

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

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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.