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 I. Measurement Feasibility**

Application No.: **NA_00046518**

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

Principal Investigator: Douglas A. Granger

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.
- For clinical trials, a description of the research will be available at www.clinicaltrials.gov. This website will not include information that can identify you. You can search the website at any time.

2. Why is this research being done?

This study 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 what types of measurements can be made in saliva.

The measurements of interest include testing chemicals that are naturally present in our bodies (i.e., hormones, DNA) and chemicals that are present in our bodies because they are in our environment (i.e., tobacco smoke, pesticides).

We are trying to figure out whether these chemicals can be measured in saliva, and whether the levels measured in saliva compare to measurements of those chemicals in urine and blood.

The samples you donate will be used to explore new methods and develop new tests for use with saliva samples. Eventually, this study will help show which analytes have the potential to be included in the larger project.

Men and non-pregnant women who are between the ages of 18 to 35 years and not currently taking prescription medications other than birth control are able to be in this study.

How many people will be in this study?

Approximately 150 participants will be in this pilot study.

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:

Visit the Johns Hopkins School of Medicine for approximately 45 minutes.

Review and sign this consent form (5-10 minutes).

Complete a brief questionnaire (15 minutes) about your health, health behaviors, medication use, and other issues that might be related to the levels of chemicals in your saliva.

Donate a saliva sample (10-15 minutes). We will ask you to gently force your saliva through a short drinking straw into a plastic tube. You will be asked to donate 1 tablespoon of saliva.

We will also ask that you also donate a urine sample (3-5 minutes). Urine will be collected by asking you to void your bladder into a collection container. This procedure will take place in a private restroom. The volume of urine donated will be approximately 2 tablespoons.

Finally, we will ask you to donate a blood sample (5 minutes). The sample will be collected by venipuncture by a laboratory technician/professional. You will be asked to donate approximately 2 tablespoons of blood.

The samples collected in the study will be coded with an ID number that cannot be linked to your name. The samples will be analyzed by project partners at Johns Hopkins University and Emory University. Results of the assays on samples you provide will not be available to you as the samples will no longer be identifiably linked to you.

How long will you be in the study?

You will be in this study for approximately one hour. There is no intention to 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.

Taking blood may cause discomfort, bleeding or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

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.

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 to measure chemicals of interest, 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 is no cost associated with participating in this study, but you will need to have transportation to and from the Johns Hopkins Medical Institutes Campus.

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

If you complete all parts of this study, you may receive a total of $50.00 to thank you for your time at the conclusion of your visit to the School of Medicine. If you do not complete all parts of this study, you may receive a partial incentive.

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, 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 calling the Johns Hopkins Privacy Officer 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

Please be sure to include the name of the principal investigator, 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.

- Study-related injury: (provided the costs are not the result of care required to treat your underlying disease or condition). Any costs that are not paid for by the study sponsor will be billed to you.

  You will not give up any of your legal rights by signing this form

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 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 other specimens given by you to the investigators for this research.
- Both Johns Hopkins and any sponsor of this research may study your data or other specimens collected from you.
- If data 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

Signature of Person Obtaining Consent
Date

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.**