Dear TU Researchers Engaged in Research with Human Subjects:

Due to the current COVID-19 outbreak, The University of Tulsa’s Institutional Review Board wants to support any investigators considering how to incorporate TU’s new Social Distancing Policy in their research protocols. Whether and when this may be advisable will vary depending on each protocol and the subjects with whom investigators are working. Examples of such changes might include changing frequency of in-person visits or replacing in-person interviews with telephone or Internet contacts, sanitization procedures, excluding people with fevers, reminding ill people not to come in etc. Although the TU IRB must review and approve revisions to protocols before they are implemented, there is one important exception provided in the federal guidelines: “where necessary to eliminate apparent immediate hazards to the human subjects.” 21 CFR 56.108(a)(4).

TU IRB Procedures for Protocol Modifications Due to COVID-19

- Should TU investigators determine that changes in their procedures are required, they can implement them immediately, without prior notice to or approval from the TU IRB.

- TU investigators will need to ensure that they are not introducing other risks, and that they may need to ask subjects to sign revised informed consent forms.

- The changes should be reported to the TU IRB as soon as possible, and the TU IRB will request justification for a delay of more than 5 business days. If a full revised protocol cannot be completed in that time, a document that describes the changes and explains how they will protect subjects can be submitted, along with copies of any new or revised subject-facing materials.

Please notify the Research Compliance Coordinator, Carmen Schaar-Walden, of any upcoming revisions that you will be submitting at carmen-schaar-walden@utulsa.edu or 918-631-3310.