

## Simplified Consent for Biobanking - English

Citation: 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.

See also: Beskow LM, Friedman JY, Hardy NC, Lin L, Weinfurt KP. Developing a simplified consent form for biobanking. *PLoS One*. 2010 Oct 8;5(10):e13302. doi: 10.1371/journal.pone.0013302.

*\*\*\*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

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using human tissue samples, such as blood. Through these studies, researchers hope to find new ways to detect, treat, and maybe prevent or cure health problems. Some of these studies may be about how genes affect health, or how genes affect response to treatment. Some of them may lead to new products, such as drugs or tests for diseases.

A “biobank” is a collection of stored samples and information. We are asking you to let us store some of your blood and health information in the Duke Biobank. This is because you have been a patient of the Duke University Health System.

You can take part in this storage project or not. This consent form gives information to help you decide. Please read it carefully and take all the time you need to make your choice. Be sure to ask us as many questions as you want.

Everyone who takes part in research should know that:

- Taking part may involve some risks.
- Taking part is voluntary. If you choose to take part, you can quit 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 blood and health information so researchers can use them in future studies.

**WHAT IS INVOLVED?** If you agree to take part, we will ask you to sign this form. We will give you a signed copy to keep. Here is what will happen next:

1. We will get a blood sample from you. We will use a needle to draw about 3 tablespoons of blood from your arm.
2. We will get some information about you and your health.
  - We will ask you for some basic information, such as your name, age, race, and family health history. We will contact you no more than once a year to update this information.
  - We will get some information from your medical record. Examples include test results, medical procedures, images (such as X-rays), and medicines you take. We will use your medical record from time to time to update this information.
  - We will get research data from any studies done using your sample and information.
3. We will store your sample and information in the Biobank, along with those from all the other people who take part. There is no limit on the length of time we will keep them. We may go on using them for research unless you decide to stop taking part in the Biobank.
4. We will let researchers use the materials stored in the Biobank for approved studies. Researchers from Duke, other universities, the government, and drug- or health-related companies can apply to use the materials. A science committee at the Biobank will review each request. There will also be an ethics review.

We will not give researchers your name or other information that could directly identify you.

5. We may contact you about additional research. We will not notify you every time your sample and information are used in a study. However, the Biobank may contact you with offers to take part in other research. There will be a new consent form just for these other studies, so you can decide then to take part or not.

We will contact you about no more than two other studies per year.

6. Some of your genetic and health information may be put into scientific databases outside the Biobank, along with that from many other people. Information that could directly identify you will never be included. However, because your genetic information is unique to you, there is a chance that someone could trace it back to you. We believe the chance this will happen is very small. But the risk may grow in the future if people come up with new ways of tracing information.

**WHAT ARE THE POSSIBLE RISKS?** The most common risks of drawing blood are brief pain and bruising.

There is a risk that someone could get access to the data we have stored about you. In some cases, it could be misused. We believe the chance this will happen is very small, but we cannot make guarantees.

**WILL MY INFORMATION BE KEPT PRIVATE?** Your privacy is very important to us and we will make every effort to protect it. Here are just a few of the steps we will take:

- We will remove your name and other identifiers from your sample and information. We will replace them with a code number. There will be a master list linking the code numbers to names, but we will keep it separate from the samples and information.
- Researchers who study your sample and information will not know who you are. They must also promise that they will not try to find out who you are.
- We will not give information that identifies you to anyone, except if required by law. Information that is shared outside Duke may no longer be protected by the federal privacy law called 'HIPAA'. But it will be protected as described in this form and may be covered by other privacy laws.

There is a federal law called GINA that makes it illegal for employers and health insurers to discriminate against you based on your genetic information. GINA will not protect you from discrimination if you apply for other kinds of insurance, such as life or disability insurance.

We also got a Certificate of Confidentiality from the federal government. This will help us fight any legal demand (such as a court order) to give out information that could identify you.

**ARE THERE ANY BENEFITS?** You will not get direct benefit. The main reason you may want to take part is to help researchers make discoveries that might help people in the future.

**ARE THERE ANY COSTS OR PAYMENTS?** There are no costs to you or your insurance. We will give you a \$25 gift card to thank you for your time.

If any of the research leads to new tests, drugs, or other commercial products, you will not get any profits.

**WILL I FIND OUT THE RESULTS OF THE RESEARCH?** You should not expect to get individual results from research done using your sample. Research is not the same as medical care.

If we discover something that is very important to your health right now, we will try but cannot promise to contact you. You can get general news about the kinds of studies being done through the Biobank at [www.dukebiobank.edu](http://www.dukebiobank.edu).

**WHAT ARE MY OPTIONS?** Taking part in the Biobank is your choice. You can choose to take part or not take part.

**WHAT IF I CHANGE MY MIND?** You can leave the project at any time. Just call 919-666-3434 and let us know.

Please note that if we have already given out some of your sample and information for researchers to study, we cannot get them back. But we will send you a form so you can tell us what to do with any of your materials that are left in the Biobank.

**WHAT IF I HAVE QUESTIONS?** For questions or more information about this project, contact Dr. Erica Lee, the Biobank Director, at 919-555-1212. For questions about your rights as a research participant, contact the Duke University Health System Institutional Review Board at 919-777-5656.