Where to attach documents in Hutch IRB

In Hutch IRB, submission documents are attached to a study's SmartForm pages. This guide is intended to support study teams in uploading documents to the correct locations.

But first, why is location of documents important?

- Longevity: The documents will live on the study record for the life of the study.
- Consistency: For efficient IRB reviews, documents need to appear in their consistent and appropriate locations.
- Structure: In certain cases, and in particular for outside participating site submissions, the system itself requires a specific structure. For example, study-wide documents are visible on a participating site workspace, and the site continuing reviews are now structured as part of the lead file continuing reviews (one study-wide CR submission).

TYPE OF STUDY

The type of study affects what SmartForm pages are populated in Hutch IRB.

For multi-site studies: A Sponsor provides study-wide materials and Fred Hutch IRB is only reviewing for the Cancer Consortium sites, and/or FH IRB is reviewing for outside Participating Sites. Hutch IRB will display:

> **"Study Related Documents" page:** Documents uploaded in this section should be **study-wide documents** applicable to all sites (such as the protocol) **or templates.**
>
> Note, any document attached to the Study Related Documents section will be visible on the workspace for each separate participating site that is added to the multi-site study, so it is important to only attach documents here that are intended for other sites to use.
>
> **"Local Site Documents" page:** Documents uploaded in this section should be **site-specific documents** applicable to just the lead file, such as the Fred Hutch Consent Form.

For single-site studies: A single-site study is one that involves only a SINGLE Cancer Consortium institution.

> **"Local Site Documents" page:** In this section you will upload both **study-wide documents and site-specific documents** because the Study Related Documents page is not available.

FILE NAMES

Please also carefully consider your file names. When you upload each document, make sure the name of the file will be clearly understandable not just to the study team but also to IRO staff and IRB members. Also, the file name is what will be populated in the result letter.

As a general rule, we encourage you to include the following information in your file name: *Study Identifier_ document description_version_date.*

Following are a few examples:

- FHIRB00012345_Protocol_version 1_01012023
- FHIRB00012345_Protocol_version 1_01012023_tracked changes
- RG12345678_Consent Script_version 3_08252023
- Facebook Banner Ad 1_version 7_05222023
- Acetaminophen_Package Insert_Rev. 09-2023
- ND-1X5_Investigators Brochure_Amendment 4_October 5 2023

SPECIFIC DOCUMENT TYPES

The table below provides guidance on where to put specific document types.

Document	Hutch IRB SmartForm Page	Location on the Page
Application form	Study Related Documents*	Under “Other attachments”
Assent Form to be used locally	Local Site Documents	Under “Consent Forms”
Assent Form Template (for the study as a whole)	Study Related Documents*	Under “Consent Forms”
Children Supplement	Study Related Documents* EXCEPTION: If our IRB will also review outside participating sites, and this supplement’s content will **not** apply to all sites, then attach this instead on the Local Site Documents page	Under “Other attachments”
Consent Form to be used locally	Local Site Documents	Under “Consent Forms”
Consent Form Template (for the study as a whole)	Study Related Documents*	Under “Consent Forms”
Consent Supplement	Study Related Documents*	Under “Other attachments”
Closure – Participating Site	Navigate to the site workspace for the individual site and click the “Add Comment” activity. In the pop-up, answer the questions and attach the closure form. (Also select IRB Coordinator to ensure our staff receives a notice of this submission.)	Under “Supporting documents”
Continuing Review Supplement	Continuing Review / Study Closure Information page	Under “Attach supporting documents”
Continuing Review Supplement – Participating Site	Navigate to the site workspace for the individual site and click the “Report Continuing Review Data” activity. In the pop-up, answer the questions and attach the form.	Under “Supporting documents”
Department of Defense Supplement	Study Related Documents*	Under “Other attachments”
Device Supplement	Devices page	Under “Attach files”
Device Manual or instructions	Devices page	For each individual device listed, attach this under “Attachment name”
Drug Supplement	Drugs page	Under “Attach files”
DSMB/DSMC reports and minutes submitted at continuing review	Continuing Review / Study Closure Information page	Under “Attach supporting documents”

Document	Hutch IRB SmartForm Page	Location on the Page
DSMB/DSMC reports and minutes submitted via MOD (for example, if changing parameters of the study)	Study Related Documents*	Under “Other attachments”
Exempt Form	Study Related Documents*	Under “Other attachments”
Expedited Review form	Study Related Documents*	Under “Other attachments”
Foundational Consent Forms that are not used to consent individuals on this study (submitted for example to support a Genomic Data Sharing request)	Study Related Documents*	Under “Other attachments” NOTE: Please combine all foundational consents into one single PDF document and name it “Foundational Consents”
FDA approval of IDE (device) application	Devices page	Under “Attach files”
FDA confirmation of IND number or IND exempt status	Drugs page	Under “Attach files”
Funding Source Documents (grants, industry contracts, etc.)	Study Funding Sources page	Under “Attachments”
Genomic Data Sharing Supplement (and related attachments)	Study Related Documents*	Under “Other attachments”
HIPAA authorization form for the local site	Local Site Documents	Under “Other attachments”
HIPAA authorization template (if it will be used for outside participating sites as a template)	Study Related Documents*	Under “Other attachments”
HIPAA Supplement	Study Related Documents* EXCEPTION: If our IRB will also review outside participating sites, and this supplement’s content will **not** apply to all sites, then attach this instead on the Local Site Documents page	Under “Other attachments”
Information Security Office Reports	Local Site Documents	Under “Other attachments”
Institutional Biosafety Committee (IBC) approval	Local Site Documents	Under “Other attachments”
Investigator’s Brochure or drug package inserts NOTE: If a revised IB is being submitted with a modification, you must also attach the sponsor cover letter or cover email.	Drugs page	For each individual drug, click +Add; then fill out the slide-in and attach the drug documentation under the question “Attach files related to this drug”
Modification Supplement	Modification Summary page (visible only once a MOD or MODCR submission is created)	Under question “Attach ONLY the Modification Supplement”

Document	Hutch IRB SmartForm Page	Location on the Page
Multi-Center Supplement	Study Related Documents*	Under “Other attachments”
Not Human Research Determination form	Basic Study Information page	Under question “Attach the protocol”
Prisoner Certification Checklist	Study Related Documents*	Under “Other attachments”
Protocol NOTE: If being revised and only a PDF format is available, include a tracked version also	Basic Study Information page	Under question “Attach the protocol”
Protocol Clarification Letters	Basic Study Information page	Under question “Attach the protocol” NOTE: These should be removed from the study record once the sponsor has updated the protocol to address the clarification and the letter is no longer needed.
Radiation Safety approval	Local Site Documents	Under “Other attachments”
Recruitment Materials (ads, flyers, scripts, questionnaires, surveys, etc.) for the local site	Local Site Documents	Under “Recruitment materials”
Recruitment Material Templates (ads, flyers, scripts, questionnaires, surveys, etc.) for this study as a whole	Study Related Documents*	Under “Recruitment materials”
Reportable New Information (RNI) Supplement	Reportable Information page	Under “Attach files”
Repository Supplement (and confidentiality pledge)	Study Related Documents*	Under “Other attachments”
Review Authorization from University of Washington Zipline or Seattle Children’s Click system	Local Site Documents	Under “Consent Forms”
Scientific Review Committee (SRC) approval documentation	Study Related Documents*	Under “Other attachments”

*For a single-site study, upload the document to the Local Site Documents page instead.