

Consent Form for Cancer Genetic Test

This Consent Form gives you information about the tumor profile test offered through Star Biosciences. These tests are voluntary. These tests involve testing your tumor cells to see if they make certain chemical materials called proteins and RNA. Some tests may involve using your genetic material (also called DNA) and you may wish to seek genetic counseling before signing this form. Read this form carefully before making your decision about testing. You should feel free to discuss your decision with your family and friends and with your healthcare team. If you decide to have the test, you will need to sign this consent form.

Purpose

Medical research is learning a lot about how cancer drugs work or do not work in stopping the growth of certain tumors. Some of this success comes from understanding more about the “molecular profile”, also called the genetic and chemical make-up, of tumor cells. Information about the molecular profile of tumor cells may help doctors’ select cancer drugs that interact with specific proteins. This form of treatment is called “targeted therapy.”

The goal of the molecular profiling test is to find out if the genetic and/or chemical make-up of your tumor can help your doctor make decisions about the best treatment options for your cancer. Treatment options may include using cancer drugs already approved by the FDA and the DCGI or drugs, which are being studied for use in your type of cancer, that are in clinical trials.

The test results and interpretations are not intended or implied to be a substitute for medical advice.

Test Procedures and Results

The test will use tumor samples already taken during your surgery as part of your regular cancer care. Your doctor will tell you if you need to have another biopsy, but this is very unlikely for the sole purpose of this profile test.

Your tumor samples will be sent to special laboratories to find out if your cancer cells have molecular markers that may be present in some cancer cells. The markers include chemical materials, such as proteins and RNA, which may cause cancer cells to grow out of control. The markers may also include changes in your DNA, called mutations.

Star Biosciences and the laboratories where the tests are done keep your results confidential and fully obey with the Health Insurance Portability and Accountability Act (HIPAA). Your results will only be released as directed by you, which could include your healthcare provider, his or her designee, to another healthcare provider as directed by you (or a person legally authorized to act on your behalf) in writing, or otherwise as required by law.

Confidentiality

Star Biosciences will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known. This signed consent form will be stored in a locked file that will be accessible only to a very small number of authorized people. We will carefully follow the coding, storage, and release plan explained in the Description of the Research section of this document.

Storage and Use of Your Information in the Star Biosciences Database

Your personal information (name, address, medical record number, social security number, etc) including information on your test results, clinical information about your case including your type of cancer, the types of chemotherapy you have received and the length of your response to each chemotherapy agent will be de-identified and stored in a Star Biosciences database. Star Biosciences will share that same information with other databases for doctors and researchers to help researchers around the world understand more about human genetic variation and how it relates

to cancer and other related diseases. As appropriate, information in the database will be used for research, educational studies, commercial purposes and/or scientific publication, your name or other personal identifying information will not be used in or linked to the results of any studies and publications.

Possible Risks

It is intended that the molecular profiling tests use tumor or biopsy samples already taken as part of your regular cancer care. Your doctor will explain the risks of any additional biopsy procedure, if that is necessary, and will ask you to sign another consent form, if applicable.

Star Biosciences takes all reasonable steps to ensure confidentiality, but strict confidentiality cannot be guaranteed.

Possible Benefits

Knowing the molecular profile of your tumor samples may help you and your doctor make more informed choices about your cancer treatment. However, there is no guaranteed benefit from having the testing done.

Financial Responsibility

The costs of the tests are sometimes covered by insurance. You can pay for the tests if your insurance does not cover the costs.

Contact Information

If you have any questions or concerns about testing, you may contact any of the following people:

- For a medical or genetic test-related question, contact your doctor.
- For questions about the process for the testing, contact Star Health Network at the following email address:
tumortest@starhealthnetwork.com

Glossary

DNA (deoxyribonucleic acid): The molecule that encodes genetic information. DNA is a double-stranded molecule held together by weak bonds between base pairs of nucleotides. The four nucleotides in DNA contain the bases: adenine (A), guanine (G), cytosine (C) and thymine (T). In nature, base pairs form only between A and T and between G and C; thus the base sequence of each single strand can be deduced from that of its partner.

Chromosomes: The self-replicating genetic structures of cells containing the cellular DNA that bears in its nucleotide sequence the linear array of genes.

Exome: All the genetic material in the parts of the chromosomes of a human that code for proteins.

Gene: The fundamental physical and functional unit of heredity. A gene is an ordered sequence of nucleotides located in a particular position on a particular chromosome that encodes a specific functional product (i.e., a protein or RNA molecule).

Genetic code: The sequence of nucleotides, coded in triplets (codons) along the mRNA that determines the sequence of amino acids in protein synthesis. The DNA sequence of a gene can be used to predict the mRNA sequence, and the genetic code can in turn be used to predict the amino acid sequence.

Gene product: The biochemical material, either RNA or protein, resulting from expression of a gene. The amount of gene product is used to measure how active a gene is; abnormal amounts can be correlated with disease causing alleles.

Genome: All the genetic material in the chromosomes of a human.

Mutation: Any heritable change in DNA sequence.

Protein: A large molecule composed of one or more chains of amino acids in a specific order; the order is determined by the base sequence of nucleotides in the gene coding for the protein. Proteins are required for the structure, function and regulation of the body's cells, tissues and organs, and each protein has unique functions. Examples are hormones, enzymes and antibodies.

RNA (ribonucleic acid): A chemical found in the nucleus and cytoplasm of cells; it plays an important role in protein synthesis and other chemical activities of the cell. The structure of RNA is similar to that of DNA. There are several classes of RNA molecules, including messenger RNA, transfer RNA, ribosomal RNA and other small RNAs, each serving a different purpose.