

To ensure that study teams modifying consent documents at the time of amendment are utilizing the most recent IRB-approved consent version, IRBMED has standardized practices for version control of informed consent documents by study teams. The standardized practices include procedures for

- accessing the most recent IRB-approved clean Microsoft Word version of the consent from Section 10-1 of the eResearch application
- uploading **only** the track-changes version as part of an amendment modifying the consent
- using standard naming conventions for uploading consent documents to eResearch

Study teams will upload the initial informed consent document for IRB review into Section 10-1 of the New Study application. For subsequent amendments that modify informed consent documents, study teams will upload **only** a track-changes version to eResearch. Study teams should not upload clean versions, as IRBMED staff will label and upload the clean version to Section 10-1.

Study teams should maintain one stack of documents in eResearch for each separate consent document. Each new version of a given document should be stacked on the previously uploaded final draft. Each subsequent track-changes version should be stacked on the previously uploaded track-changes version.

To modify a consent document, study teams must begin with the most recent IRB-approved clean version found in Section 10-1 of the eResearch application. This is the Word version of the watermarked PDF, and is editable. Study teams must not use previous versions or documents stored outside of eResearch, as those documents may not accurately reflect the final IRB-approved version.

To maintain consistency and reduce errors, study teams must utilize the standardized naming convention for informed consent documents uploaded into the eResearch application. Study teams are required to upload a track-changes version of informed consent documents to section 10-1 of the eResearch application. The title of the track-changes version of the informed consent document as it appears in eResearch should be one of the following:

- **Consent-Track**
- **Consent-Concise Subtitle-Track** (when there are multiple consents associated with the study)
- **Assent-Track**
- **Parental Permission/Assent-Track**
- **Parental Permission-Track**

The words in boldface must not be changed. On the other hand, the study team should replace the italicized phrase “Concise Subtitle” with a one- to two-word descriptor, such as “Consent-Genetic” or “Consent-Screening.”

Once finalized by IRBMED, informed consent documents may not be altered without the submission and approval of an Amendment application.

U-MIC TRANSCRIPT

Version Control of Informed Consent Documents

When consenting participants, study teams must utilize the watermarked, PDF version of the consent document uploaded to eResearch by IRBMED staff. Study teams will find this PDF in the “Approved Documents” list, under the **Documents** tab in the eResearch application.

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