# Documentation of Informed Consent and Authorization Process for Research

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

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

The subject has impaired capacity to provide consent based on **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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Name of LAR: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**\*Legal** ⬛ Legal Guardian (of Person) ⬛ Power of Attorney Healthcare

**Authority:** ⬛ Authorized Legal Representative (Relationship to Subject:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

*Please note: In accordance with IU HRPP Policy, attempts to identify and contact LARs at each hierarchy level of the Indiana State Law must be documented in the study records.*

Other individuals present with subject during informed consent process:

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

Name, Relationship Name, Relationship

Additional research team members involved in this informed consent process:

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

* Subject/Legally Authorized Representative (LAR) was given a copy of the Informed Consent and Authorization form for the study and given ample time to read them.
* The subject/LAR was given sufficient opportunity to ask questions. The subject’s/LAR’s questions were answered satisfactorily.
* The subject’s/LAR’s voluntary written informed consent was obtained prior to any research related procedures for this study.

*OPTIONAL TIP: If no other study documents record the time 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/LAR 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 stated: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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Signature of Person Obtaining Consent Date