

**Emory University School of Medicine**

**Department of Human Genetics**

**JScreen Program**

**Consent to Participate in the JScreen Program (dated \_\_\_\_\_)**

This form includes your consent to participate in the JScreen Program; a description of the JScreen Program; and the benefits, risks, and limitations of participating in the JScreen Program.

**Description of the JScreen Program**

JScreen is a genetic screening program within Emory University School of Medicine's Department of Human Genetics (the "JScreen Program" or "JScreen"). JScreen offers two types of genetic testing: reproductive carrier screening for individuals who are planning to have children and cancer genetic testing for individuals who are interested in learning about their risk for hereditary cancers. Your participation in the JScreen Program is voluntary. The purpose of the JScreen Program is to provide education and access to genetic screening to individuals residing in the United States. The personal and medical information you entered in the JScreen Program website will be reviewed by JScreen genetic counselors and staff, and your questions will be answered by JScreen genetic counselors or staff, or its contractors. If applicable, an ordering healthcare provider licensed in the state within which you reside will review your personal and medical information and, if appropriate, transmit an order for genetic testing and counseling to JScreen. JScreen will then transmit the test order with your personal and medical information and your insurance information (if applicable) to an independent testing laboratory or laboratories (the "Laboratory").

Upon receipt of a valid physician order (if applicable), JScreen will send you a collection kit(s) containing instructions for specimen collection. You will return your specimen(s) to the independent testing Laboratory for analysis, and the Laboratory will provide your genetic test results to JScreen. You will have the opportunity to speak with a genetic counselor from JScreen, its contractors or the Laboratory to discuss your test results. After the entire process is complete, JScreen will provide you with a copy of the test results. As required by law, JScreen will also forward a copy of your genetic test results to the healthcare provider who ordered the testing on your behalf.

The JScreen Program is funded in part by grants and donations from multiple sources. You may contact JScreen if you want additional information about funding of the JScreen Program. Your information may be included in de-identified aggregate data released to these funding sources. This information may include, but is not limited to, demographics, the total number of participants screened, the total number of participants screened as positive carriers, and the total number of participants referred to and completing genetic

counseling. JScreen may publish information about the JScreen Program that includes this de-identified aggregate data.

JScreen services are provided by individuals residing in various states throughout the United States and may involve the use of telemedicine as defined by the state in which the patient resides.

JScreen's genetic counseling and testing services are subject to the following conditions:

- (a) do not constitute treatment or diagnosis of any condition, disease or illness;
- (b) do not replace traditional genetic counseling
- (c) do not replace the existing primary care or other relationship of a Participant with his/her physician;
- (d) does not replace medical advice from a physician;
- (e) JScreen genetic counselors, under the supervision of a physician, are providing advice and consultation based strictly on a Participant's test results and such advice and consultation shall not constitute a treatment decision.
- (f) JScreen is not responsible for recommending or arranging for follow-up services or additional testing, diagnostic, care or treatment, which is your responsibility to pursue with your personal healthcare provider.

If you have a personal medical history, a medical condition, or family history that you are concerned about, you should also discuss your concerns directly with your healthcare provider.

You consent to the genetic counseling and genetic testing as offered herein and you consent to participate in the JScreen Program as described herein.

### **Consent to Release Test Results and Protected Health Information**

JScreen's purpose is to facilitate genetic screening by providing you with pre-test education about screening and helping you through the process of being screened and learning your results. As an integral part of this process, information must be transferred to multiple individuals in a HIPAA-compliant, secure manner. The persons or entities to whom the test results may be disclosed are listed in this Consent form. Taking part in the JScreen Program may or may not benefit you personally. We may learn new things that will help other people who have genetic conditions. Possible benefits include gaining access to genetic screening and genetic counseling services and learning about your personal and/or reproductive health risks.

The conditions included in the JScreen reproductive carrier screening panel vary in their severity and age of onset, with most having early onset and a severe clinical course. The

diseases on the screening panel include conditions common in the Ashkenazi, Sephardic and Mizrahi Jewish populations, and others common in other ethnic groups or in the general population. A complete list of diseases on the panel can be found at [www.jscreen.org](http://www.jscreen.org).

The JScreen cancer panel includes genes associated with a wide range of hereditary cancers. Each gene differs in the types of cancer with which it is associated, and the degree of risk it conveys. A complete list of diseases on this panel can be found at [www.jscreen.org](http://www.jscreen.org).

By signing this Consent form, you authorize and consent to allow the employees and agents of JScreen, the independent testing Laboratory, Emory University and the ordering healthcare provider to release your personal and medical information, genetic test results and/or genetic counseling information to:

- Your email address
- The JScreen Program staff and medical director
- The testing Laboratories and their subsidiaries
- CancerGene Connect, a website for collecting family history information, for individuals registering for the JScreen cancer genetic testing
- Your personal healthcare provider, when applicable, and the ordering healthcare provider, if different than your personal healthcare provider
- Your partner, if applicable, and when you provide specific consent
- Your insurance company and any other third-party payors, if applicable

### **Risks**

Risks associated with sample collection include dry mouth during saliva collection, and possible pain and bruising related to drawing blood, if applicable. In addition, risks could include anxiety or other potential psychological impacts related to test results.

While every effort will be made to protect your test results, medical and personal information, and protected health information as defined by HIPAA (collectively “PHI”), the JScreen Program cannot completely guarantee that your PHI will not be released. The party to whom your information is released may be able to further release the information without your consent or authorization.

If you decide to update your reproductive carrier screening and/or cancer screening in the future, your insurance plan may deny coverage.

In some families, DNA testing may discover non-paternity or some other previously unknown information about family relationships.

### **Alternate Treatment**

You may choose to seek genetic testing from the testing Laboratory or from a different laboratory without participating in the JScreen Program. Contact your personal healthcare provider for information on coordinating testing outside of the JScreen program.

### **Compensation**

You will not be compensated for your participation or any injuries sustained by you in connection with your participation in the JScreen Program.

### **Cost**

You are responsible for paying a program fee to JScreen when you register for your screening kit. This program fee covers your costs associated with the testing and genetic counseling services. The testing Laboratory may bill your insurance, if applicable. You will not be responsible for any additional out-of-pocket payments to the JScreen Program or to the Laboratory once the JScreen program fee has been paid and your insurance has been billed, if applicable. Should you need to use your personal healthcare provider to order the genetic testing and counseling, you are responsible for payment of the healthcare provider's routine charges.

### **Specimen Use**

You consent to the examination, use and disposal by the testing Laboratory of your saliva or blood specimen(s) that may be obtained from you as part of the JScreen Program. See the laboratory consent form(s) for information related to use of your specimen.

### **Limitations**

The JScreen Program, Emory University and their funding sources are not responsible for the testing, outcome, reliability or validity of your genetic laboratory screening test. By enrolling in the JScreen Program, you acknowledge that you are entering into a relationship with the testing Laboratory to undertake and provide the genetic testing. The testing Laboratory is a separate corporate entity from JScreen and Emory University. JScreen and Emory University are not responsible for the actions or the testing performed by the independent testing Laboratory.

### **Release of Genetic Testing Information**

The Genetic Information Non-Discrimination Act ("GINA") is a federal law that prohibits discrimination in health coverage and employment based on genetic information of individuals. GINA, together with already existing non-discrimination provisions of the federal Health Insurance Portability and Accountability Act, prohibits most health insurers or health plan administrators from requesting or requiring genetic information of an individual or an individual's family members, or using such information for decisions

regarding coverage, rates, or pre-existing conditions. GINA also prohibits most employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment. The following is a brief description of the coverage and limitations of the GINA statute:

- GINA discrimination protections apply to health insurance coverage and employment decisions only.
- GINA's provisions prohibiting discrimination in health coverage based on genetic information do not extend to protect decisions made by companies or entities regarding the availability to any applicant for life insurance, disability insurance or long-term care insurance.
- GINA discrimination protections in employment on the basis of genetic information do not apply to employers with fewer than 15 employees, U.S. Military, or employees of the federal government.

For more information, go to [www.GINAhelp.org](http://www.GINAhelp.org)

### **Telemedicine**

You consent to and authorize JScreen to provide services by use of telehealth or telemedicine modalities, such as via telephone, real time audio/video transmission or any electronic or fiber optic transmission of your medical information. You may withdraw your consent to the use of telemedicine at any time by contacting the JScreen staff. The potential risks or consequences of using telemedicine or telehealth may include: a potential failure of transmission of your medical information during or after the telemedicine session; transmission to an incorrect address; interception of the information by an outside entity resulting in a data breach; insufficient information to allow for appropriate clinical decision making; delays in communications due to deficiencies or failures of the electronic equipment; or, in rare instances, failure of security protocols causing a breach of privacy of personal identity or medical information. Emory University owns and operates the website and may contract with third parties for the modalities used to engage in telemedicine. The transmission of confidential medical information while engaged in telemedicine is subject to all applicable federal and state laws with respect to the protection of and access to confidential medical information.

### **Confidentiality of Your Health Information**

Any information obtained as a result of your participation in the JScreen Program will be kept as confidential as legally possible. A copy of your signed Consent form will be retained by Emory University and will be subject to Emory University's confidentiality policies. Nevertheless, Federal laws require that your privacy, security, and unauthorized access to your health information be protected.

**Agreement to Alternative Dispute Resolution**

I agree that any claim or dispute arising out of or related to the provision of health care services to me by Emory University, except as otherwise provided herein, shall be resolved by final and binding arbitration. I agree that this provision is governed by the terms of the Federal Arbitration Act. I understand and agree that this agreement includes and encompasses any claims arising out of or relating to health care services which shall be provided to me upon this admission as well as all health care services provided to me by JScreen and Emory University in the future, provided, however, that this agreement does not include and encompass any claim or dispute by either party arising out of or related to the billing or payment for health care services. I understand that this agreement is also binding on any individual or entity claiming by or through me or on my behalf. I understand that this agreement is voluntary and is not a precondition to receiving health care services. The arbitration of any claim or dispute hereunder shall be conducted in the State of Georgia in accordance with the Rules and Procedures of Henning Arbitration and Mediation Services, Inc., a copy of which is available to me upon request. I understand that I have the right to revoke this agreement no later than ten (10) days following signature and that, if I choose to revoke, I must request and execute a revocation form within this time period.

By signing below, I verify that I am the person who will submit a sample or samples for testing. I agree to the JScreen program consent guidelines. (Electronic signature must match your first and last name.)

Signature: \_\_\_\_\_ Date: \_\_\_\_\_