INFORMED CONSENT FORM

FOR PARENTS

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NCT : Not yet assigned

ISTANBUL UNIVERSITY FACULTY OF DENTISTRY CLINICAL RESEARCH ETHICS COMMITTEE

INFORMED CONSENT FORM

- FOR PARENTS-

Title of the study: The Effectiveness of Aromatherapy and Computer-Controlled Anesthesia Methods in Reducing Anxiety and Pain During Tooth Extraction in Children

Type of study: Clinical research

Purpose of the study: This study aims to evaluate the effectiveness of aromatherapy and digital anesthesia techniques in the management of dental anxiety and pain during tooth extraction in pediatric patients.

Method of the study: In this study, we are trying to understand which methods can make you feel more comfortable during tooth extraction. The participating children will be divided into four groups. Some children will receive anesthesia using the most commonly used traditional anesthesia method to numb their teeth, while others will receive anesthesia using a special device (digital anesthesia). In addition, some children will inhale a scent containing lavender and sweet orange oil before the procedure to help them relax. Before your tooth is extracted, we will check whether it is numb, and then we will perform the procedure. During this time, we will monitor your heart rate, blood pressure, and how you feel. We may ask you a few questions to understand whether the procedure makes you uncomfortable. Our aim is to determine methods that can help you feel less afraid and experience less pain during the tooth extraction.

Possible adverse effects and risks: The methods used in this study are generally safe; however, as with any medical procedure, there may be some potential risks and adverse effects. Temporary numbness, mild swelling, tenderness at the injection site, or rarely, allergic reactions may occur in the area where anesthesia is administered. Although inhalation of lavender and sweet orange oil is generally considered safe, mild side effects such as airway irritation, dizziness, or nausea may be seen in sensitive individuals. However, although rare, headaches or allergic reactions may occur in allergic individuals; therefore, allergy history will be carefully

evaluated before inhalation. The child may experience discomfort during blood pressure and heart rate measurement. Some children participating in the study may still experience mild levels of stress or fear due to the tooth extraction process. To prevent these risks, the children will be closely monitored and intervention will be provided if they feel any discomfort.

Benefits expected at the end of the study: By identifying effective methods to reduce anxiety and pain during tooth extraction, a more comfortable and stress-free treatment process will be provided for pediatric patients. The effectiveness of aromatherapy and digital anesthesia techniques will be evaluated, thereby supporting minimally invasive and patient-friendly approaches in pediatric dentistry. The risk of developing fear and negative attitudes toward dental treatment will be reduced, contributing to children approaching their future dental treatments more positively. New evidence-based approaches will be offered for dentists regarding the management of anxiety and pain during dental treatments in children. The findings obtained will contribute to the development of alternative methods applicable in the field of pediatric dentistry and to the improvement of clinical protocols.

Duration of the study: Planned as 6 months.

Institution where the study will be conducted: Istanbul University Faculty of Dentistry, Department of Pediatric Dentistry.

Number of volunteers: Approximately 132 volunteers will be included in the study.

Volunteer Initials: Legal Representative Initials: Researcher Initials:

Volunteer rights: Your participation in the research is voluntary, and you may refuse to participate or withdraw from the study at any time without being subjected to any penalty or sanction and without losing any of your rights. If you choose not to participate or if you are withdrawn from the study for any reason, there will be no interruption in your treatment related to your medical condition. Records that may reveal your identity will be kept confidential when you participate in the research, will not be disclosed to the public, and the research results will not be published in a way that would reveal your identity. If such a situation arises, additional consent will be obtained from you as a volunteer, and even if the research results are published, your identity will remain confidential. You will not assume any financial responsibility for the expenses related to the research, and you will not receive any payment. Your child will be

informed about this research in a way that they can understand, and their assent will be obtained for participation.

I was informed that a medical study will be conducted at Istanbul University Faculty of Dentistry, Department of Pediatric Dentistry by Research Assistant, and I was given the above information regarding this research. After receiving this information, I was invited to participate "voluntarily" in such a study. If I participate in this research, I believe that the confidentiality of my personal information that must remain between me and my physician will be respected with great care during this research. I was given sufficient assurance that my personal information will be carefully protected during the use of the research results for educational and scientific purposes.

During the execution of the project, I may withdraw from the research at any time by informing the researchers without providing any reason. In addition, I may be excluded from the research by the researcher, provided that no harm is caused to my medical condition.

I do not assume any financial responsibility for the expenses related to the research. I will not receive any payment.

In case any health problem occurs due to the research application, whether directly or indirectly, I was given the necessary assurance that all necessary medical interventions will be provided. (I will not be financially responsible for these medical procedures.)

If I experience any health problem during the research, I know that I can contact Research Assistant and at the Istanbul University Faculty of Dentistry, Department of Pediatric Dentistry on any day and at any time.

I am not obliged to participate in this research and I may choose not to participate. I have not encountered any coercive behavior regarding my participation. If I refuse to participate, I also know that this will not cause any harm to my medical care or my relationship with my physician. After a period of personal consideration, I decided to participate in this research project "voluntarily." I accept the invitation with great satisfaction and willingness, having been sufficiently informed about the results and effects of the research, with my free will, without any pressure, and without any promise of benefit to me.

A copy of this signed form will be given to me.

I have read all the explanations in the informed consent form. Written and verbal explanations regarding the research, whose subject and purpose are stated above, were given to me by the physician named below. I know that I am participating in the research voluntarily with my own consent, without any pressure or coercion, and that I may withdraw from the research at any time, with or without reason.

Participant's Name–Surname / Signature / Date / Address

Name–Surname of a qualified member of the research team / Signature / Date

Name–Surname of the witness to the consent process / Signature / Date / Address / Telephone Number

Legal Representative – Mother/Father / Name–Surname / Signature / Date / Address / Telephone Number