

IRBMED Document Revision Guidance

When providing a tracked change version of the consent document for an amendment:

1. Download the last approved "Clean" Word version.

For consents & recruitment materials, use the most recent system approved clean Word version of the document. Protocol documents are not watermarked, so there will be no 'system uploaded' document.

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.

+ Add Drag and drop files to upload

Name	Version
Assent Script 7-11yo-Clean-HUM00XXXXXX(0.01)	0.01
Assent Script 7-11yo-tracked(0.01)	0.01
Assent Written 12-14yo-Clean-HUM00XXXXXX(0.01)	0.01
Assent Written 12-14yo-tracked(0.01)	0.01
Consent-Clean-HUM00XXXXXX(0.01)	0.01
Consent-tracked(0.01)	0.01

IRBMED studies: Edit the most recent version of the clean informed consent document found in 10-1.1. Use the Upload Revision button to stack the new tracked-changes document on top of the tracked-changes stack. Use the standard naming conventions for stacks from the Statement of Practice on "Version Control of Informed Consent Documents".

IRB-HSBS/Dearborn/Flint studies: Upload "clean" version in 10-1.1; upload "tracked-changes" in 44.1. Click here for more detail.

Please see important information about naming, editing, uploading, and downloading documents. Upload consent documents in .doc or .docx format. Please DO NOT delete previously uploaded documents: add a marker such as "X-NOT IN USE" to the file name for any obsolete document. See the Additional Help for links to templates and guidelines.

[Additional Help](#)

2. The most recently approved clean version can be located by clicking on the **elipsis (three dots)** then selecting **View History**. Download the most recent "**SYSTEM UPLOADED DOCUMENT**" in the Notes column.

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Consent-Clean-HUM00XXXXXX(0.01)	0.01
Consent-tracked(0.01)	0.01

- Download Copy
- Upload Revision
- View History
- Delete

3. Sometimes you will see someone has inadvertently uploaded a document into the clean stack, this is why going into the document stack **Resource History** will ensure you are downloading and making revisions from **the Last Approved Clean Word** version.

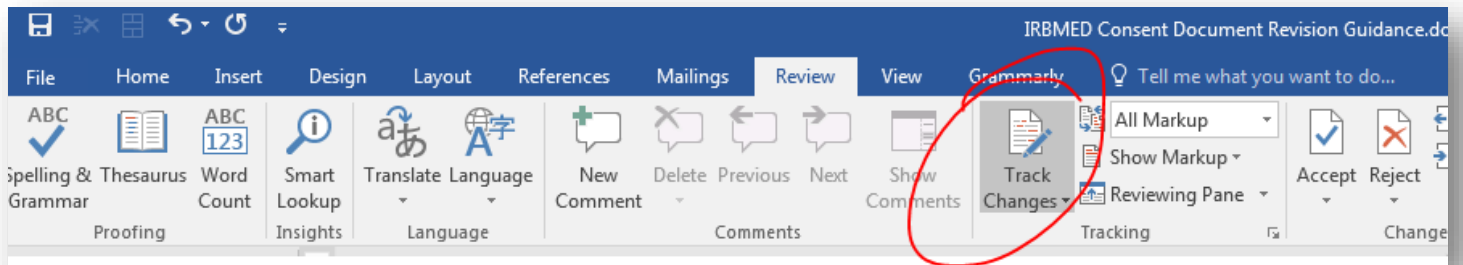
History:

Date	Version	Person	Action	Notes	Uploaded File
9/18/2017 1:52 PM	0.03	[Redacted]	File Uploaded & Edited		[Redacted]
11/4/2016 3:58 PM	0.02	Allison Kanous	File Updated	SYSTEM UPLOADED DOCUMENT	[Redacted]
11/4/2016 3:55 PM	0.01	Allison Kanous	Created		[Redacted]

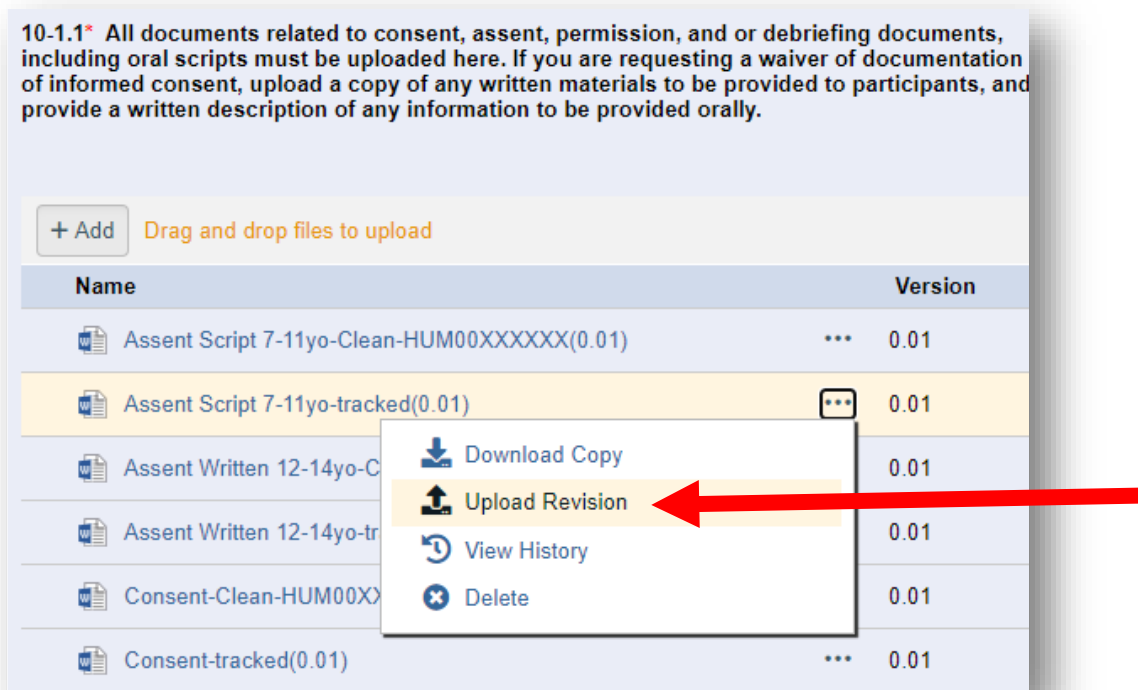
OK

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4. Make necessary revisions with **Microsoft Word's tracked changes functionality active.**



5. Upload the revised tracked document into Section 10-1.1 under the appropriate 'tracked' stack.



Do not alter or remove the coverage page.

This page is "silent", meaning it will disappear during document finalization.

Ensure consent/assent subtitle & version # are updated within the footer of the document.

Update stack title is not required. Actual document title can be different than stack title.

Do not upload any documents to the "clean" stack.

When the amendment is approved, IRBMED will watermark the approved consent document, and upload a "clean" version, which the eResearch system will finalize into a .pdf document.

Only 'Add' new document stacks for entirely new documents.

Use 'Upload Revision' for updated versions of existing documents.