FAQs on 2018 Common Rule Changes (2018CR) – January 9, 2020

Changes to the Common Rule, the primary rule regulating human subjects research, went into effect on January 21, 2019. This FAQ will be updated as new information and guidance becomes available. A number of TU policies, procedures, and forms have been updated to reflect the 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 the Expedited review process). This change is expected to increase the number of protocols that will be determined in the Exempt category.

- **EXPEDITED Protocols** – For now, The Office of Human Research Protections (OHRP) will continue to use the current list of Expedited categories. However, OHRP will publish, sometime in the future, a list of Expedited ‘Activities’ to their website. This proposed list of activities is expected to increase the number of Expedited protocols and clarify the types of activities that will fit the Expedited category. (TBA)

- **Informed Consent regulations are less cumbersome and allow more flexibility to investigators**
  - New Informed Consent Form (ICF) Instructions –please read thoroughly
  - A new “Key Information…” section and a rearrangement of content designed to aid in a subjects’ decision whether to participate or not.
  - New ‘additional elements of consent’ required to add to your form if applicable to your study–please read the ICF instructions
  - New sample Informed Consent Forms have been added that you can view and use for reference.
    - To view, scroll down the main TU IRB webpage to the “TU IRB Consent Form Options” and click on the first form: “TU IRB Informed Consent Form Instructions”. At the top of the form, you will see a list of Informed Consent Form templates, with a link to each sample form at the end of each listing.
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 the PI with a reminder to complete an annual progress report each year. Instead, the IRB Office will verify the PI’s ‘proposed end date’ and email the PI anywhere from 30-90 days of that date, to check the status and see if the study is ready to be closed out or to extend the proposed end date.

Q. When would applying the 2018CR regulations be beneficial to my currently approved Expedited or Full Board protocol (that was approved before the 2018CR effective date)?
A. When you are able to take advantage of some of the burden reducing regulations like no more annual reviews for certain categories of research (All Expedited studies and Full Board studies that the only remaining activity is the analysis of identifiable data/bio-specimens or activity to obtain follow-up clinical data),

Q. Do I need to do anything if I have an Expedited or Full Board protocol that was approved before the 2018CR effective date?
A. No. ALL current Expedited and Full Board protocols that were approved before the 2018CR effective date will continue to follow the Pre-2018 CR regulations until the study ends or until a time that you request to roll over your study to the 2018CR regulations.

- At the time you request to apply the 2018CR regs, 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 or if the date needs to be extended.

Q. Do I need to do anything 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 regulations.

Q. If I have an existing non-Exempt protocol that is still enrolling new subjects and was approved before the 2018CR effective date, do I need to roll it over to the new 2018CR regulations and submit the latest Informed Consent Form (ICF) version or can I continue to use the currently approved form?
A. No. You can continue to follow the pre-2018CR regulations through the end of the study and continue using your current Pre-2018CR ICF for the remainder of the study. If later, you decide to request to apply the 2018CR regulations, all 2018CR regulations would apply and you would have to submit an updated 2018CR ICF template.
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 projects 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 or future revisions after December 31, 2018 will be marked with that future date). As we get feedback from the research community, forms will continue to be revised and improved. Therefore, always use the latest forms from 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. When will I be required to use the new IRB Forms?
A. Immediately. Updated forms have been available since the start of the SP18 semester. PIs will be required to use the new forms immediately and old form versions (with a date earlier that the online forms) will no longer be accepted. The latest IRB forms are 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 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). Please attached a current IRB training completion certificate for each new research staff.

- 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).

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