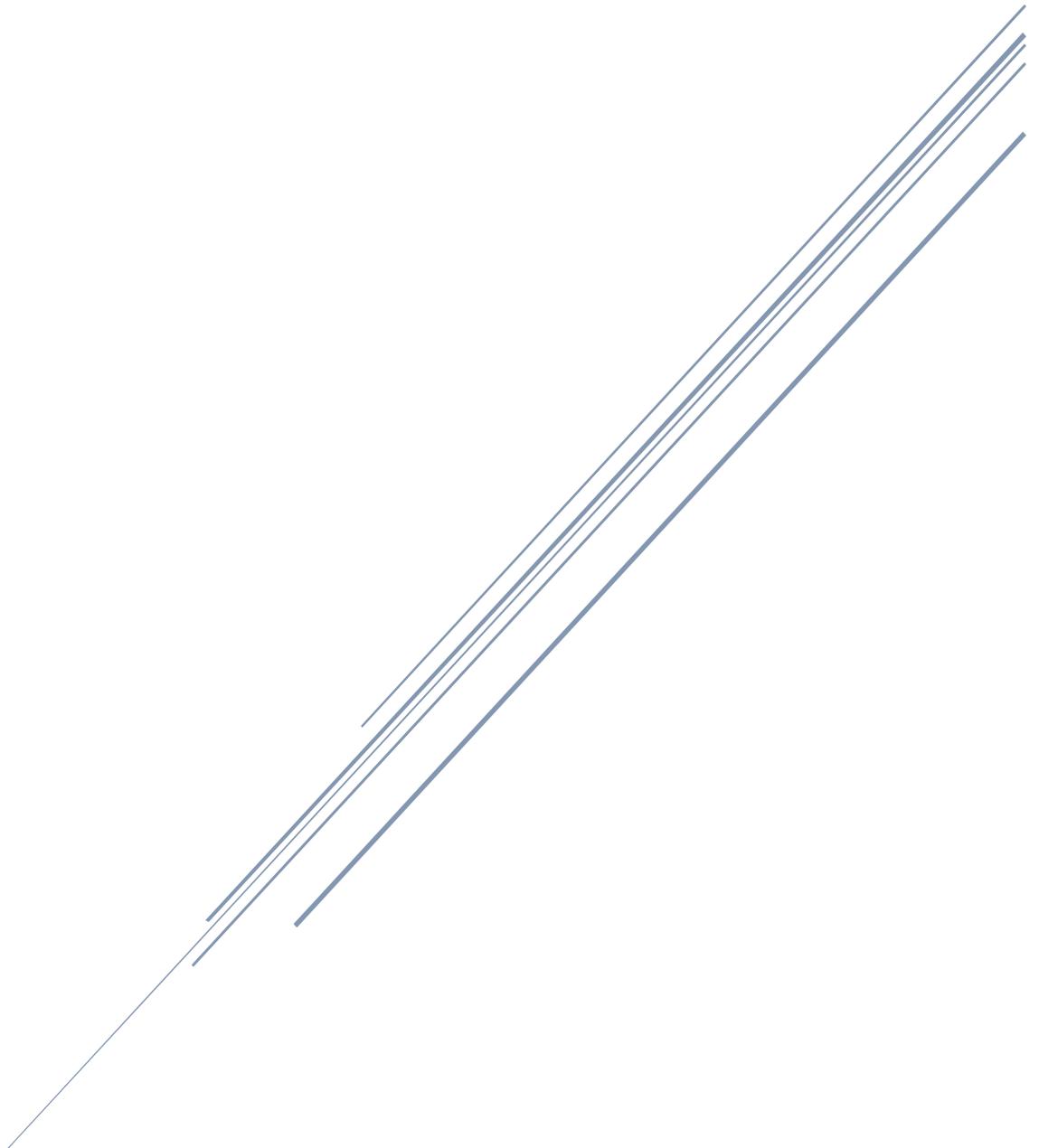


Official Title: Effect of Monazite Sands in Patients with Osteoarthritis  
of the Knee

Ethical committee Protocol No: 3.160.891

Inform consent



Document date: May 2nd , 2019

## **INFORM CONSENT TERM (TCLE)**

Effect of monazite sands in patients with osteoarthritis of the knee

Responsible for research: Prof. Dr Denise Coutinho Endringer and Dr. Marcio Fronza

This document you are reading is called the Free and Informed Consent Term (TCLE). It contains explanations about the study you are being asked to attend. Before deciding whether to participate (of your own free will) you should read and understand all the content. In 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 did not understand well. The study team will respond to your questions at any time (before, during and after the study). Your participation is voluntary, which means that you can withdraw at any time, withdrawing your consent, without any loss or penalty, by contacting one of the responsible researchers.

This research seeks to prove the beneficial effects of radiation emitted by the monazite sands in patients with osteoarthritis of the knee in order to prove and divulge to the scientific community the real benefits of this radiation in patients with this disease. If you decide to accept the invitation, you will be subjected to the following procedures: Your affected knee (s) will be fully submerged in the sand of the beach 2 (two) times per week for 30 (thirty) minutes each session in the same place, and period of the day for a period of 12 (twelve) months. You will be evaluated clinically and submitted to questionnaires and blood collection in 7 moments (at the beginning of the research, after 1, 2, 3, 6, 9 and 12 months.) You can be chosen to participate in the control group (Itapoã beach sand ) or the group tested (sands of Areia Preta beach).

The risks involved with their participation are: accidents during the bus trip (transit), problems in embarkation and / or disembarkation of buses, excessive heat that can occur on beaches, puncture accidents, phlebitis, skin infections and accidents with biological material during the blood collection, which will be minimized through the following measures: monitoring of employees and collaborating researchers during shipment, transfer, landing and during exposure to the sands, guarantee of biosafety

standards during collection of biological material and use only properly inspected by the regulatory agencies. If this procedure can generate some kind of embarrassment you do not have to do it.

You will have the following benefits when participating in the research: improvement of pain, stiffness and ability to perform your daily activities related to knee osteoarthritis. Their participation may help in further knowledge about the real benefit of monazite sands in patients with osteoarthritis of the knee.

All information obtained will be confidential. The material with your information (recordings, interviews, among others) will be kept in a safe place under the responsibility of Prof. Dr. Marcio Fronza and Prof. Dr. Denise Coutinho Endringer with the guarantee of confidentiality and confidentiality that will be destroyed after the research. Dissemination of the results will be done in a way that does not identify the volunteers. The results of this work may be presented in 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 related to its privacy.

As provided by the Brazilian research standards 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 expense that is due to your participation in the survey, you will be reimbursed if you request it. At any time, if you experience any damage from this research, you will be entitled to compensation.

You will be left with a route to this Term and any questions you may have regarding this research, you may ask directly to Prof. Dr. Marcio Fronza or Prof. Dr. Denise Coutinho Endringer, Rua José Dantas de Melo, nº 21, Boa Vista, Vila Velha-ES, CEP: 29.102-770, Tel .: (27) 3421-2087.

Doubts about the research involving ethical principles may be questioned to the UVV Research Ethics Committee located in the Rectory building in the basement: at Rua José Dantas de Melo, nº 21, Boa Vista, Vila Velha-ES, CEP: 29.102-770, Tel .: (27) 3421-2063, E-mail:

cep@uvv.br. Opening hours: Monday to Friday from 07h to 12h and from 13h to 17h and Friday from 07h to 12h and from 13h to 16h. Secretary: Sirlene Gomes Neves. Complaints and / or dissatisfactions related to the patient's participation in the research may be communicated in writing to the CEP / UVV Secretariat, provided that the claimants identify themselves, and their name will be kept anonymous.

### Consent

**Signature of the Principal Investigator:** \_\_\_\_\_ **Date** \_\_\_\_\_

**Signature of the Patient:** \_\_\_\_\_ **Date** \_\_\_\_\_