

Precision Health Consent FAQs for IU Health patients

General Overview

Q What is the IU Precision Health Consent project?

A The IU Precision Health Consent project 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 IU Precision Health Consent project 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 25,000 IU Health patients in 2020 and up to 300,000 over the next five years.

Q What are the benefits of participating?

A The purpose of the IU Precision Health Consent project 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 bio sample, participants will be adding their information to a larger bank of data which can then be used for studies and research.

While participants will not receive any individual results back based on the research done on their sample, they are automatically enrolled in All IN for Health, a program that provides access to health blogs and resources for good health. Additionally, they receive the opportunity to participate in more research studies, including clinical studies. Participants will receive the All IN for Health newsletter, which will provide updates regarding additional research projects. Participants can opt out at any time from receiving the newsletter.

Q What is a biological sample?

A A biological sample is any human fluid or tissue that can be collected for research purposes. In the case of the IU Precision Health Consent project, blood samples are used as these allow researchers to extract DNA and genetic information that is helpful in answering scientific questions like what medicines may work best with which types of genetic makeups.

Q What is the Indiana Biobank?

A The Indiana Biobank collects and securely stores biological samples for the IU Precision Health Consent project 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

Q How do I participate?

A To participate in the Precision Health Consent program, patients at IU Health hospitals (including Arnett, Ball, Bloomington, Methodist, North, Saxony, University, and West,) 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 6,000 IU Health patients have participated in the IU Precision Health Consent project by providing blood samples using a new electronic consent process that has been rolled out in clinical settings, particularly IU Health phlebotomy labs. More information can be found by visiting www.precisionhealth.iu.edu.

Q Who is eligible to participate?

A All adult patients who receive care at IU Health hospitals and associated clinics are eligible to participate in the IU Precision Health Consent project. All adult Eskenazi patients are eligible to participate in the Indiana Biobank, but are not currently a part of IU Precision Health Consent.

Q Will my consent to participate affect my care?

A 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 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.



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Q Can I change my mind?

A 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 inbiobnk@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 317.278.3458.

Q How will my samples be used?

A 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.

Q How long will my sample be stored?

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

Q Is there a fee to participate?

A 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.

Privacy and Security Questions

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

A The Indiana Biobank, which stores all of the biological samples for the IU Precision Health Consent project, 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: <https://ghr.nlm.nih.gov/primer/testing/discrimination>

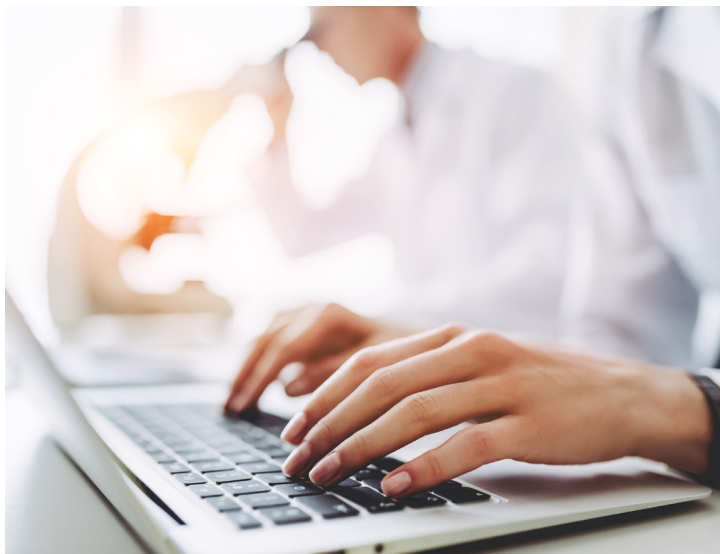
Q What are the risks of participating?

A 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.

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

A The only people who will have identifiable information about participants in the IU Precision Health Consent project 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.



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