



# eReg Guidance Document IRES IRB → eReg Integration

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## Acronyms

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**eReg:** Advarra's eRegulatory management system

**IRES IRB:** Yale University's electronic submission and review system for human subjects research studies.

**eIRB:** An electronic Institutional Review Board system

## IRB→eReg Integration

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The IRB→eReg integration is a data interface between an eIRB system and eReg that links protocols between the systems. Protocol Linking between the IRB system and eReg allows designated documents to flow into eReg from the IRB system, reducing double data entry. Designated documents of linked protocols will populate in the eReg protocol's Document Inbox, where each document can be reviewed and filed.

## IRB Currently Integrated with eReg at Yale

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- Yale University IRB (IRES IRB)

If your protocol is utilizing the Yale University Institutional Review Board as the IRB of record, you can take advantage of the integration by linking the protocol's eReg binder to its record in the IRES IRB system. If your protocol is being reviewed by an external IRB, documents will not flow into eReg.

Please note that only local site documents and finalized study-related templates will flow into a protocol's Investigator's Site File (ISF or ISF/TMF combo) in eReg. Sponsor-level documents will not flow through these interfaces into a stand-alone Trial Master File (TMF) in eReg.

\*We will be launching a second eIRB integration between Advarra IRB (CIRBI) and eReg in the near future.

## Preparing Your eReg Protocol Binder to Enable the IRB Integration

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The following steps must be completed in eReg to link your protocol's eReg binder to its IRB record and for documents to flow through the interface. If any step is not properly completed, the link will not be created, and the integration will not work.

### IRES IRB → eReg: Protocol Set-Up

- 1) Ensure the IRES IRB Protocol Number is properly listed in the IRB Protocol Number field within the eReg Details section of your protocol.





- a. All of our eReg protocol binders are imported from OnCore. Because of this, the IRB Protocol Number field is populated automatically from what is listed in OnCore. Check to ensure the number listed in this field is correct as this number is the link to the IRES IRB protocol record. To check this field, click on the **Details** section and scroll down to the **IRB Protocol Number** field. If this number is incorrect, please contact [ereg.support@yale.edu](mailto:ereg.support@yale.edu) and we will work to update it.

Protocols > 1506016099 > Details

Select Protocol

☆ Protocol: 1506016099

Actions

Details

Edit

Protocol Number 1506016099

Title

Short Title

NCT Number

Sponsor

Departments

Study Site Yale University - Yale University

**IRB Protocol Number 1506016099**

2) Add Yale Institutional Review Board as an organization.

- a. Click on **Organizations** in the lefthand column.

eREG. Menu Admin Protocols Regulatory Templates Reports SOPs Sign Documents Rev

Protocols > 1506016099

Select Protocol

☆ Protocol: 1506016099

Summary

Details

Protocol Number 1506016099

Title

NCT Number

Departments

Study Site

**IRB Protocol Number 1506016099**





b. Click **Add Organization**

☆ Protocol: 1506016099 Actions ▾

**+ Add Organization**

Organization ↑	IRB?	Laboratory?	Start Date	Stop Date	Documentation Status
No records found.					

c. Select **Yale University Institutional Review Board** from the drop-down menu and enter the appropriate start date for your protocol. Then click **Create**.

### Add Organization ✕

Organization \*  ✕ ▾

Start Date \*  📅

Stop Date  📅

IRB? \*  **Yes**  No

Laboratory? \*  Yes  **No**

▾

- 3) Ensure the **Yale University Institutional Review Board** Document Inbox is listed in the Document Inbox Section.
  - a. Click on **Document Inbox** in the left-hand column and ensure **Yale University Institutional Review Board** is listed as an inbox option.

Protocols > 1506016099

Select Protocol ▾ ☆ Protocol: 1506016099 Actions ▾

Expand All | Collapse All

**Yale University Institutional Review Board (0) >**





## Documents Included in the IRB→eReg Integration

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Approval and determination letters along with documents finalized in the IRES IRB system will flow from IRES IRB into eReg. If finalized documents are watermarked by the IRB, those watermarked copies will be sent through the interface.

Please note that the following files types cannot be accepted by eReg: .bat, .cmd, .com, .exe, .js, .jse, .msc, .ps1, .vbe, .vbs, .wsf, .wsh

Documents contained within the following sections in IRES IRB, will flow to eReg upon IRES IRB finalization/approval:

- Protocol
- Local Site Documents (Consent Forms, Recruitment Materials and Other Attachments)
- Study-Related Documents (Consent Form Templates, Recruitment Material Templates, Other Attachments)
- Drugs
- Devices

## Timing of Document Flow

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Upon finalization in the IRES IRB system, documents will flow to eReg. It may take up to 5 minutes for all documents to populate in the protocol's Document Inbox in eReg. Documents are sent in batches, so they may not all appear at the exact same time.

Documents will flow to eReg when any of the following review types are finalized with a Review Complete Status and the determination/approval letter has been sent:

- Initial Review
- Continuing Review
- Continuing Review with Modification
- Modification
- Reportable New Information (RNI)

## Filing Documents from the Document Inbox

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When documents are sent to a protocol's Document Inbox in eReg, they can be reviewed and filed into the applicable protocol Section/Requirement directly from the Inbox.

1. Select the download icon to open the document and confirm it is accurate.
2. Once confirmed, click the **Review and File** hyperlink to file the document in your eReg protocol binder.





Protocols > 2000036697

Select Protocol

☆ Protocol: 2000036697 Actions ▾

Expand All | Collapse All

Yale University Institutional Review Board (11) ▾

Document Name ↑	Received Date ↓		
Correspondence_for_RNI00003107.pdf	19 Dec 2023	1.	2.
Consent form template 2	14 Dec 2023		
Correspondence_for_2000036697.pdf	14 Dec 2023		
Device Attachment 2	14 Dec 2023		
Drug Attachemnt-2	14 Dec 2023		
Local Recruitment 2	14 Dec 2023		

Complete the fields in the **Review and File** pop-up window and click **File**. The document will now be deleted from the Document Inbox and be filed in the Section and Requirement you selected.

Please refer to the eReg Guidance Document *Investigator Site File Regulatory Templates*, located on the YCCI eReg website, for suggested naming conventions and tips on using Effective and Valid Until dates in eReg.

### Review and File

Section \*

Requirement \*

New Version of Existing Document

Document Name \* Correspondence\_for\_RNI00003107.pdf

Effective Date 19 Dec 2023

Valid Until

## Additional Resources

- eReg Guidance Document *Investigator Site File Regulatory Templates*: <https://medicine.yale.edu/ycci/researchservices/systems/ereg/>
- eReg Learning Portal (must be logged into eReg to access the Learning Portal)
- YCCI eReg website: <https://medicine.yale.edu/ycci/researchservices/systems/ereg/>
- eReg Support: [ereg.support@yale.edu](mailto:ereg.support@yale.edu)

