

Study Title

Protocol #

Participant Name: _____ **MRN:** _____

INFORMED CONSENT PROCESS

VISIT DATE ____ / ____ / ____ / (D/M/Y)

1) Has the patient signed the main study consent form? Yes No

Date consent signed ____ / ____ / ____ / @ ____: ____ hrs.

Consent Process for Study Title

The details of the above study were discussed with the participant. The study was explained in detail including all the contents of the informed consent document. The participant was encouraged to ask questions. All questions were answered to the satisfaction of the participant. The participant was given adequate time to read the informed consent form **(ICF) version** _____ and the opportunity to discuss it. **ICF version** _____ **was** signed without alteration by the participant.

The original copy of the signed informed consent document was placed in secure study file and a photocopy given to the participant.

Consent obtained by _____ **Signature:** _____

Date: ____ / ____ / ____ /

Addendum
