



Indiana Biobank



We are asking you to participate in the Indiana Biobank

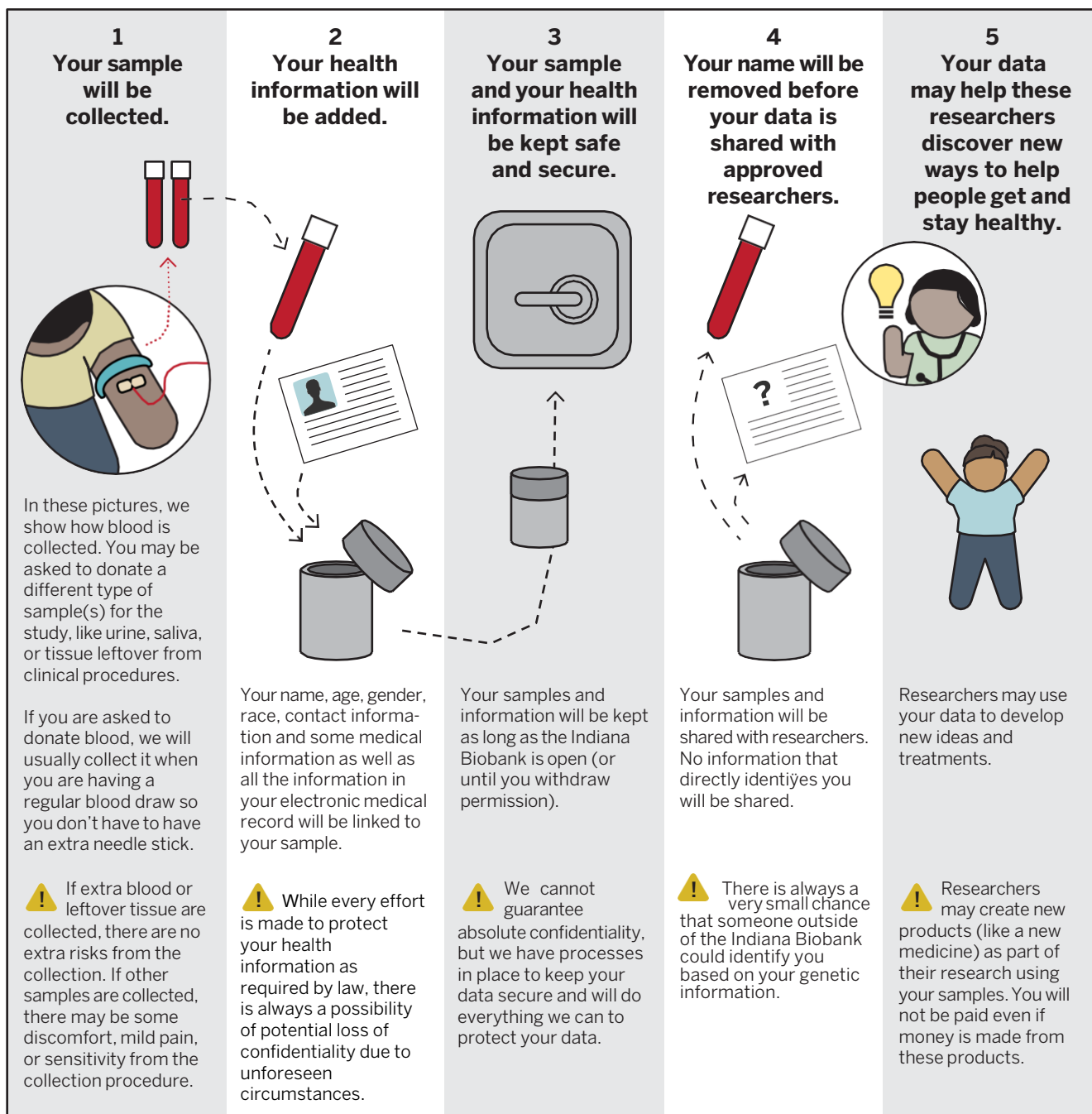
The Indiana Biobank is a collection of samples (such as blood, urine, saliva, stool, nasal swab, or tissue) from individuals matched with their electronic medical record. The samples (without the names of the individuals) are shared with researchers who use them to find better treatments for diseases 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. You do not have to participate. 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. 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 calling 317-278-0880. You may also write to Indiana Biobank at 351 West 10th Street, Rm 314, Indianapolis, IN 46202 or e-mail us at MyINBio@iu.edu. 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 **Indiana Biobank** 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 blood or 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 **Indiana Biobank**. We may also ask to keep samples that would normally be discarded.

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 **Indiana Biobank** access to your medical records until either the **Indiana Biobank** 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 **Indiana Biobank** gives each person a code number. The list of names and code numbers is kept at the **Indiana Biobank** and only **Indiana Biobank** staff can see it.

After your medical record information is released for purposes of this research study, your information may no longer be protected under federal privacy laws, such as HIPAA. However, your identifiable information will still be stored securely and only used as described in this consent.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that information, documents, or samples from this study that could identify you cannot be used in any legal action or lawsuit unless you say it is okay.

There are some types of sharing the Certificate does not apply to. The Certificate does not stop reporting required by federal, state, or local laws, such as reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate also does not stop sharing of information as described in this consent.

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

WHAT WILL BE SHARED

The **Indiana Biobank** 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. Any published results using your data will not identify you.

DNA is a type of information about you that may be learned from your sample. Every person’s DNA is unique, so it could be used to identify you and unique things about you. 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.

Your blood may also be used to grow cell lines. Cell lines are made from white blood cells that are mixed with a solution that allows cells to continue growing, keeping your cells alive for future research. These cell lines will be coded and not identified by your name. They are used for long-term chemical and genetic research and may be kept indefinitely.

WHO YOUR DATA MAY BE SHARED WITH

Only research projects approved by the **Indiana Biobank** 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.

Some data may also be provided to a government health research database or other databases for broad sharing with researchers around the world. The data sent to these databases will not contain any information which we think could be used to identify you.

OTHER GROUPS THAT MIGHT ACCESS YOUR DATA

Some other organizations may access **Indiana Biobank** 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).

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 to:
- Study how genes (genes are part of your DNA) affect health or respond to treatment (this is why DNA 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. Because the **Indiana Biobank** is not meant to support your medical care, you will not receive any information back about analysis or use of your sample(s).

If you provide your e-mail address below, you are agreeing for us to contact you if we need additional information, to see if you are willing to provide additional samples, and for other purposes. E-mail is not a secure form of communication. Others may be able to read or access information sent over e-mail.

6. Will I receive information about this study?

Researchers may discover something based on your samples that could provide you with more information about yourself. For example, your genetic information may suggest you could be at a higher risk for a particular disease or condition.

If you consent to the Indiana Biobank today, you may be contacted in the future to provide additional samples and/or health-related data. You may also receive information back about your health. Participation in these additional activities is voluntary.

If you are contacted about these additional opportunities, you will receive a separate form describing the opportunity in more detail, including whether additional samples **and/or health-related data** are being requested, whether test results will be returned to you, and whether test results may be entered into your permanent medical record and may be available to healthcare providers and others authorized to access your medical record.

Any information returned to you is not a medical diagnosis. If you have questions about your results, you should discuss them with your healthcare provider. Not all participants will receive additional information. If we do not contact you, it may be because:

1. Your sample has not been tested for certain information,
2. Your sample was tested but no relevant information was found, and/or
3. Your sample was tested, but researchers have decided to not return this type of information to participants

7. You can ask questions

For questions about this study or to leave the study contact the Indiana Biobank Team: (317) 278-0880 or MyINBio@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 Indiana Biobank:

I will be asked to provide a biological sample(s). This may include (but is not limited) to blood, urine, saliva, stool, nasal swab, breast milk, leftover clinical tissue or left over blood.

- 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 another reason. This may cause some mild pain and discomfort.
- 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 or stool, it will be collected via a standard collection kit.
- If asked to provide leftover clinical tissue, the **Indiana Biobank** team will work with my medical team to collect the sample.
- If asked to provide breast milk, a small amount would be collected from a pumped volume. This may cause some mild pain and discomfort.
- If asked to provide a nasal swab, a swab would be collected no further than a half inch into the nasal cavity. This may cause minor discomfort.
- 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 may be contacted in the future to receive health information based on my sample(s) and data. I understand that this information does not diagnose me and that I can refuse to receive this information at the time of contact.

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
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