UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title: The Penn Medicine BioBank

We invite you to take part in research by participating in the Penn Medicine BioBank (PMBB). Taking part in this research is voluntary. It does not cost anything to you or your insurance. Your choice to participate will not affect your care at Penn Medicine.

This form has information to help you decide whether to participate in the PMBB.

Please visit our website to learn more and to watch our video: https://pmbb.med.upenn.edu. You can call (215) 573-7622 or email BioBank@upenn.edu with any questions about this form or the PMBB.

If you have questions about research participant rights, please call the University of Pennsylvania's Office of Regulatory Affairs at (215) 898-2614.

WHAT IS THE PURPOSE OF THE PMBB?

The PMBB helps researchers study many health conditions, such as cancer, heart disease, and diabetes. Some studies are being done now, and some will be done in the future.

The PMBB collects and stores biosamples and health information for research use. Biosamples may be blood, urine, and other bodily fluids, and tissue when available. When biosamples are stored together for research, it's called a biobank.

This research will typically involve studying the genetic code unique to you called DNA. Researchers may study differences in your DNA that influence health, risk of disease, or response to treatment. They may look at the sequence of your genetic code, which is a research method called genotyping. Researchers may use a method called whole exome sequencing to study pieces of your DNA that code for proteins, or they may use a method called whole genome sequencing to study your DNA in its entirety.

Research may involve creating cell lines from your blood sample. Cell lines may be kept for many years and may be used to create treatments for different diseases and conditions.

Some research may lead to new products, such as drugs or tests for diseases. Sometimes the research, including studying your DNA, may be done by a for-profit company conducting research with Penn researchers or for their own research. You will not receive or share in any profits made from research arising out of your participation in the PMBB.

WHAT HAPPENS IF YOU CHOOSE TO TAKE PART IN THE PMBB?

1. Consent. If you want to participate, select "Yes" below and sign this consent form after reading all of it. This allows us to access, collect, and use your biosamples and health information as described here.
2. We access your medical record and collect information. The PMBB will periodically collect information from your medical record. This information may include, but is not limited to, any identifying information – like name, date of birth, medical record number, contact information -- and any health information – like test results, medical procedures, medical diagnosis and procedure codes, lab values, images (such as X-rays) medicines you take -- in your medical record.

3. We collect biosamples. The samples the PMBB collects may be blood, saliva, urine, other bodily fluids, and/or tissue that remains from clinical work. For blood samples, we may collect up to 4 tablespoons of blood. This blood draw order may be added to your medical record to collect a PMBB biosample when you are having blood drawn as part of your clinical care, or it may be obtained from a separate needle stick. We may obtain biosamples that are not needed for your care and that would otherwise be thrown away. The PMBB also stores the information obtained from analysis of your biosamples.
4. We store your biosamples and information in the PMBB. The PMBB stores biosamples and information about you in a coded format without your name or contact information on them. There is no time limit on how long the PMBB stores your biosamples and information about you. They may be kept until the PMBB decides to destroy them, or in the case of biosamples until they are used up.
5. We review research requests and may allow researchers to use biosamples and information about you from the PMBB for research. Researchers can only access biosamples and information after approval by the PMBB Governance Committee and an Institutional Review Board (IRB), which is charged with protecting the privacy rights and safety of human subject research. These researchers can be from the University of Pennsylvania, other universities, other non-profit organizations, the government, or for-profit companies such as drug, health-related or other companies.
6. We may contact you in the future. The PMBB may contact you again for updates about your health or to ask whether you would like to participate in surveys or research studies.

WHAT ARE THE POSSIBLE RISKS?

If we draw blood from you, the most common risks are brief pain and/or bruising.

There is a risk that someone could get access to the health information, including genetic data. The chance that this could happen is very small. We have safeguards in place to protect the confidentiality of this data, but we cannot make guarantees.

As people come up with new ways of tracing information, there is a small risk that someone could trace biosamples and health information in a scientific database back to you. This might be possible in the future, even without your name or contact information being on those biosamples or information.

A federal law prohibits employers and health insurers from discriminating against individuals based on their genetic information. This law is called Genetic Information Non-Discrimination Act (GINA). If you want to learn more about GINA, you can visit http://ginahelp.org or ask us. GINA does not cover other types of misuse of genetic information.

WHAT ARE THE POSSIBLE BENEFITS?

Taking part in the PMBB can help researchers advance science and make discoveries that might help many people with different diseases, conditions, and other health-related problems in the future. You are unlikely to get a direct benefit from taking part. You will not receive any payment for taking part.

You are unlikely to get any study results. The PMBB may inform you or your doctor about the results of analyses that would impact your health, if permitted by law.

The University of Pennsylvania, its medical school and health system (“Penn”), may publish research, and/or receive funding, royalties, or other valuable items, like equipment or services, from the government, non-profit or for-profit companies. These help pay for costs of operating the PMBB, doing research, and promoting our educational mission.

WHO AT PENN MAY ACCESS AND USE MY INFORMATION AND BIOSAMPLES?

The PMBB works to ensure that access to your information and biosamples, including identifiable information, is limited to those with a need to know.

For most individuals at Penn, including researchers, research teams and Penn support staff, access and use is limited to “coded” information and biosamples. This means the PMBB assigns a randomly generated, unique code to replace your name, contact information, and date of birth. The PMBB strictly limits who can see the answer “key” that connects this identifying information to the assigned code.

While most Penn access is to coded information and biosamples, the PMBB will provide identifying information to Penn staff if it is required for their work. This includes staff at Penn supporting offices, who are first required to sign an agreement to keep the information confidential and secure. Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases. Penn researchers may also receive and use identifying information if their research needs it and if approved by the PMBB Governance Committee and the Penn IRB.

WHO OUTSIDE PENN MAY RECEIVE AND USE MY INFORMATION AND BIOSAMPLES?

The PMBB may share your information and biosamples with researchers outside Penn but only in a coded format and only if they work with a Penn researcher and have approval from the PMBB Governance Committee and an IRB. Similarly, the PMBB may share coded information in scientific databases. The PMBB will not share your name, contact information or date of birth with researchers outside Penn.

The PMBB may share your information, including identifiable information, with organizations outside Penn Medicine that help us in our work and serve as our Business Associates as permitted by federal privacy protection regulations called HIPAA. HIPAA Business Associates must agree to safeguard your information with appropriate privacy and security protections. The PMBB may also share your information, including identifiable information, if required by law or requested by an oversight organization such as the Office of Human Research Protections. If your personal health information is disclosed outside Penn, it may no longer be covered by HIPAA.

WHAT IF I CHANGE MY MIND?

If you change your mind, just call (215) 573-7622 or email biobank@upenn.edu and let us know. You have the right to take away your permission to be part of the PMBB at any time. If you withdraw, the PMBB will no longer access, use or share your biosamples or information, except to the extent action has already been taken in reliance on this consent.

CONSENT STATEMENT

I have read all of this form and have had any questions answered.

I know enough about the purpose of the Penn Medicine BioBank (PMBB), the activities involved, and the risks and benefits to decide that I want to participate. I know that joining the PMBB is voluntary, and I choose to join.

I agree that my biosamples and health information can be accessed, stored, used, and shared with others by the PMBB for research in the future and as described above. I agree this includes health information that is subject to special privacy protections, including any behavioral health, substance use, HIV/AIDS, and genetic information. Redisclosure of such information beyond what is described in this consent is prohibited unless expressly permitted in writing by the patient or representative or otherwise permitted by applicable law.

This authorization I am providing for research use of my personal health information/biosamples and for the PMBB does not expire. I understand that I have the right to change my mind and revoke this permission as described above.

______________________________	______________________________	____________________
Name of Subject (Please Print)	Signature of Subject	Date

[Electronic Options:]

- ○ Yes, I consent. I want to be part of the PMBB.
- ○ No, I do NOT consent. I do NOT want to be part of the PMBB.
- ○ I don’t want to decide now.