TRAINING IN THE RESPONSIBLE CONDUCT OF RESEARCH (RCR)

Faculty members engaged at research at West Virginia University (WVU) are required to maintain certification in the responsible conduct of clinical research through on-line training in human subject research and the role of the IRB via the Collaborative Institute Training Initiative (CITI). I have completed the required training for the Biomedical Research Investigators module and the Social and Behavioral Research Investigators module (both in good standing through 2024) and the CITI Good Clinical Practice Course (in good standing through 2023). CITI certification includes the topics of research ethics, regulations and processes, informed consent, social and behavioral research, records–based research, genetics research, and research involving vulnerable populations. Certification must be renewed every 5 years after a review course on the above topics. I will continue to maintain these certificates throughout the K23 award period.

During the K23 award period, I will participate in a formal RCR training as follows:

1. **Format:** I will participate in the WVU Clinical and Translational Science course CTS 610 entitled "Clinical Research: Ethics and Regulatory Aspects". This is a graduate level course offered by the MS Program in Clinical and Translational Sciences through the West Virginia Clinical and Translational Science Institute (WVCTSI).
2. **Subject matter:** The CTS 610 course will address ethical and regulatory issues in conducting clinical research including publication and authorship issues, informed consent, conflict of interest, among other topics.
3. **Faculty Participation:** The CTS 610 course is directed by Dr. Joan M. Lakoski, Co-Director of the WVCTSI Professional Development Core, Adjunct Professor in the WVU School of Pharmacy, and Program Director of the MS and Certificate Programs in Clinical and Translational Sciences.
4. **Duration of Instruction:** The CTS 610 course combines both online and in-person training with 8 hours contact time with face-to-face training involving case studies and small group discussions.
5. **Frequency of Instruction:** I will enroll in the CTS 610 course in Year 1 of the K23 award. As described above, I will also maintain institutional and CITI training as required on an annual basis through K23 award period. I will also participate the WVCTSI's *Principal Investigator (PI) Academy*, which provides monthly seminars to allow investigators to learn essential skills in the development and conduct of clinical trials. These meetings will include regular instruction and feedback from regulatory experts focused on the RCR. I will also take the NIH tutorial "Protecting Human Research Participants" at the beginning of the K23 award period.

My mentoring team will play an important role in my RCR training. They will provide mentorship in research ethics during our monthly meetings and throughout the development and implementation of this project.