Dear TU Research Community:

Final revisions to the Federal Policy for the Protection of Human Subjects (a.k.a. the "Common Rule") were issued by the Department of Health and Human Services (HHS) on January 18, 2017. The majority of changes will go into effect on January 19, 2018. A few examples:

- **Continuing Review** - Will no longer be required for some minimal risk research, including studies where the only remaining activity is the analysis of identifiable data/biospecimens or activity to obtain follow-up clinical data. More details to come.
- **Exemptions** - New categories and clarification of existing categories. Some exemptions may require “limited IRB review” (similar to an expedited review process). More details to come.
- **Informed Consent Forms** - A new “Key Elements” section and a rearrangement of content designed to facilitate a potential subject's decision to participate or not.

Many of the changes to the updated Common Rule or the ‘2018 Common Rule’ (2018CR), were made to lessen administrative and investigator burden without compromising participants’ protections. Institutions have been given the flexibility to implement the 2018 Common Rule early on a study-by-study basis for studies that meet the criteria and can benefit from some of the reduced administrative burdens. Our institution has decided to take advantage of this flexibility to lessen administrative burdens and to help manage an orderly rollout of these changes.

These changes to the Common Rule will affect all research institutions who conduct human subjects research in the United States, so all research institutions are preparing during this transition time. The added flexibility in the regulations will be helpful but also means that institutions will be busy reflecting on their current practices and how to move forward with the 2018 Common Rule. We are in the process of updating our forms and procedures and ask for your patience during this transition period.

**What to Expect**

- **For existing studies**: those investigators who currently have ongoing human subject protocols approved before the effective date of January 19, 2018, there is nothing that you need to do at this time. Your study may not be affected at all, however, if your study qualifies for any burden-reducing changes, you may choose to apply the new rules to minimize your burden and will be notified no later than at the time of your next annual review.

- Informed consent template revisions available soon! You will be notified when revised Informed Consent Forms and other revised IRB documents are available on our IRB website and when the current (pre-2018 CR) forms will no longer be accepted.

- Look out for emails, notifications on the IRB webpage, and postings on the TU Portal about additional information on the 2018 Common Rule implementation. You will soon receive information explaining the main revisions of the 2018 Common Rule that would affect you.

- Informational sessions will be announced and conducted in the near future.

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