INFORMED AND FREE CONSENT FORM FOR INDIVIDUALS UNDER 18 YEARS OLD

Your child or ward is being invited as a volunteer to participate in this study and will only be invited after your consent in this form. For them to participate in this research, it is necessary that their tooth or teeth that have problems have a root still in formation and that their nerve(s) is/are necrotic (dead). We believe that this research is important because young teeth can be saved from being extracted despite infection, in a way that prevents root fracture and still allows the root to complete its formation after infection treatment. The name of the research is RADIOGRAPHIC EVALUATION OF TRAUMATIZED IMMATURE TEETH TREATED WITH REGENERATIVE ENDODONTICS AND LASER THERAPY.

PARTICIPATION IN THE STUDY

Your child or ward's participation will involve receiving root canal treatment and on the same day, the tooth will be restored. The duration of this session is expected to be approximately 1 and a half hours. After this initial session, 4 follow-up appointments will be scheduled for clinical evaluation and for taking radiographs and photographs at 6, 12, and 18 months. All procedures will be performed in the Integrated Clinic of Traumatology discipline of the Dentistry course at the Pontifical Catholic University of Paraná, located at 1155, Imaculada Conceição street, Prado Velho, Zip code 80215-901, Curitiba.

RISKS AND BENEFITS

Through this Informed and Free Consent Form, you are being advised that your child or ward can expect some benefits from the research to be conducted, such as receiving root canal treatment for one or more infected teeth in order to allow complete formation of the root, providing greater resistance to the risk of fractures. Your child will be monitored for a period of 24 months until they are discharged. The following discomforts or risk may occur: the tooth may be slightly sensitive on the day of treatment or in the days following it, and they should immediately discuss this or any other discomfort or swelling that occurs after treatment with the researcher, even if many days have passed since the treatment appointment. To minimize such risks, we as researchers will take the following measures: all care will be based on attention and patient care, in order to minimize their discomfort, and periodic radiographic controls will be performed to monitor the need for new procedures. In the event that you do not agree with the research procedure, another alternative will be to apply the material to seal the tip of the root, which corresponds to the usual standard of treatment in these types of cases. However, this carries the risk of root fracture, as it would not complete your formation. Alternatively, there is the option of extracting the tooth without perming root canal treatment.

CONFIDENTIALITY AND PRIVACY

We, as researchers, guarantee to you and your child or ward that your privacy will be respected, meaning that your name or any other information or element that may, in any way, identify you, will be kept confidential. We, as researchers, will be responsible for the safekeeping and confidentiality of the data, as well as not exposing the research data. Your child's data can only be accessed and used for this research after your consent.

AUTONOMY

We assure you and your child or ward that you will receive all results of clinical and radiographic examinations, assistance throughout the research, and we will guarantee your free access to all information and additional clarifications about the study and its consequences, in short, everything you want to know before, during, and after your child or ward's participation. We also inform you that you may refuse or withdraw consent for your child or ward's participation in this study at any time without the need for justification. If you wish to withdraw from the study, your child or ward will not suffer any harm to the assistance he or she may receive, and we guarantee the right to comprehensive and free assistance for any damage resulting from participation in the research for as long as necessary.

REIMBURSEMENT AND COMPENSATION

If you have any expenses related to your child or ward's participation in this research, such as transportation, food, among others, as well as those of your companion, there will be reimbursement of the expenses incurred. Similarly, if any damage occurs as a result of participation in the study, you and your child or ward will be properly compensated, as required by law.

CONTACT

The researchers involved in the mentioned project are Marisa Nogueira Alencar and Vânia Westphalen, affiliated with the Pontifical Catholic University of Paraná, and you can contact them at the following phone numbers: (41) 99969-3541, (41) 3015-2202, and (41) 99962-5120.

The Human Research Ethics Committee (CEP) is composed of a group of individuals who are working to ensure that your rights as a research participant are respected. They have the obligation to assess whether the research has been planned and is being conducted ethically. If you feel that the research is not being conducted in the way you envisioned or that you are being harmed in any way, you can contact the PUCPR Ethics in Research Committee (CEP) by phone at (41) 3271- 2292, from Monday to Friday, from 8:00 a.m. to 5:30 p.m., or by email at nep@pucpr.br.

DECLARATION

I declare that I have read and understood all the information contained in this Informed Consent Form and had the opportunity to discuss the information in this form. All my questions have been answered, and I am satisfied with the answers. I understand that I will receive a signed and dated copy of this document, and another signed and dated copy will be filed by the responsible research of the study.

Finally, having been informed of the content of everything mentioned here and understood the nature and purpose of the aforementioned study, I hereby give my free consent for my child or ward to participate ____, being fully aware that here is no economic value to be received or paid for their participation.

Signarute of the Researcher

Signature of the research participant’s guardian/representative

IMAGE USE

I authorize the use of my child’s or ward’s image in the form of radiographs, photographs, examination results, and other information provided through care (anamnesis), as didactic material and for scientific publication. The clinical records and radiographs will be archived for a period of 5 years and can be retrieved after this period without cost to the patient. If they are not retrieved after this period, they will be discarded.

Signature of the Researcher

Signature of the research participant’s guardian/representative

Data from the person responsible for the research participant	
Name	
Phone number	
Email Address	