

How should I name my study documents?

The IRB has changed how consent forms and other study-related documents are created, managed and stored in the IRB Information System (IRBIS). As part of this change, the IRB is no longer stamping approved documents. We recognize that this ends a convention that has been in place for many years. However, there is no regulatory requirement that documents be stamped. This was a self-imposed policy and while it was well-suited to the paper world, it is less compatible with the electronic environment in which we now operate. More importantly, the ability to identify and track approved documents is being maintained. Along with your approval letter, you may now generate a **Document List**, listing all documents associated with your study at time of approval. Study sponsors are used to seeing supporting documents listed with IRB approvals, and may actually prefer this as a means of documentation.

Each document listed in the **Document List** is identified both by a generic IRB-designated *Document Type* and by a user-created *File Name*. While you are not required to assign a *File Name* different from the *Document Type*, *you can only assure that the file is distinguishable from other documents by creating a unique File Name*. If your study is subject to external monitoring or you have more specific needs, you should create specific file names that reflect the documents' content and version.

Some examples:

1. *Document Type*: Interview Questionnaire Survey
File Name: QoL.adult.questionnaire.v3.24MAR2010.doc
2. *Document Type*: Adult Consent Form
File Name: 11-1011 AdultCF healthy Ver23MAR2012.doc
3. *Document Type*: Investigator Brochure
File Name: 11-1011_IB_mynewdrug_V3_2012MAR26.doc

Upload a uniquely named file

1. At either the **Application Consent Forms** or **Application Attachments** screen, under step #2, click the magnifying glass next to *Document Type* field to open a drop-down list of document types
2. From this drop-down list, select the document type that corresponds to the required document type listed above, under step #1
3. At the *Attachment* field, Browse for and upload your uniquely named file

Application Attachments Reference Id: 121152

Current Application: [Quick View \(HTML\)](#) [PDF](#) [View Revisions](#) [View FAQ](#) [Delete Submission](#)

Based on your responses in the application, the materials listed below are expected to be attached. If not currently available, you may be required to provide them before final approval will be granted. To attach required materials, follow the steps below.

>> 1. REVIEW REQUIRED ATTACHMENTS:

- ✓ [Other Study Protocol](#)
- ✓ [Interview Questionnaire Survey](#)
- ✓ [Translation Verification](#)

>> 2. UPLOAD ATTACHMENTS :

Use this section to upload attachments listed above. Select the appropriate Document Type for the attachment you want to upload. Click Browse to locate the attachment on your computer and click Upload Attachment. Assign each document a unique file name. [\(Why is this important?\)](#) You can also upload additional materials not listed or multiple versions of items already listed.
Do not use this section to replace documents already listed below under "Revise/Replace Previously Uploaded Attachments."

Document Type:

Attachment:

New Documents Only

Once uploaded, your documents will be listed both by *Document Type* and *File Name* under step #3:

>> 3. REVISE/REPLACE PREVIOUSLY UPLOADED ATTACHMENTS:

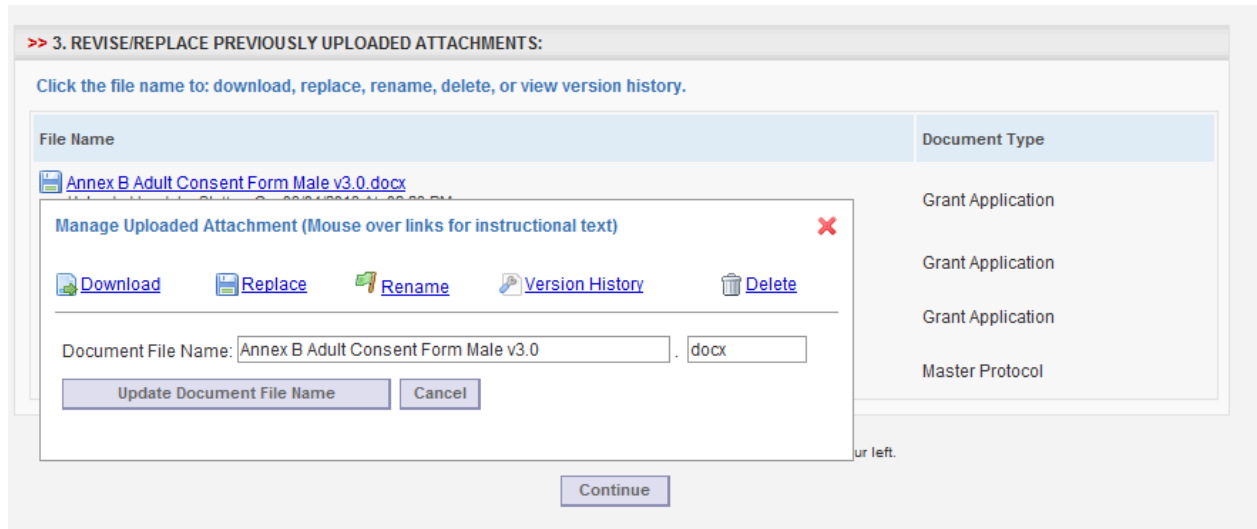
Click the file name to: download, replace, rename, delete, or view version history.

File Name	Document Type
Annex B Adult Consent Form Male v3.0.docx Uploaded by: John Slattery On: 03/04/2013 At: 02:23 PM Modified by: John Slattery On: 03/04/2013 At: 27:02 PM	Grant Application
GDAGSurvey.pdf Uploaded by: John Slattery On: 04/01/2013 At: 04:14 PM	Grant Application

Renaming your file

You may rename your file, either after upload (prior to submission) or upon study modification or at renewal:

1. At either the **Application Consent Forms** or **Application Attachments** screen, under step #3, click the relevant file name to open a pop-up window
2. Click the **Rename** option to open the renaming function
3. In the *Document File Name* field, revise the existing file name and click the *Update Document File Name* button



General Information about Document Control and Naming Conventions

- Incorporate version date and/or version number as well as file content into file name.
- Avoid using certain special characters in a file name (& * ? < # :), which may prevent document upload. A dash (-), blank space or underscore (_) may be used.
- Format dates consistently and choose a clear standard. Always include the year. For example, March 24, 2011 might be represented as 24MAR2011 or 2011_03_24 or 03-24-11.
- Use version numbers to manage revisions (e.g., V1, V2, V3). This may be useful for Protocols where both a date and version number are used to identify the document.
- Be consistent. Develop a naming convention to be used by all members of the study team. As relevant, document your naming convention in your study file and share it with team members, monitors and auditors.
- Abbreviate standard document types to reduce length of file names (e.g., MP: Master Protocol, CF: Consent Form, AF: Assent Form, IG: Interview Guide)

- Consider adding the file name to the document footer. But remember to update the footer each time the document is revised.