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Guidance on Submitting Consent Forms to the IRB

The JHSPH IRB will no longer stamp new consent documents with an expiration date. Consent documents will be approved for either a) the life of the study or b) until there is an amendment to the study that requires a change to a consent document. **Note: The rules have not changed – if the study approval lapses, no new subjects may be enrolled despite the fact that the consent form no longer contains a “valid from ‘x’ date until ‘y’ date” specification.**

Each approved consent form will be marked with a new IRB logo, an approval date, and a version number. Each subsequent amended consent document will receive a new version number in sequence. The IRB office will maintain electronic records of all the consent forms associated with your study. You will receive .pdf versions of all approved documents.

On October 6, 2008, the JHSPH IRB introduced a new set of consent form templates, with instructions at www.jhsph.edu/IRB. These forms make clear what the IRB needs to have included in consent forms to satisfy regulatory requirements and to provide participants with the information they need to make informed consent. If you use the instructions in the templates, we hope to minimize the amount of exchange between you and the IRB office to craft an acceptable consent form. The new postings included:

- Consent Form (instructional template)
- Consent Form (fill – in version)
- Oral Consent Script
- Research Assent Form (for studies involving children)
- Oral Assent Script (for studies involving children)

The new templates will be required for all new applications after November 1, 2008; however, as soon as you start using these forms, you will benefit from the new approval process.

What this means for investigators:

For studies that haven't been submitted yet: Start using the new consent document templates and instructions as soon as possible. If you do, at the annual progress report, you will not be required to submit consent forms again for review. However you will be asked that once enrollment begins, a single copy of a recently executed consent form (signed, but with the name redacted) be submitted to verify the version used. If you have multiple consent forms, select the one for submission that you consider to be the “primary” form.



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For existing studies: If you would like your existing consent forms converted to the “perpetual” version now; you may submit a revised consent(s), using the new template, at any time. Since an **electronic Word version of the document is needed**, you may submit both an amendment application and the revised consent using the new template to irboffice@jhsph.edu. You are not required to do this before your next progress report submission, because it will require some revision on your part. However, it will reduce burden in the long run, particularly for studies that span a number of years. If you wait, we will encourage you to submit revised consent documents on the new templates at the next annual renewal. However, under certain circumstances the IRB office may determine that you can continue to use the original version, either with or without the new non-expiratory approval process. In sum, your choices are as follows:

1. Submit your consent documents on the new templates with an amendment application any time before your next progress report, and receive the new “no expiration” consent form;
2. At your next progress report, request that you continue with the current process and existing consent form because enrollment is near completion; and
3. At your next progress report, request that you continue to use your existing IRB approved consent form because of specific circumstances that challenge your flexibility to submit revised documents (e.g., translations, multi-center study review complexities). You may also request having the new “no-expiration” process applied to your existing approved study consent documents.