

## **Columbia University Biobank at NewYork Presbyterian (CUB-NYP)**

Researchers at Columbia University Irving Medical Center-NewYork Presbyterian are studying how DNA (genes), the environment and other factors affect people's health and contribute to disease. In order to conduct this research, we are asking patients at Columbia-NYP to take part in the Columbia University Biobank – NewYork Presbyterian (CUB-NYP).

Before you decide to participate in the biobank, it is important for you to understand what a biobank is and what your participation will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information to decide whether or not you wish to take part in the biobank.

### **What is the purpose of the biobank?**

The purpose of the biobank is to create a research resource with biological samples, such as blood and urine, along with health records to help researchers better understand, treat, and even prevent diseases in the general population. The biobank is a resource meant to serve the Columbia-NYP research community for years, and there are no plans for it to end.

### **Why am I being asked to participate?**

You are invited to participate because you are receiving medical care at the Columbia University Irving Medical Center-NewYork Presbyterian Hospital (CUIMC-NYP).

### **What are the alternatives to participation in the biobank?**

Your participation in the biobank is voluntary so the alternative is not to participate. Your choice will not affect the treatment you receive from doctors and staff at CUIMC and NYP.



## What will happen when I participate in the biobank?

1. You will be asked to donate a blood sample (approximately 3 tablespoons) and urine sample. If these samples are not collected today, they may be collected at a future time when you have a blood draw ordered by your doctor or a separate appointment that is convenient for you. In some cases, we may ask you for a saliva (spit) or buccal (cheek swab) sample. We may also use blood, urine, or tissue samples collected as part of your clinical care now or in the future that would otherwise be thrown away.
2. We will request information about you and your health. We will collect your name, address and other contact information. We will use your electronic health records now and, in the future, to update your health information. We will store some of your health information, including your name, contact information, and medical history, in the Columbia Biobank database. Biobank staff will make a note that you are a participant in the biobank in your electronic health record.
3. We may contact you in the future. We may ask you to complete additional questionnaires about your health or contact you to get additional information and ask if you are interested in joining other research studies. We may also contact you for another biological sample. We may ask for additional samples in order to study changes in your sample over time, or because we used up the first sample you provided. If we ask you for another sample, you may always say no.
4. Your coded samples, health information, and the research results may be shared with the scientific research community. A science and ethics committee will review each request for data access. We will not give researchers outside of Columbia University Irving Medical Center-NewYork Presbyterian your name or any other information that could directly identify you.

## **What is involved in the genetic research conducted for the biobank and will I receive results?**

Genetic research is central to the research conducted at CUIMC-NYP. DNA from your blood/saliva/or tissue sample may be tested to look for genes and DNA related to health conditions. The research performed may include whole genome sequencing. The genetic data, including sequencing data, will be available for researchers to use.

Each cell in our body carries information, which is stored as a chemical called DNA. We inherit half of our DNA from each of our parents. The entire set of DNA for an individual is called the whole genome, and it is composed of about 20,000 genes that carry the instructions for your body's development and functions. In a genetic study, the DNA is analyzed in order to identify the hereditary factors related to diseases. Genetic tests may look at all of the genome, or just part of it.

Generally, we will not return individual results from research using your samples and data to you. Most research findings are not relevant to your personal health; however, in the future, this may change. While you should not expect to receive results from participation in the biobank, if the researchers involved in the biobank determine that results are of high medical importance to you, we will attempt to contact you. The information might be helpful to you or other family members. You may choose, at the end of this form, whether to be provided with research findings that may be relevant to your health and of high medical importance.

Before any genetic research results can be returned to you, they must be discussed with the researchers managing the biobank and confirmed by a laboratory that is certified to provide clinical genetic testing. You will first have a discussion with the biobank genetic counselor about the general nature of the results available and asked to decide whether you want to receive them.



You will be required to provide an additional sample and consent for this testing in a clinical laboratory. The purpose of additional testing in this laboratory is to confirm, using clinical standards, whether the gene or variant is present. The biobank will pay for this testing. You and your medical insurer may be responsible for the costs of any follow up care including additional testing and genetic counseling.

You can get general news about the kinds of studies being done through the Columbia Biobank at

<https://www.ps.columbia.edu/biobank>

If the research finding is confirmed in a clinical laboratory, the results will be placed in your medical record.

### **How will my private information be protected?**

Every effort will be made to keep your personal information confidential. However, we cannot guarantee total privacy. Your data and specimens will be given a code number, and separated from your name or any other information that could identify you. The link to this code will be kept in a password protected database that is only accessible to the biobank research team.

Access to your health information and your electronic health record is required to be part of this study. By participating in this study, you are giving us the permission to use the protected health information that can identify you. This information may include sensitive information such as genetic information, HIV status and drug and alcohol abuse history.

Some of your genetic and health information may be placed in scientific databases, along with that from many other people. These data could be used in genetic studies by other researchers outside Columbia who have permission granted to access the information in the biobank's scientific database.



## **Certificate of Confidentiality**

Information that could directly identify you will never be shared outside of Columbia University Irving Medical Center (CUIMC) and NewYork Presbyterian (NYP) unless we are required by law, or you have provided authorization to disclose the information. The following people and/or agencies will be able to see, copy, use, & share your research data: CUIMC and NYP biobank staff and other professionals who may be evaluating the biobank; authorities from Columbia University and NYP, including the IRB. The Federal Office of Human Research Protections ('OHRP') and/or the Food and Drug Administration (FDA).

Your authorization to use and share your health information does not have an expiration (ending) date. Once your health information has been disclosed to a third party (for example, a pharmaceutical company participating in a study), federal privacy laws may no longer protect it from further disclosure.

## **Certificate of Confidentiality**

To help us protect your privacy, we received a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we cannot be forced to provide information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate of Confidentiality does not stop you or a member of your family from telling others about yourself or your involvement in this research. If an insurer, employer, or other person gets your written consent to receive research information, then we cannot use the Certificate to withhold that information.



The Certificate cannot be used to resist a demand for information from representatives of the United States Government that is used for auditing or evaluation of projects they are responsible for overseeing or for information that must be provided in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should also know that this Certificate does not protect you from our responsibility to report certain communicable diseases, suspected child abuse, or danger of physical or mental harm, to appropriate agencies or authorities.

### **Which researchers can use my sample and what information will they have?**

Researchers who want to access the samples and data stored in the biobank must apply to use the information. A committee comprised of researchers, physicians, and ethicists from the medical center will review all requests to use the samples and data available in the biobank..

We will only share information that identifies you with approved researchers within Columbia/NYP. We will not share information that identifies you with researchers outside Columbia/NYP.

Coded samples and data may also be shared with researchers at other non-profit or with for-profit companies that are working with Columbia researchers. Your samples will not be sold for profit. We will not give these researchers your name or any other information that could directly identify you. We may use your samples and information to develop a new product or medical test to be sold. The university, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples and information are used for this purpose.

We may share your coded samples, DNA research information, health information, and results from research with other central tissue or data banks, such as those sponsored by the National





Institutes of Health (NIH), so that researchers from around the world can use them to study many conditions. These central banks may store samples and results from research done using the Columbia University Biobank-NYP samples and health information. The central banks may share these samples or information with other qualified and approved researchers to do more studies. We will not give central banks your name or any other information that could directly identify you. There are many safeguards in place at these banks to protect your privacy.

## **Benefits/Risks/Cost**

### **What are the benefits to me?**

Most people who participate in the biobank will not receive any direct benefit.

There is a small chance that we may identify a genetic finding of medical importance. If this is the case, and you have chosen to receive such results, there is a benefit to be diagnosed and treated early. Otherwise, this study is not likely to improve your health or directly benefit you.

### **What are the risks to me?**

There is a very small risk of bruising, brief pain, lightheadedness, or infection from drawing blood similar to what might occur from a routine blood draw that you get for your doctor.

The main risk of allowing us to use your samples and health information for research is a potential loss of privacy and breach of confidentiality. Study data and the samples will be physically and electronically secured. We protect your privacy by coding your samples and health information. Despite our best effort, unexpected situations (such as unauthorized access to a computer) could occur and someone could get access to the data we have stored about you.

We may identify risk for serious genetic conditions. Such a finding can result in unexpected psychological trauma for both you and your family. The detection of such a condition could also affect the health care needs of your siblings, children or other close relatives.

Because we cannot say with certainty how information derived from the genetic research could be used in the future, this study may involve risks that are currently unforeseeable.

Genetic Information Nondiscrimination Act (GINA) is a law that protects you from genetic discrimination by health insurance companies and employers. Participating in this research should not affect your health insurance coverage. However, you are not protected under GINA for life, long-term care, or disability insurances

### **What are the costs to me to participate in the biobank?**

There are no costs to you or your insurance to participate in the biobank.

### **Will I be paid or be given anything for taking part in the biobank?**

We will give you a \$20 gift card after enrolling in the biobank.

### **Can I end my participation in the biobank in the future?**

The biobank is a resource meant to serve the research community for years, and there are no plans for it to end. However, you have the right to leave the biobank at any time. Your choice will not involve any penalty or loss of benefits.

When leaving the biobank, please note:

- You cannot withdraw your samples and information from studies that have been started;
- Biobank staff cannot get back samples or medical information that have been shared with other research institutions; and





- Biobank staff will stop using your medical information and destroy any remaining samples if you ask us to, but we will not be able to remove existing information from our databases.

You may withdraw this consent and authorization at any time and for any reason by notifying Dr. Reilly by email at: [mpr2144@cumc.columbia.edu](mailto:mpr2144@cumc.columbia.edu), phone(212-305-9435), or via mail at address (630 West 168th Street, PH10-305, New York, NY 10032 or fax 212-305-3213).

If you wish to stay involved in the biobank and your contact information has changed, please contact us with your new contact information (address, email and phone number).

### **What if I have more questions?**

If you have more questions about this project, contact [mpr2144@cumc.columbia.edu](mailto:mpr2144@cumc.columbia.edu) or Dr. Muredach Reilly at (212) 305-9453.

If you have any questions about your rights as a research participant, or if you have a concern about this study, you may contact the office below:

Human Research Protection Office

Institutional Review Board

Columbia University Medical Center

154 Haven Avenue, 1st Floor

New York, NY 10032

Telephone: (212) 305-5883

[irboffice@columbia.edu](mailto:irboffice@columbia.edu)



## Return of results/Statement of Consent

[I agree]     [I do not agree]

that you may contact me if there are results from the genetic research that may be relevant to my health. I understand that at that time I will be told more about the general nature of the results available and asked to decide whether I want to receive them. I understand that I will be asked to sign a separate consent form and provide an additional blood sample for additional testing to confirm the results before information about them is given to me.

### STATEMENT OF CONSENT AND HIPAA AUTHORIZATION

I have read the consent form and had the chance to talk about the biobank, including the purpose, procedures, risks, benefits and alternatives with the biobank staff. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this biobank and give my authorization to use the protected health information and information collected for my participation in the biobank. I am aware that I can stop participation at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be sent an emailed a copy or given a printed copy of the signed consent form to keep for my records.

**Print Name of Biobank Participant**



**e-signature Biobank Participant**

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**Date**

Electronic date stamp and identifier of biobank staff obtaining consent via OPENSPECIMEN