

**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](mailto: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 3<sup>rd</sup>, 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 3<sup>rd</sup>, 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,

**Jon Gellert** | Account Manager, Institutions  
**Office:** (800) 562-4789  
**Direct Line:** (360) 570-1309

Cell: (253) 256-9371

Client Services: (360) 252-2500

[jgellert@wirb.com](mailto:jgellert@wirb.com) | [www.wirb.com](http://www.wirb.com)

WESTERN INSTITUTIONAL REVIEW BOARD®



Global Leader | Proven Expert

**Transparency. Predictability. Insights.** Achieve it all with MyConnexus.

[Register for your free account today!](#)

*This message contains privileged and confidential information and is intended only for the recipient(s). If you are not the intended recipient(s), you should not disseminate, distribute or copy this e-mail. If you have received this e-mail by mistake, please notify the sender immediately and delete this e-mail from your system. E-mail transmission cannot be guaranteed to be secure or error-free, as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. The sender and/or the Western Institutional Review Board, therefore, does not accept liability for any errors or omissions in the contents of this message which arise as a result of e-mail transmission. If you need additional assistance, please contact us at 1-800-562-4789.*