Instructions

*This form should be completed and signed by the local Principal Investigator who is responsible for the study implementation at his/her specific site (i.e., if the study is under an IND this page is signed by the individual who signs the Form FDA 1572; or, if the study is under an IDE this page is signed by the individual who signs the Investigator of Record form).*

Provide the following information and a digital or wet signature. A reproduced signature will not be accepted.

Protocol Number: _____

Protocol Version:
(Specify by Date, Number, or Letter) _____

Specify Type: ☐ Initial ☐ Amendment

Site Name: _____

The signature below provides the necessary assurance that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH E6 Good Clinical Practice (GCP) guidelines.

I agree to conduct the study in compliance with GCP and applicable regulatory requirements.

I agree to conduct the study in accordance with the current protocol and will not make changes to the protocol without obtaining Sponsor and IRB approval, except when necessary to protect the safety, rights, or welfare of participants.

Principal Investigator Name (print/type): _____

Principal Investigator Signature: _____ Date: _____