HUMAN SUBJECTS PROTECTION PROGRAM

Consent Process Documentation

IRB# and Title:
PI:
Study Sponsor:

Informed Consent Checklist
Version 12/08/2014

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