Using the e-Version of the Protocol Summary

University of Utah IRB

Version: January 2012

What is the e-Version of the Protocol Summary?

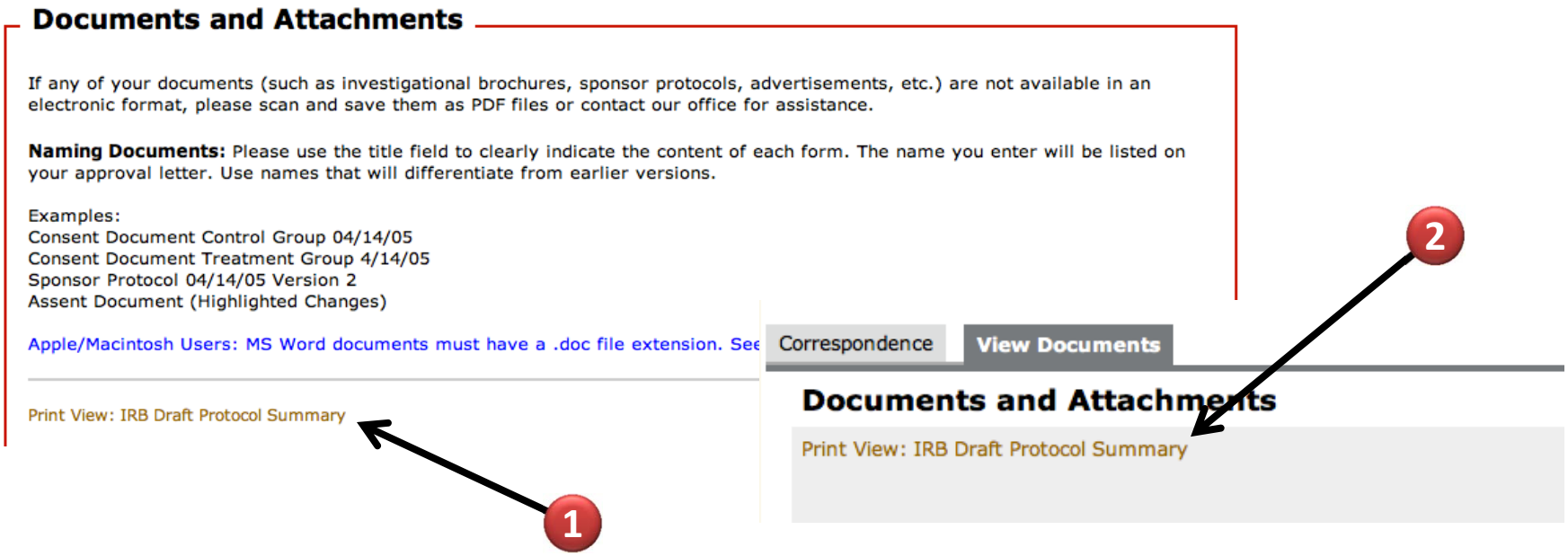
- Beginning January 2012, ERICA will create an up-to-date e-version of a protocol summary. This e-version is different than the protocol/research summary you uploaded in ERICA in the past.

- The e-version uses the answers you provide in your new study application to create a summary that you can view.

Sections in the e-Version

- A title page, with study title, investigator names, IRB approval date, and IRB number
- Background and Introduction
- Purpose and Objectives
- Study Population description, with age of participant and inclusion/exclusion criteria
- Design
- Study Procedures description, including recruitment, informed consent process, and procedures conducted with participants/data
- Statistical Methods, Data Analysis and Interpretation

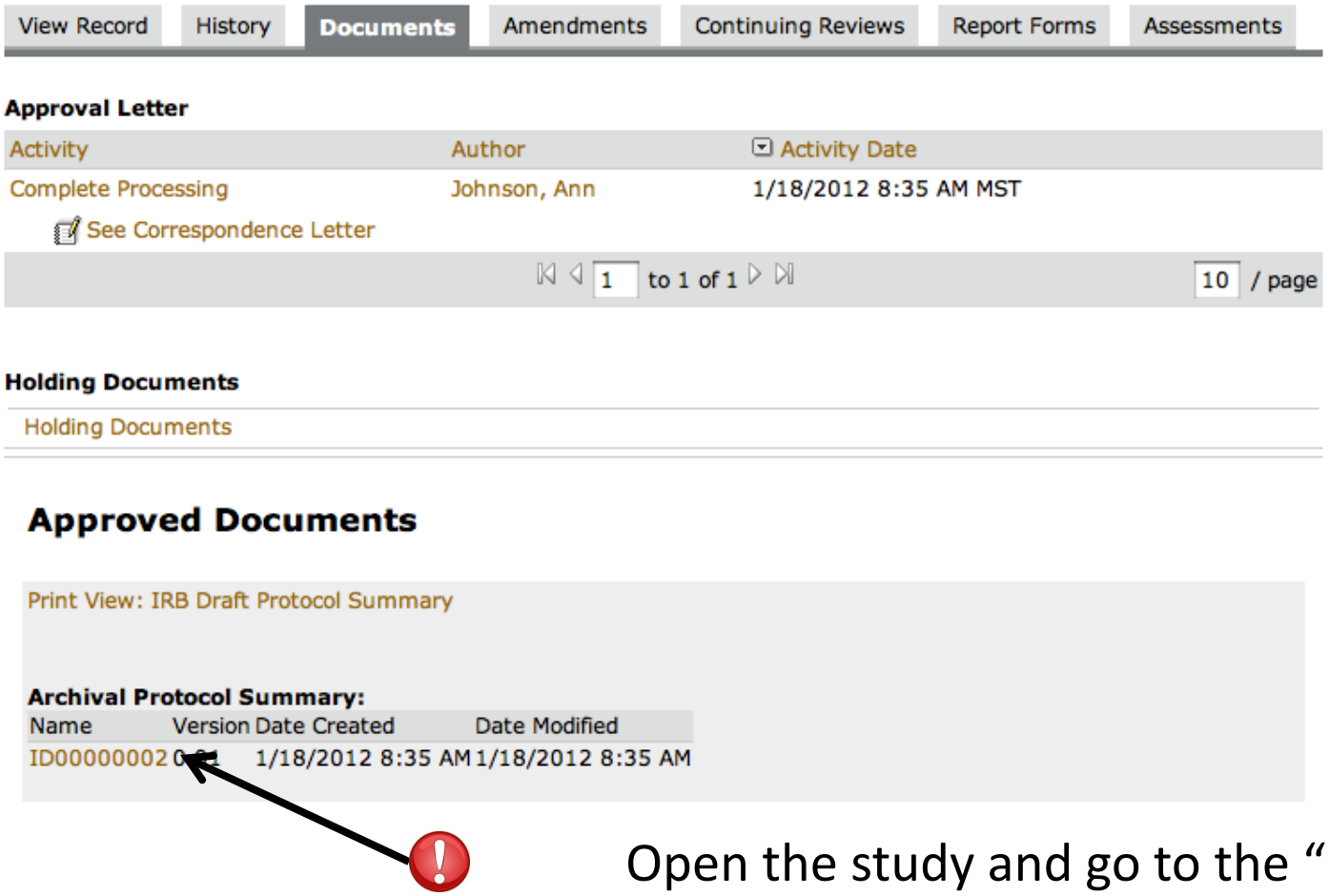
How to View the e-Version
<u>Before</u> Approval



OPTION 1: Open the application and go to the “Documents and Attachments” page

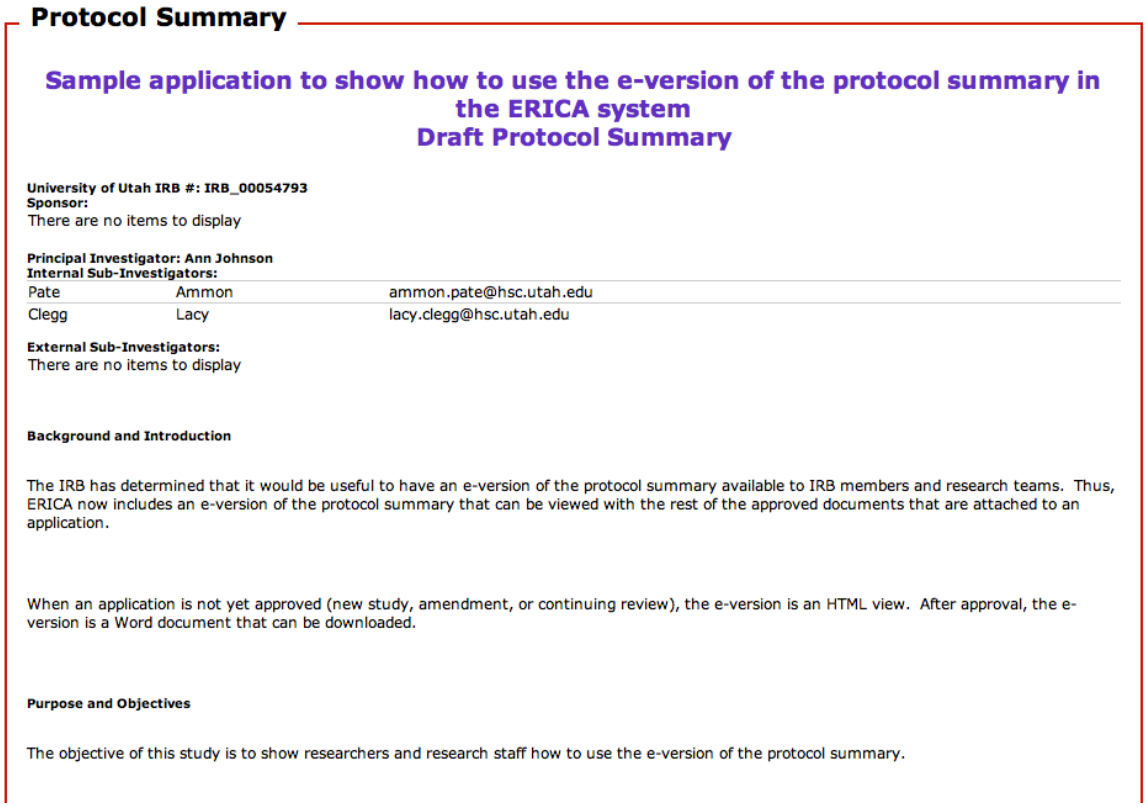
OPTION 2: Open the “Documents” tab on the application workspace

How to View the e-Version
<u>After</u> Approval



Open the study and go to the “Documents” page on the main workspace.

What the e-Version Looks Like <u>Before</u> Approval



Protocol Summary

Sample application to show how to use the e-version of the protocol summary in the ERICA system
Draft Protocol Summary

University of Utah IRB #: IRB_00054793
Sponsor:
There are no items to display

Principal Investigator: Ann Johnson
Internal Sub-Investigators:

Pate	Ammon	ammon.pate@hsc.utah.edu
Clegg	Lacy	lacy.clegg@hsc.utah.edu

External Sub-Investigators:
There are no items to display

Background and Introduction

The IRB has determined that it would be useful to have an e-version of the protocol summary available to IRB members and research teams. Thus, ERICA now includes an e-version of the protocol summary that can be viewed with the rest of the approved documents that are attached to an application.

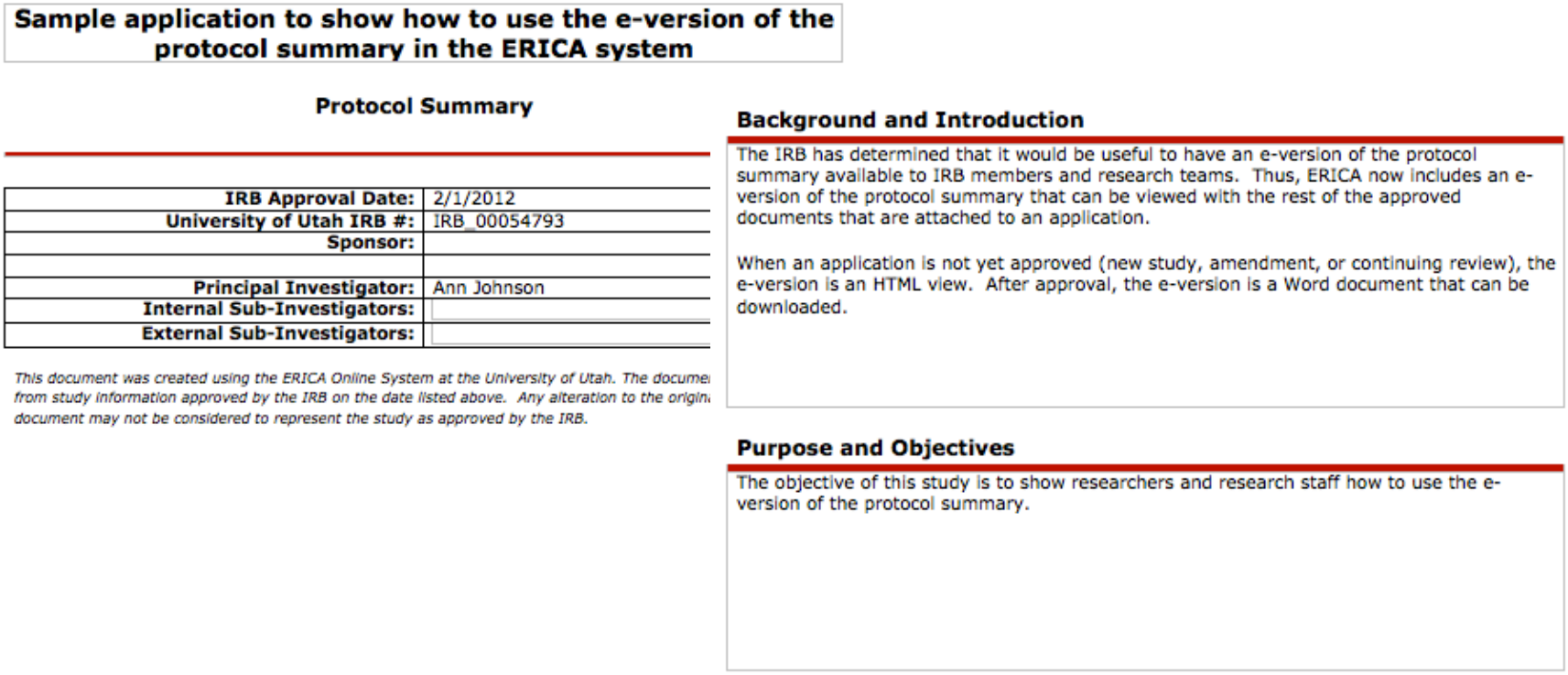
When an application is not yet approved (new study, amendment, or continuing review), the e-version is an HTML view. After approval, the e-version is a Word document that can be downloaded.

Purpose and Objectives

The objective of this study is to show researchers and research staff how to use the e-version of the protocol summary.

- If you access the e-version through an application that is not yet approved (new study, amendment, continuing review), the e-version is an HTML view.

What the e-Version Looks Like <u>After</u> Approval



Sample application to show how to use the e-version of the protocol summary in the ERICA system

Protocol Summary

IRB Approval Date:	2/1/2012
University of Utah IRB #:	IRB_00054793
Sponsor:	
Principal Investigator:	Ann Johnson
Internal Sub-Investigators:	
External Sub-Investigators:	

This document was created using the ERICA Online System at the University of Utah. The docume from study information approved by the IRB on the date listed above. Any alteration to the origin document may not be considered to represent the study as approved by the IRB.

Background and Introduction

The IRB has determined that it would be useful to have an e-version of the protocol summary available to IRB members and research teams. Thus, ERICA now includes an e-version of the protocol summary that can be viewed with the rest of the approved documents that are attached to an application.

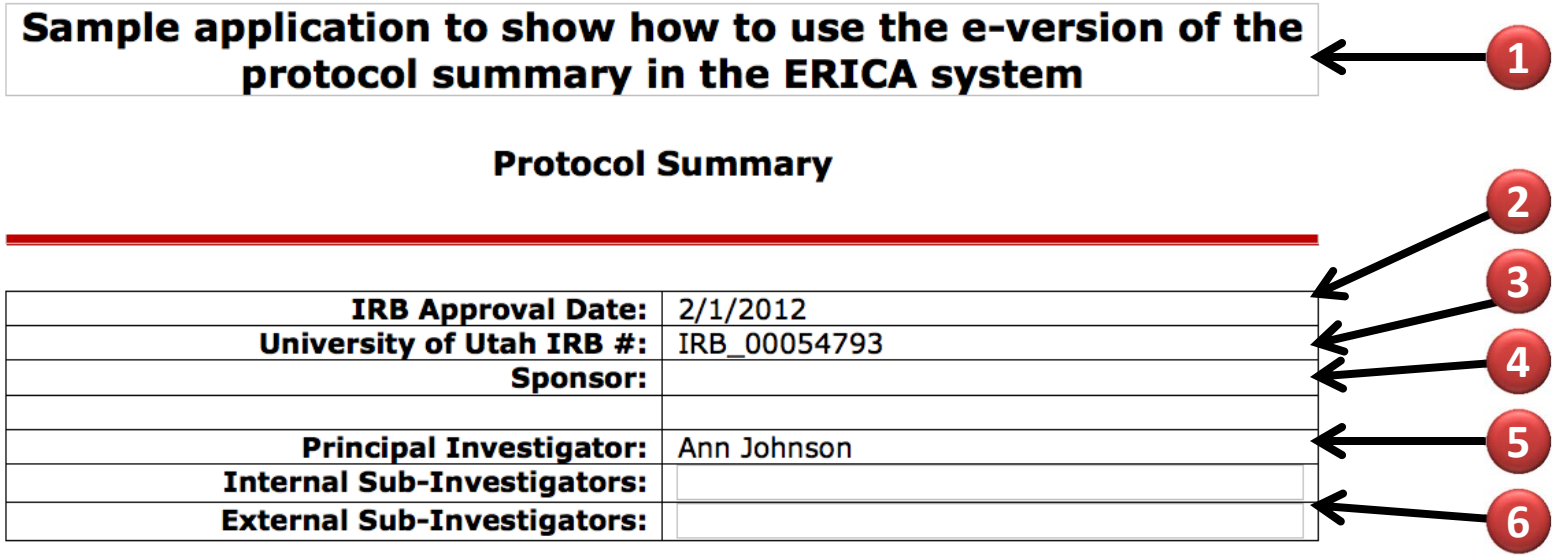
When an application is not yet approved (new study, amendment, or continuing review), the e-version is an HTML view. After approval, the e-version is a Word document that can be downloaded.

Purpose and Objectives

The objective of this study is to show researchers and research staff how to use the e-version of the protocol summary.

- If you access the “approved” version of the e-version, after an application is approved, the e-version is a Word document.

ERICA Application Fields Used in the e-Version



Sample application to show how to use the e-version of the protocol summary in the ERICA system

Protocol Summary

IRB Approval Date:	2/1/2012
University of Utah IRB #:	IRB_00054793
Sponsor:	
Principal Investigator:	Ann Johnson
Internal Sub-Investigators:	
External Sub-Investigators:	

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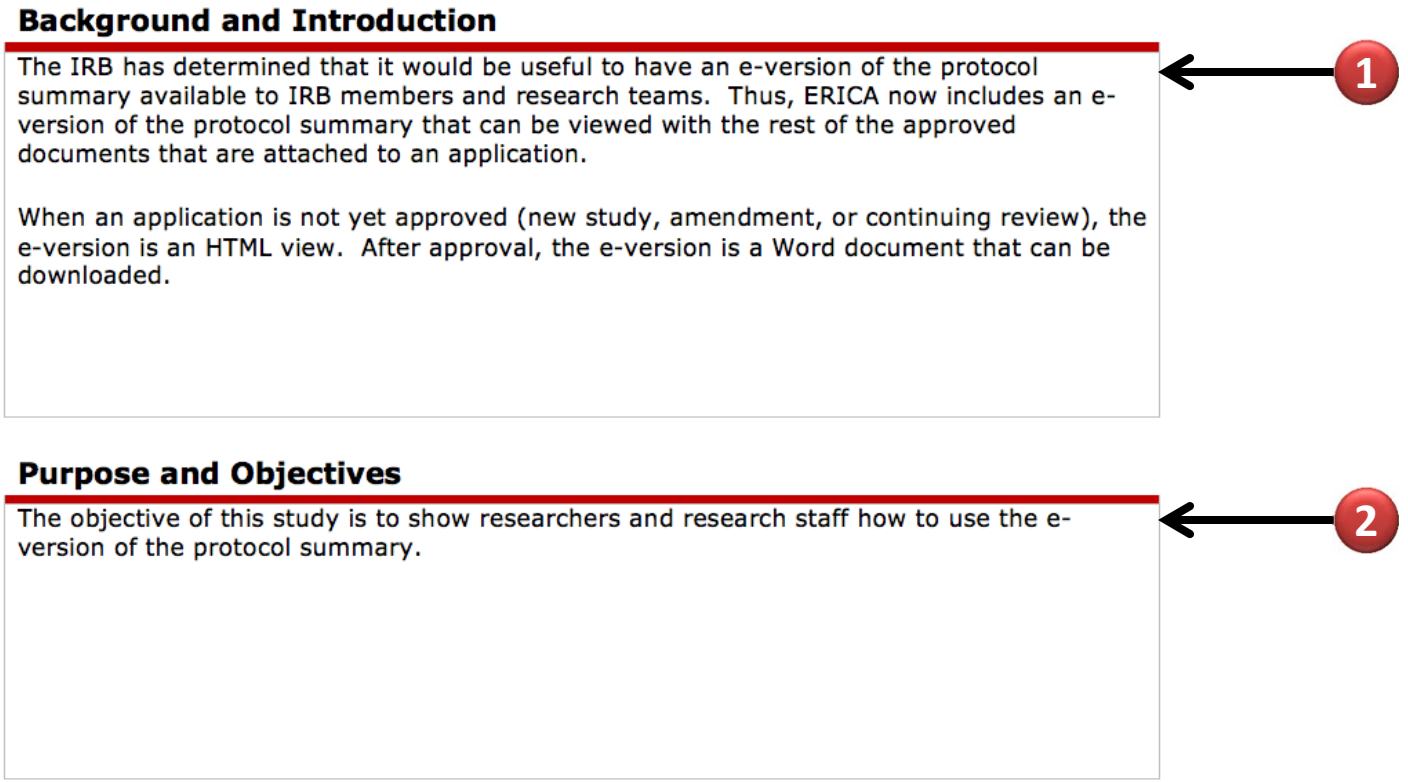
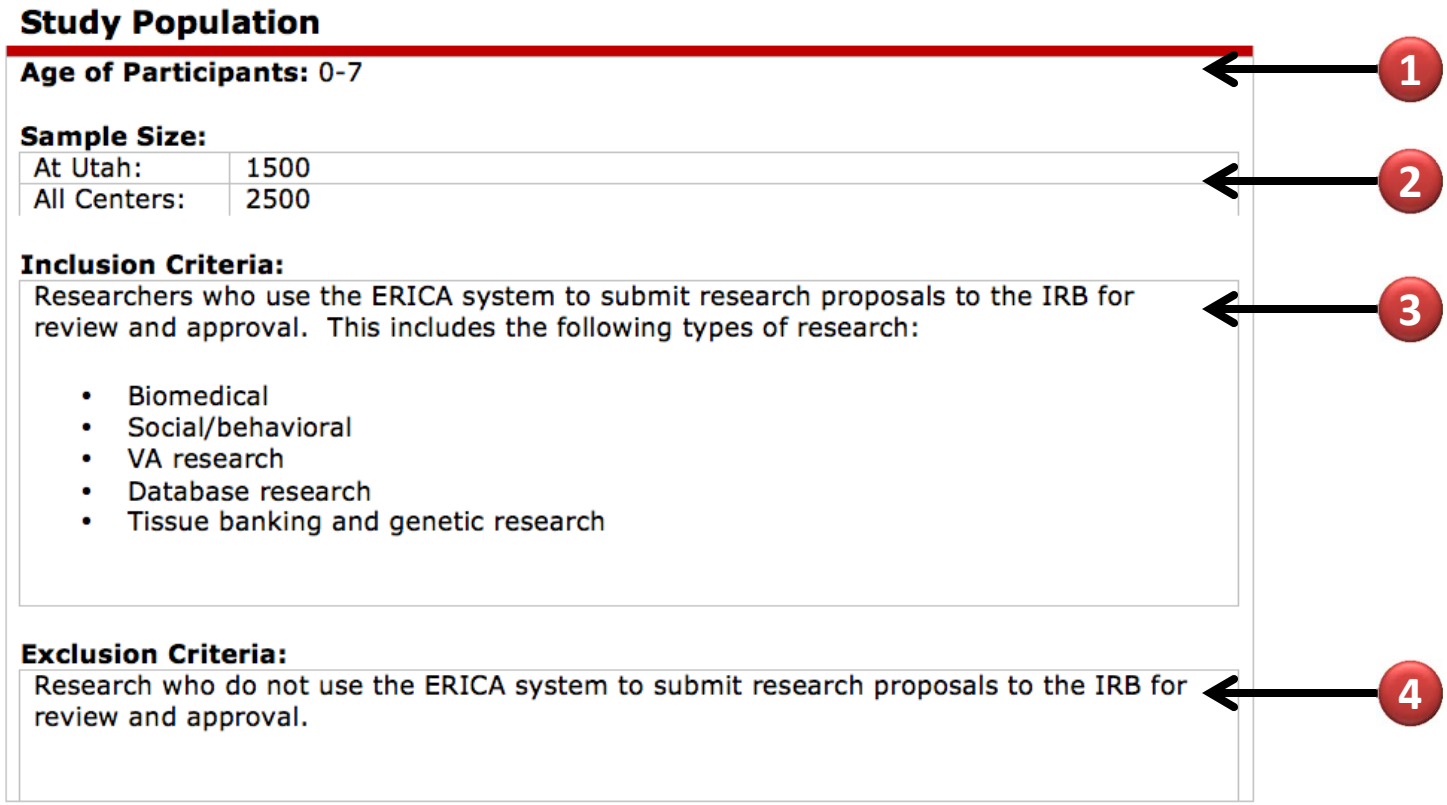
1. Title: Contacts and Title page, question 8
2. IRB Approval Date: Automatically entered based on your most recent approval.
3. IRB Number: Automatically entered based on your application.
4. Sponsor: Study Location and Sponsors page, question 5
5. Principal Investigator: Contacts and Title page, question 1
6. Sub-Investigators (internal and external): Contacts and Title page, questions 3 and 4

ERICA Application Fields Used in the e-Version



1. Background and Introduction: Contacts and Title Page, question 10
2. Purpose and Objectives: Contacts and Title Page, question 9

ERICA Application Fields Used in the e-Version



Study Population

Age of Participants: 0-7

Sample Size:

At Utah:	1500
All Centers:	2500

Inclusion Criteria:

Researchers who use the ERICA system to submit research proposals to the IRB for review and approval. This includes the following types of research:

- Biomedical
- Social/behavioral
- VA research
- Database research
- Tissue banking and genetic research

Exclusion Criteria:

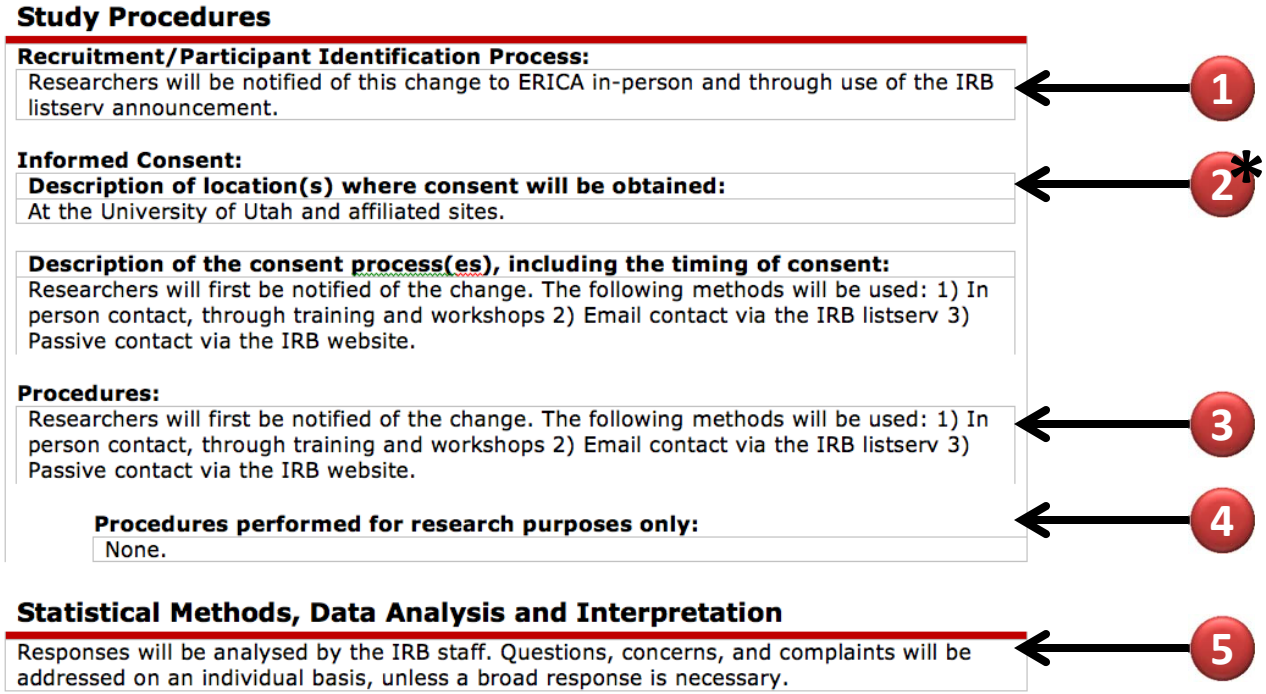
Research who do not use the ERICA system to submit research proposals to the IRB for review and approval.

1. Age of Participants: Participants page, question 2
2. Sample size: Participants page, question 4
3. Inclusion Criteria: Participants page, question 5
4. Exclusion Criteria: Participants page, question 6

ERICA Application Fields Used in the e-Version

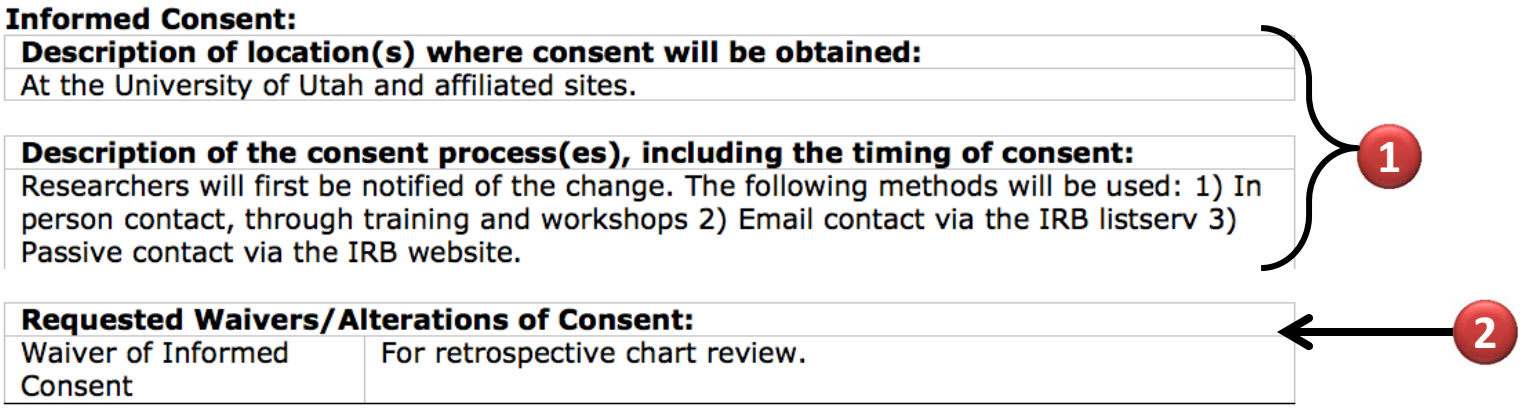
1. Design: Study Information page, question 1

ERICA Application Fields Used in the e-Version



1. Recruitment/Participant Identification Process: Study Information page, question 4b
2. Informed Consent*: See the next slide
3. Procedures: Study Information page, question 6
4. Procedures performed for research purposes only: Study Information page, question 7
5. Statistical Methods, Data Analysis, and Interpretation: Study Information page, question 9

ERICA Application Fields Used in the e-Version



Informed Consent:

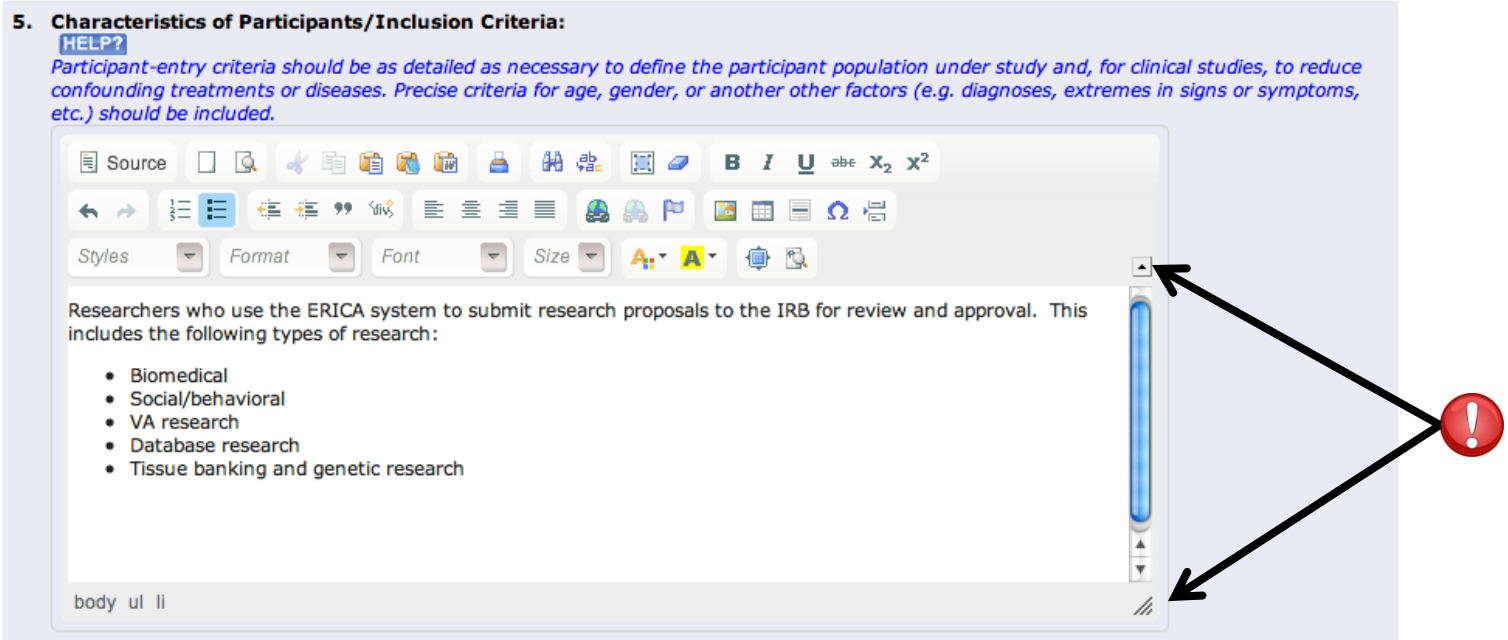
Description of location(s) where consent will be obtained:
At the University of Utah and affiliated sites.

Description of the consent process(es), including the timing of consent:
Researchers will first be notified of the change. The following methods will be used: 1) In person contact, through training and workshops 2) Email contact via the IRB listserv 3) Passive contact via the IRB website.

Requested Waivers/Alterations of Consent:	
Waiver of Informed Consent	For retrospective chart review.

1. If your application indicates that you have a consent process to obtain consent, the following sections will appear in the e-version:
   - Description of location(s) where consent will be obtained: Consent Process page, question 2
   - Description of the consent process(es), including the timing of consent: Consent Process page, question 3
2. If your application indicates that you have a waiver/alteration of consent, the following section will appear, including the full list of waivers/alterations that are approved for your study:
   - Requested Waivers/Alterations of Consent: Request for Waiver or Alteration of Consent page, questions 1 and 2 (in the pop-up window)

New Features with Text Boxes



- Many of the text boxes throughout the application are now formatting-capable. This means that you can format the text much like you would in Microsoft Word. For example, you can add bullets, numbering, bolded text, underlining, etc. Formatting-capable text boxes are distinguishable by the icon in the upper right corner of the text box. By clicking on this icon, a menu of formatting options will appear.
- Most of the text boxes in the application are resizable, allowing you to see more of the text without scrolling inside the text box. This is useful for viewing large amounts of text entered into a text box. To resize a text box, click and drag the icon in the lower right corner of the text box.

Frequently Asked Questions

- How do I change the information in the HTML e-version?
  - In order to change the text of the HTML e-version, you must change the text in the application. Use this tutorial to identify the application questions that correspond to the e-version sections.

- How do I change the information in the Word e-version?
  - Because this is a Word document, there are two ways to change the text:
    1. Change the text in the application, which would require an amendment application.
    2. Change the text directly on the Word document. Any direct alteration to the original content of the Word document may not be considered to represent the study as approved by the IRB. In order for your changes to be considered for IRB approval, you must submit an amendment application.

Frequently Asked Questions

- Can I edit the Word e-version directly once the study is approved?
  - Yes. However, any direct alteration to the original content of the Word document may not be considered to represent the study as approved by the IRB. In order for your changes to be considered for IRB approval, you must submit an amendment application.
- Is the Word e-version an approved document?
  - The Word e-version is not an official approved document; however, the information in the e-version is considered approved as part of your application. Because of this, it is not required that you maintain a copy of the e-version in your regulatory binders.
- Why are there blank fields in the Word e-version?
  - Because every study does not have applicable information for some questions in ERICA, there will occasionally be blank fields in the e-version. You may download a copy of the Word e-version and delete the blank fields if you are disseminating the e-version to others.

Frequently Asked Questions

- Why is there an HTML e-version and a Word e-version of the protocol summary?
  - The HTML e-version is used before a study is approved, as the study must go through many different states before approval. The HTML e-version requires less processing during these state changes, so ERICA will run more quickly.

    The Word e-version is a more formal document that can be easily downloaded, printed, and disseminated. However, it is only available after the study is approved.

- What is the e-version of the protocol summary used for?
  - The e-version was primarily designed to help research reviewers who use the ERICA system. The e-version provides a convenient summary so that reviewers can quickly view and understand the study without having to view the full application.

    The e-version may also be used by researchers in a variety of circumstances. Researchers are encouraged to use the e-version as appropriate for the conduct of their research.