Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Evaluating the potential of saliva as a research specimen for use in the National Children's Study: Part II. Sampling Feasibility**

Application No.: **NA_00046970**

Sponsor: **National Institute of Child Health and Development (NICHD)**

Principal Investigator: **Douglas A. Granger**

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1. What you should know about this study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Please ask questions at any time about anything you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.

2. Why is this research being done?

This research is being done to better understand the information that can be learned by using saliva as a research specimen. This is a small pilot project that will inform a larger study. We will explore the feasibility of alternative approaches to collecting saliva samples and make recommendations for sampling methods to be used in the larger project.
We are trying to determine the simplest and most time efficient way to collect saliva samples from mothers and small children (ages 3 months through 3 years). We are trying to create procedures that are easy to use when saliva samples are collected by parents at home.

After saliva is collected, we will need you to make sure that the samples are packaged correctly and then prepared for pick up or dropped off at a FedEx or UPS location so that they can be shipped to Johns Hopkins University. We will seek feedback about whether the sample collection instructions are clear, how difficult saliva collection procedures are to do at home, how much saliva was collected, how many samples can be collected without taking too much time, and how easily samples can be returned to the study site.

Eventually, this study will enable the research team to refine the instructions and collection techniques so saliva collection can be effective when included in the larger project. Before we can conduct the larger project we need to develop best practices to ensure the sampling can be completed successfully.

Women who are between the 18 to 35 years and have a child who is between the ages of 3 months and 3 years of age are able to be in this study.

How many people will be in this study?

There will be approximately 132 mother-child pairs in this study at a total of two sites. There will be about 66 mother-child pairs at Johns Hopkins.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

At a convenient time, an interviewer will come to your house and ask you to complete a brief demographics questionnaire about age, gender, and ethnicity (this will take about 5 minutes).

The home interviewer will then demonstrate how to collect saliva samples using one of two different approaches. We will provide verbal and written instructions. We will ask that you donate samples yourself and collect saliva from your child. After you have been shown the procedure, the home interviewer will leave materials with you so that you can collect saliva from you and your child on the following day. After the samples are collected, we will ask you to pack them in a special container and store them overnight in your home freezer. The next morning you will prepare the samples for pick up or drop them off at a local UPS or FedEx facility. The day after that, we will call you to ask you a short set of questions over the phone. This will take about 5 minutes. The questions will be brief and will ask you to give your opinion about the procedures, instructions, and ask for suggestions about how to improve the process of saliva collection.

We will ask you to collect 4 saliva samples from you and 4 saliva samples from your child. The first will be collected at the time you wake up, the second will be 30 minutes after you wake up, the next will be at noon, and the last will be in the early evening just before dinner.

Each saliva collection should take 3-5 minutes.

For adults, the collection procedures will involve two approaches: (1) a small foam swab (about half the length of your small finger) that will be placed under the tongue for 2 minutes. After two minutes the swab is taken out of the mouth and placed into a plastic container and (2) an approach that involves allowing saliva to pool in your mouth naturally (without swallowing) and then gently forcing that saliva from the mouth through a straw-like device into a plastic cup.

For the children, we will ask that you have them mouth the end of a long-thin foam swab (length of your middle finger). This is very similar to how you would use a thermometer to take your child's oral temperature. We will ask you to place the end of the swab (while holding on to the other end) under your child's tongue for 2 minutes. When the time is up, you will place that swab into a special container.

Each saliva donation will be less than 1/2 teaspoon.

After each sample is collected, we will ask you to record the time of day the sample was collected, and place that sample in a container in your freezer. We will provide you with a small shipping container (postage paid) for the samples.

The samples collected in the study will be coded with an ID number that cannot be linked to your name. The samples will be sent to Johns Hopkins University where we are interested in how much sample was collected, how well the instructions were followed, how long the sample was in the mail, and the temperature of the samples while they were in the mail. No resulting data will be available to you as your sample will no longer be linked to your name.

How long will you be in the study?

You will be in this study for short periods of time over 4 days total. The first day will involve a 20-30 minute home visit to explain the study procedures. The second day you will collect saliva samples at 4 specific times of day (20-30 minutes total). On the third day, you will prepare the samples to be picked up or drop them off at a UPS or FedEx facility (10 minutes, may vary). On the fourth day, you will be interviewed by phone for about 5 minutes. We will not contact you in the future about any continued involvement.

4. What are the risks or discomforts of the study?

There is a small risk to you that others could see sensitive personal information about you, which could cause embarrassment or have legal penalties. The research team will comply with Maryland law and will tell the local or state authorities if they suspect abuse or neglect of a child or dependent adult.

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

You child may not be interested or willing to cooperate with the sample collection procedures.

5. Are there risks related to pregnancy?

There are no risks related to pregnancy.

6. Are there benefits to being in the study?

There is no direct benefit to you from being in this study.

If you take part in this study, you may help others in the future. If we are able to demonstrate that saliva can be used in the larger study, this observation has potential to minimize discomfort of the child participants in the larger study.

7. What are your options if you do not want to be in the study?

Participation in this study is optional. You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

There are no costs associated with being in this study.

9. Will you be paid if you join this study?

To thank you for your time, you will receive a total of $25.00 for completing all parts of this study. Your payment will be mailed to you when the samples are received at Johns Hopkins University. If you do not complete all parts of this study, you will not receive $25.00. You may receive partial payment of $15 if you only complete the follow-up phone interview.

10. Can you leave the study early?

You can agree to be in the study now and change your mind later. If you wish to stop, please tell us right away.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- You fail to follow instructions.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

12. How will your privacy be protected?

Johns Hopkins has rules to protect information about you. Federal and state laws also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

Generally, only people on the research team will know that you are in the research study and will see your information. However, there are a few exceptions that are listed later in this section of the consent form.

The people working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may collect other information including your name, address, date of birth, and other details.

The research team will need to see your information. Sometimes other people at Johns Hopkins may see or give out your information. These include people who review the research studies, their staff, lawyers, or other Johns Hopkins staff.

People outside of Johns Hopkins may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, and other hospitals in the study and companies that sponsor the study.

We cannot do this study without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Hopkins who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by contacting the Principal Investigator of this study. The Principal Investigator can be reached by phone at 443-287-0583 or by sending a letter to:

Douglas A. Granger, Ph.D.
Professor of Nursing, Public Health, and Medicine
Director, Center for Interdisciplinary Salivary Bioscience Research
The Johns Hopkins University
525 N. Wolfe Street, Room 466
Baltimore, MD 21205
(Fax) 443-287-0544

You also may choose the option of contacting the Johns Hopkins Privacy Officer. The Johns Hopkins Privacy Officer can be reached by phone at 410-735-6509 or by sending a letter to**:**

Johns Hopkins Privacy Officer
5801 Smith Avenue
McAuley Hall, Suite 310
Baltimore, MD 21209
Fax: 410 735-6521

If you send a letter, please be sure to include the study number and your contact information.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

13. What does a conflict of interest mean to you as a participant in this study?

A conflict of interest occurs when a research investigator or Johns Hopkins has/had a financial or other interest that might affect the investigator's judgment when conducting a research study. In some situations, the results of a study might lead to a financial gain for the investigator(s) and/or Johns Hopkins.

One or more of the investigators working in this research study has/had a financial conflict of interest in connection with the study.

If you have any questions about this conflict of interest, please talk to Maggie Denny, 443-287-2902 (Mdenny1@son.jhmi.edu). This person is a member of the study team, but does not have a conflict of interest related to the study. You can also call the Office of Policy Coordination (410-516-5560) for more information. The Office of Policy Coordination manages conflicts of interest**.**

14. What treatment costs will be paid if you are injured in this study?

Johns Hopkins and the federal government do not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

- If you have health insurance: The costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.

- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of a study-related injury.

15. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

b. What do you do if you have questions about the study?

Call Maggie Denny at 443-287-2902. If you cannot reach Ms. Denny or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

Call Dr. Tina Cheng at 410 614-3862, if you have an urgent medical problem related to your taking part in this study.

d. What happens to Data, and Specimens that are collected in the study?

Scientists at Johns Hopkins work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to both this study and to future research.

If you join this study:

- You will not own the data, or the tissue, blood, or other specimens given by you to the investigators for this research.
- Both Johns Hopkins and any sponsor of this research may study your data and the tissue, blood or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, Johns Hopkins may use them for future research only with your consent or IRB approval.
- You will not own any product or idea created by the researchers working on this study.
- You will not receive any financial benefit from the creation, use or sale of such a product or idea.

e. What are the Organizations that are part of Johns Hopkins?

Johns Hopkins includes the following:

- The Johns Hopkins University
- The Johns Hopkins Hospital
- Johns Hopkins Bayview Medical Center
- Howard County General Hospital
- Johns Hopkins Community Physicians.
- Suburban Hospital
- Sibley Memorial Hospital

16. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

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Signature of Participant Date/Time

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Signature of Person Obtaining Consent Date/Time

NOTE: **A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; AND, IF APPROPRIATE A COPY OF THE CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD.**

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED FOR CONSENTING RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO CONSENT RESEARCH PARTICIPANTS.