Subject: Coming Soon - Consent Form Submission Improvements
Date: Wednesday, June 27, 2018 at 7:47:42 PM Eastern Daylight Time
From: Jonathan Gellert
To: Lally, Rachel, Jennex, Lori
Attachments: image001.gif, image002.jpg

Good afternoon,

Please forward this along to your main submitters or regulatory teams. Please don't hesitate to let me know if you have any feedback.

Initial Review Submission- Consent Form Templates Available
As part of our commitment to continuous process improvement, we are pleased to announce a simplified and streamlined approach to informed consent submissions for multi-site studies. Using the WIRB-approved sponsor consent form that incorporates the IRB's required changes, we are now creating a "consent form template" that sites can use to create site-specific consent forms. By using the consent form template created directly from the sponsor consent form, you can be confident that you are starting with the most recent WIRB and sponsor-approved language, thereby ensuring accurate version control, while saving you time and effort.

If you do not require site specific customization, WIRB will create your site's informed consent using the WIRB-approved template, as is. When completing the WIRB Initial Review Submission Form in MyConnexus, simply select "no" when prompted to submit site-specific wording in the consent customization section. WIRB will add your site-specific information included in your submission form, such as investigator name, 24-hour telephone number, and subject payment language.

If you require customized language, request the WIRB-approved consent form template from Client Services at clientservices@wirb.com. Track (redline) your site's changes on the WIRB-approved informed consent so WIRB can easily identify site-specific customizations.

WIRB will start requiring the use of IRB-approved informed consent templates(s) for initial review submissions of new principal investigators (PIs) beginning July 3rd, 2018.

**To expedite site review, WIRB recommends that sponsors/CROs provide sites with the WIRB-approved informed consent(s).

Changes in Research – Submit Changes on Most Recent IRB-Approved Consent Form
When you submit modified consent forms, track (redline) your modifications on the most recent WIRB-approved consent form. This will minimize your efforts, decrease emails between you and WIRB staff, prevent errors, and limit your downtime. Beginning on July 3rd, WIRB will require that modifications be tracked (redlined) on the most recent WIRB-approved consent form.

If you are submitting on behalf of the sponsor/CRO, use the most recent WIRB-approved consent form. If you are submitting on behalf of the site, use the site's most recent IRB-approved consent form.

Best,

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