

Informed Consent- Identification and Interpretation of a Single Genetic Variant

This form must be completely filled out and signed by patient, parent/legal guardian or legal next of kin and accompany the requisition form.

Requesting Physician: _____

CONDITION (Purpose of Testing): _____

In accordance with New York State Law, the following has been discussed with the patient/legal guardian and informed consent obtained. The following was signed in my presence.

Name of Person Obtaining Consent: _____

Signature _____ Date: _____

Please read carefully and discuss with your ordering physician/person obtaining consent before signing consent.

1. The condition stated above has been described to patient/legal guardian in detail.
2. The tests ordered above are for molecular genetic (DNA-based) tests to detect a mutation, or change within gene(s) _____
3. The patient/legal guardian may wish to obtain genetic counseling prior to signing this consent form in order to understand the testing and what the results may mean. If so, a request should be made to the physician.
4. When DNA testing detects the most common disease-causing changes in a gene, the test result is highly accurate.
5. The results of the testing may 1) indicate a predisposition to have the above specified condition; 2) confirm a clinical diagnosis of the condition; 3) indicate that the patient is a carrier of the condition; 4) or may have uncertain significance.
6. A positive test result will help determine that a patient has the specified condition, or that the patient may develop the condition with a high level of certainty. The level of certainty, if available for the ordered tests, has been discussed with the patient/legal guardian.
7. When DNA testing does not show a known genetic change, the chance that a person is a carrier or is affected is reduced. There is still a small chance to be a carrier or to be affected because current testing cannot find all the possible changes within a gene. The physician will discuss the results with the patient/legal guardian and refer to genetic counseling if indicated or desired.
8. The results of the above test become a part of the patient's medical record. Columbia University, NewYork-Presbyterian and Weill Cornell Medicine and their related entities participate in an Organized Health Care Arrangement (OHCA). This allows us to share health information to carry out treatment, payment and our joint health care operations, including integrated information system management, health information exchange, financial and billing services, insurance services, insurance, quality improvement, and risk management activities. Organizations that will follow this Notice include Columbia University, NewYork-Presbyterian sites, Weill Cornell Medicine and their related entities. Current New York State law prohibits discrimination by insurance carriers based on results of genetic tests.
9. No tests other than the tests specifically authorized above will be performed on this sample, unless specifically authorized by the patient/legal guardian. After 60 days, unless consent is given, sample will be destroyed (please see below).
10. Advanced Beneficiary Notice: Medicare/Insurance carriers may not pay for the testing, in which case you will be billed for the test

The patient/legal guardian has read and fully understands the above.

I consent to testing as described above. I decline testing at this time.

Sample Retention:

_____ By initialing here, I consent to possible future genetic research on my specimen, only if all identifying information is removed (name, address, date of birth, medical record number). Since my/my child's identifying information will be removed, I will not be contacted with any research results. The duration of the retention of my sample will depend on the individual research study. By not initialing here, my/my child's sample will be destroyed not more than 60 days after completion of testing.

Name of Patient: _____

Parent/Legal Guardian _____

Relationship to Patient: _____

Signature of patient or Parent/Legal Guardian: _____ Date: _____