

## **Collaborative Research and IRB Reliance**

Tennessee Tech University participates in collaborative, multi-institutional human subjects research. In cases where a Tennessee Tech researcher is conducting collaborative, non-exempt (i.e., Expedited or Full Board) research involving human subjects with an institution that has a federalwide assurance (FWA), it may be possible to establish a reliance agreement which allows a Tennessee Tech researcher to rely on IRB review conducted by the other institution. Tennessee Tech does not have the staff or resources to serve as the reviewing IRB or IRB of record for a multi-site study.

### **Ceding IRB Review to Another Institution**

Before you can participate in a study being conducted through an external IRB of record, the Tennessee Tech IRB must first review your cede review request to verify that you meet all the institutional requirements (such as CITI training) and decide whether it will agree to cede review to the outside IRB of record based on your research activities. If Tennessee Tech agrees to cede review to another institution's IRB, a reliance agreement (also called an IRB Authorization Agreement or IAA) will be signed by both institutions.

All reliance agreements are established on a case-by-case basis. Tennessee Tech does not enter into reliance agreements for the following protocols:

- Exempt research
- Development Only/Just-in-time applications that lack definite plans for the involvement of human subjects at the time of protocols submission
- Projects where Tennessee Tech researchers are not considered engaged in human subjects research

Tennessee Tech researchers must be prepared to follow the policies and procedures of the reviewing IRB. They are responsible for understanding the policies and procedures of the reviewing IRB and conducting the research accordingly. Specifically, it is important for Tennessee Tech researchers to understand the reviewing IRB's expectations for reporting adverse events, deviations, noncompliance, and other problems to the reviewing IRB, as well as expectations for updating personnel and enrollment status, submitting amendments, and tracking subject enrollment and status.

Below are the steps required for Tennessee Tech researchers to request ceding IRB review to another institution's IRB. The time frame for the process varies, based on whether your submission packet is complete, how long it takes to coordinate the reliance agreement with the reviewing IRB, etc. As such, please allow sufficient time for processing and review, as these steps involve multiple levels of coordination and compliance verification.

### STEP ONE: SUBMIT A "REQUEST TO CEDE IRB REVIEW" PACKET

The Tennessee Tech researcher must submit a complete [Request to Cede IRB Review](#) packet to the IRB Administrative Office at [IRB@tnitech.edu](mailto:IRB@tnitech.edu). This should only be done after the research study has been approved by the reviewing IRB.

### STEP TWO: IRB ADMINISTRATIVE OFFICE INTAKE AND PROCESSING

Upon receiving the cede-review request, the Tennessee Tech IRB Administrative Office will check the submission for completeness. If the submission is complete, the office will forward the complete packet to the IRB Chair for review.

### STEP THREE: REVIEW AND DETERMINATION BY THE IRB CHAIR

The IRB Chair will evaluate the request and determine whether Tennessee Tech is Engaged in Human Subjects Research.

- If Tennessee Tech is not engaged, no reliance agreement may be required. The faculty member will receive a **Non-Engagement Determination Email**.
- If Tennessee Tech is engaged, the IRB Chair will determine whether ceding review is appropriate.

### STEP FOUR: RELIANCE AGREEMENT

If Tennessee Tech is engaged and ceding review request is approved, the IRB Administrative Office will coordinate the execution of a reliance agreement with the reviewing IRB. Once the reliance agreement is fully executed, the Tennessee Tech faculty member will receive an official **IRB Reliance Authorization Notice** via email confirming that:

- Tennessee Tech will rely on the reviewing IRB, and
- The Tennessee Tech faculty member may begin human subjects research.

### Questions?

Please contact the IRB Administrative Office at [IRB@tnitech.edu](mailto:IRB@tnitech.edu).