

## INFORMED CONSENT DOCUMENT

Adult Version

**Project Title:** ICTS Precision Medicine Genomic Database

**Principal Investigator:** Laura Bierut, MD

**Research Team Contact:** Patricia Salyer, M.Ed., 314-286-1343

If you are the legally authorized representative of a person who is being invited to participate in this study, the word “you” in this document refers to the person you represent. As the legally authorized representative, you will be asked to read and sign this document to give permission for the person you represent to participate in this research study.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

### **KEY INFORMATION**

This is a research study conducted by Dr. Laura Bierut having to do with creating a database (an information file stored on a computer) that holds genetic testing information. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. Your participation will consist of giving the study information needed to put your genetic data into a database and to link the genetic data to your electronic medical records. The main risk to you if you participate is loss of confidentiality.

We don't expect this study to benefit you directly, but the database will help researchers learn how genetic factors affect health. By volunteering you may help someone else in the future. There is no cost to you and you will not be paid for being a volunteer participant. All of this information will be explained and is listed in more detail in this consent document. The research team must give you a copy of this signed consent document.

**WHAT IS THE PURPOSE OF THIS STUDY?**

This is a research study. We invite you to participate in this research study because you are a current or past patient at a clinic or hospital that is part of Barnes Jewish Healthcare and you have received genetic testing.

The purpose of this research study is to create an electronic database (a computer file) that can link a person’s genetic test results with the information contained in their electronic health record. All of the information from your medical records will be included in this database except your name and any other identifying information. Once enough people are included in this database, it will be a powerful way for researchers to investigate how genetic factors relate to health.

Combining information from genetic test results with health records from many people can provide clues about people’s health and diseases they have or might develop in the future. Doctors and scientists want to do research to find these clues and learn how to use them to improve health.

Genetic testing gives a picture of the makeup of your genes. DNA (or “deoxyribonucleic acid) is the building blocks of genes. Genes provide instructions for things like eye or hair color, height, and sometimes things that affect health. By including your genetic information with your electronic health records with those of many other people, we hope to use genetic research to improve your healthcare.

**WHAT WILL HAPPEN DURING THIS STUDY?**

If you decide to participate and are eligible, you will be asked to sign this consent form and provide the study team with your name, sex, date of birth, address, medical record number and the last 4 digits of your social security number in order to be able to link your genetic data to your electronic medical record. This is the only protected health information that we will collect from you. We will not collect or ask you to tell us about any physical or mental health information.

We will ask you to allow us to include your genetic data in our database. Your genetic data will be renamed using your study ID and then transferred to a secured computer system maintained by Washington University School of Medicine. Your name will not be on your genetic data file.

In the future, a researcher using the genetic database may find that you have genetic mutations that could affect your future health or the health of your children or other family members. If the researcher, together with a panel of other experts, feels that this information is very important for you or your family members to know, we would like permission to contact you or a person designated by you (in the event of your death or incapacitation). Should this happen, the research team will provide you with your findings, resources available to further discuss your findings, and advise you of any steps you can take to address the health risk to you or your family.

If we discover genetic changes that may be important for your health or the health of close family members (for example, your parents, siblings, or children), would you like us to notify you about these results?

           **Yes**                       **No**  
**Initials**            **Initials**

In the event of your death or incapacitation, may we contact your next-of-kin to discuss results of genetic testing performed on your tissues that could affect the health of your children or other family members?

\_\_\_\_\_ Yes      \_\_\_\_\_ No  
Initials            Initials

**Will you collect my social security number?**

You will be asked to provide the last 4 digits of your social security number, which will be retained by the research team. We will use this information to identify you in the electronic health record system. The last 4 digits of your social security number will not be used for any other purpose than to identify your electronic health record and only designated members of the research team will have access to it.

**Will you save my research information to use in future research studies?**

The purpose of this project is to place genetic data and electronic health data from you and many other people in a research database. We would like to use the data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies are expected to provide additional information that will be helpful in understanding genetic diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. There are no plans to provide financial compensation to you should this occur. It is unlikely that what we learn from these studies will have a direct benefit to you. By allowing us to use your data you give up any property rights you may have in the data.

We will remove identifiers from your genetic test data and your electronic health data before placing these data in the research database. Your data will be labeled with an ID number so that you cannot be easily identified. The coded genetic and health information in the database will be shared with qualified medical researchers who have received special permission to use the database in their research. When this occurs, we will not ask you for additional consent for these uses of your data. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for sharing with the research community. If your individual research data are placed in one of these repositories, only qualified researchers who have received prior approval from individuals that monitor the use of the data, will be able to look at your coded information.

If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

**HOW MANY PEOPLE WILL PARTICIPATE?**

Potentially, all patients using the BJH Medical System could take part in this study conducted by investigators at Washington University.

### **HOW LONG WILL I BE IN THIS STUDY?**

If you agree to take part in this study, your involvement will take approximately 10 minutes. There is no long-term follow up in this study; however, once your genetic tests are linked to your medical record information, your genetic and health information may be included in a future study that uses de-identified health information.

### **WHAT ARE THE RISKS OF THIS STUDY?**

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all the safety measures that we will use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other relatives. Consequently, it may be possible that researchers looking at your genetic information could guess your identity based on other genetic information that they might know about your relatives. Similarly, it may be possible that genetic information from you could be used to help identify your relatives.

To make the best use of the data that you and others donate, researchers for this study may share information from the genetic database with other scientists. Summary information (such as how frequently a genetic variant occurs in diabetic patients) may be made freely available to anyone who is interested. Other, more detailed information will remain in a controlled-access database that can only be accessed by scientists at other research centers who have received special permission to view individual-level data. Everyone with whom your data are shared must agree to a Data Use Certification that states they will protect the confidentiality of the data and will not attempt to identify you.

The data developed for this study are being stored without traditional identifiers (for example, stored only with coded ID numbers, no names). However, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.

Some genetic variations can help to predict the future health problems of you and your relatives, As a result, this information might be of interest to employers, health providers, insurance companies, and others. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a blood relative) carry a genetic disease or by leading to the denial of employment or insurance for you (or a relative). Also, patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives. We work to minimize these risks by requiring that individual-level data will only be shared with legitimate researchers who agree to use it only for research purposes and promise not to identify individuals in the shared data.

### **Genetic Research**

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and employers with greater than

15 employees to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long term-care insurance.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled “*How will you keep my information confidential?*” for more information.

### **WHAT ARE THE BENEFITS OF THIS STUDY?**

You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because it is very important that we discover ways to link genetic test results to health care information in order to provide all patients and their doctors with information that will let them live the healthiest life possible.

### **WILL IT COST ME ANYTHING TO BE IN THIS STUDY?**

You will not have any costs for being in this research study.

### **WILL I BE PAID FOR PARTICIPATING?**

You will not be paid for being in this research study.

### **WHO IS FUNDING THIS STUDY?**

This study is funded by Washington University. The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research study.

### **HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?**

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Researchers that have met ethical and privacy requirements as determined by Washington University Institutional Review Board
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Washington University’s Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was

collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will assign a study ID to all the information we collect from you. This ID will be used to label and track your data, instead of using any identifying information. A master list linking the study ID and your identity will be kept separate from the research data. Only the PI and designated members of the research team will have access to the list. Your genetic data will be labeled with a study ID only and will be stored on a password protected, encrypted server.

**Are there additional protections for my health information?**

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, “How will you keep my information confidential?”

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University’s Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

**If you decide not to sign this form, it will not affect**

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

**If you sign this form:**

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at <https://hrpo.wustl.edu/participants/withdrawing-from-a-study/> or you may request that the investigator send you a copy of the letter.

○ **If you revoke your authorization:**

- The research team may only use and share information already collected for the study.
- Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
- You will not be allowed to continue to participate in the study.

**IS BEING IN THIS STUDY VOLUNTARY?**

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, you won't be penalized or lose any benefits for which you otherwise qualify.

**WHAT IF I HAVE QUESTIONS?**

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Patricia Salyer, M.Ed., 314-286-1343. If you experience a research-related injury, please contact: Patricia Salyer, M.Ed., 314-286-1343.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email [hrpo@wustl.edu](mailto:hrpo@wustl.edu). General information about being a research participant can be found on the Human Research Protection Office web site, <http://hrpo.wustl.edu>. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

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This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

**Do not sign this form if today's date is after EXPIRATION DATE: N/A.**

\_\_\_\_\_  
(Signature of Participant)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Participant's name – printed)

Legally Authorized Representative's Name and Relationship to Participant:

**Do not sign this form if today's date is after EXPIRATION DATE: N/A.**

\_\_\_\_\_  
(Participant's name – printed)

\_\_\_\_\_  
(Signature of Legally Authorized Representative)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Name of Legally Authorized Representative - printed)

\_\_\_\_\_  
(Relationship to Participant – printed)

**Who should sign as the Legally Authorized Representative (LAR)?**

If the participant has a legal guardian or attorney-in-fact this individual must sign as the LAR.

If there is no legal guardian or attorney-in-fact the individuals listed below may sign in order of priority.

- (1) Spouse unless the participant has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas;
- (2) Adult child;
- (3) Parent;
- (4) Brother or sister;
- (5) Relative by blood or marriage.

**Statement of Person Who Obtained Consent**

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

\_\_\_\_\_  
(Signature of Person who Obtained Consent)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Name of Person who Obtained Consent - printed)

SAMPLE