FAQs on Common Rule Changes (2018CR) - January 4, 2018

Changes to the Common Rule, the primary rule regulating human subjects research, go into effect on January 19, 2018. This FAQ will be updated as new information and guidance becomes available. A number of TU policies, procedures, and forms will be updated as a result of changes to the rule.

Q. What are the most significant changes to the Common Rule that will affect me?
A. In general, most of the changes will result in LESS work for Investigators.

• **Continuing Review (annual review) is no longer required on minimal risk protocols.** This new regulation applies to: **All EXPEDITED protocols and FULL BOARD protocols where the only remaining activity is the analysis of identifiable data/biospecimens or activity to obtain follow-up clinical data.**

• **EXEMPT Protocols –** New categories and clarification of existing categories, including some Exempt categories that require “limited IRB review” (similar to Expedited review process). This change is expected to **increase the number of protocols that will be determined in the Exempt category.**

• **EXPEDITED Protocols –** The Office of Human Research Protections (OHRP) will soon publish a list of Expedited Categories to their website. This proposed list of activities is expected to increase the number of Expedited protocols and clarify the types of activities will fit the Expedited category. (TBA)

• **Informed Consent regulations are less cumbersome and allow more flexibility to investigators**
  o – A new “Key Information…” section and a rearrangement of content designed to aid in a subjects’ decision whether to participate or not.

Q. How will the TU IRB procedures change?
A. **No Annual Reviews** – for ALL Expedited protocols and Full Board protocols that meet the criteria for no annual reviews (the only remaining activity is the analysis of identifiable data/biospecimens or activity to obtain follow-up clinical data). The IRB Office will no longer contact you with a reminder to complete an annual progress report each year. Instead, the IRB Office will verify the ‘proposed end date’ and email the PI anywhere from 30-90 days of that date so the investigator can choose to either close the study or extend the project end date.

Q. What if I have an Expedited or Full Board protocol that was approved before the 2018CR effective date?
A. **ALL current Expedited and Full Board protocols that were approved before the 2018CR effective date will be subject to the revised Common Rule (2018CR).**
With respect to timing, PIs will be contacted after the effective date or at the time of the scheduled annual review if a PI submits a modification request. A letter documenting the change to the revised Common Rule (2018CR) will be sent to the PI at this point.

- **At that time of change to the 2018CR**, PIs will be asked to confirm the ‘proposed project end date’ of the study. That proposed end date will be recorded in the protocol database and a reminder email will be sent out to the PI, 30-90 days in advance, to inquire if the study is ready to be closed out.

**Q. What if I have an Exempt protocol that was approved before the 2018CR effective date?**
**A.** Current Exempt protocols that were approved before the effective date will not be affected by the 2018CR.

**Q. If I have an existing protocol that is still enrolling new subjects and was approved before the 2018CR effective date, do I need to submit the latest Informed Consent Form (ICF) version or can I continue to use the currently approved form?**
**A.** You can continue using the Pre-2018CR ICF for the remainder of the study (as long as you have no modification requests that affect the consent forms).

*If you submit a modification request that includes revisions to your ICF, we will ask you at that time to use the new consent form(s) when you submit your revisions.*

**Q. Without Continuing Review (annual review), will my protocol be approved forever?**
**A.** No. You will be asked on the IRB Application Form for your ‘proposed project end date’ (no longer enrolling new subjects, all research activities with participants has ended, all identifiable data and any links to identifiers have been destroyed). This date will be recorded and PIs will be sent a reminder email 30-90 days before that date to confirm the project end date.

*If your project ends before your ‘proposed end date’, it is your responsibility, as the PI, to contact the IRB Office to request that your protocol be closed.*

**Q. Which IRB Forms have been revised due to the 2018 Common Rule?**
**A.** The majority of IRB Forms have been revised due in part to the updated regulations or new procedures. All updated versions will be marked as (v2018CR), and future revisions will be marked with dates after the effective date of: January 19, 2018.

**Q. When will I be required to use the new IRB Forms?**
**A.** Updated forms will be available by the start of the SP18 semester. PIs will be required to use the new forms if submitting a new IRB protocol on or after the effective date of: January 19, 2018.

New IRB forms will be available on the TU IRB webpage: [https://utulsa.edu/research/office-research/research-compliance/irb-protection-human-subjects/](https://utulsa.edu/research/office-research/research-compliance/irb-protection-human-subjects/)
Q. What if I submit a new protocol close to the effective date of January 19, 2018 and will not know if the protocol is approved before or after the 2018CR effective date?

A. If you are planning to submit a new protocol close to the 2018CR effective date, please contact the Coordinator of Research Compliance at: 918-631-3310 or carmen-schaar-walden@utulsa.edu. Please check the TU IRB webpage and use the revised forms (v2018CR) if they are available.

Q. What are my responsibilities as a PI, after I receive approval of an IRB protocol?

A. You are responsible for contacting the TU IRB Office if and when:

- You wish to deviate from the described protocol and would like to formally submit a modification request (TU IRB Modification Request Form). Prior IRB approval must be obtained before any changes can be implemented *except to eliminate an immediate hazard to research participants.*

- You make changes to the research personnel working on this study (add or drop research staff on this protocol).

- At the end of the study or before you leave The University of Tulsa (TU) and are no longer a student or employee, to request your protocol be closed. *You cannot continue to reference TU on any documents (including the informed consent form) or conduct the study under the auspices of TU if you are no longer a student/employee of this university.*

- You have received or have been made aware of any complaints, problems or adverse events that is related or possibly related to participation in the research (TU IRB Adverse Events/Problems Form).