

CONSENT FORM TEMPLATE

[TITLE OF PROJECT]

Background

We are asking you to take part in a research project. Please read this information and ask any questions before you decide if you want to take part.

For this project, we will collect, store, and use tissue samples and health information for research. Tissue samples are substances from the body, such as blood, or tumors that may be removed during surgery. If you agree, your samples and some of your health information will be put into a biobank.

A biobank is a collection of samples and health information. Samples from many people are stored so they can be used for research now and in the future. Researchers apply to the biobank to ask for samples for their studies. If a study is approved, the biobank will give the researcher samples and information from many people. The biobank will not give researchers any information that could directly identify you, like your name or address. The researchers will then use the samples and information to learn more about health and many different diseases.

Some researchers may use genetic analysis in some of the research they do on your samples. Researchers can learn a lot by studying genes. Genes are pieces of DNA that give instructions for building the proteins that make our bodies work. DNA stores these instructions in the form of a code. This is the code that you inherit from your parents and that you pass on to your children. One of the methods researchers might use to study your samples is called whole genome sequencing. This allows them to look at some or all of your genetic code. Researchers may also use other methods as they are developed. Studying genes along with health information will help us to better understand what causes certain diseases. It may also help us to understand how different patients respond to treatment. This knowledge could help us to develop treatments for everyone.

Purpose

The purpose of this project is to collect tissue samples and some health information from many people. We will store these samples and information in a biobank so they can be used for research now and in the future. This research will help us understand more about health and many kinds of diseases.

Procedures

The research will be conducted at the following location(s): [LOCATIONS]

We will be collecting samples and information from people at the locations listed above. However, researchers from many different places may apply to study the samples and information stored in the biobank.

Where do samples come from?

Some tissue may be removed from your body during a procedure that is needed for your clinical care, such as a blood draw, surgery, or a biopsy. Your doctor will use this tissue first to help diagnose your medical condition and/or to decide how to treat you. Your care is the first priority.

After surgery or biopsy, or after a fluid tap, and all the tests are done, there may be some tissue and body fluids left over. The tissue and body fluids could be discarded or destroyed because they are not necessary for your care; or, you may choose to let them be used for research.

In some cases, we may take extra tissue for research. This will be done during your surgery or biopsy. We will only take this extra tissue if doing so will not significantly increase the risk to you.

We may also ask to collect and store up to 75 ml (about 5 tablespoons) of your blood for research. We can use this blood to learn more about DNA and how it is related to health and disease. For example, with diseases like cancer, we can compare the DNA from someone's blood to the DNA from his or her cancer tissue. We can do this to learn more about many diseases.

Additionally, we may ask you to give us a urine sample. We may also ask for samples like saliva or mucus by having you spit or cough into a cup, or by swabbing the inside of your cheek.

We may use your sample to create a cell line or a xenograft. This means that we would treat the cells from your sample in a way that allows us to grow them in a laboratory. We do this so that we can have an unlimited supply of cells for research for a long time, maybe forever. These cells would also be stored and used for research.

What information will you collect?

Basic Information: We will ask you for some basic information. This will include things like name, age, sex, and race or ethnic group. We will also ask about your family's health history.

Clinical Information: We will collect information from your medical records that is related to your health and/or disease history. Some examples include results of tests, medical procedures, images (such as X-rays), and medicines you take. Researchers will use this information to better understand how genes affect health and response to treatment. We will look at your medical record from time to time to update this information. This will take place for as long as your sample is stored in the biobank, which may be many years, unless you tell us to stop.

Who will have access to my samples and information?

We will store your samples and information in the biobank. We will remove your name and any other information that could directly identify you from your materials. We will replace this information with barcodes. We will keep a master list that links those barcodes to your materials. Only certain project staff can access this master list. We will keep the samples in locked freezers in locked buildings. We will keep health information and research data on secure computers. These computers have many levels of protection.

Researchers can ask to study the materials stored in the biobank. This includes researchers from [INSTITUTION], as well as from other universities, the government, and drug or health

companies. Some researchers will be from the U.S.; some may be from other countries around the world. An oversight committee will review each request. This kind of review is to make sure that any risks are minimized and that your rights and welfare are protected. If a study is approved, we might give a part of your sample and information to the researchers. We would give them your materials along with samples and information from many other people.

We may also share your materials with other biobanks and research projects.

All of the samples and information will be labeled with barcodes. We will not share information that could directly identify you (like your name, social security number, and address) without your permission.

There is no limit on the length of time we will store your samples and information. We may keep using them for research indefinitely unless you decide to withdraw from the project.

Who else will have access to my genetic information?

Researchers can do more powerful studies when they share with each other the information they get from studying human samples. They share this information with each other by putting it into scientific databases. These databases store information from many studies conducted in many different places. Researchers can then study the combined information to learn even more about health and many different diseases.

There are different kinds of databases; some are publicly accessible and some are restricted. Anyone on the Internet can access publicly accessible databases. Only researchers who apply and are approved can access restricted databases. There are many restricted databases; some are maintained by [INSTITUTION], some are maintained by the federal government, and some are maintained by private companies. Some of your genetic and health information could be placed into one or more of these publicly accessible or restricted databases.

Your name and other information that could directly identify you (such as address or social security number) will not be placed into any scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Researchers will always have a duty to protect your privacy and to keep your information confidential.

Will I find out the results of the research?

You should not expect to get personal results from research done through the biobank. Researchers will study samples and information from many people; it will take many years before they know if the results have any meaning. However, in the future it may be possible for researchers to give you your genetic research results. There is also a small chance that researchers could find something that might be important to your health. If this happens, we may contact you to find out if you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

Will I be contacted in the future about this or other research?

We may want to contact you in the future. You can decide now whether or not you want to be contacted. You can also change your mind later.

If you agree, we may contact you for several reasons. For example, over time, stored samples may be used up or decrease in quality, so we may contact you to ask for more samples. We may also contact you to update basic information or request information about your health.

Additionally, we may want to contact you to see if you want to participate in other research. We will not notify you every time your samples and information are used. 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, someone from this project will contact you. They will tell you about the study so you can decide if you want to receive more information. There will be a new consent process just for that study. You can decide then to take part or not take part. If at any time you decide you no longer want to be contacted about future studies, you can call [NAME] at [NUMBER].

I agree that my doctor or someone from this project may contact me in the future.

Yes _____ No _____ Initials _____

Potential Risks and Discomforts

What are the potential physical risks and discomforts?

When the tissue we collect is left over from a procedure that is part of your clinical care, there are no additional physical risks to you if you take part in this project. Any additional tissue we take during your procedure will not significantly increase the risk to you.

If we collect a blood sample, you may feel brief pain or have some bruising from the needle. There is also a small risk of infection, light-headedness, and fainting.

What are the potential privacy risks?

We will take many steps to protect your privacy, but because your DNA is unique to you, it is possible that someone could trace it back to you. There is also 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 also be other unforeseen privacy risks.

We believe the chance these things will happen is very small, but we cannot make guarantees. Your privacy and the confidentiality of your data are very important to us; we will make every effort to protect them. These efforts are described below under the section “How will my privacy be protected?”

How will my privacy be protected?

We will not give information that identifies you to anyone without your permission, except as required by law. This project takes many steps to protect the privacy of people who take part.

Research records are separate from medical records. We will not place any information from this project in your medical records.

Researchers who study your sample and information will not know who you are. We will give them only barcode numbers; we will not give them any information that directly identifies you. The researchers must sign an agreement that they will not try to find out who you are.

There are laws that protect against unauthorized access to your information. There is also a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study.

Potential Benefits

You will receive no direct benefit from your participation in this project. However, your participation may help the investigators better understand how to prevent, detect, and treat health problems in the future.

Alternatives

You may choose to not participate in this study.

Subject withdrawal from a study

Can I change my mind after I agree to let my samples be used?

You have the right to stop participating in this project at any time. If you want to leave the project, call [NAME] at [NUMBER] to let us know. You will be given some options and can choose what you want us to do with your unused samples. You can also tell us to stop using your medical records. However, you cannot withdraw your samples and information from studies that have already begun. We cannot get samples and information back once they are shared with other researchers. Also, it may not be possible to remove your genetic information from scientific databases once it has been distributed.

Subject Costs and Payments

You will not be asked to pay any costs related to this research.

You will not be paid for taking part in this study.

This institution does not plan to pay royalties to you if a commercial product is developed from blood or tissue obtained from you during this study.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

Your Health Information

We may be collecting health information that could be linked to you (protected health information). This protected health information might have your name, address, social security number or something else that identifies you attached to it. Federal law wants us to get your permission to use your protected health information for this study. Your signature on this form means that you give us permission to use your protected health information for this research study.

If you decide to take part in the study, your protected health information will not be given out except as allowed by law or as described in this form. Everyone working with your protected health information will work to keep this information private. The results of the data from the study may be published. However, you will not be identified by name.

People who give medical care and ensure quality from the institutions where the research is being done, the sponsor(s) listed in the sections above, representatives of the sponsor, and regulatory agencies such as the U.S. Department of Health and Human Services will be allowed to look at sections of your medical and research records related to this study. Because of the need for the investigator and study staff to release information to these parties, complete privacy cannot be guaranteed.

The people listed above will be able to access your information for as long as they need to, even after the study is completed.

If you decide to stop taking part in the study or if you are removed from the study, you may decide that you no longer allow protected health information that identifies you to be used in this research study. Contact the study staff to tell them of this decision, and they will give you an address so that you can inform the investigator in writing. The investigator will honor your decision unless not being able to use your identifiable health information would affect the safety or quality of the research study.

The investigator, [NAME], and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an

injury related to the research, you may speak with a member of the study staff: [NAME] at [NUMBER] during the day and after hours.

Members of the Institutional Review Board for [INSTITUTION] (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is [NUMBER]. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

You can get more information about the biobank by visiting our website: [URL].

TEMPLATE