

Attestation for the Use of Investigational Devices in the Conduct of a Research Study

PI _____ IRB # _____

Name of protocol: _____

I attest to the following (check all that apply):

- I have made arrangements for storage of the investigational device(s) under proper conditions (according to the manufacturer, Sponsor or FDA) and in a locked, secure area.
- I have a method for maintaining records and accountability of the investigational device(s).
- I / my staff have a method for properly dispensing the investigational device(s) and the person(s) dispensing the investigational device(s) are within their scope of practice in doing so.
- I / my staff understand the proper utilization of the investigational device(s), have been thoroughly trained in the use of the investigational device(s), and can produce certifications, credentials or other documentation of my/staff competency in the use of the investigational device(s) if asked. The person(s) using the investigational device(s) are within their scope of practice in doing so
- I or my staff will properly return or dispose of unused devices/equipment at the end of the study.
- I will properly undertake the informed consent process and will obtain a signed Informed Consent Form before using/dispensing the investigational device(s).

Principal Investigator (signature)

Date