Colorado Center for Personalized Medicine (CCPM)
Biobank Clinical Research Program Consent

COMIRB
APPROVED
For Use
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Principal Investigator: Casey Greene, PhD, Interim Director, Colorado Center for Personalized Medicine
Biobank staff can be reached at **303-724-9944**.

Purpose of the Biobank

We are asking you to participate in the Colorado Center for Personalized Medicine (CCPM) Biobank research program, at the University of Colorado. The purpose of the Biobank is to collect and store biological samples, conduct research and clinical testing on those samples, collect and store medical information, and make the samples and data available for reporting clinical genetic test results and future research. Researchers and clinicians will use the data and samples to learn how differences among people, such as in their genetic information, affect health, and risk of disease. When studying your samples and information, the Biobank will also perform some clinical genetic tests that could result in information that may be directly relevant to your health.

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

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

Please read this document carefully before you decide whether to take part in the CCPM Biobank Clinical Research Program.

If you participate in 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.**
- **Perform clinical genetic tests that may reveal results relevant to your health.**
- **Place clinical genetic test results in your UCHealth electronic medical record.**
- **Use information from your UCHealth electronic medical records to study relationships between genetic makeup and health and disease.**
- **Make your medical record information and your biological samples available for future research.**
- **Use your biological samples and data 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.**
- **If you do not wish to participate in the Biobank, as described above, please indicate that you do not wish to participate by declining this consent.**

What is Genetic Research?

Genetic research means we will study your DNA. We will get your DNA from your biological sample. DNA carries genetic information that is 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.

What are Clinical Genetic Tests?

Clinical Genetic tests are also known as DNA tests. These tests may:

- Predict your risk of diseases such as some cancers, heart diseases, and muscle diseases.
- Predict how you respond to medications. This may help a healthcare provider understand if you need a different medication or a different dose of a medication.
- Identify you as being a ‘carrier’ for a disease. Carriers usually remain healthy and do not develop disease but there may be a higher risk of a genetic disease in their blood relatives including their children.

Who Can Take Part?

The Biobank is for all people aged 18 or over who can consent for themselves.

Biobank Procedures

- **Biological sample collection.** We will collect biological samples from you to store in the Biobank. We may collect samples in any of the following ways:
  - At a future visit when you are having blood drawn for your clinical care, an extra 1-3 tubes (1-3 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. We will get blood by putting a needle into one of your veins and letting 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.
  - At a UCHealth Clinical event where you can provide a saliva sample. We will collect the saliva by having you fill a collection tube.
- **Health Information.** The Biobank will periodically collect information from your UCHealth electronic 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.** Your biological sample will be analyzed to collect genetic information. Your health information will be linked to your biological sample and your genetic information. All 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 looking at how the cells in your body work. Sometimes, information that can identify you may be used for specific research studies but it will only happen with the appropriate Colorado Multiple Institutional Review Board (COMIRB) and institutional approvals.

  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 the medical record or genetic information we collect from you. Some researchers may work at other hospitals, universities, government institutions, or at drug- or health-related companies. We may also collaborate with commercial companies (such as drug companies) to conduct additional research on your biological samples and medical record information. These companies may keep the results and accompanying medical record information to use for their own commercial purposes. For example, companies in collaboration with the university, or separately, may use your information to develop treatments and diagnostic tests for review and approval by the U.S. Food and Drug Administration (FDA). The Biobank will ask for any research findings generated by external researchers to be given to the Biobank so that, if possible, they can be used in future 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 sharing genetic information in databases like dbGaP, we hope to help additional researchers to conduct more research on more health conditions. Information that directly identifies you will **not be sent** to these databases.

  We will **not notify you** if your samples and/or information are used for other research projects.
- **Re-contact.** We may contact you again for a number of reasons including, but not limited, to:
  - Telling you more information about the results of your clinical genetic testing;
  - Asking for your permission to share individual research results with you, such as information about your genetic ancestry;
  - Asking for more samples or information;
  - Updating you about the Biobank research program; or

Inviting you to take part in other research studies.

Potential Benefits

We plan to study the information and samples in the Biobank for years to come. We hope our research will find better ways to predict, prevent, diagnose, or treat disease in the future.

If we find information in your biological sample that is directly relevant to your health, we may return the result to your UCHealth electronic medical record. In some circumstances, we may contact you about your clinical genetic test results before placing them in your UCHealth electronic medical record.

Will I be tested for all possible genetic conditions, risks, and responses to medications?

No, the Biobank will only complete limited clinical testing on some selected genetic conditions, risks, and responses to medications. Over time, the number of Biobank tests may increase. The Biobank clinical genetic test results are **NOT intended to be comprehensive or a substitute for a visit to a geneticist, genetic counselor, or healthcare provider.** If you have symptoms or concerns about a genetic condition in you or your family, you should talk to a healthcare provider.

When will I receive my clinical genetic test results?

Testing your Biobank sample may not be finished quickly, and it could be months or even years before a clinical genetic test result is available. If you do NOT hear from the Biobank about test results, you may still be at risk of getting some diseases or having adverse responses to medications. You should continue to receive healthcare from your healthcare provider as you would normally do.

How will I receive my clinical genetic test results?

Clinical genetic test results about your responses to medications will be placed directly into your UCHealth electronic medical record. For test results about your risk for most other health problems, we will reach out to you to confirm that you want the result. If you agree, then the result will be placed in your UCHealth electronic medical record. We will help you to understand what the results mean for your health and what you may want to do about this information. Further information about the process for returning clinical genetic test results can be found on our website, cobiobank.org

To generate your clinical genetic test results a test order must be placed by a physician. This physician is referred to as the "ordering provider." The ordering of the test does not create a physician-patient relationship between you and the ordering provider. The ordering provider will not communicate the test results to you, or your healthcare provider(s), and **you are solely responsible for reviewing your UCHealth My Health Connection account for Biobank clinical genetic test results. Any questions regarding your Biobank clinical genetic test results should be directed to your treating physician or healthcare providers.**

If you had a specific type of bone marrow transplant prior to donating a biological specimen to the Biobank, our clinical genetic test results may not reflect your own genetic makeup. The Biobank will not return clinical genetic test results to you if we find evidence in your medical record of an allogeneic bone marrow transplant.

Will my clinical genetic test results affect my biological relatives?

Your clinical genetic test results could contain information that may be important to your parents, your children, your siblings, and/or other relatives. You may need to discuss your results with a healthcare provider to decide if you should share your clinical genetic test results with family members.

If we discover clinical genetic information after your death that might be important to the health of your family, we will try to reach one or more contacts listed in your UCHealth electronic medical record. If we are able to contact one of your family members, we will let that individual know that we have information that may be medically important to your family.

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 the Biobank 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..
- **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.** A federal law, called the Genetic Information Non-discrimination Act (GINA), states that individuals cannot be discriminated against by most employers or health insurance companies based on their genetic information. However, GINA and associated Colorado state laws **DO NOT protect against discrimination by**

companies that sell life, disability or long-term care insurance. These laws may change over time and therefore the protections may change. Additionally, military personnel are not protected under GINA as the Dept. of Defense has their own policies protecting genetic information. You can learn more about GINA through this link: https://www.genome.gov/10002328/genetic-discrimination-fact-sheet/

- **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 have to pay to be in the Biobank?

You will not receive payment for being part of the Biobank. The initial information and support Biobank gives you will be free of charge as part of the research program. Any appointments or testing that you choose to have done because of the information we share with you will be billed to you and/or your health insurance provider.

How long will my samples and health information be stored?

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

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 the Biobank that may collect, see, or use your information include The University of Colorado Denver and University of Colorado Health and its affiliates. We cannot perform this research without your permission to see, use, and give out your information. If you do not give us this permission, then you may not participate in the Biobank.

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 does not expire. You can cancel your permission for us to use your sample(s) and information at any time by writing to the Biobank's Principal Investigator (PI), at the name and address listed below:

Casey Greene, PhD,: Colorado Center for Personalized Medicine 13001
E. 17th Place, F563, Aurora CO 80045.

If you cancel your permission for us to use your sample(s) and information, your part in the Biobank program will end and no further information about you will be collected. Your cancellation would not affect information already used for research purposes. Any clinical genetic test results already placed in your UCHealth electronic medical record would NOT be removed. Any of your research samples in the Biobank will be destroyed.

The research records (including information in your medical record) that identify you and the consent form signed by you may be looked at and/or copied 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, the U.S. Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services, 2) Partners of the Biobank, including authorized researchers and commercial companies, and 3) the Colorado Multiple Institutional Review Board (COMIRB), the Biobank program 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 program, 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.

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

- The data and biological samples given by you to the investigators for this research no longer belong to you.
- Both the researchers 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 the Biobank 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 program 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 used for research.

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, 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 the program, please contact the Colorado Multiple Institutional Review Board (COMIRB) at **303-724-1055.**

Acknowledgements and Agreements

By your signature below, you acknowledge and agree to the following:

- **I have read this entire Consent Form, or it was read to me.**
- **I have asked the Biobank research staff any questions I may have about the Biobank.**
- **I agree to participate in the Biobank clinical research program that is using my biological samples and health information to make new scientific discoveries.**
- **I understand that I may not benefit personally from my participation in the Biobank.**
- **I understand that if the Biobank finds clinical genetic test results about responses to medications that would be helpful to me and my doctors, these results will automatically be placed in my UCHealth electronic medical record.**
- **I understand that clinical genetic test results that could predict my risk for disease may be placed in my UCHealth electronic medical record. For some clinical genetic test results for particularly severe conditions, the Biobank may attempt to contact me to confirm I want to receive these results. These results will be placed in my UCHealth electronic medical record only if I agree to receive the results**.
- **I understand that, it may be many years before my biological sample is tested and, if available, clinical genetic test results are placed in my UCHealth electronic medical record. I understand that it is also possible that my biological sample may never be tested and results will never be placed in my UCHealth electronic medical record.**
- **I understand the possible risks and benefits of the Biobank clinical research program. I understand and authorize the access, use, and disclosure of my information as stated in this form. I understand that participation in this study is voluntary.**
- **I understand that my biological samples and data may be used for commercial profit in partnership with other organizations. I understand that I will not share in any financial benefit from the creation, use, or sale of such a product or idea.**

Name (Print your name) **VOID** ____________________

Signature (Sign your name) **VOID** ____________________

Today's Date(Print today's date) **VOID** ____________________