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## Hyperlinks

The Table of Contents “text” has active hyperlinks. Click to jump to any page in this document.

## Return to the Table of Contents button

There is a “return” button at the bottom of every page to help you return to the Table of Contents.
About this Document

This document provides the instructions on:

- The KC IRB document storage system.
- Signed Forms & Approval Letters.
- Printing.
KC IRB functionality includes a document storage system, allowing investigators and HSO staff to access, view, and download study documents from anywhere at any time. Documents which are stored and available via KC IRB include:

- Approved IU-specific IRB forms such as the Exempt Research Checklist, Summary Safeguard Statement, and HIPAA & Recruitment Checklist
- Approved protocol-specific documents such as protocols, data collection instruments, and informed consent documents
- Stamped informed consent documents
- Approved and signed IRB forms including Protocol Summaries, Prompt Reporting Forms, and Noncompliance Forms
- Approval letters
Current study documents and stamped consent forms are housed on the Notes & Attachments tab of KC IRB. Documents on this tab are replaced when they are updated, so this tab always houses the current, IRB-approved documents. Attachments on this tab include:

- Approved IU-specific IRB forms such as the Exempt Research Checklist, Summary Safeguard Statement, and HIPAA & Recruitment Checklist
- Approved protocol-specific documents such as protocols, data collection instruments, and informed consent documents
- Stamped informed consent documents
Current Study Documents & Stamped Consents

KC Protocol > Notes & Attachments Tab > Protocol Attachments

To view/download:

1. Open an approved protocol.
2. Click the Notes & Attachments tab.
3. Click Show next to Protocol Attachments.

Documents are displayed in alphabetical order by the Attachment Type. Each document is listed in a separate gray bar which contains information about the document. Use the drop-downs at the top of the list to filter and sort documents.

To view or download a document, click Show to expand the document details, then click View.

The Notes & Attachments tab is equipped with a selection mechanism, which allows study teams to choose specific documents then download them at all once. Previously, study teams had to download each document individually or download the entire set of documents at once.
Current Study Documents & Stamped Consents

KC Protocol > Notes & Attachments Tab > Protocol Attachments

- Sorting menus - allow user to select criteria for sorting documents
- Attachment Type, selected when the document was uploaded to KC IRB
- Attachment Description, entered when the document was uploaded to KC IRB
- Person who uploaded the document to KC IRB
The Protocol Actions tab includes a section titled Summary under the Summary & History section. This area provides a quick-glance view of all the study information in KC IRB including:

- Protocol number
- Approval and expiration dates
- Personnel
- Attachments: current study documents, which are also found on the Notes & Attachments tab, with an option to click View to open the documents
- Funding Source
- Participant Types
- Organizations, i.e. Performance Sites
- Additional information, i.e. FDA information
Summary & Previously-Approved Study Documents

KC Protocol > Protocol Actions Tab > Summary & History Panel > Summary Sub-panel

The Summary section also allows investigators to view protocol information and documents which were current at the time of previous submissions, providing a historical accounting of the study. The top of each summary includes a Sequence Number, created by actions taken on the protocol.
Summary & Previously-Approved Study Documents

KC Protocol > Protocol Actions Tab > Summary & History > Summary Sub-panel

To view/download:

1. Open an approved protocol.
2. Click the Protocol Actions tab.
3. Click Show next to Summary & History, then click show next to Summary.
4. Scroll down to Attachments to see a list of available attachments.
5. Click View next to the appropriate document.
Signed IRB Forms
Signed Protocol Summaries, Prompt Reporting Forms, and Noncompliance Forms are uploaded by HSO staff members and can be viewed in the Submission Details section of the Summary & History folder.

Click on the Protocol Actions Tab, click “show” on Summary & History, click “show” on Submission Details, and click “show” on Review Attachments.
Signed Forms & Approval Letters

KC Protocol > Protocol Actions Tab > Summary & History Panel > History Sub-panel

Approval Letters

Approval letters are stored in the History section of the Summary & History folder.

To view/download:
1. Open an approved protocol.
2. Click the Protocol Actions tab.
3. Click “Show” next to Summary & History, then click “Show” next to History.
   a. Review the list of actions and find the line marked Approved, Expedited Approval, or Response Approval. Use the dates and notation in the Comments field to confirm that you are viewing the correct action line.
4. Click “Show” next to the Correspondences line below the approval. The Approval Letter line will display.
5. Click “View” in the Actions column.
The Print function in KC IRB allows you to create and print a summary of your study, any of the current study documents (also found on the Notes & Attachments tab), or the information found on the Questionnaire tab, at any time.

To print the Protocol Summary:

1. Open an approved protocol.
2. Click the Protocol Actions tab.
3. Click Show on the Print folder.
4. Click Show next to Protocol Details.
5. All boxes will auto-populate with checks inside.
   a. To uncheck any box(es) you don’t want to include for printing, click inside the box(es) to remove the checkmark.
   b. To print only a few sections, click on select none, then check the desired section(s) for printing.
6. Click Print Selected. A PDF of the information will generate.
   a. Click Open to view the document.
Protocol Summaries

KC Protocol > Protocol Actions Tab > Print Panel > Attachments

To print Attachments:

1. Open an approved protocol.
2. Click the Protocol Actions tab.
3. Click Show on the Print folder.
4. Click Show next to Attachments; the list of currently approved attachments will display.
5. Click View next to the document.
To print Questionnaires:

1. Open an approved protocol.
2. Click the Protocol Actions tab.
3. Click Show on the Print folder.
4. Click Show next to Questionnaires.
5. All boxes will auto-populate with checks inside.
   a. To uncheck any box(es) you don’t want to include for printing, click inside the box(es) to remove the checkmark.
   b. To print only a few QU, click on select none, then check the desired QU for printing.
6. Click Print Selected. A PDF of the information will generate.
   a. Click Open to view the document.