

## Special Notice

### **Common Rule Delay**

As the January 19 Common Rule effective date was closing in on us, last evening at 4:52 pm, we receive notice from our regulators that an Interim Final Rule (IFR) was approved to delay both the effective date and general compliance date until July 19, 2018. The IFR has not been published, but may be found on the [Federal Register \(opens in a new window\)](#) as unpublished until the scheduled publication date of January 22, 2018.

The Council on Governmental Relations (COGR) released their initial thoughts on the delay.

“An eleventh hour delay of both the effective and compliance dates, however well-intentioned, presents a challenge to institutions which have strived to comply with the revised final rule on January 19, 2018 as required by regulation prior to yesterday’s notice of a pending IFR. Continued uncertainty about the final effective and compliance date with the proposal of additional rulemaking will add to that challenge.”

We concur with COGR’s assessment on this last minute delay. Yesterday, RPO staff were running to the finish line to meet the compliance date, now we are working diligently to “reverse” steps that we had already put into place to address, in particular, the change to the continuing review of non-exempt research. Researchers conducting expedited-level protocols now must continue to submit continuing reviews to comply with the pre-2018 rule. Researchers will continue to receive the standard continuing review notices. However, if you are unclear as to whether you need to submit a continuing review or not, please contact our office at 656-5040. The delay does provide us additional time to

refine changes to exemption processes as well as develop additional educational materials about the changes.

### **What this Means for Researchers**

This delay means that we are unable to roll out changes that conflict with the pre-2018 Common Rule. The following changes do conflict with the pre-2018 rule and therefore, will not be implemented at this time:

- Continuing Review Changes
- Exemption Category Changes

Changes that do not conflict with the pre-2018 Common Rule and will be implemented:

- Informed Consent Changes
- Single IRB for NIH funded projects (compliance date January 25, 2018)
- Single IRB for all other cooperative research (2020)

Please see the [Regulatory Changes \(opens in a new window\)](#) web page for information specific to the Informed Consent changes. If you have questions, please do not hesitate to contact your [IRB Research Analyst](#) for assistance. Within the week, we will release a new and improved research manual and two new dictionaries, one specific to regulatory definitions and one specific to consent language. We hope you find these new resources helpful.

We will continue to keep you posted as to this situation.