**Documentation of Informed Consent Process Tool**

IRB# \_\_\_\_\_\_\_\_\_\_\_\_

Participant Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Who Consented the Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

When Consented (Date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Where Consented (Location) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant was given the opportunity [ ]

to read the consent form and have

questions answered.

Consent form was reviewed with the [ ]

participant.

Participant expressed understanding. [ ]

Participant agreed to participate and signed consent. [ ]

Copy of Consent Form Given [ ]

*Participants must get a signed copy.*

Notes (To be used to document special circumstances and/or participant questions/concerns)

Signature of Person Obtaining Consent from Participant

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

**Documentation of Child Assent Process Tool:**

**If assent is also obtained from a minor:**

Document any special circumstances regarding the assent process below (*EX 1: a 13 year old child was assented using the IRB approved assent form for children ages 7-12. Provide justification as to why the chosen assent form was used for the individual child; EX 2: Describe whether any dissenting behaviors were observed during the assent process. EX 3: For research that requires both parents’ consent (approved under 46.406), if only one parent consent was obtained due to the second parent being “not reasonably available”, explain the reason why the second parent was not available to consent)*