The University of Chicago
Genetic Services Laboratories

Toll-free: (888) 824 3637
Local: (773) 834 0555
FAX: (773) 834 0556

CONSENT FORM

Patient Name: _____

Date of Birth: _____

I, _____, hereby authorize the submission of samples

from: _____
(patient's name, birth date & relationship to individual granting consent if not self)

for genetic testing for _____.

ACCURACY

The studies performed are specific to the condition indicated in the statement at the top of this page.

The accuracy of genetic testing is limited by the methods employed, and sometimes by the nature of the condition for which testing is requested. It is the responsibility of the referring physician, or a health care professional designated by the physician, to understand the limitations of the testing ordered, and to educate the patient regarding these limitations.

Accurate interpretation of test results may require an accurate report of the patient's family medical history, and that the reported family relationships are the true biological relationships. An incorrect diagnosis in a family member can lead to incorrect diagnoses for other family members.

There is always a small possibility of an error or failure in sample analysis; this is always a possibility with complex testing in any laboratory. Extensive measures are taken to avoid these errors.

IMPLICATIONS OF RESULTS

Because the implications of genetic testing results can be complex, involving both medical and emotional and social issues, results will only be reported through the referring physician or a professional designated by the physician, such as a genetic counselor. The issues associated with some types of genetic testing are particularly sensitive. Therefore, the laboratory reserves the right to provide testing only if genetic counseling can be provided.

INCIDENTAL FINDINGS

On occasion, in the process of testing for one genetic condition, a separate abnormality may be identified. Such findings will be reported to the referring clinician, who will explain the implications of the finding.

Genetic studies of families can sometimes reveal that the true biological relationships are not consistent with the relationships reported in the family history (such as in cases of adoption or non-paternity). It is this laboratory's policy NOT to report these findings, except in rare circumstances in which the findings indicate a medical or reproductive risk for which intervention is possible. These decisions will be made by the laboratory directors in consultation with medical, counseling and legal professionals as well as medical professionals trained in ethics (moral questions) who will determine the most appropriate means of conveying the information.

DISPOSITION OF SAMPLES

After the requested studies are complete and reported to your physician, your sample may be made anonymous (all identifying labels such as name, birth date or hospital number removed) and used for research purposes. However, given your written permission, we can hold your (child's) LABELED sample for research purposes specifically related to determining the cause of your (child's) medical problems. There is no fee for testing done on a research basis. Any information that is gained from these studies which the laboratory directors determine to be valuable for diagnostic, medical management, genetic counseling or family planning purposes will be relayed through the physician who ordered the original diagnostic testing. Samples or patient information will NOT be available to investigators outside of The

University of Chicago Genetic Services' affiliated diagnostic or research and development laboratories unless you are contacted and consent to this distribution. Participation in research studies may be discontinued at any time, without penalty, by notifying the laboratory in writing. The laboratory's address is: 5841 S. Maryland Ave. Room L-155 MC 0077, Chicago, IL 60637

The laboratory is not responsible for storing the sample; we cannot guarantee that it will be available for future use.

CONDITIONS OF CONSENT

After careful consideration, in addition to clinical testing, I have decided that my sample **(CHOOSE ONE)** :

☐ Can be used for research purposes specifically related to determining the cause of the condition stated above, and/or its related developmental and/or physical features without being stripped of identifying information.

With this option, we may contact your physician for your Protected Health Information (PHI) which consists of any health information that is collected about you related to your diagnosis (such as date of birth, medical record number, primary diagnosis, clinical features, relevant and family history, outcome). The data collected will be used to develop a database of patients being tested for genetic diseases and will be kept indefinitely for the duration of the database. This information, without any identifiers, may also be shared with researchers that are interested in further studies of this specific condition. You will be notified of any positive findings.

☐ Can be used for research purposes if stripped of identifying information. Because your sample cannot be identified, you will not be notified of any findings related to use of my anonymous sample for research purposes.

☐ Cannot be used for research purposes.

Participation in any possible future research is voluntary. If you choose not to participate, your clinical genetic testing in the Genetic Services Laboratories will not be affected.

CONFIDENTIALITY

Results and patient information are confidential and will only be released to the referring physician, unless written consent for further distribution is provided or the laboratory directors are required by law to release this information. For patients within The University of Chicago affiliated centers, policy may require that reports are provided to the medical records department.

CONSENT

Each participant will be provided with a copy of this signed consent form.

Patient or Legally Authorized Representative: _____ Date: _____

If Legally Authorized Representative please describe relationship to individual: _____

By signing this consent form, the referring clinician 1) indicates that this consent form has been reviewed with the patient and/or the patient's parent or guardian, and 2) accepts responsibility for pre- and post- test genetic counseling.

Referring clinician's Signature: _____ Date: _____