NOTE: Please obtain patient signature on consent form below. If a signed consent is not submitted, Emory Genetics Laboratory assumes that the ordering clinician has reviewed and obtained the patient’s informed consent.

INFORMED CONSENT FOR MOLECULAR GENETIC TESTING

I, (name)__________________________________________, voluntarily request of Emory Genetics Laboratory to perform DNA-based testing for (condition)_____________________________ in myself/my child (child’s name ______________________), in an attempt to determine whether I/my child am a carrier of a disease gene or are at increased risk to be affected by a genetic condition.

The following points were explained and I understand that:

• DNA testing requires a blood sample, buccal swab, muscle or skin biopsy, all of which have risks associated with obtaining the sample. Additional samples may be needed if the sample is damaged in shipment or inaccurately submitted.

• In order to perform accurate prenatal testing, samples from the affected individual, parents, or additional family members may be required.

• DNA-based studies performed are specific to the condition indicated above. 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 lack of knowledge of the complete gene structure or an inability of the current technology to identify certain types of changes (mutations) in a gene.

• These tests represent the newest service currently available for clinical laboratory testing, however, improvements will be made as scientific knowledge advances. As with any complex genetic test, there is always a small possibility of a failure or error in sample analysis. Extensive measures are taken to avoid these errors. The methods are not 100% accurate due to the possibility of rare genetic variations in the DNA of an individual or due to the complexity of the testing itself. A low error rate, estimated to be approximately 1 in 1000 samples, is thought to exist in any laboratory.

• 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 Emory Genetics Laboratory website at: www.genetics.emory.edu/testing.

• 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.

• Due to the complexity of DNA testing and potential implications of test results, results will be reported directly to the ordering provider. Patient results and information will remain confidential and may only be released to other parties with my expressed written consent.

• Emory Genetics Laboratory is not a DNA banking facility and does not guarantee the future availability of isolated DNA. Any requests for additional studies must be ordered by the referring provider and charges will be incurred. Once the test is complete, identifying information may be removed and remaining DNA samples may be used for de-identified laboratory purposes. These samples will not be available for future clinical studies. Any results obtained cannot be related back to the original source, so no results can be reported.

I can request that remaining DNA not be used for research purposes by initialing here: _______

The risks, benefits and limitations of DNA testing have been explained to me. I have read and will receive a copy of this consent form.

Patient Signature                                        Date                                        Parent / Guardian Signature                               Date

Physician/Counselor/Clinician Statement:
I have explained DNA testing to the patient/parent/guardian. The consent form and limitations of genetic testing were reviewed with the patient/guardian. I accept responsibility for pre- and post- test genetic counseling.

Clinician Signature                                        Date