EMPRESA BRASILEIRA DE SERVIÇOS HOSPITALARES
HOSPITAL UNIVERSITÁRIO ONOFRE LOPES
GERÊNCIA DE ENSINO E PESQUISA

CONSENT FORM

Clarifications

This is an invitation for you to participate in the survey: **Effects of an optimised approach to home-based respiratory care in individuals with Amyotrophic Lateral Sclerosis: a study protocol for a randomised controlled trial**, whose responsible researchers are Dr. Guilherme Augusto de Freitas Fregonezi, Dr. Vanessa Resqueti, Ms. Karen de Medeiros Pondofe, Ozana de Fátima Costa Brito, Dr. Mario Emilio Texeira Junior, Dr. Rodrigo Torres-Castro.

This study aims to investigate the effects of an optimal home-based respiratory care protocol in individuals with ALS.

The reason that leads us to carry out this study is the need for the continuous care of patients with ALS through a care model based on the integral and global intervention of patients, in health education for their families.

If you decide to participate, you must undergo a physical therapy assessment with non-invasive tests to observe lung function, respiratory muscle strength, breathing patterns, chest wall kinematics and functional physical capacity.

Participants will be randomly allocated two groups. The conventional respiratory care group (CRC) or the optimised respiratory care home-based group (ORC). The CRC group will receive education on respiratory care during quarterly hospital visits and the physiotherapist will provide settings to use or improve non-invasive ventilation and the adaptation of masks, if necessary. The ORC group will receive education on respiratory care during quarterly hospital visits and weekly home visits by a physiotherapist will provide settings to use and improve non-invasive ventilation, bronchial hygiene techniques, aspiration of upper airways, and assisted coughing through ventilation by mechanical insufflation-exhaustion and/or air stacking. Both groups will receive weekly telephone calls to monitor patients. Furthermore, all caregivers will be trained to monitor vital signs (systemic blood pressure, heart rate, and respiratory rate) and peripheral oxygen saturation.

During the research, reassessments will be made every 3 months with tests of maximum inspiratory and expiratory pressures, dynamics of mobilization of the rib cage during breathing, nasal inspiratory and expiratory pressures, measures of lung capacity. The risk forecast is minimal, that is, the risk you take is similar to that felt in a physical exam.

Momentary respiratory discomfort can occur due to the use of muscles in patients with decreased strength, but which stabilizes quickly and you will benefit from receiving physical therapy assistance for respiratory and motor care, as well as monitoring the evolution of chronic disease.

In case of any problem that you may have, related to the research, you will be entitled to free assistance that will be provided through physical therapy assistance by the responsible researchers.

Participant / Legal Responsible rubric:	Researcher rubric:

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During the entire survey period, you can answer your questions by calling _____ at XXXX-XXXX or sending an email to xxxxxxxx@xxxxxx.com.

You have the right to refuse to participate or withdraw your consent, at any stage of the survey, without prejudice to you.

The data you will provide to us will be confidential and will only be disclosed in congresses or scientific publications, with no disclosure of any data that can identify you.

These data will be kept by the researcher responsible for this research in a safe place and for a period of 5 years.

If you have any expenses for your participation in this research, it will be assumed by the researcher and reimbursed to you. If you suffer any damage proven to result from this research, you will be compensated.

Any questions about the ethics of this research, you should contact the Research Ethics Committee of Hospital Universitário Onofre Lopes, telephone: XXXX-XXXX, address: _____. xxxxxxxx@xxxxxxx.com.

This document was printed in two copies. One will stay with you and the other with the researchers in charge.

Informed Consent

After having been clarified about the objectives, importance and the way the data will be collected in this research, in addition to knowing the risks, discomforts and benefits that it will bring to me and being aware of all my rights, I agree to participate in the research **Effects of an optimised approach to home-based respiratory care in individuals with Amyotrophic Lateral Sclerosis: a study protocol for a randomised controlled trial** and I authorize the disclosure of information provided by me at congresses and / or scientific publications as long as no data can identify me.

Natal, _____/_____/_____.

Patient fingerprint

_____
Signature of research participant

Participant / Legal Responsible rubric:	Researcher rubric:

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Declaration by the responsible researcher

As the researcher responsible for the study **Effects of an optimised approach to home-based respiratory care in individuals with Amyotrophic Lateral Sclerosis: a study protocol for a randomised controlled trial,** I declare that I assume the full responsibility of faithfully complying with the methodological procedures and rights that have been clarified and guaranteed to the participant in this study, as well as maintaining secrecy and confidentiality about the identity of the same.

I also declare to be aware that if I fail to comply with the commitment now assumed, I will be violating the rules and guidelines proposed by Resolution 466/12 of the National Health Council - CNS, which regulates research involving human beings.

Natal, _____/_____/_____.

Signature of the Researcher Responsible

_____

Participant / Legal Responsible rubric:	Researcher rubric: