![IREx IRB Reliance Exchange — YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW]
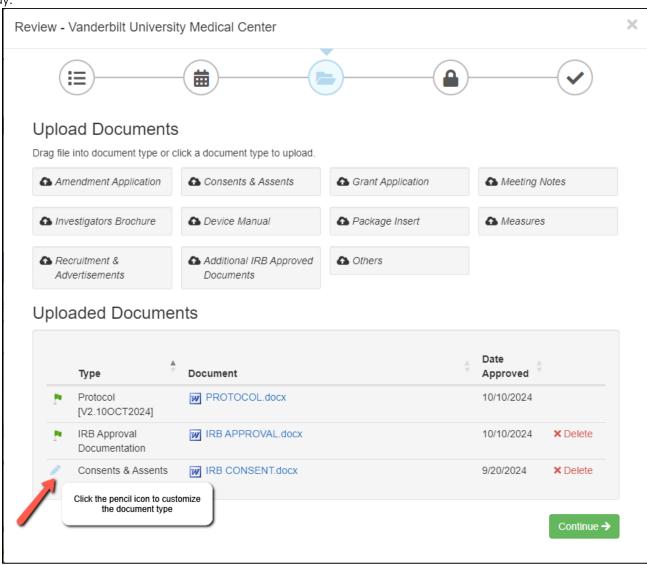
STUDY-WIDE AND SITE-SPECIFIC DOCUMENT TYPES IN IREX

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.
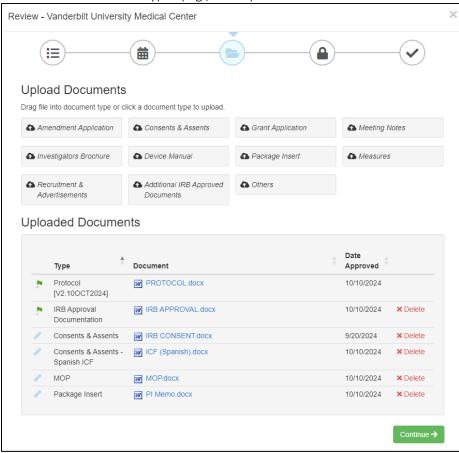

- **Protocol** (required)
- **IRB Application** (required)
- **IRB Approval Documentation** (required)
- **Consents & Assents** (required if Greater than minimal risk; option to waive if Minimal risk)
- Amendment Application
- Grant Application

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

- 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').

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').
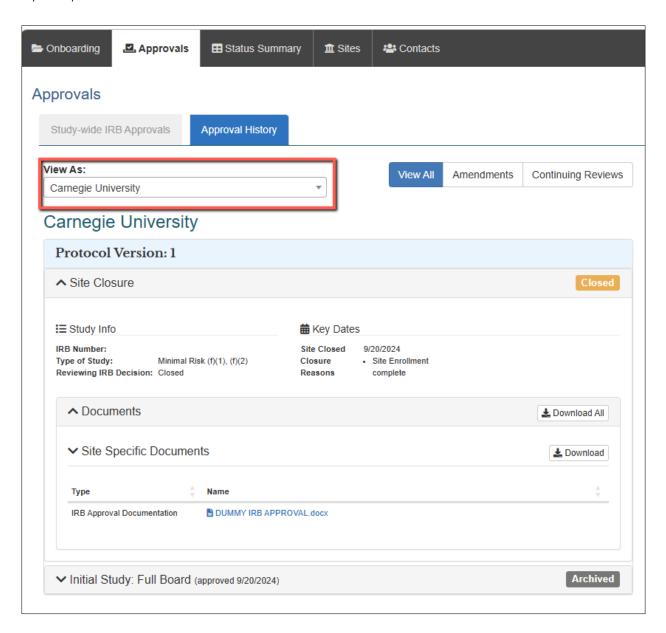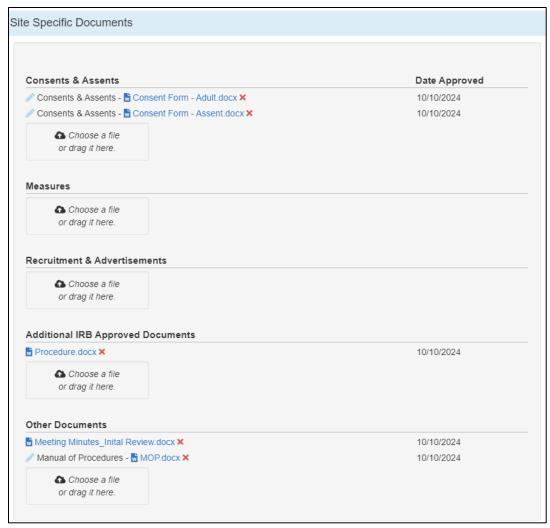
SITE-SPECIFIC IRB APPROVED DOCUMENT TYPES

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.

- **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.