## DOCUMENTATION OF CONSENT PROCESS

## Subject Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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