# Universidade Metropolitana de Santos - UNIMES

## RESEARCH ETHICS COMMITTEE

## FREE AND CLARIFIED CONSENT

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### I - DATA IDENTIFYING THE SUBJECT OF THE RESEARCH OR LEGAL RESPONSIBLE

**1**. PATIENT'S NAME:

DOCUMENT Nº: GENDER: .M ☐ F ☐

BIRTH DATE (dd / mm / yyyy):

ADDRESS:

NEIGHBORHOOD: CITY

ZIP CODE: PHONE: DDD

**2.** LEGAL RESPONSIBLE

NATURE (degree of kinship)

DOCUMENT Nº: GENDER: .M ☐ F ☐

BIRTH DATE (dd / mm / yyyy):

ADDRESS:

NEIGHBORHOOD: CITY

ZIP CODE: PHONE: DDD

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### II - DATA ON SCIENTIFIC RESEARCH

**1.** RESEARCH PROTOCOL TITLE: Associative Protocol in Dentin Hypersensitivity pain control in patients with IMH: Randomized controlled clinical trial

**2.** RESEARCHER: Ana Paula Taboada Sobral

POSITION / FUNCTION: Volunteer researcher

REGIONAL COUNCIL REGISTRATION No. 76.693

UNIMES UNIT: **Faculty of Dentistry -** Av. Conselheiro Nébias, 536 - Encruzilhada, Santos - SP, 11045-002-Brazil

**3**. RESEARCH RISK ASSESSMENT:

WITHOUT RISK x MINIMUM RISK ☐ AVERAGE RISK ☐

LOW RISK ☐ GREATER RISK ☐

(probability that the individual will suffer some damage as an immediate or late consequence of the study)

**4.**RESEARCH DURATION: 14 months

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## III - REGISTRATION OF THE RESEARCHER'S EXPLANATIONS TO THE PATIENT OR ITS LEGAL REPRESENTATIVE ON RESEARCH CONSIGNING:

1. **Justification and objectives of the research:**

The control of tooth sensitivity is fundamental to the successful treatment of Molar Incisor Hypomineralization. Therefore, the present study aims to evaluate the effectiveness of different protocols in the control of Dentin Hypersensitivity (MIH)

The objective of this work will be to evaluate, by means of a randomized and controlled clinical study, the effectiveness of different protocols for the control of dentinal hypersensitivity in patients with teeth affected by MIHI. The neural desensitization protocol will involve the use of low-power laser (Therapy XT -DMC) and the obliteration protocol will involve the use of a resinous sealant (Permaseal Ultradent).

2. **Procedures that will be used and purposes, including identification of procedures that are experimental:**

The treatment sessions will be performed by a trained researcher following the manufacturer's instructions for each product and in accordance with scientific evidence regarding treatment with low-power laser. The participants in the placebo group will use only the conventional oral hygiene kit during the four weeks of the study and will receive simulated treatment involving the application of a rubber cup with no product and sham irradiation with the laser device adjusted to 0 W.

Participants will be divided into the proposed treatments.

Group 1. Control

Group 2. Permaseal (Sealant Group)

Group 3. Low-power laser

Group 4. Low power laser + Permaseal (Sealant Group)

Patients should return after 1 week, 1 month, 3 months and 6 months after the end of the last session to be assessed according to the visual analogue pain scale.

3. **Expected discomforts and risks:** Volunteers will not be at risk during the procedures.
4. **Benefits that can be obtained:** Treatment of dentin hypersensitivity, reducing painful sensitivity.
5. **Alternative procedures that may be beneficial to the individual:** Alternative methods will not be used.

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## IV - CLARIFICATIONS GIVEN BY THE RESEARCHER ABOUT GUARANTEES OF THE SUBJECT OF THE RESEARCH CONSIGNING:

**1**. Access, at any time, to information on procedures, risks and benefits related to research, including to resolve any doubts.

**2.**The patients will be informed of the possible risks involved in the experiment, the confidentiality of the data and the existence of a placebo group.

**3.** The researchers will be provide adequate treatment for the participants in the placebo group at the end of the study and to the subjects of the other groups at the end of six months, if the pain symptoms have not improved. The treatment offered, in this case, will be that which achieved the best result in the initial four weeks of the study.

**4.** The participants will be told that they may withdraw from the study at any time for any reason, if they so desire.

**5.**The researchers will also be able to remove the participants from the study, if deemed necessary.

**6**. Safeguarding confidentiality, secrecy and privacy.

**7**. Availability of assistance, for possible damage to health, resulting from the research.

**8** Feasibility of indemnification for possible damage to health resulting from the research.

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**V. INFORMATION OF NAMES, ADDRESSES AND PHONES OF RESPONSIBLE FOR MONITORING THE RESEARCH, FOR CONTACT IN CASE OF CLINICAL INTERCURRENCES AND ADVERSE REACTIONS.**

Profa. Dra. Ana Paula Taboada Sobral

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**Faculty of Dentistry UNIMES -** Av. Conselheiro Nébias, 536 - Encruzilhada, Santos - SP-CEP: 11045-002- Brasil

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**VI - COMPLEMENTARY OBSERVATIONS**:

Not applicable.

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**VII - POST-CLARED CONSENT**

I declare that, after being properly clarified by the researcher and having understood what was explained to me, I consent to participate in this Research Protocol.

Santos, ____/_____/_____.

_____ Signature of the research subject or legal guardian

_____ Signature of the researcher (Legible name or stamp)