

**Emory University School of Medicine**

**Department of Human Genetics**

**JScreen Program**

**Consent to Participate in the JScreen Program (dated 3/29/2017)**

This form includes your consent to participate in the JScreen Program, and 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 carrier screening program within Emory University School of Medicine's Department of Human Genetics (the "JScreen Program" or "JScreen"). Your participation in the JScreen Program is voluntary. The purpose of the JScreen Program is to provide education and access to genetic carrier 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 to an independent testing laboratory.

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

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 test and genetic counseling services. The independent testing laboratory will 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.

The JScreen Program is funded in part by grants and donations from multiple funding 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.

The JScreen Program is NOT intended to replace traditional genetic counseling. If you have a personal medical history or family history that you are concerned about, you should 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 carrier 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 providing access to genetic screening, learning about your risk of having a child with a genetic condition, and providing access to genetic counseling services.

The conditions included in the JScreen 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).

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

- Your email address
- The JScreen Program staff and medical director
- The testing laboratories
- 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
- Other at risk family members, if applicable, and when you provide specific consent
- Other genetic counselors or healthcare providers to which JScreen refers you. These JScreen referred providers are authorized to provide information back to the JScreen Program regarding the outcome of the referral.

### **Risks**

Risks associated with sample collection include dry mouth during saliva collection, possible pain and bruising related to drawing blood, if applicable, and anxiety regarding 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.

### **Alternate Treatment**

You may choose to seek genetic testing for the same diseases directly from the testing laboratories 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 test and genetic counseling services. The testing laboratory will 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, the healthcare provider’s routine charges would apply.

### **Specimen Use**

You consent to the examination, disposal and use by the testing laboratory of your saliva or blood specimen that may be obtained from you as part of the JScreen Program. See the laboratory consent form 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 working with JScreen, 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.

The testing laboratory uses a sequencing methodology to screen for HexA or Tay Sachs disease carrier status. In approximately 2% of cases, an individual will be found to have a genetic change in this gene that is difficult to interpret. In this situation, a genetic counselor will recommend that you have Tay Sachs enzyme testing, which is not available on saliva. The JScreen Program will help coordinate this type of blood testing or will recommend that you pursue this testing through your local healthcare provider. The JScreen website at [www.jscreen.org](http://www.jscreen.org) provides additional information related to Tay Sachs enzyme testing.

### **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, generally prohibits 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 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.

You consent to and authorize release of your genetic testing information to your insurance company and any other third party payors.

### **Telemedicine**

You consent to and authorize your healthcare providers to provide medical and non-medical 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 for testing. I agree to the JScreen program consent guidelines. (Electronic signature must match your first and last name.)

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