

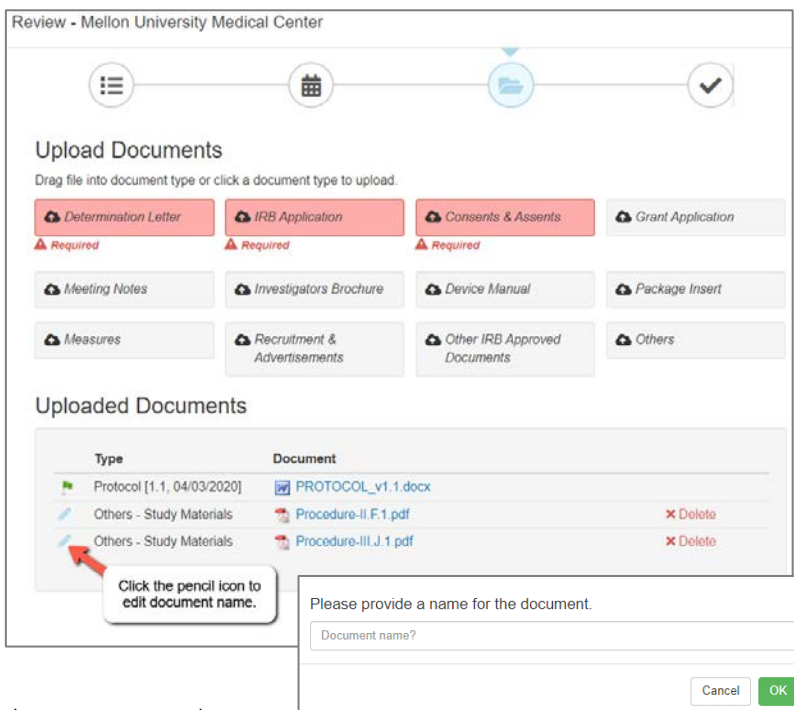
STUDY-WIDE AND SITE-SPECIFIC DOCUMENT TYPES IN IREX

IREx is used to capture and manage single IRB-approved documents and other study-related materials to Participating 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.

- **Protocol** (required)
- **IRB Application** (required)
- **Determination Letter** (required)
- **Consents & Assents** (required if greater than minimal risk; option to waive if minimal risk)
- Grant Application
- Meeting Notes
- Investigators Brochure
- Device Manual
- Package Insert (customizable document name)
- Measures
- Recruitment & Advertisements
- Other IRB Approved Documents (customizable document name)
- Others (customizable document name)



Review - Mellon University Medical Center

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

Determination Letter IRB Application Consents & Assents Grant Application
Required Required Required

Meeting Notes Investigators Brochure Device Manual Package Insert
 Measures Recruitment & Advertisements Other IRB Approved Documents Others

Uploaded Documents

Type	Document	
Protocol [1.1, 04/03/2020]	PROTOCOL_v1.1.docx	
Others - Study Materials	Procedure-II.F.1.pdf	Delete
Others - Study Materials	Procedure-III.J.1.pdf	Delete

Click the pencil icon to edit document name.

Please provide a name for the document.

Document name?

Cancel OK

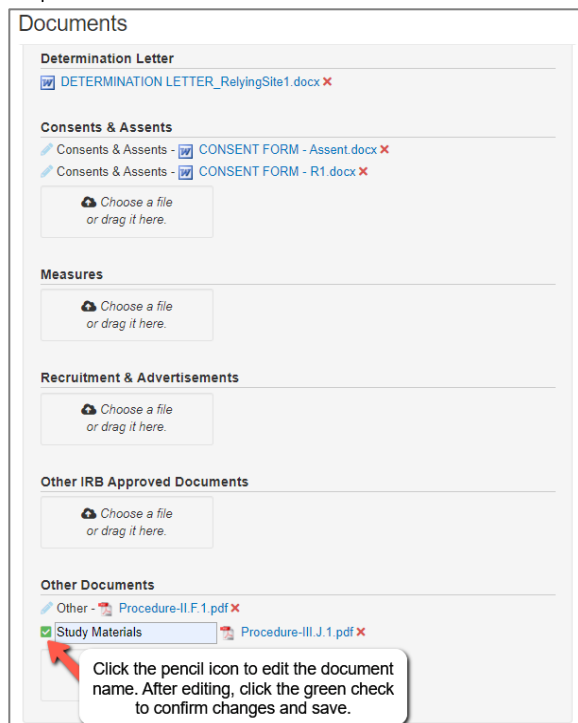
Tip: If you upload multiple files for a document type that requires a name, each file will get the name entered. However, you can edit the name using the pencil beside the file under “Uploaded Documents”.

SITE-SPECIFIC IRB APPROVED DOCUMENT TYPES

The following document types are available under the Site-specific IRB Approvals tab. Unlike the documents on the Study-wide IRB Approvals tab, these files are only available to the site for which they are uploaded.

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

Tip: Similar to study-wide documents, you can customize the document name for files that have a pencil beside the file type.



Documents

Determination Letter
 DETERMINATION LETTER_RelyingSite1.docx ✕

Consents & Assents
 Consents & Assents - CONSENT FORM - Assent.docx ✕
 Consents & Assents - CONSENT FORM - R1.docx ✕

Choose a file or drag it here.

Measures
 Choose a file or drag it here.

Recruitment & Advertisements
 Choose a file or drag it here.

Other IRB Approved Documents
 Choose a file or drag it here.

Other Documents
 Other - Procedure-II.F.1.pdf ✕
 Study Materials Procedure-III.J.1.pdf ✕

Click the pencil icon to edit the document name. After editing, click the green check to confirm changes and save.