INFORMED CONSENT FORM

I. GENERAL INFORMATION:

Study title: "**Effects of Progressive Resistance Training in Elderly Type 2 Diabetic Patients With Sarcopenia** "
ICF Version: 1.1 Jan 23, 2024
Principal investigator:
Site: National Geriatric Hospital
Sponsors: None
Timeline: From January 2024 to December 2025
Official site: National Geriatric Hospital
Participant's code:

II. INTRODUCTION

Dear sir/madam, I would like to thank you for taking the time for this interview.

My name is **TRINH NGOC ANH**

I am invesigator of this study, I am working at International Vinmec Hospital

I am doing a research with its title: Effects of Progressive Resistance Training in Elderly Type 2 Diabetic Patients With Sarcopenia

Three objectives of the study:

1. Describe the current characteristic of sarcopenia in elderly patients with type 2 diabetes.

2. Evaluating the treatment outcomes for sarcopenia in elderly patients with type 2 diabetes using progressive resistance training.

3. Exploring factors related to treatment results in the above study group.

I have been thoroughly trained in the research implementation process, ensuring compliance with ethical aspects of research and good clinical practice.

I am communicating with you about this study to invite you OR your guardian to participate in this study with us.

You are invited to participate in the study because you has type 2 diabetes diagnosed according to the American Diabetes Association (ADA) 2022 criteria, age > 60 who is being examined and treated at the Central Geriatric Hospital.

You have the right to participate or not participate in the research, you can stop participating in the research whenever you want. Your failure to participate or stop participating in the study will not affect your medical care and treatment and other benefits you are currently having.

I will provide you with full information about this research. During the process of providing information, if you have any questions, you can ask me to answer immediately to ensure you clearly understand the research.

III. RESEARCH INFORMATION

1. Why should this research be done?

This study aims to evaluate the rate and factors related to sarcopenia in elderly type 2 diabetes patients, thereby providing appropriate intervention or prevention measures for these patients.
In addition, the study also helps evaluate the effectiveness of using resistance training on top of routine treatment in elderly type 2 diabetes patients with sarcopenia, thereby providing appropriate treatment recommendations for them.

2. **What do I OR my child/grandchild/guardian need to do if I agree to participate in this research?**

Sign the consent form to participate in the study

If you agree to participate in this research, we will ask you to do the following activities:

- Outpatient examination at the National Geriatrics hospital
- Take blood for testing twice (basic biochemical parameters) at the first visit and again after 3 months.
- Measure parameters such as muscle mass and muscle strength of the upper and lower limbs every 4 weeks
- Receive instructions on basic diet and exercise and prescribe medications as recommended
- You will be given exercise equipment, instructions on how to do resistance training exercises, and several free exercise supervisions at home and hospital

3. **How many people will participate in this study like me OR my child/grandchild/guardian?**
   >200 elderly patients with type 2 diabetes

4. **What risks/disadvantages may I OR my child/grandchild/ guardian face by participating in the study?**
   Injuries or complications during resistance training may occur but the rate is quite low and we will carefully screen and monitor patients to ensure safety during exercise sessions.

5. **If there is a direct risk/disadvantage to my health, how will I OR my child/grandchild/guardian be cared for?**
   Me, other investigators, doctors and nurses at the National Geriatric hospital or medical staff supervise patients exercising at home, they will directly give support care and treatment.

6. **What benefits can I OR my child/grandchild/parent could get by participating in research?**
   Patients participating in the study will receive:

- Comprehensive geriatric evaluation examination by specialists
- Consulting on treatment and prescribing medications as recommended
- Applying new method to treat diseases (progressive resistance training using elastic bands)
- Monitor and evaluate treatment outcomes periodically

7. **If I do not participate in this study, will my condition be treated differently?**
   Currently, there is no specific treatment for sarcopenia in diabetics and the recommended measures are diet and exercise. Patients will still be advised to apply these treatment when participating in the study.

8. **Will I be informed about test results from this study? How I could receive results?**
   Results of tests and examinations during the research process will be notified directly to participants. The method of informing results ensures the confidentiality and accuracy of test results.

   Do you OR the participant's legal guardian wish to receive the test results?
   _____YES
   _____NO

9. **What are the security measures for information/records relating to me personally OR my guardian?**
   All research participant information is carefully protected to maintain privacy and sensitive patient information could not leak out.

10. **Which individuals/organizations can inspect my personal records?**
    The National Geriatric Hospital is the official site of study and has agreed to allow the implementation of the research questionnaire, as well as the collection of research data. Hanoi Medical University and the National Geriatric Hospital are the code issuers and ethics councils are governing and managing unit of the project.

11. **In case I have further questions about this study, who should I contact?**

- About the research: Contact directly with principal investigator Trinh Ngoc Anh - Phone number: 0912760684
- In case of injury related to research: Contact principal investigator Trinh Ngoc Anh directly - Phone number: 0912760684
- Regarding the rights of research subjects: Contact the Ethics Council of Hanoi Medical University - Phone number: 02438523798

Thank you very much for participating in the discussion!

Date…….	*Date…….*
Information provider	**Person to whom information is provided**
(Sign and write full name)	*(Sign and write full name)*

VOLUNTEER APPLICATION TO PARTICIPATE IN RESEARCH

I,

Declaire that

- I have read the information given for the study " **Effects of Progressive Resistance Training in Elderly Type 2 Diabetic Patients With Sarcopenia**" at the National Geriatric Hospital, ICF version [Digital version 1.1 on Jan 23, 2024, ….], and the research staff explained to me about this study and the procedures for registering to participate in the study.
- I had the opportunity to ask questions about this study and I was satisfied with the answers and explanations given.
- I have had the time and opportunity to consider participating in this study.
- I have understood that I have the right to access the data described in the information leaflet by responsible persons.
- I understand that I have the right to withdraw from the study at any time for any reason.

I agree that my primary care physicians (if any) will be notified of my participation in this study.

Check the appropriate box (this decision will not affect your ability to participate in the study):

I **Do** **Do not** agree to participate in this study.

Signed by participant OR guardian *(for research on participants who are children or the elderly who does not have decision-making capacity)* …… …	Day month Year …….....… …
Necessary,	
* Signature of witness …… …	Day month Year …….....… …
* Write the name of the witness …… …	
Signature of the investigator …… …	Day month Year …….....… …

Write the name of the investigator …… …	