

Helpful Attaching Revised Documents in ERICA for IRB Review

Your IRB at Work

The IRB reviews about...

120 New Study Applications

160 Continuing Review Applications

100 Amendments

100 Report Forms

...per week.



At Least We're Electronic...

This means that at any given time, each Administrator/Coordinator team is reviewing documents for over 150 different studies.





- Reviewers must be able to clearly determine what changes have been made in response to their requests.
- Multiple documents in each submission can make this a daunting task, but...



You can help us!

Are My Documents Helpful?

- When revised documents are submitted back to the IRB for review, make sure the changes you've made are easily identifiable.

*Let us show you how
this is done...*



In the Reviewer's Shoes...

- Reviewers are reviewing documents for multiple submissions
- They complete a checklist with their concerns/revisions
- Revisions are sent in a letter

Time passes...

- Study teams may have up to 30 days to complete the revisions.



...30 Days Later



- When revisions are submitted back to the IRB, they must be reviewed again
- When changes are easy to follow, this process is usually very quick



Document Titles

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

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

Tip: It is not necessary to include version dates in the title of the document, unless that is how you want the title of the document to appear on the final approval letter.



Highlighted Documents

Only part of the story...

- Highlighted documents show where changes have occurred, but not necessarily what those changes are.

Dr. ~~Bob~~ 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.



Tracked Changes

Now we're getting the whole story...

- To facilitate review, Microsoft Word allows you to easily make and view tracked changes and comments in a document.
- **Tracked Changes** show what was deleted, what was added, and comments can be included if needed.

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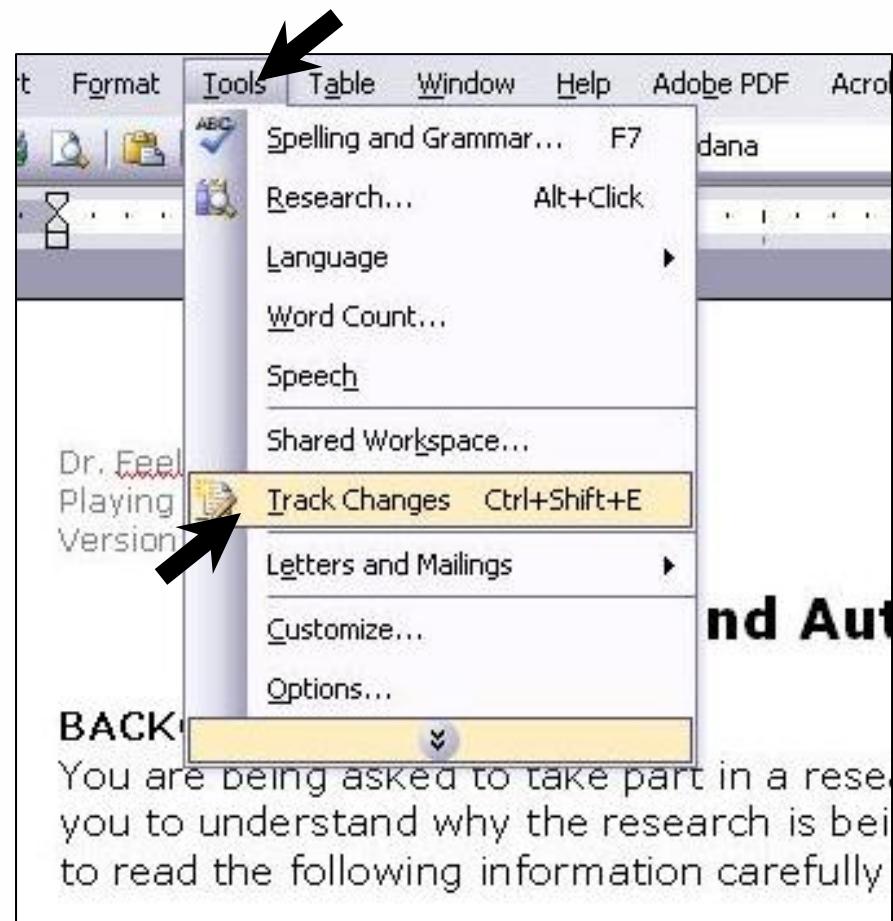
Deleted: their own age

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



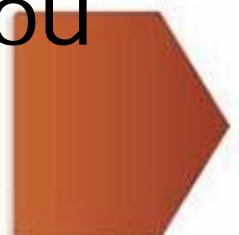
How to “Track Changes” (Word Documents)

1. In your Word document, select the **Tools** menu
2. Click **Track Changes**.



About “Track Changes”

- 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.
- As you review tracked changes, you can accept or reject each change.



How to Attach a Clean Copy of the Document

- To get rid of tracked changes and comments, you need to accept or reject the changes and delete the comments.

- On the **Track Changes** toolbar, point to arrow on the right side of the **Accept Change** button, and then click **Accept All Changes in Document**.



- Any comments that have been added may need to be manually deleted.

Two Documents

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Playing Nice with Other Children
Version 4/11/2008

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You should now
have a tracked copy
for review...

...and a clean copy
for processing.



Attach Your Documents in ERICA

- Attach your tracked document *and* your clean document in ERICA.
 - Attach the documents in the appropriate section on the **Documents and Attachments** page.
 - Documents attached in the Correspondence will **not** be approved or reviewed.



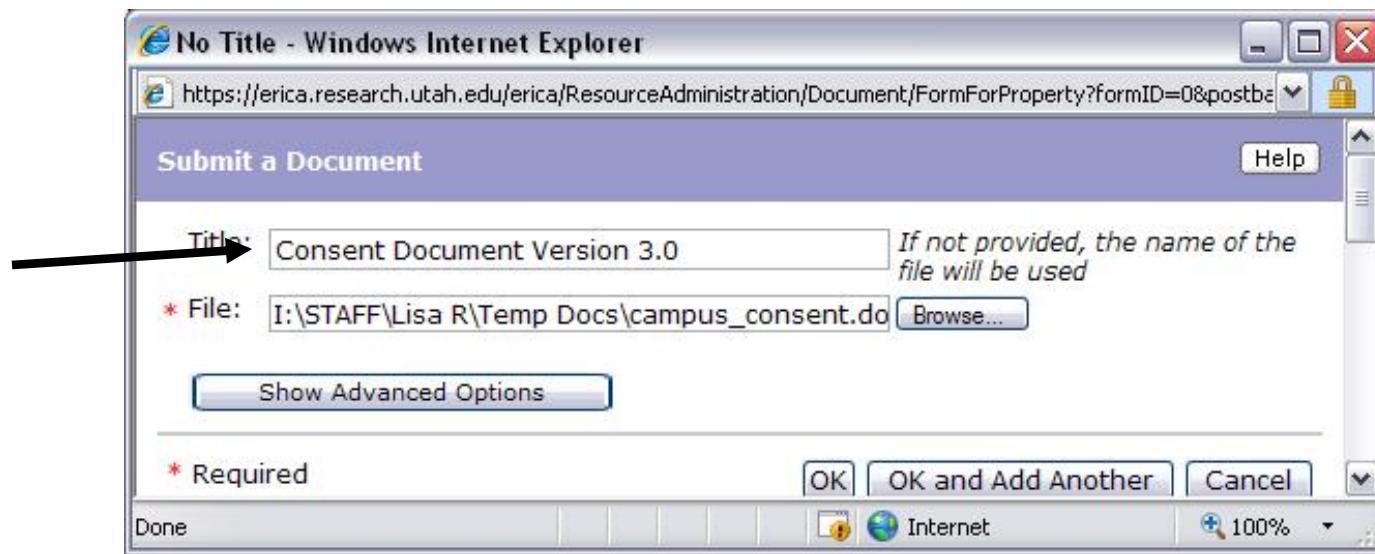
Leave the Old Versions

- 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



Who Do You Call?

If you have questions, please contact
the IRB staff:

Institutional Review Board

(801) 581-3655

irb@hsc.utah.edu

www.research.utah.edu/irb