

**Symptomatic Testing for Huntington Disease
Confirmation of Diagnosis
Informed Consent Form**

Testing Program Description and Requirements: I agree to provide a sample of my blood for the purpose of genetic testing for Huntington Disease. I understand that this is a clinical test and is not a research study. I understand that this test will only evaluate the gene for Huntington Disease and my blood will not be used for any other testing. I also understand that I have symptoms of Huntington Disease and this test is being used to attempt to confirm or exclude that diagnosis. I will be given the results and the meaning of the results by my doctor.

I have been told the following:

1. I have symptoms seen in patients with Huntington Disease.
2. This test will evaluate my gene for Huntington Disease.
3. The vast majority of people with Huntington Disease have a change in the gene that is responsible for the condition and this test will show whether or not my gene has that change.
4. Rarely, people who have Huntington Disease have test results that cannot be interpreted. It is possible that my test results will not tell me more than I know now.
5. Since I now have symptoms, it is likely that the test results will show that I have the gene for Huntington Disease.

Risks and Discomforts: A positive result could lead to serious psychological consequences included but not limited to feelings of depression, futility, despair and severe stress. A negative result can produce feelings including but not limited to guilt as well as joy. In addition, I am aware that an inconclusive result can be frustrating and can intensify the ambiguity of my risk situation or can provide relief.

My doctor has informed me that genetic counseling is available. I have been informed of other possible risks such as difficulties with confidentiality, employment, or insurance.

Physically, risks usually include the discomfort of blood being drawn from the arm which may result in a black and blue mark that should fade in a few days.

Benefits: I may learn whether or not I have inherited the gene that causes Huntington Disease. This may help me better plan my future and reduce the anxiety of not knowing.

Description of Procedures: I understand that the test requires analysis of 20cc (2 tubes) of my blood. The laboratory will provide my results for my doctor in 4-6 weeks.

Requests for more information: I understand that my doctor and the professionals involved in this testing are willing to answer my questions and to discuss my concerns with me. They are also available for my family should they have any questions.

Refusal or withdrawal of consent: I may discontinue participating at any time without prejudice to my present or future relationships, including medical care, at the University of Pittsburgh or the University of Pittsburgh Medical Center. I also understand that my doctor may stop my participation in this testing at any time. The reasons for doing this will be fully explained by my doctor and I will be helped to obtain any medical care if that is appropriate.

I understand that release of information pertaining to this testing program could cause future problems for me in the event that such information is received by insurance companies or other third parties who make decisions based upon genetic risk. Therefore, I _____ do not authorize/ _____ authorize (please place an "X" and your initials next to your decision) release of any information pertaining to this clinical testing program to my insurance carrier and other third party only as noted below:

My signature below documents that: 1) I have had the opportunity to read this form or it has been read to me; 2) a physician or physician's representative has explained all the information contained in this form and answered to my satisfaction any questions that I had; and 3) based on my understanding of the testing program, its purposes, possible risks, discomforts and benefits that I may experience; I consent to participate in this clinical testing program.

Patient's Signature

Date

Patient's Printed Name

Witness

Date

Signature of Physician
(or Physician's representative)
obtaining consent of Patient

Revised: 01/01/01