# Documentation of Informed Consent Process for Research – Reconsent

**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 revised informed consent document for the study and given ample time to read it.
* The new or changed information in the informed consent document was explained and the subject was given sufficient opportunity to ask questions. The subject’s questions were answered satisfactorily.

Comments or notes regarding changes: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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* The subject’s voluntary written informed consent was obtained prior to implementing any new research related procedures or prior to any study intervention in which new or different risks have been identified as described in the revised informed consent form for this study.

*OPTIONAL TIP: If no other study documents record the time reconsent 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.*

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

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

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

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Signature of Person Obtaining Consent Date