

**Consent to Participate
in the
Sanford BioBank**

biobank.sanfordhealth.org

(844) MY BIOBANK

(844) 692-4622

You are being asked to give a sample to the Sanford BioBank. The Sanford BioBank has two arms, the **Clinical DNA Bank** and the **Research BioBank**. The **Clinical DNA Bank** stores your DNA for use in your health care treatment, future clinical testing, or health care of a blood relative. The other arm, the **Research BioBank**, is used to store DNA, blood and tissue samples for future health research. You may choose to participate in both arms, one, or not participate at all.

Please read the following information carefully. There is no cost to participate in either the Clinical DNA Bank or Research BioBank.

What is DNA?

DNA contains genetic information that acts as a blueprint for how parts of your body are made and work, determining such things as eye and hair color. DNA is made up of long strands of repeating letters that form a code. These letters, A, C, T and G represent individual chemical units that form DNA. The order in which these letters are written is very precise. In the same way that a spelling mistake in a word could change its meaning entirely (for example, mean and meat), a single change in the sequence of DNA can lead to a change in how the body works, which may lead to disease or influence how you respond to medication.

What is genetic testing?

Genetic testing involves taking your DNA sample and determining the sequence of your genetic code. Changes in your genetic code may help your healthcare team choose the best course of treatment for you.

What is Genetic Inheritance?

Both your mother and father contribute DNA sequences that make up your genetic code. This is called inheritance. Often, changes in DNA sequence can be passed from parent to offspring and it may be important to study not only your DNA, but also the DNA of your parents and other family members, to identify the underlying causes of disease.

CLINICAL DNA BANK

What is involved in the Clinical DNA Bank?

Sanford is offering you the opportunity to have a sample of your DNA preserved for use in future clinical diagnostic testing. This DNA will be stored by Sanford and will solely be used for your health care, or for the health care of your blood relatives.

A sample of your DNA will be obtained through a blood draw (up to two teaspoons). In the event that a blood sample cannot be obtained, we may ask you to provide a sample of your saliva.

What are the risks of providing a sample for the Clinical DNA Bank?

The risks associated with having blood drawn are no greater than that you would experience from having a blood test performed as part of your routine health care. This includes some pain or bruising where the blood was taken. It is also possible, though rare, that there may be some local blood clotting or infection. Some people experience a feeling of lightheadedness or fainting when they have blood drawn. If you should experience these feelings, it is important that you tell the person who is drawing your blood, so that you can lie down immediately to avoid possible injury caused by falling.

Who will have access to my DNA sample?

Your DNA sample will be stored by Sanford for future clinical use. Until your sample is needed for clinical testing, no access will be granted. When access to your DNA sample is needed for your health care treatment or that of your blood relatives, the provider directly involved in that treatment will be granted access to your sample for testing. Any results from that testing will be incorporated into your medical record, or the medical record of your blood relative, as applicable, and re-disclosed with that medical record in the future.

Upon my death, I agree the following persons (hereinafter “my decision makers”) in the order of priority listed are authorized to consent to testing of my sample(s) in Sanford’s Clinical Biobank:

1. The personal representative of my Estate, if any;
2. My spouse, if any;
3. My adult children, if any.

I authorize my decision makers to consent to testing in accordance with Sanford’s policies as reviewed from time-to-time by the Sanford Biobank Ethics Committee. Sanford agrees to recognize the authority of my decision makers for purposes of consenting to testing of my sample(s) in Sanford’s Clinical Biobank, unless otherwise prohibited by law. If there is any dispute regarding consent for testing of my sample(s), I understand Sanford will need a court order directing testing before Sanford will move forward with testing.

You will not have any ownership rights in any specimens you contribute to the Sanford BioBank and you will not receive money or any other form of payment for these specimens. These specimens will be owned by Sanford.

You may choose to withdraw from the **Clinical DNA Bank** at any time by informing the Sanford BioBank in writing. We will destroy any remaining samples in the **Clinical DNA Bank**, however, any samples or data that has been distributed for laboratory testing or test results generated prior to your request to withdraw may continue to be used for health care purposes.

How long will my DNA sample be available?

Your DNA sample will be stored for as long as the Sanford BioBank is in operation. Storing your DNA sample indefinitely is necessary to ensure that you and your blood relatives will benefit from testing of your DNA sample when needed for their health care treatment.

There is a possibility that DNA samples may be lost in transit or will be inadequate for a future test, due to unforeseen power failures, equipment failures, floods, or other circumstances. It is also important to know that a DNA sample is not permanent. If used for one test it may be depleted so that sufficient DNA might not be available for additional testing. Sanford is not liable for damage to or loss of a DNA sample. Sanford has no fiduciary duty to you, your family, or heirs, successors, or assigns, other than to use the sample for its designated purpose and to refrain from using the sample for research or commercial purposes. Sanford has no duty to account to you or any of your family members, heirs, successors, or assigns, or to guardians, attorneys-in-fact, or trustees.

In the following section, you will be given information about providing a sample for research purposes in addition to the Clinical DNA Bank sample. At the end of this form, you will be given the choice to participate in both the Clinical DNA Bank and Research BioBank, one, or not participate at all.

RESEARCH BIOBANK

Principal Investigator: Chun-Hung Chan, PhD

WHAT IS THE PURPOSE OF THE RESEARCH BIOBANK?

The purpose of the **Research BioBank** is to collect, process, and store samples until researchers need them to do research. A major obstacle in health research is that researchers normally study diseases in patients after the disease develops, by which time many changes have already taken place in the body. We would like to store blood and tissue samples, along with health information obtained from your medical record, so that researchers can study components of your blood and tissue, such as proteins or DNA, both before and after disease develops. This may help researchers to understand the causes of disease, how to treat them, and how disease might be prevented.

The samples we collect will act as a library for researchers who are interested in studying a wide variety of human health conditions; instead of looking for volunteers for each new research study, researchers will have access to a large collection of blood, tissue and DNA samples along with medical histories all in one place, therefore greatly accelerating the pace of research.

Taking part in this **Research BioBank** does not mean we think you will develop a disease. Your samples may be used as healthy control subjects in future research studies.

WHAT IS INVOLVED IN THE PROJECT?

To participate in the **Research BioBank**, every time you have your blood drawn, we may collect up to 4 teaspoons of blood for research. If you are scheduled to undergo surgery at a Sanford facility, we may also obtain a sample of your surgical tissue **that is not needed** for diagnostic purposes and would otherwise be disposed. This will not affect the quality of care you receive from your health care team.

As part of this project we will look at your medical record from time to time to update the information for the **Research BioBank** and to collect information for future studies. This will take place for as long as your sample is stored, which may be many years unless you tell us to stop.

WHAT PERSONAL HEALTH INFORMATION WILL BE USED OR DISCLOSED?

You are authorizing Sanford BioBank personnel to copy and use information contained in your medical record. The health information that may be used or disclosed for the research includes: results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.

ARE MY RECORDS CONFIDENTIAL?

The records of the **Research BioBank** will be kept confidential in accordance with applicable law.

Your **Research BioBank** record may be reviewed by government agencies, the Sanford Human Research Protection Program, the Sanford Institutional Review Board (IRB), and appropriate Sanford personnel.

Any information that is obtained in connection with the **Research BioBank** that may identify you will remain confidential and will be disclosed only with your permission or as allowed or required by law. Your samples will be stored in a secure facility in barcoded tubes with no identifying information. The code needed to link your samples to your medical record will be stored in a secure, password protected database with access restricted to Sanford BioBank personnel only.

Confidentiality will be maintained by:

1. Assigning a unique **Research BioBank** code to your medical record and separate unique codes for your samples.
2. The code linking your **Research BioBank** sample and your identifying information will be kept in a secure, password protected database accessed only by Sanford BioBank personnel.
3. Results of tests and studies performed by researchers will not be included in your medical records. The results of the studies will not be shared with you by the **Research BioBank**.

In many cases your samples will be used without any identifying information. If a researcher using your sample needs to know who the sample came from, they will need to obtain approval from the Sanford IRB. If approval is given, the researcher may contact you to obtain separate informed consent for their study. The Sanford IRB is a group of people who review research to protect your rights and welfare.

With your permission, you may also be contacted in the future by Sanford to invite you to take part in a research study. You may decide whether or not to take part in these future studies at that time.

Your samples may also be used by researchers who are not associated with Sanford but they will not receive any identifying information about you.

HOW LONG WILL I BE IN THE RESEARCH BIOBANK?

If you decide to participate, your blood and tissue samples, as well as your health information will be stored indefinitely. You may withdraw from the **Research BioBank** at any time by informing the Sanford BioBank that you no longer wish to participate.

If you choose to withdraw from the **Research BioBank**, please make your request in writing to the BioBank. We will destroy any of your samples remaining in the **Research BioBank** and remove your medical information from our database. However, any samples or data that has been distributed to researchers, or data generated from your samples prior to your request to withdraw may continue to be used for research purposes.

WHAT ARE THE RISKS?

The risks associated with a blood draw are the same as described earlier. If you are already having your blood drawn, there are no additional risks associated with having an additional sample of blood taken. There is no risk associated with obtaining a sample of your surgical tissue beyond that associated with the risks of surgery to which you have already agreed to as part of your health care.

The biggest risk to you is the unexpected release of your personal health information. While we cannot guarantee absolute confidentiality, we will use best efforts to minimize the risk that this information would be given to someone outside of the **Research BioBank**. Your blood sample and

health information will be assigned a unique code which can be used to link back to you.

ARE THERE BENEFITS TO TAKING PART?

While there may be no direct benefits to you, other people might benefit from knowledge gained from using your samples in future research studies.

WHAT ARE THE ALTERNATIVES TO PARTICIPATING IN THE RESEARCH BIOBANK?

You may choose not to participate in the **Research BioBank**. If you don't participate, you will continue to receive treatment from your health care provider.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There are no costs associated with participating in the **Research BioBank**.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid to participate in the **Research BioBank**. Research results might someday lead to the development of a commercial medical product. You will not have any ownership rights in such product(s), nor will you receive any other form of payment or royalties from the sale of product(s) that may have been developed using your sample.

WHO IS FUNDING THE RESEARCH BIOBANK?

The **Research BioBank** is being sponsored by Sanford.

WILL I BE COMPENSATED FOR AN INJURY?

In the event that this research activity results in an injury, treatment will be available including first aid, emergency treatment, and follow-up care as needed. Payment for any such treatment is to be provided by you (you will be billed) or your third-party payer, if any (such as health insurance, Medicare, etc.). No funds have been set aside to compensate you in the event of an injury.

If you feel you have suffered a research-related injury, please contact the Sanford BioBank at (844) MY-BIOBANK or (844) 692-4622.

IS THIS RESEARCH BIOBANK VOLUNTARY?

Your participation is voluntary. You may choose not to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to withdraw your participation, you must contact the Sanford BioBank in writing. Any health information already obtained about you may still be used or disclosed as necessary to maintain the integrity or reliability of the current research. Your decision whether or not to participate will not affect your current or future relations with Sanford.

WHO MAY I CONTACT IF I HAVE QUESTIONS?

For general questions about the **Clinical DNA Bank** and the **Research BioBank**, please contact Sanford BioBank at (844) MY BIOBANK or (844) 692-4622.

For questions regarding your rights as a **Research BioBank** participant, please contact the Sanford Human Research Protection Program at (605) 312-6430. You may also call this number about any problems, complaints, or concerns you have about the **Research BioBank**.

- You may also call this number if you cannot reach research staff, or you wish to talk with someone who is independent of the research team.

To withdraw from the **Clinical DNA Bank** or the **Research BioBank** please make your request in writing to:

Sanford BioBank
2301 E 60th St. N
Sioux Falls, SD 57104

When making your request, please indicate whether you wish to withdraw from the Clinical DNA Bank, the Research BioBank, or both.

For more information about the Sanford BioBank please visit biobank.sanfordhealth.org.

CONSENT TO PARTICIPATE IN THE SANFORD BIOBANK

- I have read (or have had read to me) the contents of this form and have had my questions answered.
- If you wish to participate in the **Clinical DNA Bank**, the **Research BioBank**, or **both**, please sign in the appropriate boxes below.

Please do not tear off.

CLINICAL DNA BANK

YES, I give my consent for Sanford to collect and store indefinitely a sample of my DNA for future clinical uses.

Participant Signature

Date of Birth

Participant Name, Printed

Date

RESEARCH BIOBANK

YES, I give my consent for my blood and/or tissue to be collected and used for the Sanford Research BioBank.

I give my permission to be contacted by researchers about participation in future research studies

Participant Signature

Date of Birth

Participant Name, Printed

Date