STUDY TITLE: DISCOVER TOGETHER BIOBANK

STUDY NUMBER: IRB# 2017-3726

FUNDING ORGANIZATION: Cincinnati Children's Hospital Medical Center

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KEY INFORMATION ABOUT THIS RESEARCH PROJECT

What is the purpose?
We are asking for your permission to participate in a research project lead by Cincinnati Children's Hospital Medical Center (CCHMC). The main purpose of this project is to build a biobank at Cincinnati Children's, called the Discover Together Biobank. A biobank is a collection of samples, such as blood, saliva (spit), and DNA, and information that is stored and then used for future research. This future research could be done by researchers here at Cincinnati Children's, as well as researchers from other research centers. By building a biobank of samples, collecting data from those samples, and linking that data to medical records and survey information, we hope to better prevent, identify, and treat disease. This includes learning more about how genes play a role in certain diseases or conditions, like reactions to medications and health.

Your sample has genetic information, or genes, that are made from DNA. DNA is like an instruction book for how your body is formed and works.

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.

Who will we ask and why would you want to participate?
We are asking many groups of people to participate in this biobank. This includes patients being seen in different clinics at the hospital, people from the communities around Cincinnati Children's and people participating in other research studies at Cincinnati Children's.

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 other children and teens later.

What will happen if you participate?
Participation involves a small amount of effort. We are asking for your permission to do three things as part of this project:

First, we would like to collect a sample from you, such as blood or spit. If applicable, we may also collect body fluids (e.g. urine) or tissues that are left over after planned medical tests/procedures are done. If you have a procedure at a later date, this consent allows us to collect leftover tissue, blood and body fluids from that procedure. It also allows us to use leftover tissue, blood, and body fluids that may already be stored.

Second, if you are a patient at Cincinnati Children's, we would like to review your medical record from time to time to collect information that may be helpful for future research studies.

Third, if you already have a stored research sample and/or information about that sample, we would like your permission to move it to this Discover Together Biobank.

Fourth, if you have already undergone clinical or research genetic/genomic testing, we would like your permission to copy this data to the Discover Together Biobank. This data may contain information about you that is unrelated to the original reason for testing.

How long will we keep your sample and information?
Your samples and information will be stored in the biobank forever.

What else should you know up front?
Participation in this biobank includes allowing researchers at Cincinnati Children's and their collaborators, who may be at another research center or for-profit company, to use and share the following information for future research:

- Information related to your clinical or research genetic/genomic tests.
- Information from your electronic medical record (if you have one) and any other information that you may provide to the biobank, like answers to surveys.
- Information about your samples, such as the type and amount of sample.
- Information that was generated from your samples in this biobank (both the processed and raw data).
- 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.

In all cases, 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.

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.

Cincinnati Children's may also contact you in the future about your interest in other research projects or to collect more information or samples. You are free to say "No" without any impact on your overall participation in this biobank and without any impact on your ongoing care at Cincinnati Children's.

It is also possible that we may learn something new about you from one or more of the future research projects. If this happens, we may try to contact you to see if you are interested in learning this information. You are free to say "No" without any impact on your overall participation in this biobank and without any impact on your ongoing care at Cincinnati Children's.

What happens if you want to end your participation?
You are free to end your participation in this biobank at any time. If you choose to end your participation you will be provided with two options for withdrawal from the biobank.

First, 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.

Second, you may choose to have all collected samples and information destroyed.

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.

WHAT ELSE DO YOU NEED TO KNOW ABOUT THIS RESEARCH PROJECT?

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 will 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) for the biobank. 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 up front 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 than 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.

- **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.

WHAT ARE THE POTENTIAL BAD THINGS RELATED TO PARTICIPATING IN THIS RESEARCH PROJECT?

There may be some risks and discomforts of participating:

- **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.

- **Leftover Tissue:** If applicable, leftover tissue or material may be collected from a procedure that was clinically planned. The tissue or material that is collected will be tissue or material that would ordinarily be discarded (thrown away). As such, there will be no extra risk in collecting a portion of the tissue or material for research use.

- **Confidentiality:** There is a risk that someone could gain access to the information we have stored about you. 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.

  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. We believe the chance of this happening is very small, but this risk may change in the future.

  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 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.

WHAT DO WE WANT YOU TO KNOW ABOUT GENETIC RESEARCH AND RETURN OF RESULTS FROM FUTURE RESEARCH?

Although no specific genetic testing is being done as part of this biobank project, a goal of this project is to make your samples and linked health information available for future research. This future research could involve different genetic/genomic tests. There is a possibility that we may determine that we need to tell you about one or more of these tests results. For some people, hearing about genetic test results can be uncomfortable, causing frustration, anxiety, depression, anger or fear.

We can arrange for you to talk with a genetic counselor if you would like to discuss any concerns about the possibility of learning genetic test results. If a genetic result is found from a future research project that we want to tell you about, we will also ensure that appropriate genetic counseling is made available to answer your questions. 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, a counseling fee may be billed to your insurance.

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.

WILL YOU BE PAID TO BE IN THIS RESEARCH STUDY?

You will not be paid to participate in the biobank.

Tissues or body fluids collected for this research or future research may result in the development of a product that could be patented/licensed and sold. You will not be paid if this happens.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions, concerns, or complaints about this research study, you can contact the Principal Investigator listed on page 1 of this document.

If you would like to talk to someone who is not part of the research staff, or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the Cincinnati Children's Institutional Review Board at 513-636-8039.

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?
CCHMC will need to use and share your PHI as part of this study. This PHI will come from:
- Your CCHMC 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).

Who will share, receive and/or use your protected health information in this study?
- Staff at all the research study sites (including CCHMC)
- 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 CCHMC 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 expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your other medical care be impacted?
By signing this document you are agree to participate in this research study and give permission to CCHMC to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

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 should participate in this research you will document your consent 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 Date

_____ _____
Signature of 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