



Discover Together Biobank

IRB# 2017-3726

Key Information:

The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

If you are 18 years and older: This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of it for your records.

Parents/Guardians: You have the option of having your child or teen join this research study. This is a parental permission form. It explains this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. If you sign this form, you will receive a signed copy for your records.

COMBINED Parental Permission/Assent: If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say “you” in this form, we mean you or your child; “we” means the study doctor and other staff.

Reason for the Study:

The main reason for this research study is to build a biobank at Cincinnati Children’s, called the Discover Together Biobank (DT Biobank). A biobank is a collection of samples, such as blood, saliva (spit), and medical information that is stored and then used for future research. Your sample also has genetic information, or genes, that are made from DNA which is like an instruction book for how your body is formed and works.

This future research could be done by researchers here at Cincinnati Children’s, as well as researchers from other research centers. Researchers who use the biobank may look at single genes, multiple genes, the exome (the most active part of our genes), or the genome (all the information in our DNA). Because science is changing and improving quickly, we can’t predict all the tests that could be done. Researchers may also do tests on your samples that don’t involve DNA. There may also be a chance that your sample is not sequenced or looked at by researchers.

We hope to better prevent, identify, and treat diseases by building a biobank of samples, collecting data from those samples, and linking that data to medical records and survey information. This

Investigator:

Mike Pauciolo, MBA

Contact Info:

(513) 803-7107

DiscoverTogetherBiobank@cchmc.org

Funding:

*Cincinnati Children’s
Research Foundation*



includes learning more about how genes play a role in certain diseases or conditions, like reactions to medications and health or why some people stay healthy while others get sick.

Procedures:

You will be asked to provide a sample such as blood or spit and allow the Discover Together Biobank (DT Biobank) access to:

- Your Cincinnati Children's medical record
- Any stored samples, and information about such samples, from other research studies
- Any data from genetic testing you may have undergone in the past

This information will be a part of Discover Together Biobank forever. However, you are free to withdraw your consent at any time.

More detailed information about the study procedures can be found under *"(Detailed Procedures)"*

Risks to Participate:

All potential risks to participating in Discover Together Biobank are common. Please refer to the bulleted list below for more information. We do not know all of the side effects that may occur.

- **Blood Draw:** You may feel some pain if your blood is drawn. Numbing medicine may be given. There is a small chance the needle will cause bleeding, a bruise, or an infection.
- **Confidentiality:** There is a risk that someone could gain access to the information we have stored about you or your child. Even without your name or other identifiers, there is also a very small risk that someone could trace the information in a database back to you using your genetic information. There are laws against the misuse of a person's health and genetic information, but they may not give full protection. We believe the chance these things will happen is very small, but we cannot make guarantees.

To help to lessen these risks, we have obtained a Certificate of Confidentiality (CC) from the US government. It protects your ability to remain confidential in a research project by giving us the right not to identify you, even under a court order or subpoena. Still, the Discover Together Biobank may report medical information (if you need medical help), probable harm to yourself or others, or probable child abuse or neglect, and the government may see your information if it audits us. The CC does not prevent you or a member of your family from voluntarily releasing information about your involvement in research. If an insurer, employer, or other person obtains your written consent to receive research information, then the Discover Together Biobank may not use the Certificate to withhold that information.

- **Unknown risks:** There may be other risks that we do not know about yet.

Benefits to Participate:

Your decision to participate in this biobank may help others in the future, but it may not help you now. We hope that we will learn more about how information from our samples or genes play a role in



certain diseases, reactions to medications, and health. This may later improve care and treatment options, as well as play a role in the prevention of certain health problems, which may help the community later.

Other Options:

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive. Your alternative to participating in this research study is to not participate.

Payment:

You will not receive payment for taking part in this study. Your information and samples (both identifiable and de-identified) may be used to create products, including some that could be patented/licensed and sold. If this happens, there are no plans to tell you, pay you, or to give any compensation to you or your family.

Additional Study Information:

The following is more detailed information about this study in addition to the Key Information.

If I have Questions or would like to know about:

| Who to talk to... | You can call ... | At ... |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| <ul style="list-style-type: none"> • Emergencies • General study questions • Research-related injuries • Any research concerns or complaints | <p>PI: Mike Pauciulo, MBA</p> | <p>Phone: (513) 803-3842</p> |
| <ul style="list-style-type: none"> • Emergencies • General study questions • Research-related injuries • Any research concerns or complaints | <p>Discover Together Biobank Coordinator</p> | <p>Phone: (513) 803-7107</p> |
| <ul style="list-style-type: none"> • Your child’s rights as a research participant | <p>Institutional Review Board This is a group of scientists and community members who make sure research meets legal and ethical standards.</p> | <p>Phone: (513) 636-8039</p> |

Detailed Procedures:

The research team will answer any questions that you have about participating in this research project. Here are some more details on what will happen if you decide to participate in the research biobank:



- **Consent process:** You will be asked to review this consent form and will be given a chance to ask any questions. If you decide to participate, you will be asked to sign this consent form and will be given a copy for your records. A copy of the consent form will also be saved in your medical record.
- **Sample collection:** We may collect a sample from you for the biobank. If you are having blood drawn for another reason, we will just collect an extra tube (around a teaspoon). You may also have the option of providing saliva (spit) or buccal (cheek swab) sample instead of blood. Also, if you have given a sample for a research biobank at Cincinnati Children's in the past, we may not need a new sample. We may also collect and store leftover tissue and body fluids that were collected for clinical purposes.
- **Sample/data processing:** We will process and use your samples and sample byproducts for scientific studies, such as whole exome and whole genome sequencing. Sometimes sequencing may take place in the lab at Cincinnati Children's or your sample may be coded and sent to an outside lab or company for sequencing. We don't know upfront exactly what testing will be done on your samples or when testing will be done. Because the way we process raw research genomic/genetic data is changing all the time and the research setting is different from the clinical setting, researchers could find different results than those found clinically. You should not expect to hear about research results, but if you do, the results would need to be confirmed by a clinical lab. There is also a chance that your samples or data may not be looked at by researchers. You may be contacted by our study team to see if you are interested in other research projects or in collecting more information or samples.
- **Surveys:** We may ask you to fill out some surveys. These surveys may ask questions about family and medical history as well as contact information, such as the best way to reach you.
- **Electronic Medical Record Review:** If you have one, we will look at your Cincinnati Children's electronic medical record and link that information to results from testing done on your samples, such as genetic testing.

Change of Mind/Study Withdraw:

You can leave the research at any time; it will not be held against you. Importantly, if your samples or data have already been given to researchers for their approved research, we won't be able to get those samples or information back, even if you decide to end your participation.

If you choose to end your participation you will be provided with two options for withdraw from the biobank:

- **Option 1:** You may choose to allow the biobank to keep your sample and information from your medical record, but no new information may be collected. We will remove all identifiers like birthdate and address before any future research use.
- **Option 2:** You may choose to have all collected samples and information destroyed.



Privacy:

Efforts will be made to limit the use and disclosure of your personal information, including research studies and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Samples and/or data collected for or generated from this study could be shared and used for future research. Samples and/or data may be shared with other collaborators at Cincinnati Children's and possibly with outside collaborators, who may be at another institution or for-profit company. Collaborators from another research center or for-profit company MUST have a Cincinnati Children's physician or researcher involved in the study in order to access your samples and information from the DT Biobank.

We will never give sensitive information like your name or social security number to any researchers outside of Cincinnati Children's. We will not sell samples or information to these researchers.

All future researchers will be given the least amount of information needed to meet the goals of their research project. Researchers that use biobank samples and information must agree to never try to identify a participant from a coded research dataset. Researchers will only be allowed to use the provided samples and information for approved research purposes. Any researchers planning to do research with information that may identify you will need to have extra review and approval by the Cincinnati Children's Institutional Review Board (IRB). An IRB is a group of scientists and non-scientists who look at research studies like these and makes sure research participants' rights and welfare are protected.

Information/samples collected during this research may be de-identified, stored for use in future research, or distributed to another investigator without your additional informed consent.

It is important to know that steps will be taken to protect your identity. Your information will be stored electronically, and we will use encryption (coding) and other security methods to make sure that the information is protected.

Information from future research on your samples and data may be published; however, you will not be identified in such publication. The publication will not contain information about you that would enable someone to figure out your identity as a research participant without your permission. Also, it is possible that information collected for this biobank or from your samples will be put in a public database, available to anyone on the internet. If this happens, the database will not contain information that would enable someone to identify you.

Return of Results:

Most tests done on samples or images obtained in research studies are only for research and have no clear meaning for healthcare.

You may be contacted by the DT Biobank study team if the research with your information or samples gives results that do have meaning for your health, we will contact you and ask if you would like to know what our researchers found. You can say No to hearing about the results at that time if you



desire. Saying “no” will not impact your overall participation in this biobank or your ongoing care at Cincinnati Children’s.

If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

Genetic Testing Details:

Although no specific genetic testing is being done as part of this biobank project, future research could involve different genetic/genomic tests. There is a possibility that we may need to tell you about one or more of these tests results.

For some people, hearing about genetic test results can cause discomfort, frustration, anxiety, depression, anger, or fear. If you would like to discuss any questions or concerns about the possibility of learning genetic test results, we can arrange for you to talk with a Genetic Counselor (GC), a healthcare professional who specializes in medical genetics and can assess risk of an inherited condition.

Please note if you speak with a genetic counselor about a clinically found result or with a genetic counselor who is not a member of the study team, you may have to pay for those additional services yourself.

Some other things to keep in mind about genetic testing:

- If you have a genetic disorder, testing could confirm that your condition is hereditary, raising questions about risks to other family members, or for family planning. This may impact relatives who learn that they may be at risk for a disorder.
- Unexpected results, unrelated to the primary reason for the genetic test may be found.
- Information about parentage may be found, including unknown adoption and paternity (fatherhood). Information about parentage will not normally be shared with you. However, it is possible that this may happen as part of returning other results or if required by law. Information about parentage will not be shared with any family members.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your “protected health information” (called PHI for short).

What protected health information will be used and shared during this study?

Cincinnati Children’s Hospital Medical Center (Cincinnati Children’s) will need to use and share your PHI as part of this study. This PHI will come from:

- Your Cincinnati Children’s medical records
- Your research records



The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).
- Clinical or research genetic/genomic test results and/or other related information
- Survey response and/or other information that you may provide to the biobank
- Sample information such as the type and amount of your sample
- Processed and raw data generated from your samples in this biobank
- In some cases, a portion of your sample (e.g. blood, saliva, etc.) or byproduct of your sample (e.g. plasma, DNA, etc.) from the biobank.

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites (including Cincinnati Children's)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Your permission will never expire.

Will your child's other medical care be impacted?



By signing this document, you/your child agree to participate in this research study and give permission to Cincinnati Children's to use and share you/your child's PHI for the purpose of this research study. If you refuse to sign this document you/your child will not be able to participate in the study. However, you/your child's rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

While you/your child are participating in this research study you may not be able to access some of your/your child's health information that is related to the study. Any request for this information can be fulfilled once the study is completed.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you/your child should participate in this research, you will document your permission by signature below.

You will receive a copy of this signed document for your records.

Printed Name of Research Participant

Signature of Research Participant
Indicating Consent or Assent

Date

Signature of Parent or Legally Authorized
Representative*

Date

* If signed by a legally authorized representative, a description of such representative's authority must be provided

Signature of Individual Obtaining Consent

Date