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## **Invitation to Participate in a Research Project on Childhood Caries**

We would like to ask if you and your child would like to participate in a research project.  
This document provides information about the project and what participation entails.

### **What is the project and why do we want you to participate?**

Caries (tooth decay) is becoming increasingly common among younger children, particularly noticeable among 6-year-olds. We have long known that the risk of caries is influenced by tooth brushing and dietary habits. There also appear to be connections between caries and oral bacteria, social conditions, and the environment in which children live, but we need more knowledge about this.

The purpose of the project is to investigate what protects 6-year-olds from developing caries by examining oral health-related behaviors, dietary habits, the oral microbiome, exposure to chemicals from plastics, and guardians' perspectives on the child's oral health. A better understanding of protective factors can help improve oral health in younger children. You are being asked to participate in the study because your child will turn 6 years old in 2024 and will therefore receive a call from the Public Dental Service for a regular oral health examination.

We obtained your contact information from your dental clinic at the Public Dental Service. The research project is led by Karlstad University and Region Värmland. The application has been approved by the Ethics Review Authority, with the reference number Dnr 2023-05861-01.

### **How does the project work?**

When you participate in this study, as a guardian, you will be asked for your consent for your child to be included in the study. In connection with this information, you will be asked if your child can participate in the study. If you want oral information, contact one of the persons listed at the end of this information.

Your child's participation means that during the regular oral health examination, we will collect information about your child's teeth (any caries, fillings). We will also collect saliva by placing a small cotton roll in your child's mouth for about two minutes. Otherwise, the visit will be handled as during a regular examination of your child but will take a little more time, about 10 additional minutes.

We will also ask for your help in collecting a urine sample (10 ml) from your child. You will then hand this over to the dental staff. You will receive collection materials and instructions in connection with the call for the examination, which will come after you have given consent to your participation.

Participation also involves you filling out a questionnaire with questions about your background, habits, and attitudes towards oral health, as well as your child's dietary and oral health habits. The questionnaire will also cover questions about health behaviors and life issues. The questionnaire takes about 20 minutes to complete and is done while your child is being examined. If you need an interpreter, please inform the dental clinic well in advance of the visit. The same questionnaire will be sent to all guardians with children of the same age in Värmland.

During the visit, as a guardian, you may also be asked to participate in an interview at a later date. The interview will cover questions about your experiences with your child's oral health and dental care. The interview will take place at a location and time of your choice and is expected to take about 30–60 minutes. The interview will be conducted by a researcher and will be recorded and then transcribed.

### **Possible consequences and risks of participating in the project**

The clinical examination of your child is the same as during a regular examination and follows the guidelines at the dental clinic. The saliva sample is a common procedure in dental care and is performed by experienced dental staff.

It may be uncomfortable to be examined in the mouth, and some may have less positive experiences from previous dental care or feel dental anxiety. If the child feels uncomfortable during the examination, the examination can be stopped at any time.

Neither the questions in the interview nor the questions in the questionnaire involve any risks. Some questions and conversations during the interview may be perceived as revealing but will be handled voluntarily. If you have any concerns about your child's teeth/oral health, follow-up conversations/advice with the dental care will be offered.

### **Participation is voluntary**

Your and your child's participation is voluntary, and you/your child can choose to withdraw at any time. If you/your child choose not to participate or want to withdraw, you/your child do not need to provide a reason, and it will not affect your/your child's future care or treatment. If you/your child want to withdraw your participation, you should contact the project manager (see below).

### **How will I get information about the project results?**

The results of the project will be published continuously in both Swedish and international scientific articles and conferences. You can access the results by contacting the project managers (see below).

### **What happens to my information?**

The project will collect and register information about you and your child. We will save the information and samples you provide during the clinical examination to compare your child's oral health with other children's oral health. Your answers and results will be treated so that

unauthorized persons cannot access them. The information will be stored in IT systems with sufficient security to store sensitive personal data. When researchers handle your information, your names, personal numbers, and addresses will be replaced with an ID code. This is called pseudonymization and ensures that your survey responses cannot be linked to you as a person. Only the data manager has a code key that can link the ID code to you and your child, and the code key is stored so that unauthorized persons cannot access it. According to the rules for research, your information will be stored for 10 years from the end of the research project, after which it will be deleted (destroyed).

The information (clinical part and questionnaire) will be transferred as numbers to a data file that will be statistically analyzed. The statistics will only tell how guardians generally answer the questions and not how individual persons have answered. It will also not be possible for anyone else reading the data files to identify you, your child, and your/your child's information through the data files.

In the compilation of the interviews, no names will be included. Quotes from the interview may appear in the presentation of results, but without these being traceable to you as an individual. The recordings will be stored digitally and protected with a username and password.

Your and your child's personal data will be processed in accordance with the EU General Data Protection Regulation (GDPR). The legal basis for processing your personal data is to perform a task of public interest (research). If you choose to withdraw your participation in the study, no further personal data will be collected about you and your child.

The personal data collected before then may, as a general rule, be used in the research. Read more about the different legal bases here: <https://www.kau.se/hur-ska-jag-skriva-forskningspersonsinformation-och-samtycke>

Yours answers, your child's information, and your/your child's results will be treated so that unauthorized persons cannot access them. Karlstad University, together with Region Värmland, are responsible research managers and data controllers. Each research manager is independently responsible for their own processing of personal data, but personal data will be shared/transferred between the research managers within the framework of the study. Personal data will also be processed by data processors. According to the EU General Data Protection Regulation (GDPR), you have the right to access the information about you that is handled in the project free of charge, and if necessary, have any errors corrected. You can also request that information about you be deleted and that the processing of your personal data be restricted. If you want to access the information, you should contact the project manager (see below). If you are dissatisfied with how your personal data is handled, you have the right to file a complaint with the Swedish Authority for Privacy Protection, <https://www.imy.se>, which is the supervisory authority. Contact details for the Data Protection Officer at Karlstad University are email: [dpo@kau.se](mailto:dpo@kau.se), via phone (switchboard): 054 700 10 00. For more information on how Karlstad University processes personal data,

see <https://www.kau.se/gdpr>. Contact details for the Data Protection Officer at Region Värmland are email: [dataskyddsbud@regionvarmland.se](mailto:dataskyddsbud@regionvarmland.se), via phone: 010-831 41 99. For more information on how Region Värmland processes personal data, see <https://regionvarmland.se/regionvarmland/om-regionen/personuppgiftsbehandling>.

### **What happens to my child's samples?**

The samples (saliva, urine) collected in the project are stored coded in a so-called biobank. The name of the biobank is Värmland Biobank with registration number 924, and it is located at the Central Hospital in Karlstad. The main responsible party for the biobank is Region Värmland.

The samples will be sent for analysis to a suitable facility within Sweden. All the aforementioned samples will be coded (pseudonymized), which means they cannot be directly linked to you as a person. The code key is stored at Karlstad University so that unauthorized persons cannot access it.

You have the right to refuse to have the samples stored without explanation. If you consent to the samples being stored, you have the right to later and without explanation withdraw (revoke) that consent. Your samples will then be discarded or anonymized. If you want to withdraw consent, you should contact the project managers, see below.

The samples may only be used in the manner to which you have consented. If you agree that we may keep and use your samples for future purposes, you must specifically consent to this. If additional research that is not yet planned is added, the Ethics Review Authority will decide if you should be asked again.

### **Insurance and compensation**

There is no need for insurance for your participation in the project. The clinical examination is conducted within Folktandvården Värmland and is covered by patient injury insurance. No compensation is provided for your/your child's participation in the study.

### **Project manager**

The person responsible for the project is Ulrika Lindmark, Professor of Oral Health Science at Karlstad University.

### **Contact Information**

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