

University of Pittsburgh
Institutional Review Board
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CONSENT TO BE A SUBJECT IN A RESEARCH STUDY

TITLE: University of Pittsburgh: Coordinating Center for Genetic Factors Contributing to Oral Health Disparities in Appalachia

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SOURCE OF SUPPORT: National Institute of Dental and Craniofacial Research, U.S.A.

Why is this research being done?

Dr. Marazita and Dr. Weyant invite you to be in a study to learn more about dental health in families, including behaviors, genes (those factors that determine a person's physical characteristics and have been passed to them from their parents), and periodontal (gum tissue) factors. Oral health

varies greatly among different people. The purpose of this study is to identify which genes, attitudes, and behaviors play a role in people's oral health, so that risk factors for oral health problems can be better understood.

Who is being asked to take part in this research study?

You are a member of one of approximately 700 families from West Virginia or Western Pennsylvania with at least one child between 1 and 18 years old, who is being asked to participate in this study. Your family is part of a representative sample of similar families in [NAME OF] County.

What procedures are being performed for research purposes?

You and your family will be asked to participate in a 4-part examination process during this visit. You and your family will also be asked to return every two years, for a total of three or four visits over five to seven years. If you agree to participate, you will undergo the following procedures during this visit. You have the right to participate in only one, two, three, or all four parts of the examination:

Part 1) Questionnaires: You will be asked a series of questions about your behaviors, thoughts, and opinions regarding dental health, general health, prevention, family relationships, parenting practices, social relationships, alcohol, drug and tobacco use, and mental health (for example, self esteem and mental illness). Demographic information (for example, age) and general health history (for example, vaccinations and frequency of check ups) also will be recorded. In addition, you will be asked to complete questionnaires that focus on medical symptoms, dental anxiety, and social history. You will be given an opportunity to examine these questionnaires and do not have to answer all the questions. This part of the study will take about 2 hours.

Part 2) Dental, Microbiological and Tobacco Examinations: You will be given a dental screening to document the presence of oral conditions, including dental decay (cavities), gum infections (called gingivitis and periodontitis by dentists), tooth alignment and crowding, dental or oral injury, and a variety of other conditions of the teeth and mouth (for example, thin enamel). The dental exam will be conducted by a licensed dentist or dental hygienist and is similar to a routine checkup visit to a family dentist, except no x-rays will be taken. During this exam, you will be asked questions regarding your dental status, such as history of tooth injury, and brushing and flossing habits. All people have different kinds of bacteria present in their mouth, so the purpose of the oral microbiological exam is to test your saliva ("spit") and the plaque on your teeth for bacteria that could cause cavities or gum infections. For this examination, you will provide a saliva sample by chewing on a wax pellet and then spitting into a vial. You will have a test to check the flow of your saliva. Your saliva will also be used to check if there is any evidence of tobacco use. A plastic strip will be placed on your tongue to collect saliva. The inside of your cheek may also be scraped to collect a sample. Dental instruments and special toothpicks will be used to scrape and collect dental plaque from your teeth and tongue. A long Q-tip will be used to collect a throat swab from the back of your throat.

If any dental problems are found, you will be given referral information and can seek dental care at your own expense. Dental care will not be provided as part of this study. This part of the study will take about 1 hour.

Part 3) Blood sample for DNA studies: Approximately one and one half teaspoons blood will be

used to evaluate your DNA for genes relating to dental health, such as those which affect cavities, tooth development, or wound healing. If you are unwilling to give a blood sample, you have the option of providing a saliva (spit) sample or having the inside of your cheek swabbed with several cotton swabs to collect cells that contain DNA. If necessary, you could also be provided some mouthwash to rinse to collect the DNA. This part of the study will take 5 minutes or less, and will only be done at one visit, unless the sample is insufficient to complete the study.

Part 4) Water Sampling: You have been sent a vial to collect a sample of your drinking water from your home. This water will be tested for fluoride, a mineral in some people's water that can prevent cavities. Please bring this vial with you to your appointment.

What are the possible risks, side effects, and discomforts of participating in this research study?

- 1) The questions in the interviews and questionnaires may be personal. If any information about child abuse, neglect, or mistreatment is uncovered, then the law requires that it be reported.
- 2) The dental screening infrequently causes some slight gum bleeding, which usually stops within a few minutes. If you have a serious gum infection, you may be sensitive to the gum examination. There is a rare risk that probing your gums may cause an abscess, or infection, of the gum tissue. Although this is rare and usually goes away within a short period of time, it might be painful and require treatment with antibiotics.
- 3) The gum examination is usually not a risky procedure for most healthy people. But, if you have had previous bacterial (infective) endocarditis, certain specific and serious congenital (present from birth) heart conditions, or artificial heart valves or have had a knee or hip replaced, this examination could place you at risk for a bacterial infection that would affect your heart and the joints in your bones. You will be asked if you have ever had any of these heart or joint problems, and if so, you will be asked to obtain and take an antibiotic (either amoxicillin or clindamycin, azithromycin, or clarithromycin) at your own expense an hour before the gum examination. If you have the reduced ability to resist infection, this examination could place you at risk for developing an infection. If you have the reduced ability to form blood clots, you could be at risk for mild, but prolonged bleeding during some of the exam procedures. Prior to the dental exam, you will be asked in detail about having either of these conditions. If you have a reduced ability to resist infection or form blood clots, you will be excused from all parts of the examination that might cause bleeding.
- 4) Collection of tooth plaque, as well as the tongue and cheek scrapings, is likely to be briefly uncomfortable. The throat swab will likely lead to a brief gagging response.
- 5) The needle puncture of your vein to obtain the blood sample may infrequently result in pain and soreness, bruising, fainting, and rarely infection. This procedure will be performed by individuals trained and experienced in obtaining blood samples so as to minimize these risks.
- 6) In the unlikely event of a breach of confidentiality, there is a very remote possibility that the genetic information could affect your ability to be insured, employed, or your family relationships. Such problems are probably rare. You can ask the investigators about the likelihood of the research discovering anything that would lead to these problems.

What are the possible benefits of participating in this research study?

By participating, you may learn more about your own dental and overall health. You will receive verbal and written feedback about your dental screening. If your dental screening reveals any

significant problems, you will also receive names of some dentists or other health professionals who could help with any related dental/medical needs. The information obtained from your participation in this research study may eventually lead to a better understanding and better treatments for oral health problems.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of this study?

You will be promptly notified if any new information develops during the conduct of this research study, which may cause you to change your mind about continuing to participate.

Will I or my insurance company be charged for the cost of any procedures performed as part of this research study?

If you are required to obtain the prophylactic antibiotic from your family doctor, you or your insurance will be charged the cost of the antibiotic. The study will reimburse any costs that you pay out-of-pocket to obtain the antibiotic.

Will I be paid if I take part in this research study?

You will be paid \$5.00 for each procedure of the study that you complete, with an added \$5.00 if all four procedures are completed, up to \$25.00 for one visit. Each time you return for the study (every 2 years for a total of 3 or 4 visits), you will be paid these same amounts. Over a 5 – 7 year period, you could potentially receive \$75 - \$100 dollars depending on the total number of visits. You will also be reimbursed for any out-of-pocket expenses, including long distance communication, transportation, parking, one meal, prophylactic antibiotics, and any costs of obtaining a blood sample at a local lab.

Who will pay if I am injured as a result of taking part in this study?

University of Pittsburgh researchers recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator listed on the first page of this form.

Emergency medical treatment of injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency, you will be responsible for the costs of this follow-up care unless otherwise specifically stated. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

Who will know about my participation in this research study?

Any information obtained about you from this research study will be kept as confidential as possible. All information about you or your involvement in this research study will only be accessible to the investigators involved in this study and their research staff, and will not be released to anyone without your written permission. Records and information pertaining to your identity and involvement in this research study will be stored in locked file cabinets at the [School of Dentistry of

the University of Pittsburgh OR LOCAL SITE]. Computer records will be kept in password protected, secured databases. Your identity on data records, donated blood and dental samples, and DNA will be indicated only by code number. Records linking the codes to your personal identifying information will be stored in a separate, secure location. You will not be identified by name in any publication of the research results unless you sign a separate form giving your permission.

Will this research study involve the use or disclosure of my identifiable medical information?

This research study will NOT involve the use or disclosure of your identifiable medical information from your hospital or physician records, or future medical information that might become available during your participation in this study. This study will record some of your personal health or medical information, which will be kept separate from your medical records, and used only for research purposes.

Who will have access to identifiable information related to my participation in this research study?

The information learned about you during this study will not be released to anyone (for example, relatives, personal physicians, insurance companies, or any other third party) without your prior written permission. However, in the unlikely event that an interviewer identifies someone who is considered to be at immediate risk for harming him or herself or others, they will need to inform the appropriate agencies, as required by Pennsylvania law. Any information about child abuse, neglect, or mistreatment must also be reported. These research records, just like hospital records, may be subpoenaed by court order or may be inspected by federal regulatory authorities.

In addition to the investigators listed on the first page of this consent form and their research staff, the following individuals may have access to identifiable information related to your participation in this research study. Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In addition, authorized representatives of the University of Pittsburgh may have access to this information for the purpose of making participant payments.

For how long will the investigators be permitted to use identifiable information related to my participation in this research study?

The investigators may continue to use identifiable information related to your participation in this research study for at least 5 years following the completion of the research study.

May I have access to my personal research information resulting from my participation in this research study?

You will be notified if you have any dental problems. You will not be provided with your personal research or genetic information obtained during this study.

Is my participation in this study voluntary?

Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC Hospital or affiliated health care provider, or your current or future relationship

with a health care insurance provider or with the University of Pittsburgh. If you turn 18 during the course of the study, your parent's permission is no longer valid, and you will be re-contacted to give permission as an adult.

May I withdraw, at a future date, my consent for participation in this research study?

You do not have to take part in this study and, should you change your mind, you can withdraw from the study at any time by submitting a dated, written request to withdraw to Dr. Marazita, who is listed on page 1 of this form. Any research information recorded before your withdrawal may continue to be used in the research study. Your decision to withdraw from this research study will have no effect on your current or future medical care at a UPMC Hospital or affiliated health care provider, or your current or future relationship with a health care insurance provider or with the University of Pittsburgh. You may be removed from the study by the investigators, if the information you provide is incorrect. If you withdraw or are removed from this research study, your biological samples, blood sample, and DNA will be destroyed.

Will my DNA samples be used for future studies?

Dr. Marazita will control the use of your biological samples and genetic material for this study, and will store your biological samples with codes in freezers at the University of Pittsburgh and West Virginia University. In the future, new research may identify other factors that could be involved in oral health. If this happens, Dr. Marazita would also like to examine them. Thus, if you agree, your biological samples and DNA will be saved for future testing of newly identified factors involved in oral health. When all of her research studies of oral health are completed, any remaining biological samples and DNA will be destroyed at that time. If you do NOT agree, your biological samples and DNA will be discarded at the end of this particular research study. You may also be contacted in the future to be invited to participate in additional research, but that future involvement is voluntary as well. If you turn 18 during the course of the study, your parent's permission is no longer valid, and you will be re-contacted to give permission as an adult regarding the use of your DNA samples.

Your blood sample and its DNA used in this research study may contribute to a new invention or discovery. Sometimes, these inventions or discoveries may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products related to oral health. If the research investigators are able to develop new products from the use of your biological sample or genetic material, they currently have no plans to share any money or other rewards with you. You retain the right to have your blood sample and its DNA destroyed if you decide to withdraw from this research study.

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I give my permission for Dr. Marazita to save my biological samples and genetic material, with personal identifiers, for use in other genetic research projects involving the study of oral health.

YES _____ NO _____

I give my permission to be re-contacted to obtain my consent if there is a desire to use my biological sample or genetic material, with personal identifiers, in other research projects involving the study of different diseases or conditions.

YES _____

NO _____

Initial & Date

VOLUNTARY CONSENT AND AUTHORIZATION

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask additional questions at any time about this research study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

Adults aged 18 and over:

Participant's Signature

Date

Children aged 1 – 17:

I understand that, as a minor (age less than 18 years), _____ is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for their participation in this research study.

Parent's Name

Relationship to Participant (Child)

Parent's Signature

Date

Children who can sign their name:

This research has been explained to me, and I agree to participate.

Child's Name

Child's Signature

Date

Verification of explanation for children who can sign their name:

I certify that I have carefully explained the nature and purpose of this research study to the above-named child in age-appropriate language. They have had an opportunity to discuss it with me in detail. I have answered all their questions, and they have provided assent to participate in this study.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date

All participants:

CERTIFICATION OF INFORMED CONSENT

I certify that the nature and purpose of this research study have been explained to the above-named individual(s), and the potential benefits and possible risks of study participation have been discussed. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Investigator's Printed Name

Investigator's Signature

Date