Dear TU Research Community:

**On January 17, 2018 – HHS and 15 Other Federal Departments and Agencies Announce an Interim Final Rule (IFR) - That Delays by 6-months the 2018 Common Rule Effective Date to July 19, 2018.**

Most provisions in the revised Common Rule were scheduled to go into effect on January 19, 2018. This interim rule was meant to provide regulated institutions with additional time to prepare to implement these revisions.

Until July 19, 2018, regulated entities will be required to comply with the pre-2018 Common Rule (for federally funded studies). This means that (for federally-funded studies) before July 19, 2018, institutions may only begin implementing provisions of the 2018 Common Rule that do not conflict with the pre-2018 Common Rule. An example of a revised provision that does not conflict with the pre-2018 rule is one that addresses new elements of informed consent (revised rule at § 116(b)(9), (c)(7)-(9)). It is permissible to incorporate these new elements of consent now because the pre-2018 rule does not prohibit including these elements in informed consent. Since eliminating the requirement for continuing annual review in certain circumstances (i.e. Expedited protocols) would conflict with the Pre-2018 Common Rule, this will not be allowed (for federally-funded studies) until the 2018 Common Rule effective date.

Federal departments and agencies listed in the IFR are also in the process of developing a notice of proposed rulemaking (NPRM) seeking public comment on a proposal for further delay in the required implementation of the revised Common Rule (for example, until January 21, 2019). If such an NPRM is published, after consideration of the public comments, the federal departments and agencies will determine whether a final rule to further delay the 2018 Common Rule will be issued.

Many institutions, including The University of Tulsa, that review predominantly non-federally funded human research studies are moving forward with the implementation of the 2018 Common Rule for non-federally funded studies as planned, since it will reduce administrative burdens for all stakeholders.

If you have any questions, please contact the Research Compliance Coordinator, Carmen Schaar-Walden at carmen-schaar-walden@utulsa.edu or 918-631-3310