**DOCUMENTATION OF CONSENT PROCESS**

**Study Title:**

**PI:**

**IRB#:**

**Subject Name/Initials:**

**Consent Version and Date:**

**Person Conducting Consent/Assent Process:**

Person obtaining consent must initial each completed step below:

 Informed consent was discussed with the subject and/or authorized representative for the above-referenced study. A copy of the consent form was provided for the subject and/or authorized subject representative to review.

 Subject and/or authorized subject representative was given adequate time to read the consent form and discuss the study with study investigators and/or family members.

 All questions were answered. Subject and/or authorized subject representative was given time to discuss.

 Subject and/or authorized subject representative signed and dated the informed consent. A copy of the consent form was provided to the subject and/or authorized subject representative upon conclusion of the consent process.

 During the informed consent process, the following questions were asked by the subject and/or authorized representative and were answered by study personnel:

 Consent has been signed prior to any study procedures being performed.

**Consent process documented by:**

 Print Name

*NOTE: Please follow your organization’s site-specific rules regarding consenting and who may obtain and document the consent/assent.*

 Signature Date