Michigan Medicine Pathology **Request and Consent to Genetic and Molecular Testing at Tempus Laboratories**	MRN: NAME: BIRTHDATE: CSN:

LABORATORY NAME, CITY AND STATE:	GENETIC TESTING REQUESTED FOR:
Tempus Labs, Inc. 600 West Chicago Avenue, Suite 775, Chicago, Illinois 60654	_____ _____ (name of condition)

Your healthcare provider has determined that genetic testing on your tumor/cancer may be helpful in determining a future plan for your care. This document outlines the details you should consider before making a decision to proceed with this testing.

You have the option to provide consent for your healthcare provider to send a portion of your existing or anticipated tumor biopsy (a sample) and the associated surgical pathology report (along with a blood specimen and/or additionally clinical information, as deemed appropriate by your provider in some instances) to an outside institution called Tempus Laboratories.

What is the purpose of this testing?
The purpose of this testing is to identify unique changes to the genetic code of your tumor, called your tumor's "molecular signature." These unique genetic changes in your tumor may provide valuable information to help your oncology team select the most appropriate treatment for your care. The results could also indicate which active clinical trials are well-matched for your specific tumor and whether you may be eligible for enrollment.

What are the limitations of genetic testing?
Accuracy – Accuracy is limited by the techniques used and information that you provided to your doctor about yourself and your family members, including medical history and biological relationships.
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.

What will happen to my samples and where will this testing be done?
Your samples will be de-identified and re-labeled with a code number only known to Michigan Medicine, to further protect your privacy, and shipped to Tempus Laboratories in Chicago, IL, where your requested clinical testing will be performed. Tempus is a federally licensed external genetic testing laboratory partner, which provides clinical diagnostic services to the University of Michigan, under strict regulatory oversight. Once testing on your tissue sample is completed, any unused portion of the paraffin block will be returned to Michigan Medicine for long term archival in the Department of Pathology (at least ten years). Your blood sample, if one is collected as part of this test, will be utilized for reference germline analysis by Tempus, with any unused portion discarded after two weeks. The raw molecular results data and processed molecular results report, as derived from testing of your sample(s), will be electronically transferred back to Michigan Medicine. Additionally, your clinical data and results data will be retained by Tempus in de-identified form to allow for repeated and/or subsequent analysis efforts as requested by your provider and for Tempus's internal analysis activities, including validation of the de-identification process.

Who will have access to the sample taken?
The sample will be handled at all times by trained clinic staff, who will securely ship the specimen(s) to Tempus Laboratories, where similarly trained and licensed laboratory staff will carry out processing and analysis, per a strict and validated protocol.

What are the risks of testing?
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. Your doctor has explained other physical risks involved in your testing procedure if it includes activities in addition to a blood draw. 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.

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How will I be notified of my results?
The results from this testing will be forwarded back to your healthcare provider and saved securely in your electronic medical record at Michigan Medicine, in a section of the overall medical record with added "need-to-know" access only. Your healthcare provider will review the results of the testing with you and will discuss any available treatment options based on the results.

What else can this testing tell me?
The primary purpose of this testing is to provide information on the genetic make-up of your tumor to help your doctor make decisions on your future cancer treatment. The genetic changes in your tumor are *acquired* changes that are unique to your tumor and develop over time as your tumor grows and changes. As part of this testing, however, it is possible that we may also detect changes in the genetic code that you were born with and are inherited in your family. These gene changes are called *germline* variants. Some *germline* gene changes may provide information on an individual's overall risk for different forms of cancer, and may indicate that an individual has inherited a *hereditary cancer syndrome*. This additional information may be used by your healthcare providers to make decisions on future cancer screenings or options for cancer risk reduction. These *germline* findings may also have implications for the care of other family members who may also be at risk to inherit the hereditary cancer syndrome identified.

While these *germline* variants may be identified as part of your tumor testing, it should be noted that this testing is NOT considered a clinical-grade test for evaluation of hereditary cancer syndromes. Some inherited *germline* gene changes may be missed with tumor testing. If you or your healthcare providers are concerned that you may have inherited a hereditary cancer syndrome, formal consultation with a cancer genetic specialist is available at Michigan Medicine through the Cancer Genetics Clinic or the Breast and Ovarian Cancer Risk Evaluation Clinic (ph. 734-647-8902/ fax 734-763-7672).

If you sign the consent document, below, it confirms your agreement and our commitment to obtain results that may be of help to your healthcare providers in selecting the best treatment for your cancer. This consent specifically gives us your permission to either internally test your tissue sample(s) or send them and any required clinical data to our external molecular testing laboratory partner, Tempus Laboratories. The data that results from this testing will be only used clinically, for the specific purpose of the management of your malignancy.

If your specimen is forwarded to Tempus Laboratories, your insurance company may be billed by Tempus for performing these tests. However, under no circumstances would you ever be directly billed for testing at Tempus if your insurance does not provide coverage for this type of molecular tumor analysis or if you do not have insurance coverage.

I HAVE READ AND UNDERSTOOD 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.

_____ **Date:** _____
Signature of Patient or Legally Authorized Representative (if patient is unable to sign) (mm/dd/yyyy)

_____
Printed Name of Legally Authorized Representative (if patient is unable to sign)
Relationship: ☐ Spouse ☐ Parent ☐ Next-of-Kin ☐ Legal Guardian ☐ DPOA for Healthcare ☐ Other (specify): _____

_____ _____ _____
Obtained and Explained by (Printed Name and Signature) Title Pager/Provider No.

Date: _____ **Time:** _____ **A.M. / P.M.**
(mm/dd/yyyy)