

Text Examples

The following are content fragments for possible use when communicating to a study team via ESTR.

Changing information on an Initial Submission

In this workspace (webpage), please click the silver button labeled "edit study" on the left side of the screen and make the following changes:

Changing information on a Follow-On Submission

In this submission workspace (webpage), please click the silver button labeled "edit submission" on the left side of the screen and make the following changes:

Changing specific text in the SmartForm

On the SmartForm page titled <heading> page, question #<#>: Please <instructions regarding what to do> in the space provided. Click "continue" to save the change and advance to the next page of the SmartForm.

Changing documents attached to the SmartForm-version 1

When you are done revising the <document name> in the ways described <above>; in this workspace (webpage), please click the silver button labeled "edit study" (on the left side of the screen), and click "continue" until you reach the page labeled <heading>. For question #<#>, please click "Update" beside the document named <document name>, upload the revised document via the pop up window, and click "ok". On the SmartForm, click "continue" to save the change and advance to the next page.

Changing documents attached to the SmartForm- version 2

When you are done revising the <document name> in the ways described <above>; please go to the <heading> page of the SmartForm. For question #<#>, please click "Update" beside the document named <document name>, upload the revised document via the pop up window, and click "ok". Then click "continue" to save the change and advance to the next page.

Document location correction

In review of the submission, I see that documents are included however; they are not attached to the appropriate spaces of the SmartForm. To help with this and future reviews, it is important to attach documents only to the appropriate locations of the SmartForm. Please click the silver button labeled "edit study" on the left side of the screen and make the following changes:

- (1) Go to the <heading> page of the SmartForm
- (2) Save a copy of the <document name> to your computer
- (3) Click the "delete" button beside that document to remove it from the page
- (4) Click "save" in the center of the blue bar on the screen





- (5) Click <back or continue> until you get to the page entitled <heading>
- (6) Click "Add" on the table beside question #<#>
- (7) Upload the <document name> via the pop up which appears <As applicable when adding docs to the Supporting Documents page: "Select <document category> from the dropdown.">
- (8) Click "ok" on the attachment pop up
- (9) Click "save" in the center of the blue bar on the screen
- (10) <As applicable, repeat description of any steps OR "Click "exit" in the center of the blue bar on the screen to return back to the submission workspace (webpage)".>

Exiting the SmartForm

When all the changes to the SmartForm are complete, click "save" which appears in the center of the blue bar on the screen, and then "exit" to return back to the submission workspace (webpage).

Sending changes back to the IRB

Once all the changes are completed, please return to this submission workspace (webpage) and click the "submit changes" activity on the left side of the screen (marked with a red arrow).

Additional Notes

Depending on the audience (new user, or experienced), some additional notes can be added.

Comments and submitting changes

Please note that you will have the opportunity to describe changes and/or rationale when you complete the requested updates to the documents/SmartForm and submit changes back to me for review (by clicking on the 'submit changes' activity). Please do not click 'add comment' in this workspace to communicate with members of the IRB office, as it does not send an email and might be missed.

<u>Human Subjects Training reference</u>

By clicking on the "project contacts" tab in this workspace (link just below the workflow image), I can see that the Human Subjects Training on file for <study team member name(s)> has expired or is soon to expire. To ensure this is updated, please <instructions>. You can monitor the status of study team member training by viewing the expiration which appears on the "project contacts" tab.