UNIVERSITY OF SÃO PAULO
SÃO PAULO MEDICAL SCHOOL

INFORMED CONSENT FORM

Official Title of the Study:

Safety and Effectiveness of Different Interface Models for Non-Invasive Ventilation Support in Preterm Infants with a Gestational Age of 28 Weeks or Greater

NCT Number:	NCT Pending (or insert NCT number if assigned)
Document Date:	September 19, 2025
Principal Investigator / Author:	André Luis Bispo Neves Master's Research Project in Child Health
Advisor / Co-Investigator:	Prof. Cintia Johnston, Ph.D.

This document contains the official Informed Consent Form submitted to ClinicalTrials.gov in accordance with 42 CFR 11.48 and ClinicalTrials.gov Results Data Element Definitions.

FREE AND INFORMED CONSENT FORM

We invite you to voluntarily participate in the research study "Safety and effectiveness of different interface models for non-invasive ventilation support for preterm infants with a gestational age of 28 weeks or greater." This study aims to understand which mask or prong is safer and more effective for preterm newborns with a gestational age greater than or equal to 28 weeks, in order to determine which mask or prong is safer and more effective for babies born prematurely who need help breathing.

Your baby was invited because they were born prematurely and are in the NICU. Babies born at this age who need this breathing assistance will be randomly assigned to different types of masks. Only the masks will be different and randomly selected; the type of ventilation will be individualized and adjusted according to each child's needs.

The newborn will be assessed six times a day throughout the entire time the mask is worn, and their record will be filled out with information that will be analyzed later. During the use of these masks, skin lesions may occur due to the fragility of the newborn's skin and the pressure of the mask on the skin; when this occurs, a dressing will be applied to protect and heal the skin.

This research will help us understand what the best type of mask is for newborns using this therapy and what we can do to minimize any skin lesions that may arise.

The masks will be chosen according to the baby's size and the manufacturer's specifications. Care will also be taken with the fit and positioning, and inspections will be frequent in order to prevent or identify any possible problems early. Your baby will be monitored by a healthcare team throughout the entire period.

After the data collection and analysis are complete, the researchers involved commit to presenting the results to the ICU manager, the multidisciplinary team, and making them available at the Hospital's Continuing Education Center.

You may refuse or withdraw your consent to participate at any time. There are no personal expenses for the participant at any stage of the study. There is also no financial compensation related to your participation. The researchers commit to using the data obtained only for scientific purposes. It is also important to say that this research may be published in journals and other types of communication within the scientific community, with full guarantee of confidentiality.

Expenses arising from the research will be reimbursed by the principal investigator; if necessary, the participant is entitled to compensation for any damages arising from this research. In the event of damages arising from the research, the research participant will receive full and immediate assistance, free of charge, for as long as necessary (CNS Resolution No. 466/12 item IV.3, letter gehe and Resolution 510/2016 Chapter IV § 2 and Chapter III, Art. 9° V).

At any stage of the study, you will have access to the professionals responsible for the research to clarify any doubts. The principal investigator is André Luis Bispo Neves, who can be found at

Rua da Barra, 705 - Jardim Cruzeiro / Feira de Santana-BA / CEP: 44015-430 / Telephone: (75) 3602-7202 Extension 295, Mobile: (75) 99263-7926 or by email: andrelbneves@gmail.com. If you have any concerns or questions about the ethics of the research, or if you need further clarification related to ethical issues, please contact the CEP Research Ethics Committee of the State University of Feira de Santana, which is responsible for overseeing all research involving human subjects evaluated by this Committee, and is located at the STATE UNIVERSITY OF FEIRA DE SANTANA, CAU III, Room CEP/UEFS, Avenida Transnordestina, S/N. Neighborhood: Novo Horizonte. Feira de Santana - Bahia. Postal Code: 44036-900, WhatsApp 75 9847-7655, email: cep@uefs.br. Opening hours: Monday to Friday: 8:00 - 12:00.

I was sufficiently informed regarding the study "Safety and effectiveness of different interface models for non-invasive ventilation support for preterm newborns with a gestational age greater than or equal to 28 weeks." I am aware and agree that one of the skin lesion assessments involves taking photos of my child's face; these photos will not be published. This record will be made by the NICU physiotherapy team, previously trained for this purpose. The photographs will be stored in a folder with the patient's identification number to preserve the identity of the research participant, with access only to members of this research, guaranteeing the secrecy, confidentiality, and security of the participants' data, as stated in CNS Resolution No. 466 of 2012. The images will be used for analysis; there will be no disclosure of these images.

I discussed the above information with the Principal Investigator André Luis Bispo Neves or person(s) delegated by him (.....) regarding my decision to participate in this study.

The objectives, procedures, potential discomforts and risks, and guarantees were made clear to me. I voluntarily agree to participate in this study, sign this consent form, and receive a copy signed by the researcher.

_____	_____
Signature of participant / legal representative	Principal Investigator Signature
Date: ___ / ___ / _____	Date: ___ / ___ / _____