Documentation of Consent Process

Study Name _____ Protocol # _____

Patient # _____ Patient Initials _____

Clinical research coordinator (CRC) explained the arms, methods, anticipated benefits and potential risks of participating in this study and informed the patient that participation is voluntary and that they can withdraw from the study at any time. Subject was given ample time to review Informed Consent Form (ICF) and ask questions. All of subject's questions were answered prior to signing ICF. The patient was given a signed copy of informed consent for their records prior to any study related procedures. Subject received HIPAA notice and signed and given a copy of HIPAA authorization for research form. CRC reviewed emergency numbers and procedures to follow should he/she need medical attention when clinical site is closed.

Date	Procedure
_____	Patient/subject provided with Informed Consent Form
_____	Consents reviewed with subject
_____	HIPAA authorization form reviewed with subject
_____	Patient agreed to participate in study
_____	Consent version # _____ signed and dated
_____	HIPAA form signed and dated (if applicable)
_____	Copy of signed consent was given to patient/subject

_____ _____

Signature of Person Obtaining Consent Date