

Instructions for Completion of the eBridge Amendment SmartForm

Step 1: Create a New Amendment:

1. Locate your Study
2. In the **Study Workspace**, in the **Left Navigation** area, select the **New Amendment** button.
(Note: Only one amendment can be opened at a time for each study.)

Page 1:

- 1.1. Give this amendment a title; it doesn't matter what you name it
- 1.2: Select review type:
 - a. Full Committee – if there is an increase in risk, increase in study population of 20% or more
 - b. Expedited – for administrative changes, i.e., addition or removal of study team members or principal investigator
- 1.3: Language entered here populates on the approval letter; it's important to be specific & choose the correct words.
- 1.4: Select source of amendment from drop-down list – Investigator or Sponsor initiated
- 1.5: Select as many options that apply or select "Other" and explain in Q1.5.1

Page 2a:

2a1: Provide very specific description of all proposed changes including name & title, roles and responsibilities related to the study. Additionally, list the location (section) of each change made within the Study Smart Form, protocol, consent form, Investigator Brochure, advertisement, etc. and the reason for the proposed change(s).

2a2: Select "Yes" or "No"

Page 2b:

2b.1: If proposed change(s) affects the informed consent process or form, please respond "Yes" & complete 2b.1.1

2b.1.1: Please reference the revised consent document or list each change and location. Additionally, please specify if subjects will be re-consented or otherwise notified of the changes or not.

2b.2: Question deleted.

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Page 2c:

2c.4: If proposed change(s) affect the current access, use, and/or type of PHI collected for the study, please respond “Yes” & complete 2b.1.1

2.c.4.1: Please specify the changes and if subjects will be informed of the changes or not.

Page 3:

3.1: Enter the name of any documents that were changed related to purpose of the amendment.

Page 4:

Review Page 4 for instructions on what to do next.

Step 2: Modify Existing Study (if applicable):

1. In the **Amendment Workspace**, in the **Left Navigation** area, select the **View/Edit Study** to amend the study. Make changes to the appropriate sections. .

Step 3: Modify Consent(s) if applicable:

1. Locate currently approved consent :
 - a. In the **Amendment Workspace**, select the **Consents/Docs** tab:
 - i. **Word consent:** (In the Amendment Workspace) , Click, the “ Consents/Docs” tab. Find current paper consent in Word version located in the “Other Documents” section by selecting the link. Save on your hard drive & then open the document. **Accept previous changes, and turn on “Track Changes” to record new changes.** Save. Upload revised consent form in Section 52 of the Study Smart Form
 - ii. **Adobe consent:**

To amend the study-specific user sections of Adobe consent forms, the IRB asks that you use one of two methods to facilitate review.

A. “Highlighting” changes within the form using cross-outs, bold and/or colored text:

 1. To show the toolbar allowing “highlighting”, first place your cursor in the section you wish to amend. Then click on “View, Toolbars, Properties Bar”. Using the options in the toolbar, cross out text to be altered and highlight new text using a contrasting color.

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2. In section 2a.1 of the Amendment SmartForm, describe the nature and reason for the -changes to the consent form.

3. When using this option, please also submit a “clean” copy of the consent form with the final text as it should appear in the amended version.

4. Upload both the amended and clean copies of the consent form to Section 52 of the study SmartForm

B. Listing changes by Consent Form section in the Amendment SmartForm:

1. In section 2a.1 of the Amendment SmartForm, for each proposed change (section number, page number, etc.), list the original text and the amended text.

2. In section 2a.1 of the Amendment SmartForm, describe the nature and reason for the –changes to the consent form.

3. Upload the amended “clean” copy of the consent form to Section 52 of the study SmartForm.

- i. Changes to the IRB-defined template should be requested using the “ICF Template Change Form: Petition to Change Informed Consent Form Required Language.”

Step 4: Submit amendment:

1. In the **Amendment Workspace**, select the **Submit to IRB** link located in the **Left Navigation** under the **My Activities** section.