How to amend an Adobe informed consent form

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.

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.

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