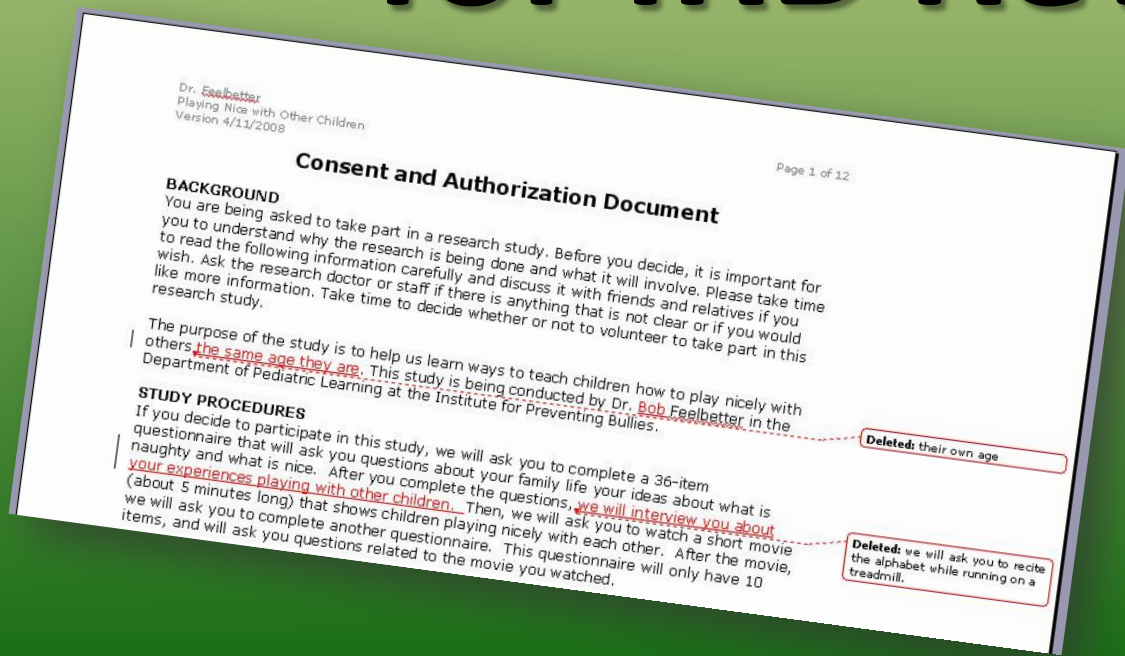


>Helpful

Tracking Documents for IRB Review

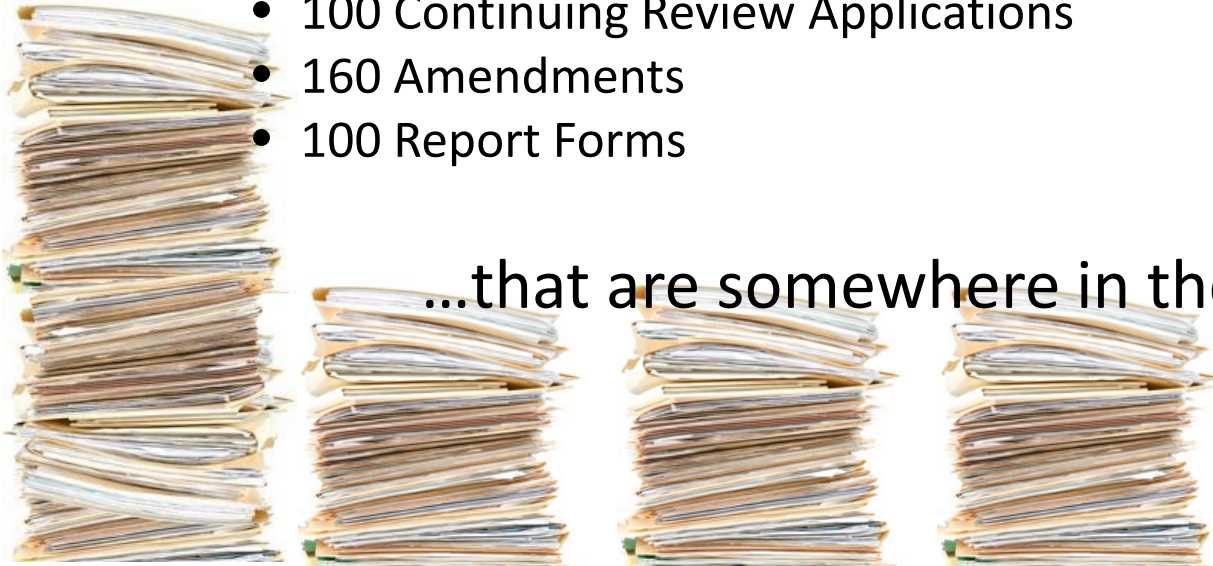


University of Utah IRB
Version: March 2012

The IRB staff at work...

- The University of Utah IRB currently has over 4,000 active protocols.
- This translates into about:
 - 120 New Study Applications
 - 100 Continuing Review Applications
 - 160 Amendments
 - 100 Report Forms

...that are somewhere in the IRB process each week.



The IRB staff at work...

- This means that at any given time, the IRB staff is reviewing documents for hundreds of different studies.
- Multiple versions of documents, different review requests, etc. can make this a daunting and time-consuming task, but you can help!

The typical IRB reviewer

- Board members review applications and documents for multiple applications each month.
- They complete a checklist that includes a list of their concerns, questions, and required revisions.
- The revisions are translated into a letter drafted by the IRB staff.

TIME PASSES...

- The IRB staff and board members then check the completed revisions. Depending on how long it takes the study team to respond, this can be up to 30 days after they were sent.

The typical IRB reviewer

- When changes made to the application are easy to follow, checking the revisions is usually a very quick process.
- However, if changes are not easy to follow, the process can be cumbersome and time-consuming, and often results in revisions being re-requested, or additional clarifications being required.

Are my documents helpful?

- The way you track and attach your documents can **significantly** affect how quickly your revisions get reviewed, and ultimately, how quickly your study gets approved.
- To make sure your revised documents are speaking IRB language, follow some simple steps...

Step #1: Title Your Document Clearly

- Choose a title that shows the evolution of the document during the IRB review process:

Consent Forms:

Name	Date Created	Date Modified
Consent Document	3/11/2008 5:13 PM	3/11/2008 5:13 PM
Consent Document Pre-Board Revisions (Tracked Copy)	3/13/2008 4:03 PM	3/14/2008 4:03 PM
Consent Document Pre-Board Revisions (Clean Copy)	3/13/2008 4:04 PM	3/14/2008 4:04 PM
Consent Document Final (Tracked Copy)	04/01/2008 9:32 AM	04/01/2008 9:32 AM
Consent Document Final (Clean Copy) Version: 04/01/08	04/01/2008 9:34 AM	04/01/2008 9:34 AM


- It is not necessary to include version dates in the title of the document. ERICA time stamps every action in the system.
- HOWEVER, if you need the version date to appear in your final approval letter, make sure it is part of the title. ERICA processes the document exactly how it is uploaded.



Step #2: Track Your Changes

- When making changes to previously-approved or previously-reviewed documents, make sure you prepare
 1. A tracked copy of the document showing the changes you've made; and
 2. A clean copy of the revised document for processing.

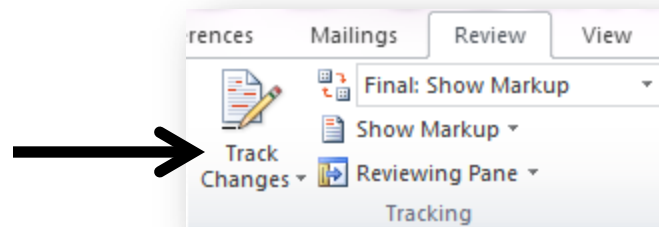
Track Changes in MS Word 2010

- If you ever need help with any function in any version of Word, click the “Help” icon  and type in the topic you need help with. In this case, typing “Track Changes” will return many helpful results.



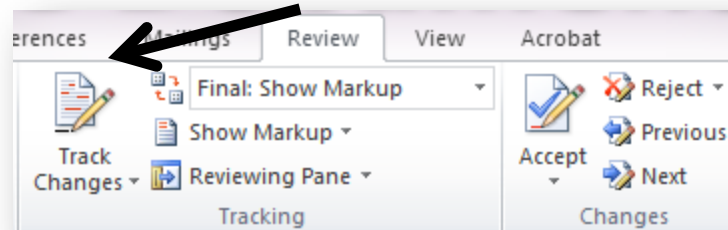
- **In Microsoft (MS) Word 2010:**

1. On the **Review** tab, in the **Tracking** group, click the **Track Changes** button.



Track Changes in MS Word 2010

- Make the changes you want by inserting, deleting, or moving text or graphics. You can also change formatting.
- Balloons show insertions or deletions, formatting changes, and comments.
- **In Microsoft (MS) Word 2010:**
 1. Click the “Track Changes” button to turn on tracking.
 2. Click the “Track Changes” button again to turn off tracking.



Is it okay to highlight the changes?

- No – highlighted documents show where changes have occurred, but not necessarily *what* those changes are.

Dr. ~~Feelbetter~~
Playing Nice with Other Children
Version 4/11/2008

Page 1 of 12

Consent and Authorization Document

BACKGROUND

You are being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the research doctor or staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study.

The purpose of the study is to help us learn ways to teach children how to play nicely with others **the same age they are**. This study is being conducted by Dr. ~~Bob Feelbetter~~ in the Department of Pediatric Learning at the Institute for Preventing Bullies.

STUDY PROCEDURES

If you decide to participate in this study, we will ask you to complete a 36-item questionnaire that will ask you questions about your family life your ideas about what is naughty and what is nice. **After you complete the questions, we will interview you about your experiences playing with other children.** Then, we will ask you to watch a short movie (about 5 minutes long) that shows children playing nicely with each other. After the movie, we will ask you to complete another questionnaire. This questionnaire will only have 10 items, and will ask you questions related to the movie you watched.

Is it okay to highlight the changes?

- **Tracked Changes** show what was deleted, what was added, and comments can be included if needed. This is all critical information for IRB review.

The screenshot shows a document titled "Consent and Authorization Document" with tracked changes. The document is on page 1 of 12, dated 4/11/2008, and is by Dr. Feelbetter. The text is as follows:

Dr. Feelbetter
Playing Nice with Other Children
Version 4/11/2008

Page 1 of 12

Consent and Authorization Document

BACKGROUND
You are being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the research doctor or staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study.

The purpose of the study is to help us learn ways to teach children how to play nicely with others the same age they are. This study is being conducted by Dr. Bob Feelbetter in the Department of Pediatric Learning at the Institute for Preventing Bullies.

STUDY PROCEDURES
If you decide to participate in this study, we will ask you to complete a 36-item questionnaire that will ask you questions about your family life your ideas about what is naughty and what is nice. After you complete the questions, we will interview you about your experiences playing with other children. Then, we will ask you to watch a short movie (about 5 minutes long) that shows children playing nicely with each other. After the movie, we will ask you to complete another questionnaire. This questionnaire will only have 10 items, and will ask you questions related to the movie you watched.

Comments in red boxes:

- Deleted: their own age
- Deleted: we will ask you to recite the alphabet while running on a treadmill.

“Compare View” in Adobe

- You can identify what has changed between two versions of a PDF file by using the “Compare View” function.

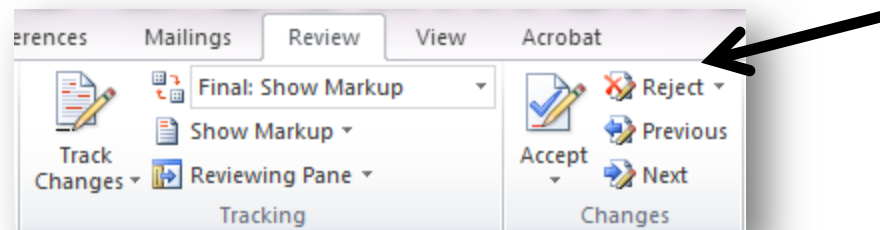
Table 5.15. TEAEs during the Treatment Period of N01276 experienced by at least 5% of all subjects (ITT Set)

UCB SOC MedDRA preferred term	BRV 50mg/day N=68 n (%)	BRV 100mg/day N=20 n (%)	Total N=88 n (%)
Any SOC	52 (76.5)	11 (55.0)	63 (71.6)
Gastrointestinal disorders			
Nausea	3 (4.4)	2 (10.0)	5 (5.7)
General disorders and administration site conditions			
Fatigue	5 (7.4)	2 (10.0)	7 (8.0)
Infections and infestations			
Nasopharyngitis	4 (5.9)	1 (5.0)	5 (5.7)
Metabolism and nutrition disorders			
Decreased appetite	6 (8.8)	1 (5.0)	7 (8.0)

- See: <http://adobe.ly/xqvrc7> for instructions.

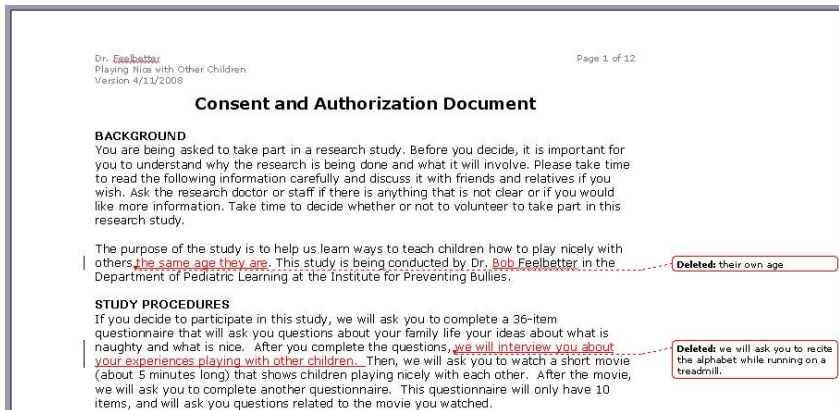
Step #3: Prepare a Clean Copy

- After you've created a tracked changes copy of your revised document and saved a copy of it, you need to prepare a clean copy of the revised document for processing.
- To get rid of tracked changes and comments, you need to accept or reject the changes and delete the comments.
- **In Microsoft (MS) Word 2010:**
 - To remove tracked changes, use the **Accept** and **Reject** commands on the **Review** tab in the **Changes** group.
 - On the **Track Changes** toolbar, you can use the arrow under the **Accept** button, and then click **Accept All Changes in Document**.
 - Any comments that have been added may need to be manually deleted.

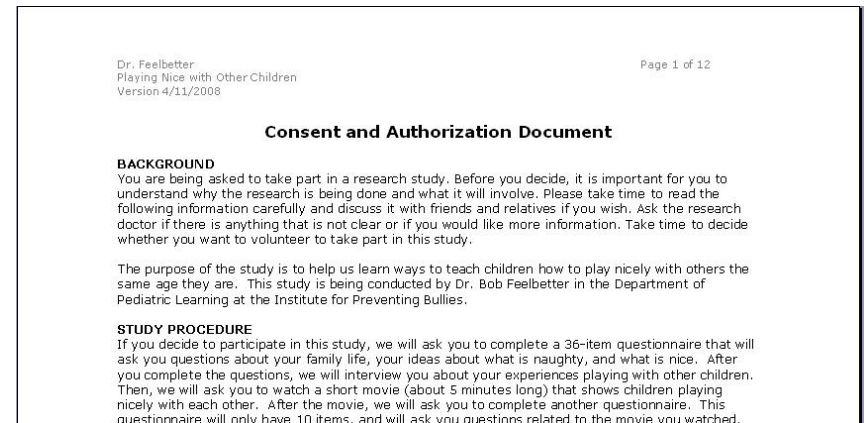


Step #4: Attach Your Revised Documents

- You should now have two documents:



A tracked copy
for review....



...and a clean copy for
processing.

Step #4: Attach Your Revised Documents

- Leave the old versions in ERICA!
 - Don't delete previous versions of the documents
 - Reviewers need to be able to reference old documents and see the changes that have been made over time
 - Only the most recent version of the document will be approved



Don't forget the title



- The final approval letter will show the title of the document as you have uploaded it
 - If your sponsor requires the document to be titled a specific way, make sure you enter the title appropriately

A screenshot of a Windows Internet Explorer browser window. The title bar reads "No Title - Windows Internet Explorer". The address bar shows the URL "https://erica.research.utah.edu/erica/ResourceAdministration/Document/FormForProperty?formID=0&postba". The main content area is titled "Submit a Document" and includes a "Help" button. The "Title:" field contains the text "Consent Document Version 3.0" and has a note: "If not provided, the name of the file will be used". The "File:" field contains the path "I:\STAFF\Lisa R\Temp Docs\campus_consent.do" and a "Browse..." button. Below the fields is a "Show Advanced Options" button. At the bottom, there are "OK", "OK and Add Another", and "Cancel" buttons. A black arrow points to the "Title:" field. The status bar at the bottom shows "Done", "Internet", and "100%".

Questions?

Contact the IRB if you have questions.

801-581-3655

irb@hsc.utah.edu