

## INFORMED CONSENT TO TAKE PART IN A PLM BIOBANK INITIATIVE BIOSPECIMEN COLLECTION STUDY

For more information about the study, please read the research subject information form carefully. If you have any questions, feel free to contact Lauren Kaplan, the study coordinator from our research team at [lauren@patientslikeme.com](mailto:lauren@patientslikeme.com).

**TITLE OF STUDY:** PLM Omics Discovery Biomarker Project  
**INVESTIGATOR:** Renee Deehan Kenney, PhD  
**PHONE NUMBER:** (617) 500-1623  
**SPONSOR:** PatientsLikeMe

### Why is this study being done?

- Researchers at PatientsLikeMe are studying how **biomarkers in blood, urine, and feces** relate to the presence and severity of disease, symptoms, and response to treatments.
- To perform this research, we are asking patients to have a blood specimen, urine specimen, and fecal (stool) specimen collected for the PatientsLikeMe BioBank.
- Collecting these specimens will add to the PLM BioBank, where a portion of your specimen can be securely shared with other researchers and used for future research studies.
- Taking part in this research study is completely voluntary. Your participation may help us better understand, treat, and even prevent diseases that affect others.

### Who is paying for this study?

- PatientsLikeMe is paying to collect samples for the PLM BioBank.

### Who is being studied?

- You are being invited to this study because:
  - You are a member of PatientsLikeMe
  - You read and understand English
  - You are age 18 or older

## What will happen during this study?

- We will collect 50 ml of your blood (5 tubes, about 3 tablespoons total) from you at your home or a place selected by you.
- We will ask you to collect a urine specimen in a container provided by us.
- We will ask you to provide a fecal (stool) specimen in a container provided by us.
- At the scheduled time of collection, a phlebotomist (professional who draws blood) and PLM staff will arrive at the location you select.
- A PLM staff member will review this Informed Consent Form and answer any questions you may have.
- If you agree to participate and sign the Informed Consent Form, the phlebotomist will proceed with the blood collection by inserting a needle into a vein in your arm.
- At the time of the blood draw, you will also be asked about the last time you ate or drank anything.
- A total of five tubes (50 ml, about 3 tablespoons) of blood will be removed and labeled with a code.
- Your urine and fecal (stool) specimens will also be labeled with a code for secure identification.
- All the coded samples will be taken immediately to processing facilities, and then transferred securely to the PLM BioBanking facility.
- If you have blood, urine or fecal (stool) samples that are stored in another biobank, and you have permission to request they be transferred to the PLM BioBank, the PLM staff can assist you in contacting that facility to have those samples sent to the PLM BioBank.
- You may be asked to repeat the specimen collections no sooner than one month but no more than six months after the first sample was collected.
- You may be asked by a PLM staff member to participate in PLM media related activities. If this occurs, you will be presented with a media release form explaining potential PLM media engagements. If you choose to provide media consent, you will have the ability to withdraw your media signature at any

time. In the event you choose to consent to the media release your bio-specimen will remain de-identified throughout the duration of the study. By signing this document, you allow PLM staff to contact you to participate in future media activity.

- You give PatientsLikeMe permission to conduct research studies on your data and on the specimens you provide for as long as PatientsLikeMe keeps your sample.

### **How are my samples and health information stored in the Biobank?**

- Staff at the PLM BioBank will randomly assign a de-identified code (unique identifier) to your samples.
- Your name, PLM user ID, or other information that easily identifies you will not be stored with your samples.
- The key to the code will be stored securely in a separate file, accessible only to key researchers working on the PLM BioBank Initiative.
- The coded samples in the PLM BioBank will be held under secure conditions and accessible only to key researchers at the PLM BioBank.

### **How long will the PLM BioBank keep my samples and information?**

- We will securely store your samples and information indefinitely.

### **What are the potential risks of being in the study?**

- There is the small possibility of minor bruising or bleeding at the site where blood is drawn.
- There is a small risk of light-headedness or feeling faint associated with blood draws.
- It is possible that a participant could be identified using information shared on PatientsLikeMe (and/or combined with your sample or other data sources).
- We will endeavor to minimize any risks by only sharing de-identified information with partners and others.
- As with any online related activity, the risk of a data breach is always possible. PatientsLikeMe takes commercially

reasonable technical precautions to help keep our members' data secure.

- We believe there are small risks associated with this research study. There is a possibility that participants may feel uncomfortable sharing information online.

### **Does being in this study provide any benefit?**

- Participating in this study probably will not provide a direct benefit to you.
- You may receive a newsletter or other information that will tell you about the research discoveries from this or other projects from the PatientsLikeMe BioBank Initiative. This information will not identify you or describe any of your personal results.
- Generally, we will not return individual results from research using your samples and data to you.
- In the future, when research results are published, they may show that certain groups (for example, racial, ethnic, or men/women) have markers that are associated with increased risk of a disease. If this happens, you or others may learn that you are at increased risk of developing a disease or condition; this does not mean that you absolutely will or will not develop that condition.

### **Will it cost me anything to be in this study?**

- There is no cost to you to take part in this study.

### **Will I be paid for being in this study?**

- You will not receive any payment or compensation for your participation in this study.
- PLM will pay for travel and related costs for participants who screen out based on where they live. This is not payment for participation but allows the inclusion of people who would otherwise not be able to participate.

### **Do I have to be in this study?**

- Your participation in this study is completely voluntary and you can withdraw at any time without penalty or loss of benefit. You can choose not to respond to any invitations for biospecimen collection at any time.

- The investigator or the Institutional Review Board (IRB) can also stop your participation at any time (for example, if the study is ended early).

### **Can I stop allowing my samples and information to be stored and used for research?**

- Your participation in this study is completely voluntary and you can withdraw your permission at any time without penalty or loss of benefit. If you do, your samples stored in the PLM BioBank will be destroyed. However, it will not be possible to destroy samples and information that have already been given to researchers. Once a specimen has been analyzed by a researcher, PLM cannot remove your sample or information from their research process.
- You can choose not to respond to any invitations for biospecimen collection at any time.
- The investigator or the IRB can also stop your participation at any time.
- If you decide to withdraw from the PLM BioBank, please contact the PLM BioBank staff by email at [lauren@patientslikeme.com](mailto:lauren@patientslikeme.com), or in writing at:

PatientsLikeMe BioBank Initiative  
160 Second Street  
Cambridge, MA 02142

### **Who will have access to my sample and/or medical information?**

- The research team at PatientsLikeMe, and any research partners working with PatientsLikeMe, will have access to your PatientsLikeMe data and de-identified coded samples that are collected for the PLM BioBank.
- Your coded samples and health information may also be shared with researchers at other institutions or with for-profit companies that are working with PatientsLikeMe researchers.
- Your samples and information may be used to develop a new product or medical test to be sold. PatientsLikeMe researchers and partners may benefit if this happens. There are no plans to pay you if your samples and information are used for this purpose.

- We will not share information that identifies you with researchers outside PatientsLikeMe.
- We may share your samples or your DNA sequence information, your health information, and results from research with other central tissue or data banks, such as those sponsored by the National Institutes of Health, so that researchers from around the world can use them to study many conditions.
- If we publish the results of the research, we will only include de-identified information.
- Your name, or other identifiable information will not be included in any report to partners or any publications or presentations that come from this research.
- We do not release any individual information stored in the PLM BioBank to insurance companies. The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects you from discrimination based on your genetic information. It means that you cannot be denied health insurance or employment based on any genetic test results. The law does not apply to life insurance or long-term care insurance.

### **For what other research might my samples be used?**

- It is not possible for us to list every research project that may be done. Also, we cannot predict all of the research questions that will be important in the future. As we learn more, we may use your samples and information to answer new types of research questions related to human diseases.
- PLM plans to do many types of biological and genetic research with your samples, for example, research on neurological disease, cancer, diabetes, mental illness, or respiratory disease to name a few.
- Genetic research potentially done by PLM may include looking at some or all of your genes and DNA to see if there are links between specific genes and different types of health conditions.
- PLM may create a "cell line" from your sample that will allow researchers to have an unlimited supply of your cells for research.

- PLM may use your cells to create pluripotent stem cells. This type of cell can be used to create different types of tissue, for example, heart, muscle, or lung cells. Your cells might be used in research that alters genes in the cells in order to study different diseases and normal healthy processes. Your cells might be mixed with other human cells, animal cells, or grown in lab animals like mice.
- PLM may share your samples and any cell lines that are created, your DNA sequence information, your health information, and results from research with other central tissue or data banks, such as those sponsored by the National Institutes of Health, so that researchers from around the world can use them to study many conditions.
- PLM may ask you about your experience and attitudes in participating in this type of research and/or in receiving research results back to you in the form of data derived from collected specimens.

**Who do I contact if I have questions about the study?**

- Lauren Kaplan is the coordinator of our study team. For questions, complaints or more information about this research, you may contact her at [lauren@patientslikeme.com](mailto:lauren@patientslikeme.com) or (617) 500-1623.
- If you have questions, complaints or concerns about your rights as a research subject, contact the New England IRB at 800-232-9570 or 617-243-3924 or [info@neirb.com](mailto:info@neirb.com).

We will contact you if there is any new information that might affect your willingness to continue in the study.

“By signing below, I agree that I am at least 18 years old, have read and understood this research subject informed consent form, have had my questions answered, and consent to participate in this research study.”

\_\_\_\_\_  
Signed

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

Consent obtained by:

\_\_\_\_\_  
Signed (PLM Staff consenting)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

## VOLUNTEER'S STATEMENT

I agree that I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. I may contact, Renee Deehan Kenney, if I have any more questions about taking part in this study.

I understand that my participation in this research project is voluntary. I know that I may quit the study at any time without harming my future medical care or losing any benefits to which I might be entitled. The investigator in charge of this study may decide at any time that I should no longer participate in this study.

If I have questions, complaints or concerns about this study or questions about research subjects' rights, I can contact:

**New England Independent Review Board**  
**Telephone: 1.800.232.9570**  
**[INFO@NEIRB.com](mailto:INFO@NEIRB.com)**

By signing this form, I have not waived any of my legal rights.

I have read and understand the above information and authorize the use and disclosure of my private health information. I agree to participate in this study and understand that I will be given a copy of this signed and dated form for my own records.

\_\_\_\_\_  
Study Participant (signature)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Participant's Name

\_\_\_\_\_  
Person who explained this study (signature)

\_\_\_\_\_  
Date