UNIVERSITY *of* MARYLAND
BALTIMORE

RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title: *My* Healthy Maryland Precision Medicine Research

Study No.: HP-00095517

Principal Investigator: Stephen Davis, MBBS, Phone: 410-328-2488

CONCISE SUMMARY

We are asking you to take part in a voluntary research study called *My* Healthy Maryland Precision Medicine Research (*My* Healthy Maryland). The purpose of this study is to create a resource for researchers to learn more about health and disease.

If you agree to sign up for *My* Healthy Maryland, you will:

- Provide or allow access to a sample of your blood, saliva, tissue, and/or a cheek swab.
- Let us use information from your medical record for research.
- Choose to fill out optional on-line surveys about your health, lifestyle, and family.
- Agree to receive email or text messages with study updates, quick polls, or educational information.
- Allow us to contact you in the future to ask for more samples or information, or to ask you to be in other research studies. You can say no to any future request.
- Let scientists use your samples and health information for research.

Your initial participation will take less than 30 minutes. Your sample and health information will be stored and used for research indefinitely. You can leave the study at any time.

The risks of this study include:

- possible loss of confidentiality,
- and if we need to collect a sample, there could be discomfort, bruising, fainting or infection (rare) from a blood draw, or minor irritation from a cheek swab.

If you want to learn more about this study, please keep reading.

PURPOSE OF STUDY

My Healthy Maryland aims to find new and better ways to prevent and treat rare and common diseases. We will collect health-related information from you and up to 250,000 adults over the next 5-10 years. With this large amount of information, we will look for patterns in the data to find better ways to stop, identify, and treat a wide range of diseases. You do not have to have any particular disease or condition or be a patient in the University of Maryland Medical System to participate in this study.

PROCEDURES

Sample Collection: We may collect a sample from you in any of the ways listed below.
We may use a sample already collected from you such as:

- blood that is left over from your regular medical care,
- a sample stored at University of Maryland from another study you are participating in,
- or a sample of tumor or other tissue from your body, collected during a surgery or other procedure you have had or will have as part of your regular medical care, if that sample is not needed for diagnosis.

We may collect a new sample such as:

- up to two tablespoons of blood drawn from a vein in your arm,
- a saliva sample by spitting into a container,
- or cheek swabs by rubbing the inside of your cheeks with up to 4 cotton tipped swabs, for 30 seconds each.

Saliva or cheek swabs may be collected at home. We will send a kit and pay for return postage.

Health Questionnaires: You may be asked to fill out surveys about your health, lifestyle, and family health history.

Medical Records: We will collect health information from your electronic health record (EHR) and the Chesapeake Regional Information System for our Patients (CRISP). This will keep going unless you withdraw from the study.

CRISP is a system for sharing your health information with different healthcare providers. This includes doctors, hospitals, labs, and more, in Maryland, D.C., and nearby areas. We might get copies of your medical treatment and test records from CRISP. If you want to learn more about CRISP or decide not to share your records through it, you can visit www.crisphealth.org. Keep in mind, if you opt out of CRISP, they will not be able to give us data for this research.

Research Uses:
Your samples and data will be stored securely in the *My* Healthy Maryland biobank and used indefinitely for research purposes. A wide range of genetic tests may be done, from studying a single gene to genome sequencing, which looks at your entire genetic code. Other methods to study your genes and how they work may be used as they are developed. Your blood, tissue, or saliva sample, if you provide one, may be used to study other markers of health and disease including proteins and other chemicals and molecules that are produced by your body.

Your samples and data, labeled with a code instead of personal information, may be shared with researchers at, for example:

- the University of Maryland,
- other universities,
- the government (National Institutes of Health (NIH)),
- or commercial entities.

We might put some of your genetic and health information into large scientific databases run by the University of Maryland, the government (like NIH), or commercial entities. Your information will be labeled with a code. Information that can directly point to you (like your name or address) will not be put in the databases.

Each request to use your samples and data must be approved by the Institutional Review Board (IRB).

Research Results: From time to time, we may share with you general results from *My* Healthy Maryland research. Research done with your sample could reveal something, such as a genetic change, that might affect the management of your health or that of your family. You may have an opportunity to learn about your genetic results in the future, though it may be a year or more before this happens. If you are not contacted, it does not mean that there are no findings. This study does not replace genetic counseling for suspected genetic conditions. If you or your doctor suspect you have a genetic disease, you should be evaluated as part of your regular medical care.

POTENTIAL RISKS/DISCOMFORTS

- We may not need to collect a new sample from you but if we do, blood draws can cause discomfort, bruising and in rare cases fainting and infection, and cheek swabs can cause minor irritation.
- Your health or genetic information could be released or discovered by mistake. There is a risk that you could be identified by information shared with large scientific databases. This is because genetic information is unique to each person. It could be linked to you even without your name or other information.

We believe that the chance these things will happen is very small. But we cannot promise it will not happen. The steps we will take to keep your information private are described below. Additionally, it is against federal law (Genetic Information Nondiscrimination Act, or GINA) for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law, however, does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

POTENTIAL BENEFITS

You will not benefit directly by taking part in this study. Research using your samples may contribute to improvements in health care. You may benefit if you learn important information about your health.

ALTERNATIVES, COSTS AND PAYMENTS TO PARTICIPATION

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at University of Maryland, Baltimore, or other healthcare systems, will not be affected. It will not cost you anything to take part in this study. You will not be paid for taking part. If any of the research leads to new products, such as drugs or tests for diseases, you will not make any money.

Health Insurance Portability and Accountability Act (HIPAA)

AUTHORIZATION TO OBTAIN, USE, AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Your study information, medical records and linked samples are confidential. Your information and samples will be treated as privately as possible under local, state, and federal laws. But we cannot promise complete secrecy. To protect your identity, we will:

- Label your sample and information with a code instead of personal information.
- Only share your personal information with researchers who are approved by the IRB to use it. Researchers have to promise to keep your identity secret.
- Store your information in locked cabinets.
- Use password-protection to limit access to electronic data.
- Get a **Certificate of Confidentiality** from the NIH. This means we do not have to give out any information that identifies you in a court case, even if they have a subpoena. But we still have to give your information to the funding agencies, the Office of Human Research Protections (OHRP), or IRB if they ask for it.
- Not identify you by name in publications and scientific reports coming from this research.

The specific health information that can be used or shared are:

- name, date of birth, gender, race, ethnicity, contact information, medical record numbers, and social security numbers,
- information you have given through the surveys you complete,
- information obtained from your electronic health record (EHR) and CRISP including, but not limited to, diagnoses, medications, provider notes, laboratory, and other test results,
- and test results performed for the purpose of this research, including genetic tests.

We will do our best to make sure your personal information can only be seen by those who really need it. The people and organizations who will use or share this information are:

- the Principal Investigator and his research team,
- Vibrent Health; the commercial research organization that maintains the *My* Healthy Maryland application,
- authorized researchers approved by the University of Maryland IRB,
- organizations that will coordinate compliance such as offices within UMSOM; the University of Maryland, Baltimore,
- Chesapeake Regional Information System for our Patients (CRISP),
- and federal agencies that have authority over the research, including the OHRP.

Some groups that might need to check your information to make sure everything is done correctly are:

- the IRB,
- the University of Maryland and UMMS,

- the OHRP,
- the Food and Drug Administration,
- the Department of Health and Human Services,
- and other funding groups.

Everyone who uses this information will be careful to keep it confidential. You may call the UMSOM Privacy Official (410-706-0337) with questions about your rights and protection under privacy rules.

RIGHT TO WITHDRAW

You can leave the study at any time. There are no negative consequences if you decide to leave the study. It will not affect your current or future healthcare, and if you are an employee or student at UMB, your employment or academic status will remain the same. If you leave the study, we will destroy any research samples we have left. We will stop collecting information from your medical record. We will keep the data we already have from you, but will not do any new research. It may not be possible to remove your genetic and health information from scientific databases once it has been given out.

Please contact Dr. Stephen Davis at 410-328-2488 or the Study Team at myhealthymaryland@som.umaryland.edu if you:

- decide to leave the study,
- have questions, concerns, complaints,
- or need to report a medical injury or any problem you believe may be related to the study.

UNIVERSITY STATEMENT

The University of Maryland, Baltimore (UMB) is committed to providing subjects in its research studies all rights due to them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in this study. This study has been reviewed and approved by an Institutional Review Board (IRB). The IRB is a group of scientists, physicians, experts, and community representatives. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research studies.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research study subject. The contact information for the IRB and the HRPO is:

University of Maryland, Baltimore
Institutional Review Board
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037s

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

______________________________ Participant's Signature

______________________________ Investigator or Designee Obtaining Consent Signature

Date:______________________________

Date:______________________________