

Indiana Biobank FAQs for IU Health patients

General overview

What is the Indiana Biobank?

The Indiana Biobank is a statewide Initiative developed by Indiana University School of Medicine and IU Health in order to expand their capabilities delivering individualized patient care, specifically tailored to an individual based on their DNA. The Indiana Biobank gives every IU Health patient the opportunity to participate in this effort by donating a biological sample (in this case blood). The goal of the project is to enroll up to 300,000 over the next five years.

What are the benefits of participating?

The purpose of the Indiana Biobank is to find better treatments for dreaded diseases of today and the future, tailored to individuals based on their DNA or genetic information. By providing a biological sample, participants will be adding their information to a larger bank of data which can then be used for research studies. Each person's sample is unique and helps ensure future treatments work for everyone.

What is a biological sample?

A biological sample is any human fluid or tissue that can be added to Biobank. Blood samples are used as these allow researchers to extract DNA which is genetic information that is helpful in answering scientific questions, like what medicines may work best with which types of genetic makeups

How does the Indiana Biobank work?

The Indiana Biobank collects and securely stores biological samples that are de-identified and coded so that no personally identifiable information remains. The de-identified samples and data are provided to approved researchers doing discovery research to cure and treat diseases.

Participating in the project

How do I participate?

To participate in the Indiana Biobank, patients at IU Health locations across the state are being asked to donate an extra vial of blood as part of a regularly scheduled blood draw. The blood sample is stored at the Indiana Biobank, a repository of blood samples and linked to an individual's electronic medical record (again, no patient identifying information is relayed to the approved researcher, only de-identified information). To date, more than 75,000 IU Health patients have participated in the Indiana Biobank by providing blood samples.

Who is eligible to participate?

All patients who receive care at IU Health hospitals and associated clinics are eligible to participate in the Indiana Biobank

Will my consent to participate affect my care?

NO. Your decision to provide, or to not provide, a biological sample does not affect your care in any way. If you say **yes** to the collection of an additional tube of blood, IU Health team members will collect this sample at your next blood draw or when it is most convenient for you. If you say **no**, it will not affect your relationship with your care team or the services you receive.

Can I change my mind?

Your participation is completely voluntary, and you may withdraw your consent any time. Any research data already obtained will remain part of the research that has been conducted. You can contact the Indiana Biobank via email at MyINBio@iu.edu or **317.278.0880** with questions or to withdraw from this study. For questions about your rights as a research participant or to discuss problems, complaints or concerns about the research study, contact the Indiana University Human Subjects Office at **800.696.2949**.

How will my samples be used?

Your sample will be used in research studies and projects to help try and find cures—tailored to individuals—for the dreaded diseases of today and those that may come to light in the future.

(continued on next page)



How long will my sample be stored?

Your biological sample will be stored for an indefinite period of time, unless you ask for your sample to be removed.

Is there a fee to participate?

There is no cost to you or your insurance. You will not be paid for participating, and your participation will not affect your ability to participate in any other research, should you choose to.

Registration questions

Q: I enrolled in the Indiana Biobank but do not have any other labs scheduled for today or in the near future. Should I go get my blood drawn now?

A: You can wait until the next time you are having other labs drawn. The Indiana Biobank sample is just a small tube and will not interfere with any other tests. Waiting will simply save you an extra trip to the lab.

Q: I enrolled in the Indiana Biobank while registering for my lab appointment. Do I need to tell the phlebotomist that I need my sample drawn?

A: You're welcome to mention it to your phlebotomist, but your Biobank order may take some time to appear in your chart. You do not need to wait for the order. If it hasn't shown up by the time you're called back, the sample can be drawn the next time you have bloodwork done.

Q: I enrolled in the Indiana Biobank a few years ago, but I'm being asked to enroll again. Why?

A: The Indiana Biobank may contact you again if your original sample has already been used in a research study. It's completely up to you whether you'd like to provide another sample.

Privacy and security questions

How will my privacy be protected? Where will my personal information be stored such as name, address, email, etc.?

The Indiana Biobank follows the same HIPAA rules as other U.S. healthcare organizations, including IU Health. Participants' basic information is collected (name, address, email, etc.) and stored in a HIPAA compliant database. At the time of consent, no personal health information is collected. Participants are assigned a study ID, and their biological sample and identifying information are stored based on this ID. No one other than specified study personnel have access to this information.

In addition, this information is protected through the National Institute of Health's Certificate of Confidentiality. This certificate protects against forced disclosure of personally identifiable information in any civil, criminal, administrative, legislative, or other proceeding whether

at the federal, state or local level. This research also 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: ghr.nlm.nih.gov/primer/testing/discrimination

What are the risks of participating?

There is a physical risk related to the blood draw such as pain and bruising around the needle stick. There is a possible loss of confidentiality of personal and medical information. Since every person's DNA is unique, it could be used to identify you. Although there can be no absolute guarantee of security, every precaution will be taken to ensure that your sample and personal health information are maintained in a highly secure place.

Some de-identified data may also be provided to a government health research database for broad sharing to approved investigators. This information will be de-identified and will not contain your name, date of birth, address or phone number. There is a slight risk that there could be a breach in the security of this database resulting in the access of information.

Will people outside of IU Health get identifiable patient information about me? Will people inside of IU Health know who I am?

The only people who will have identifiable information about participants in the Indiana Biobank are staff of the Indiana Biobank. They are bound by all of the privacy and confidentiality rules outlined above, in addition to all internal protections and mechanisms for keeping patient information and biological samples secure and confidential.

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. Participants of the Indiana Biobank may be contacted in the future to see if they would like to learn about this information. Participants who are contacted can tell us that they do not want this additional information. It is important to remember that the information we provide will not include medical diagnoses. If you have questions about this information, you should discuss it further with your medical provider. Furthermore, not all participants of the Indiana Biobank 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.



Indiana University Health

Scan the QR code for more information
or visit iuhealth.org/biobank.

