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 PRENATAL GENETIC TESTING**

I, __________________________, voluntarily request of Emory Genetics Laboratory to perform fetal cytogenetic, molecular or biochemical testing, in an attempt to determine whether my fetus is at increased risk for: (indication) _________________________. I understand that the cells required for such an analysis are obtained in amniotic fluid or chorionic villus sampling (CVS) by a transabdominal or transcervical procedure. A separate consent discussing the risks and limitations of the prenatal procedure was provided by my physician. This consent pertains to genetic testing at Emory Genetics Laboratory.

The following points were explained and I understand that:

- Viable fetal cells are required to complete the test(s) requested. Additional samples may be needed if the sample is damaged in shipment or inaccurately submitted. Occasional attempts to obtain a viable culture may be unsuccessful or the chromosome preparations may be of poor quality. In these cases, the prenatal procedure may need to be repeated to complete the requested genetic studies.

- In order to perform accurate prenatal testing, additional cytogenetic, molecular or biochemical studies, or samples from the affected proband, parents, or additional family members, may be required to interpret the results. Testing of other persons may be required prior to the laboratory accepting the prenatal sample.

- Genetic studies performed are specific to the indication listed 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. For molecular genetic testing, 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.

- 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.

- 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 clinical diagnosis, 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.

- Although the likelihood of a misinterpretation of the cytogenetic, molecular or biochemical result is considered to be extremely small, a complete and correct diagnosis of the condition of the fetus based on the cytogenetic, molecular or biochemical analysis cannot be guaranteed. The results in no way guarantee the health of my baby. Approximately 3-5% of all pregnancies have birth defects which cannot be detected by testing amniotic fluid/CVS.

- Due to the complexity of genetic testing and potential implications of test results, results will be reported only through the ordering provider. Patient results and information will remain confidential and may only be released with my expressed written consent.

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

Patient: __________________________ Date ____________

Spouse/Partner (optional): __________________________ Date ____________

**Physician/Counselor/Clinician Statement:**

I have discussed test limitations and the consent form with the patient. I accept responsibility for pre- and post- test genetic counseling.

______________________________ Date ____________

Clinician Signature

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