

Patient Informed Consent

Why am I being asked to give consent?

You are being asked to sign this consent form because you want to have a molecular/genomic analysis performed to help your physician understand more about your cancer and we need your permission to run the test. The results may help your doctor make decisions about how to treat your cancer. It is important you know the purpose of the test and what will happen to your samples and the test results after we run the test. Please carefully read this consent form and ask your doctor or their staff any questions you have before you sign it. Make sure you get all of your questions answered to your satisfaction before you sign this form. You can also take this form home to discuss it with friends or family, if you wish. You will be provided with a copy of this form after you sign it.

By signing this consent form, you agree that NantHealth, Inc. and its laboratories (“NantHealth”) may perform molecular/genomic testing on your blood and/or tissue samples and use your information in the ways described in this form. Having this test done is voluntary; you do not have to take it.

What do I have to do?

After you sign this form, you will need to give two tubes of blood (about four teaspoons). The needle stick may hurt. There is a small risk of bruising and fainting and a rare risk of infection. If your doctor orders a tissue based test (such as GPS Cancer), you will also need to give a sample of your tumor. You might be able to use an existing biopsy of your tumor instead of having a new biopsy. Your doctor will decide what is needed and will help get the samples to NantHealth. If a new biopsy is needed, your doctor will explain the risks. Sometimes you might need to give additional samples if the lab can’t process what your doctor sends. Your doctor will explain the situation if this happens.

What is the test and what is its purpose?

There are two tests available. Your doctor will choose the test(s) that are best for you and tell you which test(s) will be ordered for you.

1. **GPS Cancer** uses your tissue and your blood and involves the sequencing of DNA and RNA to look for changes between your normal cells and your tumor/cancer cells. It also looks for changes in some of your genes that might predict your body’s response to certain anti-cancer medications (this is called pharmacogenomics). This information can help your doctor plan a personalized treatment program for you.
2. **Liquid GPS** uses only your blood to (1) assess DNA and RNA changes and expression in your blood that may be related to your cancer and (2) monitor your condition throughout your treatment.

Your DNA carries the instructions for each cell in your body. Your entire genetic material, made up of DNA, is called the genome. An exome is the part of your genome that includes only the part of DNA that tells your cells how to make certain things (proteins) to function properly or to grow. Performing a molecular/genomic analysis of your DNA is a way to check if there are changes (variants) in your DNA that might make it send different directions to your cells. Your DNA directs cells to make proteins using RNA as the messengers. Analyzing RNA is a way to check whether the changes in your DNA will actually direct changes in the proteins that give your tumor/cancer cells the instructions they use to grow.

Your doctor can use the test results with your other medical information to guide your treatment. Examples of this would be that your doctor decides to give you a certain chemotherapy that targets the specific DNA or RNA changes in your tumor (biomarkers), your doctor decides not to prescribe a certain anti-cancer medication because of your risk for increased side effects, your doctor adjusts the dosage of a certain anti-cancer medication to work better for you, your doctor determines that you might be a good candidate for a clinical trial based on the results, or your doctor wants to monitor how your treatment plan is affecting your cancer/tumor.

Optional Secondary Genetic Screening (Tissue-Based Testing only)

If your doctor orders a tissue-based test (such as GPS Cancer) and we are able to produce DNA results from the samples provided, you can choose to participate in an optional part of the test called “secondary genetic screening.” If you choose, NantHealth will perform a second analysis of the data from your DNA test results to look for changes that aren’t normal (genetic abnormalities) in some of the genes known to be related to whether a person will develop cancer (predisposition genes), including some that are recommended by the American College of Medical Genetics (ACMG). If you have genetic abnormalities, it can mean you might have an increased risk for particular types of cancers and other medical conditions. Since genetic abnormalities can be inherited, there is a chance that other family members related to you by blood could also carry these genetic abnormalities. Please note that this secondary screening does not look for all types of genetic abnormalities in these genes and it doesn’t screen all genes that might be associated with an increased cancer risk. Additional information regarding the genes and types of genetic abnormalities included in this screening is available at www.nanthealth.com and www.gpscancer.com

If you want to have this secondary screening done, please mark the appropriate box by your signature below. Your doctor will talk about the results of this part of the test with you and might recommend that you talk to a genetic counselor.

If you are a workers compensation patient, you cannot have this secondary screening. If you are not currently a workers compensation patient, but you seek workers compensation coverage in the future, the secondary screening results could impact your coverage decision, so please discuss this part of the test with your doctor before you decide you want to do it.

Who gets my test results and what happens to my samples?

NantHealth’s lab staff will use your samples to run the analyses. Your test results will be sent directly to your doctor and their staff when the test is completed and will become part of your medical record. You can also request they be shared with other healthcare providers or your family. Talk to your doctor about who you want to receive your results. NantHealth may also use or disclose your information as described in NantHealth’s Notice of Privacy Practices (available at www.nanthealth.com or upon request), including disclosure to other health care providers, your insurance carrier for claims processing, health care clearinghouses, or health plans that have a relationship with you. NantHealth will comply with applicable laws if it discloses your information. NantHealth will also store your results as required by law.

NantHealth may also remove information that identifies you (like your name and street address) from your results and any information received about you from your doctor and may use, disclose, and store the resulting de-identified information for as long as it believes it is useful for quality control, research and other purposes that are allowed by law, including research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from.

If there is any tissue or blood left after the test, NantHealth may destroy, return (usually to a pathology lab), or store for as long as it believes it is useful such residual material as permitted by applicable law. NantHealth may also remove any information that identifies you from such residual material and may use them for quality control, research, and other purposes if permitted under applicable law. If you or your samples are from New York, NantHealth will destroy any remaining sample within 60 days after your analysis is done.

These activities may help improve the tests NantHealth can offer to patients and in understanding more about cancer and other health problems. There may not be any direct benefit to you from these activities.

What are the limitations and risks of having this test?

The test results may help you and your doctor make choices about your health care, but it is also possible that the test will not find any genetic/genomic change that explains the disease you have or how your doctor can treat it. This doesn't mean your disease isn't caused by a change in your genes, but just that with the current knowledge, doctors and scientists don't yet understand how to interpret all of the results. The pharmacogenomics portion of the test looks at a limited number of your genes for potential reactions to certain anti-cancer drugs. It does not look at all genes or all medications, so you may have other variants that affect the way you react to other drugs. The testing process relies on highly skilled technicians and reliable technology. The methods NantHealth uses are reliable, but as with any laboratory test, there is the small chance that an error may occur, that there might be ambiguities in the results, or that no results are obtained. The quality of the results might be different based on the amount and quality of the samples provided for testing. For example, testing may not be possible or the results may be impacted if the tumor content in your tissue sample is not enough. You may learn things about yourself or your blood-related family that you did not expect or that are upsetting. Your relatives may learn that they are at risk for a disease. It might be frustrating or upsetting if the results of the test do not find the cause of your disease or help your doctor find a new therapy.

Continued on next page >>

Consent

I understand that this test is voluntary. By signing below, I agree to the following:

1. I authorize my doctor to collect and send to NantHealth my tumor tissue and/or blood sample. I authorize NantHealth to analyze my samples and return my results to my doctor. The test results will be put in my medical record and used by my doctors and other authorized parties for my health care.
2. I have discussed the test, and its purpose, benefits, risks, and limitations with my doctor. I have asked any questions and I have had them answered to my satisfaction.
3. I understand that I am responsible for my bill as described in the Patient Agreement of Financial Responsibility form I have received with this Consent form.
4. **Option to Receive Secondary Findings.** [Not Available for Workers Compensation Patients] By marking ONE box below, I am choosing whether or not to have secondary genetic screening results about genetic abnormalities in cancer predisposition genes (described above) sent to my doctor:

YES, I want to have a secondary screening performed and to receive secondary findings (if DNA results are obtained from my tissue sample).

NO, I do not want to have a secondary screening performed.

Patient Name (please write clearly)

Signature of Patient/Legal Representative*

Date

*If signed by a legal representative, describe relationship to the patient and authority to act for the patient

Your doctor will give you a copy of this signed consent form for your records. For further information about this testing or this consent form after you have talked to your doctor, please contact NantHealth at **(844) MY-OMICS (696-6427)**.

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 (866) 728-3945.

Authorization for Future Contact

From time to time, researchers from NantHealth, its affiliated companies or outside academic medical centers, pharmaceutical companies or other collaborators might want to ask you to participate in certain clinical trials or research studies. In some cases, you might be a particularly good candidate for a trial or study because of your genomic information and, in certain instances, you may be financially compensated for participation in these studies.

May NantHealth identify and contact you using your name, phone number, street address and email address in the future to get your permission to participate in future clinical trials and research studies?	YES	NO
May NantHealth give your name, phone number, street address and email address to outside researchers for a fee to identify and contact you in the future to get your permission to participate in future clinical trials and research studies?	YES	NO

You do not have to select yes to either of these questions. NantHealth may not withhold its testing service or refuse to test your samples based on your answer to these questions. Those persons who receive your health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You may change your mind and take back this Authorization at any time, except to the extent that NantHealth has already acted on it. To revoke this Authorization, you must write to NantHealth at GPS@NantHealth.com. This Authorization expires 50 years from the date signed. You will be given a copy of this Authorization once you have signed it.

 Patient Name (please write clearly)

 Signature of Patient/Legal Representative* Date

*If signed by a legal representative, describe relationship to the patient and authority to act for the patient