UNIVERSITY OF MICHIGAN HOSPITALS & HEALTH CENTERS

BIRTHDATE

NAME

REG. NO.

Request and Consent to Genetic Testing

My provider has ordered **genetic testing** for: _____
(name of condition)

The **sample** that will be tested is:

☐ Blood ☐ Cheek Swab ☐ Skin ☐ Tissue (*specify origin/type*): _____

☐ Urine ☐ Plasma ☐ Cerebrospinal Fluid ☐ Fibroblasts ☐ Cultured Cells ☐ Amniotic Fluid ☐ Chorionic Villus sample (CVS)

☐ Other (*specify*): _____

The **type of test** I will receive is:

☐ *Carrier Status* – To find out whether I have a disease-causing gene that could be passed down to my children.

☐ *Diagnostic* – To confirm the presence or absence of a specific disease or condition, or to help my doctors determine the appropriate course of treatment.

☐ *Predictive/Presymptomatic/Screening* – To find out if I have one or more gene changes that increase the risk of developing a certain disease or condition some time in the future, even if I have no signs or symptoms today.

☐ *Prenatal* – To find out whether my fetus/unborn child has a certain disease or condition.

☐ *Other:* _____

The **limitations** of genetic testing include:

- *Accuracy* – Accuracy is limited by the techniques used and information I provide to my doctor about myself and my family members, including medical history and biological relationships. Previously unknown or unclear information (like mistaken or incorrect paternity, adoption, disease or carrier status of tested or untested relatives) may impact the accuracy of results.
- *Laboratory Processing* – All laboratories have strict rules for handling samples. In rare cases, though, problems may occur in handling a sample at the laboratory, which may lead to incorrect results. Examples of these problems include mislabeling, contamination, or misinterpretation of findings. Sometimes the test itself may not work properly. Sometimes the laboratory may need a second sample in order to complete the test.
- *Implications of Results* – Sometimes genetic testing does not provide a "yes" or "no" answer. The test may reveal a gene change that does not predict with certainty whether a person will develop a disease, how severe the condition may be, or when symptoms may appear. In other words, the significance or meaning of a certain test result may not be known.

Genetic testing may help my doctor choose the most appropriate preventive or therapeutic treatment; or help me and my family make important life planning decisions. The **physical risks** of testing are usually small. For blood draws, they include bruising, pain, and infection at the site where the blood was taken. For amniocentesis, they include cramping, bleeding, infection, leaking of amniotic fluid after the procedure, and miscarriage. My doctor has explained other physical risks involved in my testing procedure. **Other risks** of genetic testing include breach of privacy, impact on family relationships, and insurance or employment discrimination. Federal and state laws protect privacy and protect citizens from insurance and employment discrimination to some degree. More information on these protections is available under "Policy and Law" at http://www.MiGeneticsConnection.org.

The testing will be done at:

☐ M-LABS, Michigan Medical Genetics Laboratories, Molecular Pathology Laboratory, (CAP # 17142-01/CLIA # 23D0366712)

☐ Other Lab (*specify*): _____ ☐ NOT Certified ☐ Certified: CAP/CLIA #: _____

Individually identifiable results will be released only to the ordering physician, or as described in the *UMHS Notice of Privacy Practices*. I **donate** and authorize the University of Michigan to own, use, retain, preserve, manipulate, analyze, or dispose of any **excess tissues, specimens, or parts of organs** that are removed from my body during the testing procedures, and are not necessary for my diagnosis. The University may use or retransfer these items to any entity for any lawful purpose, including education and retrospective research on anonymous specimens.

Financial Responsibility. I understand that I am responsible for any testing-related fees not covered by my health plan, including non-authorized or non-covered testing. I will be responsible for payment of all completed service charges once testing has begun. If a test is cancelled before set-up, there will be no charge, but if it is cancelled afterwards, a set-up fee will be charged. If it is cancelled after the test is performed, the full service fee will be charged, even if I choose not to receive results.

I HAVE READ AND UNDERSTAND THE INFORMATION ON THIS FORM BEFORE I SIGNED IT. I ACCEPT THE RISKS LISTED ABOVE OR DISCUSSED WITH MY DOCTOR, NURSE, OR OTHER HEALTH PROFESSIONAL.

Signature of Patient or Legally Authorized Representative
(if patient is a minor or unable to sign)

Printed Name of Legally Authorized Representative
(if patient is a minor or unable to sign)

Relationship: ☐ Spouse ☐ Parent ☐ Next-of-Kin ☐ Legal Guardian ☐ DPOA for Healthcare

Consent Obtained, Explained and Witnessed by: _____ Provider No. _____ Date: _____ Time: _____ A.M. / P.M.

31-10010	VER: A/11 HIM: 06/11	White – Medical Record Yellow – Patient Pink – Ordering Physician Gold – MMGL	University of Michigan Hospitals and Health Centers	REQUEST AND CONSENT TO GENETIC TESTING

Replaces: 2202430