Version 2 – October 8, 2024. The original Spanish version is available upon request.

INFORMED CONSENT FORM

Through this document, you are being invited to participate in the study entitled *"Validation of Operators and Inter-Rater Variability in the Diagnostic Strategies for ICU-Acquired Weakness"*, led by physical therapists Óscar Arellano, specialists in Intensive Care Physical Therapy at Clínica INDISA. Please read this information carefully. If you have any questions, do not hesitate to ask the investigators for clarification.

1. What is the purpose of this study?

The objective of this research is to evaluate the feasibility of quadriceps muscle and peripheral nerve ultrasound as tools for physical therapists working in the intensive care unit (ICU). Additionally, we aim to analyse the correlation between the results obtained through these techniques and the clinical scales used by physical therapists to assess muscle strength. This evaluation will help identify different causes of weakness in patients hospitalized in the ICU and intermediate care units.

2. Who can participate in this study?

Since many patients admitted to the ICU are at high risk of developing muscle weakness and various motor sequelae, early detection of this condition is essential. To achieve this, it is necessary to validate the assessments performed by physical therapists. This pilot study focuses on validating those evaluations; therefore, patients hospitalized in the Adult Critical Care Unit at Clínica INDISA who are capable of providing informed consent may participate.

3. Why should I consider participating in this study?

This study does not offer any direct benefit to participating patients. However, it will provide valuable information on how to assess muscle weakness and muscle mass loss in ICU patients. Your participation will contribute significantly to improving the care and recovery of critically ill patients experiencing muscle weakness. Thus, this research will provide meaningful data to advance scientific knowledge and, consequently, benefit society.

4. What does my participation involve?

As part of your participation, certain evaluations will be conducted that are commonly performed by physical therapists in the Critical Care Unit. These include:

- Muscle and peripheral nerve ultrasound: Images will be obtained of the muscles in your thighs and the nerves in your arms and legs using a portable ultrasound device.
- Strength and mobility assessment: Your muscle strength will be assessed manually, along with your level of mobility—for example, the level of assistance required to sit up

or stand. These evaluations will be performed three times by three different physical therapists, respectively.

- Access to medical records: Clinical data related to your hospitalization will be collected and recorded throughout the study period.

5. Are there any risks associated with my participation?

The potential risks of participating in this study include allergic reactions to the ultrasound gel and risks related to mobilization performed by physical therapists in the Critical Care Unit. These risks are mitigated by the exclusion criteria of the study and by following safety protocols for patient mobilization in both the ICU and Intermediate Care Unit.

6. What happens if I want to withdraw from the study?

Participation in this study is entirely voluntary. You may withdraw at any time by informing the principal investigators, without any impact on the standard treatment of your condition. Likewise, your attending physician or the investigator may recommend that you withdraw from the study

7. Does participation involve any cost?

There are no costs for participating in this study, and no additional materials are required. Treatment for any conditions or complications unrelated to the study must be covered by you or your healthcare provider. This study does not provide any monetary compensation for participation. However, obtaining additional information about your neuromusculoskeletal condition may facilitate early detection of muscle weakness related to your hospitalization, enabling your healthcare team to consider comprehensive, multidisciplinary treatment strategies, if necessary.

8. Will my information be kept confidential?

Your clinical information will be collected and securely stored by the principal investigator, Óscar Arellano-Pérez. Participant data will be recorded in Excel. All results will be presented anonymously—your identity and personal information will not be disclosed to third parties.

For any questions or concerns, you may contact the lead investigator, Óscar Arellano-Pérez, at the email address: areellano@gmail.com or phone: +56961479414. You may also contact the Scientific Ethics Committee of Clínica INDISA at: cec@indisa.cl or phone: +56 2 23625460.

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Consent Statement

By signing this document, I confirm that I have been informed about the objectives, procedures, and risks of this study. I acknowledge that I have read this informed consent form and, by signing below, agree that I clearly understand my participation in the study. My name and signature indicate my voluntary willingness to participate.

Date: _____ / _____ / _____

Full name of participant: _____

National ID (RUT): _____ Signature: _____

As the principal investigator, I confirm that the study objectives, procedures, and risks were properly explained. I have answered all questions to the best of my ability, and this informed consent was signed voluntarily and with full understanding.

Name of principal investigator: _____

Date: _____ / _____ / _____ Signature: _____

Name of witness: _____

Date: _____ / _____ / _____ Signature: _____