

Consent for My Healthy Maryland Precision Medicine Research

Principal Investigator: Stephen Davis, MBBS, FRCP, FACE, MACP
University of Maryland School of Medicine
Phone: 410-328-2488

The University of Maryland School of Medicine is committed to finding better ways to treat diseases and promote health through research. *My Healthy Maryland* Precision Medicine Research is a research study that will be a valuable resource used to understand how genes and other factors contribute to health and disease. The purpose of the *My Healthy Maryland* study is to gather health-related information, or data, about you and many other people for research. By looking for patterns in the data, researchers can make discoveries that may lead to improvements in the prevention, diagnosis and treatment of common and rare disease in patients throughout Maryland and beyond.

Up to 250,000 adults who live in Maryland will be enrolled in the study over the next 5-10 years. You do not need to be a patient in the University of Maryland Medical System to join.

If you agree to be in the study:

- You will complete simple surveys about your health, your lifestyle and your family.
- We will get information from your medical records.
- You will give a cheek swab sample or we may obtain a sample that was collected from you for another purpose. This sample will contain your genetic material, or DNA.

The *My Healthy Maryland* team will study your sample, survey and health data for research. Other approved scientists may also use your sample and data for research. We will not give your name or identifying information to researchers outside of the *My Healthy Maryland* study team. All samples and data collected will be stored securely to ensure your privacy is maintained.

The study will go on for an indefinite period of time. Your initial participation will take less than two hours. Over the course of the study, we will contact you regularly through either email or text messages with study updates, quick polls, educational information and other research opportunities. You can say yes or no to any future request or activity. We will contact you if there are medically important research results to share with you. You will be able to decide if you want to receive your personal results, if there are any to share. The risks of this study include possible loss of confidentiality or privacy. If there is a data breach, someone could see or try to misuse your health or genetic data. There are many protections in place to minimize this risk. There may be minor discomfort from collection of the cheek swabs. Your participation

is voluntary. You can leave the study at any time. If you are interested in learning more about this study, please continue.

What will happen if I take part in this study?

If you join *My Healthy Maryland* Precision Medicine Research study, you will fill out surveys about your health, family history and your lifestyle. The surveys will be administered on your mobile phone, tablet or computer. Over the course of the study, you may be asked to fill out more surveys about, for example, the work you do, how much you sleep, your physical activity or the foods you eat. We will also ask you if you have moved or changed your phone number or email address. You can also choose to give us the name and number of another person to contact if we cannot reach you.

What will happen if I take part in this study? We will collect a sample containing your DNA to use for research.

As a part of this study, we will collect a biological sample from you. This can be a blood sample, saliva sample, or a sample of the cells from the inside of your cheek.

Some people have blood or saliva samples that were collected during another study and are stored at the University of Maryland. If you have a stored sample, we may be able to obtain that sample for our research. Or we may be able to get blood that is left over from a sample collected for your regular medical care. If we can get a sample either of these ways, we will let you know.

If not, we will mail you a kit to collect cheek cells. Collecting cheek cells is easy. You simply rub 1 or 2 soft-tipped swabs on the inside of each cheek for 30 seconds. The kit will include instructions for collection and a return mailing envelope with the postage pre-paid.

Finally, we may ask you to give more samples in the future. If we ask, you can say no if you do not want to give another sample.

What will happen if I take part in this study? We will obtain information about your health from your electronic health record(s) wherever you receive your health care.

To get more detailed information about your health, we will collect information from your electronic health record(s), or EHR for short. One way we can get your information is for you to link your EHR to our secure *My Healthy Maryland* database. You will be able to do this through the *My Healthy Maryland* website. We will also get information directly from the places where you receive your healthcare.

Examples include information about your health problems, test results, medical procedures, images such as X-rays, and medicines you take. Health records can contain sensitive information. They may contain information about your mental health, genetic conditions, or use

of alcohol or drugs. They may show sexual or other infections, including HIV status. From time to time, we will obtain updates from your EHR. This will go on indefinitely unless you withdraw from the study. We take all precautions to protect the confidentiality of your health records. We will review how your privacy is protected later in the Confidentiality section of the consent process.

CRISP

Chesapeake Regional Information System for our Patients (CRISP) is a health information exchange that supports the sharing of patient electronic health record among health care providers such as doctors, hospitals, laboratories, radiology centers, and other health care providers or facilities in Maryland, the District of Columbia, and other parts of the Mid-Atlantic region. By participating in this study, you agree that researchers may receive copies of any of your medical treatment and test records that are available through CRISP. More information about CRISP, including information about your right to decline to make your medical records available through CRISP, can be found at www.crisphealth.org. You understand that, if you choose to opt out of CRISP, CRISP will no longer be able to provide data for the purpose of this research study.

What will you do with my data and samples? The *My Healthy Maryland* team will study your samples, and your survey and health data for research.

Your samples will be stored indefinitely in the *My Healthy Maryland* biobank. A biobank is a secure storage place for samples. Your samples will be used to study genes for research purposes. Genes are pieces of DNA that have the instructions needed to make our bodies work. DNA stores these instructions in the form of a code. You inherit this code from your parents and you pass it on to your children. 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 sample, if you provide one, may be used to study other markers of health and disease including proteins and other chemicals that are produced by your body.

Your survey and health record data will be stored in secure databases. Your health data will be linked to your genetic and other sample data with a code. Your sample and health data will be combined and studied with data from lots of other people. Studying samples and data from many people can help researchers better understand the connections between genes and disease. It is important to understand that we will not necessarily study your sample and data right away. It will be stored until it is studied with samples and data from other individuals.

Research Results You will have an opportunity to learn about your genetic results in the future. Our plan to return results is still under development.

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. For example, a genetic change could predict your risk for disease or your response to medication. You will 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 get testing and be treated as part of your regular medical care.

Data Sharing Your samples and data will be stored and used for an indefinite period of time and may be shared with qualified scientists. All sample and data sharing must be approved by special review boards called IRBs. If you want to have your samples removed from the research, contact the Principal Investigator, Dr. Stephen Davis at 410-328-2488, or by emailing the Study Team at myhealthymaryland@som.umaryland.edu.

Your samples and data may be shared with qualified researchers from University of Maryland, other academic institutions, government institutions such as the National Institutes of Health, or commercial entities. Research using your samples and health data could include genetic or other analyses on nearly any disease or condition. Each request to use your samples and data must be approved by an Institutional Review Board, also called an IRB. An IRB is a special committee that reviews research to make sure that participants' rights and wellbeing are protected.

We may put some of your de-identified genetic and other data into one or more large scientific databases for use by researchers outside the study team. These databases could be maintained by the University of Maryland, government institutions like NIH, or by commercial entities. Sharing data can speed up discoveries related to health by creating larger databases for more researchers to access and analyze. If we share data, it will be labeled with a code. Data that could directly identify you, such as your name or address, will never be placed into any scientific databases. Access to your individual data will be limited to approved scientific researchers who agree to strict database use policies.

We will store and use your samples and data for an indefinite period of time, including after your death, unless you withdraw from the study. If at any time you wish to have your samples removed from the study you may do so by contacting the Principal Investigator, or by emailing the Study Team.

Potential Risks The main risk of this study is possible loss of confidentiality. If there is a data breach, someone could see or try to misuse your health or genetic data. There are protections

in place to minimize this risk. There may be minor discomfort from collection of the cheek swabs.

The main risk of the study is loss of confidentiality. This could happen if there is a data breach. A data breach is when someone sees or uses data without permission. If someone sees data we have about you, even without your name, there is a chance someone could figure out who you are. They could misuse your data. If this happens, you may feel negative emotions like frustration, anger, embarrassment or worry. We will tell you if there is a data breach.

We will gather data from you through the ***My Healthy Maryland*** application or website. There is a risk to your privacy whenever you use an app or a website. Generally, there is no additional risk to your privacy if you use them as part of the research study. That said, there may be additional risk to your privacy because of the amount of data in your ***My Healthy Maryland*** record. There may also be a risk to your privacy when talking with study staff. To minimize risks to privacy, please use the app and website, and talk with research team members in a place and time that feels comfortable for you.

Your DNA is a type of private information that is unique to you. If there is a data breach, someone could try to use your health or genetic information to discriminate against you. A federal law called the Genetic Information Non-Discrimination Act (GINA) will help protect you from health insurance or employment discrimination based on genetic information obtained about you. This law makes it illegal for health insurance companies, group health plans and most employers to use genetic information against you. However, it does not apply to life, disability or long-term care insurances.

There is a risk that you could be identified by information shared with large scientific databases because even without a name or other identifiers, genetic information is unique to each person.

We believe that the chance these things will happen is very small, but we cannot promise that this will not happen. We will take many precautions to keep your information private. The precautions are described later in the Confidentiality section of this consent process.

Potential Benefits

You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study. You may feel good about participating in research that contributes to improving the quality of health and healthcare in your community, the State of Maryland and beyond. You may also benefit if you learn important information about your health.

Alternatives, Costs and Payments to Participants

You do not have to take part in this research study. No matter what you decide, it will not affect your healthcare at University of Maryland, Baltimore or other healthcare systems.

It will not cost you anything to take part in this study.

You will receive a \$5 gift card upon completion of initial surveys and receipt of your sample. If any of the research with your samples or data leads to the development of new products, such as drugs or tests for diseases, the money made from the sale of those products will not be shared with you.

Privacy and Confidentiality

Your privacy and the confidentiality of your data is very important to us. Your data and samples will be treated as privately as possible under local, state, and federal laws. However, we cannot promise complete secrecy. To protect your confidentiality we will:

- Label your stored sample and data with a code instead of your name or other personal identifiers.
- Store data in a secure cloud-computing environment and in UMB databases that follow rigorous standards to protect data confidentiality.
- Secure paper records in locked cabinets and locked offices.
- Limit who is allowed to see data that directly identifies you to the research team and other people who have a need to see this information.
 - A commercial research organization maintains the online application that your data is collected and stored on. A limited number of their staff will be able to see your personal data to do their work.
 - Organizations that may inspect and copy your data to make sure the project is done properly include the IRB and other representatives of the University of Maryland, representatives of the federal Office of Human Research Protections (OHRP), the Food and Drug Administration, the Department of Health and Human Services or other funding organizations.
 - Everyone using study information is trained in privacy practices and will work to keep your information confidential.
- Not identify you by name in publications and scientific reports resulting from this research.
- We have obtained a Certificate of Confidentiality from the NIH. This means that we cannot release or use data, documents, or samples that may identify you in any action or suit unless you say it is okay. This protection includes federal, state, or local proceedings. An example would be a court subpoena. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some contagious diseases, and threats to harm yourself or others. This Certificate does not stop you from giving out information. If you consent to share research information with an insurer, employer, or other person, the Certificate does not apply. This means you need to be sure to protect your privacy too.

Right to Withdraw

You can leave the study at any time. If you refuse to take part, or if you leave the study, you will

not be punished or lose any benefits you are owed. There are no negative consequences if you decide to leave the study. It will not affect your current or future health care. If you leave the study, we will not perform any new research with your data or sample. We will stop collecting data from your medical record. We will keep the data we already have from you and your samples. We may keep your sample to check the results of past studies. If researchers already have your data or samples for their studies, we cannot get it back. It may not be possible to remove your genetic and health data from scientific databases once it has been given out.

If you decide to leave the study, if you have questions, concerns, complaints, or if you need to report a medical injury or any problem at any time that you believe may be related to the study, please contact Dr. Stephen Davis at 410-328-2488.

University Statement Concerning Research Risks

The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the IRB if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

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

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

Take as much time as you need to decide if you would like to join. You can review these screens as many times as you like.

Concise Summary

Health Record and CRISP

Research Results and Data Sharing

Potential Risks and Benefits

Privacy and Confidentiality

Have Questions? Contact the My Healthy Maryland Precision Medicine Research Team

Email: myhealthymaryland@som.umaryland.edu

Phone: [410-706-6140](tel:410-706-6140)

We will respond during regular office hours, Monday through Friday 8:00 a.m. to 4:00 p.m.

Consent Agreement

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.

If you agree to participate in this study, please sign your name below.

Participant's Signature

Date: [auto completed the date participant signs]

Health Insurance Portability and Accountability Act (HIPAA)
**AUTHORIZATION TO OBTAIN, USE AND DISCLOSE PROTECTED HEALTH
INFORMATION FOR RESEARCH**

Study Name: My Healthy Maryland Precision Medicine Research
UMB IRB Approval Number: HP-00095517
Researcher's Name: Stephen Davis, MBBS, FRCP, FACE, MACP
Researcher's Contact Information: University of Maryland School of Medicine
Phone: 410-328-2488

This research study will use health information that identifies you. If you agree to participate, the Principal Investigator, will use just the health information listed below.

The Specific Health Information To Be Used or Shared:

- 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
- Test results, including genetic and other tests performed for the purpose of this research

Federal laws require the Principal Investigator to protect the privacy of this health information. He will share it only with the people and groups described here.

People and Organizations Who Will Use or Share This Information:

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

This Authorization Will Not Expire. But You Can Revoke it at Any Time.

To revoke this Authorization, send a letter to Dr. Stephen Davis (University of Maryland Medical Center, 22 S. Greene Street, Room N3W42, Baltimore, MD 21201) stating your decision. He will withdraw you from the study and he will stop collecting health information about you. This researcher might not allow you to continue in this study. He can use or share health information already gathered.

Additional Information:

You can refuse to sign this form. If you do not sign it, you cannot be in this study. This will not

affect the health care you receive. It will not cause any loss of benefits to which you are otherwise entitled.

- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher or the UMSOM, to give it to them.
- The Principal Investigator will take reasonable steps to protect your health information. However, federal protection laws may not apply to people or groups outside the UMSOM or UMB.
- Except for certain special cases, you have the right to a copy of your health information created during this research study. You may have to wait until the study ends. Ask the Principal Investigator how to get a copy of this information from him.

My signature indicates that I authorize the use and sharing of my protected health information for the purposes described above. I also permit my doctors and other health care providers to share my protected health information with the Principal Investigator for the purposes described above.

Privacy Questions? Call the UMSOM Privacy Official ([410-706-0337](tel:410-706-0337)) with questions about your rights and protection under privacy rules. Other Questions? Call the researcher named on this form with any other questions.

Sign your name here

Date: [Autocompleted the date participant signs]