

**RESEARCH INFORMED CONSENT / HIPAA AUTHORIZATION FORM****IRB# 2006-0258****TITLE OF STUDY:** Geisinger MyCode® Community Health Initiative**PRINCIPAL INVESTIGATORS:** AH Buchanan, MS, MPH, CGC and CL Martin, PhD, FACMG, DABMGG**QUESTIONS OR PROBLEMS:** 1-855-636-0019 (toll-free)**24-HOUR HOSPITAL SWITCHBOARD:** 570-271-6211

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**In this consent form, “You” always refers to the person taking part in the study. If you are a parent, guardian, or legally authorized representative (LAR), please remember that “You” refers to the person taking part in the research study.**

Geisinger Clinic invites you to take part in a study called the MyCode® Community Health Initiative (MyCode for short). The goal of this research is to learn more about human health and disease, to find better ways to keep people healthy, and to help them when they are sick.

By signing up for MyCode you agree to allow Geisinger to save your blood and saliva samples and use them for research. You also agree to allow scientists doing research with your samples to use information in your Geisinger records.

**Please read this form or have it read to you before you decide whether to take part in this research. Your participation in this research is voluntary. You can choose not to participate. If you choose to participate, you can change your mind and stop at any time by contacting the MyCode study team. Your decision will not affect your status as a Geisinger patient. Your usual care or access to care at Geisinger will not change if you say no. You will not lose any benefits to which you are otherwise entitled if you decide not to join the study or if you decide to stop taking part after you join.**

**If you take part in this research study, please keep this document for your records.**

**THIS FORM WILL TELL YOU:**

- Why we are doing this research
- The benefits and risks of being a part of this research
- How we will collect samples of your blood or saliva
- How we will use your samples and information for research
- How we will protect your privacy

**WHY DOES GEISINGER WANT TO KEEP MY BLOOD AND SALIVA SAMPLES?**

Information that is in your blood or saliva can provide clues about your health and diseases you have or might get. Geisinger doctors and scientists want to do research to find these clues and learn how to use them to improve health.

Some of these clues are found in your DNA (which is also known as deoxyribonucleic acid). DNA makes up your genes. Genes provide instructions for things like eye or hair color, height, and sometimes things that affect health. Everyone's DNA is slightly different. By studying the DNA of many different people and comparing it to information in their medical records, we hope to find differences in DNA that help people stay healthy or, in some cases, get sick. Your blood also contains proteins and other chemicals that can provide clues about your health, and we may also study those.

Many people are needed to provide samples to do this research. We have samples from tens of thousands of Geisinger patients, and plan to collect more. Our goal is to enroll up to 1,000,000 Geisinger patients in this study.

MyCode is a research study at Geisinger Clinic. MyCode activities (such as collecting, storing, or testing samples) may be paid for by the following sources:

- Geisinger's own funds
- Government grants
- Grants from non-profit agencies that support research and/or
- Commercial partners (such as drug companies)

**WHAT WILL HAPPEN WHEN I PARTICIPATE IN MYCODE?**

When you agree to participate in MyCode, you give us permission to:

- Collect samples of your saliva or blood (not more than 2 tablespoons at a time) and store them in a biobank, which is a safe, secure place for storing the samples.
- Use your samples for research studies that we approve. This might include research that studies your DNA (your genes).
- Use information from your Geisinger medical record for Geisinger approved research studies. This information might include diseases you have, medicines you take, and results of medical tests you get.
- Use your Geisinger health insurance records and any health insurance records that appear in your Geisinger medical records.
- Contact you in the future to get more information or tell you about other research studies.
- Tell you about results we get from studying your samples that might help you.
  - About 3-5% of participants are expected to receive results. As additional types of results are added, more participants could receive results.

### **HOW WILL YOU COLLECT MY MYCODE SAMPLES?**

There are several ways we might collect your samples:

- A phlebotomist will collect a MyCode blood sample when you have blood drawn because your doctor ordered tests
- You can volunteer to provide MyCode blood samples when you aren't already having blood drawn for tests your doctor has ordered
- MyCode can access leftover blood samples that are not of any clinical use from other lab tests
- You might be asked to provide a saliva (spit) sample using a kit we will provide

### **WILL GEISINGER SHARE MY SAMPLES AND MY INFORMATION?**

Your samples, and the information that we get from studying your samples, or your medical record may be shared with other researchers. These researchers may work for:

- Geisinger

- Universities, medical schools, or other research facilities
- Government agencies like the National Institutes of Health (NIH)
- Public agencies, foundations or other groups that conduct or sponsor research or
- Companies that do medical research, like drug companies

Researchers must get permission to use your samples and information from two Geisinger committees - the Geisinger Institutional Review Board and the MyCode Governing Board.

The **Geisinger Institutional Review Board** is responsible for reviewing research that involves people. They decide if the research is done in a way that:

- Limits the possible harm to the participants
- Makes sure that the risks of participating are reasonable and
- Protects your privacy

The **MyCode Governing Board** makes sure that research that uses your samples and information will:

- Be a good use of the samples and information in the MyCode biobank and
- Help us learn more about health and disease

## **HOW WILL YOU PROTECT MY PRIVACY?**

In most cases, researchers do not need information that could identify you when they are doing research using your MyCode samples and data. Your samples and research data will be given a special code or study identification (ID) number. These ID numbers will be used to label samples and data when they are used for research, instead of information like your name or birth date that could be used to identify you.

Information that links you to your ID number will be kept in a secure file that is protected by Geisinger. Only a few people on the MyCode team will have access to this file. All of these people have been trained to protect your information. Information that can identify you will be given to Geisinger researchers only when it is necessary for the research, and with the approval of the Geisinger Institutional Review Board and the MyCode

## Governing Board.

If a non-Geisinger researcher wants information that identifies you, a member of the MyCode team will contact you to see if you want to learn more about the study the researcher is doing. If you agree to learn more about their study, the MyCode team will give the researcher your contact information. The researcher will then contact you to provide more information about their study. You have the right to decide whether:

- You want to learn more about their study
- You want to take part in their study

All researchers who use MyCode samples or information are required to protect your privacy. We will **not** tell you every time your samples and/or information are used for research studies.

Some genetic information that is uncovered by studying your DNA is unique to you (like fingerprints). When your genetic information is shared, we will make every effort to protect it. Researchers will promise not to try to identify you using any information they are given. The chance of anyone identifying you is small.

To help us protect your privacy, we have obtained a Certificate of Confidentiality (COC) from the National Institutes of Health. The COC gives us the legal right in certain situations not to share research information that may identify you. These situations include any federal, state, local, civil, criminal, administrative, or legislative order or other legal proceedings. For example, if we receive a subpoena telling us to share your research information with the court or another individual, our COC gives us the right to **not** share that information. We will use the COC to resist any demands for information that can identify you, except when information is requested in order to:

- audit or evaluate federally funded projects or
- meet the requirements of the federal Food and Drug Administration (FDA).

A Certificate of Confidentiality does not stop you or your family members from sharing information about yourself or your participation in this research. If you give your written (signed) consent for an insurer, employer, or someone else to receive your research information, then we cannot use the COC to withhold that information.

Our Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities in suspected cases of child abuse and neglect, or if you may hurt yourself or someone else.

### **WHO ELSE HAS THE RIGHT TO ACCESS MY PROTECTED HEALTH INFORMATION?**

Protected health information (PHI) is information about your health or your medical care that was collected by a healthcare provider (like Geisinger) that can be used to identify you. Geisinger will make every effort to protect your PHI, but we cannot guarantee that your information will be safe.

Geisinger is required by law to protect your health information. Some laws that protect your PHI only apply to hospitals, doctors' offices, and other healthcare providers. If your PHI is shared outside of Geisinger, some federal privacy laws may not apply.

Your PHI may be shared if it is required by law. Regulatory organizations may inspect and/or copy your research records (including information in your medical record) for quality assurance. These organizations include the U.S. Food and Drug Administration and the U.S. Department of Health and Human Services. These organizations must follow federal laws to protect your privacy when we are required to share your information. The chance that Geisinger will be required to share your PHI with these agencies is small.

Geisinger also has departments responsible for making sure researchers follow these laws and other research rules. Staff members in these departments may look at your research records to make sure we follow these rules.

## **ARE THERE BENEFITS TO BEING A PART OF MYCODE?**

The main benefit of being a part of MyCode is helping researchers learn more about human health and disease. This will lead to better ways to treat disease and keep people healthy.

There is a chance that researchers might find information that could be important to your health (and the health of your family members) when they study your MyCode samples. Based on what we know today, we will find information that will be useful for medical care in about 3-5% of MyCode participants. The chance of finding information important to your health will increase as we learn more about health and disease. As additional types of results are added, more participants could receive results.

Geisinger has a team of experts who will decide what results should be given to MyCode participants and how we should tell them. Examples of such results are increased risk of developing serious diseases like heart disease or cancer or how a person might respond to a medicine.

We will only inform you when we find information that we believe can be helpful in your medical care. At this time, we will **not** tell you about health problems for which there are no medical treatments.

Geisinger is committed to helping you understand and use the information that we might return to you as a result of your participation in MyCode.

Looking for changes in your genes related to healthcare can take a long time. The majority of participants will not hear from the MyCode team. If you do not hear from anyone on the MyCode team:

- Your sample may not have been studied yet OR
- You may not have any of the gene changes that we are studying at this time

It is important to know that participation in MyCode is not a substitute for clinical genetic testing that might be recommended based on your health or your family history. If you have questions or are concerned about potential genetic changes in your family, discuss this with your doctor.

## **WHAT HAPPENS IF A RESEARCHER FINDS INFORMATION THAT COULD BE IMPORTANT FOR MY HEALTH CARE?**

If we find information that we think you should know to help your medical care, we will:

- Tell you about the result and what it means for your health
- Tell your Geisinger healthcare provider
- Put this information in your medical record and
- Work with you to make sure that you understand what you should do about this information

Information about your increased chances for a health problem may be important for your parents, your children, your siblings, and other blood relatives. If you give us permission to contact your family, the MyCode team will work with you to make sure that your family members also benefit from this information. If your family members are not Geisinger patients, we will help them contact genetic professionals near where they live who can help them. You and your family members will:

- Get information that tells you what we found in your sample
- Get information that explains why you have a higher chance of having a health problem
- Be able to call or email licensed genetic counselors who can give you more information

We plan to continue studying MyCode samples for years to come. If we find information after your death that might be important to the health of your family, we will try to identify your personal representative (the person who is able to access your medical information after your death) and will share this information with them. We will try to identify your personal representative through the contacts in your medical record. If information is shared with your personal representative, we will encourage them to share information with your blood relatives.

The initial information and support Geisinger gives you will be free of charge. Any appointments or testing that you choose to have done because of your increased chance of a health problem will be billed to you and/or your health insurance provider.

## **ARE THERE ANY RISKS TO BEING A PART OF MYCODE?**

There are no risks involved in giving a saliva sample.

If you give a blood sample for MyCode there is a small risk of bleeding, bruising, infection at the needle site, or fainting (this is rare).

If we tell you that you have a higher chance of having a health problem because of something we find from studying your sample, there is a risk that you might be surprised or upset.

There is a chance that your MyCode samples and information may be shared or used inappropriately. Geisinger takes the protection of your privacy **very seriously** and works hard to keep your information safe. We cannot guarantee that your information will be kept private. We think the risk of your information being shared or used inappropriately is small. We also do not know every possible risk that might come up in the future.

## **CAN MY GENETIC INFORMATION BE USED AGAINST ME?**

The Genetic Information Nondiscrimination Act (GINA) is a federal law that makes it illegal for some companies to use genetic information against you.

These companies include:

- Health insurance companies
- Group health plans
- Most employers

The Genetic Information Nondiscrimination Act does not protect against discrimination by companies that sell life, disability, or long-term care insurance. At this time, the chances we would be required to share your genetic information with companies like this are small.

## **DOES BEING IN MYCODE COST ME ANYTHING?**

There is no extra cost to you or to your insurance company for being a part of MyCode.

If you are one of the people who get information from MyCode about your health, medical appointments or testing you choose to have done because of this information will be billed to you and/or your health insurance provider. For example, if we find that you have an increased chance of

getting breast cancer, your doctor may want you to have mammograms more often than most women. The cost of these mammograms may be covered by your health insurance policy, or you may have to pay for them.

### **WHAT ARE MY RIGHTS AS A PARTICIPANT?**

Being a part of this study is your choice. If you decide to participate now, but change your mind at any time later, you can then withdraw from MyCode. Your decision will have no effect on the medical care you receive from Geisinger.

If you wish to stop and no longer participate in MyCode, please write or call us using the contact information below. If you choose to call, we will send you a form to sign and return to us to complete the withdrawal process.

Phone: 1-855-636-0019

Address: MyCode (MC 44-00)

100 North Academy Avenue Danville, PA 17822-2630

If you choose to stop being a part of MyCode we will not collect any new samples or information from you. Your samples in the MyCode biobank will be destroyed. If your information has been shared with researchers, these researchers may keep using the information they have for research.

You will not own any information, medical tests, medicines, or other products that are created from research that used samples and information from MyCode. You will not get any of these products for free or get any money or other payment from the sale of any such product(s).

Call the Geisinger Institutional Review Board (IRB) at 844-542-3299 or 570-271-8663 and reference study #2006-0258

- If you have questions about your rights as a research participant.
- If you have questions, concerns or complaints about the research.

### **HOW LONG WILL MYCODE LAST?**

There is no planned end date for MyCode. Your samples and information will be kept and used for research purposes as explained in this form until they are no longer useful for research or the study ends.

You must sign this form to join MyCode.