

DOCUMENTATION OF INFORMED CONSENT

Study Title: _____

Staff Present during Consent: _____

- Prior to any study-related procedures, the participant was given ample time to review the informed consent form and ask questions regarding the study.
- All inclusion and exclusion criteria have been met.
- The purpose, procedures, risks, benefits (if any), voluntariness, and alternatives were discussed, understood, and accepted.
- Once all questions and concerns were answered, the participant agreed to participate and signed the informed consent form and HIPAA Privacy form.
- The participant was given a copy of the signed consent and HIPAA Privacy form for their records.

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