

A. Core Informed Consent Principles

Principle	Key Requirement
Voluntary Participation	Participation is voluntary, without coercion or undue influence
Prior to Study Procedures	Consent obtained before any study-specific procedures
Adequate Information	Purpose, procedures, risks, benefits, alternatives explained
Understandable Language	Information provided in a language understandable to the participant
Opportunity to Ask Questions	Adequate time given for questions and clarification
Assessment of Understanding	Investigator ensures participant comprehension
Right to Withdraw	Participant may withdraw at any time without loss of standard care
Ethics Committee Approval	Only EC-approved ICF and PIS used
Documentation of Consent	Written, signed, and dated consent
Copy to Participant	Signed copy of ICF provided to participant
Protection of Vulnerable Participants	Additional safeguards applied where applicable
Impartial Witness (When Required)	Witness required for illiterate participant/LAR
Re-Consent	Re-consent for protocol changes or new safety information
Ongoing Process	Consent is continuous throughout the study

B. Informed Consent Documentation – Based on Participant Condition

Participant Condition	Consent Given By	ICF Details Filled By	Signature / Thumb Impression Requirements
Literate Participant	Subject (signature & date)	Subject	Subject: Signature & date Legally Acceptable Representative: Blank Investigator (PI/Co-I): Signature & date Witness: Blank
Illiterate Participant	Subject (thumb impression)	Impartial Witness (IW)	Subject: Thumb impression (<i>do not write name or date</i>) Legally Acceptable Representative: Blank Investigator (PI/Co-I): Signature & date Witness: IW signature & date
Unconscious / Vulnerable Participant	Legally Acceptable Representative (LAR) – signature & date	Legally Acceptable Representative	Subject: Blank Legally Acceptable Representative: Signature & date Investigator (PI/Co-I): Signature & date Witness: Blank
Unconscious / Vulnerable Participant with Illiterate LAR	LAR (thumb impression)	Impartial Witness (IW)	Subject: Blank Legally Acceptable Representative: Thumb impression (<i>do not write name or date</i>) Investigator (PI/Co-I): Signature & date Witness: IW signature & date