PARTICIPANT INFORMATION SHEET

ASSESSMENT OF BODY COMPOSITION AND PREVALENCE OF SARCOPENIA FOLLOWING INTENTIONAL WEIGHT LOSS WITH MEDICATIONS (SEMAGLUTIDE OR TIRZEPATIDE) IN INDIVIDUALS WITH OBESITY

Version 2.0 (January 14, 2025)

Principal Investigators, Department/Unit, and Institution

Dr. XXX. Department of Endocrinology. Hospital Clínico San Carlos.

Contact phone numbers: XXXX

We are contacting you to provide information about a research study in which you are invited to participate. This study has been approved by the Research Ethics Committee of the Hospital Clínico San Carlos.

Our goal is to ensure you receive accurate and sufficient information to help you decide whether or not to participate in this study. Before making your decision, please read this document—which contains details about the project—carefully. You are welcome to ask any questions that may arise or request clarification on any aspect of the study. We will be happy to address any concerns you may have at any time. Furthermore, you may consult with anyone you deem appropriate.

Voluntary Participation

Please be aware that your participation in this study is entirely voluntary, and you may choose not to participate. If you do decide to participate, you may change your mind and withdraw your consent at any time, without any negative consequences.

There is no financial compensation provided for your participation in this study.

Description and General Objective of the Study

The primary objective of this study is to examine changes in weight and body composition following the treatment of obesity with medications. We aim to understand how weight loss influences the various components of your body composition (specifically, the amount of fat and lean or muscle mass lost). In addition, to obtain a more precise assessment, tests measuring muscle strength and function will be conducted. A loss of muscle function is associated with a reduced capacity to perform daily living activities.

Pharmacological treatment leads to a decrease in appetite and, consequently, a reduction in food intake. If protein intake is insufficient and muscle-strengthening exercise is not performed regularly, your body may experience a deficit in muscle mass—persisting for weeks or months, depending on the duration of the treatment and the amount of weight lost. If the loss of weight and muscle mass becomes excessive and cannot be offset by an appropriate diet and exercise, you may experience fatigue, increased difficulty in

performing daily activities (such as walking briskly or climbing stairs), or the need for greater exertion when lifting heavy objects.

Over the course of the study, you will be asked to attend a maximum of 3 appointments (before starting the pharmacological treatment, and again after 6 and 12 months of continuous treatment) to undergo the following assessments:

- Current weight and height, measurements of waist and calf circumference, blood pressure, and heart rate.

- A nutritional survey regarding your dietary habits and daily exercise.

- Quality-of-life questionnaires (you may complete these at home, if you wish, and bring the filled-out forms to your hospital visit).

- Body composition analysis, using a scale that automatically measures body fat, lean muscle mass, and total body water.

- Muscle strength assessments, consisting of two simple tests:

o Hand-grip dynamometry: This involves using a handheld, "clamp-like" device that you squeeze with your dominant hand to measure your grip strength (repeated 3 times).

o Chair-stand test: This involves standing up and sitting down 5 consecutive times, as quickly as possible. This test helps us evaluate the strength of your legs. •
Nutritional ultrasound: measurement of the amount of fat (measured in the abdomen) and the size of the thigh muscle, using a simple procedure—an ultrasound scan.

These assessments take approximately 30–40 minutes per appointment. You may also have follow-up visits every 2–3 months—depending on the healthcare professional(s) you see (physician, nurse, and/or dietitian-nutritionist)—to monitor your progress, adherence to your diet and exercise plan, any potential side effects, or adjustments to your medication dosage.

Risks, discomfort, and potential benefits of participating in the study

These data will provide a better understanding of your physical status—specifically, your muscular strength and the amount of fat lost following pharmacological treatment. Additionally, through questionnaires, we will gain insight into your quality of life and the type of exercise you perform.

None of these tests pose any risk to you, as they are non-invasive (involving no needles or discomfort). Ultrasound imaging is a safe technique, even for pregnant individuals.

Data collection will be conducted using a coded system. Only the researcher, the Ethics Committee, and health authorities will have access to this information, in accordance with LOPD 3/2018 and RD 1090/2015.

Implications of the information obtained through your participation

You may receive information regarding the tests performed, should you wish to do so.

The data gathered from these assessments will contribute to a broader understanding of how pharmacological obesity treatment affects body composition, muscle function, and quality of life—findings that will also be shared with the scientific community.

Ethical considerations

This study adheres to all recommendations for conducting clinical research, including the Declaration of Helsinki, and has been approved by a Clinical Research Ethics Committee.

Protection of personal data

All data concerning you and your health collected during the study will be handled with the strictest confidentiality: your name and personal medical information will be replaced by a code, ensuring that no individual participant can be identified. The only person with access to the coding key is the study's principal investigator. The Center is responsible for the processing of your data and will implement all necessary security measures to ensure its protection. In accordance with Organic Law 3/2018 on the Protection of Personal Data and the Guarantee of Digital Rights, you may exercise your rights to access, modify, object to, or delete your data. You also have the right to restrict the processing of any inaccurate data, to request a copy of the data you provided for the study, or to have such data transferred to a third party (data portability), where applicable. To exercise these rights, please contact the study's principal investigator (Dr. XXX, Department of Endocrinology and Nutrition, Hospital Clínico San Carlos; telephone: XX; email: XXX). Furthermore, should you be dissatisfied, you have the right to contact the Data Protection Agency (Agencia de Protección de Datos). For more detailed information, please consult the following link: https://www.aepd.es/sites/default/files/2019-10/guia-ciudadano.pdf.

Contacts

If you have any questions or concerns in the future regarding the study or your participation in it, please contact XXXX

INFORMED CONSENT

ASSESSMENT OF BODY COMPOSITION AND PREVALENCE OF SARCOPENIA FOLLOWING INTENTIONAL WEIGHT LOSS VIA MEDICATION (SEMAGLUTIDE OR TIRZEPATIDE) IN INDIVIDUALS WITH OBESITY

Please sign at the bottom of the page if you agree to the following:

1. I have read and understood the written information provided to me.

2. I have had the opportunity to ask questions and discuss this assessment with the physicians.

3. My questions have been answered to my satisfaction.

4. I have received sufficient information regarding the study and the assessments to be performed.

5. I understand that I am free to decline the proposed assessments, and that doing so will not negatively affect my ongoing medical care or follow-up.

6. It is possible that this study may not yield conclusive results regarding my current health status; rather, it focuses solely on the relationship between my nutritional habits, physical activity, and body composition outcomes.

7. I consent to my written consent form and other data being made available to the Hospital Clínico San Carlos and the clinical research project in which I am participating, with the assurance that confidentiality will be maintained and that my data will not be made public in any way that could lead to my identification.

8. I understand that I have the right to access, rectify, erase, or object to the processing of my personal data, in accordance with Organic Law 3/2018 on the Protection of Personal Data. These rights may be exercised by submitting a written request to: Hospital Clínico San Carlos, c/ Martín Lagos s/n, 28040 Madrid. Email: buzgen.hcsc@salud.madrid.org; you may also contact the person in charge of the study: XXXX

9. I wish for the study's principal investigator/physician to share with me any information derived from the research and analysis of my samples that may be relevant and applicable to my health:

☐ YES ☐ NO. Contact phone number or email address:.....

10. I provide my consent freely to participate in this study.

Participant's Full Name **Date** **Signature**

_____ _____ _____

Full Name of the Patient's Legal Representative

_____ _____ _____

Name of Physician/Investigator

_____ _____ _____