**INFORMED CONSENT FORM**

**FOR CHILDREN**

DOCUMENT DATE: 08 December 2025

NCT : Not yet assigned

**ISTANBUL UNIVERSITY FACULTY OF DENTISTRY CLINICAL RESEARCH ETHICS COMMITTEE**

**INFORMED CONSENT FORM**

**- FOR CHILDREN –**

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

**Type of study:** Clinical research

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

**Method of the study:** In this study, we are trying to understand which methods may help you feel more comfortable during tooth extraction. Participating children will be divided into four groups. Some children will receive anesthesia using the most commonly used conventional 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 causes any discomfort. Our aim is to identify methods that can help you feel less scared and experience less pain during 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 possible 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 applied. Although inhalation of lavender and sweet orange oil is generally considered safe, mild side effects such as respiratory irritation, dizziness, and nausea may be seen, especially in sensitive individuals. Additionally, although rare, headaches or allergic reactions may occur in allergic individuals; therefore, allergy history will be carefully evaluated before inhalation. Children may feel discomfort while blood pressure

and heart rate are being measured. Some participating children may continue to experience mild stress or fear due to the tooth extraction process. To prevent these risks, children will be closely monitored and, if they feel any discomfort, intervention will be provided.

**Expected benefits 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, supporting approaches that improve communication with children in pediatric dentistry. The risk of developing fear and negative attitudes toward dental treatment will decrease, contributing to children's more positive acceptance of future dental treatments. New approaches will be offered for dentists regarding anxiety and pain management in children during dental treatments. The findings obtained will contribute to the development of alternative methods that can be applied in pediatric dentistry and to the improvement of clinical protocols.

**Duration of the study:** It is planned to last for 6 months.

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

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

**Rights of the volunteer:** 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 program for any reason, there will be no interruption in the treatment related to your condition. Records that reveal your identity will be kept confidential, will not be disclosed publicly, and the research results will not be published in a way that could identify you. If such a situation arises, additional consent will be obtained from you as a volunteer, and your identity will remain confidential even if the research results are published. You will not bear any financial responsibility for the expenses related to the research, and no payment will be made to you.

I was informed that a medical study would be conducted by Research Assistant at the Istanbul University Faculty of Dentistry, Department of Pediatric Dentistry, and the information above regarding the study was conveyed to me. After 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, which should remain between me and the physician, will be approached with great care and respect during the study. I was given sufficient assurance that my personal information would be carefully protected during the use of the research results for educational and scientific purposes.

I may withdraw from the study at any time by notifying the researchers without giving any reason. Additionally, I may be excluded from the study by the researcher provided that no harm is done to my medical condition. I will not bear any financial responsibility related to the expenses of the study, and no payment will be made to me.

In the event that any health problem occurs due to direct or indirect reasons related to the research application, I was guaranteed that all necessary medical interventions would be provided. (I will not bear any financial burden related to these medical interventions.)

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

I am not obligated to participate in this research, and I may choose not to participate. I have not encountered any coercive behavior regarding my participation. I know that if I refuse to participate, this will not cause any harm to my medical care or my relationship with my physician.

After a reasonable period of thought, I have decided to take part in this research project as a “volunteer.” I accept, with great satisfaction and willingness, the invitation made to me, having been sufficiently informed about the results and implications of the study, with my free will, without being under any pressure, and without any promise of benefit made 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 described above were provided to me by the physician named below. I understand that I am participating voluntarily in the research without any pressure or coercion, and that I may withdraw from the study 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**