RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title: *My* Healthy Maryland Precision Medicine Research

Study No.: HP-00095517

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

CONCISE SUMMARY

We are asking you to take part in a 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:

- Give a sample of blood, saliva, or a cheek swab.
- Let us use information from your medical record for research.
- Be asked to fill out simple 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,
- 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.

Taking part is voluntary. If you want to learn more about this study, please keep reading.

PURPOSE OF STUDY

There is still a lot to understand about how to better treat common and rare diseases. *My* Healthy Maryland is a large study to find new and better approaches for disease prevention and treatment. We will collect health-related information from you and many other people. We will look for

patterns in the data. These patterns can help researchers make discoveries. These discoveries may lead to better ways to stop, identify, and treat common and rare diseases.

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

PROCEDURES

Sample Collection: If we can, we will use a sample stored at University of Maryland from another study you are participating in, or we will use blood that is left over from your regular medical care. If that is not doable, we will collect a sample from you in any of these ways:

- A blood draw, no more than two tablespoons.
- A saliva sample by spitting into a container.
- 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.

Medical Records: We will collect health information from your electronic health record 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 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. 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 samples and data may be shared with researchers from:

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

Each request to use your samples and data must be approved by the Institutional Review Board (IRB). The IRB is a special committee that reviews research to make sure your rights and health are protected.

Large Scientific Databases

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.

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.
- 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.
- 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.

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 TO PARTICIPATION

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, healthcare at University of Maryland, Baltimore, or other healthcare systems, will not be affected.

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

PAYMENT TO PARTICIPANTS
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.

CONFIDENTIALITY AND ACCESS TO RECORDS
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.

We will do our best to make sure your personal information can only be seen by those who really need it. 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,
- or other funding groups.

Everyone who uses this information will be careful to keep it confidential.

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. There are no negative consequences if you decide to leave the study. It will not affect your current or future healthcare. If you leave the study we will destroy any samples we have left. We will stop collecting information from your medical record. We will keep the data we already have from you and your samples, 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.

No matter what choice you make about this study, if you are an employee or student at UMB, your employment or academic status will remain the same.

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

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

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	Investigator or Designee Obtaining Consent Signature
Date:_____	Date:_____

Health Insurance Portability and Accountability Act (HIPAA)

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

Name of Study Participant:_____

_____

Date of Birth: _____ Medical Record Number: _____

Name of this Research Study:	*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 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

- Authorized researchers approved by the University of Maryland IRB
- 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 Office of Human Research Protections

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. 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 care you receive at FPI and UMMS. 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, the UMSOM, FPI, or UMMS 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, UMB, FPI, or UMMS.
- 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.

Name (printed): _____ Date of Birth: _____

Signature: _____ Date: _____

Privacy Questions? Call the UMSOM Privacy Official (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.