Instructions for Unnecessary Stamp and Duplicate Document Removal

Starting June 1st, 2024, the IRB will now **only stamp documents that feature subject signatures** (ICFs, minor assent forms, HIPAA authorization forms). Because of this change, previously stamped documents from other categories will need to have their stamps removed as the stamp includes an expiration date that will no longer be valid. Starting July 1st, 2024, **all ACTIVE locally reviewed studies [studies open to enrollment and accruing subjects) will need to be updated** before the next continuing review can be filed. **Previously stamped versions must be removed** to reduce the risk of confusion or non-compliance at the time of CR, as the IRB will NOT stamp previously stamped documents that do not require stamps. **Please see the presentation given at the 5/23/2024 Facts and Snacks session for screenshots and more details.**

NOTE: All documents previously submitted to the IRB are preserved in the eIRB system after being deleted.

Step 1:
- From the main study page click the "Documents" tab
- Make a note of all documents that have duplicates (in any section), including when a clean and tracked changes version are present or when previous versions are present alongside the most current version.
  - When filing the modification, the duplicates will need to be deleted.
  - Duplicates may be in different sections (Study Related vs Site Related Documents)
- Make a note of all documents that have a copy present in the "Final" column of the Document tab and then download a copy from the **"Draft"** column (**excluding the generated snapshot, do not edit or remove this document) (do not download documents to unsecured devices, place them on a secure MHS device or network drive and delete them once reuploaded to the MHS IRB portal)**
  - **Do not download the copy from the final column, this copy features a stamp and may not have the correct formatting.**

Step 2:

- File a modification by clicking "Create Modification/CR" on the page for the study and specifying that the submission is a modification/update.
  - **Note:** This cannot be filed as part of a Modification/CR or as part of another modification
- Complete the "Modification Summary" and "Modification Details" section.
  - Under "Modification Summary" complete question 1 as appropriate, leave question 2 blank, and put "**Administrative modification to remove duplicate documents and remove unnecessary document stamps**" in the text box for question 3.
  - You will **not** need to complete the Modification Request Form

Step 3:

- You will need to find the corresponding documents in the active modification to the documents that you noted in the "Documents" tab and delete all but one clean copy of the current version.
- **With the exception of ICFs and assent forms,** all stamped documents will need to be **deleted** and reuploaded from their section in the active modification to create a version that is not stamped.
  - Do not "stack"/update these documents, delete and reupload them.
  - Be sure to upload each document to the same section and with the same title as was previously present.

Step 4:

- Remember to click "Save" once the appropriate documents have been deleted and reuploaded to save your work.
- Once all changes have been made and the PI has confirmed that all the documents are IRB-approved versions, the PI or PI Proxy will need to click "Submit" on the left-hand side of the main page to move the submission from pre-submission to pre-review.
  - This sends the modification to the IRB staff for processing.
- The assigned IRB specialist will reach out with any questions or requests as necessary before processing the changes.

May 23, 2024