



U-MIC TRANSCRIPT

Document version comparison in eResearch

In submissions to the IRB, explicit change tracking in uploaded documents promotes clarity and consistency, making it easier for the IRB to review the changes and determine whether the research continues to meet regulatory standards.

Many applications, including Microsoft Word, Excel, and PowerPoint, as well as some PDF software, offers a tracked changes feature, which marks revisions made to a document. The study teams are expected to provide the track-change copies of the study documents for IRB review.

A **Compare** feature has been built into eResearch Regulatory Management, which enables users to compare two versions of the same document by displaying change tracking. This feature can be accessed by the regulatory staff and/or the board members at the following locations in eResearch when documents are uploaded for review:

1. IRB application (Edit/View interface) sections
2. The **Change Tracking** tab in HUM, CR, and AE/ORIO submissions
3. The **Amendment audit trail** for AMEs when they include revised documents

This U-MIC provides additional information and screenshots for each of the scenarios listed above.

1. IRB application (Edit/View interface) sections

To use this feature within the IRB application, first enter the **Edit/View** interface, either from the submission's main workspace or from a section link in the reviewer checklist.

Submission workspace:

Edit / View

- View Amendment Forms
- View Study
- Amendment Audit Trail
- Printer-Friendly Amendment
- Printer-Friendly Coversheet
- Application Checklist
- Submission Summary

Study Team

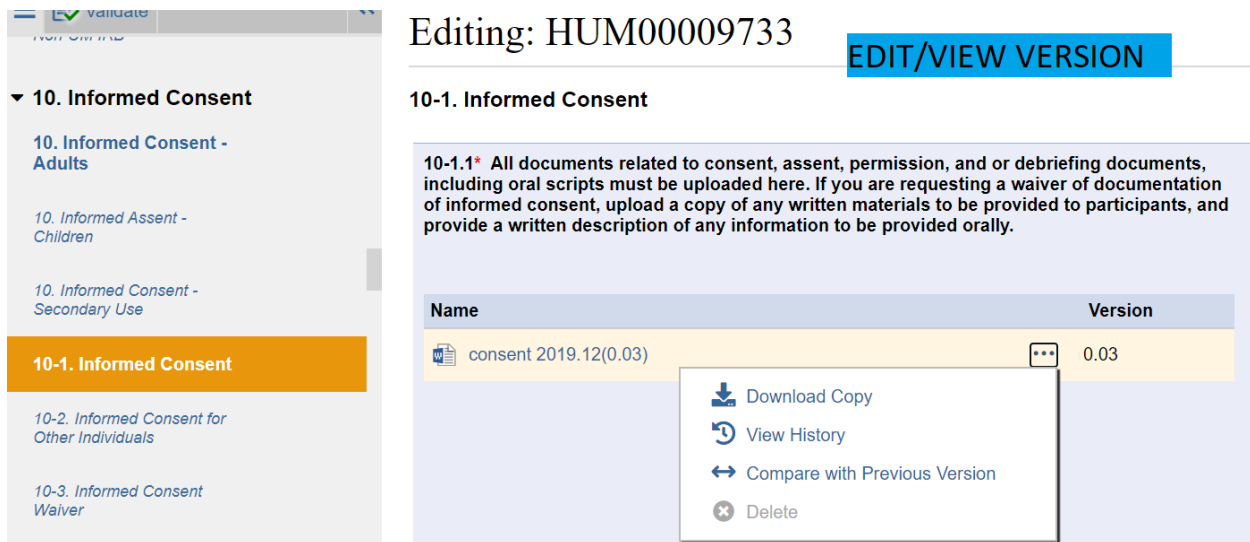
Main Notes

1 Pre-Submission

Or, the reviewer checklist:

Section:	10-1 Informed Consent Documents
Checklist Item:	Question 10-1.1 - Does the informed consent accurately and adequately describe the research?


From an eResearch section that prompts users to upload documents—such as 10-1.1, where consent documents are uploaded, or 5.1.1, where researchers upload their protocols—click the ellipsis to view additional options. Note that these options are not available from the “Printer Friendly Version” interface.



Editing: HUM00009733 EDIT/VIEW VERSION

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
 consent 2019.12(0.03)	0.03

- Download Copy
- View History
- Compare with Previous Version
- Delete

Choosing the **View History** option opens a pop-up window; check the boxes next to the document versions you want to compare and click the **Compare** button, which launches Microsoft Word.

History:

Compare	Date	Versic
<input checked="" type="checkbox"/>	12/4/2019 11:22 AM	0.03
<input type="checkbox"/>	12/4/2019 11:21 AM	0.02
<input checked="" type="checkbox"/>	11/20/2019 8:35 PM	0.01

Compare

Note that any changes you make to the downloaded comparison document are not saved to the document file stored in eResearch.

The ellipsis also offers a **Compare with Previous Version** option, which opens the two newest versions of a document within a stack for comparison. Keep in mind, however, that multiple versions of a document may be



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uploaded during a submission-and-review cycle, so the **Compare with Previous Version** option may not, for example, show all changes made between the time of the document's most recent approval and that of submission of a new draft in an amendment application.

Editing: HUM00009733 [EDIT/VIEW VERSION](#)

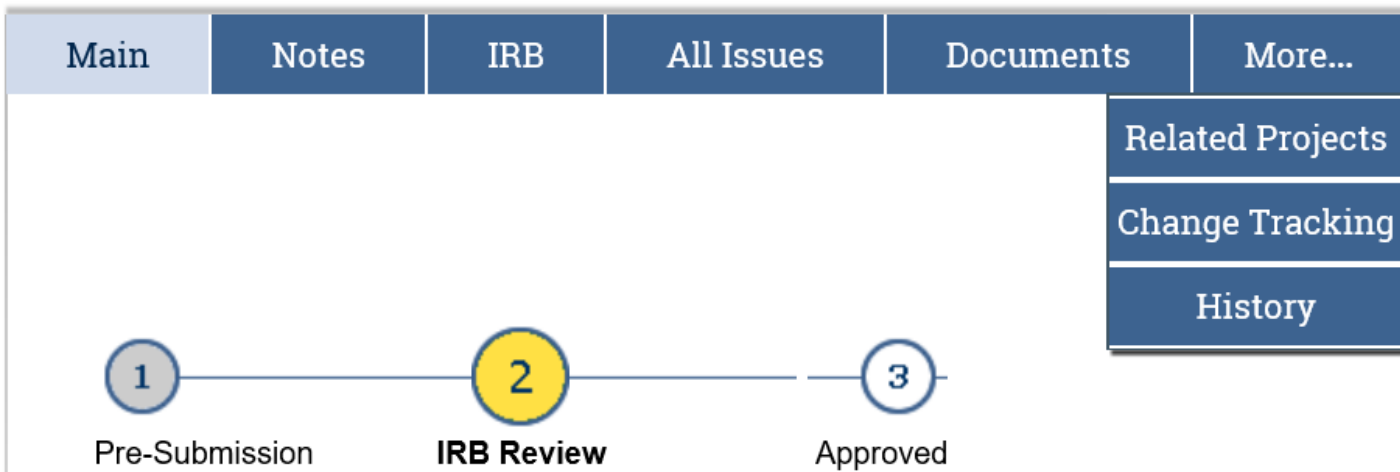
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Name	Version
consent 2019.12(0.03)	0.03

- Download Copy
- View History
- Compare with Previous Version
- Delete

2. The **Compare** function is also accessible from the **Change Tracking** tab in HUM, CR, and AE/ORIO submissions.



Activity	Author	▼ Activity Date
Change Log: Page 10-1. Informed Consent	CoreSuperAdmin, IRBMed	12/4/2019 11:40 AM
On Page 10-1. Informed Consent		
Change Log: Page 02. Sponsor/Support Information	CoreSuperAdmin, IRBMed	11/20/2019 8:49 PM
On Page 02. Sponsor/Support Information		
Change Log: Page 01-2. Standard Study Information	CoreSuperAdmin, IRBMed	11/20/2019 8:48 PM
On Page 01-2. Standard Study Information		
Change Log: Page 41. Subjects Vulnerable to Coercion	CoreSuperAdmin, IRBMed	11/20/2019 8:46 PM
On Page 41. Subjects Vulnerable to Coercion		

Clicking any **Change Log** link on the audit activity list opens the **Activity Details** page for the document in question. If a revision has been uploaded as part of a particular change, a **Compare** button appears within that document's row.

3. In amendments, the **Compare** function is accessible in the amendment audit trail.

Edit / View

▶ **Study Team**

- [View Amendment Forms](#)
- [View Study](#)
- [Amendment Audit Trail](#)
- [Printer-Friendly Amendment](#)
- [Printer-Friendly Coversheet](#)
- [Application Checklist](#)
- [Submission Summary](#)

Main
Notes

1

Pre-Submission



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Activity Details (Change Log: Page 10-1. Informed Consent)

Author:	IRBMed CoreSuperAdmin (unknown)
Logged For (Application):	keneaton_friend test submission
Activity Date:	12/4/2019 11:40 AM

Property Changes	Documents	Notifications
Property	Old Value	New Value
Application		HUM00009733
activityType		_Protocol_Change Log
author		IRBMed CoreSuperAdmin
name		Change Log: Page 10-1, Informed Consent
Application.10 Informed Consent.Consent Documents {consent 2019.12(0.03)}.name	res_irbmed_20181112-workingStandardConsentTemplate_0.docx	consent 2019.12
Application.10 Informed Consent.Consent Documents {consent 2019.12(0.03)}.targetURL	consent 2019.12	consent 2019.12 Compare
Application.10 Informed Consent.Consent Documents	0. 01	0. 03

NOTE: The system does not allow IRB staff and reviewers to use the **Compare** function by clicking through from the Reviewer Checklist. This brings up only a one-page, non-sortable “Change Log for Submission” view, which may display a **Compare** button, but it is unfortunately nonfunctional.

Staff Review for HUM00009733 - IRB Staff Reviewer
HUM00009733 - keneaton_friend test submission

[Print Version of Submission](#)

[Change Log for Submission](#)

[All Issues](#)

[Manage Action Items for HUM00009733](#)

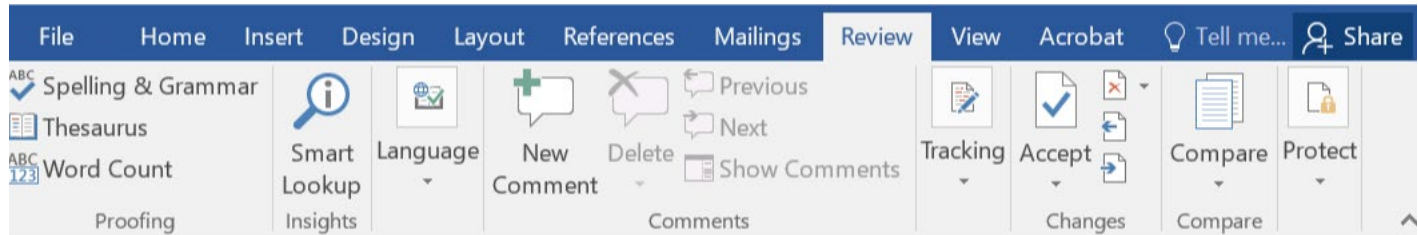


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Document version comparison in eResearch

Standard “Compare” function within Microsoft Word

To compare documents from different eResearch document stacks—or even from different studies—the user may download both documents to their desktop and then utilize Microsoft Word’s **Compare** function, which is located under the **Review** tab.



For more information about Word’s Compare feature, search Microsoft’s <http://search.office.com> page with the terms “compare” or “compare documents.” For additional information about eResearch’s Compare feature, consult ITS Training Resources for eResearch Regulatory Management. <https://its.umich.edu/academics-research/research/eresearch/regulatory-management/reference-materials>.

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