# Documentation of Informed Consent/Assent and Authorization Process for Research

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

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

The subject is a minor.

As determined by the IRB, consent for the subject’s participation is required from ⬛ one parent

(or) ⬛ both parents.

Consent was provided on subject’s behalf by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(name(s) of individuals)*

**\*Legal Authority:** ⬛ Parent(s) ⬛ Legal Guardian

*Please note: In accordance with IU HRPP Policy, attempts to identify and contact the second parent must be documented in the research record.*

Other individuals present with subject during informed consent process:

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

Name, Relationship Name, Relationship

Additional research team members involved in this informed consent process:

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

* Parent(s)/Guardian was/were given a copy of the Informed Consent and Authorization form for the study and given ample time to read them.
* If applicable, the Assent form was reviewed with the minor subject.
* The Parent(s)/Guardian (and minor subject, if applicable) was/were given sufficient opportunity to ask questions. All questions were answered satisfactorily.
* The Parent(s)/Guardian’s voluntary written informed consent (and written assent from the minor subject, if applicable) was/were 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 (and assent form, if applicable) was given to the Parent(s)/Guardian (and minor subject, if applicable) 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/Parent/Guardian 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 Parent/Guardian to keep.

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

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

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

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

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

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

Signature of Person Obtaining Consent Date