Patient Name: _____
Medical Record Number: _____

UPMC LIFE CHANGING MEDICINE

HEREDITARY CANCER AND CARDIOLOGY GENETIC TESTING ACKNOWLEDGEMENT FORM

UPMC Clinical Genomics Laboratory
300 Halket Street, Pittsburgh, PA 15213
Phone: (412) 641-2949 Fax:(412) 641-2893

I, _____
(name of patient or substitute decision-maker)

have been asked to carefully read all the information contained in this form. I have been given the chance to ask questions about anything that I do not understand. (If the decision-maker signing this form is not the patient, references to "I," "my" or "me" should be read as if referring to "the patient," when applicable.) I request that a sample of saliva, blood, or tissue be submitted for genetic testing. I understand that this sample is being examined for the following condition(s):

_____

I understand that genetic counseling should occur before and after testing to help me understand how the results affect me and my family.

Results

The testing could have the following results:

- **Positive** test results (a pathogenic variant in a gene(s) is identified) - This may mean that I have the condition related to the gene in which the pathogenic variant is identified, am at risk for developing this condition, or am a carrier of the condition and could pass it to my children.
- **Negative** test results (no pathogenic variant in the gene(s) tested is identified) - This rules out most of the chance that there is a genetic cause to the condition being tested, however this result may occur even if I have a genetic basis to the condition I am being tested for. Not all changes in genetic material that contribute to disease can be identified by testing because the knowledge of genes is incomplete and always changing. Current technology may not be able to identify the gene(s) that is causing my condition.
- **Uncertain** test results (a variant of unknown clinical significance in a gene(s) is identified) - Some genetic changes are not well understood and their clinical significance is unknown. Additional testing of myself or other family members may be helpful to understand the significance of the result. An uncertain result might be revised in the future into a positive or negative result. Until then, the result is uninformative.

Potential Risks

- Testing may predict that another family member has a risk for developing or is a carrier of this condition.
- Testing may identify risk of another condition to me and my family, even if no symptoms of the condition currently exist.
- In some cases, genetic testing can reveal that the true biological relationships in a family are not as they were reported. This includes situations where the stated father of an individual is not the biological father, or the parents of an individual are related by blood. It may be necessary to report these findings to the health care provider who ordered the test.
- I may have been clinically misdiagnosed and therefore the appropriate genetic testing may not have been recommended.
- Although DNA testing usually yields precise information, several sources of error are possible. These include, but are not limited to, errors in processing of the sample, technical problems, and inaccurate information regarding family relationships.

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- Federal law extends some protections regarding genetic discrimination (http://www.genome.gov/10002328). If a pathogenic variant is identified, obtaining disability or life insurance and employability could be affected. There may be some concern regarding health insurance rates. All test results are released to the ordering health care provider and are confidential to the extent allowed by law.

Cost I understand that the testing may not be covered by my health insurance and therefore the financial responsibility is mine. I will be responsible for payment after the genetic testing has begun, even if I decide not to receive results. Any request for additional studies must be made by my authorized health care provider and will incur an additional charge. **I understand that I will be contacted twice, prior to the test starting only if my out-of-pocket cost (coinsurance, deductible, non- covered services) is estimated to be more than $350. I also understand the laboratory will automatically proceed with testing if I do not notify the lab to cancel testing within 3 days after their second attempt to contact me.**

Validation of Results The performance characteristics of this test were validated by our laboratories. The U.S. Food and Drug Administration (FDA) has not approved this test; however, FDA approval is currently not required for clinical use of this test. Our laboratories are authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing.

The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

My signature below acknowledges my understanding of, and agreement to, having this genetic test(s):

Patient/Guardian Signature _____ Date _____ Time _____

Health Professional Statement: I have explained DNA testing including its risks, benefits and limitation to the patient or legal guardian. All questions have been answered to the best of my ability.

_____	_____	_____	_____
Print Name	*Signature*	*Date*	*Time*

Interpreter Statement: (if applicable) Execute if an interpreter is provided to assist the individual in understanding this informed consent form:
I have translated the information and advice presented orally to the individual to be treated by the person obtaining this consent. In addition, I have sight translated the consent form (read it aloud in his/her language). To the best of my knowledge and belief he/she understood this explanation.

_____	_____
Print Name	*Cyracom ID (if applicable)*

_____
Signature (Not required if a Cyracom Interpreter Was Used)