TERMS OF FREE AND INFORMED CONSENT (TCLE)

"EFFECTIVENESS OF A PROBIOTICAL SUPPLEMENTATION IN ATENUATION OF CLINICAL OUTCOMES IN PATIENTS WITH NEURODEGENERATIVE DISEASES"

This document you are reading is called the Free and Informed Consent Form (TCLE). It contains explanations about the study you are being invited to participate in. Before deciding whether to participate (of your own free will) you must read and understand all the content. At the end, if you decide to participate, you will be asked to sign it and you will receive a copy of it . Before signing, ask questions about anything you don't understand. The study team will answer your questions at any time (before, during and after the study).

Your participation is voluntary, which means that you can withdraw your consent at any time, without this bringing you any harm or penalty , simply by contacting one of the responsible researchers.

This research seeks to evaluate the effects of using the probiotic mix called k10 in patients diagnosed with Alzheimer's and Parkinson's disease. If you decide to accept the invitation, you will be subject to the following procedure(s):

- Measurement of vital signs and collection of anthropometric data;
- Blood collection to perform serum cortisol test;
- Neurological assessment;
- Cognitive assessment;
- Psychiatric evaluation;
- UPDRS, HOEHN and YAHR motor assessment;
- Image recording in video and photo.

The risks involved with your participation are: mild gastrointestinal discomfort, and allergy in patients with hypersensitivity to the microorganisms present in the probiotic mix , which will be minimized through the following measures: in case of gastrointestinal discomfort, observe the next 12 hours of evolution of the condition and if the aggravation and/or presence of epigastric pain is identified, the research team must be communicated and seek a doctor immediately, in the case of allergic processes, the use of the probiotic must be immediately interrupted, the research team communicated, and in the case of in case of worsening of the allergic condition with difficulty breathing, redness on the body and other signs such as changes in vital signs, you should immediately seek an emergency unit for evaluation and management carried out by a qualified professional. If this procedure can cause any kind of embarrassment, you do not need to do it.

You will have the following benefits by participating in the research: receive a free K10 probiotic mix whose beneficial effect in the treatment of symptoms of degenerative neurological diseases such as Alzheimer's and Parkinson's. Your participation will help to increase knowledge about the treatment of Parkinson's and Alzheimer's.

All information obtained will be confidential and your identity will be preserved, except in cases where the participant himself is interested in disclosing it to third parties or to any stranger to this document, in which case the researchers and the organizing company cannot be held directly responsible. or indirectly, by the act, as well as the volunteer or his person in charge exempts them from any and all civil and criminal liability for the act. The material with your personal information and medical data will be stored in a safe place under the responsibility of Gon1 Gestora de Projetos Ltda. with the guarantee of maintenance of secrecy and confidentiality. The dissemination of the results will

be done in such a way as not to identify the volunteers. The results of this work may be presented at meetings or scientific journals, however, it will only show the results obtained as a whole, without revealing its name, institution to which it belongs or any information that is related to its privacy.

As provided by the Brazilian norms for research with the participation of human beings, you will not receive any type of financial compensation for your participation in this study. If you have any expenses that are due to your participation in the research, you will be reimbursed, if you request it. At any time, if you suffer any damage demonstrably resulting from this research, you will be entitled to compensation.

You will have a copy of this Term and any questions you may have about this research, you can ask directly the leading researcher **xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx** , at the address at Avenida **xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx** CEP: xxxxxxxxxxxxxxxxxx , or with the **GON1 project management team** located at Avenida Nossa Senhora dos Navegantes, 955, room 719, Enseada do Suá , Vitória, ES, CEP 29050-335, or by calling **0800 616 4444** , and/or by e-mail: adm@gon1.com.br . Search ISRCTN13536327 https://doi.org/10.1186/ISRCTN13536327

Doubts about the research involving ethical principles may be asked to the **UVV Research Ethics Committee** located on the 3rd floor of the INOTEC building, at Rua Comissário José Dantas de Melo, nº 21, Boa Vista, Vila Velha, ES, CEP: 29.102-770 , Phone: (27) 3421-2063, E-mail: cep@uvv.br .

Opening hours: Monday to Thursday, from 8:00 am to 11:00 am. Complaints and/or dissatisfactions related to the patient's participation in the research may be communicated in writing to the Secretariat of the CEP/UVV, provided that the complainants identify themselves, and their name will remain anonymous.

FREE AND CLEAR CONSENT

I declare that I was duly informed and clarified by the researcher about the research EFFECTIVENESS OF A PROBIOTICS SUPPLEMENTATION IN ATENUATION OF CLINICAL OUTCOMES IN PATIENTS WITH NEURODEGENERATIVE DISEASES (ALZHEIMER AND PARKINSON), of the procedures involved in it, as well as the possible risks and benefits arising from my participation. I have been assured that I can withdraw my consent at any time, without prejudice or penalty.

Participant Name (Patient or Guardian): _____

CPF:_____

Signature: _____

Digital

Researchers:

_____	_____	_____
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	**xxxxxxxxxxxxxxxxxxxxxxxxxxxxx**	**xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx**
Lead Researcher	Assistant Researcher	Assistant Researcher