Caring

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Elements of Informed Consent

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45 CFR part 46 section 116

§ 46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. **The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.** No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

45 CFR part 46 section 116

General Requirements

- Lay Language
  - Understandable to subject
  - Intended population

- No exculpatory language
  - No wording that waives or appears to waive the rights of the subject

- Required elements are appropriately included

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Required Elements

1. Research Purpose and Procedures
   - Statement that the study involves research
   - Purpose of the study
   - Duration of Participation
   - Description of procedures
   - Identify what is experimental
     - “What is research?”
     - “What is routine/usual care?”

Statement that the study involves research - MyCode

Geisinger Clinic invites you to take part in a project called the MyCode® Community Health Initiative (MyCode for short). 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 health record.*

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.*

Please read this whole document carefully before you decide whether or not to take part in this ***research****. 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 for* ***research***
- ☐ *How we will protect your privacy*

Purpose of the study - MyCode

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 health 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.

Duration of Participation - MyCode

HOW LONG WILL THIS STUDY LAST?

There is no planned end date for MyCode. Your samples and information will be kept until they are no longer useful for research, or the project ends.

Description of procedures - MyCode

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 studies that analyze your DNA (your genes)*

☐ *Use information from your Geisinger medical record for research studies that we approve; This information might include diseases you have, medicines you take, and results of medical tests you get*

☐ *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*

Description of procedures - MyCode

HOW WILL YOU COLLECT MY MYCODE SAMPLES?

There are several ways we might collect your samples:

- ☐ *A phlebotomist will collect a blood sample when you are having blood drawn because your doctor ordered tests*
- ☐ *You can volunteer to provide MyCode blood samples when you aren't already having blood drawn for test your doctor has ordered*
- ☐ *You might be asked to provide a saliva (spit) sample using a kit we will provide*

Description of procedures - MyCode

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, then we will:

☐ *Tell you about the research result and what it means for your health;*
Tell your 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, and/or your siblings. If you give us permission to contact your family, then 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, then 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

Description of procedures - MyCode

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 or 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.

Description of procedures - MyCode

Each time I have a blood draw, a blood sample may be collected and used for MyCode research. If we find information that we determine to be important to your health care, we may share that information with you and your doctor and place it in your electronic medical record.

A member of the Geisinger MyCode team may contact me to ask if I want to participate in future MyCode approved studies and to collect additional information.

Required Elements

2. Risks and Discomforts
   - Description of foreseeable risks and/or discomforts
     - Physical
     - Psychological
     - Social
     - Financial

Risks & Discomforts - MyCode

ARE THERE ANY RISKS TO BEING A PART OF THIS PROJECT?

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 discover from studying your sample, then 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.*

Required Elements

3. Potential Benefits
   - Reasonable expected benefits to subject
   - Reasonable expected benefits to others/ society

4. Alternate Procedures or Treatments
   - Description of any alternative treatments for condition being studied

Potential Benefits - MyCode

ARE THERE BENEFITS TO BEING A PART OF THIS PROJECT?

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 only about 2% (1 in 50) of MyCode participants. The chance of finding information important to your health will increase as we learn more about health and disease.

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

Potential Benefits - MyCode

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 (like Alzheimer's disease or Huntington's disease).*

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.

Research that uses your samples and information may not be finished quickly. There is a chance that you will not hear from any researchers. 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*

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Required Elements

5. Confidentiality of records identifying the subject

- *Includes information required by federal regulations regarding patient privacy rights (“Privacy Rule”)
  - *HIPAA Authorization to Use and Disclose Information for Research Purposes*
- Extent that confidentiality will be maintained
- Meaningful description of PHI that will be used and disclosed
- Description of each purpose for use and disclosure
- Who has access to PHI
  - FDA, OHRP, Cooperative Group
  - Sponsor and/or monitors
- Information about expiration of the authorization
- Warning that once released, no longer protected by Privacy Rule

Confidentiality / HIPAA Authorization - MyCode

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.

Confidentiality / HIPAA Authorization - MyCode

If a non-Geisinger researcher wants information that identifies you, then 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, then the MyCode team will give the researcher your contact information. Then the researcher will contact you to tell you more about their study. You have the right to decide whether or not:

☐ *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 projects.*

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Confidentiality - MyCode

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) …*

Confidentiality / HIPAA Authorization - MyCode

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.

Federal and state laws are in place to protect your PHI. Geisinger has departments that are responsible for making sure researchers follow these and other laws. Staff members in these departments may look at your research records to make sure we are following these laws.

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.

Confidentiality / HIPAA Authorization - MyCode

The chance that Geisinger will be required to share your PHI with these agencies is small. If your PHI is shared outside of Geisinger, then some federal privacy laws may ***not*** *apply. Some of these laws only apply to hospitals, doctors' offices, and other healthcare providers.*

Geisinger will make every effort to protect your PHI, but we cannot absolutely guarantee that your information will be safe.

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.

Required Elements

6. Research – Related Injury or Ilness
   - Studies with greater than minimal risk
   - Description of plans for medical treatment
   - Description of plans for compensation
     - Clearly state who will pay for treatment if a subject is harmed
     - Geisinger template language
   - Where to obtain additional information

Required Elements

7. Contact Information
    - Questions about the research
    - Subjects' rights
    - Research-related injury or illness

8. Voluntary Participation
    - Statement that participation is voluntary
    - Decision to not participate
        - No penalty
        - No loss of benefits
    - May decide to withdraw at any time

Contact Information - MyCode

TITLE OF STUDY: Geisinger MyCode® Community Health Initiative

PRINCIPAL INVESTIGATORS: DJ Carey, PhD, DH Ledbetter, PhD, WA Faucett, MS, LGC

QUESTIONS OR PROBLEMS: 1-855-636-0019 (toll free)

24-HOUR HOSPITAL SWITCHBOARD: 570-271-6211

For questions about your rights as a research participant, please contact the Geisinger Institutional Review Board at 570-271-8663. When you call them, please give them the study number 2006-0258.

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Voluntary Participation - MyCode

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Being a part of this project is your choice. If you decide to participate now, but change your mind at any time later, then 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
100 North Academy Avenue

Danville, PA 17822-2630

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Voluntary Participation - MyCode

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, then 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).

Additional Elements

1. Unforeseeable Risks to subject or fetus
2. Circumstances for termination by investigator without subject’s consent
3. Any additional costs as a result of participation
4. Consequences of subject’s decision to withdraw from study and procedures for orderly termination
5. Significant new findings will be shared that may affect a subject’s willingness to participate
6. Approximate number of subjects to be enrolled

Additional Costs - MyCode

DOES BEING IN THE STUDY 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, then 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, then 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.

Approximate Number - MyCode

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 500,000 Geisinger patients in this project.

Studies with genetic component

“The Genetic Information Nondiscrimination Act of 2008 (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This protection does not include life insurance, disability insurance, or long-term care insurance.”

GINA - MyCode

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.

Consent Process

- First Impression
- Ask Permission

- Always ask if you can talk to them about the study
- How do you introduce yourself
- How do you make sure they understand the study
- What do you think are the key elements of the consent
- How do you make sure they have enough time to think about the study

Contact

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