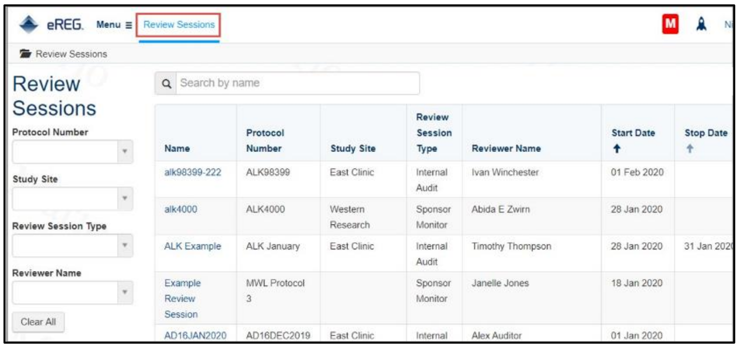
Advarra eReg for External Monitors

This guide is to be used by External Monitors during eReg Review Sessions.

Find the Protocols to Which You're Assigned

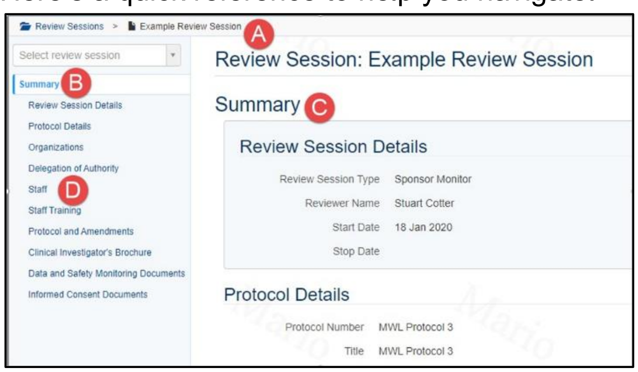
From the **Main Menu**, click the star next to Review Sessions to add it to your Favorites Bar. Then, click **Review Sessions** to open the Review Sessions landing page.



This page displays, in table format, the Review Sessions to which you are assigned. You can see the protocol's name, number, and study site as well as the Review Session type and any start and stop dates for your assigned review. Click the **name** of the Review Session you want to view to open it.

Understand the Review Session Record Layout

Although the information that appears from Review Session to Review Session might be different, all the records have the same layout. Here's a quick reference to help you navigate.



- **A.** The breadcrumb trail at the top of the page shows you which record you are reviewing now. You can click the Review Sessions link there to return to the list of assigned sessions.
- **B.** When you click a section in the left pane (such as Summary here), the details of that section appear on the right (**C**). The Summary section is unique in that it shows information from all the protocol's sections.
- **D**. The sections included in the protocol's Review Session. If you click a section name, the requirement information for that section appears on the right. From there, you can review document and signature status information.

Review the Protocol Information

To review the information, either select the **Summary** section and scroll through the information on the right or click a specific section to review those details. There are some sections where you can click hyperlinks to access further information:

- If the Review Session includes an **Organizations** section, click an organization's name to open a page that shows the regulatory tracking items. Additionally, any relevant regulatory tracking documents appear here for download. If there are multiple versions of a document, each version appears on its own row. Lab credentials (e.g., CAP, CLIA) for the local lab are accessible through the Nebraska Medicine organization.
- If the Review Session includes a **Staff** section, click a staff member's name to open a page that shows more information about that staff member, including their protocol staff roles and staff credentials (e.g., medical licenses, CVs, CITI training). Any relevant credential documents, as well as their signature status, are listed here. If there are multiple versions of a document, each version appears on its own row.

Download or View Documents and Signature Information

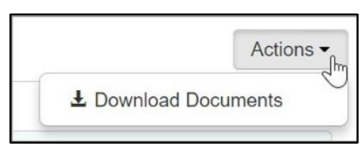
When documents are listed under a requirement, click the download icon next to the document's name to view the document.

The document is either downloaded or opens in another browser tab.

For documents that are electronically signed, the document that opens combines the original document with the signature details. Some signature details may appear on the last page instead of within the document.

Download All Documents

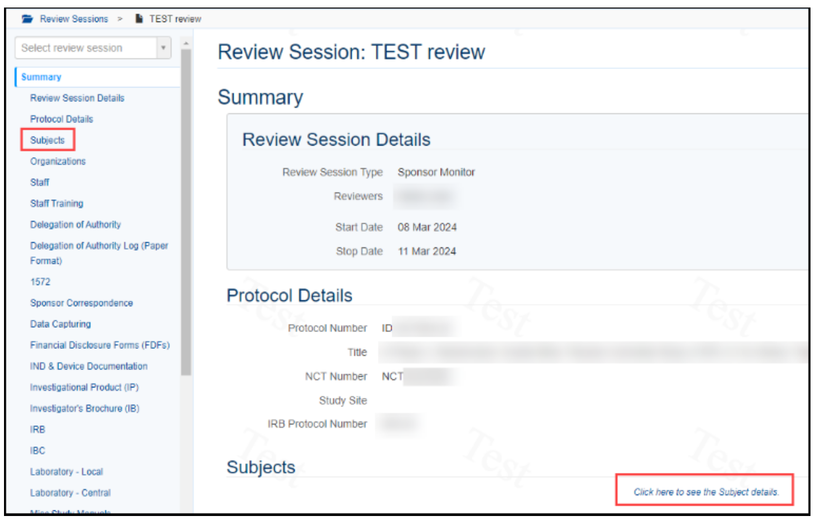
To download all documents currently available in the Review Session, choose the **Download Documents** option from the Actions button menu.



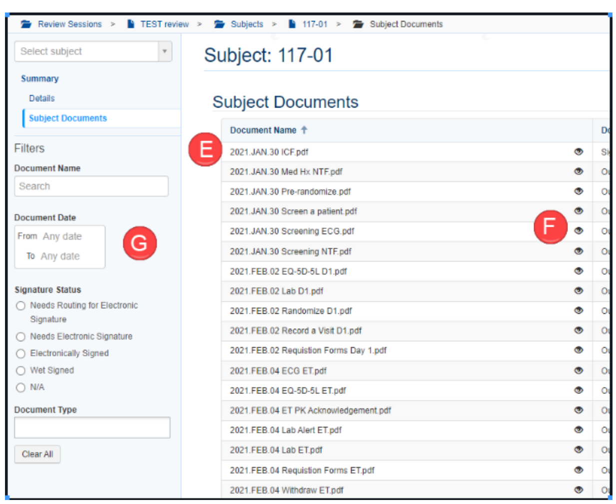
When you choose Download Documents, any documents that are available in the Review Session are downloaded into a zip file. The documents include the signature information. The top-level folder is named after the protocol, and subfolders reflect the names of protocol sections that have documents. If a protocol section doesn't have any documents for you to view, that section isn't represented in the zip file.

Subject Binders

Some studies may include a Subjects section. This is where you can find subject documentation. Click the Subjects section in the left panel or the hyperlink that says Click here to see the Subject details in the Summary section.



Subjects are listed by Subject or Participant ID. Clicking on the **subject's ID hyperlink** will open a section with all the subject's documentation.



E. The suggested naming convention for subject documents is **YYYY.MMM.DD [file type]**.
F. To view documents, click the **eye icon**. You will not be able to download subject documents, but you will be able to view them.
G. Search for specific documents by using **Filters** on the left side.

Tips and Troubleshooting

I'm not seeing the Review Session I'm expecting to see.

When Review Sessions are created, they are given a date range during which they are available. If you don't see a session when you log in, check with the study's coordinator to see whether a date range might need to be adjusted.

What do the icons next to document names mean?

In addition to the download icon (labeled **A** in the screenshot below), you might see:

B. A list icon to show that the document has related documents.

C. A speech bubble to show that the document has comments associated with it.

Why can't I see the subject information I need to review?

If you are unable to find the subject documents in the Subject section, contact the study's coordinator to request that they are added to the review session.

Additional training (elearning) is available upon request. Please advise your study coordinator to contact the CTMS team for further instruction.