

## 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, Carnegie University, in IREx for the study below:

<b>Study Title:</b>	Diabetes Heart Study MIND
<b>Type of Review / Approval:</b>	Initial Study: Full Board
<b>Expiration Date:</b>	11/7/2021
<b>Study Link:</b>	<a href="https://test.irbexchange.org/feature-branch/public/s/project/3030731">https://test.irbexchange.org/feature-branch/public/s/project/3030731</a>

**Principal Investigators & Study Contacts:**  
 Use this [Quick Guide](#) on how to access approved study documents for your site. 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 login.
- ❑ 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 refresh the page or sort by **Type** to bring the protocol back to the top of the list.
- ❑ 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.

CARNEGIE UNIVERSITY MEDICAL CENTER

35 studies

You are participating in 35 studies

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Approval History | Status Summary

View All | Amendments | Continuing Reviews

Protocol Version: 10.29.2020, v1.0

Initial Study: Full Board (approved 11/23/2020) Current

Study Info | Key Dates

IRB Number: Reviewing IRB Decision: approved  
 Review Cycle: 12 mo

Submitted for Local Review: Local Review Conducted:  
 Local Review Completed: Reviewing IRB Submitted: 11/16/2020  
 Reviewing IRB Reviewed: 11/18/2020  
 Reviewing IRB Approved: 11/23/2020

Documents Download All

Global Documents Download

Type	Name	Date Approved
Protocol 10.29.2020, v1.0	<a href="#">Protocol Document_v1_0_10.29.2020.docx</a>	11/8/2020
IRB Approval Documentation	<a href="#">DHS-MIND_IRB Approval Memo_11.08.2020.docx</a>	11/8/2020
Consents & Assents	<a href="#">ICF_DHS-MIND_10.29.2020.docx</a>	11/8/2020
Consents & Assents	<a href="#">ICF_SPANISH_DHS-MIND_10.29.2020.docx</a>	11/8/2020

Site Specific Documents Download

Type	Name	Date Approved
IRB Approval Documentation	<a href="#">DHS-MIND_IRB Approval Memo_11.08.2020.docx</a>	11/23/2020
Consents & Assents	<a href="#">ICF_CARNEGIE UNIV_11.16.2020.docx</a>	11/23/2020
Consents & Assents	<a href="#">ICF_CARNEGIE UNIV_CHINESE_11.16.2020.docx</a>	11/23/2020
Measures	<a href="#">CES-D_Depression Questionnaire_11.16.2020.docx</a>	11/23/2020
Recruitment & Advertisements	<a href="#">Recruitment Video_Script_11.16.2020.docx</a>	11/23/2020

**Tip:** Sorting by **Date Approved** will move your newest documents to the top of the list.

## 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, Carnegie University, in IREx for the study below:

<b>Study Title:</b>	Diabetes Heart Study MIND
<b>Type of Review / Approval:</b>	Study-Wide Amendment: Full Board
<b>Amendment #</b>	Amend 1, Add Cholesterol Panel
<b>Change Summary</b>	The protocol has been updated to include a cholesterol panel at the baseline visit.
<b>Expiration Date:</b>	11/7/2021
<b>Study Link:</b>	<a href="https://test.irbexchange.org/feature-branch/public/s/project/2993212">https://test.irbexchange.org/feature-branch/public/s/project/2993212</a>

**Principal Investigators & Study Contacts:**  
Use this [Quick Guide](#) on how to access approved study documents for your site. 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 in descending order with the newest on top. 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.

The screenshot shows the 'Approval History' tab with a filter menu containing 'View All', 'Amendments', and 'Continuing Reviews'. The 'Amendments' filter is selected. Below the filter, there are three protocol version sections:

- Protocol Version: 05.02.2021, v3.0**
  - Site Amendment: Full Board #Amend 7, PI Change (approved 7/8/2021) - **Current**
  - Continuing Review: Full Board (approved 10/22/2021) - **Archived**
  - Study-Wide Amendment: Full Board #Amend 5, Add Functional MRI (fMRI) (approved 5/12/2021) - **Archived**
- Protocol Version: 01.15.2021, v2.0**
  - Study-Wide Amendment: Full Board #Amend 1, Add Cholesterol Panel (approved 1/22/2021) - **Archived**
- Protocol Version: 10.29.2020, v1.0**
  - Initial Study: Full Board (approved 11/23/2020) - **Archived**

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.

The screenshot shows the 'Approval History' tab with the 'Amendments' filter selected. A red arrow points to the 'Amendments' filter. The first amendment is highlighted with a red box:

- Site Amendment: Full Board #Amend 7, PI Change (approved 7/8/2021) - **Current**

A tooltip is shown over the 'change summary' link, displaying the text: "The protocol has been updated to include a cholesterol panel at the baseline visit."