

# Continuing Review Application Tutorial





*This tutorial is intended to provide you with more in-depth and practical assistance as you complete your **Continuing Review Application.***

# Introduction

The application includes help text (in **blue** font) throughout, and there are also several sections with pop-up guidance (designated by the icon). **Help?**

This tutorial is intended to provide you with more in-depth and practical assistance as you complete your Continuing Review Application.

-  Frequently-asked questions and their answers will be designated by this icon.
-  Questions or sections that are brand-new with this update are marked by this icon.

Additional questions or comments about the application or this tutorial should be directed to the IRB in writing at [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu).

# Create a Continuing Review Application

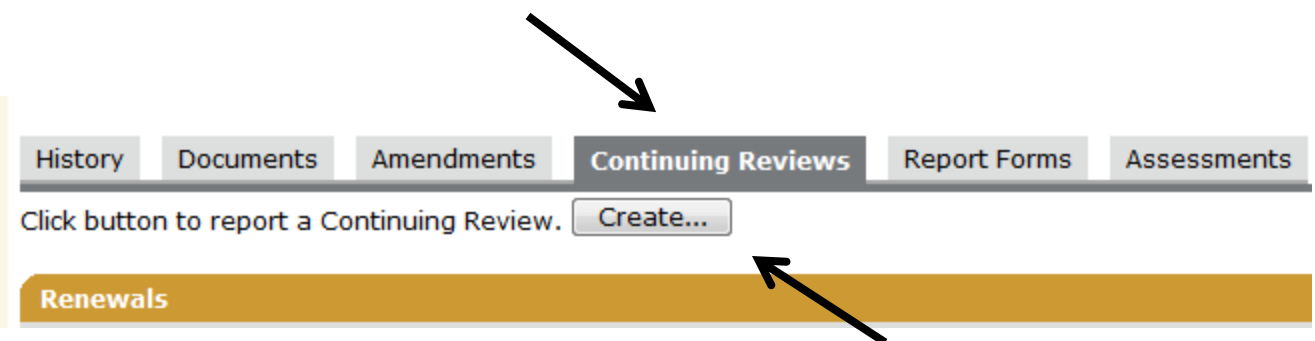
1) Log into ERICA.



2) On the “IRB Studies” tab, click on the study title you want to create a Continuing Review for.



3) On the “Continuing Reviews” tab, click on “Create...”.



# Status Page

## 1. Status

1. Is the study permanently closed to the enrollment of new participants?

Yes  No [Clear](#)

If yes, answer the following questions:

a. Are you continuing to or planning to perform interventions (e.g., tests, physical or psychological exams, administer medications or treatments) on subjects in order to gather data about them?

Yes  No [Clear](#)

b. Are you continuing to or planning to interact with any subjects (e.g., letters, phone calls, interviews or re-contact participants) in order to gather data about them?

Yes  No [Clear](#)

c. Are you continuing to or planning to gather any private identifiable information about subjects (e.g., chart reviews, receipt of information from health care entities)?

Yes  No [Clear](#)

d. Does your study have a sponsor/monitor who still needs to conduct their official close-out visit and who may require access to patient's records or contact with a participant?

Yes  No [Clear](#)

e. Are you continuing to or planning to analyze the data for this study?

Yes  No [Clear](#)

If yes, does your study data contain participant identifiers or a link/code to identify study participants?

Select "no" if de-identified data has been sent to a sponsor, data coordinating center, or other entity for analysis and no additional analysis will occur at this site.

[HELP?](#)

Yes  No [Clear](#)

1. Indicate if the study is **permanently** closed to new participants. If it is *not* you do not need to complete sections a-e.
  - If you can select "Yes" to question 1, and "No" to sub-questions a-e, then your study can be closed.
  - If you would like to submit a final project report for the study, you would no longer be able to access participant data or records and would no longer be able to contact them for research purposes. If the study is closed, a New Study Application would be required to access participant data or records and to contact research participants.

## Progress of Study and Enrollment Information

### 2. Progress of Study and Enrollment Information

1. Will consent forms be used to consent or re-consent participants after this application is approved?

Yes  No [Clear](#)

*If yes, attach a copy of each consent form to the Update Study Application. Each consent document must be on a blank watermark template, to allow for a new approval stamp and expiration date.*

Question 1. This question should read Yes if:

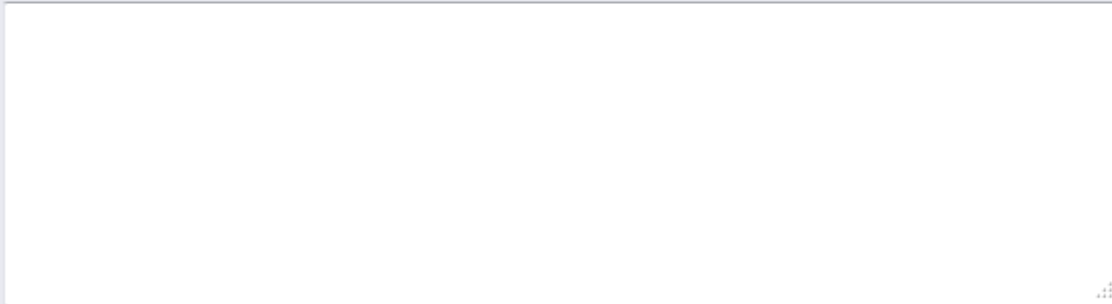
- Consent Documents have been used in the past.
- The study team is going to continue enrolling new participants with Consent Documents in the future. And/or
- The study team will need to re-consent participants for some reason.  
If the study team is re-consenting participants this needs to be explained somewhere in the Continuing Review Application.

\*If the study team answers Yes to this question they need to attach the Consent Document with a clean footer so it can be stamped with a new approval date. This is done back on the main page through clicking on the “Update Study” button.

**2. Describe the progress of the study, observations of the participants studied, and reason (s) for continuing the study:**

A large, empty rectangular text input field with a light gray border and a small grid icon in the bottom right corner.

**3. What results (preliminary or final) have been obtained from the study? If the study is part of a multi-center trial, this should be stated and any available results provided. If there are no results that are appropriate to report to the IRB at this time, this should be stated and explained:**

A large, empty rectangular text input field with a light gray border and a small grid icon in the bottom right corner.

**Please attach any abstracts or publications:**

Add

Name	Version	Date Created	Date Modified
There are no items to display			

Question 2 is a good space to provide more detail of the progress of the study and Question 3 should document results that have been obtained from the study thus far.

4. Enrollment Information

	At Utah Total	All Centers Total
Originally Approved	1000	
Currently Approved	1000	

← Currently approved enrollment numbers

Please complete the following chart carefully as incomplete or erroneous information may lead to a delay in the processing of this application.

	At Utah (all sites for which you are responsible)			All Centers Total
	Male	Female	Total	
Number enrolled since last IRB approval				
Number enrolled since the study began				

*In order to enroll a greater number of participants than originally stated, by regulation you **must** submit an amendment in section 4.2 requesting an increase in enrollment. **This amendment must be approved BEFORE more enrollees are entered into the study.***

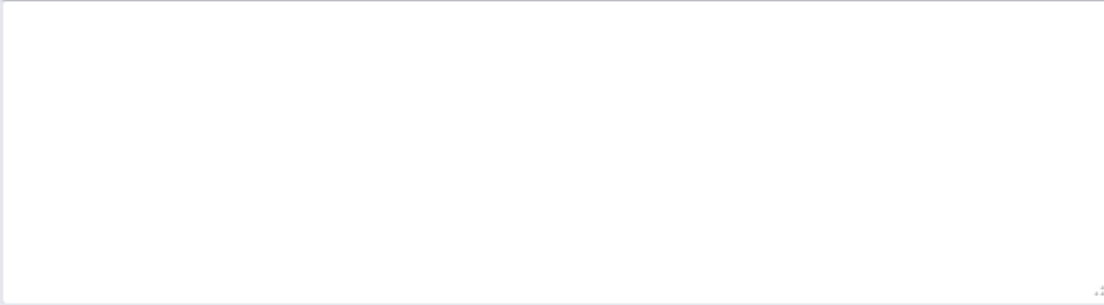
Question 4. This table describes the enrollment from the past year and from the lifetime of the study.

The blue section is for this site only or all of the participants who have been enrolled under the Principal Investigator that is listed on this application. The purple Section is the entire study. If there is only one site the Totals should be the same for the blue box and the purple box.

The bottom row is the entire enrollment from the beginning of the study. The row above that is enrollment in the past year.

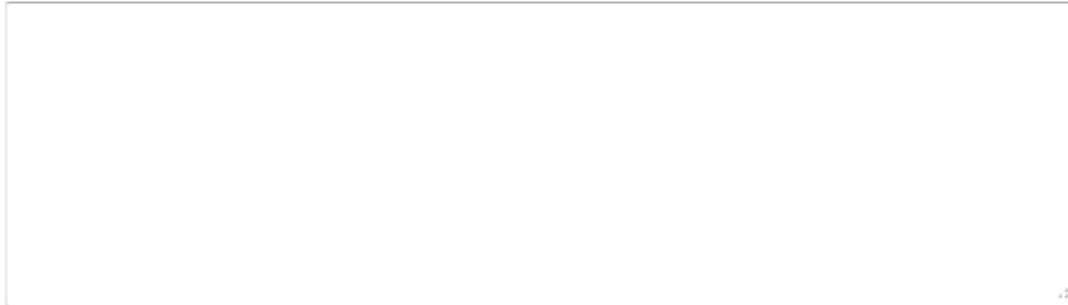
The numbers in the plain box above the colored box is what the study team is currently approved to enroll. If the number of those enrolled presently exceeds that number the study is over-accrued. During the review process, enrollment numbers are used to validate statistical analysis, justify procedures, and assess the risk/benefit ratio and other considerations. In order to enroll a greater number of participants than originally stated, by regulation you must submit an amendment requesting an increase in enrollment (even if the study team is accessing charts instead of consenting individuals face-to-face). If you over-enrolled the study team needs to submit a report form to document the protocol deviation.

**5. Describe participant enrollment and its effect on the study design and scientific merit. If under-accrued, describe any plans for increasing enrollment during the next approval period. If a multicenter trial, also discuss enrollment at other sites.**



**6. How many participants withdrew from the study at your sites since last approval?**

**a. What were the reasons for their withdrawal?**



Question 5: This is where the study team can discuss enrollment and in particular plans to increase enrollment if the study is experiencing low enrollment. If the study team feels that enrollment is low but expected this should be documented here.

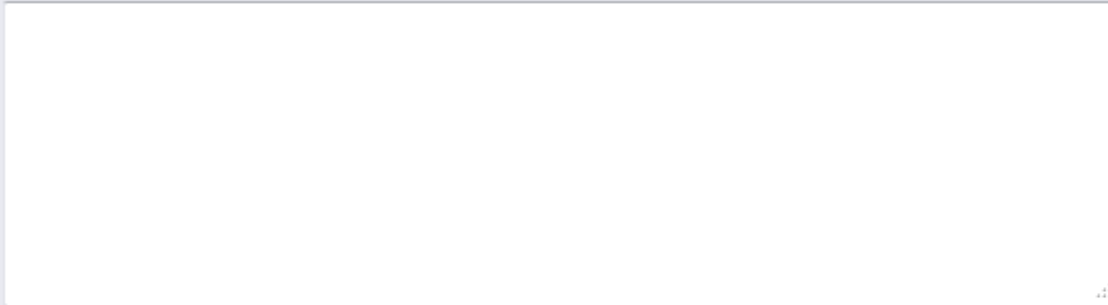
If the study design has multiple types of participants this is a good place to discuss in more detail the enrollment progress of the different enrollees. For example, if you have completed an arm or group of participants and no longer need to use a consent document for this group you should document this here.



# Events

## 3. Events

1. Provide narrative summary of any available information regarding adverse events which have occurred since the last IRB review.



**Adverse event definition** = Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).

**What is the IRB looking for in the narrative summary?** = In many cases, such a summary could be a simple brief statement that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure.

**What if my study is behavioral science research?** = Adverse events are rare in behavioral science research. If there have not been any adverse events, a simple statement that there have been no adverse events is acceptable.

Question 1. For this question the study team should provide a summary of the adverse events that have happened in the last review period even if they have been previously reported to the IRB.

There is always the possibility of an adverse event even if it is just a survey or chart review. NA or Not Applicable are not appropriate answers and the help text in blue provides examples of what are appropriate answers.

2. Have any additional risks to participation in this study been identified (from any site or other relevant source) since last approval? If reports or amendments identifying additional risks have been submitted since last approval, please mark "yes".

Yes  No [Clear](#)

a. If yes, please provide a description of the additional risks, explain how the risk-benefit ratio of the study is affected, and state whether the risks have been added to the consent form.

3. Have any unanticipated problems involving risks to participants or others occurred since the last IRB review?

[HELP?](#)

Yes  No [Clear](#)

[Information on Unanticipated Problems.](#)

a. If yes, please describe the unanticipated problems and explain how they affect the risk-benefit ratio of the study, and whether the unanticipated problems should be added to the consent form(s).

4. Have there been any complaints about the research since the last IRB review?

Yes  No [Clear](#)

a. If yes, please provide a summary of these complaints and action(s) taken to resolve them.

5. Have all unanticipated problems and events been reported as required by University of Utah IRB policy?

Yes  
 No  
[Clear](#)

*If no, please submit a report for these events and problems immediately.*

The rest of the questions found on the Events page ask for more information regarding risks, unanticipated problems, and complaints.

# Safety Monitoring



## 4. Safety Monitoring

**The currently approved safety monitoring plan includes the following elements:**

**Type of reports produced:**

Interim analysis

**Frequency of safety monitoring:**

Monthly

**1. Describe the findings identified since last IRB review through the conduct of the safety monitoring plan (i.e. safety findings, study progress, interim analysis, etc.):**

The Safety Monitoring page only generates if you have indicated in the main application that your study has a safety monitoring plan. The “Type of reports produced” and “Frequency of safety monitoring” information is pulled from the main application. The response provided in Question 1 should match this information.

A safety monitoring plan outlines the specific parameters for ensuring the safety of participants/patients throughout the study. This may include monitoring medical outcomes, exclusion criteria, and adverse events. If the study is in fact not monitoring these things the Update Study Application (Page 4, Question 8) needs to be updated and an amendment added to the Continuing Review Application documenting why the study team is changing the response.

**2. Attach the most recent safety monitoring report (such as a DSMB report), collected safety data, or other interim reports since last IRB review.**

*All safety monitoring reports must be submitted to the IRB via the Report Form upon their receipt. Attach only the most recent safety monitoring report here.*

Add

Name	Version	Date Created	Date Modified
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There are no items to display

If the study team indicates in Question 1 of this page that the sponsor has said that the study should continue as planned, some documentation of this correspondence should be attached to Question 2. If no formal document was created such as a DSMB report the study team should attach some documentation of the sponsor indicating this even if it is an email correspondence from the sponsor or DSMB.

# Amendments

## 5. Amendments

A list of amendments associated with this study since the last approval date.

Name	Date Submitted	IRB #
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1. Are there any changes to be made now? (Including scientific design, procedures, participant population, or any minor changes.)

Yes  No [Clear](#)

If the study team needs to make any changes to the study application at the same time that they need to submit a Continuing Review Application they can submit an amendment as part of the Continuing Review Application. Just select “Yes” on this page and it will generate the Amendment Application as a part of this application.

\*If you need help with the amendment application please see the Amendment Application Tutorial.

# Report Forms

## 6. Report Forms

*These are "Read Only" copies of the report forms since the last approval date.*

Name	Date Submitted	IRB #
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This page lists all of the report forms that the study team have submitted since the last approval date. The study team does not need to do anything on this page.

# Documents and Attachments

## 7. Documents and Attachments

These are "Read Only" copies of the approved and revised documents.  
Please use the "Update Study" portion of the application to attach any revised documents.

**Approved eProtocol Summary:**

Name	Version	Date Created	Date Modified
ID00000002	0.01	4/4/2013 10:35 AM	4/4/2013 10:35 AM

[Print View: IRB Draft Protocol Summary](#) ← Draft version of the Protocol Summary generated by ERICA.

**Updated eProtocol Summary:**

Name	Version	Date Created	Date Modified
There are no items to display			

**Approved Consent Forms:**

Name	Version	Date Created	Date Modified
Colonna ConsentandAuthorizationCoverLetter corrected revision - Clean Copy.docx	0.01	3/1/2013 1:20 PM	3/1/2013 1:20 PM

**Updated Consent Forms:**

Name	Version	Date Created	Date Modified
There are no items to display			

This last page displays all of the documents that have been attached and approved previously as well as the documents that have been uploaded as part of the Continuing Review Application.

The only documents that should be re-uploaded at continuing review are documents that have been stamped with an expiration date and are still being used (Consent Documents, Cover Letters, EDW request forms, etc) and documents that are being modified or added. If a document is being modified please attach both a tracked copy of the document and a "clean" copy of the document.

\*In order to add documents to the Continuing Review Application the study team needs to go to the Update Study Application to add documents.

\*The IRB is no longer requesting Research/Protocol Summaries but now one is generated by ERICA using the responses found in the application. As the study team works on an application the draft of the protocol can be accessed through clicking on the Print View: IRB Draft Protocol Summary link. After the study is approved a final eProtocol Summary will be generated and stored under the Documents tab.

# Instructions and Finish

## 8. Instructions and Finish

1. To view errors in this application, select the "Hide/Show Errors" option at the top or bottom of the page. If you have errors on your application, you won't be able to submit it to the IRB.

### Changes to the Update Study Application

2. Be sure to make all proposed changes to the Update Study portion of the application by selecting the "Update Study" button located on the left side of the amendment or continuing review workspace, which will be available once you select the "Finish" button at the top or bottom of this page.
3. To attach updated or new documents with this application, you may access the Documents and Attachments page in the Update Study application.
4. If you are proposing changes to any ancillary applications (i.e. RDRC-HUS or RGE), you must access these applications through the Update Study application on the Ancillary Applications page. All changes to ancillary applications must be approved by the corresponding committee prior to IRB approval of the amendment.

### Submitting the Completed Continuing Review Application

5. Selecting the "Finish" button alone will NOT submit the application to the IRB. You MUST also select the "Submit" option on the workspace after you've selected the "Finish" button. Only the PI can submit the application to the IRB.
6. If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.