Amendment Application

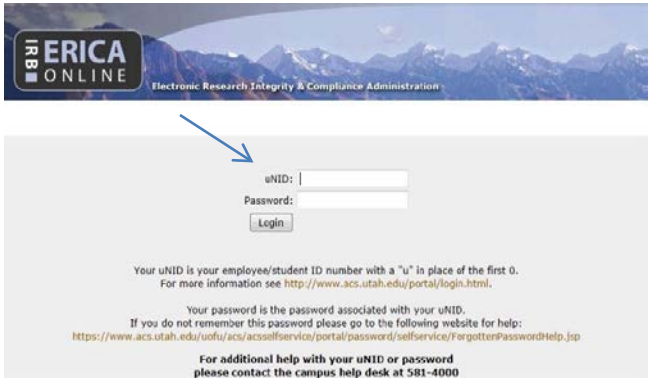
Tutorial

Introduction

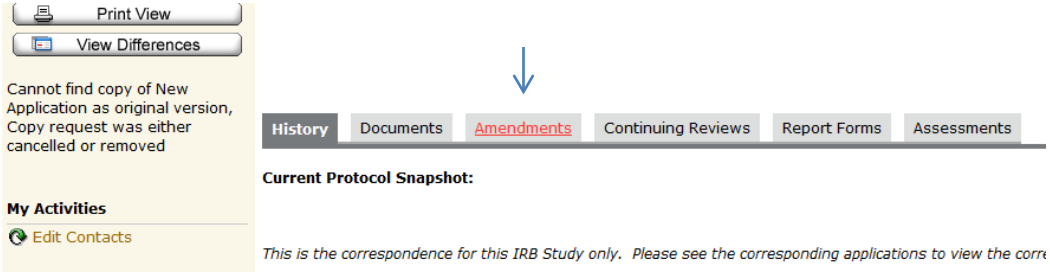
- The Amendment Application is used to make any necessary changes to a study between annual reviews of an application.
- The application includes help text (in blue font) throughout, and there are also several sections with pop-up guidance (designated by the icon).
- This tutorial is intended to provide you with more in-depth and practical assistance as you complete your Amendment Application.
- Additional questions or comments about the application or this tutorial should be directed to the IRB in writing at irb@hsc.utah.edu.

Create an Amendment Application

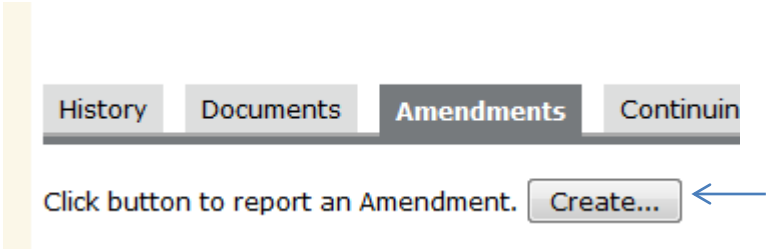
1) Log into ERICA.
2) Select the study for which you are creating the Amendment.



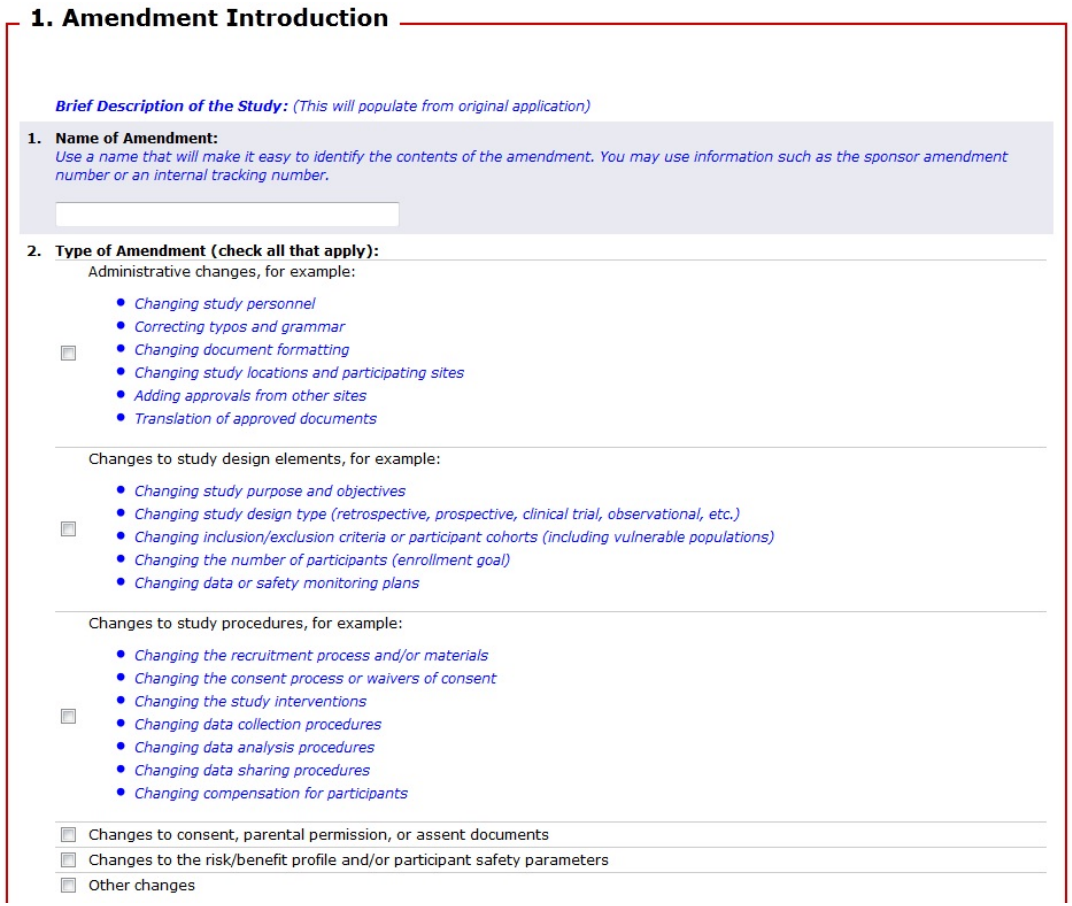
3) Click on the Amendments tab.



4) Click the button to create an Amendment.



Filling out the Amendment Application – Amendment Introduction



1. Amendment Introduction

Brief Description of the Study: *(This will populate from original application)*

1. **Name of Amendment:**
Use a name that will make it easy to identify the contents of the amendment. You may use information such as the sponsor amendment number or an internal tracking number.

2. **Type of Amendment (check all that apply):**

Administrative changes, for example:

- *Changing study personnel*
- *Correcting typos and grammar*
- *Changing document formatting*
- *Changing study locations and participating sites*
- *Adding approvals from other sites*
- *Translation of approved documents*

Changes to study design elements, for example:

- *Changing study purpose and objectives*
- *Changing study design type (retrospective, prospective, clinical trial, observational, etc.)*
- *Changing inclusion/exclusion criteria or participant cohorts (including vulnerable populations)*
- *Changing the number of participants (enrollment goal)*
- *Changing data or safety monitoring plans*

Changes to study procedures, for example:

- *Changing the recruitment process and/or materials*
- *Changing the consent process or waivers of consent*
- *Changing the study interventions*
- *Changing data collection procedures*
- *Changing data analysis procedures*
- *Changing data sharing procedures*
- *Changing compensation for participants*

Changes to consent, parental permission, or assent documents

Changes to the risk/benefit profile and/or participant safety parameters

Other changes

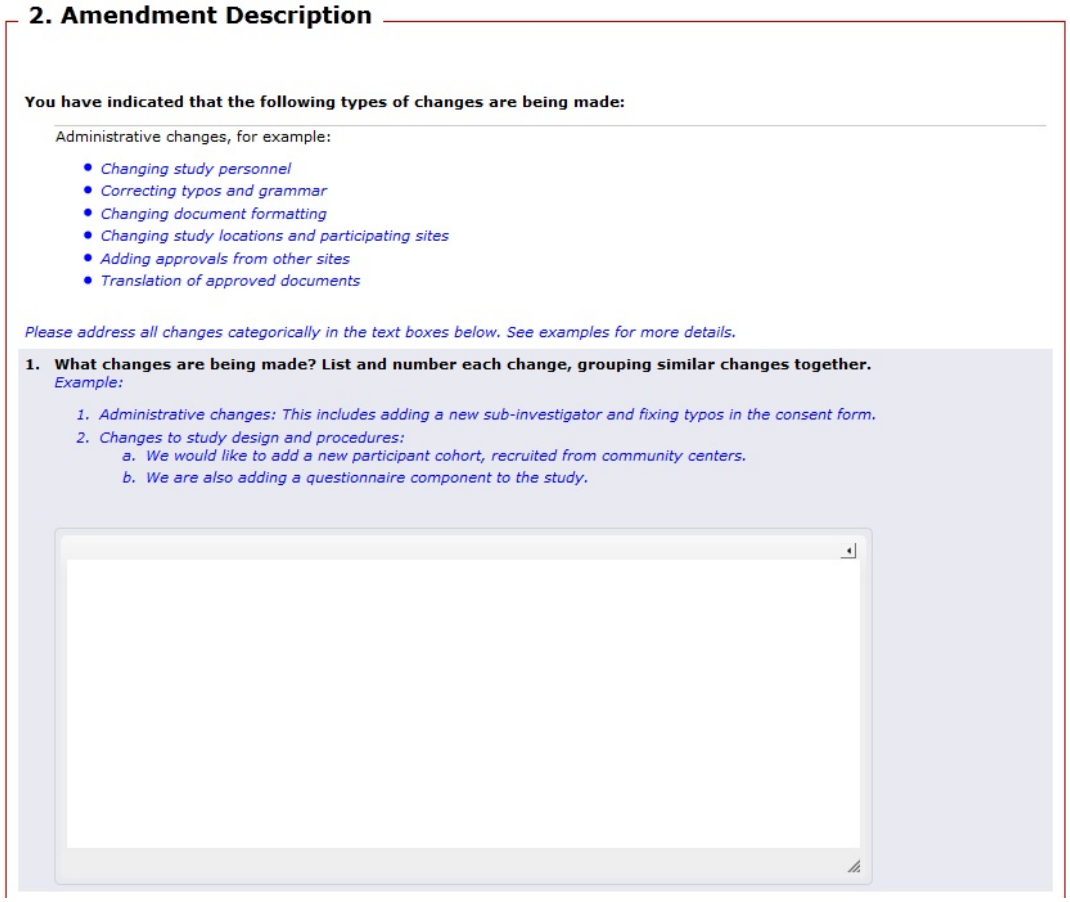
1) (Name of Amendment) Select a name that best describes the Amendment's purpose.
   a) Use a short, brief description that will be helpful for both you and the IRB reviewer to identify what is being changed.
   b) Examples: "IB Update" or "Adding Co-investigator"
   c) If this section is not filled out, it remains unnamed and can be confusing both for the reviewer and for future compliance purposes when identifying what was changed with each amendment associated with a particular study.
2) (Type of Amendment) Select one or more box(es) to best designate what type of changes are being made.

Filling out the Amendment Application – Amendment Introduction (continued)

3) (Current Status of the Study) Choose one option that states if the study is still enrolling participants, if it is permanently closed to enrollment, or if enrollment has been suspended for the time being.

4) (Total Number of Participants Enrolled To Date)
   a) Remember—Data *about* people are still considered "human subjects" by the IRB, so even if you have not contacted the patients whose charts you have reviewed, you still should enter the number of charts as your "participants."
   b) "At Utah" generally means participants who are recruited from or enrolled at University of Utah sites, or it can also refer to participants the University of Utah IRB is responsible for protecting.
   c) If your study is **not** multi-center, the "All Centers" total should match the "At Utah" total.
   d) If the study **is** multicenter, the "All Centers" total should be greater than the "At Utah" total.

Filling out the Amendment Application – Amendment Description



2. Amendment Description

You have indicated that the following types of changes are being made:

Administrative changes, for example:

- *Changing study personnel*
- *Correcting typos and grammar*
- *Changing document formatting*
- *Changing study locations and participating sites*
- *Adding approvals from other sites*
- *Translation of approved documents*

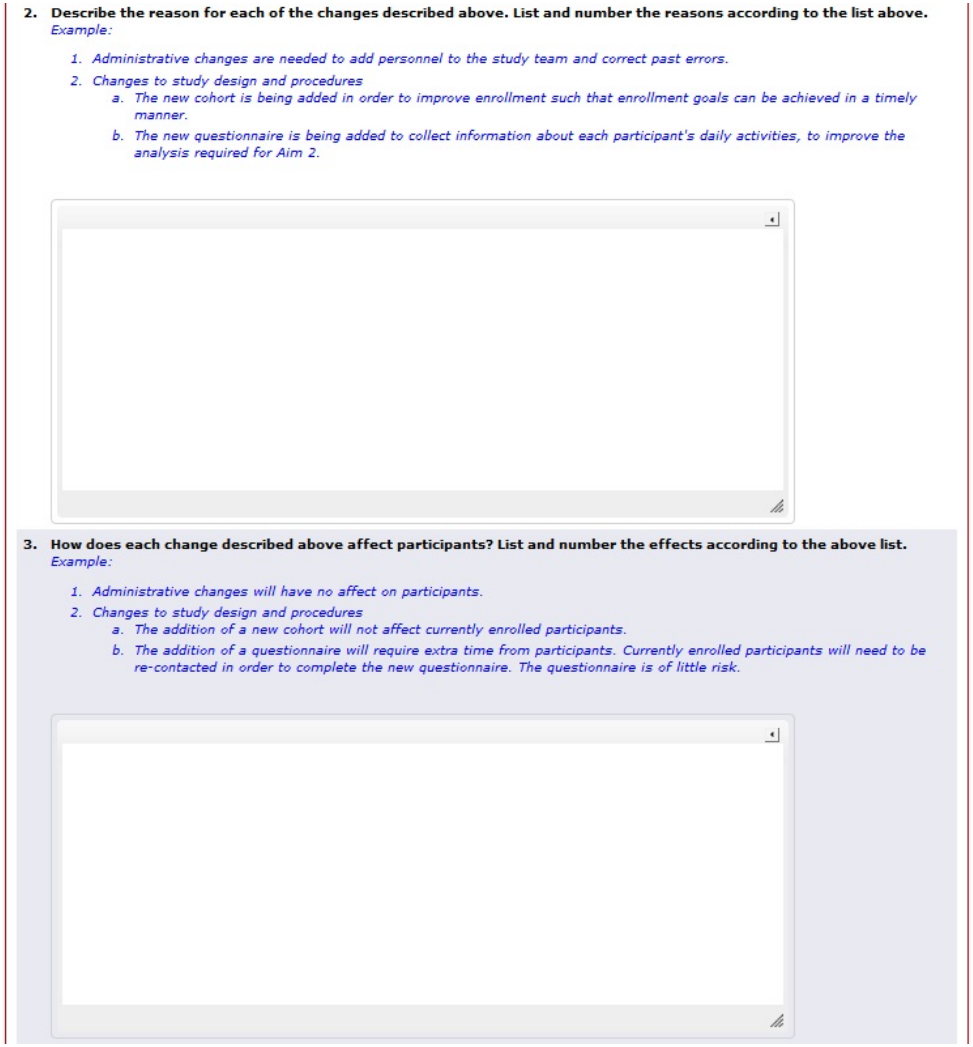
Please address all changes categorically in the text boxes below. See examples for more details.

1. What changes are being made? List and number each change, grouping similar changes together.
Example:

1. *Administrative changes: This includes adding a new sub-investigator and fixing typos in the consent form.*
2. *Changes to study design and procedures:*
   a. *We would like to add a new participant cohort, recruited from community centers.*
   b. *We are also adding a questionnaire component to the study.*

1) (What changes are being made?) Describe in your own words the actual changes taking place in the current amendment, stating items as thoroughly as possible.
   a) Be specific. Example: Instead of simply stating that a new co-investigator will be added, use his/her name.
   b) Avoid copying and pasting the changes page directly from a sponsor protocol or IB.
   c) When possible, state what documents and/or sections of the application have been updated as a result of the modifications.

Filling out the Amendment Application – Amendment Description (continued)



2. Describe the reason for each of the changes described above. List and number the reasons according to the list above.
Example:

1. *Administrative changes are needed to add personnel to the study team and correct past errors.*
2. *Changes to study design and procedures*
   a. *The new cohort is being added in order to improve enrollment such that enrollment goals can be achieved in a timely manner.*
   b. *The new questionnaire is being added to collect information about each participant's daily activities, to improve the analysis required for Aim 2.*

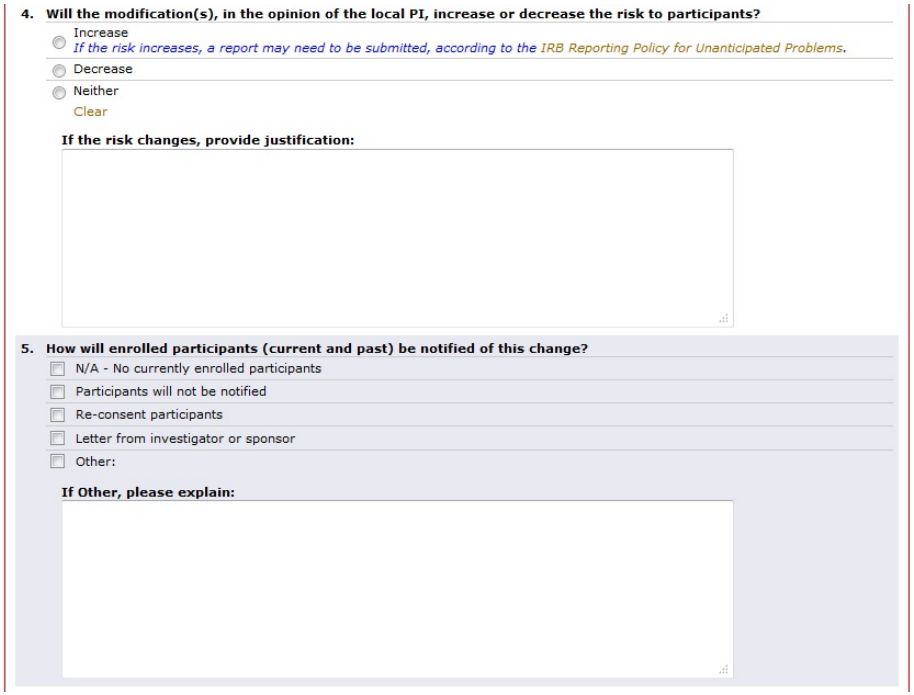
3. How does each change described above affect participants? List and number the effects according to the above list.
Example:

1. *Administrative changes will have no affect on participants.*
2. *Changes to study design and procedures*
   a. *The addition of a new cohort will not affect currently enrolled participants.*
   b. *The addition of a questionnaire will require extra time from participants. Currently enrolled participants will need to be re-contacted in order to complete the new questionnaire. The questionnaire is of little risk.*

2) (Describe the reason for each of the changes described above.) Describe why the changes are being made. Provide a short explanation of the reasons the alterations are being made and what they intend to affect or modify.

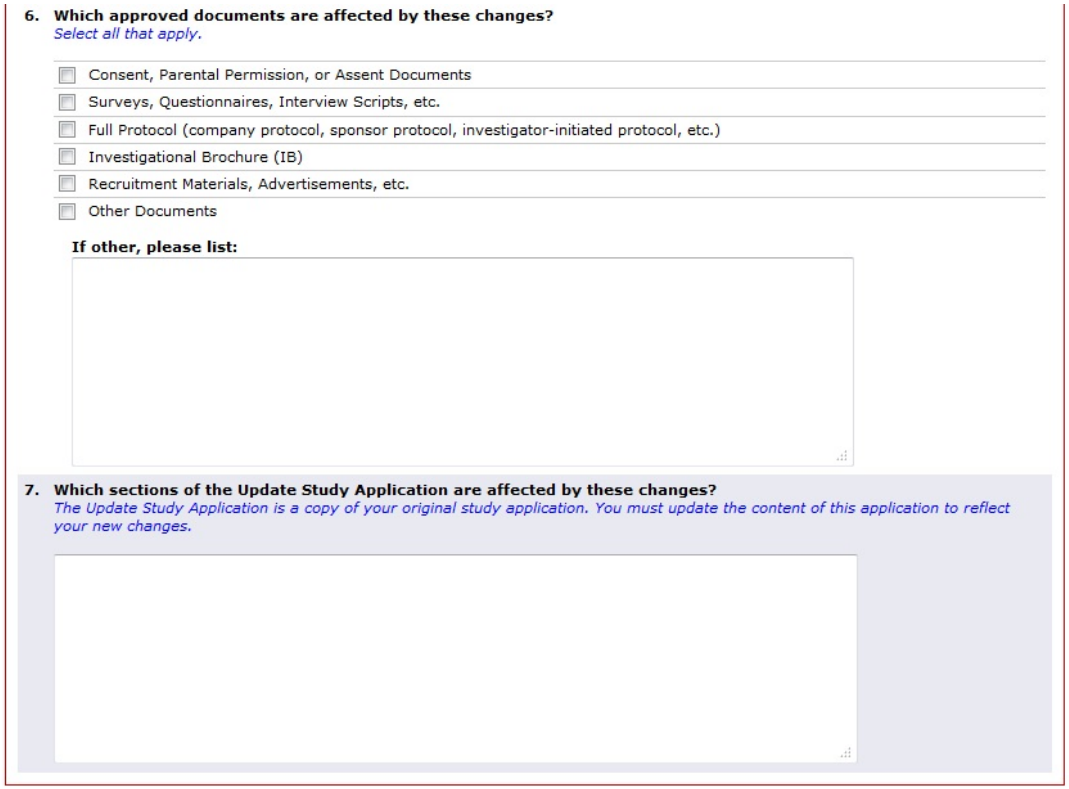
3) (How does each change described above affect participants?) Describe modifications to anything that would change processes for participants, require more or less from them, or otherwise adjust or alter the procedures to be different than what was originally stated in the application or consent forms.

Filling out the Amendment Application – Amendment Description (continued)



4) (Will the modification(s), in the opinion of the local PI, increase or decrease the risk to participants?) Select one of the options according to what the PI believes as far as the change in risk this amendment proposes.
   a) An "increase" usually takes place when a sponsor updates the protocol with several adverse events related to a study drug, procedures, etc.
      1. If this option is selected, please fill out the subsequent text box labeled "If the risk changes, provide justification"
      2. In this box, enter the PI's reasoning for continuing the study, even with the newly proposed risk changes.
   b) A "decrease" would be something such as removing a procedure or no longer collecting PHI from participants.
   c) The "neither" option would be selected if the risk determination remains the same (e.g., modifying a study procedure slightly, updating study personnel, an updated IB with no new proposed risks, etc.)
5) (How will enrolled participants (current and past) be notified of this change?) Select how participants will be informed of the updates, or if they will be advised of the changes at all.
   a) Please only select "N/A – no currently enrolled participants" if your current enrollment is **zero**.
   b) If you will not be notifying participants, select the option "Participants will not be notified."

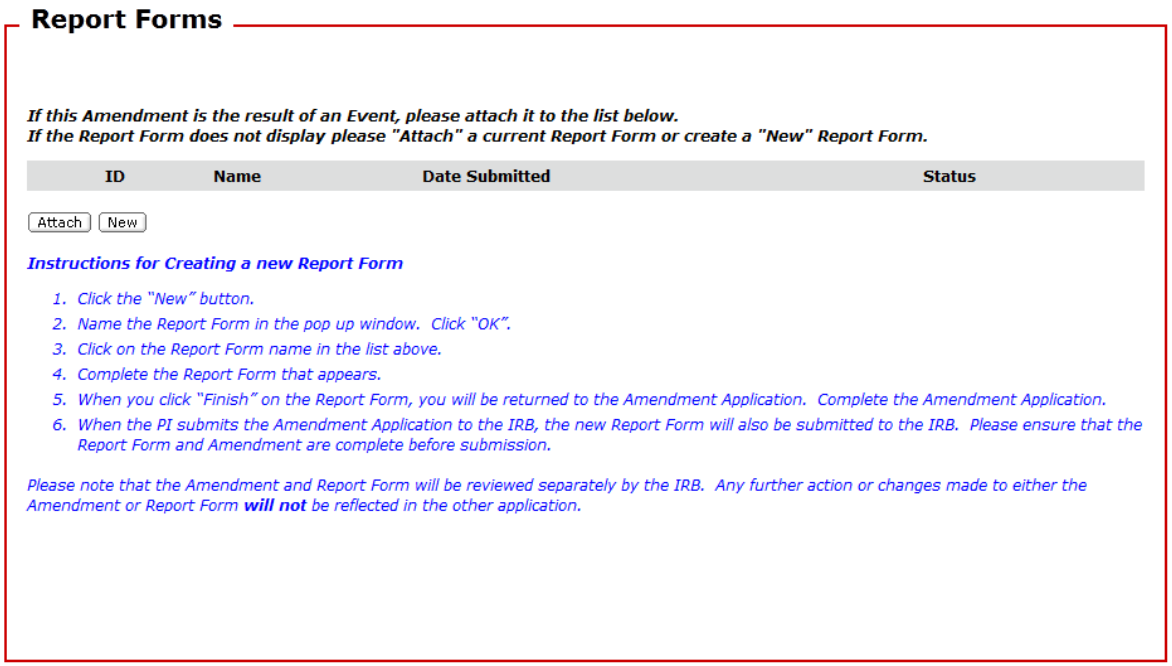
Filling out the Amendment Application – Amendment Description (continued)



6) (Which approved document are affected by these changes?) Select all documents that have been updated as a result of the this amendment. *Please remember to attach all updated documents in the **UPDATE STUDY APPLICATION** before submitting!* ** If "Investigational Brochure" is selected, an additional section will be required. See the Investigational Brochure page in this tutorial for instructions.

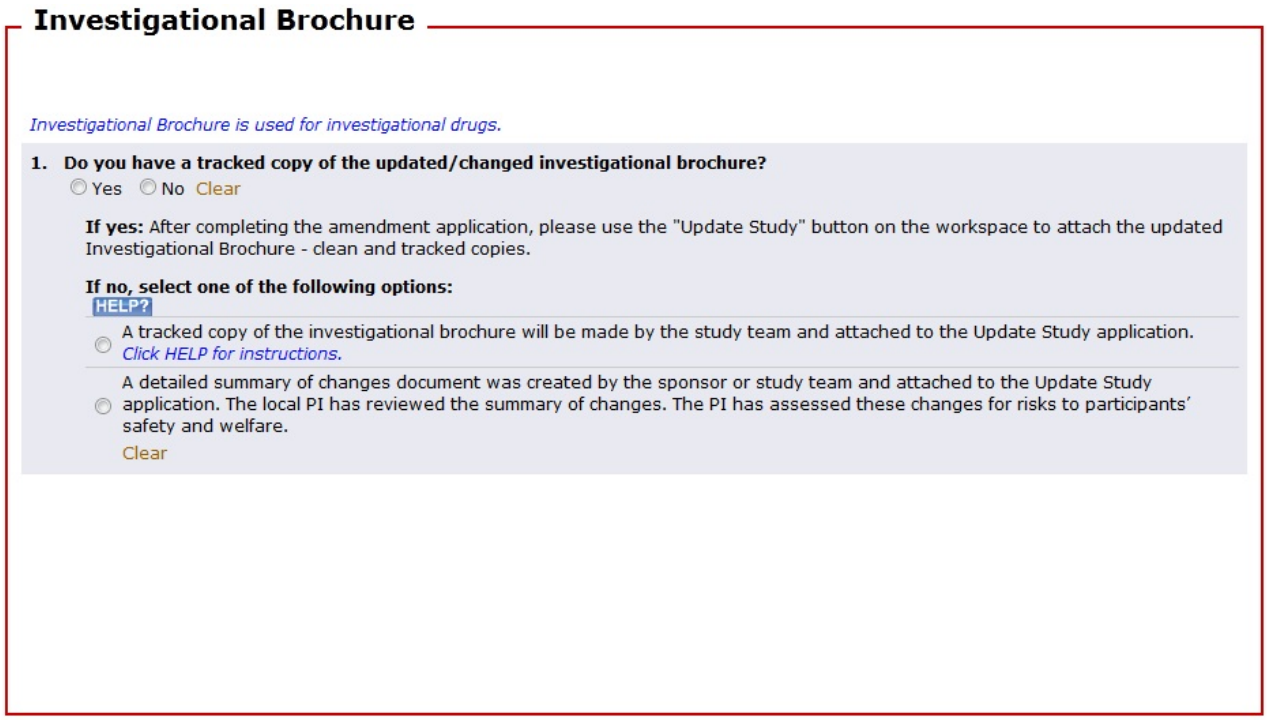
7) (Which sections of the Update Study Application are affected by these changes?) Please scan/review the entire Update Study Application to make note of what should be changed as a result of this amendment. For instance, if you are increasing the number of participants, you would note that the Participants section is being updated. *Do not forget to implement the changes noted in this question in the **UPDATE STUDY APPLICATION***.

Filling out the Amendment Application – Report Forms



1) If a Report Form is required, please follow the instructions on this page to attach an existing or create a new Report Form for the study.
2) For more information on reporting requirements or filling out a report form, please see the Event Reporting section of our website: http://www.research.utah.edu/irb/adverse/index.html.
3) If no Report Form is required, click “Continue,” and move to the next page of the Amendment Application.

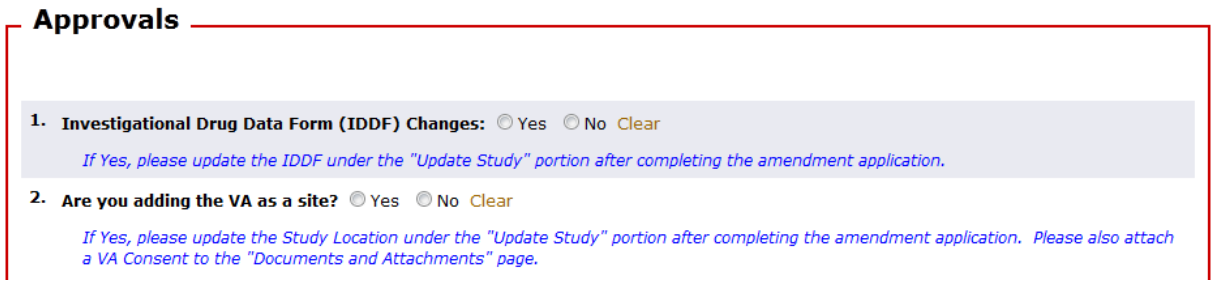
Filling out the Amendment Application – Investigational Brochure



1) (Do you have a tracked copy of the updated/changed investigational brochure?) Please select "Yes" or "No" accordingly.
   a) If there is a tracked copy, please attach it in the Investigational Brochure section of the Update Study Application, in addition to a clean copy.
   b) If no tracked copy is available, select one of the options provided (i.e., a tracked copy of the IB will be made by the study team and attached, or a summary of changes is attached along with the assurance from the local PI that these changes have been reviewed by him/her.)

      ** It is suggested that the local PI comment on the changes that have been made to the Investigational Brochure with respect to how the changes affect the local protocol so the board will have enough information to make an approval determination.

Filling out the Amendment Application - Approvals



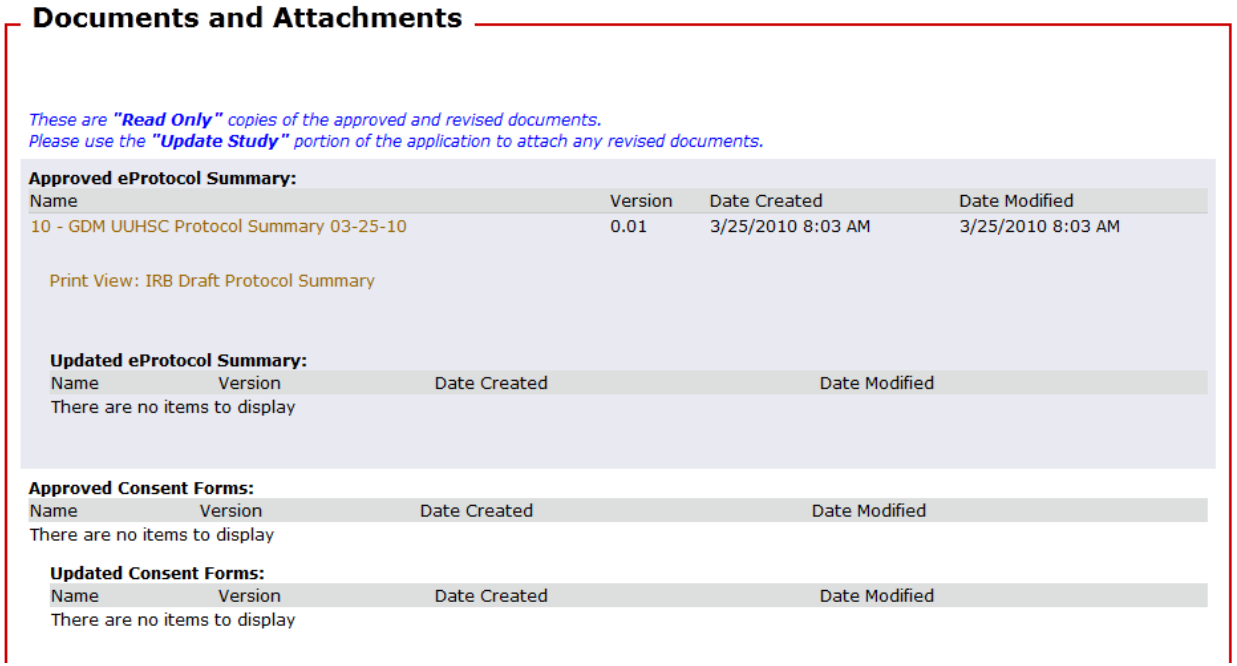
1) (Investigational Drug Data Form (IDDF) Changes) If there are changes to the Investigational Drug Data Form, select "Yes," and update the "Update Study" Application in the IDDF section accordingly.

* If your study does not involve a drug or has no changes to the IDDF (this is the case for the majority of amendments), select "No."

2) If this is an amendment to add the Veterans Affairs Medical Center as a site, please select "Yes," and complete the following in the Update Study Application:
   a) Modify the Study Location and Sponsors section, question #2 to include the Veterans Affairs SLC Heath Care System (VAMC).
   b) Attach a VA Consent in the Documents and Attachments section under "VA Consent Documents."
      1. For any questions regarding the VA Consent Template, please contact Caroline Keller, caroline.keller@va.gov.
   c) VA Approval will be required as an ancillary approval with this amendment.

* If this amendment does not add the VAMC as a site, select "No," and continue through the application.

Filling out the Amendment Application – Documents and Attachments



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
10 - GDM UUHSC Protocol Summary 03-25-10	0.01	3/25/2010 8:03 AM	3/25/2010 8:03 AM

Print View: IRB Draft Protocol Summary

Updated eProtocol Summary:

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

Approved Consent Forms:

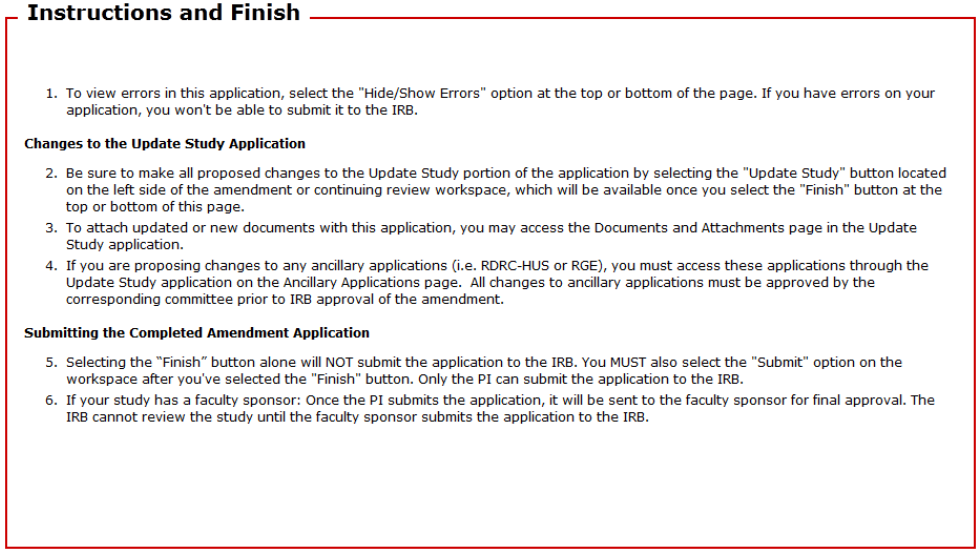
Name	Version	Date Created	Date Modified
There are no items to display			

Updated Consent Forms:

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

1) This section will show you what documents are currently in the “approved” state (prior to approval of this amendment).
2) New, updated documents cannot be attached here, but must be attached in the Documents and Attachments section of the Update Study Application.

Filling out the Amendment Application – Instructions and Finish



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 Amendment 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.

- Before finishing the Amendment Application, be sure to thoroughly check all portions of the **Update Study Application** to update any section that is affected by the changes included in the Amendment.
  a) Examples:
     1. If you are increasing the number of participants, update the "Participants" section, question #4 to reflect the newly requested enrollment total.
     2. If you are adding a co-investigator, update the "Contacts and Title" section, question #3 to add the particular individual.
  b) For more in-depth directions for how to fill out any particular section in the Update Study Application, see the "New Study Application Tutorial" on our website (http://www.research.utah.edu/irb/index.html). This is a good resource that thoroughly outlines what should be included in each section and clarifies the questions you are asked in the application.

** If you have not made changes to the Update Study Application before submitting your Amendment Application, it is most likely incomplete and will be sent back to you for further revisions. **

- Follow these final directions (see red box above) in order to submit the Amendment Application to the IRB for review; they are included at the end of each Amendment Application before you click "Finish."