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Guidance: Document Control and Naming Conventions for Study Documents

Disclaimer: No one at the JHSPH IRB Office is a document control expert, but we have developed our own system to help us manage our forms and templates. The guidance below combines information collected on the web and things that we have learned internally. The IRB will not require use of a naming convention for study submissions, but it would make things easier for us and for you.

Why is Document Control Important?

The beneficial side effect of creating a good document control system is time efficiency. No one likes wasting time trying to find the right document version, with the latest revisions, to circulate to colleagues or to submit with an IRB application. In addition, documents associated with human subjects research studies may be subject to audit, may be shared, may be destroyed, and may need to be accessed for validation purposes. It is important that the documents be organized in a system which facilitates easy access and to insure that the correct versions documents are being accessed throughout the study. Otherwise, data integrity and study management could be challenged.

What's in a Name?

Research studies involve numerous documents, and one of the challenges for investigators is how to organize their submissions, and keep track of changes. The IRB has the same problem because we often modify our forms to add new questions or reword text, and we must organize electronic submissions under review. Documents need unique names which distinguish them from other documents, and version numbers to distinguish each revision. If a revision undergoes sequential edits, using dates helps keep it clear which version is the most recent one. Otherwise, the only way to tell whether one document is different from a modified version is to visually compare them, side by side. And who has the time (or patience) to do that?

Electronic File Naming Versus Document Naming

To Information Systems specialists, “document control” generally means some sort of electronic history generated when a document is added to a system. One may track back the upload date and time of a specific document using such systems. But, if you haven't “named” the document that you upload, there may be no way to tell if it is identical to the preceding document, or different, without comparing the two. The creator/revisor of the document must “christen” the document with a unique name.

Creating a Naming Convention



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There are some general rules about naming.¹

1. Avoid using special characters in a file name (&*?></\, etc.) as they may cause problems with electronic formatting.
2. Use underscores instead of periods or spaces. Periods have a specific electronic file name function (e.g., “.pdf”), and spaces may be read as something else.
3. Keep the length of the file name as short as possible, as some systems limit the length.
4. Make the file name sufficiently descriptive that it will be easy to find, and easy to relocate if misfiled. The context of the file should be clear.
5. Some records have set retention schedules, so the date of creation may be useful to include when you are scheduling data destruction. Format dates consistently.
6. If using dates, choose a clear standard. The international standard is YYYYMMDD. We receive documents from many places, so we prefer (and it’s easier to read) DDMonYY. Example: 26Mar12.
7. Use version numbers to manage drafts and revisions, for example “v1, v2_1.”
8. Include the document control name in small font in the header or footer of the document, not just in the electronic name of the document.
9. **BE CONSISTENT. Develop a naming convention and have everyone use it. It makes no sense to have everyone on the study team develop their own personal naming convention.**

Example: Naming Convention for Study Documents filed with the JHSPH IRB Office. These documents would be filed in an electronic file folder with the PI’s name and IRB number.

Example of IRB FORMAT

Date_Pi Last Name_IRB #_Title of Document_Ver #_Disposition

- Date will be entered as: Day, Month, Year Example: 07Oct08
- For approved documents, date will be the Date of Approval
- Disposition = Approved, Clean, Final Logo, Final No Logo

To ensure consistency, the following information will be used to name saved WORD or PDF documents:

¹ “Best Practices for File-Naming.” http://www.records.ncdcr.gov/erecords/filenaming_20080508_final.pdf. Many of the ideas in this guidance came from this source.



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- (1) Date – Date of Approval
- (2) PI Last Name
- (3) IRB #
- (4) Title of Document
- (5) IRB Version # *(For consents and recruitment materials submitted to the IRB. We number them sequentially so that we may track each approved version.)*
- (6) Disposition – Approved, Clean, Final No Logo, Final Logo

Examples of how entries will appear are as follows: *(they will never see any of these except the Final Logo)*

- | (1) | (2) | (3) | (4) | (5) | (6) |
|-----|---------|-----------------|----------------------------------|-----|-----|
| ➤ | 15Jan08 | _Smith_00001234 | _Child Assent_V1_Clean.doc | | |
| ➤ | 25Jan08 | _Smith_00001234 | _Child Assent_V1_Approved.doc | | |
| ➤ | 25Jan08 | _Smith_00001234 | _Child Assent_V1_FinalNoLogo.doc | | |
| ➤ | 25Jan08 | _Smith_00001234 | _Child Assent_V1_FinalLogo.pdf | | |

Sample PI Naming Convention

- (1) Date worked on
- (2) PI Last Name
- (3) IRB Study No.
- (4) Document Type (RP: Research Plan, CF: Consent Form, AF: Assent Form, Adult FGG: Adult Focus Group Guide, IG: Interview Guide, etc.)
- (5) Version number
- (6) Initials of person working on the document (if several people edit)

- | (1) | (2) | (3) | (4) | (5) | (6) |
|-----|---------|-----------------|----------------|-----|-----|
| ➤ | 26Mar12 | _Smith_00001234 | _RP_v3_jp | | |
| ➤ | 28Mar12 | _Smith_00001234 | _AdultCF_v2_as | | |