Informed Consent Process and Documentation

Written informed consent will be obtained from the parents or legal guardians of all neonates before any study-related procedures are initiated. The consent process will be conducted in a quiet environment by the lead researcher, ensuring that the legal guardians fully understand the nature, purpose, and potential risks of the study.

Key elements included in the Informed Consent Form (ICF):

- **Study Purpose and Procedures:** A clear explanation that the study investigates the effects of a 15-minute foot reflexology session (3 times daily for 72 hours) on the infant's comfort and physiological stability during Therapeutic Hypothermia.
- **Voluntary Participation and Withdrawal:** Explicit statement that participation is entirely voluntary and that guardians may withdraw their consent at any time without any penalty or loss of benefits to the infant's standard medical care.
- **Confidentiality:** Assurance that all personal and clinical data will be de-identified using study codes and kept strictly confidential, accessible only to the research team.
- **Risk and Safety Monitoring:** Information regarding the continuous monitoring of the infant's vital signs and the strict "session termination criteria" (e.g., changes in temperature or heart rate) to ensure the infant's safety always takes precedence over the research.
- **Contact Information:** Provision of the principal investigator’s contact details for any questions regarding the study or the infant's rights.