INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Precision Medicine to Population Health (P2P)

You are invited to take part in a pilot of a study to better understand how a person's social environment, culture, behaviors, genetic traits and physical environments put a person at risk for certain diseases and impacts their ability to recover. You were selected to take part in this study because you are part of the INresearch.org online volunteer registry and responded that you are available and interested in participating in this research. Please read this form and ask any questions you have before agreeing to be in the study.

The study is funded by Indiana University and being performed by Dr. Bernice Pescosolido at the Indiana University Network Science Institute.

ABOUT THE STUDY

STUDY PROCESS AND GOALS
You are being asked to take part in a research study pilot. Your participation will help us evaluate our processes and refine the questionnaire and procedures to be used in the study. You will be asked questions about your health and lifestyle and to give a saliva (spit) sample. By giving this information, you are agreeing that it can be used in future research studies. We are doing this research study because we are trying to find out more about how genetics and environment affect how and why people become sick and what helps them get and stay healthy. To do this, we will study the question answers, saliva samples and personal health information from Indiana residents. We do not know today what health problems will be important to study tomorrow, so the small amount of saliva you give will be stored and used by researchers at a later time. This sample and your personal health information will be stored in the Indiana Biobank located on the IU School of Medicine campus.

IF YOU TAKE PART IN THE STUDY, YOU WILL DO THE FOLLOWING:

- Give Personal Health Information – You will give your personal health information in two ways: by answering questions and giving researchers the ability to see your medical record. The questions will be asked by a trained interviewer using a tablet computer in the privacy of your home. The questionnaire will take approximately 60 minutes and include questions about your health, behaviors, social networks, illnesses and attitudes.

- Give a saliva sample – Saliva will be collected in one plastic tube provided to you. You will be asked to not drink, eat or smoke for approximately 30 minutes before giving the saliva sample. You will be asked to spit into the tube until the tube is filled to a specific mark, which is approximately 2- 3 tablespoons of saliva. You are allowed up to 15 minutes to fill the tube with saliva, but the tube needs to be closed at 15 minutes.

NUMBER OF PEOPLE TAKING PART IN THE STUDY
If you agree to participate, you will be one of 25 people participating in this pilot and one of 10,000 persons per year taking part in the Indiana Biobank.

LENGTH OF YOUR PARTICIPATION:
The questions and saliva sample collection will take about 2 hours. The saliva sample and related personal health information will be stored in the Indiana Biobank for as little or as long as is helpful for research. If you agree to participate in the study, you are giving your permission to allow your sample and information to be used for research, both now and in the future; however, you can stop taking part in the study at any time.

WHAT WILL HAPPEN TO YOUR SAMPLE

ABOUT THE BIOBANK

Your sample and personal information will be stored at the Indiana Biobank. A "biobank" is a collection of samples and information stored for future research use (kind of like books in a library). Samples from the Indiana Biobank can be “checked out” by researchers, but researchers must first submit an application and the Biobank must approve of their research. Researchers use the biobank to work on health challenges such as finding the causes of illnesses and developing new treatments.

The Indiana Biobank also links your sample to your medical record information. This is all confidential, secure and private. Researchers who access your information through the Biobank will not know who you are. To explain how this works, there are three types of information you need to know about:

1. Biological factors – This is information like DNA, or genetics, that can be learned from your saliva sample.
2. Health information – These are things like illnesses you’ve had, test results, etc. that can be learned from your medical record (the records your doctors keep about your health).
3. Identifying information – This is information like your name, medical record number, or the last four digits of your social security number that can be used to identify you as an individual.

For the biological factors learned from your sample to be most useful for research, your sample needs to be linked to your health information. "Linked" means that both your health information and your biological factors are available to be viewed at the same time. This will greatly increase the usefulness of your sample for medical research purposes because researchers can compare how biological information learned from your saliva may be related to health outcomes learned from your health information (disease risk, body measurements like weight and cholesterol, etc.). Identifying information about you may be used to access your medical record and link it to your Biobank record. This identifying information will not be given to researchers. Researchers who access your information through the Biobank will only be able to see your biological factors and your health information. This means they will not know whose information they have. Any information that can be used to identify you will only be seen and kept confidential by the Indiana Biobank staff.

STORAGE OF YOUR SAMPLE AND ACCESS TO YOUR INFORMATION

Your saliva sample will be labeled so that it can be linked to your health information, both the questions you answer and your medical record. The sample will be stored in a secure, protected place belonging to and managed by the Indiana Biobank at the IU School of Medicine. The sample will be registered and processed by an experienced technician. No information about you will be recorded on the sample itself. Instead, a barcode label will be placed on the tubes containing your saliva sample. This barcode can then be scanned by authorized Biobank staff and your information can be brought up on a secure computer. The barcode is a secure, confidential way to link your sample to your health information. The sample and information will be accessed only by authorized staff at the Indiana Biobank. Biological samples (like your saliva sample) and health information in the Indiana Biobank will be made available only to researchers who have agreed, in writing, to follow all laws and regulations about the use of human biological materials. The researchers will include federally funded researchers and researchers at a variety of organizations, such as universities and drug companies. The researchers will not know that the saliva and health information came from you. Researchers will not be able to ask for a specific person’s information or saliva sample. Instead, they will ask the Indiana Biobank to find them samples from people that fit certain characteristics (for example: Caucasian women age 18-24 who have not had ovarian cancer). Information in the Indiana Biobank will not be used for treatment purposes. Results of any research involving the Indiana Biobank will not be shared with you.

RISKS OF TAKING PART IN THE STUDY

FEELING UNCOMFORTABLE ANSWERING QUESTIONS
Some people may find specific questions sensitive or embarrassing, while others may not. You have the right to refuse to answer any specific question you want.

POTENTIAL LOSS OF CONFIDENTIALITY
By the P2P study and Biobank

The study team will make every effort to keep your information confidential, but there is always some risk of loss of confidentiality of personal and medical information. DNA can be taken out of the saliva sample. Every person's DNA is unique so it can be used to identify you as an individual. Because DNA studies may be performed on your sample, it is possible that if a loss of confidentiality happened, it may reveal information that could affect your life such as employability, or the ability to get health insurance. Although there is no absolute guarantee of security, every precaution will be taken to make sure your sample and personal health information are kept in a highly secure place and that no unauthorized person can see your information. More about the steps that are taken to protect your confidentiality can be found further along in this document.

By a study led by a researcher who is given access to information

Your health information may be used by other studies in the future or may be provided to a government health research database for sharing with approved investigators. This information will not include any information about who you are. It only contains information such as diseases you've had, test results, etc. Researchers call information that can't be traced back to its owner "de-identified" information. You may have heard it called anonymous information. There is a slight risk that that your de-identified information could be leaked if there is a breach in the security of these other studies or the government database system. Safeguards are in place to lower the chance of this happening.

LACK OF CONTROL OVER FUTURE USE OF YOUR INFORMATION
Since we cannot know the exact questions that will be studied by researchers in the future, we cannot tell you what specific studies your sample will be used for. At any time, you may contact the Indiana Biobank to remove your sample from their database. It's important to know that once the Biobank shares your sample with researchers, it cannot be taken back. Researchers who already have your sample will still be able to use it, but it will be deleted from the Biobank so that it will not be there for researchers to use in any future studies.

SALIVA
I agree to provide my saliva sample for the purpose described above (research regarding preventing, treating, and curing diseases).

Please Initial: Yes_____ No _____

BENEFITS OF TAKING PART IN THE STUDY

There is no direct benefit to you for taking part in this study, but this research may benefit the general public. It may help us better understand the cause of illnesses and health conditions like Alzheimer's, cancer, diabetes, arthritis, osteoporosis, and infectious diseases, just to name a few. This research is important for preventing, treating, and curing future diseases.

ALTERNATIVES TO TAKING PART IN THE STUDY

Instead of being in the study you may decide you don't want to and decline. This will not affect your participation in other research studies and it will not affect your health care.

CONFIDENTIALITY

Efforts will be made to keep your survey responses and identity confidential. We cannot guarantee absolute confidentiality. Breaches of confidentiality are minimized by assigning each study participant a unique identification number and using this to identify all study data records. A single linkage connecting the study identification number with each participant's name will be kept in a password-protected database on a limited-access university server. Access to study data records will be given only to individuals who are members of the project research team. Any paper forms will be securely stored in locked cabinets. All personnel who are involved in this research will have successfully completed CITI human subjects training. This training covers protecting the confidentiality of research participants.

We may be forced to give your personal information if required by law. Your identity will not be included in reports of study results or databases in which results may be stored.

Organizations that may look at and/or copy your research records for quality assurance and data analysis include the study investigator and his/her research team, the Indiana University Institutional Review Board or its designees, the study sponsor, 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.

PROTECTION OF GENETIC INFORMATION
This research follows the Genetic Information Nondiscrimination Act (GINA), a federal law that 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 to discriminate against you based on your genetic information. For more information about GINA, you may wish to visit this website: http://ghr.nlm.nih.gov/spotlight/the-genetic-information-nondiscrimination-act-gina

FINANCIAL INFORMATION

COSTS TO YOU
There is no cost to you for participating in this study.

WHAT YOU WILL GET FOR YOUR PARTICIPATION
To thank you for your participation, you will be given a $75 gift card for completion of the questionnaire, and an additional $25 gift card for supplying the one saliva sample.

RESEARCH PRODUCTS
It is possible that a researcher's work that involves your sample may lead him or her to design a product to be sold. If so, please know that you will not share in the profits or losses in the sale of these products.

HOW MEDICAL CARE WILL BE PAID FOR IF YOU ARE INJURED
It is not likely that you will be injured while participating in this study. If you are injured, necessary medical treatment will be provided to you and billed the same way your medical care is usually billed. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to understand what kind of health care coverage you have and what it pays for. There is no program in place for the study to pay for your

medical care if you are injured while participating in the study. However, you are not giving up any legal rights or benefits to which you are otherwise entitled. If you are participating in research that is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher, Dr. Bernice Pescosolido, at **812-855-6256** or the study research director, Dr. Hank Green at **812-855-6005**, or by email at hdgreen@indiana.edu.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or offer input, contact the IU Human Subjects Office at 800-696-2949 or irb@iu.edu.

IT'S YOUR DECISION

Taking part in this study is completely optional. Make sure you understand what you've read in this form before you agree to participate. If there is anything you've read is not clear, ask questions.

ALTERNATIVES TO PARTICIPATING

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 to participate in this study will not affect your current or future relations with Indiana University. If you decide to participate, but later change your mind, you may withdraw permission to use your sample or personal data at any time by contacting the principal investigator, Dr. Bernice Pescosolido at 812-855-6256. You should ask for your sample to be discarded and/or your personal identifiers removed and it will be done. Any research data that has been obtained from your biological sample up until that time will remain part of any research already conducted. Your sample may need to be discarded in the event of unforeseen circumstances such as flood, fire, earthquake, tornado or electrical failure.

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.

I AGREE FOR [GROUP 1] TO SHARE [MY INFORMATION] WITH [GROUP 2] TO USE FOR RESEARCH PURPOSES:

- **GROUP 1**: The Principal Investigator and the Research Team*, treating providers, and hospitals, clinics or other places where I have received treatment
- **MY INFORMATION**: Includes, but is not limited to: information provided by you directly to the Research Team, hospital records and reports; admission histories, and physicals; X-ray films and reports; operative reports; laboratory reports; treatment and test results; immunizations; allergy reports; prescriptions; consultations; clinic notes; and any other medical or dental records needed by the Research Team.
    - **I understand that this release also applies to information about hospitalizations or treatment that may include**:
        - Mental health records
        - Psychotherapy Notes
        - HIV (AIDS)
        - Sexually transmitted diseases
        - Alcohol / Substance abuse
    - 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 these records, I may not be able to be in this research study. I will contact the study team if I wish to limit the Research Teams' access to these records.
- **GROUP 2**: The Research Team*, IU Institutional Review Board and its designees, Research Sponsor and its representatives, Research Organizations, the Department of Health & Human Services or other US or foreign government agencies as required by law.

  * **The Research Team includes**: the Principal Investigator, his/her staff, research coordinators, research technicians and other staff members who provide assistance to the Research Team and the Indiana Biobank Research Sponsor, Lilly Endowment.

I AGREE THAT THIS AUTHORIZATION WILL BE VALID UNTIL THE RESEARCH ENDS AND ALL MONITORING IS COMPLETE.

I UNDERSTAND THAT THE RESEARCH TEAM CANNOT GUARANTEE ABSOLUTE PRIVACY.
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 TO:

1. REFUSE TO SIGN THIS FORM. Not signing the form will not affect my regular health care including treatment, payment, enrollment in a health plan, or eligibility for health care benefits. However, not signing the form means that I will not be able to participate in this research study.

2. 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 this information not be given to me until the study is finished. The Principal Investigator may not grant access to this information if it will affect the integrity of the study data while the study is still in progress. Therefore, I may have to wait until the study is finished for this information to be given to me.

3. CANCEL THIS RELEASE OF INFORMATION/AUTHORIZATION AT ANY TIME. If I choose to cancel, I must notify the Principal Investigator for this study in writing at: P2P study, 410 W. 10th Street, Suite 1000, 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 canceled 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. RECEIVE A COPY OF THIS FORM.

PARTICIPANT'S CONSENT/AUTHORIZATION

I have read the information in this form and had the opportunity to ask questions about what I read. I willingly agree to participate in this research study. I may withdraw from this study at any time without fear of changing the quality of medical care that I may seek or receive in the future from the doctors participating in this study. I have received (or will receive) a copy of this form for my records and future reference.

Participant's Printed Name: _____

Participant's Signature: _____ **Date:** _____
(must be dated by the participant)

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____ **Date:** _____