Traditional Consent for Biobanking - English

This “traditional” form was constructed for research purposes to contain the same information as our simplified form, but with a level of detail and complexity similar to that found in actual consent forms used by major US biobanks. For details, please see:

- Beskow LM, Lin L, Dombeck CB, Gao E, Weinfurt KP. Improving biobank consent comprehension: a national randomized survey to assess the effect of a simplified form and review/retest intervention. *Genet Med*. 2017 May;19(5):505-512. doi: 10.1038/gim.2016.157.

****As with any consent template materials, be sure to customize to your needs before using!****

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Consent to Participate in the Duke Biobank

Medical researchers are trying to learn more about cancer, heart disease, diabetes, and other health problems. Much of this research is done using human tissue samples (such as blood) and health information. Researchers often study blood and information from people who have health problems and from people who do not. Through such studies, they hope to find new ways to detect, treat, and maybe even prevent or cure health problems. Some of these studies may be about how genes affect health, or how genes affect response to treatment. (Genes, which are made up of DNA, have all the information needed to build and operate a human body.) Some of the studies may lead to new products, such as drugs or tests for diseases.

A “biobank” is a collection of stored samples and information. This collection is called the Duke Biobank (or just “the Biobank” in the rest of this form). The director of the Biobank is Dr. Erica Lee.

You are being asked to contribute a blood sample and health information to the Duke Biobank. This is because you have been a patient of the Duke University Health System.

Research projects like the Duke Biobank include only those people who choose to participate. The purpose of this consent form is to give you information to help you decide if you want to participate. Please read it carefully and take your time making your decision. As the Biobank staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research project. The nature of the project, risks, inconveniences, discomforts, and other important information about the project are listed below.

Everyone who takes part in research should know that:

- Research is intended to gain new knowledge. You may or may not benefit from participating. Participating may also involve some risks.
- Participating in research is completely voluntary. You can choose not to participate. If you choose to participate, you can discontinue at any time.
- No matter what you decide, now or in the future, it will not affect your medical care.

WHY IS THIS PROJECT BEING DONE?

The purpose of the Biobank is to collect and store human tissue samples (such as blood) and health information. The stored materials will then be used by researchers in future studies.

The goal is to have at least 20,000 people enroll in the Biobank.

WHAT IS INVOLVED IN THIS PROJECT?

If you agree to participate, you will be asked to sign this consent form. You will be given a signed copy of the consent form to keep. Here is what will happen next:

1. <u>We will get a blood sample from you</u>. We will draw 50 ml (about 3 tablespoons) of blood from a vein in your arm by needle stick.

   From this sample, the Biobank will be able to get things like plasma, serum, blood cells, DNA, and RNA. ‘DNA’ is short for deoxyribonucleic acid. DNA stores information in the form of a code. This is the code that you inherit from your parents and that you pass on to your children. Parts of DNA that have complete messages are known as ‘genes.’ Genes give the instructions for building the proteins that make our bodies work.

2. We will ask for some information about you and your health.

    - First, we will ask you to fill out a Biobank Questionnaire. This questionnaire asks for some basic information, such as your name, age, racial and ethnic groups, and family health history. We will contact you no more than once a year to update this information. This will happen for as long as your information is stored in the Biobank.
    - Second, we will collect some information from your medical records at Duke. Examples include information about lab results, medical procedures, images (such as X-rays), and medications. This is because future researchers need to know if you have any health problems. They may also need to know about any treatments you have had and how well the treatments worked. We will look at your medical record from time to time to update this information. This will happen for as long as your information is stored in the Biobank.
    - Third, we will collect research data from any future studies done using your sample and information.

3. We will store your sample and information in the Biobank. Your blood and information will be kept in the Biobank along with those from all the other people who participate. They will be stored indefinitely. We will keep using them for research as long as they are useful, unless you decide to stop participating or we close the Biobank.

4. We will let researchers use the materials stored in the Biobank for approved studies. Researchers can apply to study the samples and information stored in the Biobank. This includes researchers from Duke University, as well as from other universities, the government, and drug- or health-related companies. Some researchers will be from the U.S., some may be from other countries around the world.

    Each application will be reviewed by a science committee at the Biobank. An ethics review will also be done. This kind of review is to make sure that risks are minimized and that the rights and welfare of people who participate in research are protected.

    If a study is approved, a part of your blood and some information about your health might be distributed to the researchers, along with samples and information from many other people. We will not give researchers your name or any other information that could directly identify you without your permission.

5. We may contact you in the future with offers to participate in additional research. You will not be notified every time your sample and information are used in a study. However, some researchers might apply to do a study for which they would need to contact you. For example, they might want to ask you to give another sample or to fill out a survey. Or they might ask you to do a phone interview or come in to be seen by a researcher or doctor.

    If a study like this is approved, the Biobank will contact you first. We will tell you about the study so you can decide whether it is okay for us to give the researcher your name. If you give permission, the researcher will then contact you to tell you more about the study. There will be a new consent process just for that study. You can decide then whether to participate or not.

    We will make sure researchers do not contact you about more than two studies like this per year.

6. Some of your genetic and health information may be placed in scientific databases outside the Biobank. In order to do more powerful research, it is often helpful for researchers to share data they get from studying tissue and health information. They do this by putting it

into one or more scientific databases, where it is stored along with data from other studies. Researchers can then study the combined information to learn even more about human health and disease.

If you agree to participate in the Biobank, some of your genetic and health information might be placed into one or more scientific databases. There are many different kinds of databases where your information may go. Some are maintained by academic institutions, some by the federal government, and some by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called “dbGaP.”

Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. Nobody will know just from looking at a database that the information belongs to you.

However, because your genetic information is unique to you, there is a chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future if people come up with new ways of tracing information. Researchers will always have a duty to protect your privacy and to keep your information confidential.

WHAT ARE THE POSSIBLE RISKS OF THIS PROJECT?

<u>Physical Risks</u>. Like any other time you have blood drawn, you may feel brief pain or have some bruising from the needle. Infection, excess bleeding, clotting or fainting is also possible, but unlikely.

<u>Privacy Risks</u>. There is a risk that someone could get access to the data we have stored about you. If those data suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. There are laws against this kind of misuse, but they may not give full protection. There may be other unforeseen privacy risks.

We believe the chance these things will happen is very small, but we cannot make guarantees.

WILL MY INFORMATION BE KEPT PRIVATE?

Federal privacy rules give safeguards for privacy, security, and authorized access. We will not give information that identifies you (name, social security number, address, telephone number, or any other direct personal identifier) to anyone without your permission, except if required by law.

Your privacy and the confidentiality of your data are very important to us and we will make every effort to protect them. Here are some of the steps we will take:

- We will remove your name and any other information that could directly identify you from your sample and information. We will replace this information with a code number. There will be a master list linking the code numbers to names, but it will be kept separate from the samples and information.
- Samples will be kept in locked freezers in locked buildings. Health information and research data will be kept on secure computers with very limited access. These computers have many levels of password protection. All Biobank staff sign a pledge to keep your identity a secret.
- Research records are separate from medical records. No information that we get or create as part of this project will be placed in your medical record.

- Researchers who study your sample and information will not know who you are. They will be given only a code number and not any information that directly identifies you. The researchers must sign an agreement that they will not try to find out who you are. They must also promise to keep the coded materials secure.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the Duke University Health System and the Duke University Health System Institutional Review Board. A reviewer who looks at your research record may also need to look at your entire medical record. Your information may also be disclosed to outside reviewers for monitoring purposes. If this happens, it may not be covered by federal patient privacy rules (called 'HIPAA'), but it will be protected by other federal privacy rules.

Genetic Information Nondiscrimination Act. There is a Federal law, called the Genetic Information Nondiscrimination Act (GINA), that makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law will protect you in the following ways:

- Health insurance companies and group health plans may not request genetic information from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Certificate of Confidentiality. To further protect you, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the Biobank cannot be forced to disclose information that may identify you, even by subpoena. A "subpoena" is a command to give information to a judge or court. The Biobank will use the Certificate to resist any demands for information that would identify you, except as explained below.

- The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).
- In addition, we will disclose information about you without your consent if the information is something that the law says we must report to state health officials or the state attorney's office. For example, we have to report sexually transmitted diseases, domestic violence, child abuse, elder abuse, and threats to harm yourself or others.

You should understand that a Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in the Biobank.

ARE THERE ANY BENEFITS?

You should not expect to get direct health benefits if you decide to participate in the Biobank. The main reason you may want to participate is to help researchers make discoveries that might benefit people in the future.

ARE THERE ANY COSTS OR COMPENSATION?

There are no costs to you or your insurance for participating in the Biobank. We will give you a $25 gift card to pay you for the time it took for you to join the Biobank.

Your sample and information will be used only for research. You should know that research sometimes leads to discoveries that may one day have commercial value. For example, research could lead to new tests, drugs, or other medical products. By agreeing to participate in this project, you authorize the Biobank to make your samples and information available for these uses.

In the event that research using samples and information stored in the Biobank leads to a product that could be sold commercially, there are no plans to compensate you. Development of new products usually relies on the study of samples and information from hundreds or thousands of people, not on any one person. Researchers, Duke University, and/or others may own these products and profit from their sale.

The Duke University Health System and/or the developers will assert all rights of ownership in the samples and information, as well as all rights arising from use of the samples and information.

WILL I FIND OUT THE RESULTS OF THE RESEARCH?

You should not expect to get individual results from research done using your samples and information. Researchers must study materials from many people over many years before they can know if the results have meaning. The results will not affect your care right now. They will not be given to your doctor and will not be put in your medical record.

There is a small chance that researchers could discover something that might be very important to your health or medical care right now. For example, they might find that you have a condition not previously diagnosed. Or they might find that you have a gene or other risk factor that is known to increase the chance that you or a member of your family could get a disease in the future.

We will offer to tell you a finding like this only if it is about a serious disease for which a treatment is available. We will send a letter by certified mail asking you to contact Dr. Lee, the Biobank director. Dr. Lee will arrange a time for you to meet with her or another health care provider to go over the information. Notification will be sent to the last address you provided to us. Therefore it is important that you inform us of any change in your address. Research findings will not be released over the telephone or by mail or email.

It is important to note that, even if we find something important to your health, we cannot guarantee that you will be contacted. Research is not the same as medical care. If we do not contact you about your results, do not assume that means everything is okay. Talk to your doctor if you have any questions or concerns about your health.

You can get general news about the kinds of studies being done through the Biobank at www.dukebiobank.edu and a quarterly newsletter that you will receive if you join the Biobank.

WHAT ABOUT MY RIGHT TO DECLINE PARTICIPATION?

Participating in the Biobank is completely voluntary. You can choose to participate or not participate. No matter what you decide, now or in the future, it will not affect your medical care. Refusing to participate or discontinuing participation at any time will involve no penalty or loss of benefits to which you are otherwise entitled.

WHAT ABOUT MY RIGHT TO WITHDRAW FROM THIS PROJECT?

If you agree to participate in the Biobank, you have the right to discontinue participation at any time. If you decide you want to withdraw, please contact the Duke Biobank office at 919-666-3434. We will ask you to indicate in writing on an official participant withdrawal form if you want your unused blood to be destroyed or if your blood (with all identifying information removed that would link the sample to you) could continue to be used for research.

Please note that if we have already distributed some of your sample and information for researchers to study, we cannot get them back. Also, we cannot destroy knowledge already gained from the study of samples and information. But if you change your mind about participating in the Biobank, you can tell us not to give your materials out for any more studies.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You should feel free to ask any questions. Your questions should be answered clearly and to your satisfaction.

For questions or more information about this project, or if you have complaints, concerns or suggestions about the research, contact Dr. Lee at 919-555-1212 during normal business hours. You can also call the Duke Biobank office at 919-666-3434. You can leave a message at these numbers after hours, on weekends, and on holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board Office at 919-777-5656.