Protocol: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Consent or Assent version: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ IRB approval date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Subject ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date consented: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**\_\_\_\_\_ The subject’s identity was verified using at least 2 identifiers.**

 □ Full name □ DOB □ Address □ Phone number □ EMR photo

□ *Check if NA*

**\_\_\_\_\_ The subject has a legally authorized representative (LAR).**

□ Parent □ Legal guardian or loco parentis □ Other LAR relationship\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**\_\_\_\_\_ The consent form was given to the subject/LAR with ample time and opportunity to allow the subject/LAR to inquire about details of the study and consider whether or not to participate.**

**\_\_\_\_\_ The person conducting the informed consent discussion fully reviewed the consent form with the subject/LAR including, but not limited to, risks and benefits, other treatment options, the right to withdraw from the study at any time, information on who to contact for study related questions, and other elements listed in ICH GCP 4.8.10**

**\_\_\_\_\_ The subject/LAR was given the opportunity to ask questions, and questions were answered to the subject’s/LAR’s satisfaction.**

**\_\_\_\_\_ The consent form was signed and dated by the subject/LAR and the person conducting the informed consent discussion.**

**\_\_\_\_ A copy of signed consent form was given to subject/LAR.**

**\_\_\_\_\_ A copy of the signed consent form was placed in the subject’s medical record, if required by IRB.**

**\_\_\_\_\_ The original signed consent form was placed in subject’s research file.**

**\_\_\_\_\_ The informed consent discussion was conducted, and informed consent was obtained prior to completion of study procedures.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Conducting Informed Consent Discussion Date