

**CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION**

Sponsor / Study Title: Myriad Genetics, Inc. / “Myriad Collaborative Research Registry™ (MCRR)”

Protocol Number: ONC-013

Principal Investigator: Jeff Jasper, Ph.D.

Contact: MCRR@myriad.com

KEY INFORMATION

You are being asked to participate in a registry at Myriad Genetics, Inc. (MGI). A registry collects information (data and samples) about a group of individuals. In this registry, information will be collected about patients who receive genetic testing during routine clinical cancer care. The main purpose of this registry is to create a resource to enable researchers to see how information gathered from your genes relate to cancer treatment and management. If you agree and sign and date this consent form, your information (data and samples) collected from the genetic test will be stored for current and future genetics research. The information will only be used in a de-identified fashion, meaning your specific identity will not be known to those evaluating the data or samples.

An investigator involved with this registry has an ownership interest in MGI, the company sponsoring this research study. Please speak with your medical provider if you have questions about this.

PURPOSE AND PROCEDURES

If you consent to participate, enrollment into the registry will occur after your genetic test is ordered during routine clinical cancer care. MGI is asking for your permission to retain any residual genetic samples and data collected for research purposes.

All living things are made of cells. Genes are the part of the cells that contain the instructions which tell our bodies how to grow and work and determine physical characteristics such as hair and eye color. DNA and RNA are materials that make up your genes. Residual samples refer to leftover genetic material obtained from the samples you provided for the genetic test.

MGI may collect the information below from you, your medical provider, the test request form for the genetic test, clinical laboratory databases, or third-party databases.

- **Personal cancer history:** Age at time of diagnosis, cancer type, and information about what the cancer looks like clinically

- **Previous cancer management:** Information about your cancer treatment, any changes to your treatment, and the reason for change
- **Family cancer history:** Information about whether your family members have a history of cancer or not
- **Results of molecular testing:** Information about tests you have and the results of those tests
- **Clinical outcomes:** After receipt of test results, follow-up information regarding your treatment plan and your health
- **Demographic information:** Personal information, such as your name, date of birth, race and ethnicity

CONFIDENTIALITY

Genetic samples will be securely stored at Myriad Genetic Laboratories, Inc. (“MGL,” an affiliate of MGI) and may be stored at a third-party location. Data will be securely stored in MGI’s commercial database and third-party locations that have been reviewed and approved by MGI. Your residual samples and data will be stored for an unlimited amount of time and will be coded, which means that your name or other identifying information will not be connected to it.

Data and any residual samples will be used by MGI and others for future research studies. If other researchers request samples or data, the sample and data will be labeled with a code number instead of your name. The coded samples will not be linked to any personal identifiers (for example, name, address, phone, and/or email). MGI will keep test results confidential and is in full compliance with all Health Insurance Portability and Accountability Act (HIPAA) regulations.

Researchers may share what they learn with other health professionals and scientists through research publications, but your information will be completely de-identified. Additionally, de-identified samples and data from this study may become available to researchers through controlled-access public databases. Information that could directly identify you will never be included. Researchers who want access or study the information must apply to the database separately.

COSTS

There are no additional costs to you for participating in this registry. Also, you will not be paid for being part of the registry.

FUTURE GENETICS STUDIES

If you consent to this registry, your residual genetic samples and data will be stored for an unlimited amount of time. These samples (for example, DNA, RNA) will remain frozen at MGL or at a third-party location, and may be tested in future genetic studies (but only after removal of information that could identify you as the source of the material, as described above under “Confidentiality”). Future research on your sample may include projects like sequencing of all of your DNA. This is called whole genome sequencing (WGS). WGS provides complete genetic information that is unique to you. MGL will keep your sample until it is all gone, becomes

unusable, or until they decide to discard the sample. If your sample remains stored beyond your lifetime, your sample will be used as described in this document.

If there is a commercial product developed as a result of the testing done in this registry, you will not be paid for the use of your information.

You may be contacted by MGI in the future by phone or be invited to participate in future research studies. These communications may be unsecure and carry typical risks associated with such transmissions. By agreeing to testing and signing this consent, you agree that (a) you understand the foregoing and understand the typical risk of email, SMS and text message transmissions, and (b) you give Myriad permission to communicate with you by email, SMS, or text message.

RESULTS OF GENETICS STUDIES

Knowledge of how genes and other factors affect health and disease is gathered by studying groups of people. This registry is not meant to test your individual medical status but is for research only. Therefore, MGI will not provide you with the individual results of any future research done on your sample(s) for this registry. However, you will continue to receive genetic results as part of your standard clinical care. If you have any questions about whether any other genetic tests would be useful to you, please ask your medical provider.

RISKS AND BENEFITS OF GENETICS STUDIES

There are no specific risks or benefits associated with participating in this registry. MGI has taken steps to safeguard your genetic testing information, so the risk of loss of confidentiality is small. However, if confidentiality is broken, results of genetic testing may become available. In the rare situation where this may occur, the knowledge of this information has the potential to lead to discrimination in employment or insurance. Because they are regarded as a health risk and, therefore, an economic risk, someone with a known genetic condition indicating a susceptibility to develop a disease or condition might be denied a job, or denied health or life insurance. Carriers for a genetic disorder might be discriminated against (for example, viewed as having the potential to have a child with a genetic condition). There may be other risks that are unknown.

There is a federal law, called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans and most 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.

NEW FINDINGS

New important information, surrounding issues related to subject data, privacy, and/or confidentiality that may influence your willingness to continue participation in the registry, will be provided to you.

ALTERNATIVE TO PARTICIPATION

This registry is for research purposes only. The only alternative is to not participate in this registry.

WITHDRAWAL OF SAMPLES AND DATA FOR GENETICS STUDIES

You have the right to withdraw your consent at any time and may request that data and samples you give to MGI and MGL be destroyed. If you choose to do so, please refer to MGI's Privacy Policy, accessible online, for more information. Although you are free to withdraw your consent, it is possible the samples may have already been used for research purposes and data derived from such research will not be destroyed. In that event, MGI will promptly destroy any remaining samples and data that are identifiable. Also, there is a possibility that samples and data cannot be destroyed if they have already been de-identified because there will be no way of linking the sample to you.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this registry, your medical provider will use and share health data about you. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your medical visits, including all test results, personal cancer history, previous cancer management history, and clinical outcomes.

Health data may come from your medical provider, the test request form, clinical laboratory database(s), and/or third-party database(s).

For this registry, study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of MGI, its subsidiaries (for example, MGL), and third parties.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

This authorization does not have an expiration date. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign and date this document. Your permission to use and share health data about you will last until the Precise treatment registry is finished unless you revoke it (take it back) sooner. You may revoke (take back) your permission to use and share health data about you at any time by writing to the Investigator at the address listed on the first page of this form.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your participation in this registry is voluntary. You can decide not to be in the registry, and you can change your mind about being in this registry at any time. If you decide not to take part in this registry, there will be no penalty to you, and you won't lose any benefits. MGI can stop your participation at any time without your consent.

WHOM TO CONTACT ABOUT THIS STUDY

During the registry, if you have questions, concerns or complaints about the registry such as:

- Eligibility to participate in the registry;
- Subject privacy and confidentiality;
- Future use of your Protected Health Information (PHI) and samples collected, as applicable;

Please contact MGI at the email address listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:
Study Subject Adviser
Advarra IRB
6100 Merriweather Dr., Suite 600
Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser:
Pro00061430.

Consent to Take Part in the Myriad Collaborative Research Registry™ (MCRR) and Authorization to Use and Disclose Health Information for Research

When you sign and date this form, you are agreeing for MGI, its subsidiaries, and third parties to retain your residual genetics sample and all data as described in this consent form. You are also agreeing to let MGI use and share the health information collected as part of this research as explained above. This means that you have read this consent form and you have decided to volunteer. A copy of this form will be available to you for your records.

Additionally, by signing and dating this form, you acknowledge the following statements about the use of data and residual samples in future research studies:

- De-identified information that may be used will not require re-contact for future research.
- Identifiable information that may be used will require re-contact for future research, and you agree for MGI (or other researchers) to contact you.