EFFECTIVE DATE: March 2023

The Principal Investigator is the individual of record who assumes the authority and responsibility for the conduct of a clinical study. The purpose of this Policy and Procedure is to provide information on the responsibility of the investigator(s) in regards to Good Clinical Practice (GCP) and clinical trials. The rights and welfare of the individual clinical research subject must always be the paramount consideration in conducting clinical research. Accordingly, clinical research must be conducted in a manner that protects the rights, welfare and confidentiality of the human subject and also assures data credibility by protecting the integrity of accurate data that has been demonstrably collected according to the approved protocol.

This Policy and Procedure applies to Principal Investigators, Sub-Investigators, Clinical Research Coordinators, and any other USA personnel that perform significant, trial related tasks. USA non-research personnel who perform trial related tasks are not required to complete GCP training if the research task in which they will be performing is within their normal scope of practice and/or duties. This Policy and Procedure will also apply to non-USA personnel who perform significant trial related tasks on USA property or facilities.

Good Clinical Practice (GCP) is an international ethical and scientific quality standard that helps ensure that the results of a clinical trial are credible and that the rights, welfare and confidentiality of the human subject are protected. Good Clinical Practice provides guidance on the best practices for the way a clinical trial is designed, conducted, performed, monitored, audited, recorded, analyzed, and reported.

The individual of record who assumes the authority and responsibility for

through a class or course, academic training program, or certification from a recognized clinical