"View Differences"
Tutorial

*This tutorial will show you how to view tracked changes to the **New Study application** or **Update Study application** using the "View Differences" button.*

What is the Update Study Application?

- The Update Study Application is an **editable copy** of your full (new study) application that you completed to receive initial IRB approval.

- The Update Study Application copy can be modified when you submit an amendment, to reflect changes that you make during the study.

- When an amendment is approved, the Update Study Application copy becomes the new version of your full application.

What is "View Differences"?

- "View Differences" is the way that ERICA tracks the changes made to a full application so that an unchanged application can be easily compared to a revised application.

- View Differences is used to show you the differences between an unchanged Update Study Application and a revised Update Study Application when you do an amendment (or continuing review + amendment).

When to use View Differences?

- Study teams can use View Differences during the Amendment Creation state to see all of the changes for their amendment.

- Study teams can use View Differences during the PI Corrections/Revisions state to see the revisions they have made as requested by the IRB staff and board.

- IRB staff and board members can use View Differences to verify that changes described in an amendment application were made appropriately by the study team.

What View Differences *Doesn't* Do

- View Differences **does not track the changes you make inside of documents** that are attached in the application. You must use the "track changes" options within the document in order to track changes inside the document.

- View Differences does not track the changes to amendment applications, continuing review applications, or report forms; it only tracks changes to the Update Study Application.

How to Use View Differences

Continue through this tutorial to learn how to access and navigate the View Differences workspace.

Amendment Workspace

Amendment Creation
Edit Amendment
Print View
View Differences
Update Study

2 → View Differences

1 → Update Study

IRB_00037783 - AM_Test AM   **Current Status:** Amendment Creation

PI:

Title:

Note: Use the "Submit" option on the left to forward the application to the IRB. Only the PI is able to submit an application for review.

My Activities

- ✖ Withdraw
- ✉ Send Invoice
- ✉ Payment Received
- 📝 Internal Comments
- 🔄 Submit for IRB approval
- ✉ Notify Study Team

Correspondence   View Documents

No data to display.

◁◁ ◁ no results ▷ ▷▷   25 / page

1. Once you have created your amendment, click the **Update Study** button on the amendment workspace. Make all of the changes to the Update Study application as are required for your amendment. Save the changes and return to the amendment workspace.

2. Click the **View Differences** button to view the tracked changes between the unchanged version of the Update Study application and the changed version.

View Differences Workspace Heading
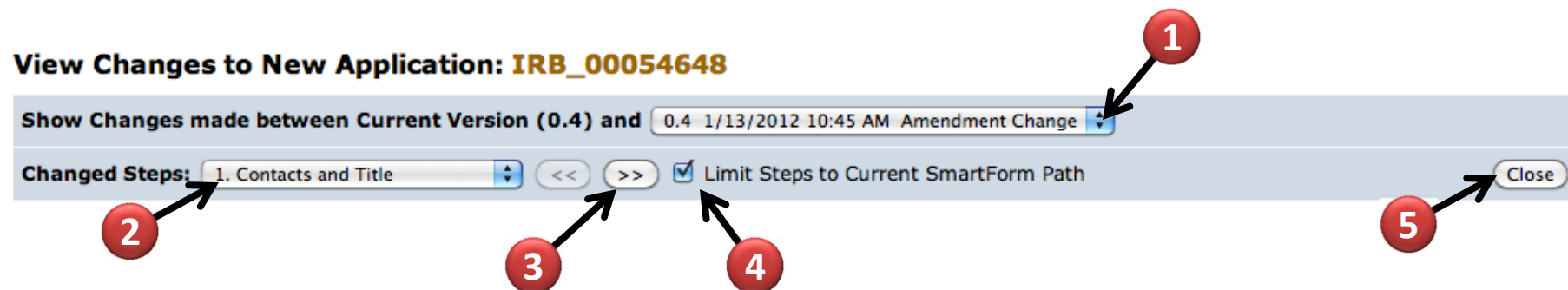
1. This drop-down menu is used to view different "sets" or "time points" when changes were made to the Update Study application. You may enter the Update Study application several times throughout the course of the amendment in order to make changes. Each time you do this, ERICA saves each revision session separately based on the review state. For example,
   - if you enter the Update Study application two times during the "Amendment Creation" state, this counts as one time point;
   - If you enter the Update Study application two times, once during the "Amendment Creation" and once during the "PI Corrections" state, this counts as two time points.
2. This drop-down menu lists each page of the application completed for your study. You can jump to a desired page to view the tracked changes on that page.
3. These arrow buttons allow you to scroll through each page of your application in sequence to view the tracked changes on that page.
4. When this checkbox is selected, the menu and arrows in parts 2 and 3 above will only show the pages with tracked changes, instead of every page of your application.
5. The close button exits you from the View Differences workspace back to the amendment workspace.

View Differences: Examples of Change Tracking

The following pages give you key examples of change tracking that will help you understand the utility of View Differences.

If you have questions about View Differences that are not answered by this tutorial, please contact the IRB at 801-581-3655 or irb@hsc.utah.edu.

- *Note that due to the January 2012 New Study application update, the View Differences feature may track formatting differences between the old version of the application and the new version. These formatting differences will not be tracked after your first amendment.*

View Differences: Yes/No Questions

b. **Will the Principal Investigator consent participants?** ⊙ Yes ○ No

1 → Old Value: [None]

7. Is a substantial percentage of the participant population anticipated to be non-English speaking?
If the question is not applicable (e.g., chart or record review), please select "no."

○ Yes ⊙ **No**

2 → Old Value: yes

1. View Differences shows that question b on this page was changed. The **differences** bar shows that the old value was "None" or not selected. This means that the original version of the Update Study application had this question blank. However, the changed version shows the question marked as "Yes".

2. View Differences shows that question 7 on this page was changed. The **differences** bar shows that the old value was "Yes" and the changed version shows the question marked as "No".

View Differences: Adding Text to Text Boxes

9. **Study Purposes and Objectives:**
The objectives should be stated in such a way that the reader can determine the appropriateness of the study design. If appropriate, state the specific hypotheses being tested and/or study aims. Use lay language.

Recently, in conjunction with the community of Irgandi and the local health department, a community health worker program has been established to assist in village health care needs. This research project aims to conducting focus groups in to assess the community's perception of the health worker program and perceived and actual compliance among the community members. This focus group will also be used to assess health needs perceptions among community members.

Lastly, we will include members of the focus group in a training program for weighing and measuring children under the age of 5 who reside in the community.

We will consider using focus group results in a presentation to the health department for educational purposes.

1. View Differences shows that question 9 on this page was changed. This is a question with a text box for the answer. The **highlighting** shows that new text was added to the text box.

View Differences: Deleting Text in Text Boxes

10. Background and Introduction:
Identify the research area being studies and provide a review of the literature that provides the basis for understanding the objectives of the study. This review should be written such that scientists outside the investigator's area of expertise can understand the issues involved.

Any information about previous research related to this study involving animals and/or humans should be summarized. Include studies on pregnant animals if the research is conducted on pregnant women, fetuses, or neonates.

Recently, in conjunction with the community of Irgandi and the local health department, a community health worker program has been established to assist in village health care needs.

Recently, in conjunction with the community of Irgandi and the local health department, a community health worker program has been established to assist in village health care needs. ~~This research project aims to conducting focus groups in to assess the community's perception of the health worker program and perceived and actual compliance among the community members.~~ ~~This focus group will also be used to assess health needs perceptions among community members.~~

1. View Differences shows that question 10 on this page was changed. This is a question with a text box for the answer. The **differences** bar shows that new text was deleted from the text box, indicated by the strike-through text.

View Differences: Checkbox Questions

1. View Differences shows that question 1 on this page was changed. This is a question where you can select multiple options using checkboxes. The **differences** bar shows that three new checkbox options were selected/added, while one checkbox option was de-selected/removed.

2. This question also has a text box associated with it. The **differences** bar shows that new text was deleted from the text box, indicated by the strike-through text.

View Differences: Adding multiple entries to a list
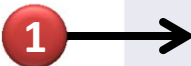
3. **Internal Staff and Sub-Investigator(s) (Within the University of Utah):**
*Internal Staff and Sub-Investigators have read-only access to the IRB applications and do not receive notifications from the ERICA system. Add persons here who **are responsible for the design, conduct, and reporting of research.***

HELP?

Name	Email	Training	Person Obtaining Consent
Lacy Clegg	lacy.clegg@hsc.utah.edu	3/28/2006 S	☑
Ammon Pate	ammon.pate@hsc.utah.edu	9/6/2007 SM	☐

Differences

Added: Lacy Clegg

Added: Ammon Pate

1. View Differences shows that question 3 on this page was changed. This is a question where you can add multiple entries. The **differences** bar shows that two new persons were added as internal staff and sub-investigators. This means that the original version of the Update Study application had this question blank. However, the changed version shows the question with two persons added.

View Differences: Changing Entries on a List

4. **Indicate other locations that are participating in the study for which you, as the PI, are responsible:**
This section must be completed if the University of Utah is the lead site of a multi-site study or if the University of Utah is acting as the Data Coordinating Center for other sites. Other locations may include: Other colleges or universities; Primary and secondary schools or school districts; other hospitals, clinics, or health care facilities; laboratories; businesses.

Click "Add" to complete information for each participating site. If this study does not have additional sites for which you are responsible, continue to question 5.
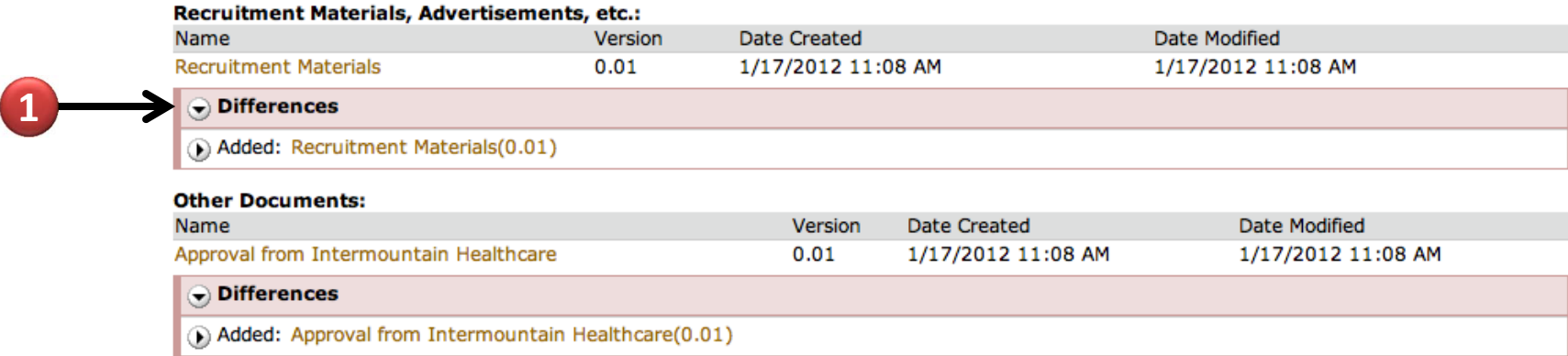
Site Name	Site Investigator	Investigator/Main Contact
View Irgandi, Kuna Yala, Panama	no	

Differences

Changed: Irgandi, Kuna Yala, Panama

Site Name	Site Investigator	Investigator/Main Contact
View Irgandi, Kuna Yala, Panama	no	

Differences

Changed: Irgandi, Kuna Yala, Panama

Location: Irgandi, Kuna Yala, Panama.b. Site Address	
New Value: 1234 Irgandi Way Kuna Yala, Panama	
Old Value: [None]	
Location: Irgandi, Kuna Yala, Panama.c. Site Phone	
New Value: 123-456-7890	
Old Value: [None]	
Location: Irgandi, Kuna Yala, Panama.d. Investigator	
New Value: no	
Old Value: [None]	

1. View Differences shows that question 4 on this page was changed. This is a question where you can add multiple entries and each entry has multiple fields for answers. The **differences** bar shows that an existing entry was changed.

2. By clicking the ⊙ icon next to the changed entry, a drop down list of all the changes to this entry will appear. The **highlighting** shows that new values/text were added to this entry.

View Differences: Attaching New/Revised Documents

Recruitment Materials, Advertisements, etc.:

Name	Version	Date Created	Date Modified
Recruitment Materials	0.01	1/17/2012 11:08 AM	1/17/2012 11:08 AM

1 → ▼ **Differences**

▶ Added: Recruitment Materials(0.01)

Other Documents:

Name	Version	Date Created	Date Modified
Approval from Intermountain Healthcare	0.01	1/17/2012 11:08 AM	1/17/2012 11:08 AM

▼ **Differences**

▶ Added: Approval from Intermountain Healthcare(0.01)

1. The **differences** bar shows that two new documents were added on the Documents and Attachments page.