

Indiana INGENIOUS Online Recruitment

Informed Consent/HIPPA Authorization

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

A Prospective Randomized Trial to Assess Cost and Clinical Outcomes of a Clinical Pharmacogenomic Program at Indiana University Health

You are invited to participate in a research study entitled "A Prospective Randomized Trial to Assess Cost and Clinical Outcomes of a Clinical Pharmacogenomic Program at Indiana University Health". You were selected as a possible study subject because you have been prescribed or are currently taking one or more of the targeted list of 27 medications listed in the study. Should you agree to enroll in the study, your pharmacogenomic test results will be placed in your medical record and you will have access to results via your "My IUH Portal". We ask that you read this form and ask any questions you may have before agreeing to be in the study. The study is being conducted Todd Skaar, PhD: Associate Professor Medicine at the Indiana University School of Medicine. The study is funded by a grant from the National Institutes of Health.

PURPOSE:

The purpose of this study is to find out how a patient's genes, also called their genetic profile, affect how a medication works in their body. Each individual is different in terms of their genetic profile and these genetic differences can sometimes affect whether the medication works well or causes side effects. Your genetic profile is important to find out because if a doctor knows that your particular genetic profile puts you at an increased risk of a medication side effect, then a different medication can be prescribed. This study is designed to analyze your genetic profile to help find out if one or more of the targeted 27 medications are affected by differences in your genes. In the study, this genetic information will be provided to your doctor so that he or she can make the best decision about which medication to prescribe for you. In addition, the study will also analyze whether the information gained helps to reduce your overall cost of care by reducing the number of side effects caused by medications you are prescribed. This study does not include any new investigational drugs or devices. All laboratory testing will be performed by an approved laboratory. In addition to finding out how a patient's genes affect how a medication works in their body, the specimen collected may also be sent to the Indiana Biobank. Samples sent to the Indiana Biobank will be linked to your personal health information and will be used to help researchers study why some people develop diseases and others do not.

NUMBER OF PEOPLE TAKING PART IN THE STUDY:

If you agree to participate, you will be one of 6,000 who will be participating in this research.

PROCEDURE FOR THE STUDY:

You have been prescribed 1 or more medications that this study will evaluate. Your doctor will be informed if you choose to participate in this clinical study. If you agree to be in the study, you will do the following things. We will draw one small tube of blood from a vein in your arm. The volume of blood drawn will be approximately 1 teaspoonful. This blood sample will then be analyzed in our laboratory to determine your genetic profile. The results of this genetic profile will then be used to find out if one or more of the targeted 27 medications are affected by differences in your genes. The results of this genetic test will be provided to your physician who will then decide whether a change is needed in your prescribed medication.

A portion of your blood sample will also be shared with the Indiana Biobank for future research use. Samples sent to the Indiana Biobank will be identified with your name, date of birth, gender and medical record number. A corresponding case report form will also be sent along with the sample. Information on this form will allow your sample to be linked to your personal health information and used for future, unspecified research. It is impossible to know at this time all of the ways in which the specimen might be used in the future. Examples of studies that may be done include those that test why some people develop cancer or those that try to predict who will develop a particular disease. These studies may also try to find targets for future treatments.

Databases containing sample and medical record information will be maintained and accessed only by authorized staff managed by the Indiana Biobank. Biological samples and health information in the Indiana Biobank will be made available only to medical researchers who have approval to perform research studies. Any research that involves your sample or information will be approved by an Institutional Review Board (IRB) to make sure it is ethical and has the potential to improve health. The Indiana Biobank will release your sample and medical information for research purposes only when a researcher has received approval from the Indiana Biobank and the Institutional Review Board (IRB). The Indiana Biobank will only release de-identified samples and information to researchers. Any information that can be used to identify you will only be known to and kept confidential by the Indiana Biobank staff. Published results from research using your sample will not identify you.

RISKS OF TAKING PART IN THIS EFFORT:

Blood sample: The risks of drawing blood are minimal but include discomfort, bruising and, rarely, infection. To minimize the risks and discomfort only trained personnel will collect blood during this study. If you agree to participate in the study, you may elect to withdraw at any time. If you feel uncomfortable at the time of the blood

draw you may request to withdraw from the study. Blood will be drawn by experienced personnel and whenever possible it will be obtained at a time when blood is being obtained for other tests your doctor has ordered.

Loss of confidentiality is a potential risk as part of your participation. Every effort has been made to reduce this risk. Databases containing sample and medical record information will be maintained and accessed only by authorized staff managed by the Indiana Biobank. Biological samples and health information in the Indiana Biobank will be made available only to medical researchers who have approval to perform research studies. Any research that involves your sample or information will be approved by an Institutional Review Board (IRB) to make sure it is ethical and has the potential to improve health. The Indiana Biobank will release your sample and medical information for research purposes only when a researcher has received approval from the Indiana Biobank and the Institutional Review Board (IRB). The Indiana Biobank will only release de-identified samples and information to researchers. Any information that can be used to identify you will only be known to and kept confidential by the Indiana Biobank staff. Published results from research using your sample will not identify you.

Another risk of your participation is the possible loss of confidentiality of personal and medical information. DNA, which contains the code that identifies you as a person, can be taken out of the blood sample. Every person's DNA is unique. Therefore, it could be used to identify you. Because genetic studies (involving the study of DNA) may be performed on your sample, it is possible that such a loss of confidentiality may reveal information that might affect your life course, employability, or insurability. Although there can be no absolute guarantee of security, every precaution will be taken to ensure that your blood sample and personal health information are maintained in a highly secure place and that no unauthorized person has access to your information.

BENEFITS OF TAKING PART IN THE EFFORT:

The benefits of participating in this study may include a lower risk of medication side effects and possibly better medication effectiveness. A patient's genetic profile affects many commonly prescribed medications. By participating in this study, your genetic profile will be provided to your doctor and then he or she can determine the best medication for you. By performing the genetic testing in this study, the Investigators believe that the participants will experience a reduction in potential adverse events associated with their medications.

ALTERNATIVES TO TAKING PART IN THE STUDY:

Instead of being in the study, you have these options: You may refuse to participate in the study and care and treatment will not be affected.

CONFIDENTIALITY:

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published. De-identified results obtained by this study will be used to help educate healthcare professionals and improve standards of care by analyzing how Personalized Medicine and Pharmacogenetics impact clinical outcomes and overall costs of care.

Researchers interested in Personalized Medicine and Pharmacogenetic Testing may have access to secure databases that contain de-identified participant demographic, pharmacogenetic and healthcare cost data.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, the study sponsor, National Institutes of Health, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) who may need to access your medical and/or research records.

Information from analyses of your coded samples and your coded medical information will be put into databases along with information from the other research participants. These databases will be accessible by the Internet. Your coded medical information and information from more detailed analyses of your coded samples will be put in a controlled-access database. The information in this database will be available only to researchers who have received approval from an NIH Data Access Committee. Please note that traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will NOT be put into either the public or controlled-access databases for this project.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Samples sent to the Indiana Biobank will be identified with your name, date of birth, gender and medical record number. This information will allow the sample to be linked you're your medical record information. Every effort will be made to keep your personal health information confidential. Databases containing sample and medical record information will be maintained and accessed only by authorized staff managed by the Indiana Biobank.

Biological samples and health information in the Indiana Biobank will be made available only to medical researchers who have approval to perform research studies. Any research that involves your sample or information will be approved by an Institutional Review Board (IRB) to make sure it is ethical and has the potential to improve health. The Indiana Biobank will release your sample and medical information for research purposes only when a researcher has received approval from the Indiana Biobank and the Institutional Review Board (IRB). Published results from research using your sample will not identify you.

GENETIC INFORMATION:

This research follows the Genetic Information Nondiscrimination Act (GINA), a federal law which generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or an individual's family members, or using such information for decisions regarding coverage, rates, or preexisting conditions. GINA also prohibits employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment. Furthermore, the researchers have adopted strict privacy and confidentiality procedures for maintaining your genetic information as described in this consent form. You should be aware, though, that if your genetic information were accidentally released to the wrong source, federal law does not protect against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance or by adoption agencies.

COSTS:

Taking part in this study may lead to added costs to you or your insurance company. You or your insurance company will be responsible for the following costs: Costs associated with changes to medications prescribed will be the responsibility of the subject or their insurance carrier. Medication changes based on the subject's specific genotype (as determined by the pharmacogenetic testing performed in this study) will follow FDA, Manufacturer and standards of care for the medications involved you will not be responsible for these study-specific costs: The study will pay for all costs associated with the genetic testing that will be conducted on the participant's DNA sample collected via blood draw.

PAYMENT:

If you were contacted by a research assistant and agree to enroll and participate in the study, you will be compensated after successfully enrolling in the study in the form of a gift card for the sum of \$50.00.

COMPENSATION FOR INJURY:

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled. If you are participating in research which is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

FINANCIAL INTEREST DISCLOSURE:

One or more individuals involved in this research might benefit financially from this study. The Institutional Review Board (an ethics committee which helps protect people involved in research) has reviewed the possibility of financial benefit. The Board believes that the possible financial benefit is not likely to affect your safety and/or the scientific integrity of the study. If you would like more information, please ask the researchers or study staff.

CONTACTS FOR QUESTIONS OR PROBLEMS:

For questions about the study or a research-related injury, contact the researcher Dr. Todd Skaar at (317) 274-2810. If you cannot reach the researcher during regular business hours (i.e. 8:00 AM-5:00 PM), please call the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949. After business hours, please call 317-312-3222 and ask the operator to page the clinical pharmacologist.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

VOLUNTARY NATURE OF STUDY:

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Indiana University Health Systems. If you do withdraw from the study, you may request that your demographic and clinical data and any unused sample be destroyed from the Indiana Biobank. However, data and samples that have already been distributed to approved researchers will not be retrieved.

AUTHORIZATION FOR RELEASE OF HEALTH INFORMATION FOR RESEARCH:

You have the right to decide who may review or use your Protected Health Information ("PHI"). The type of information that may be used is described below. When you consider taking part in a research study, you must give permission for your PHI to be released from your doctors, clinics, and hospitals to the research team, for the specific purpose of this research study.

What information will be used for research purposes?

This form is to allow the release of your health information to be used for the research described above. Your health information includes information that can identify you. For example, it can include your name, address, phone number, birthday and medical record number.

This permission is for health care provided to you from May 1, 2014 through June 30, 2018

I understand the information listed below will be released and used for this research study:

- Hospital discharge summary
- Radiology records
- Medical history / treatment
- Consultation
- Laboratory / diagnostic tests
- EKG report
- EEG report
- Pathology reports
- Operative report (about an operation)
- Diagnostic imaging report

Specific Authorizations:

I understand that this release also pertains to records concerning hospitalization or treatment that may include the categories listed below. I have the right to specifically request that records NOT be released from my health care providers to the Research Team. However, I understand that if I limit access to any of the records listed below, I may not be able to be in this research study.

- Alcohol / Substance abuse
- HIV (AIDS)
- Mental health records
- Psychotherapy Notes
- Sexually transmitted diseases
- Sickle Cell Anemia
- Other

I will contact the study team if I wish to limit the Research Teams' access to these records:

Who will be allowed to release this information?

I authorize the following persons, groups or organizations to disclose the information described in this Release of Information/Authorization for the above referenced research study:

- Indiana University Health/ Riley Hospital/Methodist Hospital/University Hospital
- Indiana University Health Physicians
- Eskenazi Health/Wishard Hospital
- IUMG - Primary Care Physicians
- Eskenazi Health Physicians
- Indiana Network for Patient Care (INPC)

Who can access your PHI for the study?

The people and entities listed above may share my PHI (or the PHI of the individual(s) whom I have the authority to represent), with the following persons or groups for the research study:

- The researchers and research staff conducting the study at Indiana University and IU Health
- Principal Investigator: Todd Skaar, PhD
- The members and staff of the Human Subjects Office
- The members of the Institutional Review Boards (IRB) that approve this study
- Indiana University and/or Indiana University affiliated institutions with compliance and financial oversight, including but not limited to:

Office of Research Compliance
Office of Research Administration

HIPAA Privacy and Security Compliance Office
General Counsel's Office
Internal Audit

US or foreign governments or agencies as required by law
Federal agencies with research oversight responsibilities including but not limited to:
The United States Department of Health & Human Services (DHHS)
Office for Human Research Protections (OHRP)
Office for Civil Rights (OCR)
National Institutes of Health (NIH)
Data and Safety Monitoring Boards and others authorized to monitor the conduct of the study

Expiration date of this Authorization:

This authorization is valid until the following date or event:

When the research ends and required monitoring of the study has been completed.

Efforts will be made to ensure that your PHI will not be shared with other people outside of the research study. However, your PHI may be disclosed to others as required by law and/or to individuals or organizations that oversee the conduct of research studies, and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals. Thus, the Research Team cannot guarantee absolute confidentiality and privacy.

I have the right:

1. To refuse to sign this form. Not signing the form will not affect my regular health care including treatment, payment, or enrollment in a health plan or eligibility for health care benefits. However, not signing the form will prevent me from participating in the research study above.
2. To review and obtain a copy of my personal health information collected during the study. However, it may be important to the success and integrity of the study that persons who participate in the study not be given access until the study is complete. The Principal Investigator has discretion to refuse to grant access to this information if it will affect the integrity of the study data during the course of the study. Therefore, my request for information may be delayed until the study is complete.
3. To cancel this release of information/authorization at any time. If I choose to cancel this release of information/authorization, I must notify the Principal Investigator for this study in writing at: Indiana University School of Medicine, Division of Clinical Pharmacology, 950 W. Walnut Street, Room 402, Indianapolis, IN 46202. However, even if I cancel this release of information/authorization, the Research Team, Research Sponsor(s) and/or the Research Organizations may still use information about me that was collected as part of the research project between the date I signed the current form and the date I cancel the authorization. This is to protect the quality of the research results. I understand that canceling this authorization may end my participation in this study.
4. To receive a copy of this form.

Do you have any questions about the consent form or the study in general at this time?

Yes No

You have indicated that you have questions about the consent form or the study. Please provide your contact information so that the study coordinator can address your questions.

Name

e-mail Address

Phone

SUBJECT'S CONSENT/AUTHORIZATION

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study. I have received (or will receive) a copy of this form for my records and future reference.

Please draw your signature in order to agree to the terms of this consent.

SUBJECT'S CONSENT/AUTHORIZATION

The study team may conduct other studies examining people's opinions or experiences with getting a pharmacogenomics profile. I agree that I may be contacted by the study team about potential future studies about getting a pharmacogenomics profile. At that time, I may choose to be in the future study or not.

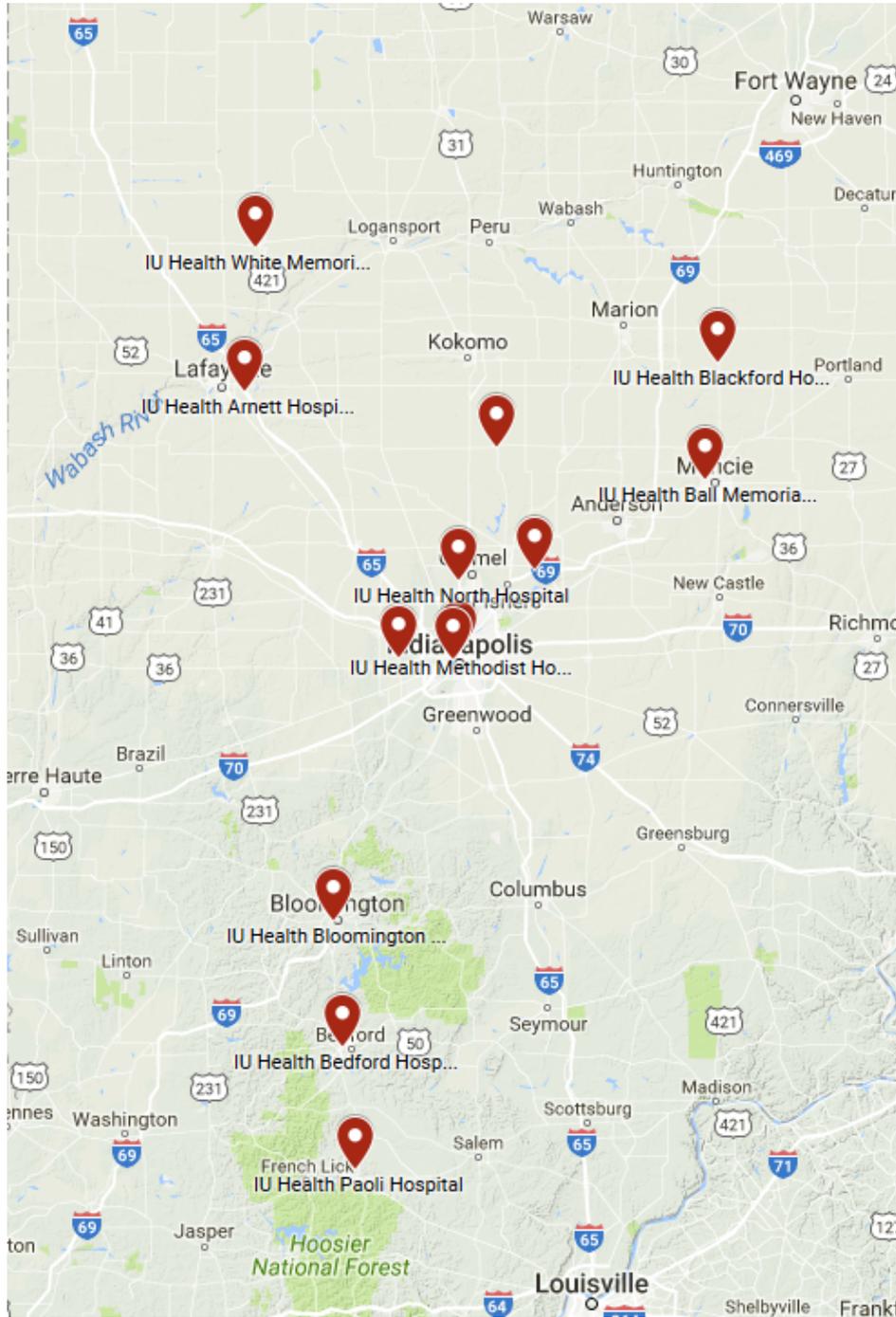
Please draw your signature in order to agree to the terms of this consent.

Thank you for consenting to participate in our study.
You will be sent a completed copy of this informed consent via email.

- I prefer to receive the document via email.
 I prefer to receive the document via regular mail

As part of this study you will be required to go to a participating IU Health facility to have your blood drawn within 5 days of the doctor visit that qualified you for this study. You will be sent a lab requisition form via email that will contain instructions for the hospital staff. Please indicate the IU Health facility you intend to visit for this lab work.

After your blood has been drawn we will process a \$50 subject participant payment that will be mailed to your home address. It will take 7-10 business days in order for a check to be produced before being mailed to you.



IU Hospital Location

- Arnett
- Ball Memorial Hospital
- Bedford
- Blackford
- Bloomington
- Methodist
- North
- Paoli
- Saxony
- Tipton
- University
- West
- White

Please enter your email address

Please re-enter your email address for confirmation.

Please enter your mailing address.

Case Report Form

First Name

Last Name

Middle Name or Initial

Medical Record Number

Date of Birth

Last four-digits of SSN

Phone Number

Birth Sex

 Female Male

What do you consider to be your Ethnicity

- Non-Hispanic/Latino
- Hispanic or Latino
- Prefer not to Answer

What category best describes your race?

- American Indian or Alaskan Native
- Asian
- Black or African American
- More than One Race
- Native Hawaiian or Pacific Islander
- White
- Prefer not to answer

INGENIOUS Questionnaire

1. Attitude
It is a good idea to get genetic testing to find out whether you will respond to a certain medication. (Check one.)
- 5-Strongly Agree
 4-Agree
 3-Neither agree nor disagree
 2-Disagree
 1-Strongly Disagree
2. Sharing.
Do you plan to share test results with anyone? (Check all that apply)
- No
 Yes, with family members
 Yes, with friends
 Yes, with health professionals
 Yes, with others
 Unsure
- Which family members do you plan to share this information with?
- 1.1, Spouse/Partner
 1.2, Parents
 1.3, Children
 1.4, Brothers/sisters
 1.5, Other
- Who else to you intend to share this information with?
-
3. Health Literacy.
How confident are you filling out medical forms yourself. (Check one.)
- Extremely confident
 Quite a bit confident
 Somewhat confident
 A little bit confident
 Not at all confident
4. Information-Seeking Item.
Overall, how confident are you that you could get health-related advice or information when you needed it?
- Extremely confident
 Very confident
 Somewhat confident
 A little confident
 Not confident at all

Biobank Patient Survey

1. The informed consent was provided to me in a way that was understandable.

- Strongly Agree
- Agree
- Neither
- Disagree
- Strongly Disagree

2. I was able to have my questions about the study answered by reading information in written material, by asking someone in person, or by speaking with someone by telephone.

- Strongly Agree
- Agree
- Neither
- Disagree
- Strongly Disagree
- Not applicable, I did not have any questions

Please check any and all of the ways that you feel information could be better provided in order for you to decide whether or not you wanted to participate in the study:

- More information
- In person explanation
- Other suggestions
- No other changes are necessary

Please provide other suggestions

Date Consented

(Please click "Today" button)