is written in the 'Active User Account' column. The person has an active eReg user account only if 'Yes' is listed in the column. If it is blank or 'No', please have the staff member submit an eReg user access request form. Once the contact activates their user account, they will be able to electronically sign documents and delegated tasks in eReg.

	First Name	Last Name	Home Organization	Active Contact	Active User Account
	Kacey	Richards	Yale Center for Clinical Investigation	Yes	Yes

Filing Documents

1. Where do I file credential documents in eReg?

The eReg Support Staff in the Yale Center for Clinical Investigation (YCCI) centrally manage the following contact credential documents in eReg on behalf of study teams:

- Curriculum vitae (CVs)
- Medical licenses (MLs)
- Good Clinical Practice (GCP) training certificates
- Signature samples





eReg Support staff have access to GCP training certificates for Yale University employees and medical licenses. You may receive requests from ereg.credentials@yale.edu for updated credentials that we do not have access to, such as investigator CVs and GCP training for YNHH-affiliated staff.

Please provide credentials to the ereg.credentials@yale.edu inbox if you see that they are missing from eReg or soon to expire.

2. Where do I file organization (IRB and Laboratory) documents in eReg?

The eReg Support Staff in the Yale Center for Clinical Investigation (YCCI) centrally manage the following regulatory tracking items in eReg on behalf of study teams, for the Yale IRB and Yale-affiliated labs:

- IRB Regulatory Items:
 - 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

For external IRBs and non-Yale labs, please provide the above regulatory documents to the ereg.credentials@yale.edu inbox if you see that they are missing from eReg or soon to expire.

3. Why are the Staff Credentials and Organization Regulatory Tracking items not located in my protocol when they are filed at the contact/organization level?

Yale is leveraging the ability to centrally manage staff credentials and organization regulatory tracking items in the staff records and organization records, respectively (not at the protocol-level). Staff and Organizations added to a protocol record are linked their central records where their regulatory documents are filed.

For staff credentials and organization regulatory tracking items to flow into a protocol record, the documents must be selected as requirements in the protocol outline for the specific protocol staff role or IRB/Lab. If you do not see credential documents or organization regulatory tracking items listed in your protocol, but you see them at the contact or organization level, check your protocol outline requirements. YCCI has preselected Protocol Staff Role credential requirements and organization regulatory tracking items as requirements in each of the newer protocol templates, but if you are using an older template (before 2022) or need additional documents to pull in or other Protocol Staff Roles, you will need to make these selections manually.



To Edit Required Protocol Staff Credentials:

eREG Menu Admin Protocols Regulatory Templates Reports SOPs Sign Documents Review Sessions INDS Test Kacey Richards

Protocols > YSM-GENERAL

Select Protocol

☆ Protocol: YSM-GENERAL

Overview

Title YSMGENERAL
NCT Number NCT00000000
Departments

Actions

- Connections
- Lock Protocol
- Protocol Outline
- Settings

Staff Edit

Required Credentials

Protocol Staff Role	Conflict of Interest	Curriculum Vitae	Documentation of Dangerous Goods Training/ International Air Transport Association Training	Good Clinical Practice Training	HIPAA Privacy and Security Training	Human Subjects Protection Training	Medical License	Modified Rankin Scale	NIH Stroke Scale	Signature Sample	SOCRA/ACRP	System Training Document
Abandoned												
Added to OnCore Based on Contract Status, No Initial IRB or OnCore Record Found												
Administrator Only												
Advanced Practice Registered Nurse (APRN)												
Affiliate Coordinator												

Required Credentials

Protocol Staff Role	Conflict of Interest	Curriculum Vitae	Documentation of Dangerous Goods Training/ International Air Transport Association Training	Good Clinical Practice Training	HIPAA Privacy and Security Training	Human Subjects Protection Training	Medical License	Modified Rankin Scale	NIH Stroke Scale	Signature Sample	SOCRA/ACRP	System Training Document
Abandoned	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Added to OnCore Based on Contract Status, No Initial IRB or OnCore Record Found	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Administrator Only	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Advanced Practice Registered Nurse (APRN)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Affiliate Coordinator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Affiliate Principal Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Affiliate Sub-Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
All Research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
All SOC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Approved - Not Fully Executed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Billing Reconciliation Contact	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Budget	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Budget Final	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Business Manager	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CRSL Project Managers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cell Therapy lab	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Charge Matching Research Contact	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clinical Research Assistant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clinical Research Coordinator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clinical Trials Assistant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>





To Edit Organization (IRB/Lab) Regulatory Tracking Items:

Organizations ▾

Edit

Required Regulatory Items

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

Organizations ▾

Required Regulatory Items

IRB

- IRB Compliance Statement
- IRB Federalwide Assurance Number
- IRB Membership List
- IRB Registration
- IRB Roster
- IRB SOP

Laboratory

- CAP
- CLIA
- COLA
- Lab Director CV
- Lab Director Medical License
- Normal Range Values
- Other
- State Certificate

Save Cancel





To view all credential documents for staff listed in your protocol record, select the person’s name and click “Go to Contact Credentials” in the Credentials section:

Protocols > YSM-GENERAL > Staff > Kacey Richards

Select staff

Staff: Kacey Richards

Summary

Details

Contact: Kacey Richards

Start Date: 03 Sep 2021

Stop Date:

Credential Status: Incomplete

Go to Contact Credentials

Credential Type ↑	Status	Valid Until
Curriculum Vitae	Incomplete	
Good Clinical Practice Training	Complete	

To view all regulatory tracking documents for organizations listed in your protocol record, select the organization name and click “Go to Laboratory/IRB Regulatory Tracking” in the Laboratory/IRB Regulatory tracking section:

Protocols > YSM-GENERAL > Organizations > YNHH/Department of Laboratory Medicine

Select organization

Organization: YNHH/Department of Laboratory Medicine

Summary

Details

Organization: YNHH/Department of Laboratory Medicine

Start Date: 12 May 2021

Stop Date:

IRB?: No

Laboratory?: Yes

Documentation Status: Complete

Go to Laboratory Regulatory Tracking

Regulatory Item ↑	Status
CAP	Complete

While you can view all credentials and regulatory tracking items for your Staff and Organizations, only the documents applicable to your protocol based on Staffs’ and Organizations’ Start and Stop Dates will be available in Review Sessions.

4. How do I file IRB and other committee approvals?

Upon receipt of a committee approval letter (IRB, PRC, PPRC, YNHH RSC, etc.), upload the letter to the appropriate protocol section in eReg (see eReg Guidance Document – Regulatory Templates for





available sections). The approval letter serves as the main document for that committee review. Do not stack approval letter on one another.

Add the following associated documents and communications as Related Documents to each approval letter:

- Application and/or submission screenshot
- Submission acknowledgement of receipt
- Notification of outcome letter
- Required modifications letter
- Team notification of approval
- Other relevant correspondence

Screenshot of a sample IRB Initial Approval Letter and Related Documents:

The screenshot displays a document entry in the eREG system. At the top, the document title is "IRB Initial Approval Ltr_2021.06.29.pdf". Below this, there is a "Details" section with an "Edit" button. The details include: File: Sample IRB Initial Approval Ltr_2021.06.29.pdf; Effective Date: 29 Jun 2021; Valid Until: (blank); Comments: (blank); Signature Requirement: None. Below the details is a "Related Documents (4)" section with an "Add Related Document" button. The related documents listed are: "2021.06.30 Team Notification of Approval.pdf" (dated 30 Jun 2021), "2021.06.29 Notification of Approval from IRB" (dated 29 Jun 2021), "IRB Initial Submission_2021.06.28.pdf" (dated 28 Jun 2021), and "2021.06.27 Sponsor Approval of Consents for Submission.pdf" (dated 27 Jun 2021). Each document entry has a link icon and a close icon.

5. Where do I file Yale Human Research Protection Program (HRPP) Authorization to use an External IRB?

Upon receipt of the Yale HRPP Authorization Letter in IRES-IRB, upload the letter to the “Other Committee Approvals & Acknowledgements” section of the Investigator Site File in eReg. The authorization letter serves as the main document.

Add the following associated documents and communications as Related Documents:

- Application and/or submission screenshot
- HRPP Acknowledgement of External IRB Approval letter
- Notification of reliance confirmed





- PI notification of authorization
- Other relevant correspondence

Screenshot of a sample HRPP Authorization Letter and Related Documents:

HRPP Authorization Ltr_2021.12.21.pdf Edit

Details

File HRPP Authorization Ltr_2021.12.21.pdf

Effective Date 21 Dec 2021

Valid Until

Comments

Signature Requirement None

Related Documents (3) Add Related Document

- 2021.12.21 2000031290 reliance confirmed.pdf 🔗 ✕
21 Dec 2021
- 2021.12.21 Team Notification of Authorization.pdf 🔗 ✕
21 Dec 2021
- HRPP Submission_2021.12.08.pdf 🔗 ✕
08 Dec 2021

6. How do I file protocol training?

File the IRB-approved protocol in both the Protocol section and in the Staff Training section. Route the protocol document to the applicable staff for electronic signatures from the Staff Training section only. Select the meaning “Read and Understood.” The electronic signatures serve as documentation of protocol training.

If wet signatures on a paper training log are collected, all training for that protocol version must be collected as wet signatures. Additional signers can be added as training is documented. Individual training attestations and/ or additional logs can be uploaded as related documents.

It is recommended that wet-ink training logs and attestations are not collected, and electronic signatures are used exclusively, if the protocol is managed in the eReg system.

7. Can I upload training videos to the Staff Training section?

Videos that are 25 megabytes or fewer can be uploaded as a document in eReg; however, video files cannot be routed for electronic signature. To document training for a video uploaded in the Staff Training section, select a signature requirement of Wet Signature. Individual training attestations and/ or training logs can be uploaded as related documents. Multiple signers and their training date(s) can be added. The training dates will populate into the Staff Training Tracker.





8. Where do I file Investigational Drug Services (IDS) documents?

The regulatory templates for drug studies include a section titled Investigational Product. There are a number of Requirements within the section that are used to organize IDS documents. IDS documents that require site staff training should also be filed in the Staff Training section of the Investigator Site File and should be routed for electronic signature from that section to document training.

9. What do I use as the Effective Date and Valid Until date?

The effective date is the version date of the document, the signature date, or the date of IRB-approval if approval is required prior to use. The Valid Until date is the day after the document's expiration date, if applicable. See eReg Guidance Document – Regulatory Templates for further guidance and examples.

While some documents may be valid indefinitely (never expire), other documents may be valid only until a new version is received or a new version is IRB-approved for use. For example, a Laboratory Manual is effective as of the document's version date and does not expire. Upon receipt of a new Laboratory Manual, change the Valid Until date for the outdated version to the Effective Date of the new version. The new, current version will not have a valid until date until a subsequent version is available for use.

10. What if the document I am filing does not have an effective date nor expiration date?

A document uploaded to a requirement must have either an Effective Date or Valid Until date entered in the Create Document or Create Document Version window. We recommend using 01 Jan 1900 as an effective date for documents without any version control.

See eReg Guidance Document – Regulatory Templates for further guidance.

Importing Protocols and Staff from OnCore into eReg

1. When are protocols imported from OnCore into eReg?

All protocols requiring International Conference on Harmonization (ICH) Good Clinical Practice (GCP) compliance will automatically be imported from OnCore into eReg by the eReg Support staff for those departments who are using eReg. The import occurs upon completion of the protocol risk assessment in OnCore. See the [eReg Protocol Import/Creation Guide](#) for additional information.

2. Where do I find my protocols in eReg?

In the Protocols menu of eReg, you can search by protocol number (HIC number), protocol title, or NCT number. If the HIC number is not available when the protocol is built in OnCore, a placeholder number will be used in OnCore and will flow into eReg. Once the HIC number is entered into OnCore, it will update in eReg.





You can “favorite” specific protocols by selecting the star icon to the left of the protocol number. Favorited protocols will appear on your eReg landing page when you log in.

3. How do I add study staff from OnCore into eReg?

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 the Staff section of protocols in eReg. Staff members must first be added to the eReg system before they can be added to a protocol.

Refer to the eReg Guidance Document – Regulatory Templates and the eReg Learning Portal for more information on adding staff to protocols.

Regulatory Templates

1. Can I move the order of Sections and Requirements in a protocol record?

Regulatory Templates have been built so that all sections and requirements are in alphabetical order. You can change the section order by clicking the six dots to the left of a section name and dragging it up or down when you are in the protocol outline.

 Protocol >

 Regulatory Documents >

You can change the order of requirements within a section when you are in the “Choose Requirements” menu.

Review Sessions

1. Are eReg reports available to monitors and auditors during Review Sessions?

Auditors and Sponsor Monitors do not have access to reports and the Staff Training Tracker report is not included in Review Sessions. YCCI Reviewers have access to reports.

eReg System

1. Is eReg compliant with 21 CFR Part 11?

Yes, Advarra eRegulatory Management System (Advarra eReg) is a 21 CFR Part 11 compliant system. Please see the [YCCI eReg website](#) for 21 CFR Part 11 Compliance Documents.

2. How are protocols archived in eReg upon IRB Closure?

Once a protocol is permanently closed with the IRB of record, the protocol can be locked in eReg. Yale Regulatory Coordinator, Yale Regulatory Manager, and Yale Administrator roles have permission to lock protocols. Locked protocols remain in eReg indefinitely and can be selected for





review sessions as needed. See the Yale eReg System Assessment document for additional details related to archiving.

3. Can I change my email settings/preferences?

Certain user roles have the ability to manage contact records, including email notification preferences and frequency. Email Settings are under the Details section of a contact record. Contact eReg Support if you do not have access to change the frequency of your Electronic Signature Notifications and/or Expiring Protocol Document Notifications.

eReg System Training

1. How can new staff receive eReg training?

New eReg users must fill out the [eReg User Access Request Form](#). Upon submission of the form, eReg Support will assign the appropriate training.

System training for Advarra eReg is role-based. All users will complete system training via [Advarra University](#). Additional content-specific training will be required for certain user roles and will be conducted on a regular basis by YCCI.

User Access

1. What is the Yale-eReg login page?

<https://yale-ereg-prod.forteresearchapps.com>

It is recommended to bookmark the Yale eReg Production page for easy access.

2. Who do I contact to obtain eReg access for a new internal staff member?

New internal staff members must complete the [eReg User Access Request Form](#). The same form is used for internal and external users.

3. Who do I contact to obtain eReg access for an auditor or monitor?

Request that the external user completes the [eReg User Access Request Form](#). The same form is used for internal and external users.

4. What do we need to provide to obtain eReg access?

To obtain eReg access, a user must have the following items:

All Users: 1) Completed eReg User Access Request form and 2) Completed eReg system training

Internal Yale/YHH Users ONLY: 3) Completed Signature Sample form; 4) Good Clinical Practice (GCP) Training Certificate and 5) CV and/ or ML (if applicable to their role)

Certain Internal eReg User Roles: 6) Completed YCCI content-specific training





See eReg System Training section for additional information about the training requirements.

5. Can we submit the User Access Request form on behalf of a PI, study team member or a study monitor?

No, users (both internal and external) must submit their own user access request, as it includes an attestation. The attestation indicates they have read and understand Yale University's [Information Technology Appropriate Use Policy](#).

Additional Resources

What additional resources are available?

- YCCI eReg website (<https://medicine.yale.edu/ycci/researchservices/systems/ereg/>)
 - eReg Guidance Document – Delegation of Authority
 - eReg Guidance Document – Electronic Signatures
 - eReg Guidance Document – Regulatory Templates
 - eReg Guidance Document – Review Sessions
 - eReg Guidance Document – Sending Copies from Investigator Site File to Trial Master File
 - eReg Guidance Document – Staff Training Protocol Section
 - eReg Protocol Import/Creation Guide
 - Yale eReg System Assessment Document
 - YCCI Training Slides
- Advarra University (<https://advarrauniversity.learnupon.com/store>)
- eReg Learning Portal
- Yale eReg Support Team (ereg.support@yale.edu)
- Yale eReg Credentials Team (ereg.credentials@yale.edu)

