MAYO CLINIC

Name and Clinic Number

Approval Date:
Not to be used after:

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Right Drug, Right Dose, Right Time – Using Genomic Data to Individualized Treatment (Right Protocol)

IRB#: 12-003371

Principal Investigator: Suzette J. Bielinski, Ph.D., and Iftikhar Kullo, M.D.

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

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CONTACT INFORMATION

You can contact …	At …	If you have questions or about …
Principal Investigators: Suzette J. Bielinski, Ph.D. Iftikhar Kullo, M.D. **Study Team Contact:** Mayo Clinic Biobank Study Coordinators	**Phone:** 507-538-6916 507-284-6442 Phone: 507-293-0203 1-866-613-2386 **Address:** 200 First St. SW Rochester, MN 55905	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Subject Advocate **(The RSA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information
Research Billing	**Rochester:** (507) 266-5670	▪ Billing or insurance related to this research study

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1. Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you are a Mayo Clinic Biobank participant who lives in Olmsted County and uses Mayo Clinic for your healthcare. We are enrolling 1,000 Biobank participants in this study.

2. Why is this research study being done?

This research is being done to better understand how genetic information can affect medical care of patients.

Genetic information is stored in segments called genes. Each of us has about 25,000 genes that we inherit from our parents. Genes are the instructions that tell our bodies how to grow and develop. Genes are made up of chemical letters known as DNA. There are differences in the DNA between people. These differences are called **genetic variants**.

You are being asked to provide a blood sample so Mayo Clinic researchers can study your DNA to find out if you have genetic variants that play a role in how your body responds to certain prescription drugs. In this study, we are interested in genetic variants that may:

- affect whether some people need a lower or higher dose of a prescription drug
- affect whether some people are at an increased risk of side effects to a prescription drug

By doing this study, we are developing a way to incorporate information about prescription drug related genetic variants into the medical record. Some information about your genetic variants will be put into your medical record so that can be used for your clinical care. Furthermore, we hope to identify new genetic variants related to how people's bodies respond to prescription drugs.

3. What will happen to you while you are in this research study?

When you enroll in this study, you will:

- Provide a sample of blood (about 4 tablespoons).
- Give us permission to put some of your genetic information in your medical record. **If you do not want your genetic information put in your medical record, you should not participate in this study.**

In the future, we will put some genetic information in your medical record. This information falls into three different categories:

1. ***Genetic variants that may affect how your body responds to certain prescription drugs.***

   Only genetic variants that are approved by the Mayo Clinic Pharmacy and Therapeutic Committee will be put in your medical record. This expert committee will approve variants that have been found to be important in determining drug dose and use. Genetic information not approved by this committee will be used for research purposes only and will not go into your medical record.

   It will probably be two years after you sign this consent form before any genetic information is put in your medical record. This is how long it will likely take to run the genetic tests, confirm the results, and develop the best way to put the information in your medical record. The genetic information will not apply to all of the medications you take.

   Your genetic information will be available on your Mayo Clinic Online Patient Account (located at www.mayoclinic.org). If you have questions about this genetic information, you can contact the Center for Individualized Medicine Patient Information Line at 507-XXX-XXXX or 1-866-XXX-XXXX (Toll Free).

2. ***Urgent Clinically Actionable Genetic Variants.***

   This study may find that you have one or more rare genetic variants that you and your healthcare provider should know about. An example of this is a condition called malignant hyperthermia. When people with this condition get general anesthesia, their body temperature rises causing severe muscle contractions. If this happens and they

are not treated, they could die. This could be prevented by using a different anesthesia.

Experts in the Center for Individualized Medicine will decide which genetic variants might require urgent clinical action. If any such genetic variants are found, you will be contacted and your health care provider will be informed at no cost to you. However, any costs associated with the clinical follow-up will be the responsibility of you and your insurance provider.

3. Non-Urgent Genetic Variants.

Through this study we may find additional genetic variants that relate to an increased risk for specific health condition. Again, experts in the Center for Individualized Medicine will identify those genetic variants for which you may be able to do something to improve your health. If any of these are found, you will be contacted and offered the option to learn these results through a free consultation with a genetic counselor. You do **not** have to receive this information. It will be your choice. You and/or your insurance provider will be responsible for any costs associated with clinical follow-up related to this genetic information.

In the future, we also may:

- Occasionally ask you to complete additional questionnaires or be interviewed. You may decide at that time if you want to take part. You can always say no.
- Offer you the option to participate in other studies. You can always say no.
- Ask you for additional blood samples. Reasons for a new sample might include having used up the first sample you provided or to run new tests. You can always say no.

4. How long will you be in this research study?

There is no specific end date for this study. This study will build resources at Mayo Clinic to incorporate genetic information into clinical care. Therefore there is no intention to end the study. You are agreeing to be part of ongoing research surrounding drug related genetic information at Mayo Clinic. At some point in time, the Mayo Clinic Pharmacy and Therapeutics Committee may determine that use of specific genetic variants related to prescription drugs is

part of regular clinical care. At that time, your genetic information may no longer be considered part of research, but instead, part of clinical care.

5. What are the possible risks or discomforts from being in this research study?

Blood Draw Risks: The risks of drawing blood include pain, bruising, lightheadedness, and fainting. Infection at the site of the needle stick is a rare side effect. These are the same risks you face any time you have a blood test.

Confidentiality Risk: As with all research, there is a chance that the confidentiality of your medical information could be compromised; however, we take precautions to decrease this risk.

Genetic Testing: The risks of learning genetic test results may include emotional upset or insurance or job discrimination.

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law.

Be aware that this new Federal law doesn't protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Members of the US military may not have the same protections under this law. More information about GINA can be found at www.ginahelp.org or you can ask a member of the research team to give you additional details about GINA.

6. What are the possible benefits from being in this research study?

This study may not make your health better. The information provided by this research project, may help your health care provider make better prescription drug choices for you. This may help you avoid some prescription drug-related side effects or complications.

7. What if you want to leave this research study?

If you choose to withdraw from this study *before* your genetic information has been added to your medical record:

- no genetic information from this study will be added to your record, and
- you will not be contacted again to provide new information or asked to participate in additional studies related to this project.

If you withdraw *after* some of your genetic information has been added to your medical record:

- your blood sample will be destroyed and no new genetic information will be added to your medical record;
- the genetic information from this study already in your medical record cannot legally be deleted (it will be permanent). However, the interpretation of your genetic information will only be updated as needed to ensure that your healthcare provider has the most accurate and up-to-date information possible;
- you will not be contacted again to provide new information or participate in additional studies related to this project.

If you want to withdraw, contact the Center for Individualized Medicine Patient Information Line at 507-XXX-XXXX, or toll-free at 1-XXX-XXX-XXXX or write to the following address and tell us you wish to withdraw from the study.

Center for Individualized Medicine
ATTN: Notice of Revocation of Authorization for the RIGHT Protocol
200 1st Street SW
Rochester, MN 55905

8. Will you be paid for taking part in this research study?

No, you will not be paid for taking part in this study.

9. What tests or procedures will you need to pay for if you take part in this study?

You won't need to pay the following;

- blood draw
- genetic tests
- consultation with genetic counselor

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles. This includes any follow-up procedures related to your genetic results that may be recommended by your clinician or genetic counselor. If you decide to follow up, any further medical testing will be considered part of your clinical care, and will not be paid for by the research study.

10. Who is funding the study?

This study is funded by National Human Genome Research Institute of the National Institutes of Health, Mayo Clinic Center for Individualized Medicine and Mayo Clinic Center for the Science of Health Care Delivery.

11. What will happen to your blood samples and information?

We will keep your blood sample for future research and possibly at other institutions. If you do not want your blood sample to be used for future research, you should not take part in this study.

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Medical and Genetic Information
It is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases. The information is stored along with information from other studies. Researchers can then study the shared information to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information may be placed into one or more national scientific databases, such as dbGaP. Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. Because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Researchers will always have a duty to protect your privacy and to keep your information confidential.

There is a very small chance that some commercial value may result from the use of your donated sample or information. If that happens, you won't be offered a share in any profits.

12. How will your privacy and the confidentiality be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. All of the written documents you provide will be stored in locked cabinets or scanned into password protected computer files. The information entered into your medical record will also be held to the high standards of confidentiality at Mayo Clinic. Your blood sample will be identified only by a code number.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

Approval Date:
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- 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 or share your health information?

- Mayo Clinic research staff involved in this study.
- Researchers using national scientific databases, such as dbGaP.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other US or government agencies in other countries) that oversee or review research.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy, however once your information is shared outside Mayo Clinic we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection

Name and Clinic Number

Approval Date:
Not to be used after:

ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number, and /or study name, and
- Your contact information.

Your permission lasts forever, unless you cancel it.

ENROLLMENT AND PERMISSION SIGNATURES:

Your signature documents your permission to take part in this research.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	: AM/PM
Printed Name	Date	Time

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Signature