

Consent to Participate in a Research Study
Longitudinal Pulmonary Vascular Disease Phenomics Program (L-PVDOMICS)
L-PVDOMICS Biobank Consent
Consent for Use of Specimens for Future Research
Study title: L-PVDOMICS Biobank Specimen Banking

Sponsor: National Institutes of Health (NIH), Heart, Lung and Blood Institute, (NHLBI)

PI: XXX

Study Coordinator: XXX

You have been asked to join the Longitudinal - Pulmonary Vascular Disease Phenomics Program (L-PVDOMICS) research study with its separate consent. You are now being asked to allow use of your blood, urine and DNA collected in the L-PVDOMICS study to be used in future research studies. The purpose of this consent form is to provide a written review of the discussion of research information you had with the research team. It is also for use as a reference.

Please note:

- **You are being asked to allow future research studies to make use of your stored blood, urine and DNA collected in the L-PVDOMICS study**
- **Carefully consider the risks of the research**
- **Your decision to participate is completely voluntary**

1. INFORMATION ON THE RESEARCH

Why Are You Being Asked To Take Part In This Research?

You are invited to have your blood, urine and DNA collected by the L-PVDOMICS study to be placed into a biobank to be used in future research studies that are linked to the research data being collected in the L-PVDOMICS study. A biobank is a centralized collection of biological samples and health information that can be used by researchers for future studies in any disease area. The L-PVDOMICS study will maintain your biological samples for use during the study. At the end of the study, any remaining biological samples will be transferred to a central biobank of the L-PVDOMICS study, or to the National Heart, Lung and Blood Institute (NHLBI) Biological Specimen and Data Repository Information Coordinating Center (BioLINCC) biobank.

Joining this part of the study is voluntary. While you will have no direct benefit, there is a potential benefit to society through the better understanding of disease processes or the development of new treatments. You are invited to participate because you have agreed to be in the L-PVDOMICS study. You can participate in the L-PVDOMICS study whether or not you agree to the long-term study's unused samples after the study is over. Once the L-PVDOMICS study is completed and your data and samples have been transferred to the biobank, you may not withdraw your consent for future use of your specimens and data.

Having your biological samples collected during the L-PVDOMICS study and stored is in addition to those collected in the parent PVDOMICS study that you already completed. If you agree to having your biological samples stored that were collected in the L-PVDOMICS study, the samples will be linked to your samples previously stored in the biobank.

Why Is This Study Being Done?

As part of the L-PVDOMICS study, you agreed to have blood, urine and DNA collection for specific purposes related to the goals of the L-PVDOMICS study. At the end of the L-PVDOMICS study, there may be biological samples left over. We would like to put your unused biological samples into a central biobank at a location determined by the leadership at the NHLBI for long-term storage and use in future research. The plans for this future research are unknown.

It is important for you to understand that researchers outside of the L-PVDOMICS study may apply to the biobank for use of your biological samples and related data for any research purpose. These data and samples may be used for studies having to do with pulmonary hypertension, or other medical areas of interest. Also, your stored samples will be linked to your study data to help answer research questions. Researchers who request use of samples and data are required to undergo a review process by NHLBI before any samples or data are released.

How Many People Will Take Part In The Study?

All participants who agree to the L-PVDOMICS study will be asked to participate in the biobank.

What Is Involved In The Study?

No additional tests or biological samples are needed for you to be part of the biobank. We are only asking for your permission to allow us to send the unused samples that were collected as part of the L-PVDOMICS study to the central biobank for storage and future research.

How Long Will You Be In The Study?

Your biological samples will be stored for as long as they are useful to researchers.

2. RISKS AND DISCOMFORTS

What Are The Risks Of The Study?

The main risk of participation in the biobank is accidental discovery of your medical information collected from research, which can mean a loss of privacy.

There are more privacy risks with genetic testing. Because your genetic information is unique to you, there is a chance that someone could trace it back to you even without having your name or other personal information in the biobank. The risk of this happening is very small. It is also possible for genetic tests to disclose family secrets involving paternity or adoption accidentally. There may be other privacy risks that we do not know about.

Your privacy and the confidentiality of biological samples are very important to us, and we will make every effort to protect them, including:

- 1) New random identification numbers (codes) will be assigned to your biological samples prior to going into the central biobank. This coding will stop any linking of the samples with your identity. The L-PVDOMICS Data Coordinating Center at the Cleveland Clinic in Cleveland, Ohio will be responsible for creating the biobank information and will organize the samples going into the biobank. The Data Coordinating Center does not have access to any of your personal information, such as your name, address, phone number, social security number, or e-mail address. There is no link of the central biobank codes to your name or other personal information. Through this process, the data and biological samples will be de-identified.
- 2) Biological samples are only available to researchers under terms and conditions in line with this informed consent document and NHLBI policies. Each request is reviewed in detail. Researchers who are approved to get biological samples are expected to take data protection measures and to respect the privacy of research participants.
- 3) A federal law, called the Genetic Information Nondiscrimination Act (GINA), effective May 21, 2010, generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on genetic information. This law will protect you in the following ways: (1) Health insurance companies and group health plans may not request your genetic information that we get from this research. (2) Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. (3) Employers with 15 or more employees may not use your genetic information from this research when making a decision to hire, promote, or fire you or when setting terms of your employment. This federal law does not apply to companies that sell life insurance, disability insurance, or long-term care insurance and does not protect you against use of this information for an already diagnosed genetic condition or disease.

3. PRIVACY AND CONFIDENTIALITY

Your name and participation in these studies will be held strictly confidential. Your research samples will be identified only by an ID number (not your name). Only the Principal Investigator, XXX, of the L-PVDOMICS study at your site and his or her study coordinator will have access to the numeric code, which identifies you by name. No group health company's or insurance company will ever be allowed to access to the genetic results. These are some things to remember:

Although the genetic information about you is shared with other research investigators in the study, the information will be anonymous: other investigators will be unable to link the results to you.

Results from any research using your biological samples and data may be presented in publications and at professional meetings but no individuals will be identified.

As part of the publication process, genetic results may be placed in databases that are available to other researchers outside the study, but no personal identifying information will be included.

However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- The U.S. Department of Health and Human Services
- The XXX Institutional Review Board or Human Subjects Protection Program
- The National Institutes of Health (NIH), their agents or study monitors

Protected Health Information

The XXX has rules to protect information about you. Federal and state laws also protect your privacy. Generally, only people on the research team will know that you are in the research study and will see your information. However, there are a few exceptions that are listed in this section of the consent form.

Why will this information from your biological samples be used and/or given to others?

- To do the research
- To report the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

Who may use your information from the study?

- XXX research staff involved in this study
- The XXX Institutional Review Board that oversees the research.
- Researchers involved in this study at other institutions
- The National Institutes of Health (NIH)
- The Data Coordinating Center (at the Cleveland Clinic)
- The Observational Safety Monitoring Board (OSMB) for this study
- Future researchers who may request study data or samples from the National Heart, Lung and Blood Institute Biological Specimen and Data Repository Information Coordinating Center (BioLINCC) repository where the study data and samples will be stored when the study is over.

We will use and disclose your information only as described in this consent form; however, people outside the XXX who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

The use and disclosure of your L-PVDOMICS information has no time limit. You can cancel your permission to use your samples in the biobank at any time during the L-PVDOMICS study by contacting the Principal Investigator of this study, XXX at XXX. However, once your samples are sent to the biobank they cannot be withdrawn as they are de-identified.

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4. COSTS

You will not be charged for any costs of biobank storage. There will be no additional compensation for participating in the biobank.

Will the biological samples have commercial value?

The biosamples are owned by the NHLBI and distribution is based on review and determination by the NHLBI. Although biological samples put in the L-PVDOMICS biobank will not be used for commercial purposes (that is, they will not be sold or used for manufacturing of a product), the results from studies done using these samples may lead to a new medical, genetic, drug, or other commercial product. Neither you, nor your family, will be entitled to receive profits from the sales of any products developed directly or indirectly from that research.

5. QUESTIONS

If you have question about your rights as a research subject, you should contact the Institutional Review Board at XXX.

6. VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. Your refusal to participate will not affect your treatment or benefits at XXX. You may participate in the larger L-PVDOMICS study and opt not to participate in the biobank.

7. SIGNATURE

Statement of Participant

I have read the above information and have all my questions answered to my satisfaction. Signing this form does not waive any of my legal rights. By initialing my preference and signing below, I agree to take part in the L-PVDOMICS biobank.

Please indicate your choice by putting your initials next to one of the sentences below:

_____ (initials) I agree to allow my unused biological samples from the L-PVDOMICS study to be put into the L-PVDOMICS biobank and used for future research including genetic testing by researchers who were not part of L-PVDOMICS. The plans for this future research are unknown as of today.

Or,

I do not wish to take part in the L-PVDOMICS biobank by initialing and signing below.

Deleted: _____ (initials) . I agree to allow my unused biological samples from the L-PVDOMICS study to be put into the L-PVDOMICS biobank and used for future research except for genetic testing., The plans for this future research are unknown as of today.¶

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Or,

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_____ (initials) I do not agree to allow my unused biological samples from the L-PVDOMICS study to be put into the L-PVDOMICS biobank and used for future research.

Name of Participant (please print): _____

Signature of Participant

Date (mm/dd/yyyy)

Printed Name and Signature of Person Obtaining Authorization

Date (mm/dd/yyyy)

CONSENT FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

Printed Name of Impartial Witness

Signature of Impartial Witness*

Date

*Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent and any other written information supplied to the subject.

Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance