



STATEMENT OF PRACTICE

Version Control of Informed Consent Document(s)

Effective: September 8, 2014

Revised: October 9, 2014

I. Statement

To assure that study teams are utilizing the most recent IRB approved consent version when making modifications at the time of amendment, IRBMED has standardized practices for version control of informed consent documents. The standardized practices, further detailed below, include procedures for:

- Accessing the most recent IRB approved clean version of the consent from the eResearch application in Section 10-1 (Word version)
- Uploading **only** the track changes version as part of an amendment modifying the consent
- Using standard naming conventions for uploading consent documents into eResearch

II. Uploading Consent Documents into 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 which modify informed consent documents, study teams will **only** upload a track changes version to eResearch. Study teams should not upload “clean” versions as IRBMED 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 (for studies with multiple consent documents). Each new version for 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.

Informed consent documents uploaded in eResearch need to follow the standard naming convention outlined below in Section IV.

Do NOT delete any documents or stacks of documents from eResearch; these are retained for historical reference purposes.

III. Accessing the Most Recently Approved Consent Documents

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.

Target: Staff	File Name: SP.VersionControlInformedConsent...
Distribution: Staff	SP Number: SP.602.01
Lead(s): J. Birk, K. Sasamoto	
Approved By: P&G Committee	Original Implementation Date: 2014.09.08
Approval Date: 2014.10.21	Page Number: Page 1 of 3



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Study teams must continue to use the IRB approved, watermarked consent documents when consenting subjects; these are available under the “Approved Documents” tab in eResearch.

IV. Standard Naming Convention for Informed Consent Documents

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

Note: Words identified above in bold must not be changed; words identified in italics may be modified by the study team. The informed consent subtitle should be a one to two word descriptor, such as: Consent-Genetic, Consent-Screening, etc.

10-1. Informed Consent

10-1.1* All documents related to consent, assent, permission, and or debriefing documents, including oral scripts must be uploaded here. If you are requesting a waiver of documentation of informed consent, upload a copy of any written materials to be provided to participants, and provide a written description of any information to be provided orally.

	Name	Version	
<input type="button" value="Upload Revision"/>	Consent-Blood Draw-Tracked History	0.01	<input type="button" value="Delete"/>
<input type="button" value="Upload Revision"/>	Consent-Tracked History	0.01	<input type="button" value="Delete"/>

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V. Finalization

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

VI. References

1. UMIC Presentation: [Version Control of Informed Consent Documents](#)

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