PT. INIT: _____
PT. #: _____

Protocol #:_____

Source Documentation

CONSENTING PROCESS

On the _____day of _____, I discussed the possibility of participating in a clinical research trial for Protocol _____
_____,
with the above subject. The study was explained in detail including, but not limited to the contents of the informed consent, purpose of the study, visits and procedures involved, risks and benefits, alternative treatment, confidentiality, the right to withdraw from the study at any time, treatments provided, arms of the study and randomization. The subject was encouraged to ask questions. All questions were answered to the satisfaction of the subject. The subject was given adequate time to read the informed consent and the opportunity to discuss it. The subject demonstrated understanding of the informed consent and would like to participate. The informed consent was singed without alteration and a copy was given to the subject.

The informed consent was signed on _____/_____ at _____am/pm to any study-related procedures being performed.

Specific items/concerns noted during the consent process:

_____

_____

_____

_____

_____

_____

_____ _____
Signature of person obtaining consent Date