REQUIREMENTS FOR FILES IN IRB MENTOR

Documents that are typically required, such as consent documents, are requested via file upload questions within the relevant application sections in IRB Mentor.

Required File Naming Convention

o Label file names using a <u>simple</u> and informative naming convention: Name of File Type—Name of Subject Group (if applicable)—Language (if applicable)—Date Submitted—Version (if submitting revision on same date).

 Examples:

  A Spanish consent form for parents of minors submitted on Jan 1, 2023 would be labeled as: Consent-Parents-Spanish-1.1.23-V2

  A recruitment email script submitted on Jan 1, 2023 for which there is only one group of participants and no additional languages would be labeled as: Recruitment Email-1.1.23

o Revised versions of any documents would follow the same naming convention with a different submission date at the end or a version note in the file name if the revision is submitted on the same date as the original.

o Do not include your name, study title, or extraneous wording or formatting when naming your files. These elements do not enhance the IRB's understanding of what the file is and only adds visual clutter, making it difficult to flag the correct approved versions (which will be flagged as approved on the protocol information page).

Required Spacing and Formatting on Consent Documents

o Make sure that the bottom margins of your consent documents have at least one inch of space on all pages to enable the approved consent documents to be stamped by the IRB office. The various consent templates posted on the IRB website should be used; they contain the proper spacing for the bottom margin by default.

o Make sure that consent documents appear as they will appear when read by participants. Remove all instructions to investigators that may appear on the templates and samples prior to uploading them to your application.

Approved Stamped Consent Documents

o   Approved consent forms may be stamped at the bottom of each form. You must use the stamped version(s) of your approved consent documents when a stamp appears on the form.

o   If you are doing an online survey where the consent information is embedded into the text preceding the survey, you may use an unstamped version so long as you: 1) include a link to the stamped version that participants can print/download, and 2) the text on the version preceding the survey does not deviate in any way from the stamped version.

Deviations from approved stamped consent documents are protocol violations. It is <u>your</u> responsibility to ensure consistency even if the IRB did not catch a discrepancy. If you wish to modify an approved consent document, submit a modification request to the IRB. Refer to our [User Guide for Post-Approval Reporting](#) for instructions on how to submit a modification request to the IRB.

Requirements for Attachments

o   If you have multiple documents of a certain type (e.g., consent forms for different groups of participants), they should be submitted as <u>separate</u> attachments. This helps the IRB office to better compare revisions with original documents. Separating consent attachments also enables the IRB office to stamp each approved consent document at the end of the approval process in those cases where a stamp is needed.

o   If you will be embedding consent information into an online survey, submit the consent information as a separate attachment so that it can be stamped by the IRB office when approved.

o   Translations of documents, when applicable, should be included for the specific file upload question, along with a [Verification of Translation Accuracy Form](#).

o   If you have a web link to a study document, the IRB will still require that you attach all documents to your application. The IRB will not fill out data instruments on external sites such Qualtrics or Google Forms in order to review your data instruments or consent documents.

o   Most file upload questions allow for different file types, including Adobe PDF and Microsoft Word. It is preferred that all documents are uploaded as PDF files to enable the side-by-side

file comparison feature in Mentor.

o Make sure that each file has an extension included (for example .pdf). The comparison feature will not work unless the file has been saved with an extension.

Making Revisions to and Replacing Files

o You do not need to highlight or enable track changes in a revised file unless this is requested by the IRB. The document comparison feature in Mentor will allow users to see what has changed across iterations of the same file for PDF documents. Always submit a clean, final PDF version with no track changes or highlights, especially when submitting files that participants will see.

o If asked to make revisions to an attached file, you will not be able to delete the previous file. This is to enable the IRB to compare new documents with previous iterations. If you inadvertently upload the wrong file, please rename the file to "delete" using the edit option in the context menu for the file.

o Use the features available on the context menu for the file to perform various actions on the file, including the replace feature to replace an old version of a file with a revised version. Please use this replace feature to avoid confusion regarding which file will be reviewed.

Answer ✎

*Consent Document Attachment(s)

Review our user guide for file requirements before you upload any files. This is required reading if you will be uploading an attachment.

Make sure that your consent document(s) are each submitted as separate attachments; that they meet the requirements for stamping b (no highlights or track changes).

⋮ ▤ Consent Form - Training Intervention.pdf (Consent Documents) 04/10/2023 Edit ✎

Compare to Prior Version	orm - Youth Survey.pdf (Consent Documents) 04/10/2023 Edit ✎
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