GUIDANCE: Approving and Stamping IRB Documents in RUTH

This document provides guidance on which documents will be finalized, and which documents will receive an Institutional Review Board (IRB) approval stamp.

As part of the review process, the Program for the Protection of Human Subjects (PPHS) reviews all study-related documentation included in the submission in RUTH. Upon approval of the project, certain study-related documents will be finalized. Some of the documents that are finalized will also receive the IRB approval stamp.

Finalized documents: Study documents that are reviewed and approved by the PPHS will be finalized upon approval of the project. When a document is finalized, it is listed in the approval letter under 'Documents Reviewed'.

Stamped documents: Any materials given to participants directly, mailed to a participant, seen by a participant (e.g. flyer, MyChart recruitment messages) or discussed with a participant over the phone prior to consent will be stamped. In general, all recruitment materials, consent forms, assent forms, research information sheets, or HIPAA authorization forms will receive an IRB approval stamp.

Please note, documents seen by or given to participants after they were consented to participate in the study will not be stamped. This includes but is not limited to participant diaries, medication/study wallet cards, etc.

Where can I find my stamped documents in RUTH?
Once a document is stamped in RUTH, the document will be converted to a PDF document and will be listed under the Final column under the Documents tab on the parent study.

Please refer below for a full list of the categories of documents that will get finalized and/or stamped.

Finalized and stamped	Finalized, not stamped	Not finalized and not stamped
• IRB Protocol/Protocol • Protocol • Consent Form* • Recruitment Materials** • HRP-503 application*** • Research Information Sheet/Standalone HIPAA***	• DSMB charter • Data safety monitoring plan • Device Attachment • Drug Attachment • HIPAA Request forms (Decedent, De-identified, Limited Data, HIPAA Waiver or Alteration of Authorization)	• Ancillary Review Form • HIPAA Wizard • Other IRB Correspondence • Other (e.g. worksheets and checklists)

	• Non-validated questionnaires/evaluation instruments • Validated questionnaires/evaluation instrument • Study participant-facing, non-recruitment • Certificate of Confidentiality • FCOI documentation • FDA documentation • PRMC Documentation • Reliance-External IRB document • sIRB – Local context survey • sIRB – SMART IRB checklist • sIRB – Supporting document	

* All consent forms uploaded in section 1 (Consent Forms), Local Site Documents section of the RUTH SmartForm will be stamped.

**All recruitment documents uploaded in section 2 (Recruitment Materials), Local Site Documents section of the RUTH SmartForm will be stamped.

***When adding a document under section 3 (Other Attachments), Local Site Documents, the study team must select the right document category. It's important that all documents are correctly labelled when uploading them to the RUTH SmartForm. If a document has the wrong label, it may not get the IRB stamp when it's needed.

Note: this guidance does not affect the R2R project process.