

STUDY-WIDE AND SITE-SPECIFIC DOCUMENT TYPES IN IREX

IREx is used to capture and manage single IRB approved documents and other study related materials to Relying Sites for the life of the study, including both study-wide and site-specific approval documents. This overview describes the available document types and customization options.

STUDY-WIDE IRB APPROVED DOCUMENT TYPES

The following document types are available under the Study-wide IRB Approvals tab, which is where the Overall Study or Lead Site's approval is posted. Once uploaded and published, these documents are available for download by all sites on the study.

Review - Vanderbilt University Medical Center

Upload Documents

Drag file into document type or click a document type to upload.

Amendment Application

Consents & Assents

Grant Application

Meeting Notes

Investigators Brochure

Device Manual

Package Insert

Measures

Recruitment & Advertisements

Additional IRB Approved Documents

Others

Uploaded Documents

Type	Document	Date Approved	
Protocol [V2.10OCT2024]	PROTOCOL.docx	10/10/2024	
IRB Approval Documentation	IRB APPROVAL.docx	10/10/2024	Delete
Consents & Assents	IRB CONSENT.docx	9/20/2024	Delete

Click the pencil icon to customize the document type

Continue →

- Protocol (required)
- IRB Application (required)
- IRB Approval Documentation (required)
- Consents & Assents (required if Greater than minimal risk; option to waive if Minimal risk)
- Amendment Application
- Grant Application

- Meeting Notes
- Investigators Brochure
- Device Manual
- Package Insert
- Measures
- Recruitment & Advertisements
- Additional IRB Approved Documents (customizable document name)

Please describe the document type

Cancel OK

- Others (customizable document name)

Tip: To better organize documents for your sites, you can customize documents by relabeling the **Additional IRB Approved Documents** and **Others** document types (e.g., 'MOP').

Review - Vanderbilt University Medical Center

Upload Documents

Drag file into document type or click a document type to upload.

Amendment Application Consents & Assents Grant Application Meeting Notes

Investigators Brochure Device Manual Package Insert Measures

Recruitment & Advertisements Additional IRB Approved Documents Others

Uploaded Documents

Type	Document	Date Approved	
Protocol [V2.10OCT2024]	PROTOCOL.docx	10/10/2024	
IRB Approval Documentation	IRB APPROVAL.docx	10/10/2024	Delete
Consents & Assents	IRB CONSENT.docx	9/20/2024	Delete
Consents & Assents - Spanish ICF	ICF (Spanish).docx	10/10/2024	Delete
MOP	MOP.docx	10/10/2024	Delete
Package Insert	PI Memo.docx	10/10/2024	Delete

Continue →

Tip: Descriptors can be added to the **Consents & Assents** and **Package Insert** document types; the descriptor will be added to the end of the document type (e.g., 'Consents & Assents – Spanish ICF'; 'Package Insert – Sucraid Oral Solution').

Please describe the document type

Consents & Assents - Spanish ICF

Cancel OK

SITE-SPECIFIC IRB APPROVED DOCUMENT TYPES

The following document types are available under approval history. Ensure the correct institution is selected in the “View As” drop down. Unlike the documents on the Study-wide IRB Approvals tab, these files are only available to the site for which they are uploaded.

Onboarding

Approvals

Status Summary

Sites

Contacts

Approvals

Study-wide IRB Approvals

Approval History

View As:
Carnegie University

View All

Amendments

Continuing Reviews

Carnegie University

Protocol Version: 1

Site Closure

Closed

Study Info

Key Dates

IRB Number:

Type of Study: Minimal Risk (f)(1), (f)(2)

Reviewing IRB Decision: Closed

Site Closed 9/20/2024

Closure Reasons

- Site Enrollment complete

Documents

Download All

Site Specific Documents

Download

Type	Name
IRB Approval Documentation	DUMMY IRB APPROVAL.docx

Initial Study: Full Board (approved 9/20/2024)

Archived

Site Specific Documents

Consents & Assents

Consents & Assents -
Consent Form - Adult.docx

10/10/2024

Consents & Assents -
Consent Form - Assent.docx

10/10/2024

Choose a file
or drag it here.

Measures

Choose a file
or drag it here.

Recruitment & Advertisements

Choose a file
or drag it here.

Additional IRB Approved Documents

Procedure.docx

10/10/2024

Choose a file
or drag it here.

Other Documents

Meeting Minutes_Initial Review.docx

10/10/2024

Manual of Procedures -
MOP.docx

10/10/2024

Choose a file
or drag it here.

- **Consents & Assents** (required if greater than minimal risk; option to waive if minimal risk; customizable document name)
- Measures
- Recruitment & Advertisements
- Additional IRB Approved Documents (customizable document name)
- Others (customizable document name)

Tip: Like study-wide documents, you can customize the document name for files that have a pencil beside the file type by adding a descriptor.