

## Patient Informed Consent

*Please read this informed consent carefully and discuss with your physician before signing. This form must be completely filled out and signed by you, your parent/legal guardian or legally authorized representative.*

### **Why am I being asked to give consent?**

You are being asked to sign this informed consent because you and your physician have elected to have a molecular analysis of your cancer tumor performed. This analysis may better inform on the treatment of your cancer. This informed consent seeks your agreement to perform molecular testing on your biological samples.

### **General description and purpose of the test**

The purpose of this test is to detect changes at the molecular level of the obtained sample(s) and to understand what the potential consequences of these changes are for your health and treatment decisions. The test results, together with other information about you and your condition (such as your medical history), may be used by your physician to assess which drugs may potentially match the genomic and/or proteomic profile of your cancer. This may include, depending on your physician's evaluation of the test results and other information, FDA-approved therapies or clinical trials for investigational therapies.

### **How the test will be carried out**

Your physician will request the test, and the testing may be performed by mProbe, Inc. ("mProbe"), DBA OncoOmicsDx, and its reference laboratories. The testing performed on your biological samples may include the following:

- *Proteomics analysis:* This is a quantitative assessment of the tumor-specific proteins produced by the cells in your sample and may provide your physician with information regarding the absence or presence of proteins in your tumor, which may indicate resistance or sensitivity to certain chemotherapy drugs.

Please ask your physician for further information regarding the test.

### **Test results**

Your test results are sent directly to your physician, his or her designee, other healthcare providers involved directly in your care, or to another healthcare provider as directed by you (or a person legally authorized on your behalf) or as required or authorized by state or federal law.

Tissue blocks submitted to the lab for analysis will be returned to the source address (usually a pathology lab) upon the completion of testing. If you decide that you do not want your tissue to be used or stored by the original storage facility for future use, please notify your doctor in writing. Your doctor will direct the tissue storage facility to destroy any remaining identifiable samples.

Data from your test results as well as any of the residual material remaining may be stored, used and disclosed for quality control, research, and other purposes, as permitted by and consistent with applicable laws. These activities may aid in the development of improved testing capabilities and in understanding

more about the causes, risks, treatments, or prevention of cancer and other health problems. All readily individually identifiable health information (including your name and street address) will be removed in accordance with applicable law to create such anonymized data and samples.

**Limitations, risks, and potential benefits**

The test results may help you and your physician make more informed choices about your health care. However, it is possible that the results will not provide any benefit, as much about genetics/genomic/proteomics in health remains unknown and the interpretation and reporting of your results will be based on currently available information and technology. mProbe may not yet understand the significance of certain variations that are identified, and testing may not yield findings that your physician finds helpful in identifying possible treatments. Also, the testing process relies on highly skilled technicians and reliable technology. The methods are reliable, but as with any laboratory test, there is the small chance that an error may occur or that no results are obtained. The quality of the results can also vary based on the quantity and quality of the samples provided for testing. In some cases, testing may not be possible, or the results may be impacted, if tumor content is not sufficient or not detectable.

**Consent**

I understand that this testing is voluntary. By signing below, ***I acknowledge and consent*** to testing as described in this informed consent and to the following in connection with such testing:

1. A sample of my tumor will be analyzed. I am aware that the results from testing these samples will be put in my medical record and used by my physicians for my health care.
2. The test and its limitations have been satisfactorily explained to me. I acknowledge that I have discussed the benefits, risks and limitations of this testing with my physician and/or other health care professional, who has answered my questions to my satisfaction.
3. I will cooperate with mProbe by providing documents needed for insurance billing and appeals and understand that I am responsible for my bill after all appeals and financial assistance for which I qualify have been exhausted.

\_\_\_\_\_  
Participant Name (please write clearly)                      Reference # (if available)

\_\_\_\_\_  
Signature of Participant/Legal Representative              Date

If signed by a legal representative, describe relationship to participant and authority to act for participant:

\_\_\_\_\_

You will receive a copy of this informed consent for your records. For further information about this testing, please contact your physician. If there are any questions regarding this informed consent document, please contact [orders@OncoOmicsDx.com](mailto:orders@OncoOmicsDx.com) or 301-977-3654.

**FOR ORDERING PHYSICIANS:** Some states may have additional requirements for informed consent. Please ensure you comply with those requirements and provide a copy of any additional consents obtained from the patient.

***Please fax reviewed and signed consent forms to 1.833.985.0131 or [orders@OncoOmicsDx.com](mailto:orders@OncoOmicsDx.com).***