



Huntington Disease: Informed Consent for Presymptomatic Testing

University of Iowa
Division of Medical Genetics
Testing Protocols

Patient's Name _____

Hospital Number _____

DOB _____

I _____ choose to participate in presymptomatic testing for the presence of the Huntington disease (HD) gene. I have been told that I am at risk for HD because there is a history of this disorder in my family. I understand genetic material will be evaluated only for the gene change responsible for HD and will not be used for any other testing. This test will most likely tell me if I have or have not inherited the gene that causes HD.

I understand I must participate in a testing protocol that provides genetic counseling and any necessary follow up care. I agree to participate in the minimum of three counseling sessions required for the testing. There will be at least two sessions prior to the test result session. Sessions will last 1-3 hours. These sessions will include information about HD, genetic testing, consequences of results and available support services.

I understand a neurological exam is recommended. I am aware this examination may disclose that I have clinical signs of HD and I will be told of my results.

I understand the test does have some limitations. First, it is not known if everyone who is affected with HD has the same change in the gene causing the disease. Second, occasionally the result of gene analysis cannot be interpreted with confidence.

I understand there can be three outcomes to the test:

1. The gene change in my Family might not be interpretable, so my test results will not tell me more than I know now.
2. I do not have the HD mutation.
3. The HD gene mutation is present and I will develop HD.

I understand my participation in this program is voluntary and I can terminate my participation at any time without jeopardy to my medical care. I understand if at any time my continued participation in this program is considered injurious to my health or disadvantageous to me, the testing staff may recommend postponement of the testing.

The information provided is technical and receiving it will be stressful. Because of this, I am encouraged to bring a close friend, spouse, or other family member not at risk for HD to accompany me through the test procedures. I understand the professionals involved in this testing are willing to answer my questions and to discuss my concerns with me throughout the testing procedure. Counselors will assist me in arranging for any additional professional counseling and support I may need. Risks of this testing include:

A. concerns of a psychological nature. I understand the testing may be lengthy and does require a waiting period before results are available. These events may cause me to confront difficult psychological issues. Since I may withdraw from the testing protocol at any time and the process is a long one, decisions about my continued participation may evoke anxiety. An uninterpretable result can be frustrating and can intensify the ambiguity of the risk situation. Knowing I do not have the common mutation for HD can produce mixed emotions. I may also have to confront the fact I have inherited the mutation that causes HD and will develop the disease. I am aware the testing cannot predict when I first will show signs of HD nor can it predict the severity or rate of progression of HD. This will also mean that my children will have a 50% chance of inheriting the HD mutation.

B. possible difficulties with employment or insurance.

C. discomfort of a blood draw and a bruise. I understand this test requires me to provide 20cc (two tubes) of my blood.

D. financial liability. I will be responsible for the costs of the laboratory testing and counseling regardless of the outcome of my testing. In some cases, medical insurance will not pay for this testing.

I understand results of my testing will not be available to any one other than the professionals involved and is not to be released to any second party without my written consent. Test results will be given only to me and only in person.

_____ has explained to me the purposes of the testing protocol and I agree to participate in this testing program. I acknowledge the possible risks, discomforts, and benefits I may experience. I have read and I understand this consent form.

Participant Date

Witness to Signature Date