Date: February 1, 2023
Title: Clinical trial in skin conditions of the foot using a cream enriched with *Melaleuca alternifolia* essential oil.
Description of document: The document describes, among other things, the purpose, the procedures, the risks, and the potential benefits of study. It was authorized by the Bioethics Committee of the University of Extremadura (Register No.: 55/2017).

INFORMED CONSENT

Project: Use of essential oils as natural therapies against dermatophytosis and new diagnostic techniques

Participant: _____Participant ID#: _____

Center: _____Center ID#: _____

Researcher(s): _____

The principal investigator, _____ _____

PLEASE READ THE INFORMATION CONTAINED IN THIS DOCUMENT CAREFULLY AND MAKE SURE YOU UNDERSTAND THIS RESEARCH PROJECT. PLEASE, IF YOU AGREE TO PARTICIPATE IN THIS STUDY, PLEASE SIGN THIS DOCUMENT. BY SIGNING YOU ACKNOWLEDGE THAT YOU HAVE BEEN INFORMED OF THE CHARACTERISTICS OF THE PROJECT, ITS REQUIREMENTS AND ITS RISKS AND THAT YOU FREELY AGREE TO PARTICIPATE IN IT. A COPY OF THIS DOCUMENT WILL BE GIVEN TO YOU.

PURPOSE OF THE STUDY.

You have been invited to participate in a research study aimed at testing the results of tea tree oil-enriched moisturizer in dermatophytosis

PROCEDURES AND DURATION OF THE STUDY.

The only procedure you will undergo will be to have an ultrasound on your foot and apply the cream that will be given to you for the time you are asked to do and according to the established guideline. The duration of the project will be 6 months, during which you authorize us to take photographs of the dermal lesion you present and ultrasound scans in order to observe the improvement of the skin. The data you provide will be used exclusively for non-profit research purposes.

RESULTS OF THE STUDY.

At the end of the study, you will be informed of the overall result of the study if you wish, but NOT of your personal result, which will be treated with total confidentiality in accordance with the Declaration of Helsinki and Law 14/2007, on Biomedical Research.

RISKS ARISING FROM PARTICIPATION IN THE STUDY.

The risks associated with data collection are minimal. The material used will be disinfected before and after contact with each participant in order to eliminate the risks of infection and contagion. The data will be obtained by qualified personnel. The cream that will be given to the patient does not have any allergens.

PROCEEDS.

Participation in the project will not be financially rewarded. Apart from the above, it is estimated that the development of the study in which he will participate will lead to medium-term benefits in the treatment of dermatophytoses through natural therapies.

COSTS.

The cost of extracting and processing the data, as well as the subsequent analyses, will be covered by the project. There will be no cost to you for your participation.

CONFIDENTIALITYOF YOUR DATA.

In accordance with current legal regulations, the results of the information obtained will be treated with total confidentiality. The data collection protocol will be archived, and each participant will be assigned a password in such a way that the information obtained cannot be related to the identity of the subject. The data will be anonymized, ensuring the impossibility of inferring their identity, for their study and potential subsequent analysis.

The principal investigator undertakes that the confidentiality of the data that may be obtained in this project will be scrupulously observed, and that the personal data of the participating subjects will be known only to the study researchers.

The principal investigator undertakes not to use the data for studies other than those of this project and not to transfer the data to other possible research projects or teams.

For everything not provided for in this document, the current legislation on the protection of personal data will be applied (Law 41/2002, of 14 November, basic regulation of patient autonomy and rights and obligations in matters of clinical information and documentation, BOE 274 of 15 November 2002; Organic Law 3/2018 of 5 December on the Protection of Personal Data and Guarantee of Digital Rights, BOE 294 of 6 December 2018), on biomedical research (Law 14/2007, of 3 July, on Biomedical Research; Official State Gazette 159 of 4 July 2007) and any other that may be applicable.

The results of the study may be published in scientific journals or general publications. However, information concerning your participation will be kept confidential.

You will receive a copy of this Informed Consent signed by you.

STATEMENT OF THE SPONSOR.

I have been informed by the staff related to the mentioned project:

- About the advantages and disadvantages of this procedure.
- The purpose for which my data will be used.
- That the data I provide will be used exclusively for non-profit research purposes.
- That my data will be provided anonymously to the researchers of the project.
- That at any time I can request generic information about the studies for which my data have been used.

I understood the information I received and I was able to ask all the questions I thought appropriate.

You have the right to participate or not to participate in the research and to withdraw your consent at any time.

I HAVE BEEN PROVIDED WITH A COPY OF THIS DOCUMENT. I AGREE TO PARTICIPATE IN THIS STUDY.

Name:..... Signature: .....

Statement by the investigator that he/she has duly informed the donor/participant.

Name:..... Signature: .....

Plasencia, _____