# Documentation of Informed Consent and Authorization Process for Research

**IRB Study #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Protocol ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Subject Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Subject Study ID: \_\_\_\_\_\_\_\_\_\_\_\_**

Other individuals present with subject during the informed consent process:

Name: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Relationship: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Name: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Relationship: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Additional research team members involved in this informed consent process:

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

* Subject was given a copy of the study’s informed consent document and authorization form and given ample time to read them.
* The subject was given sufficient opportunity to ask questions. The subject’s questions were answered satisfactorily.
* The subject’s voluntary written informed consent and authorization were obtained prior to any research related procedures for this study being conducted.

*OPTIONAL TIP: If no other study documents record the time that consent was obtained (in relation to any other procedures performed at that visit), consider documenting the date/time of the signature here on your Process Documentation:*

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time: \_\_\_\_\_\_\_\_\_\_\_\_\_

* A [signed]\* copy of the informed consent was given to the subject to keep.

*OPTIONAL TIP: FDA and IU policy allows the consent copy given to subjects to be signed or unsigned. If your study requires you to follow Good Clinical Practices, however, you are required to provide the subject/LAR with a signed copy of the informed consent. “Signed” should also be included here when it is your standard practice to do so, as this should reflect your typical process.*

* A signed copy of the completed authorization form was given to the subject to keep.

Additional Comments: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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Person Obtaining Consent completed all procedures stated above: ⬛ **Yes** ⬛ **No**

If No, describe deviations from the procedures as stated: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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Signature of Person Obtaining Consent Date