Informed Consent Form (English Version)

This form applies to human subject research not governed under Article 8 of the Medical Care Act, including questionnaire-based studies, interviews, and specimen collection.

(This informed consent form must be explained in detail to the participant by the principal investigator. The participant should carefully consider the information before signing.)

You are invited to participate in this research study. This information and consent form provides important details about the study. The principal investigator will explain the study procedures to you and answer any questions you may have.

Study Title: Prevalence and Associated Factors of Sarcopenia in Stroke Patients: A Cross-Sectional Observational Study

Institution: Department of Physical Medicine and Rehabilitation, Cishan Hospital, Ministry of Health and Welfare, Taiwan

Funding Source: Ministry of Health and Welfare Research Grant Program (Year 114)

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◆ ◆ 1. Introduction

Sarcopenia is a condition characterized by loss of muscle mass and muscle strength, which may lead to weakness, functional decline, and even increased mortality. In addition to aging, factors such as poor nutrition, reduced physical activity, and chronic diseases may contribute to sarcopenia.

Stroke is one of the leading causes of death and disability worldwide. In recent years, both the age of stroke patients and the incidence of early-onset stroke have increased.

"Stroke-related sarcopenia" refers to sarcopenia caused by stroke or the worsening of pre-existing sarcopenia. This condition may negatively affect recovery and quality of life. However, few studies have compared sarcopenia characteristics between post-acute and chronic stroke patients.

This study aims to explore the relationship between stroke and sarcopenia to improve future patient outcomes.

◆ 2. Purpose of the Study

This study aims to investigate the relationship between stroke and sarcopenia.

Specifically, we aim to determine the prevalence of sarcopenia in stroke patients at different stages and to identify factors associated with sarcopenia.

We will also compare differences between:

- Post-acute care stroke patients
- Chronic stroke patients
- Different age groups (40–65 years vs. >65 years)
- Sex and stroke severity

◆ 3. Study Duration and Sample Size

The study will be conducted from the date of IRB approval until May 31, 2026.

A total of 80 participants will be enrolled:

- 40 chronic stroke patients
- 40 post-acute care stroke patients

◆ 4. Inclusion and Exclusion Criteria

You may participate if:

- You are aged 40 years or older and diagnosed with stroke
- You have sufficient cognitive and physical ability to complete the assessments
- You provide informed consent

For chronic stroke patients, consent must be provided by the participant.
For post-acute care patients, consent may be provided by a legal representative if cognitive impairment is present.

You cannot participate if:

- You have had lower limb musculoskeletal or neurological conditions within the past 6 months
- You have severe cardiopulmonary disease or require oxygen therapy
- You have had severe infection or major illness requiring hospitalization within the past month

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◆ 5. Study Procedures

This study requires only a one-time assessment lasting approximately 50–55 minutes.

The assessments include:

- Body composition analysis (BIA)
- Quadriceps muscle strength measurement

- Ultrasound measurement of quadriceps and gastrocnemius muscles
- Calf circumference
- Handgrip strength
- Walking speed
- SARC-F questionnaire
- Mini Nutritional Assessment (MNA)
- EQ-5D quality of life questionnaire

All procedures are non-invasive and conducted by trained professionals.

◆ 6. Data Storage and Confidentiality

Your personal data will be kept strictly confidential.

Your identity will be replaced with a study code. Identifiable information will not be disclosed.

Data will be stored securely (locked cabinets and encrypted electronic files) and retained until 2030, after which it will be destroyed.

◆ 7. Use of Data

No biological samples will be collected.

Your data will not be used for other research without additional approval. If future use exceeds the original scope, your consent will be obtained again.

◆ 8. Risks and Discomforts

This is a non-invasive study with minimal risk.

Possible risks include:

- **Risk of falls** during walking tests (similar to daily activities)
- Staff will supervise to ensure safety
- If a fall occurs, appropriate medical evaluation will be provided

Research staff will be present at all times.

◆ 9. Benefits

This study may not provide direct benefit to you.

However, it may help improve understanding of sarcopenia in stroke patients and contribute to future prevention and treatment strategies.

◆ 10. Compensation and Insurance

If injury occurs due to the study, Cishan Hospital will provide necessary medical care and compensation according to regulations.

No additional financial compensation will be provided.

◆ 11. Participant Rights

Participation is voluntary.

You may withdraw at any time without affecting your medical care.

Your privacy will be protected. Study results may be published, but your identity will not be disclosed.

◆ 12. Commercial Interests

This study is not expected to generate any commercial benefits or patents.

◆ 13. Withdrawal

You may withdraw at any time.

Data collected before withdrawal may still be used for analysis.

◆ 14. Signature

Participant Name: _____
Signature: _____
Date: _____

Legal Representative (if applicable): _____
Relationship: _____
Date: _____

Witness (if applicable): _____
Date: _____

Principal Investigator / Research Staff: _____
Date: _____