INFORMED CONSENT FORM FOR EXaCT1 TEST

This form must be completely filled out, signed by patient, parent/legal guardian or legal next of kin and maintained in the patient's Medical Record at the physician's office.

REQUESTING PHYSICIAN: __________________________________________________________

REASON FOR TESTING: ____________________________________________________________

TO THE PATIENT: Please read the following carefully and discuss with your ordering physician or the person obtaining consent before signing consent.

_________________________________________ has explained to me, in a way that I understand, the following:

The purpose of the EXaCT1 test is to look for genetic mutations (changes) that developed in your cancer cells, not in your normal cells. Information about mutations in your cancer cells may help your doctor plan your treatment. Changes or mutations in your cancer cells are not inherited, meaning they were not passed to you from your mother or father. After you have discussed this test with your doctor, you may agree to have the EXaCT1 test performed by signing this form.

The EXaCT1 test will not look for changes or mutations in your normal cells, nor was it designed to provide proof of any family relationships. It was not designed to tell you if you were born with an inherited mutation that might increase your risk for cancer or other diseases. Nor was it designed to tell you if you carry an inherited mutation that could increase the risk of disease in your children. This is because the EXaCT1 test is designed to find mutations that developed in your cancer cells only. If you want to know if you inherited any genetic mutations, or wish proof about family relationships, talk with your doctor about the tests designed to look for this information.

Although the EXaCT1 test is not designed to find inherited changes (mutations), occasionally the EXaCT1 test may suggest, but not confirm, the presence of an inherited mutation. While performing the EXaCT1 test, this information may suggest you could benefit from having other tests designed to look for inherited mutations. Later in this form there is a place for you to indicate whether you would want to know about possible inherited mutations in your normal cells. If you decide you want to know, your doctor can arrange for you to talk with a genetic counselor.

The results of the EXaCT1 test will be included in your medical record and will be available to individuals/organizations with legal access to your medical record, on a strict "need-to-know" basis, including, but not limited to the physicians and nursing staff directly involved in your care, your current and future insurance carriers, and other people specifically authorized by you to gain access to your medical records.
Costs: You and/or your health plan/insurance company will need to pay for the costs of the EXaCT1 test and service you receive. You will be responsible for any deductible and co-payments required by your insurance company for your medical care. Some health plans will not pay for the costs of the EXaCT1 test. If your insurance company denies payment for this test, you may be personally responsible for a component of its cost. We have financial counselors that can work with you if you need support. In special cases, costs may be offset for eligible patients enrolled in clinical studies.

**Statement of Consent:**

By signing below, you acknowledge that you have read this form or have had it read to you and that your doctor has explained the risks, benefits, and alternatives to having EXaCT1 testing and the risks and benefits of any alternatives including not being tested.

By signing below, you confirm that you have had a chance to ask questions and your questions have been answered to your satisfaction and that you fully understand the information provided to you.

☐ I consent to EXaCT-1 testing.  ☐ I decline EXaCT-1 testing at this time.

☐ Yes, I would want to know if the EXaCT-1 test obtains information that may suggest I have an increased risk of cancer or other diseases in myself or my family.

☐ No, I do not want to know if the EXaCT-1 test obtains information that may suggest I have an increased risk of cancer or other diseases in myself or my family.

**Signatures:**

Patient Name: ___________________________ Signature: ___________________________ Date: __________

Note: If the patient is under eighteen (18) years of age, the permission of the patient's parent or legal guardian must be obtained, unless the patient is married or the parent of a child.

Parent/Guardian of Patient: ___________________________ Signature: ___________________________ Date: __________

In accordance with New York State Law, I have discussed the testing specified above with the patient/legal guardian. I have discussed the possible results of the test and the availability of genetic counseling. I am satisfied that the patient or the patient's legal guardian who signed above understands the information set forth above. This informed consent was signed in my presence.

Name of Person Obtaining Consent: (Print Name): ___________________________

Signature: ___________________________ Date: __________

10/23/17