

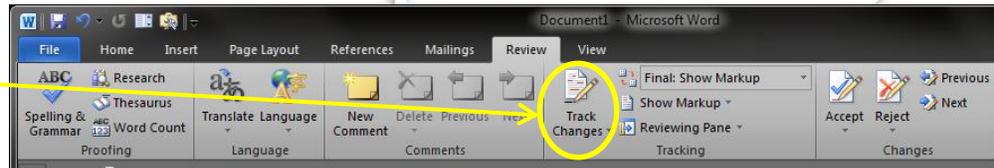
Making Changes to Your Consent Document(s):

- (1) Make sure you start with the current approved version of the consent.
 - a. Go to 10-1 of the eResearch application
 - b. Find the document you wish to amend
 - c. Download to your desktop

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
Informed Consent - (English Version "clean") History	0.01
Informed Consent - April 2010 History	0.01
Informed Consent - English (March 2010 Amendment) History	0.03
Informed Consent - Spanish (March 2010 Amendment) History	0.01
Informed Consent (English version "clean") - March 2010 amendment History	0.03
Informed Consent (Spanish version "clean") - March 2010 Amendment History	0.01
Informed Consent (Spanish) - April 2010 History	0.01
informed consent--Spanish History	0.01

- (2) Enable the **Track Change** feature in Word



- (3) Make all desired changes

- (4) Create a descriptive title starting with the amendment # (e.g., AME1234 Focus Group)

- (5) Upload the clean version to section 10-1 of the application

- (6) Upload the track-change version to section 44 of the application – Using the title created following instruction above, also indicate it is a **track-change version**

44.1 Please upload any additional supporting documents related to your study that have not already been uploaded. Examples include, but are not limited to, data collection sheets, newsletters, subject brochures, and instructional brochures.

Name	Version
AME00049401: Section 44-Support Docs History	0.02
2012 Non-recruitment Study Contact Materials History	0.01
2012 Non-recruitment Study Contact Materials-SPN History	0.01
2012 Data Collection Overview w/TRACK CHANGES History	0.03
2012 Informed Consent Information Sheet w/TRACK CHANGES History	0.02
2012-IRB-Memo-FINAL-MAR2012 w/TRACK CHANGES History	0.02
2012-MAR-Duplicate of Informed Consent History	0.01
2012-Oral Consent Script at Each IW Session w/TRACK CHANGES History	0.02
2012-Pretest-PM Bio-Saliva Consent Form w/TRACK CHANGES History	0.01
2012-Pretest-PM Bio-Blood Consent Form w/TRACK CHANGES History	0.01
2012-Pretest-PM Bio-PM Consent Form w/TRACK CHANGES History	0.01

- (7) If any of the documents in 10-1 have **NEVER** been used with human subjects and are now obsolete you may delete them.

If any of the documents in 10-1 **HAVE** been used with human subjects and are now obsolete, you may move them to section 44 and add “obsolete” to their title

For questions please contact the IRB at (734) 936-0933 or irbhsbs@umich.edu