Laboratory of Personalized Genomic Medicine
Department of Pathology and Cell Biology

COLUMBIA UNIVERSITY MEDICAL CENTER

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Informed Consent – Columbia Whole Genome or Whole Exome Sequencing

Please read the following form carefully and discuss with your ordering physician before signing consent.

This consent is intended for the comprehensive sequencing of malignant ("cancerous") and non- malignant tumors and diseases of the blood cells. If this consent form is used for a pediatric patient, the word "you" also refers to your child.

Description of the Comprehensive Sequencing Tests

Whole Genome Sequencing (WGS) and Whole Exome Sequencing (WES) are new types of genetic testing that examine a person's DNA to determine if any changes exist that can cause disease. DNA carries the instructions for your body's development and function. It is contained in all of the cells that make up your body's tissues. Your entire unique genetic material, made up of DNA, is known as a genome. An exome is a portion of the genome, and includes only the DNA that is directly responsible for telling cells how to make the right parts, or proteins, to function properly. A gene is a small segment of DNA that controls the production of a single protein. The WGS/WES tests search through the DNA for changes that can cause disease. Currently, researchers and doctors know some of the genetic changes that can cause disease, but not all of them. Because WGS/WES examines a larger portion of the DNA than traditional tests, it might discover the cause of disease in cases where other tests did not. WGS/WES may also reveal information about unexpected diseases. Sometimes we may need to run more than one test on your blood or tissue samples to understand changes in your DNA. For example, DNA directs a cell to make proteins using a "messenger" substance called RNA. Sequencing this "messanger RNA," also called a transcriptome, can sometimes be a good way to check whether changes in DNA will actually direct changes in the proteins that give your tumor or abnormal blood cells the instructions they use to grow.

Reasons for Testing

Taking part in this test is voluntary. The decision to undergo the WGS/ WES test is made by you and your doctor. In general, the test is used when your doctor would like to have information about genetic changes that might explain the characteristics of your tumor or blood disorder or to assess the likelihood that the disease will respond to specific medications.

Testing

The test requires using a piece of tumor tissue, and two tubes (two teaspoons) of blood to serve as a sample of your normal cells.
If you have a disease of the blood, we will obtain blood and/or bone marrow as the disease samples, and a swabbing of cheek cells from your mouth to serve as the normal cells instead. DNA and RNA will be isolated from your disease tissue, blood and/or cheek cells, and then read by a machine called a sequencer.

Test Interpretation

Once the DNA/RNA is read, the information obtained is analyzed for differences between your own normal cells and that obtained from your tumor or abnormal blood cells. Some changes may cause the disease, determine its behavior, or affect the treatment chosen for your condition. To find the changes most likely to have caused or influenced your disease, we will do the following:

The changes in your DNA will be compared with a list of changes that are known to cause diseases with symptoms similar to yours. Changes found in the disease sample will be compared with your normal cells from your blood or cheek cells to confirm that the changes are specific to your tumor or abnormal blood cells. Sometimes changes occur that are not important to disease. These changes, also called "variants," may be present in your normal sample. We will exclude these from our report. Sometimes we will find changes in your normal DNA unrelated to your tumor or blood disorder that may be of significance to your health. You will have a chance below to tell us whether you want to receive this information.

Result Reporting

There are several kinds of results that may be reported. Results will go directly to your doctor or your other healthcare provider who ordered the test.

1. Positive for disease-causing change(s): You may have one or more genetic changes in your tumor tissue or abnormal blood cells that are known to cause a specific condition or predict its clinical behavior. The changes would be assumed to be the cause of your symptoms or features of your condition.
2. No disease-causing change(s) found: It is possible that the test will not find any genetic change that could explain the disease you have. This type of test result does not mean your condition is not influenced by genes, but rather that with current technologies and knowledge we cannot say that there are specific genetic changes causing the disease in your case. The result would not affect whatever current diagnoses doctors may have given for your condition.

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3. Changes with uncertain significance: Sometimes the test will find a change that may be important, but has not been reported or seen before in people with your condition. Such a change may or may not be the cause of your disease. The lab would report it as a "change or variant with uncertain significance" if there is evidence strongly suggesting that it is related to your condition.
4. "Secondary findings": These are test results that are not related to the disease for which the test was ordered. They might indicate that you may have or be at risk for a potentially serious condition. Some of these diseases might appear later during your lifetime and knowing about them might help to prevent development of serious medical conditions.

Secondary Findings
You may choose to be informed or not to be informed of secondary findings. Since this test provides information about changes in a large number of genes, changes might be detected that are not related to the disease for which the test was performed. Some of these findings might have significant immediate effects on your health care management. On an attached sheet is a list of genetic conditions that the American College of Medical Genetics and Genomics (ACMG) recommends be returned to people who have the WGS/ WES test. The presence of one or more of these changes can put a person at risk of certain cancers, potentially fatal heart conditions, and other serious health problems. If you find out that you have one of these genetic changes, you may be able to take preventive measures to guard against developing the disease or be able to lessen the seriousness of the disease outcome.

These secondary findings in risk genes may also have implications for your family. Based on your results we may suggest that you speak to a genetic counselor or discuss genetic testing on your family members. Any such additional testing would be discussed with the appropriate family member and addressed in a different consent.

Results That Will Not Be Reported
There are a few types of secondary results that will not be included in the report your doctor gets.

1. Some changes in genes might make a person slightly more likely to develop a type of common condition that happens in adults, such as diabetes or heart disease. These changes do not guarantee that the condition will develop. Because it is not yet clear how these changes will affect an individual's health or future medical care, they are not looked at in detail and are not included in the report.
2. Some changes in genes might make a person significantly more likely to develop a type of condition that happens in adults, such as Alzheimer's disease. However, these changes still do not guarantee that the condition will develop in a given individual, and even though the increased risk is known, no action can be taken to modify it. Because it is not yet clear how these changes will affect an individual's health or future medical care, they are not looked at in detail and are not included in the report.
3. You might be carrying a change that could have effects on your children, if your partner carries a similar change. This is called "carrier" status. We will not report your carrier status for any disease. If you are concerned about carrier status for conditions that might run in your family, you should discuss this possibility with your doctor or genetic counselor and consider getting tested separately for carrier status.

Potential Risks and Discomfort
You may learn medical information about yourself or your family that you did not expect. Learning that you are at risk for a disease other than the condition for which you were tested, which may or may not be preventable or treatable, could lead to emotional or psychological distress.

Your relatives may be upset to learn that they may be at risk for a disease.

The test will give us a lot of information, but we won't know what all of it means right away. It is possible that this test will not find the cause of your disease or help us identify a new therapy. This could be frustrating or upsetting. Although there are laws to prevent employment and health insurance discrimination based on genetic findings, there are currently no laws to prevent the use of genetic information to determine eligibility for life, disability or long-term care insurance.

Privacy Protections
The results of the WGS/ WES contained in the clinical report will become part of your medical record. You may choose to limit the clinical report such that it reflects only the DNA findings in your disease tissue that are known to affect the diagnosis or prognosis of your condition or that can guide the choice of specific therapies. Reported test results are stored in the laboratory's computer

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records, and are normally automatically sent to the electronic medical records (EMRs) of New York Presbyterian Hospital and Columbia University Medical Center. 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.

If you do not want the complete WGS/WES results to be sent to these personal medical records, you must inform us about this below. Unless you tell us not to transmit them, the complete WGS/WES report, including secondary findings in risk genes will become part of your EMR. Even if they do not become part of the EMR, the results may be made available to individuals/organizations with legal access to your medical record, on a strict "need-to- know" basis. Those with legal access include, but are not limited to, the doctors and nursing staff directly involved in your care, your current and future insurance carriers (after your consent is obtained), and others specifically authorized by you or your authorized representative to gain access to your medical records.

Options for Clinical Sequencing

Please read each sentence below and think about your choices for the WGS/WES tests performed. We want to know 1) whether you want to learn about secondary findings, 2) whether a complete report including secondary findings in risk genes should be transmitted to the EMR, 3) whether we can store your sample for future use, and 4) whether you wish to be contacted in the future. No matter what you decide to do, it will not negatively affect your current care.

You may say "I do" or "I do NOT" agree to each of the following choices. Please circle your choice and write your initials next to it.

1) **Secondary Findings:**

I do _____ (Initial)

I do NOT _____ (Initial)

want to learn about secondary findings in risk genes, specifically those related to the conditions on the attached list as suggested by the ACMG.

2) **Electronic Medical Records (EMRs):**

Please answer only if you selected to learn about secondary findings in question 1. If you chose not to learn about secondary findings, these findings will not be transmitted to your EMR.

I do _____ (Initial)

I do NOT _____ (Initial)

want my complete WGS/WES reported results transmitted to my EMRs within the New York Hospital- Presbyterian (NYP) and Columbia University Medical Center. If I do NOT want my complete WGS/WES reported results transmitted to my EMR, I understand that this means that my results related to secondary findings in risk genes will not be reported in the EMR and all other results related to my condition will be transmitted to my EMR. I understand that the complete WGS/WES results will continue to be part of the laboratory's electronic information system. If complete test results are not entered into the hospital or university medical center EMRs, future doctors may not have access to those results, which may include secondary findings in risk genes. I understand that I must assume responsibility for informing my future doctors about such findings of the WGS/WES test that relate to my healthcare.

3) **Sample Storage:**

We recognize that your clinical condition may change and/or newer sequencing technologies may become available over time. We would like to store your tissue, DNA, and RNA samples and the data they generate in case new information becomes available that we think might benefit you or your family.

I do _____ (Initial)

I do NOT _____ (Initial)

give permission for Columbia University Medical Center to store my samples for future clinical testing.

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4) Future Contact for Clinical Purposes:

In the event that new information becomes available that might benefit me:

I do _____ (Initial)

I do NOT _____ (Initial)

give permission for Columbia University Medical Center to contact me.

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Research

Information learned from additional research testing may help future patients with cancer or other diseases. The results of testing done solely for the purposes of research will be returned to you only if the findings have a direct impact on your current condition. In all other cases research results will not be returned to you and not become a part of your medical record. Because this is a new test, it is important to keep track of the types of genetic changes we find at the time the test was ordered and are able to connect to particular diseases. This helps us improve our diagnostic capabilities. Hence, whichever choice you make below regarding storage and future use of your samples and WGS/WES data, information about the type of disease and symptoms associated with the reported genetic findings at the time of initial testing will be preserved. This might not directly benefit you, but it might benefit future patients with similar conditions.

Samples: We would like to store your leftover DNA and RNA samples indefinitely. We would like to be able to use these leftover specimens for research. Samples used solely for the purpose of research about the disease may be de-identified by removing your name, medical record number and other identifying information

5) I do _____ (Initial)

I do NOT _____ (Initial)

give permission for Columbia University Medical Center to use my leftover samples for research.

Sequencing data: There is no intention to routinely reanalyze your WGS/WES results. However, as our knowledge of the genetic basis of disease expands there may be instances where we want to re-analyze data that have previously been collected. If you agree, we would like to store the results of your WGS/WES and related testing in a database. It is possible to store these data with or without identifying information. If the data are stored in a manner that includes your name and other identifying information the opportunity will still exist to link back to you and your clinical situation in the future. If, during a re-analysis, we discover something that would directly impact your care for your current condition, every effort will be made to communicate this information to you. We will do our best to make sure that the personal information contained in this database is kept private. For example, if information from this testing is published or presented at scientific meetings, your name and other personal information will not be used. However, we cannot guarantee total privacy. Your personal information may be given out if required by law.

6) I do _____ (Initial)

I do NOT _____ (Initial)

agree to my WGS/ WES and related data being stored indefinitely in a database.

7) (Please answer only if you have chosen "I do" above for question 6).

I do _____ (Initial)

I do NOT _____ (Initial)

agree to having my stored WGS/ WES and related data in a database that includes identifiers.

8) <u>Future Contact for Research Purposes</u>:

I do _____ (Initial)

I do NOT _____ (Initial)

give permission for Columbia University Medical Center to contact me for the purposes of participating in future research.

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Costs

Although research funds will pay for certain research-related items and services, you and/or your health plan/insurance company will need to pay for the costs of the clinical tests and services 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 the costs of these newer tests. Check with your health plan or insurance company to find out what they will cover.

If your insurance company denies payment for the tests and services, you may be personally responsible for these costs.

Statement of Consent

I have read the consent form and talked about the WGS/WES testing, including the purpose, procedures, risks, benefits and alternatives with my doctor. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this testing and associated research. I can stop being a part of the research database at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

Signatures:

WGS/WES Testing Participant

Print Name: _____ **Signature:** _____ **Date:** _____

Parent/Guardian of WGS/WES Testing Participant (if participant <18 years old)

Print Name: _____ **Signature:** _____ **Date:** _____

Person Obtaining Consent

Print Name: _____ **Signature:** _____ **Date:** _____

Current List of genes for reporting of Secondary Variants (v 3.2, Miller et al., 2023 https://doi.org/10.1016/j.gim.2023.100866)

Gene	Gene MIM	Disease/Phentyope	Disorder MIM	Phenotype Category	Inheritance	SF List Version	Variants to report
ACTA2	102620	Familial thoracic aortic aneurysm	611788	Cardiovascular	AD	1.0	All P and LP
ACTC1	102540	Hypertrophic cardiomyopathy	612098	Cardiovascular	AD	1.0	All P and LP
ACVRL1	601284	Hereditary hemorrhagic telangiectasia	600376	Miscellaneous	AD	3.0	All P and LP
APC	611731	Familial adenomatous polyposis	175100	Cancer	AD	1.0	All P and LP
APOB	107730	Familial hypercholesterolemia	144010	Cardiovascular	AD	1.0	All P and LP
ATP7B	606882	Wilson disease	277900	Miscellaneous	AR	2.0	P and LP (2 variants)
BAG3	603883	Dilated cardiomyopathy	613881	Cardiovascular	AD	3.1	All P and LP
		Myofibrillar myopathy	612954	Cardiovascular	AD	3.1	All P and LP
BMPR1A	601299	Juvenile polyposis syndrome	174900	Cancer	AD	1.0	All P and LP
BRCA1	113705	Hereditary breast and ovarian cancer	604370	Cancer	AD	1.0	All P and LP
BRCA2	600185	Hereditary breast and ovarian cancer	612555	Cancer	AD	1.0	All P and LP
BTD	609019	Biotinidase deficiency	253260	Metabolic	AR	3.0	P and LP (2 variants)
CACNA1S	114208	Malignant hyperthermia	601887	Miscellaneous	AD	1.0	All P and LP
CALM1	114180	Long-QT syndrome type 14	616247	Cardiovascular	AD	3.2	All P and LP
		Catecholaminergic polymorphic ventricular tachycardia	614916	Cardiovascular	AD	3.2	All P and LP
CALM2	114182	Long-QT syndrome type 15	616249	Cardiovascular	AD	3.2	All P and LP
		Catecholaminergic polymorphic ventricular tachycardia	616249	Cardiovascular	AD	3.2	All P and LP
CALM3	114183	Long-QT syndrome type 16	618782	Cardiovascular	AD	3.2	All P and LP
		Catecholaminergic polymorphic ventricular tachycardia	618782	Cardiovascular	AD	3.2	All P and LP
CASQ2	114251	Catecholaminergic polymorphic ventricular tachycardia	611938	Cardiovascular	AR	3.0	P and LP (2 variants)
COL3A1	120180	Ehlers-Danlos syndrome, vascular type	130050	Cardiovascular	AD	1.0	All P and LP
DES	125660	Dilated cardiomyopathy	604765	Cardiovascular	AD	3.1	All P and LP
		Myofibrillar myopathy	601419	Cardiovascular	AD	3.1	All P and LP
DSC2	125645	Arrhythmogenic right ventricular cardiomyopathy	610476	Cardiovascular	AD	1.0	All P and LP
DSG2	125671	Arrhythmogenic right ventricular cardiomyopathy	610193	Cardiovascular	AD	1.0	All P and LP
DSP	125647	Arrhythmogenic right ventricular cardiomyopathy	607450	Cardiovascular	AD	1.0	All P and LP
		Dilated cardiomyopathy	615821	Cardiovascular	AD	1.0	All P and LP
ENG	131195	Hereditary hemorrhagic telangiectasia	187300	Miscellaneous	AD	3.0	All P and LP
FBN1	134797	Marfan syndrome	154700	Cardiovascular	AD	1.0	All P and LP
FLNC	*102565*	Dilated cardiomyopathy	n/a	Cardiovascular	AD	3.0	All P and LP
		Hypertrophic cardiomyopathy	617047	Cardiovascular	AD	3.0	All P and LP
		Myofibrillar myopathy	609524	Cardiovascular	AD	3.0	All P and LP
GAA	606800	Pompe disease	232300	Metabolic	AR	3.0	P and LP (2 variants)
GLA	300644	Fabry disease	301500	Cardiovascular Metabolic	XL	1.0	All hemi, het, homozygous P and LP
HFE	613609	Hereditary hemochromatosis (c.845G>A; p.C282Y homozygotes only)	235200	Miscellaneous	AR	3.0	p.C282Y homozygotes only
HNF1A	142410	Maturity-Onset of Diabetes of the Young	600496	Miscellaneous	AD	3.0	All P and LP
KCNH2	152427	Long-QT syndrome type 2	613688	Cardiovascular	AD	1.0	All P and LP
KCNQ1	607542	Long-QT syndrome type 1	192500	Cardiovascular	AD	1.0	All P and LP
LDLR	606945	Familial hypercholesterolemia	143890	Cardiovascular	AD	1.0	All P and LP
LMNA	150330	Dilated cardiomyopathy	115200	Cardiovascular	AD	1.0	All P and LP
MAX	154950	Hereditary paraganglioma-pheochromocytoma syndrome	171300	Cancer	AD	3.0	All P and LP
MEN1	613733	Multiple endocrine neoplasia type 1	131100	Cancer	AD	1.0	All P and LP
MLH1	120436	Lynch syndrome	609310	Cancer	AD	1.0	All P and LP
MSH2	609309	Lynch syndrome	120435	Cancer	AD	1.0	All P and LP
MSH6	600678	Lynch syndrome	614350	Cancer	AD	1.0	All P and LP
MUTYH	604933	*MUTYH* -associated polyposis	608456	Cancer	AR	1.0	P and LP (2 variants)
MYBPC3	600958	Hypertrophic cardiomyopathy	115197	Cardiovascular	AD	1.0	All P and LP
MYH11	160745	Familial thoracic aortic aneurysm	132900	Cardiovascular	AD	1.0	All P and LP
MYH7	*160760*	Hypertrophic cardiomyopathy	192600	Cardiovascular	AD	1.0	All P and LP
		Dilated cardiomyopathy	613426	Cardiovascular	AD	1.0	All P and LP
MYL2	160781	Hypertrophic cardiomyopathy	608758	Cardiovascular	AD	1.0	All P and LP
MYL3	160790	Hypertrophic cardiomyopathy	608751	Cardiovascular	AD	1.0	All P and LP
NF2	607379	*NF2* -related schwannomatosis	101000	Cancer	AD	1.0	All P and LP
OTC	300461	Ornithine transcarbamylase deficiency	311250	Metabolic	XL	2.0	All hemi, het, homozygous P and LP
PALB2	610355	Hereditary breast cancer	114480	Cancer	AD	3.0	All P and LP
PCSK9	607786	Familial hypercholesterolemia	603776	Cardiovascular	AD	1.0	All P and LP
PKP2	602861	Arrhythmogenic right ventricular cardiomyopathy	609040	Cardiovascular	AD	1.0	All P and LP
PMS2	600259	Lynch syndrome	614337	Cancer	AD	1.0	All P and LP
PRKAG2	602743	Hypertrophic cardiomyopathy	600858	Cardiovascular Metabolic	AD	1.0	All P and LP
PTEN	601728	*PTEN* hamartoma tumor syndrome	158350	Cancer	AD	1.0	All P and LP
RB1	614041	Retinoblastoma	180200	Cancer	AD	1.0	All P and LP
RBM20	613171	Dilated cardiomyopathy	613172	Cardiovascular	AD	3.1	All P and LP
RET	*164761*	Familial medullary thyroid cancer	155240	Cancer	AD	1.0	All P and LP
		Multiple endocrine neoplasia type 2A	171400	Cancer	AD	1.0	All P and LP
		Multiple endocrine neoplasia type 2B	162300	Cancer	AD	1.0	All P and LP
RPE65	180069	*RPE65* -related retinopathy	204100, 613794	Miscellaneous	AR	3.0	P and LP (2 variants)
RYR1	180901	Malignant hyperthermia	145600	Miscellaneous	AD	1.0	All P and LP
RYR2	180902	Catecholaminergic polymorphic ventricular tachycardia	604772	Cardiovascular	AD	1.0	All P and LP
SCN5A	*600163*	Long QT syndrome type 3	603830	Cardiovascular	AD	1.0	All P and LP
		Brugada syndrome	601144	Cardiovascular	AD	1.0	All P and LP
		Dilated cardiomyopathy	601154	Cardiovascular	AD	1.0	All P and LP
SDHAF2	613019	Hereditary paraganglioma-pheochromocytoma syndrome	601650	Cancer	AD	1.0	All P and LP
SDHB	185470	Hereditary paraganglioma-pheochromocytoma syndrome	115310, 171300	Cancer	AD	1.0	All P and LP
SDHC	602413	Hereditary paraganglioma-pheochromocytoma syndrome	605373	Cancer	AD	1.0	All P and LP
SDHD	602690	Hereditary paraganglioma-pheochromocytoma syndrome	168000, 171300	Cancer	AD	1.0	All P and LP
SMAD3	603109	Loeys-Dietz syndrome	613795	Cardiovascular	AD	1.0	All P and LP
SMAD4	*600993*	Juvenile polyposis syndrome	174900	Cancer	AD	1.0	All P and LP
		Hereditary hemorrhagic telangiectasia	175050	Miscellaneous	AD	1.0	All P and LP
STK11	602216	Peutz-Jeghers syndrome	175200	Cancer	AD	1.0	All P and LP
TGFBR1	190181	Loeys-Dietz syndrome	609192	Cardiovascular	AD	1.0	All P and LP
TGFBR2	190182	Loeys-Dietz syndrome	610168	Cardiovascular	AD	1.0	All P and LP
TMEM127	613403	Hereditary paraganglioma-pheochromocytoma syndrome	171300	Cancer	AD	3.0	All P and LP
TMEM43	612048	Arrhythmogenic right ventricular cardiomyopathy	604400	Cardiovascular	AD	1.0	All P and LP
TNNC1	191040	Dilated cardiomyopathy	611879	Cardiovascular	AD	3.1	All P and LP
TNNI3	191044	Hypertrophic cardiomyopathy	613690	Cardiovascular	AD	1.0	All P and LP
TNNT2	*191045*	Dilated cardiomyopathy	601494	Cardiovascular	AD	1.0	All P and LP
		Hypertrophic cardiomyopathy	115195	Cardiovascular	AD	1.0	All P and LP

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Gene	Gene MIM	Disease/Phentyope	Disorder MIM	Phenotype Category	Inheritance	SF List Version	Variants to report
TP53	191170	Li-Fraumeni syndrome	151623	Cancer	AD	1.0	All P and LP
TPM1	191010	Hypertrophic cardiomyopathy	115196	Cardiovascular	AD	1.0	All P and LP
TRDN	*603283*	Catecholaminergic polymorphic ventricular tachycardia	615441	Cardiovascular	AR	3.0	All P and LP
		Long QT syndrome	n/a	Cardiovascular	AR	3.0	All P and LP
TSC1	605284	Tuberous sclerosis complex	191100	Cancer	AD	1.0	All P and LP
TSC2	191092	Tuberous sclerosis complex	613254	Cancer	AD	1.0	All P and LP
TTN	188840	Dilated cardiomyopathy (truncating variants only)	604145	Cardiovascular	AD	3.0	P and LP (truncating variants only)
TTR	176300	Hereditary transthyretin-related amyloidosis	105210	Miscellaneous	AD	3.1	All P and LP
VHL	608537	Von Hippel-Lindau syndrome	193300	Cancer	AD	1.0	All P and LP
WT1	607102	*WT1* -related Wilms tumor	194070	Cancer	AD	1.0	All P and LP