PATIENT INFORMATION SHEET - INFORMED CONSENT

Name and surname:

NHC:

Age: **Gender:**

Contact telephone number:

Project Title: ProMuscle STUDY: Clinical Trial on the Use of a Hydroxymethylbutyrate (HMB)-Enriched Protein Module in Patients with Deficient Protein Intake and/or Increased Protein Requirements
Main researcher: Jose Manuel García Almeida.
Participating Centers:
1. Virgen de la Victoria University Hospital

We would like to request your collaboration to participate in a project whose objective is to identify the role of nutrition in a group of patients with deficient protein intake and its effect on muscle mass. To do this, we are going to ask for the participation of subjects with deficient protein intake who will be attended by the Endocrinology and Nutrition service.
Before signing this informed consent, please read the information provided below carefully and ask any questions you consider appropriate.

What does it mean to participate?
Patients who agree to participate and sign the informed consent will be interviewed to take anthropometric and clinical data. Subjects will follow the usual clinical practice by Endocrinology-Nutrition, exercise guidelines and nutritional recommendations will be given.

Voluntary participation
Your participation in this study is voluntary and you can override your decision and withdraw consent at any time without explanation, without altering your relationship with the doctor or adversely affecting your treatment or the care you may need. You should also know that you can be excluded from the study if the study investigators see fit. Your participation in the study will not result in any cost or financial benefit to you.

Overview
Malnutrition is a common problem in patients with various pathologies due to the underlying disease and/or treatments that have side effects at the gastrointestinal level. Improving the nutritional situation is essential to cope with the disease and to make the treatments received more effective. Therefore, the prevention of malnutrition should be routinely incorporated into the management of patients.

What is the objective/importance of this study?
The aim is to know the nutritional status of patients and assess whether this is related to the evolution of the disease and the changes in body composition that occur, assessing it with new techniques.

Why have you been asked to participate?

You are completely free to choose whether or not to participate in the Study. Your decision will not influence your medical care. Your responsibility as a participant is to agree to the use of information from your medical record and, if necessary, to communicate in the best possible and truthful manner, accurate information about your past and present medical history, if relevant to the Study.

What does your participation consist of? What kind of tests or procedures will you have?

Once your Endocrine doctor has verified that you can be included in the study and once you sign the informed consent to participate, you will be given a series of surveys by your doctor and you will be referred for nutritional assessment on a first visit, where you will be asked a series of questions where your body composition will be determined by bioimpedance (phase angle) and nutritional ultrasound. You will also be measured your muscle strength using a grip dynamometer (squeeze with your hand) and a measurement with physical function tests, all of which will be evaluated by qualified health professionals.

Completion of the study

The volume of the donated peripheral blood sample is in line with the determinations to be made in ESTUDIO ProMuscle**.** However, if after the study has been completed there is a surplus of the samples of biological origin that you have donated, you can decide what should be done with these remaining samples. To do this, select one of the following options:

□ Destruction.

□ Free transfer to the Biobank of the Andalusian Public Health System (SSPA) for Biomedical Research, this donation being generic and not linked to the objectives of this study. In any case, these samples will be used in accordance with the provisions of Organic Law 3/2018, of 5 December, on Biomedical Research. If you agree to donate your samples to the SSPA Biobank, you will have to read and sign the Information Document for the Donation of Biological Samples to the Biobank for Biomedical Research that your doctor will give you. Therefore, together with the informed consent, donors will be provided with the INFORMATION DOCUMENT FOR DONATION OF BIOLOGICAL SAMPLES AND INFORMATION ASSOCIATED WITH THE BIOBANK FOR BIOMEDICAL RESEARCH, and in this way those surplus biological samples (plasma/serum, RNA, genomic DNA and/or protein, adipose tissue) generated at the end of the project, may be used in future projects, considering their scientific relevance and the strategic value of these bioresources. (The donation of these surpluses to the SSPA Biobank, Malaga, will be considered the required Contingency Plan).

How are you going to guarantee the confidentiality of the information?

The biological samples donated and their personal and clinical data associated with these samples will be confidential and will be treated in accordance with Regulation (EU) 2016/679, General Data Protection and Organic Law 3/2018, of 5 December, on Biomedical Research. The confidentiality of the data obtained and the anonymity of the patients will be guaranteed, with only access by the researchers participating in the study, by the Clinical Research Ethics Committee or by the health authorities. However, the data may be provided to the patient and the doctors who treat them if they are required to facilitate a better evaluation and treatment of the case. The data resulting from this study may be published or presented at congresses and scientific meetings, guaranteeing the confidentiality of personal data. In order to protect the confidentiality of the participants' personal information, the following measures have been taken: a) All data that can identify the participant will be kept separate from the rest of the information collected in the different questionnaires of the study. The personal data will be separated from the clinical data of the patients in order to protect the identity of the participants at all times. b) Each case of the study will have an identification number that will be the one that appears in the databases. c) The analysis of the information will always be done in an aggregated form and never individually. d) All the researchers involved in the project undertake to comply with the necessary rules to preserve the confidentiality of the information provided by the participants. e) All the databases of the project will be electronically protected

with codes that limit access only to the researchers of the project. The project will be carried out following the guidelines of the Declaration of Helsinki (Fortaleza 2013) and the standards of Good Clinical Practice.

Risks of the research for the patient:

There is no additional risk from participating in the study since a food supplement marketed under the usual conditions and with the authorized doses will be used, as well as no extraordinary test will be carried out.

INFORMED CONSENT – WRITTEN CONSENT OF THE PATIENT

ProMuscle STUDY: Clinical Trial on the use of a protein module enriched with Hydroxymethylbutyrate (HMB) in patients with deficient protein intake and/or increased protein requirements.

Participant:

I (name and surname) _____

I have read the information sheet that has been given to me.

I have been able to ask questions about the study.

I have received enough information about the study.

I have spoken with:

□ Which aims to carry out tests to evaluate muscle mass, strength and function.
□ That I have been duly informed of the conditions of my participation.
□ That my participation is completely voluntary and I can withdraw from the study at any time. I agree to undergo the procedures and to provide the necessary information to the physician or research team staff, when requested.
□ That I have received a copy of the patient information and informed consent form for me to have.

Signature of the participant Signature of the legal representative (if necessary)

Participation Compliance
Date: 20

Name and signature of the person responsible for obtaining consent

Date: 20

For any additional information, you can contact the Researcher: Rocio Fernández Jiménez, e-mail: rociofernandeznutricion@gmail.com, Biomedical Research Technician (IBIMA)

REVOCATION OF CONSENT

I hereby CANCEL any authorization contained in this document, which is null and void from the moment of signature.

The repercussions that this annulment could have on the evolution of my process have been explained to me and, consequently, I understand and assume them.

In.....a.....of.....of 20..

Patient's signature
(or legal representative if applicable)

Name and surname:.....