University Health System

Human Subjects Institutional Assurance

IRB Protocol Number	Study Title

Policy and Procedure Compliance

- I and my research staff have completed the research scope of practice and have completed all requirements for the University Health System (the "Health System") credentialing process.
- I agree to comply with and to require compliance by research staff, with the policies and procedures of the Health System, as well as the Supplemental Conditions attached and incorporated hereto at Addendum A.
- I have read and understand the Health System Human Protections Policy and the Health System Policy concerning HIPAA compliance.
- All occurrences causing or having potential to cause injury to patients, visitors and/or staff are to be reported to the Health System Risk Management at the time of the occurrence in accordance with the Health System Policy on Occurrence Reporting 5.015.
- I will provide the Health System with all study drug supplies and I understand that the Health System Pharmacy Department will dispense all drug supplies according to its Investigational Drug Policy 2.0201. Documentation of sponsor/monitor contacts, including visit log and correspondence, will be maintained in my office and, for drug studies, also in the Pharmacy. Upon closure of the study all pharmacy research records will be given to me for storage.
- I agree to notify corporate communications prior to any media release of research results that would identify the Health System as the clinical site.

Education

- I and my research staff have completed the appropriate initial and continuing education and training about human subject protection, such as CITI training or equivalent.
- I have completed training for Sunrise orders and documentation.

Financial Costs of Research Study

- I have disclosed all requirements of this study that could result in charges being generated that are not Standard of Care and that would be paid for by this study and/or me as Principal Investigator. Agreement(s) will be established between the Health System and a representative of the Academic Institution whose signature is binding for any research study in which charges may be generated.

Select the type of signatures provided:	Method of Submission
○ Option A. A **scanned copy** of an original signature	Print, obtain signatures, then scan and submit an electronic (PDF) file of this signed form
○ Option B. **Electronic signature** applied to this document	When final digital signature is applied, lock the document & submit this Adobe Acrobat version

P.I. Signature _____ Date_____

P.I. Name (typed)_____