INFORMED CONSENT FORM

Final version - Ed n° 1 March 11th, 2020

Protocol Code: Prot. N° GIU-PPA-0420

Place and date _____

I undersigned _____

Born at _____ on I____I____I____I

Residing at _____ n° _____

city _____ Province of _____

DECLARE

To accept the proposal to undergo the clinical trial titled.:

MONOCENTRIC CROSSOVER STUDY TO ASSESS THE TOLERABILITY AND THE EFFICACY OF A MIX OF PROBIOTIC STRAINS DOSES VS PLACEBO IN ATHLETES PERFORMANCE

I, the undersigned, have been adequately informed about the purposes of the study and its methodologies. In particular, I am aware of the need to follow the instructions and rules that have been explained to me and which I fully understand. I am aware of the potential benefits that may arise from my participation in the study, as well as any potential risks and associated inconveniences. I have been assured that, predictably, there will be no worsening of my clinical condition. I understand that I may suspend my participation in the trial at any time and request to be treated with any standard therapies for a condition I may suffer from, without any obligation on my part to justify this decision, unless it is due to the appearance of unforeseen or unexpected disturbances or side effects. In such cases, I commit to promptly informing the Responsible Physician of their nature and extent.

I declare that my consent is an expression of a free decision, not influenced by promises of money or other benefits, nor by obligations of gratitude, friendship, and/or kinship towards

the Responsible Physician. I hereby authorize the use and disclosure, in an anonymous form and for scientific and administrative purposes only, and in compliance with current regulations on privacy protection, of the trial results, including clinical data concerning me.

I freely give my consent to participate in the study, to have photographs taken concerning my condition and its treatment, and to use them, along with disease-related data, for medical, scientific, educational, and informative purposes.

I confirm that I have received a copy of this Informed Consent, the Information Sheet, and the Privacy Notice.

Participant:
First and Last Name in block letters: _____
Signature: _____
Date: _____

Investigator:
First and Last Name in block letters: _____
Signature: _____
Date: _____

Witness (if necessary)
First and Last Name in block letters: _____
Signature: _____
Date: _____

Notes

This consent statement must be personally signed and dated by the patient and the individual who conducted the discussion regarding informed consent.
Please indicate the name of the physician who informed the patient about the proposed trial.
If the patient is unable to read or sign, an independent witness not affiliated with the Investigator or the Sponsor must be present during the entire discussion regarding informed consent. The witness must personally sign and date the informed consent statement after the form itself and any other written information have been read and explained to the subject, and the subject has provided verbal consent to participate in the study.