**CONSENT FORM**
**Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals**
**IMAGINE Research Program: Toward Precision Medicine at Baylor College of Medicine**

H-52758 – IMAGINE Research Program: TOWARD PRECISION MEDICINE AT BAYLOR COLLEGE OF MEDICINE

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## Concise and Focused Presentation

The purpose of this research study is to learn more about the genetic and biological causes of different health conditions and diseases. Taking part in this study is voluntary. As an alternative, you can choose not to take part in this study.

If you choose to participate, you will be asked to give us permission to collect and use your samples (e.g., blood or saliva) and data. Samples can be collected from your routine clinical care or through a research visit/research draw. The data from your samples will be linked to the information in your medical record existing now and in the future. The collected samples and information will be stored and available for use indefinitely, or until you choose to withdraw your participation. There are no costs to you, and you will not get paid to participate. If you are a student, participating in this study will not impact academic performance. If you are an employee of Baylor College of Medicine or one of its affiliates, participating will not affect your employment status. While there is no direct benefit to participants, you may receive results about your genetic risk for certain conditions that are of clinical relevance to you or your family that could be impactful to current or future health matters.

The risks to you may include potential bruising or discomfort related to blood draw, learning your genetic testing results may cause emotional distress or uncomfortable feelings, and there is a potential loss of privacy. We take many steps to protect your information, but as with any research study, there is always a chance that your identity could become known. However, the study personnel will make every effort to minimize these risks. You may not get any direct health benefits from taking part in this study. We hope what we learn from this study will help us understand the causes of a range of medical conditions and develop new and more effective treatments.

## Background

If the person being asked to take part in this research study is not able to give consent to be in the study, you are being asked to give permission for this person to be in the study as his /her decision maker. In the following paragraphs, "you" may refer to you or your child/dependent.

You are invited to take part in a research study conducted by Baylor College of

Medicine. Please read this information and feel free to ask any questions before you agree to take part in the study.

We are asking you to take part in a study that aims to understand the biological causes of common and rare diseases. Our study is focused on understanding genetic risk factors for health and disease. Genes are pieces of DNA that provide the instructions for building the proteins that make our bodies work. These instructions are stored in the form of a code, the genetic code. This is the code that you inherit from your parents and that you may pass on to your children.

Mutations are changes in this code that could cause a protein to not be produced or to not work properly. Mutations may make someone more likely to develop a disease or have changes in their physical appearance such as hair or eye color. In some cases, we will also study how these mutations may lead to changes in the expression of genes (RNA) and proteins.

**Purpose**

The main purpose of this study is to understand biological causes (e.g., genetic) and risk factors of common and rare diseases to develop more effective diagnostic tools and new treatments.

If we identify a genetic change (mutation) in you that could affect your clinical care, we may share that information with you.

**Procedures**

The research will be conducted at the following location(s):

- Baylor College of Medicine

**<u>What information will be collected?</u>**

**Basic and Clinical Information**: We will collect basic demographic (e.g., age, sex) and clinical information from your existing and future medical records that is related to your health and/or disease history throughout the course of the study. Some examples include results of tests, medical procedures, images (such as X-rays), and medicines you take. We may look at your medical record from time to time to update this information to inform our research. Additionally, we may request to collect health, demographic, socioeconomic, educational, financial, or other data through the use of optional surveys or questionnaires to inform our research.

**Genetic information**: by participating in this study, you allow us to obtain your genetic information based upon your sample or samples provided for the purposes of research and to potentially help inform of medically relevant findings.

There may be certain situations when the same clinical genetic test we are using for our program and study has been ordered in a clinical setting outside of research. In that situation, by signing this consent form, you would elect to share basic demographics, clinical details (including reports), genetic information, leftover samples and sample information for the purposes of research under our study.

**Study Samples**

Doctor and hospital visits sometimes require patients to give blood samples. We plan to collect blood samples (no more than 20 mL or 4 teaspoons at a time) for research when you are already having blood taken for a clinical visit or during a research only visit or draw. For this study, you give permission for us to collect your blood samples, store them for research, and use some of the blood samples to sequence your DNA.

If we can't collect blood, or if the blood we collect isn't enough, we may collect the next time you come in for a blood draw, request you come in for a research visit, or under limited circumstances, a saliva/buccal collection may be offered.

Leftover samples from standard clinical tests may also be stored and used for research if you consent for this study. By participating, you give us permission to keep these leftover samples for research.

If any tissue will be removed during a diagnostic or surgical procedure you have agreed to undergo as part of your routine medical care, by signing this consent you allow us to use it to study the sample for the purposes of this research. No extra tissue will be taken from you during your surgery for use in this study.

As part of this project, your samples could be used to create cell lines that will keep reproducing and can be used for many research purposes. These cell lines could be shared with qualified researchers but would be coded and not linked to identifiable information for your privacy.

**Who will have access to my samples?**

To facilitate this study, the following types of entities will have access to your samples:

- BCM approved Laboratory and Lab Staff– Genetic testing
- BCM approved Biobank and Biobank Staff– Processing and long-term storage of research samples
- BCM approved Researchers
- Study Coordinators, study technical and ancillary support teams and study Management

We will remove your name and any other information that could directly identify you from your samples before using them for research. We will replace this information with barcodes or alphanumeric codes. We will keep the samples in freezers in locked

buildings at Baylor College of Medicine or with a contracted affiliate. We will keep health information and research data on secure computers that have many levels of protection. Your samples will be kept indefinitely unless you request that they be destroyed.

**What are some examples of genetic results that may be delivered with this program?**

Some examples may include, but are not limited to:

- American College of Medical Genetics and Genomics (ACMG) Secondary Findings, such as BRCA 1 and 2, Lynch Syndrome, Familial Hypercholesterolemia, some limited cardiac conditions, some limited cancer mutations, etc.
- Information that may impact how you respond to certain medications (pharmacogenomics)
- Other genes of importance to the study

**Will I get the results of my DNA analysis?**

Analysis of your DNA can reveal many things about you, including the mutations that have caused the disease that you or members of your family have. Some of the information may be important to your present or future health, some of it may have nothing to do with your health, and for much of it we will not know how it might affect you or your family's health.

Since we will have information on part or all of your DNA sequence, there is the potential for us to discover changes or mutations that put you at risk for diseases that you may or may not currently have. Therefore, this information will only be given to you if the genetic change(s) has/have a clear and known association with serious or life-shortening disease for which risks, a potential treatment, or medical management is available. Additionally, information that can be used for clinical decision-making (such as negative results) may be returned. You may receive new information on your personal genetic risk as new information becomes available.

A one-time, optional genetic counseling visit may be offered to participants with clinically relevant findings under the scope of the study.

**Sharing and Access to Clinically Relevant Identifiable Results**

**The genetic results from this study will appear in your medical record and may be shared with:**

- You or your legally appointed guardian or representative

- Baylor Medicine/Baylor College of Medicine physicians and care teams who have access to your medical record
- Baylor College of Medicine study team
- Baylor Medicine Affiliates or Vendors associated with the research study
- Health Information Exchanges (HIE), with whom you will or may have already agreed to share your health information with. HIE's (including Care Everywhere) are used to enable the ability for healthcare providers, healthcare systems, and organizations to share and receive patient information electronically between systems. Examples include healthcare providers and public health entities. If you have opted out of a health information exchange, the information will not be shared with that exchange.
- Any care providers in which you have chosen to share your individual results with through your own means

Once your result data is part of the medical record (such as results from genetic testing), it remains part of your record. It is subject to Baylor College of Medicine or affiliate medical record policies and HIPAA and accessible for the purposes of our study.

**Clinical Reuse**

Your sequenced genetic information will be securely stored and may referenced and used in the future for additional clinical uses. This means your family doctor or healthcare provider may be able to order additional genetic tests, as they become available, that will reference and use your existing sequenced genetic information without having to provide a new sample. This is termed as "Clinical Re-Use."

Any additional tests ordered by your family doctor or healthcare provider for clinical re-use will require acknowledgement or additional consent before they can be completed and may be subject to insurance or out of pocket costs. This is outside of the scope of the study.

To facilitate the ability to offer clinical re-use of your genetic information in the future, your medical record may be updated to reflect that you have participated in this study and/or your genetic information is available to be re-used for future clinical tests.

**Data Sharing and Future Use:**

Our research study enrollment and operational team members are able to identify who has participated in the study. This enables us to recontact you. For optional or voluntary activities and/or other study opportunities in the future, you may choose to decline participation and your enrollment in this study will not be impacted.

We may recontact participants about additional research opportunities, provide voluntary surveys or questionnaires, ask for additional samples, offer testimonial

opportunities, or obtain data regarding quality of experience. We may use the data collected as part of the program to improve operational processes and initiate quality improvement efforts to establish recommendations for best practices and optimal participant experiences for our study and similar studies generated in the future.

We share limited, identifiable information with our clinical testing partners in order to connect you to your samples/tests. This enables us to return your testing results back to you and/or your healthcare providers as a clinical benefit and enables the ability to conduct clinical reuse.

Examples of information sent to our clinical testing partners include but are not limited to:

· First name
· Last name
· Medical record number
· Date of birth
· Order date
· Other order-related information

**Sharing and Future Research Studies with Identifiable Private Information**
Information that identifies you may be removed from your identifiable private information collected as part of this research, and after such removal, your information may be used for future research studies or distributed to another investigator for future research studies without additional consent/authorization from you.

**Sharing and Future Research Studies with Identifiable Biospecimens**
Information that identifies you may be removed from your identifiable biospecimens collected as part of this research, and after such removal, your biospecimens may be used for future research studies or distributed to another investigator for future research studies without additional consent/authorization from you.

**Genome Sequencing Potential**
Your identifiable biospecimens(s) will be or may be sequenced in whole or in part so that your genetic information can be compared to others' genetic information.

We will not ask you for permission to use your samples or information for these studies. To do more powerful research, 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, where it is stored along with information from other studies. Researchers can then study the combined 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 might be placed into one or more scientific databases.

Your name and other information that could directly identify you will never be placed into a scientific database. There are many different kinds of scientific databases; some are maintained by Baylor College of Medicine or another institution, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called: "dbGaP." A researcher who wants to study the information must apply for permission to use the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are risks associated with data collection and sharing. They are described in more detail in the risks section.

**Sharing of Collected Research Data**
A purpose of this research study is to share your samples and information with qualified researchers to help advance medicine. We may share your samples and information, removed of direct identifiers, with scientists and researchers from Baylor College of Medicine and its affiliates, other universities, governments, hospitals, health related companies, including for-profit companies, or research institutes throughout the world.

Examples include:

- Baylor College of Medicine and its affiliated clinicians, providers and entities participating in the research
- Baylor College of Medicine, including any entity or contractor engaged by BCM to support the research
- Baylor College of Medicine sample collection, sequencing, interpretation, and biobanking partners
- Individuals and entities with access to publicly accessible research databases into which the study data are placed
- Federal and state agencies or other domestic government bodies if required by law and/or necessary for oversight purposes. A representative from the FDA may review your medical records
- Hospital accrediting agencies
- The Institutional Review Board

**Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study**

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning alcohol abuse
- Specific information concerning drug abuse
- Specific information concerning sickle cell anemia
- Specific information concerning psychiatry notes
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Identifiable biospecimens
- Genetic testing result information
- CPT codes and medical billing information

**Use or Disclosure Required by Law**

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations, or interventions.

Baylor College of Medicine is required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research does not involve treatment. Baylor College of Medicine may not condition (withhold or refuse) treating you on whether you sign this Authorization.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, data coordinating center may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of

the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must email the study team at AskIMAGINE@bcm.edu.

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

**Potential Risks and Discomforts**

The risks of a blood draw include pain, anemia, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.

There is a risk of loss of private information. This risk always exists, as with any research study, but there are procedures in place to minimize the risk. The information, as well as the specimens stored for the purposes of the research, does not contain your name or other direct identifiers, they will be coded. Further, all data is stored on secure, password-protected servers following Baylor College of Medicine policies and procedures.

The use of large databases, especially of genetic data, increases the privacy risks and has additional risks:

- Privacy Risks - Your name and other information that could directly identify you (such as email or phone number) will not be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. This loss of confidentiality has been growing across industries. Since the database includes genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. If your private information was misused it is possible you would also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

● Insurance Risks: 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 most larger employers 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.

● Genetic Testing Risks: Results that our expert team believes are medically relevant may be shared with you or your healthcare providers. Learning your genetic testing results may cause emotional distress or uncomfortable feelings, as some individuals may not have symptoms and are unaware of their genetic risks.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

**Potential Benefits**

You may receive no direct benefit from participating. Research done with the samples and information may lead to a better understanding about disease and what can be done to prevent or treat disease. If you receive medically important genetic results, you and your family may benefit by learning about the increased risks of the associated medical condition and learning information that would help guide choices regarding preventative or clinical care of the associated medical condition.

**Alternatives**

You may choose to not participate in this study.

**Subject Costs and Payments**

You will not be asked to pay any costs related to this research and you will not be paid for taking part in this study.

Study-related sample collection (including DNA testing) and laboratory processing and analysis will be covered as part of the study.

A one-time, optional genetic counseling visit may be offered to participants with clinically relevant findings under the scope of the study. If you have clinically relevant findings and are not currently under the care of a primary care physician or clinical geneticist, Baylor Medicine may offer the opportunity to establish care with a Baylor Medicine physician or affiliate. This would allow you to follow-up on clinically relevant findings related to this study. Any follow-up care resulting from the genetic counseling visit or that occurs after the genetic counseling visit will be considered outside of the scope of the study and are billable to you or your insurance through normal clinical or hospital billing practices (this includes but is not limited to: diagnostic testing, physician office visits, etc.).

This institution may use your biospecimens (even if identifiers are removed) for commercial profit, however, the institution does not plan to pay royalties (share with you

in the commercial profit) to you if a commercial product is developed from any biospecimens (blood or tissue) obtained from you during this study.

**Subject's Rights**

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be able to access the consent form to review at any time. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time.

Please contact the study staff at askIMAGINE@bcm.edu if you decide to withdraw or stop taking part in this study.

If you request to withdraw from the study, your samples collected or obtained for the purposes of this study will be destroyed. However, if your data was already used for the purposes of a research dataset, we may not have the ability to remove your data because it is already removed of your direct identifiers.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, RICHARD GIBBS, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: 713-798-8870 or email askIMAGINE@bcm.edu.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

***FOR REFERENCE ONLY***

**Agreement to be in the study**

By signing your name below, you agree to be in this study and acknowledge and agree to the terms and conditions in the above consent form and in summary, agree to the following:

1. You acknowledge you have been given the opportunity to fully read this form and ask any questions
2. You attest to being at least 18 years or older
3. You agree to fully participate in the study and share your samples and information as outlined above
4. You authorize that your information may be used as part of the databases we create for the study and acknowledge that we will remove information that can directly identify you when we create datasets for researchers
5. You give us permission to store your research samples and left-over clinical samples for future research
6. You agree to have your genetic information transferred to your medical record, indicated in your record, and may be shared with other health systems and entities
7. You agree that Baylor College of Medicine may contact you for future research and information relating to your health
8. All rights and obligations herein may be transferred by Baylor College of Medicine to any successor organization.

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Subject Printed Name

_____

Subject Signature

_____

Legally Authorized Representative Signature (if applicable)

_____

Date