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CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

STUDY TITLE: Dental Effects of Hypophosphatasia

PRINCIPAL INVESTIGATOR: Ann Griffen, DDS, MS

CONTACT TELEPHONE NUMBER: 614-292-3525

SUBJECT'S NAME: _____ DATE OF BIRTH: _____

NOTE: The words "you" and "your" are used in this consent form. These words refer to the study volunteer whether a child or an adult.

1) INTRODUCTION

We invite you to be in this research study. Using this form as a guide, we will explain the study to you. If you have any questions about the study, please ask. By signing this form, you agree to be in this study. If you do not want to be in this study, all regular and standard medical care will still be available to you here at Nationwide Children's Hospital. Participation is voluntary. You can leave this study at any time.

You will be given a signed and dated copy of the consent form (and the assent form if a child participant is at least 9 years old).

2) WHY ARE WE DOING THIS RESEARCH STUDY?

This is a study to find out how Hypophosphatasia affects teeth and if and how treatment for hypophosphatasia can affect the teeth.

3) WHERE WILL THE STUDY BE DONE AND HOW MANY SUBJECTS WILL TAKE PART?

This study will be done at Nationwide Children's Hospital and The Ohio State University. Up to 200 subjects will participate.

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4) WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?

☐ *For participants who are **not** dental patients at Nationwide Children's Hospital in Columbus, OH:*
Here is what will happen during the study. We will send you a packet of forms that ask you questions about your dental health and your overall health. You will complete them and return them either by mail in a pre-paid postage envelope or by fax. In the packet we will ask for contact information for your dentist, and there will be a HIPAA release form for you to sign giving your dentist the permission to share your dental records with us. We will then send forms to your dentist to fill out. Or if you prefer, we can send you the forms to you to give to your dentist. You or your dentist will send the completed forms back to us. With your permission, we may contact you to clarify information on the form or ask for additional details. Do you give your permission for us to contact you about this? (Initial)

_____ YES _____NO

☐ *For participants who **are** dental patients at Nationwide Children's Hospital in Columbus, OH:*
Here is what will happen during the study. You will fill out a packet of forms that ask you questions about your dental health and your overall health. If you are a patient at Nationwide Children's Hospital, we will use the information from your dental records at NCH for the study. With your permission, we may contact you to clarify information on the form or ask for additional details. Do you give your permission for us to contact you about this? (initial)

_____ YES _____NO

Although this information only needs to be provided once, since we are interested in the long-term effects of Hypophosphatasia we may contact you in the future to follow your progress. Do you give your permission for us to contact you about this?

_____ YES _____NO

Please send us teeth that are lost. We are interested in the effects of Hypophosphatasia on the structure of teeth. We would like to do laboratory analyses on any teeth that are lost. If you are willing to donate any of your teeth that are lost, you can give them directly to us at the NCH dental clinic or we will provide a pre-paid mailing container.

5) WHAT ARE THE RISKS OF BEING IN THIS STUDY?

There are no known risks associated with participating in this study except for the small chance of loss of confidentiality of your study information, but we will take careful precautions to protect your private information.

6) ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

Although there may be no benefit to you from being in this study, we hope to learn something that could help others.

7) WHAT ARE THE COSTS AND REIMBURSEMENTS?

There are no medical or dental costs associated with being in the study. The research project will pay any expenses for mailing forms or copying records.

8) WHAT HAPPENS IF BEING IN THIS STUDY CAUSES INJURIES?

We believe that there is very little chance that injuries will happen as a result of being in this study.

9) WHAT HAPPENS IF I DO NOT FINISH THIS STUDY?

It is your choice to be in this study. You may decide to stop being in this study at any time. If you decide to stop being in this study, call the study team at the number on page 1 of this form. If you stop being in the study, there will be no penalty or loss of benefits to which you are otherwise entitled.

10) OTHER IMPORTANT INFORMATION

If you are an employee of Nationwide Children's Hospital or the Research Institute at Nationwide Children's Hospital, your job or performance appraisal will not be affected in any way if you decline to participate or withdraw your consent to participate in this study.

The final study results will not be shared with you individually.

Nationwide Children's Hospital is a teaching hospital and we are committed to doing research. Doing research will enable us to learn and provide the best care for our patients and families. You may be asked to participate in other research studies in the future. You have the right to decide to participate or decline to participate in any future studies. We will not share your contact information with researchers outside Nationwide Children's Hospital.

11) HOW WILL MY STUDY INFORMATION BE KEPT PRIVATE?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances when this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

The results from this study may be published but your identity will not be revealed.

Information collected for this study includes information that can identify you. This is called "protected health information" or PHI. By agreeing to be in this study, you are giving permission to this study team to collect, use, and disclose your PHI for this research study. You are also giving permission to your doctors and other health care providers to disclose your protected health information for the purposes described below. Information collected is the property of Nationwide Children's Hospital, its affiliated entities, and/or the sponsor.

Some of the information collected as part of this study will be sensitive, such as information relating to your Hypophosphatasia diagnosis.

- **PHI that may be used or disclosed will include:** Names (individual); address (including city, state, zipcode and county); birth date; race; personal medical record numbers; biometric identifiers (e.g. full face photographic images, description of appearance); medical history including HPP diagnosis, HPP lab values, HPP genetic information, and HPP drug treatment; dental history; dental radiographs and images.

People or Companies authorized to use, disclose, and receive PHI collected or created by this research study:

- PI and study staff
- The Nationwide Children's Hospital Institutional Review Board (the committee that reviews all human subject research)

Reasons why the use or disclosure is being made:

There is a risk that someone could gain access to your information. Although there are legal protections, we cannot guarantee that your information could not be misused. But your privacy and the confidentiality of your information are very important to us, and we will make every effort to protect them.

You may decide not to authorize the use and disclosure of your PHI. However, it is needed for this study, so you would not be able to be in this study. If you agree to be in this study and later decide to withdraw your participation, you may withdraw your authorization to use your PHI. This request must be made in writing to the Principal Investigator at **4126 Postle Hall 305 W. 12th Ave. Columbus, OH 43210**. If you withdraw your authorization, no new PHI may be collected and the PHI already collected may not be used unless it has already been used or is needed to complete the study analysis and reports.

There is a risk that someone could get access to the information (data) we have collected about you. If those data suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. The Genetic Information Nondiscrimination Act of 2008 (GINA) says that group and individual health insurers may not use your genetic information to determine whether you are eligible for insurance, how much you have to pay, nor can they request or require that you take a genetic test. We cannot guarantee that this will fully protect you. Your privacy and the confidentiality of your data are very important to us. We will make every effort to protect them.

The results from this study may be published but your identity will not be revealed.

The PHI collected or created under this research study will be used or disclosed as needed until the end of the study. The records of this study will be kept for an indefinite period of time and your authorization to use or disclose your PHI will not expire.

With your permission, we would like to store your PHI for future research purposes, and as part of such future research purposes, your PHI may be disclosed to people or entities not listed above, such as researchers not involved with this study, government agencies, research foundations, or

pharmaceutical or device companies sponsoring future research. This future research may or may not be related to your medical problem. This future research may include sensitive information. Any future research projects will be reviewed and approved by an Institutional Review Board which protects the rights, welfare, and safety of human research subjects. If your PHI is used or disclosed in future research studies, absolute confidentiality cannot be guaranteed. Information shared for future research may be shared further with others and no longer be protected by federal privacy rules.

If you decide at any time that you do not want your PHI stored for future research, you must make this request in writing to the Principal Investigator at **4126 Postle Hall 305 W. 12th Ave. Columbus, OH 43210.** Once we receive your written request, we will destroy your PHI. However, if we have already shared your PHI with another individual or entity, we will not be able to destroy any of the PHI that are no longer in our possession.

Nationwide Children's Hospital retains the right to cease storage and destroy the PHI at any time without sending notice to you or obtaining your consent.

You do not have to agree to use of your PHI for future research in order to be in this study, and your decision will not affect the care you receive from the study doctors or Nationwide Children's Hospital.

I agree to allow my PHI to be stored and used for future research as described above: (initial)

_____ YES _____ NO

12) WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions about anything while on this study or you have been injured by the research, you may contact the Principal Investigator at 614-292-1509, Monday – Friday, between 7:30am - 3:30pm.

If you have questions, concerns, or complaints about the research; if you have questions about your rights as a research volunteer; if you cannot reach the Principal Investigator; or if you want to call someone else, call (614) 722-2708, Nationwide Children's Hospital Institutional Review Board, (the committee that reviews all research involving human subjects at Nationwide Children's Hospital).

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Subject's Name _____Date of Birth_____

SUBJECT or SUBJECT'S PARENT OR PERSON AUTHORIZED TO CONSENT ON BEHALF OF THE CHILD (SUBJECT TO THE SUBJECT'S GENERAL MEDICAL CARE)

I have read this consent form and I have had an opportunity to ask questions about this research study. These questions have been answered to my satisfaction. If I have more questions about participating in this study or a research-related injury, I may contact the study team. By signing this consent form, I certify that all health information I have given is true and correct to the best of my knowledge.

I have been given a copy of the Nationwide Children's Hospital Notice of Privacy Practices. If allowed by law, I understand that my right to any information that is created or collected by Nationwide Children's Hospital for this study can be temporarily suspended if necessary for the purposes of this research project. I also understand that my right to access to this information from this study will be reinstated upon completion of this research unless I have been told by the Principal Investigator that I will not receive study results.

I agree to participate in this study or I give permission for my child to participate in this study. I will be given a copy of this consent form with all the signatures for my own records.

CONSENT SIGNATURES

_____ _____ _____

SUBJECT or SUBJECT'S LEGAL REPRESENTATIVE **DATE & TIME AM/PM**

_____ _____

PERSON OBTAINING CONSENT **DATE & TIME AM/PM**

I certify that I have explained the research, its purposes, and the procedures to the subject or the subject's legal representatives before requesting their signatures.