



Indiana Biobank



We are asking you to participate in the Indiana Biobank (the IB)

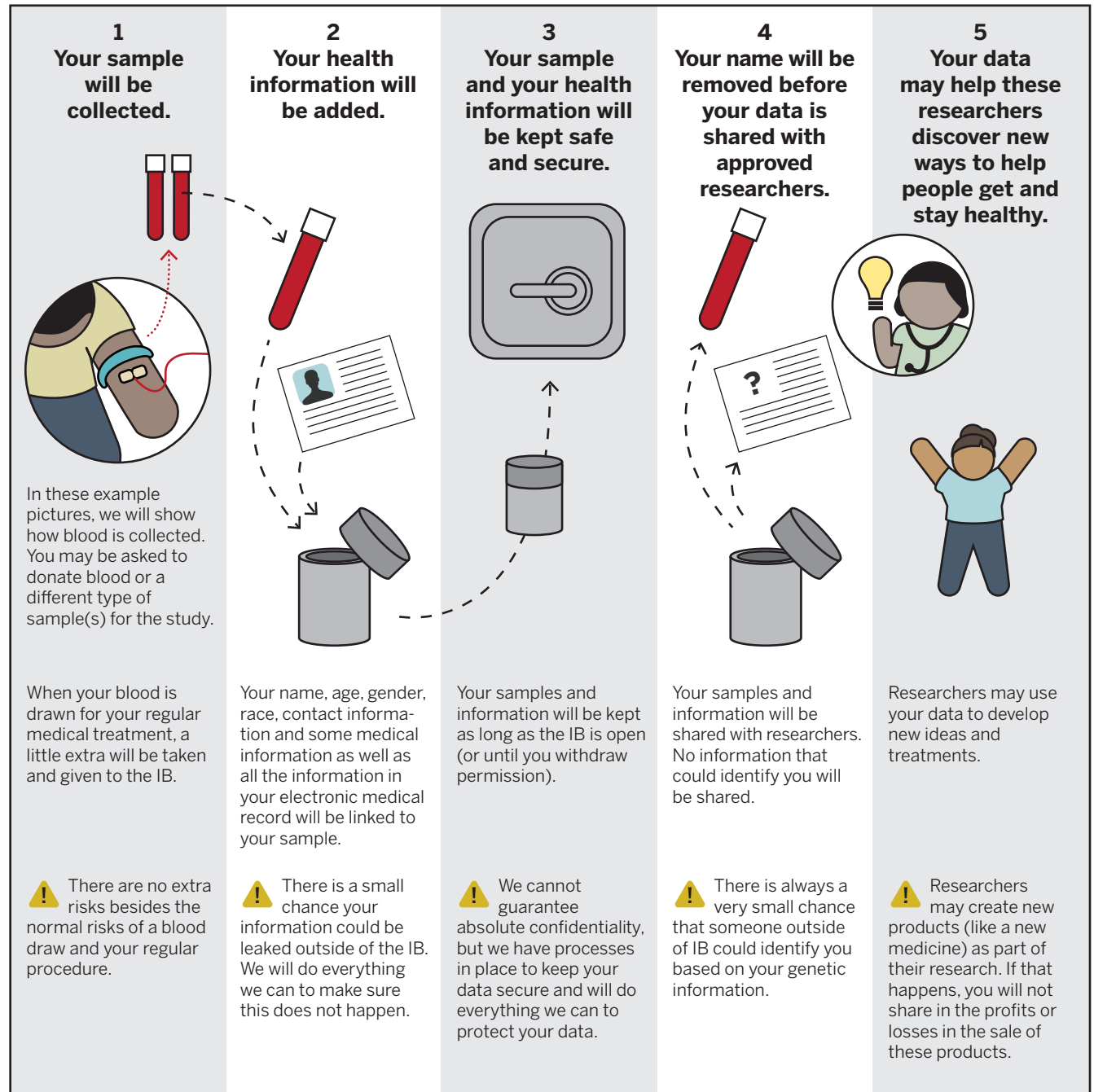
The IB is a collection of samples (like blood, urine, and tissue) from individuals matched with their electronic medical record. The samples (without the names of the individuals) are shared with researchers who use them to find better treatments for diseases and health conditions. If you are providing consent for another person to participate, such as your child or an adult who cannot provide their own consent, 'you' and 'your' refers to the person who will be participating in the study.

Taking part in this study is voluntary

You will be asked to read this consent/authorization to use your samples and medical record information and decide whether you want to participate. You may choose not to take part in the study. Your choice will not affect your relationship with Indiana University and IU Health, and you do not have to sign this document in order to receive treatments or benefits from Indiana University or IU Health. If you do not sign this document, you cannot participate. There is no cost to you for taking part. You will not receive any payment or benefit.

You can change your mind

You may leave the study and withdraw your permission to use your data at any time by writing to Indiana Biobank 410 W. 10th St. Suite 1000 Indianapolis, IN 46202. If you do, your samples and the link to your health information will be destroyed. If your data has already been shared with researchers, they can keep using the information they have for research but the IB will no longer have your information to share with anyone else.



What will happen in this study?

1. Your sample will be collected.

You will be asked to provide one or more samples: including, but not limited to, blood, saliva, urine, or remnant samples (leftover tissues from a procedure). We will work with you and your medical providers to acquire the sample. For example, if your blood is drawn for your regular medical treatment, we may ask for a little extra will be taken and given to the IB.

2. Your health information will be added.

We will collect information about you such as your age, gender, race, medical information including genetic data, etc. Your samples will be linked to your electronic medical record. IU Health will give the IB access to your medical records until either the IB is closed or you withdraw permission. Other health information may be collected from your insurance company, and/or state or community organizations.

3. Your sample and your health information will be kept safe and secure.

Your sample and your medical record information together are your "data." The IB gives each person a code number. The list of names and code numbers is kept at the IB and only IB staff can see it.

4. Your name will be removed before your data is shared with approved researchers.

HOW YOUR INFORMATION WILL BE PROTECTED AND WHAT WILL BE SHARED

The IB will remove your name and other identifying information before sharing your data for research. Researchers studying your data will not know who you are because they will only see the code (no name or other identifying information). Researchers will not have access to the list of names and codes.

One other kind of information about you that might be learned from your blood is DNA. We may use DNA

collected in this study for analyses such as whole genome sequencing, which shows the exact order of the base pairs (chemical letters) of your DNA. Other technologies may be used as they are developed.

Every person's DNA is unique, so it could be used to identify you and unique things about you. However, there are rules on how people can use this information. This research follows the Genetic Information Nondiscrimination Act (GINA), a federal law which generally makes it illegal for health insurance companies, most employers, and other groups to request the your genetic information and discriminate against you based on it. For more about GINA, visit: <https://ghr.nlm.nih.gov/primer/testing/discrimination>.

WHO YOUR DATA MAY BE SHARED WITH

Only research projects approved by the IB steering committee may receive data for research. Researchers may be from Indiana University, other universities, government agencies (like the Indiana State Department of Health), or private companies that work on developing new tests or treatments. Any published results using your data will not identify you.

OTHER GROUPS THAT MIGHT ACCESS YOUR DATA

Some other organizations may access IB records and your information: the IU Institutional Review Board (or its designees), and state or federal agencies with oversight responsibilities for this research, including the Office for Human Research Protections (OHRP) and the National Institutes of Health (NIH).

Some data may also be provided to a government health research database for broad sharing with researchers around the world, but the data will not contain any information which could identify you. After your data is shared with the groups listed above, the law may not require them to protect it.

You have the right to request a copy of the personal health information collected during the study; however, to ensure the integrity of the study, you may not be given access until the study is complete.

To protect your privacy, this research is covered by a Certificate of Confidentiality from the NIH. The IB may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone outside the IB:

- (1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
- (2) if you consent to the disclosure, including for your medical treatment;
- (3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
- (4) for the purpose of auditing or program evaluation by the government or funding agency.

A Certificate of Confidentiality does not stop you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical provider, or any other person outside the IB, you must provide consent to allow the IB to release it.

5. Your data may help researchers discover new ways to help people get and stay healthy.

Your data could be used in many different ways such as:

- Study how genes (genes are part of your DNA) affect health or respond to treatment (this is why DNA is one of the things that might be shared).
- Better understand what keeps people healthy and what makes people sick.
- Create new medicines and/or vaccines.
- Create new ways to test for, treat, or cure illnesses.

You will not share in the profits or losses from any product or service created using your data.

The Indiana Biobank is not meant to support your clinical treatment. You will not receive any information based on researchers' use of your sample.

You can ask questions

For questions about this study or to leave the study contact the Indiana Biobank Team: (883) 545-0564 or MyPHC@iu.edu. To ask about your rights as a research participant or discuss concerns, contact the IU Human Subjects Office: 800-696-2949 or irb@iu.edu.

I understand that if I participate in the biobank:

- I will be asked to provide a biological sample(s). This may include, but is not limited to blood, urine, saliva, or remnant samples.
- If asked to provide a blood sample, if possible, a small amount of blood will be collected, usually when I am getting my blood drawn for other reasons.
- If asked to provide saliva, it will be captured by spitting into a small tube, or by a small sponge inserted into the mouth.
- If asked to provide urine, it will be collected via a standard urine collection cup.
- If asked to provide remnant (tissues leftover from other procedures), the IB team will work with my medical team to collect the sample.
- The Indiana Biobank will be able to access information about me from my electronic medical record and other sources about my health and wellness, possibly including my insurance company, and/or state or community organizations.
- My genetic and health information will be shared with researchers outside of the Indiana Biobank.
- No identifying information (like my name) will be shared with researchers.
- My donation will be kept secure at the Indiana Biobank for an unlimited amount of time unless I withdraw permission by contacting the Indiana Biobank.
- I could be contacted to be asked to participate in future research, or to be asked to provide additional samples in the future. I understand I can refuse at any time for any reason.

I have read the information explaining the study and am willing to participate in the Indiana Biobank.

PARTICIPANT INFORMATION:

FIRST NAME

MIDDLE NAME

LAST NAME

EMAIL

STREET ADDRESS

CITY

STATE

ZIP

PHONE NUMBER

PARTICIPANT SIGNATURE

DATE

LEGAL AUTHORIZED REPRESENTATIVE OR PARENT/LEGAL GUARDIAN INFORMATION:

FIRST NAME

MIDDLE NAME

LAST NAME

EMAIL

STREET ADDRESS

CITY

STATE

ZIP

PHONE NUMBER

LEGAL AUTHORIZED REPRESENTATIVE OR PARENT/LEGAL GUARDIAN SIGNATURE

DATE

PERSON OBTAINING CONSENT:

FULL NAME

CONSENTER SIGNATURE

DATE