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We are asking you to participate in the

The [REDACTED] 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.

Taking part in this study is voluntary

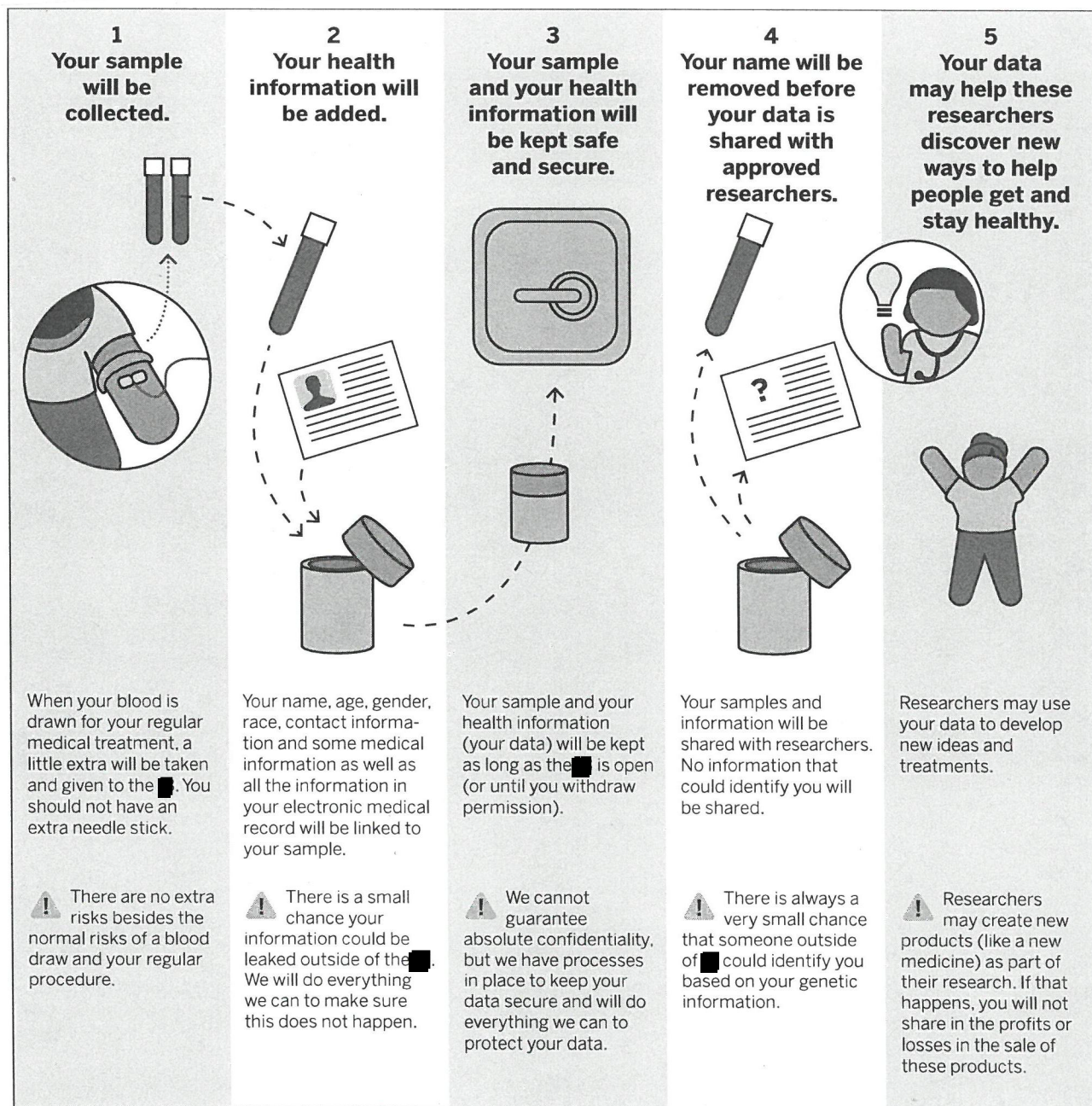
You will be asked to read this consent/authorization to use your samples and medical record information and decide whether you want to participate. You may choose not to take part in the study. You do not have to participate. Your choice will not affect your relationship with [REDACTED], and you do not have to sign this consent/authorization in order to receive treatments or benefits from [REDACTED] or [REDACTED]. If you do not sign this consent/authorization, 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 [REDACTED]. 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 [REDACTED] will no longer have your information to share with anyone else.

You can ask questions

For questions about this study or to leave the study [REDACTED] about your rights as a research participant or discuss concerns, contact the Human Subjects Office: [REDACTED]



What will happen in this study?

1. Your sample will be collected.

When your blood is drawn for your regular medical treatment, a little extra will be taken and given to the [REDACTED]. You should not have an extra needle stick for your donation.

2. Your health information will be added.

We will collect some personal health information about you such as your name, age, gender, race, contact information and some medical information. Your sample will be linked to your electronic medical record. [REDACTED] will give the [REDACTED] access to your medical record, including any mental health information, for this linking until the [REDACTED] is no longer open (or until you withdraw permission).

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 [REDACTED] gives each person a code number. The list of names and code numbers is kept at the [REDACTED] and only [REDACTED] 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

Researchers will see your data. The [REDACTED] will remove your name and other identifying information before sharing your data for research. Researchers who study your data will not know who you are because they will only see the code (no name or other identifying information). Those working on research projects 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. DNA is what you inherit from your parents and pass on to your children. 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, group health plans, and most employers to request the genetic information we get from this research and discriminate against you based on your genetic information. For more about GINA, visit: <https://ghr.nlm.nih.gov/primer/testing/discrimination>.

WHO YOUR DATA MAY BE SHARED WITH

Only researchers/research projects approved by the [REDACTED] steering committee may receive data for research.

Researchers may be from [REDACTED] other universities, government agencies (like the [REDACTED] State Department of Health), or private companies that work on developing new tests or treatments.

Any published results from research on your sample will not identify you.

OTHER ORGANIZATIONS THAT MIGHT ACCESS YOUR DATA

There are other organizations that may access [REDACTED] records and your information: the [REDACTED] 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 information is shared with the people and companies listed above, the law may not require them to protect your information.

You have the right to see and keep 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.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the [REDACTED]

NIH. The researchers 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 who is not connected with the research:

- (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 prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers 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.