**INFORMED CONSENT**

*EFFECT OF A NUTRITIONAL SUPPORT SYSTEM TO INCREASE SURVIVAL AND REDUCE MORTALITY IN PATIENTS WITH COVID-19 IN STAGE III AND COMORBIDITIES —— A BLINDED RANDOMIZED CONTROLLED CLINICAL TRIAL*

Date: July, 2020.

PRINCIPAL INVESTIGATOR: Fernando Leal, M.D., MSc, DSc.

POSITION: Responsible investigator.

STUDY SITE ADDRESS: ISSEMYM TOLUCA ARTURO MONTIEL ROJAS MEDICAL CENTER".

**1.Participation:** We request your authorization, so that you: _____, to participate voluntarily in a research project whose objective is to determine the effect of a nutritional support system to reduce complications in patients with COVID-19 and comorbidities in stage III, taking into account the effect of nutrition on the complications of the disease. It is expected that, by performing this nutritional support, immunity will be stimulated, the inflammation response will be regulated, the absorption of nutrients at intestinal level will be improved and their organism will have the necessary elements to reduce complications in patients with COVID-19, in addition to improving their nutritional status.

**2. Study procedures:** Before starting the study, a lottery will be held to see if you will receive the conventional nutritional treatment or the nutritional support system (NSS) (you can be on either one). If you agree to participate in the study, you will undergo the following procedures: A) Clinical and dietary history. B) Clinical and anthropometric evaluation: arm circumference and tricipital fold will be measured at baseline and during the study. C) Blood samples will be collected for analysis. D) NSS nutritional support: at protocol entry you will be assigned to a study group where you will be told whether you will receive supplementation. E) The review sessions will be recorded to collect evidence and your identity and data will be safeguarded by the research team. This evidence will not be disclosed without your prior written consent.

**3. Approximate Number of Participants and Expected Duration of their Participation in the Study:** The number of participants to be included in this study is 240 people who voluntarily wish to participate in this study. The duration of the study will be 21 days from the beginning of the nutritional treatment and the supplementation according to the corresponding group, and the time may be shorter if there is recovery from the disease or discharge from the service. Before starting the study, a lottery will be held to see if you will receive the conventional nutritional treatment or the nutritional support system (NSS) (you can be in either of the two). We hope that the NSS will bring benefits to your health. Previous studies by other investigators have observed that patients diagnosed with COVID-19 and inadequate nutritional status may be more likely to develop critical stage COVID-19.

**4.Risks and possible reactions:** There may be some allergic effect or intolerance to any of the supplements that is unpredictable until not consumed, if so intake should be discontinued until assessed at daily consultation. There may be unpredictable risks beyond the investigator's knowledge. The study is classified as minimal risk. There is a possibility of a small bruise from sampling or gastrointestinal distress from taking the nutritional support. We hope that the NSS will bring benefits to your health. Previous studies by other investigators have shown that patients diagnosed with COVID-19 and inadequate nutritional status may be more likely to develop a critical stage of this disease, so undergoing this study may have favorable results in terms of days of hospitalization and decreased risk of complications.

**5. Voluntary Participation/Withdrawal from the Study:** Your participation in this study is completely voluntary, and even if you choose to participate, you are free to leave the study at any time without providing any reason. This will not affect your future medical treatment in any way. In the event that you do not participate or withdraw your consent from the present study there are guidelines that have been established by the Secretary of Health for the detection and care of COVID-19. You will not receive any monetary compensation for your participation in this study.

**6. Confidentiality:** All data collected will be coded in such a way that you will not be identified by name (data will be recorded with a code, e.g., letters and numbers without your name) and will be used to meet the purpose of the study and may be used in future related scientific studies.

**7. Questions / Information:** During the study, you may request updated information about the study from the researcher. Fernando Leal, *M.D., MSc, DSc.* 5521094339.

**I FREELY AGREE TO PARTICIPATE IN THIS STUDY**

To be signed simultaneously, (this is the same date), by all parties:

Name of Subject: _____

Signature: _____ Date: _____

**Name of Witness 1:** _____ Relationship: _____

Address: _____

Signature: _____ Date: _____

**Name of Witness 2:** _____ Relationship: _____

Address: _____

Signature: _____ Date: _____

This Section is exclusive to the research group.

I have explained to Mr. (a)_____ the nature and purpose of the research; I have explained the risks and benefits of his participation. I have answered questions to the extent possible and have asked if he/she has a question. I agree that I have read and know the applicable regulations for conducting human subjects' data and I adhere to them.

Folio Assigned: _____

Name and Signature of Person Obtaining Informed Consent: _____

Date: _____