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Informed Consent for DNA Testing

Please send a copy of the front and back of insurance cards for each family member (if separate cards are issued for each member).

Date:

Name:

Address:

City/State/Zip Code:
Phone No.:

Email Address:

Test Financial Hardship Award

I would like the following members of my family to receive the MEDgomics DNA-based pMED3 Autism and Mitochondrial Disease tests (www.medgomics.com) and the companion MitoGen and Ex20pMED3 analyses when relevant. The list of these names is below under **pMED3-A and MitoGen.**

I would like the following additional family members to receive the Enhanced Family Testing (EFT). pMED3 Autism-pfe is performed in conjunction with the pMED3 Autism and Mitochondrial Disease Tests (list these names below under "pMED3-A pfe Test"). pMED3 Autism-pfe is less costly because it involves a more focused analysis in the context of the detailed analysis of the affected family members.

Steve Sommer, MD, PhD provided information on testing in the context of a clinical genetics personalized medicine consultation. Affected patient medical history and family histories were gathered. As part of his clinical practice, Dr. Sommer is Medical Director of the MEDomics testing laboratory. Explanations of relevant MEDomics Next Generation Sequence-based testing were provided and my questions about testing have been answered.

I understand that biological samples (blood, saliva, or cheek cells) will be sampled using standard techniques which carry little risk. I understand that the blood, saliva, or cheek cells will be used for the purpose of attempting to determine if I and/or members of my family are carriers of genetic mutations, or are affected with, or at increased risk to someday be affected with, the genetic disease of interest.

MitoMED Autism / Mitochondrial Disease

Name	Date of Birth	Gender (M/F)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

MitoMED Autism-EFT Test (Enhanced Family Testing)

Name	Date of Birth	Gender (M/F)
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

☐ If additional children or parent are/is part of the testing, please check this box AND list their name, date of birth, and gender on the back of this consent.

NOTE THAT THIS CONSENT INCLUDES COMPANION MITOCHONDRIAL GENOME TESTING (MITOGen) (www.medgomics.com) AND FOLLOW-UP: i) EXOME TESTING (Ex20pMED3) and ii) auxAut TESTING THAT WILL BE PERFORMED SHOULD THE pMED3 TEST NOT BE DEFINITIVE. The Ex20pMED3 Test provides sequence-based analysis of the protein encoding regions within the remaining 18,000+ genes. The analysis is broader, but necessarily less detailed, than the pMED3 Autism Test which covers 1405 genes. The MitoGen Test provides a detailed sequence analysis of the mitochondrial genome, the "mini chromosome", that is found within the mitochondria. Mitochondria are the energy factories of the cell and the location of certain metabolic pathways. If appropriate, family testing for addiction or bipolar disease can be performed.

I understand that:

1. In some cases, the DNA test directly detects an abnormality, called a mutation, in the gene, and the test can be highly accurate. In other cases, the DNA test is unable to identify an abnormality although the abnormality may still exist. This event may be due to our current lack of knowledge of the complete gene structure or an inability of the current technology to identify certain changes (mutations) in the gene.
2. Samples from the biological parents and from certain other relatives may substantially enhance the power of testing.
3. The testing generally involves substantial effort over months. Sophisticated laboratory testing is followed by highly sophisticated computer-based "bioinformatics" analysis, which is followed by interpretation performed by senior geneticists who are "mutation experts". Every effort is made to minimize the direct cost of testing to the family.
4. This testing is complex and utilizes specialized materials so that there is always some small possibility that the test will not work properly or that an error will occur. There is a

low error rate even in the best laboratories. My signature below acknowledges my voluntary participation in this test.

5. I understand that my sample is not being banked. MEDgomics does not return DNA samples to individuals or physicians. However, in some cases it may be possible for MEDomics to further analyze the remaining DNA upon request.

6. The accuracy of genetic testing is limited by the methods employed, the clinical diagnosis, and the nature of the specific condition for which testing is requested. In some cases, the test will detect an abnormality, called a mutation, in the gene. In other cases, the test is unable to identify an abnormality although an abnormality may still exist. This event may be due to the current limitations of knowledge or an inability of the current technology to identify certain types of changes (mutations) in a gene.

7. There are several categories of test results that may be reported including:

    a. A clinically significant abnormality IS detected, known to be associated with a genetic disease.
    b. A clinically significant abnormality IS NOT detected; however, the patient clinical diagnosis may still be correct. This event may be due to medical science's current lack of knowledge of all the gene(s) involved with the disease or the inability of the current technology to identify certain types of mutations in the gene(s) which cause the disease.
    c. A result of uncertain clinical significance is detected. Additional testing of the patient and/or other family members may be recommended to help determine the significance of the result.
    d. Unexpected test results may be found. From these tests, information may be learned about you, your child/children or your family that is not directly related to the clinical reason for ordering the test.

8. The results will either be reported directly to me or through a physician, genetic counselor, or certified genetics professional. The result reports are confidential and will only be released to other medical professionals or other parties with my express written consent. All laboratory data is confidential and will not be released from MEDgomics. Participation in DNA testing is completely voluntary.

9. It is the responsibility of the referring physician or health care provider to understand the specific utility and limitations of the testing ordered, and to educate the patient regarding these limitations. Specific information describing indications, methodology and detection can be found on the MEDgomics' website at http://medgomics.com. Accurate interpretation of test results is dependent upon the patient's clinical diagnosis or family medical history and that the reported family relationships are true biological relationships. An erroneous clinical diagnosis in the patient or family member can lead to an incorrect interpretation in the laboratory result. Genetic testing in family members can sometimes reveal that true biological relationships are not consistent with the reported biological relationships. For example, non-paternity may be detected, which means that the stated father of an individual is not the true biological father.

10. In the event definite diagnosis is not obtained from the above requested test, a subsequent test (such as the MEDgomics' Ex20pMED3™ Test) will be reflexed (upgraded as clinically indicated). The MEDomics' Ex20pMED3^{M} Test will be performed to analyze the coding sequence and the exon/intron boundaries of the approximately 18,000+ additional protein-coding genes. Please see http://medomics.com/tests.html#exome for a detailed description of the test.

11. The individuals listed above receive a MEDgomics Financial Hardship Award. There are no out-of-pocket expenses (deductible and copay) if insurance pays at least a "half way reasonable small amount" for the family, i.e. if insurance must pay at least 25% of the billing amount. Note that MEDgomics loses multiple thousands of dollars for test completion if reimbursement is only 25%. If necessary, persistent efforts will occur over many months to obtain reasonable insurance reimbursement. In the small fraction of

cases, in which at least 25% insurance reimbursement does not occur, then the test(s) cannot be completed under the Financial Hardship Award unless the family chooses to pay the incremental amount to reach 25% of billing reimbursement. Alternatively, MEDgomics agrees to cancel completion of the testing, thereby losing substantial funds that were already invested in the testing. BOTTOM LINE: The family is not required to pay any out-of-pocket deductibles or co-pays for this testing.

12. I have a copy of this consent form.

    I had this DNA testing explained to me. I understand the limitations outlined above, and I have had the opportunity to receive answers to my questions. I understand that the power of testing is substantially improved by co-analysis of DNA from the biological parents.

PLEASE SIGN AND DATE THIS FORM BELOW:

Signature of Parent 1: _____

Date: _____

Printed Name of Parent 1: _____

Date: _____

Signature of Parent 2: _____

Date: _____

Printed Name of Parent 2: _____

Date: _____

Signature of Patient (if applicable): _____

Date: _____