

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to us about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. *Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.*

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: Proteomics and Genomics of Enamel and Dentin

1.2 Company or agency sponsoring the study: National Institute of Health

1.3 Names, degrees, and affiliations of the researchers conducting the study: Ninna MRP Estrella, DMD, MS; Jan CC Hu, BDS, PhD; James P. Simmer DDS, PhD

2. PURPOSE OF THIS STUDY

2.1 Study purpose: We want to learn more about what causes tooth defect that runs in the family. Tooth defects that we are study may include extra teeth, missing teeth, teeth of abnormal shape, color, surface roughness, softness or sensitivity. You are being asked to be in this research study because you or someone in your family has the tooth condition that we are studying. We want to identify the specific genes that cause tooth defects in different families.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study? A person with dental defect(s) that runs in his/her family can join the study. A person who has a parent, a sibling or a child with dental defect(s) can also join the study.

3.2 How many people (subjects) are expected to take part in this study? The tooth defects we study are rare. In the last 10 years, we have identified and studied 64 families. We will keep an open enrollment for the entire time of this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you decide to take part in this study, we will do three things: 1) check your teeth, 2) take photos and radiographs of your teeth, and 3) collect about 1 tablespoon of blood from your arm.

- It will take 1 visit to have your teeth checked and to have photos and radiographs of your teeth taken. If you can provide existing dental radiographs of diagnostic quality, we do not need to take new ones. There will be no charge to you to have this exam and/or radiographs.
- The blood sample will be collected at a laboratory near you. We will make arrangement with the laboratory that you and family members use to collect the blood sample. There will be no charge to you for this blood sample collection. If you are not able to provide blood sample, we will accept saliva sample collected from buccal swab or spit.
- We will look at your dental records.
- We may talk to your doctor or dentist about you.
- We will continue to analyze the samples until the underlying cause is identified or until the end of this study.

When you completed those three things, we will send a \$50 check to you at the address you specified.

4.2 How much of my time will be needed to take part in this study?

The visit for checking your teeth and take photos/radiographs of your teeth may take 2 hours. The blood sample collection may take 30 minutes depending on the laboratory. All study procedures are considered routine and we do not anticipate taking excessive amount of time. In rare situations, such as blood samples lost in transit, we may contact you again for collecting the sample. If you agreed and provided the needed sample, you will be given another \$50 subject fee.

4.3 When will my participation in the study be over?

When your dental photos and radiographs are evaluated, and your blood sample is determined to be suitable for study analysis, your active participation of the study is completed. In addition to the time above, we will continue to analyze information and sample collected from you after your active participation. We plan to continue the study for 10 years.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks may include:

- The blood drawing may hurt.
- You could get a bruise after the blood drawing.
- Some people feel afraid of the dental check up and x-rays of teeth. Although we like to assure you that the amount of radiographic exposure is no more than what you would have received during a routine dental appointment.
- The dental exam may reveal existing conditions that require treatment.
- The analysis of the blood samples may reveal information not related with your dental condition.
- Sometimes the questions we ask may make you feel embarrassed or uncomfortable.

We will try to minimize these risks by:

- We will make arrangement to have experienced laboratory conduct the blood drawing.
- We will not take additional radiographs if you can provide useful radiographs taken by your dentist.
- We will not be able to treat the dental diseases identified through the exam and radiographs. We can provide copies of the photos and dental radiographs to you so you can seek treatment.
- Sample analysis will be conducted at our laboratory and the University of Michigan facilities. However, in some cases, we may need to send samples for analysis at the National Human Genome Research Institute's (NHGRI) Large-Scale Sequencing Program at Yale Center for Genome Analysis (YCGA). Samples sent to YCGA will be de-identified, analyzed and consumed for the present study. However, the remaining, de-identified samples if any may be used by NHGRI for future research. Because of the sample and data being de-identified, it will not be possible to withdraw the sample/data in the future once they have been submitted. Please indicate whether you would allow your de-identified sample and data be submitted to NHGRI?

- YES NO

Whether you would allow your de-identified sample be used by NHGRI for future research?

- YES NO

You can participate in the present study without donating sample to NHGRI for future research.

- We plan to publish what we learn in this study. Information about your DNA will go into databases, dbSNP, dbGaP (GWAS), 1000 Genomes, and NHGRI Genome Sequencing Program (YCGA), maintained by the National Institutes of Health (NIH). DNA is the set of instructions your body uses to function. None of the information we publish, discuss with others, or submit to NIH's databases will include your name or any other details that someone could use to identify you. The information gathered pertaining to the dental conditions investigated in this study may be too general to be useful to you and your family. We do not intend to reveal information beyond the purview of this study, which is designed to determine cause(s) of dental defects.
- You may receive general study results but not your genetic profile. Please let us know now whether you would like to know the results of the study.

- YES NO

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

- If you wish to know more about genetic testing, you may consult your family doctor.
- If we report the study findings, we will not mention you or your family in any way.
- If you don't feel comfortable answering our questions, please let us know right away.

As with any research study, there may be additional risks that are unknown or unexpected at this time.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

We have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when we are careful to avoid them. Please tell us about any injuries, side effects, or other problems that you have during your active participation in this study.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. In general, the chance of finding the specific cause is about 50% with current technology. When a cause is determined through study of your family, you may be able to better understand the specific dental defect in your family and what's the likelihood of this defect happening in the future generation. By learning about the cause(s) of dental defects, we hope to understand tooth development better and eventually help devise ways to better treat dental defects.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, we will tell you if we learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

Your participation in the study is voluntary. If you decided not to join the study, it will not affect your possibility of receiving care at the University of Michigan.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell us why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of us using “Contact Information” listed in Section 10 (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

There will be no harm to you if you decided to leave the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why we may need to end your participation in the study. Some examples are:

- ✓ We believe that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions required by the study.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. These research-related items are listed in Section 4.1 above. If you get a bill you think is wrong, call us using the number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Blood drawing services needed to collect the study sample
- Monitoring for side effects or other problems
- Treatment of complications
- Deductibles or co-pays for above mentioned services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to us or call your health plan’s **medical reviewer**.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will be given a \$50 check through mail when you completed the dental exam, have photos/radiographs taken (or provided them), and have blood sample collected.

8.3 Who could profit or financially benefit from the study results?

The researchers conducting the study and the University of Michigan do not receive any financial benefit from the study results.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

Everything we learn about you in this study will be confidential. If we publish the results of the study in a scientific magazine or book, we will not identify you in any way.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment

We will send your blood or saliva sample to a laboratory for DNA analysis. We won't label your sample with your name or any other information that someone could use to identify you. Information about the DNA in your sample will go into databases maintained by the National Institutes of Health (NIH). Other scientists have access to NIH's databases and may use your DNA information in their research. The information that goes into NIH's databases will not include your name or any other details that someone could use to identify you.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
 - Make sure the study is done safely and properly
 - Learn more about side effects
 - Analyze the results of the study

- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical or dental record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, we will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over. Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan Notice of Privacy Practices. This information is also available on the web at <http://www.med.umich.edu/hipaa/npp.htm>. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?

Your permission will not expire unless you cancel it. You may cancel your permission at any time by writing to us using the "Contact Information" listed in Section 10 (below).

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.*)
- Other (specify): _____

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: James P. Simmer, DDS, PhD
Mailing Address: 1210 Eisenhower Place, Ann Arbor, MI 48108
Telephone: (734) 975-9318 (US Country Code: 001)

Study Investigator: Jan CC Hu, BDS, PhD
Mailing Address: 1210 Eisenhower Place, Ann Arbor, MI 48108
Telephone:(734) 975-9315 (US Country Code: 001)
Email: janhu@umich.edu

Study Investigator: Ninna MRP Estrella, DMD, MS
Mailing Address: 1011 N. University Avenue, Ann Arbor, MI 48109-1278
Telephone:(734) 763-7820 (US Country Code: 001)

You may also express a concern about a study by contacting the Institutional Review Board listed below, or by calling the University of Michigan Compliance Help Line at 1-888-296-2481.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 200, Room 2086
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (US Country Code:001)
Fax: 734-763-1234 (US Country Code: 001)
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy, contact the University of Michigan Health System Privacy Officer at 1-888-296-2481.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. *(Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Research Subject:

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Legal Representative (if applicable):

Signature of Person Legally Authorized to Give Consent _____ Date: _____

Name (Print legal name): _____ Phone: _____

Address: _____

Check Relationship to Subject:

Parent Spouse Child Sibling Legal Guardian Other: _____

If this consent is for a child who is a ward of the state (for example a foster child), please tell the study team immediately. The researchers may need to contact the IRBMED.

Reason subject is unable to sign for self: _____

Principal Investigator (or Designee):

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name: _____ Title: _____

Signature: _____ Date of Signature: _____

Witness (optional):

I observed the above subject (or his/her legally authorized representative, if applicable) sign this consent document.

Name: _____

Signature: _____ Date of Signature: _____