Dear TU Research Community:

NEW TU IRB Forms available for the Revised Common Rule (2018CR)

The revised IRB Forms are now available on the TU IRB webpage: https://utulsa.edu/research/office-research/research-compliance/irb-protection-human-subjects/. If you are planning on submitting a new IRB protocol, please use the revised TU IRB forms (v2018CR).

All TU IRB forms have been reviewed and updated to meet the requirements of the revised Federal Policy for the Protection of Human Subjects (a.k.a. the "Common Rule") that were issued by the Department of Health and Human Services (HHS) on January 18, 2017 and that will go into effect on January 19, 2018.

What is new about the TU IRB forms?

- **New forms** include:
  - FAQs (Frequently Asked Questions), FAQs on different topics will be added/updated
  - PDF of the revised Common Rule regulations
  - Chart on the TU IRB process regarding the 2018CR
  - New List of Exempt Categories-2018CR
  - Human Subjects Research checklists * checklists on different topics will be added/updated

- There is a new and separate informational document (TU IRB ICF Instructions-FAQs) that gives instruction on how to use the new Informed Consent Form templates. PIs MUST READ THIS DOCUMENT BEFORE COMPLETING THE INFORMED CONSENT FORM TEMPLATE. This document:
  - explains which Informed Consent Form (ICF) to use
  - lists the new 9 additional elements of informed consent that are required to add to your consent forms when applicable to your study
  - lists other required information to add to your form when applicable
  - explains when you can request to waive documentation of consent or other parts of consent
  - lists examples of additional signed consent to add to your form when applicable

- **Revised Informed Consent Form (ICF) templates:**
  - have a ‘key information’ section, at the beginning of the form, that should summarize the main information that prospective participants need to help them decide whether to participate in the study or not.
  - have been re-formatted to questions/answers, to aid in participant comprehension.

- **The TU IRB Application Form** has been revised:
  - to remove any duplicate questions and requests additional study information that may need further attention
  - the information in the headings and/or sub-headings may have changed, so please read each section carefully
  - in some sections, pre-approved statements have been added that the PI can choose from, when completing the section
  - information on the criteria needed in order to waive documentation of consent (signed consent) or waive parts of consent have been added

- **The TU IRB Annual Progress Report Form** has been revised:
  - This form will ONLY be used for annual reports to Full Board that are still enrolling new subjects and are requesting an additional one year approval extension
  - Final Reports will no longer be required when closing out a protocol (the title has been changed accordingly)
  - *PIs are still required to contact the TU IRB with any complaints, problems or adverse events
  - PIs will no longer be required to submit full protocol renewal submissions every three years on protocols still enrolling new subjects (language has been removed from the form)
  - *The TU IRB at its discretion may require PIs to submit a new protocol submission if it deems appropriate (ex. so many modifications that the protocol is confusing to review)

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