Using the new consent forms in Adobe Acrobat

11.16.2009
Why has the IRB revised the consent form template?

• The new templates are simpler, shorter, and more patient-friendly, with less fixed template language.

• Adobe Acrobat reader (version 8.0 or higher), Adobe Standard or Adobe Professional are needed to use the templates.

• The new templates will only be required for NEW studies; continuing studies keep their present form.
Which template should I use for my study?

Currently there are 6 versions of the new consent forms:

- **A-Interventional studies** – for studies involving drugs devices, surgery or psychotherapy
- **A-Com** – for studies that are non-clinical interventions such as education with community groups or patients
- **A-Com without HIPAA** - for studies that are non-clinical interventions such as education with community groups or patients in which no Protected Health Information is collected or used
- **B-Banking** – for banking of clinical records or biospecimens at MCW/FH
- **X-Non-interventional studies** – for observational studies, surveys, and non-interventional behavioral studies *NOTE: most social and community studies will use this form*
- **X-without HIPAA** – for studies in which no Protected Health Information is collected or used
Which template to use (cont.)

- Beginning **December 1, 2009**: new study consent forms should be created using the *Adobe Acrobat* consent form templates
  
  Exception: Cancer Cooperative Group studies

- When you open a new study, please go to the IRB website and open/save the consent form. This insures that you are using the most up-to-date form.

- If you have a study that does not work with any of the current templates, contact the IRB office – Word templates remain available for special situations.
How do I complete the Adobe consent form?

• Instructions are in red italic type; they will not appear when printed.
• IRB-required template language is in black type and cannot be changed.
• Sample text, which can be used, modified, or deleted as appropriate for your study, appears within editable fields in blue type. To change this text for your study, simply highlight the text and begin typing or copy and paste from an existing document.
• Optional text sections can be hidden or made visible by using the check box.
• Additional modules for special case scenarios can be found on the IRB website. These modules can be copied and pasted into the appropriate study-specific text boxes.
How do I submit and receive approval of the Adobe consent form?

• Before submission, please check the form to be sure the appropriate text boxes have been filled in and check boxes marked or unmarked.
• After the consent form is completed, save the form on your computer and upload it to the study application (Section 52).
• If the reviewer/committee requests changes, open your original (or most recently revised) form and make the changes. Save and upload the new version to the study application (do not delete the previous version from eBridge).
• The IRB approved consent form will be uploaded in the Study Workspace under the Consents/Docs tab.
What if I need to change the black language?

• If you propose a change to required language, a petition to the IRB office should be completed using the “ICF Template Change Form”. This form is found on the Consent Form Templates page of the IRB website.

• The IRB office will email the decision which, if approved, will include the revised consent form with the template changes incorporated.

• Requested changes to template language should be made prior to IRB submission of the study.
• When I copy and paste in text, it appears in Greek, or is a different font or size from the rest of the document. How do I fix this? The ‘Properties Bar’ allows for changes to font, font size, font color, boldness, italicization, and some paragraph indentation. To view go to View, Toolbars, and click Properties Bar. Drag the additional toolbar into your toolbars at the top of the window. Select the text to be changed and modify as needed.

• I copied in text, but it is not all visible. After copying and pasting text into the consent, click outside the text box to make the inserted text appear.

• I would like to include a chart/table into my consent. Word or Excel tables cannot be imported. If a table or chart is needed, an attachment should be used or you can contact us for help with importing a chart.
• **Do the adobe consents allow track changes?** The adobe templates allow commenting and markup. Please see “Adobe Commenting Options” found on the Consent Form Templates page of the IRB website.

• For additional tips and hints please see “Tips, Hints, and Frequently Asked Questions” found on the Consent Form Templates page of the IRB website.

• If you have a question about which template is appropriate for your study (A, A-Com, B, or X) or have a special circumstance that does not fit the available templates or just are simply stuck and frustrated, please contact Kristin Bastian (456-4408, kbastian@mcw.edu) or Patricia Witt (456-4585, pwitt@mcw.edu).