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

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

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
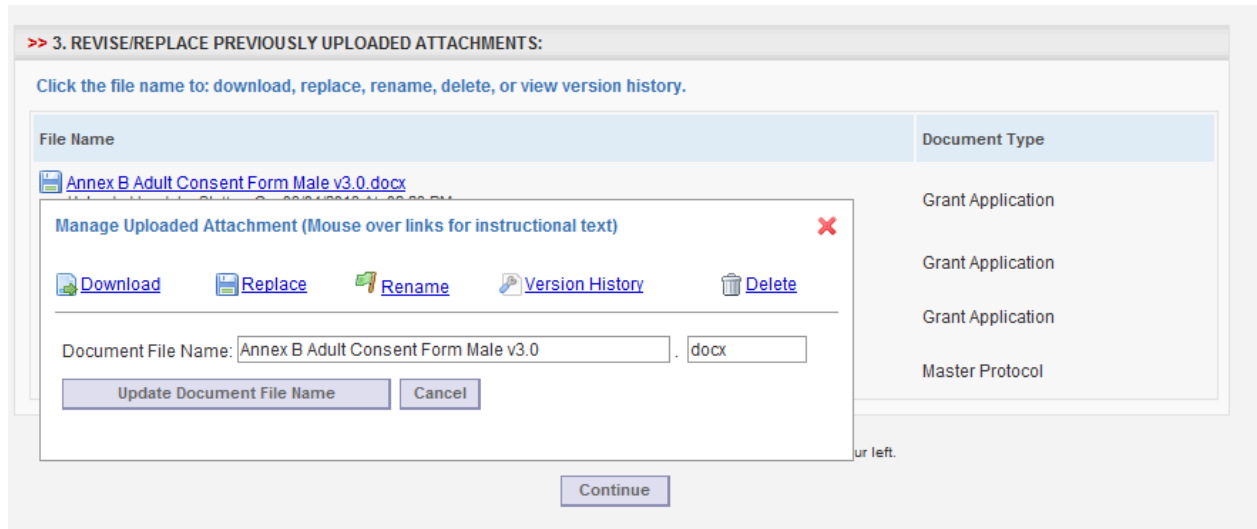
General Information about Document Control and Naming Conventions

- 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.