

UTHSC IRB
Guide to Using the New Application (Form 1) PI Response Form

How to navigate the PI Response to Review form:

1. If you get lost while inside the PI Response form, look at the top of your iMedRIS page- the name of the form you are in (or the process that you are undertaking) will be in black letters with a light blue background.
2. If it says, "PI Response to Review," you are in that form.
3. If it says, "Routing Form," you are in the Routing form (i.e., the package) that you created when you first submitted your submission. The Routing form will have your old application, consent forms, and other study documents within it, and you will have the capability to revise each form there.
4. If it says anything else in the light blue background, it is usually referring to a process that you are undertaking, like checking out a document (described below). You can always hit the "Back" button the top right-hand side of your screen to get back to the places you have been before, such as the Routing form or the PI Response to Review form. You can always hit "Home" on the top right-hand side of your screen and start over by opening your "Submission Response" in your "Incomplete Tasks." Lastly, you can pick one of the navigation "bread crumbs" in the middle of the top of your screen to return to a different part of the process or a different form; the bread crumbs are separated by arrows such as this: ">".

How to create a revised application:

1. When responding to the provisos concerning the application, in section 3.0 ("Issues Requiring a Response") of the PI Response form, click on the green bar that says "Click here to edit/view a revised copy of the Routing Form" to make changes to the application.
2. Then click on section 2.0 ("Study Application") of the Routing Form and click on the green bar that says "Click here to create a revision to the attached application." The application will appear.
3. Click on "Add revision" on the right-hand side of the application. Confirm that you want to create a revision.
4. Once inside the new version of the application, make the appropriate changes. Be sure to hit "save and continue" after each change is made, and answer any additional new questions that may be presented after you have changed any answer choices.
5. If you log out and then want to come back to your revised application, click on the 1st green bar in the PI Response form. Then in section 2.0 of the Routing Form, your revised application should appear under the green bar there. You do not have to click the green bar here again. Simply click "Edit/View" to access it and make further changes, saving as you go.

Editing Sub-forms:

Exempt: If you have provisos pertaining to questions 590 to 699, you will need to edit the exempt sub-form. Go to section 503. At the top of the screen there should be two green bars. Click the one that says "edit sub-form". Use the table of contents on the left hand side to find the appropriate question. Change your answer to the appropriate question. Thereafter, you may receive questions that you have not received before. You should continue through the application by hitting "save and continue" (or "close form" when applicable) until you reach section 1200 "Site information" so that all appropriate questions are answered and saved in this sub-form. If you choose to answer provisos pertaining to the sub-form in more than one session, you will need repeat the steps previously described and begin where you left off.

UTHSC IRB

Guide to Using the New Application (Form 1) PI Response Form

Expedited: If you have provisos pertaining to questions 701 to 802, you will need to edit the exempt sub-form. Go to section 700. At the top of the screen there should be two green bars. Click the one that says "edit sub-form". Use the table of contents on the left hand side to find the appropriate question. Change your answer to the appropriate question. Thereafter, you may receive questions that you have not received before. You should continue through the application by hitting "save and continue" (or "close form" when applicable) until you reach section 1200 "Site information" so that all appropriate questions are answered and saved in this sub-form. If you choose to answer provisos pertaining to the sub-form in more than one session, you will need repeat the steps previously described and begin where you left off.

Informed Consent/HIPAA sub-form If you have provisos pertaining to questions 3345-3500, you will need to edit the Informed consent/HIPAA sub-form. Go to either section 3325 or 3329 (you will have one or the other). At the top of the screen there should be two green bars. Click the one that says "edit sub-form". If you have more than one sub-form click the appropriate group (group 1, 2, 3, etc). Use the table of contents on the left hand side to find the appropriate question. Change your answer to the appropriate question. Thereafter, you may receive questions that you have not received before. You should continue through the application by hitting "save and continue" until you reach "close form" and then choose "close form". If you need to edit more than one informed consent sub-form, or if you have been asked to add an additional sub-form because your study involves more than one consent process, scroll down to the bottom of the screen and either edit the next sub-form or begin the new sub-form. If you choose to answer provisos pertaining to the sub-form in more than one session, you will need repeat the steps previously described and begin where you left off.

How to create a revised consent form:

Changes to the consent form should be done in *only one* of following two ways:

1. Revise a consent form within iMedRIS without using tracked changes and without attaching 2 documents per each consent form (i.e., a clean and a highlighted copy):
 - a. Changes can be made to the existing consent form within the system in section 3.0 ("Issues Requiring a Response") of the PI Response form; click on the green bar that says "Click here to edit/view a revised copy of the Routing Form."
 - b. Then click on section 4.0 ("Consent Form") of the Routing Form and click on the green bar that says "Click here to attach a new consent form." (Note: if you did not upload the consent form in the appropriate place when you first created the Form 1, you may have to go to the section entitled "Attach Additional Study Documents" and click on the green bar that says "Click here to attach any study document" to find the consent.)
 - c. Click the "Add Revision" on the right-hand side of the consent form. Confirm that you want to create a revision.
 - d. Click the grey bar that says, "Check-out Document."
 - e. WAIT on the pop-up box to appear that says, "Open, Save, Cancel." If your web browser will not allow pop-ups, you will have to allow them. For more information concerning pop-us access the
 - f. Save the document to your desktop (or somewhere you can easily remember to locate it) and rename it if you need to in order to recognize it on your desktop. If you have a MAC, usually the document will automatically download to your desktop without asking you where you want it to be saved. If it automatically downloads, it could be named "consent document" or sometimes it will be a random set of letters like "XBCTIH."

UTHSC IRB

Guide to Using the New Application (Form 1) PI Response Form

- g. After you click “Save,” it will ask you if you want to open the document. You should open it and make changes to *that specific* document. DO NOT make changes to any other similar document that you have on your computer and DO NOT try to “check in” any other document besides the one you “checked out,” as iMedRIS will not be able to track and highlight all the specific changes you made if this occurs. Because iMedRIS can track changes in the exact document you “check out,” you do not need to use tracked changes to highlight what you have done. Simply make your changes and then save your changes within Microsoft Word. You can then close that document on your desktop. NOTE: While you are making changes to the document, remember to keep your browser open and your iMedRIS session timed in (i.e., do not let your session expire) so that you can “check in” the document when you are finished revising it.
- h. Go back to your web browser screen and click the grey bar that says, “Complete Checkout.”
- i. Then click the grey bar that says, “Check-in Document.”
- j. A pop-up window will appear in which you should click “Browse.” This part works just like attaching a document to an email.
- k. Search for the correct document on your desktop (or wherever you saved it originally).
 - l. When you find it, double-click on it, *or* click once and then click “Open.”
 - m. Then click “Save Selected File.” The pop-up should disappear.
 - n. Now that the document is “checked in” to iMedRIS, click “Save Consent.”
 - o. Make sure that the checkbox beside this consent is checked and hit “Save Attachments.”
 - p. You will complete this same procedure for each of the consent forms that you need to revise.
 - q. Now that you have created a revised consent within iMedRIS, you can compare your old and new consent form by clicking “Home” (you are leaving the PI Response to Review form), clicking “My Studies,” opening the corresponding study, clicking “Informed Consent,” clicking the yellow folder icon beside the revised consent form, checking the 2 boxes of the versions you wish to compare, and clicking, “Compare Consent Versions.” The red font denotes deleted text and the blue font denotes added text.
2. Revise a consent form using tracked changes, and upload a clean and a tracked copy of each consent:
 - a. Changes can be made to the existing consent form within the system in section 3.0 (“Issues Requiring a Response”) of the PI Response form; click on the green bar that says “Click here to edit/view a revised copy of the Routing Form.”
 - b. Then click on section 4.0 (“Consent Form”) of the Routing Form and click on the green bar that says “Click here to attach a new consent form.” (Note: if you did not upload the consent form in the appropriate place when you first created the Form 1, you may have to go to the section entitled “Attach Additional Study Documents” and click on the green bar that says “Click here to attach any study document” to find the consent.)
 - c. Click “Add Document.”
 - d. Change the selection to “Add an informed consent from an existing document that you already have.”
 - e. You have now been directed to the title page for the consent. Give the newly revised consent form the same title as the old consent; however, at the end of the title, you must put “-clean” or “-highlighted,” depending on which one you are uploading.

UTHSC IRB

Guide to Using the New Application (Form 1) PI Response Form

- f. The version date must match the preparation date located in the footer of the consent form.
 - g. The version number should be the next *whole* consecutive number from the version number of the old consent form. For example, if the old consent was Version 1.0, the new consent should be Version 2.0. If the last number was Version 1.4, the new version number should be Version 2.0.
 - h. Choose the correct language for the consent form.
 - i. You can add other comments in the “Comments” box, but this is not necessary.
 - j. Click the grey bar that says, “Upload Your Consent Document.”
 - k. A pop-up window will appear in which you should click “Browse.” This part works just like attaching a document to an email.
 - l. Search for the correct document on your computer (wherever you saved it originally).
 - m. When you find it, double-click on it, *or* click once and then click “Open.”
 - n. Then click “Save Selected File.” The pop-up should disappear.
 - o. Now that the document is “checked in” to iMedRIS, click “Save Consent.”
 - p. Make sure that the checkbox beside this consent is checked and hit “Save Attachments.”
 - q. Complete the same procedure for the other copy (i.e., the clean or the highlighted copy) of the same revised consent.
 - r. You will complete this same double-step (uploading a clean and highlighted copy) procedure for each of the consent forms that you need to revise.
3. Remember you may only choose *one* of the above two options for revising documents. Please call with any questions concerning this issue.

How to create any other revised document:

Changes to other documents can be done in *one* of the same two ways as listed above for consent forms. You would look for these other documents (such as project descriptors, advertisements, etc.) behind the big green bar in the PI Response to Review, which leads you into the Routing form, and then behind the green bar in the section labeled, “Attach Additional Study Documents.”

NOTE: These instructions pertain specifically to a Form 1 PI Response to Review form. The PI Response to Review form for Form 2’s, 3’s, 4’s, etc. vary slightly in one aspect or another, but the instructions listed above should help you revise documents in any case.