Principal Investigator:
IRB #:

DOCUMENTATION OF CONSENT PROCESS

Subject Initials: _____

Person obtaining consent initial each completed step in the process:

____ Informed consent was discussed with subject for the above referenced study. Copy of the consent form was provided for subject and/or authorized subject representative 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 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

_____ _____
Signature Date