HOW TO ACCESS APPROVED STUDY DOCUMENTS FOR MY SITE

ABOUT: *IREx is used to track Single IRB approvals for Relying Sites for the life of a study, including initial approval, continuing reviews, study-wide amendments, and site amendments.*

NOTIFICATION OF APPROVALS

Relying Site HRPP Liaisons and study team contacts receive an email notification anytime an approval is published for their site in IREx. The email identifies the type of approval and the expiration date of the approval.

Dear Liaisons and Study Contacts,

Mellon University Medical Center has shared IRB approval for your institution, Middle-earth College of Agriculture, in IREx for the study below:

Study Title:	Main Impacts of Non-Dairy on FULlness
Type of Review / Approval:	Initial Study: Full Board
Expiration Date:	4/26/2023
Study Link:	https://staging.irbexchange.org/s/project/6629625

Principal Investigators & Study Contacts:

NEW We've made accessing your approval documents more user friendly - use this Quick Guide to see the changes.
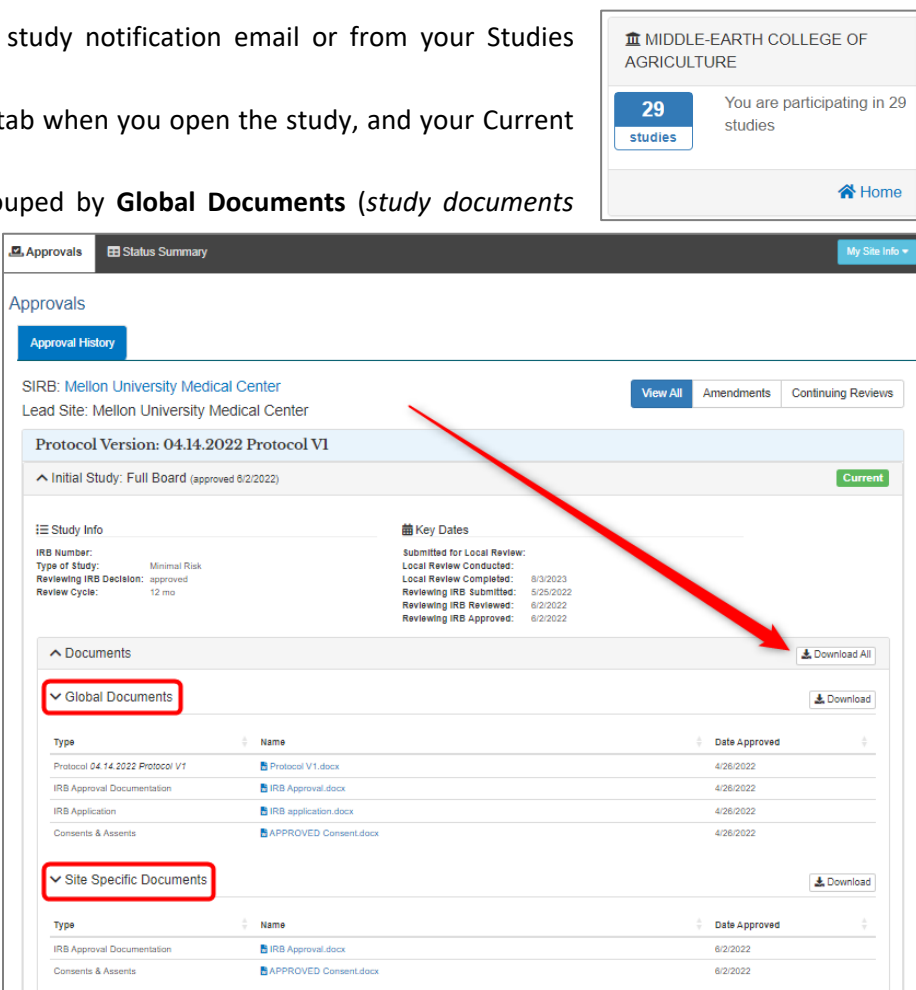
If you have any questions about your approval or future submissions, please contact the Study Manager (Coordinating Center/ Lead Study Team) or Reviewing IRB. If needed, contact information is listed on the study page above the study title in IREx.

Thank you for using IREx,
The IREx Team

ACCESSING INITIAL/CURRENT APPROVAL DOCUMENTS IN IREX

- ☐ Access your study via the link in the study notification email or from your Studies Dashboard when you log in.
- ☐ You will land on the **Approval History** tab when you open the study, and your Current Approval will be listed first.
- ☐ Your approved documents will be grouped by **Global Documents** (*study documents approved for use at all sites*); and **Site-Specific Documents** (*documents approved for use at your site only*).
- ☐ You can expand and sort your documents by **Type**, **Name**, or **Date Approved** to easily locate specific documents.
- ☐ You can use the **Download** buttons to download the group of Global Documents and Site-specific Documents. Use the **Download All** button to download BOTH Global and Site-Specific documents in one.

  Tip: Sort the **Date Approved** to move your newest documents to the top of the list.

🏛 MIDDLE-EARTH COLLEGE OF AGRICULTURE

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NOTIFICATION OF STUDY-WIDE AND SITE AMENDMENTS

When a study-wide amendment or site amendment approval is published to IREx for your site, the approval notification will include a change summary and an amendment #, if entered by the lead study team.

Dear Liaisons and Study Contacts,

Mellon University Medical Center has shared IRB approval for your institution, Middle-earth College of Agriculture, in IREx for the study below:

Study Title:	Main Impacts of Non-Dairy on FULlness
Type of Review / Approval:	Study-Wide Amendment: Full Board
Amendment #	Amend 1, Add Cholesterol Panel
Change Summary	The protocol has been updated to include a cholesterol panel at the baseline visit.
Expiration Date:	4/26/2023
Study Link:	https://staging.irbexchange.org/s/project/6629625

Principal Investigators & Study Contacts:

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If you have any questions about your approval or future submissions, please contact the Study Manager (Coordinating Center/Lead Study Team) or Reviewing IRB. If needed, contact information is listed on the study page above the study title in IREx.

Thank you for using IREx,
The IREx Team

ACCESSING OTHER APPROVALS IN IREX

The **Approval History** tab shows a history of all approvals for each site. The approvals are listed from newest to oldest. For additional help finding the approval you need, IREx allows you to **filter** approvals by their review type. For example, you can filter by Amendments only or Continuing Reviews only.

When viewing Amendments in IREx, IREx displays the **Amendment #** and description (if provided), **change summary**, and **approval date**. Users can hover over the change summary to see the description.