

Consent Form: Biobank research study

Colorado Center for Personalized Medicine (CCPM), 13001 E. 17th Place, F563, Aurora CO. 80045.
Principal Investigator: Kathleen C. Barnes, Ph.D.
Biobank staff can be reached at **303-724-9944**.

Purpose of the Study

We are asking you to participate in the Biobank research study. The study is part of the Colorado Center for Personalized Medicine (CCPM) at the University of Colorado. The purpose of this study is to collect and store biological samples, conduct research on those samples, collect and store medical information, and make the samples and data available for future research. Researchers will use the data and samples to learn how differences among people, such as in their genetic information, affect health, and risk of disease.

Participation in the Biobank research study is completely up to you. If you decide not to participate, your decision will not affect your health care in any way. Your alternative is not to participate in the study.

Please read this document carefully before you decide whether to take part in the Biobank study.

If you join the Biobank, you are giving us permission to:

- Collect biological samples from you. Biological samples can include blood, other bodily fluids, and leftover tissue.
- Process the biological samples to collect information about your genetic makeup and to analyze your genetic ancestry.
- Use information from your medical record.
- Make that information and your biological samples available for future research.

The primary benefit of the study is to help future research into the causes of health and the risk of disease. The primary risk is concerns from finding out something medically relevant about yourself.

What is Genetic Research?

Genetic research means we will study your genetic information. DNA contains your unique genetic information. We will get your DNA from your biological sample. DNA makes up the genes that serve as the "instruction book" for the cells in your body and determines what color skin, hair, and eyes you have, and influences health and disease. When we do genetic research, we may only look at small parts of your DNA, or we may look at all of your genetic information, known as your genome.

Who Can Take Part?

This study is open to all people aged 18 or over who can consent for themselves.

Study Procedures

Biological sample collection

We will collect biological samples from you to store in the Biobank. There are a number of possible ways we may collect samples from you. We may collect samples in any of the following ways:

- At a future visit when you are already having blood drawn for your clinical care, an extra 1-2 tubes (1-2 tablespoons) of blood will be taken from you for the Biobank. You will not need to have an extra needle stick.
- A research blood sample from you just for this research program, even if your doctor or other healthcare professional has not ordered a clinical blood test. In this case, we will get blood by putting a needle into one of your veins and let the blood flow into a tube.
- Leftover biological samples from any of your clinical tests or procedures ordered by your doctor or other healthcare professional.

Health Information

Researchers will periodically collect information from your medical records. This information could include

- What illnesses and treatments you have had and how well the treatments have worked,
- Results from x-rays or laboratory tests,

- Billing information, and,
- Information in your records from sources outside of our hospitals.

Research

A portion of your biological sample will be analyzed to collect some genetic information. Your health information will be linked to your biological sample and your genetic information. All of this information will be stored so that it is available for future research. Types of research that may be done include looking for medically important differences in people and finding information on genetic ancestry. We may also do additional analysis of your biological specimen, such as examining your body's cellular processes.

Researchers who are not part of the Biobank will have to ask for permission from the Biobank to study any of the biological samples or any of the medical or genetic information we collect from you. Some researchers may work at other hospitals, universities, government institutions, or at drug- or health-related companies. Researchers who are not part of the Biobank will not have access to information that can directly identify you, such as your name, address, or medical record number. The Biobank will ask for any research findings to be given to us so that if possible, they can be available for additional research.

We may share the data generated from future research with other researchers or databases, such as those sponsored by the National Institutes of Health (NIH). One such database is called dbGaP, which collects data from genetic research. By broadly sharing results in databases like dbGaP, we hope to help additional researchers to conduct more research on more health conditions. Information which directly identifies you will not be sent to these databases.

Re-contact

We may contact you again for a number of reasons including to:

- Ask for your signed permission to talk with you about something we have learned about your sample that might be medically relevant. If you give this additional permission, and we discover information that is of significant medical importance, we will share this information with you. We cannot guarantee that we will find such information to give to you;
- Ask for your signed permission to share individual research results with you, such as information about your genetic ancestry;
- Ask for more samples or information;
- Update you about the Biobank research study; or
- Invite you to take part in other research studies.

Potential Benefits

Most likely, there will be no direct benefit to you for participating in the Biobank clinical research study. We hope that the information and samples in the Biobank will help researchers learn more about how differences in individuals contribute to health and disease. We hope that the researchers will find better ways to predict, prevent, diagnose, or treat disease in the future.

Potential Risks and Discomforts

Privacy and confidentiality

Through all stages of sample and data collection, storage, sharing, and analysis, your privacy and confidentiality will be protected. All information and samples used by this study will be protected using secure computers and systems, and locked files, so that only authorized people can access it. There is a very small risk in any effort like this of a breach in security systems. Because some information such as your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small.

To help us protect your privacy, we have obtained a legal document called a Certificate of Confidentiality. The Certificate of Confidentiality helps us to protect your information from most subpoenas or other legal demands. These protections apply only to your research records. The protections do not apply to your medical/health records at any participating hospital. With your permission, your samples, data and health information can still be shared for purposes you agree to, such as with other researchers for research purposes.

Blood Collection

If you give a blood sample for the Biobank there is a small risk of pain, bleeding, bruising, or infection at the needle site, or in rare cases, fainting. Should you have any discomfort during the blood sample collection, please inform the staff member performing the procedure.

Genetic information

Federal and State laws provide some protections against discrimination based on genetic information. For example, the Genetic Information Non-discrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not prevent companies that sell life insurance, disability insurance, or long-term care insurance from using genetic information as a reason to deny coverage or set premiums.

Unknown risks

There may be unknown risks, stresses, or discomforts to you that we do not know about. There may also be unknown risks to groups of individuals like yourself.

Will I be paid to be in the study?

You will not receive payment for being part of this study and you will not have to pay anything to be in this study.

How long will my samples and health information be stored?

If you decide to be in this study, there is no limit on the length of time we will store your samples and health information. We may keep using them for research unless you decide to stop participating or we close the Biobank.

What safeguards are in place for use of research information?

Researchers will be granted access to samples, health information and coded genetic information only if they meet all ethical, scientific, and regulatory criteria for approval by the University of Colorado Denver and other overseeing agencies and institutions.

Who will see my research information?

The University of Colorado Denver and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. The institutions involved in this study that may collect, see, or use your information include: The University of Colorado Denver and University of Colorado Health. We cannot do this study without your permission to see, use, and give out your information. If you do not give us this permission, then you may not join this study.

We will see, use, and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this obligation. We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use your sample(s) and information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below.

Dr. Kathleen C. Barnes, PhD: Colorado Center for Personalized Medicine, 13001 E. 17th Place, F563, Aurora CO 80045.

If you do cancel your permission for us to use your sample(s) and information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already used for research purposes. Any of your research samples in the Biobank will be destroyed.

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as: 1) federal offices such as the Office of Human Research Protections that protect research subjects like you and 2) the Colorado Multiple Institutional Review Board (COMIRB), the Biobank study team, and officials at the University of Colorado Health hospitals.

Information about you that will be seen, collected, used, and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous, current, and future Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Biological samples and the data with the samples.

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data, tissue, blood, and other samples collected from you during this study are important to this study and to future research. If you join this study:

- The data and biological samples given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data or biological samples.
- If data, tissue, blood, or other samples are in a form that identifies you, University of Colorado Denver or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- Biological samples may be used for commercial profit in partnership with other organizations. You will not share in any financial benefit from the creation, use, or sale of such a product or idea. One example of a commercial product is a cell line.

How will you keep me informed about the Biobank study and the Colorado Center for Personalized Medicine?

As we collect more biological samples, we plan to provide information to you on the progress of the Biobank, the work of the Colorado Center for Personalized Medicine (CCPM), and our research findings through news articles, brochures, and our website **cobiobank.org**.

What if I have questions?

If you have any questions about this study, please call the Biobank at **303-724-9944** or email us at **ccpm-biobank@ucdenver.edu**.

If you have questions about your rights as a research subject or the conduct of this study, please contact the Colorado Multiple Institutional Review Board (COMIRB) at **303-724-1055**.

Agreement to be in this study and use my data

I have read this information about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use, and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study:

Name: Print your name _____

Signature: Sign your name _____

Today's Date: Print today's date _____

Patient Name (Last, First) and MR#

OR

Place Patient Sticker Here

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