NORTHERN ARIZONA UNIVERSITY | College of Engineering, Forestry, and Natural Sciences
School of Informatics, Computing, and Cyber Systems

Human Subject Informed Consent
Frequently Asked Questions

Title of Study: *Quantifying the biological component of early childhood caries health disparities in preschool children of Northern Arizona*.

Principal Investigators: Dr. Viacheslav Fofanov

Dear Participant:

This FAQ is part of an informed consent process for a research study. It will provide information that will help you to decide whether you wish your child to participate in this study. It will help you to understand what the study is about and what will happen during the course of the study.

Part I. Why is this study being done?

Early Childhood Caries (ECC) is the most prevalent chronic disease in children, occurring 5 times as frequently as asthma. It is defined as the presence of one or more decayed, missing or filled teeth (due to caries) in a child less than 6 years of age. In the U.S., dental caries is found in the primary teeth of approximately 23% of the children aged 2-5 years. Arizona has one of the highest rates of dental caries in the nation, and Northern Arizona has some of the highest rates in the State. This means, for example, that by age 3 as many as 44% of Northern Arizona's children (as opposed to 32% statewide) have untreated dental caries. The typical explanations for this disease (like access to dental care), explain only a fraction of the cases we observe, and we suspect a biological explanation.

This type of tooth decay is caused by bacteria (*Streptococcus mutans* and *Streptococcus sobrinus*) that live in the mouth (between teeth and along the gum line). These bacteria are fairly common (1 in 5 children in the US and 2 in 5 in Northern Arizona are thought to have them). These bacteria process sugars we naturally get from food and produce acid, which weakens tooth enamel leading to decay. We suspect that the strains of these bacteria that are present in children of Northern Arizona are different from those present elsewhere in the United States, and that the Northern Arizona strains have different (possibly more delayed or active) acid production patterns. We wish to test this by collecting and testing caries-causing bacteria from children of Northern Arizona.

By conducting this study we hope to accomplish the following goals.

1. Understand how different, in terms of bacterial genomes and acid production, are the northern Arizona strains of ECC-causing bacteria from bacteria found in the rest of the United States.
2. Determine if we can use measurements on ECC-causing bacteria to predict tooth decay 6 month, 1 year or 1.5 years in advance.

If successful, this study will help us understand why Northern Arizona has such high caries (tooth decay) rates and if the biology of the bacteria that causes this disease can be used to better guide the treatment of Norther Arizona's children.

Part II. Who may take part in this study and who may not?

To be eligible for this research study, your child must meet the following criteria

- Child must be older than 1 years old, but younger than 6 years old (1-5 year olds).
- Parent or guardian giving consent must be able to read and understand English.

Part III. How many subjects will participate and how long will the study take?

We will conduct this study over the course two school years – Fall 2017 until Spring 2019. During each semester we hope to recruit up to 200 children, for a total of between 200 and 800 individuals, depending on how many children participate in the study more than once. We expect the process of collecting oral samples to take under 5 minutes.

Part IV. What will you and your child be asked to do if you take part in this research study?

If you agree to have your child participate our research study, you will be asked to do the following:

1. Sign this consent form and send back with your child to your pre-school / daycare.
2. Fill out a brief 3 question survey.

The trained dental hygienists of the SMART SMILES program, that already visit your school, will collect your child's saliva and plaque samples during their next visit. The sampling process involves a simple swipe of a sterile cotton swab along the gum line and a wooden toothpick to pick up any visible deposits of plaque on your child's teeth. The whole process should take less than 5 minutes.

Part V. What do we plan to do with your information and samples?

The samples (cotton swabs and toothpicks) will be tested for *Streptococcus sobrinus* and *Streptococcus mutans* – the bacteria that cause early childhood caries. If we detect any of these bacteria in your child's sample, we will grow them up in petri dishes, sequence their genomes and genes, compare them to the genomes of *Streptococcus sobrinus* and *Streptococcus mutans* from other parts of the country, and assess when and how much acid these bacteria produce. We have designed our study in such a way that only the bacterial material and genomes/genes will be analyzed**. NO HUMAN GENETIC MATERIAL WILL BE SEQUENCED AND ANALYZED AS PART OF THIS STUDY**.

On repeat visits, if you and your child decide to participate in the next sampling campaign, we will check the number and extent of teeth that show tooth decay to see if the biology of the previously collected samples could be used to predict future tooth decay outcomes. For any repeat visits to the school (we plan to come back every 6 months for the next two years), we will send out a separate consent form. If you agree to participate in one sampling event, you are under no obligations to participate in another.

Part VI. Are there any costs or benefits for you for participating in this research study?

No. There are no costs or monetary benefits for participating.

Part VII. How will information about you be kept private or confidential?

The information we obtain during this study will be treated as confidential. Each child that participates in the study will have a unique participant ID assigned to them at each collection event. The consent form which links the participant ID with personally identifiable information (such as first and last name) will be stored in locked file cabinets. Your questionnaire answers and your child's bacterial samples will be identified only by your participant ID and will be not be stored in the same place as your personally identifiable information.

After five years following conclusion or termination of this study, your consent form will be destroyed, permanently removing our ability to connect samples and outcomes to individual children. Your child's physical samples (swabs) will also be destroyed 5 years after conclusion of the study.

Part VIII. What will happen if you do not wish to take part in the study?

Participation in this study is entirely voluntary. If you do not want to enter the study you may do so without penalty and without loss of benefits to which you are otherwise entitled. In particular your participation in this study will **NOT** in any way impact the services provided by the SMART SMILES technicians and will not affect your or your child's relationship with your School, Northern Arizona University or SMART SMILES program.

Part IX. Can I withdraw my child's information and samples after sample collection?

Yes. If at any point after we have collected your sample you wish to withdraw your consent and remove your child's samples from the study, you may do so. You'll need to submit your request in writing to eccproject@nau.edu.

Part X. Who should I contact if I have any questions?

Please feel free to contact us at eccproject@nau.edu. A project team member will contact you to respond to any questions you may have.

Part XI. I do not want my child to participate in this study. What should I do?

Only the children with signed parental consent will be asked to participate in the study. You can return this form, indicating "NO" on your desire to have you child participate. Or you can simply not return this form to your school.