

Click IRB Reference Guide

Attaching New and Revised Documents



This Guide will help me to know

- Where to attach documents in the SmartForm for Single Site Studies
- How to add a new document to the SmartForm
- How to update a current document with a revised version

Where do I attach documents in the Click IRB SmartForm (Single Site Studies*)?

SmartForm Page		Documents
Basic Information Section 7		<ul style="list-style-type: none"> • Investigator protocol** and Protocol Clarification Memos (if applicable) • Sponsor protocol with Site Supplement** • DHHS (Department of Health and Human Services) protocol
Funding Sources		<ul style="list-style-type: none"> • Grant application (if SCRI is prime recipient of award)
Drugs	Section 1	<ul style="list-style-type: none"> • Package insert and/or Investigator Brochure (IB)
	Section 3	<ul style="list-style-type: none"> • Communication from the FDA or sponsor with the IND number if the IND number is not in the protocol
Device	Section 1	<ul style="list-style-type: none"> • Product labeling/device instructions
	Section 3	<ul style="list-style-type: none"> • Communication from the FDA or sponsor with the IDE / HDE number if the IDE/HDE number is not in the protocol
Local Site Documents	Section 1 Consent Forms	<ul style="list-style-type: none"> • Consent, Parental Permission, and Assent forms** • For a waiver of documentation of consent, the Information Sheet** provided to the subjects
	Section 2 Recruitment Materials	<ul style="list-style-type: none"> • Advertisements, including printed, audio, and video • Recruitment materials** and scripts**
	Section 3 Other Attachments	<ul style="list-style-type: none"> • HIPAA forms (Legacy Studies) • Sample consent forms from the sponsor that do not need to be stamped • Financial Interest Management Plan/Summary/Information • Survey Instruments, Questionnaires, Interview Scripts • Data Collection Forms • DSMB Charters • List of References or Copies of Manuscripts • Completed checklist of meeting Department of Energy requirements (if applicable)
Continuing Review / Study Closure Section 4		<ul style="list-style-type: none"> • Research progress report • Sponsor progress/annual report (if available)

*For information about External IRB studies and Multi-Site Study Attachments, please see guides for External IRB Studies and Multi-Site IRB Studies.

**Templates are generally found in the Click IRB Library, but translated forms and template recruitment materials may be found on the IRB website

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Attaching New and Revised Documents

How do I attach a new document?

1	Create the document. Save the document to your local files.						
2	Go to the SmartForm in Click IRB and navigate to the relevant page where you need to attach a document (e.g., Local Site Documents).						
3	<p>Click Add.</p>  <p>Local Site Documents</p> <p>1. Consent forms: (include consent, parental permission, and assent forms, if applicable; templates available in the Library) ?</p> <p>+ Add</p> <table border="1"> <thead> <tr> <th>Document</th> <th>Category</th> <th>Date Modified</th> </tr> </thead> <tbody> <tr> <td>Consent Form(0.01)</td> <td>Consent Form</td> <td>7/31/2018</td> </tr> </tbody> </table> <p>Update</p>	Document	Category	Date Modified	Consent Form(0.01)	Consent Form	7/31/2018
Document	Category	Date Modified					
Consent Form(0.01)	Consent Form	7/31/2018					
4	<p>Click Browse, choose the file you wish to add, fill out the name and version number as needed, and click OK (or OK to ADD Another if you wish to add an additional document).</p>  <p>Add Attachment</p> <p>1. * File to attach: <input type="text"/> Choose File</p> <p>2. Name: (if not supplied, the file name will be shown) <input type="text"/></p> <p>3. Version number: <input type="text"/></p> <p>* Required</p> <p>Choose Selection OK OK and Add Another Cancel</p>						
5	<p>Click Save and then Exit.</p>  <p>1 Save 2 Exit Hide/Show Errors Print Jump To</p>						

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Attaching New and Revised Documents

How do I update an existing document with a new version?

- Navigate to the 'Documents' tab or the folder where the document is saved (if you choose the latter, be sure you are updating the correct version) and select the Word version of the document to be revised. On the documents tab, this will appear under the "Draft column".
- If the document has tracked changes (from previous revision), accept all changes to create a clean, Word version of the document.
- Make the new revisions to the document using the tracked-changes function in Word. Update the version date in the header of the document, if applicable.
- Save the tracked-changes version to your local files.

Note: In Click IRB current IRB-approved versions of documents can be found on the relevant page of the study SmartForm or by visiting the **Documents** tab in the parent study record. See "Where can I find current and previous versions of my documents in Click IRB?" later in this guide.

SmartForm View (shows documents on specific SmartForm page):

1

Local Site Documents

1. **Consent forms:** (include consent, parental permission, and assent forms, if applicable; templates available in the [Library](#)) ?

+ Add

Document	Category	Date Modified
Update Consent Form(0.01)	Consent Form	7/31/2018

Word Version in the SmartForm

Documents Tab (shows all documents):

History	Funding	Project Contacts	Documents	Follow-on Submissions	Reviews	Snapshots
Word Versions				PDF Versions (Consents will have IRB stamp)		
Study Related Documents						
Draft		Category		Final		Last Finalized
Revised protocol 7.26 Grant Application		IRB Protocol Sponsor Attachment		Revised protocol 7.26 Grant Application		7/26/2018 3:40 PM 7/16/2018 2:58 PM
Site Related Documents						
Draft		Category		Final		Last Finalized
Flyer.docx Consent Form		Recruitment Materials Consent Form		Flyer.pdf Consent Form		7/16/2018 2:58 PM 7/17/2018 4:02 PM
						Document History
						History History

Word Versions

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Attaching New and Revised Documents

2

Navigate to the SmartForm in Click IRB and navigate to the relevant SmartForm page (e.g., if you are changing a consent form or a recruitment material, you would go to the Local Site Documents SmartForm).

3

Click the **Update** button next to the document to replace with updated Tracked version, or click **Add** if it is a new document.

Note:

- Always select **Update** to replace an existing document with an updated version. Do **not** delete documents in the Click system except when they are no longer going to be used for the study.
- **You should only include a tracked version of the document.** No clean versions are necessary for MS Word documents. If the file is a PDF, then attach both tracked and clean versions.

Local Site Documents

1. **Consent forms:** (include consent, parental permission, and assent forms, if applicable; templates available in the [Library](#)) ?



Click here if you want to add a NEW document



Click here if you want to revise an EXISTING document

Document

Category

Date Modified

Consent Form(0.01)

7/31/2018

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Attaching New and Revised Documents

Click **Browse**, choose the file to add, update the name and version number as needed, and click **OK**. Do **NOT** click **OK and Add Another** when updating a document.

4

Add Attachment

1. * **File to attach:** Choose File

2. **Name:** (if not supplied, the file name will be shown) If you want a specific document name to appear in the study SmartForm and approval letters that is different than the file name, include it here

3. **Version number:** If you want a different versioning system than automatically assigned by the system

* Required

5

Click **Save** and then **Exit**.

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Attaching New and Revised Documents

Where can I find current versions of my documents in Click IRB?

SmartForm

The most recent version of a document appears in the study SmartForm. Navigate by clicking “View Study” or “Printer Version” on the parent study record and select the page with the documents you wish to see.

Study SmartForm View:

1

Local Site Documents

1. **Consent forms:** (include consent, parental permission, and assent forms, if applicable; templates available in the [Library](#)) ?

+ Add

Document	Category	Date Modified
Consent Form(0.01)	Consent Form	7/31/2018

Update

Word Version in the SmartForm

Documents Tab

The documents tab on the main study workspace will have the tracked versions from the SmartForms and the clean, finalized PDF versions of your documents. Find your stamped consent forms in the “Final” column.

2

History Funding Project Contacts **Documents** Follow-on Submissions Reviews Snapshots

Word Versions

PDF Versions (Consents will have IRB stamp)

Study Related Documents

Draft	Category	Final	Last Finalized	Document History
Revised protocol 7.26 Grant Application	IRB Protocol Sponsor Attachment	Revised protocol 7.26 Grant Application	7/26/2018 3:40 PM 7/16/2018 2:58 PM	History History

Site Related Documents

Draft	Category	Final	Last Finalized	Document History
Flyer.docx Consent Form	Recruitment Materials Consent Form	Flyer.pdf Consent Form	7/16/2018 2:58 PM 7/17/2018 4:02 PM	History History

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Attaching New and Revised Documents

Where can I find previous versions of my documents in Click IRB?

Document History

To see previous version(s) of a document, visit the Study SmartForm or the Documents tab and click the **History** link. Clicking the history link allows you to access all previous version(s) of the document.

Local Site Documents

1. **Consent forms:** (include consent, parental permission, and assent forms, if applicable; templates available in the [Library](#))

Document	Category	Date Modified	Document History
Consent Form(0.01)	Consent Form	7/31/2018	History

History	Funding	Project Contacts	Documents	Follow-on Submissions	Reviews	Snapshots
Study Related Documents						
Draft	Category	Final	Last Finalized	Document History		
Revised protocol 7.26 Grant Application	IRB Protocol Sponsor Attachment	Revised protocol 7.26 Grant Application	7/26/2018 3:40 PM 7/16/2018 2:58 PM	History History		
Site Related Documents						
Draft	Category	Final	Last Finalized	Document History		
Flyer.docx Consent Form	Recruitment Materials Consent Form	Flyer.pdf Consent Form	7/16/2018 2:58 PM 7/17/2018 4:02 PM	History History		

Document History Details

Clicking the History link will display previous versions and dates and times of upload:

Resource History for Revised protocol 7.26

Title: Revised protocol 7.26
File: 2018.03.26 HRP-503 Protocol - HIPAA Section DRAFT_TCP.docx
Owner: PI NI
Author:
Content Type: Document
Version: 0.03
Description:

History:

Date	Version	Person	Action	Notes	Uploaded File
7/26/2018 3:37 PM	0.03	PI NI	File Uploaded & Edited		2018.03.26 HRP-503 Protocol - HIPAA Section DRAFT_TCP.docx
7/18/2018 2:58 PM	0.02	PI NI	File Uploaded & Edited		HRP-503 - TEMPLATE PROTOCOL 8.17.15.docx
7/16/2018 2:03 PM	0.01	PI NI	Created		HRP-503 - TEMPLATE PROTOCOL 8.17.15.docx

More questions? Contact the [Institutional Review Board](#) by email or at x77804.