



## **PRE-CELL**

A pre-cellular therapy observational study in early Huntington's Disease  
UC Davis Health System

### **What is the PRE-CELL Study?**

PRE CELL is an observational study (no intervention). A group of up to 40 patients with early-stage Huntington's Disease (HD) will be enrolled in this observational trial to establish a baseline and study changes over time in measures of movement, thinking, behavior, brain imaging, blood and spinal fluid markers. The information from the study assessments will help Dr. Wheelock and the research team learn more about the rate of change in these measures in people with early-stage HD. Participants enrolled in this study may be eligible to participate in a future planned study of stem cell therapy for Huntington's Disease.

### **Who Can Participate?**

- People over 18 years of age that have tested positive for the HD gene expansion (CAG repeat number 38 and above)
- Early stage Huntington's Disease with some movement changes, but stable mood and thinking skills
- Must have a caregiver or informant willing to come to all study visits and complete observations forms
- Women and men with childbearing potential must agree to adequate birth control measures for the length of the study
- Additional study criteria apply that can be discussed with the study coordinator

### **What are the study procedures?**

If you are interested in participating, Dr. Wheelock and the research team will first have to determine if you are eligible. That will be done by reviewing your medical records and performing a research screening visit. There will be physical and neurological examinations, and written and verbal tests to assess your mood and thinking skills. There will also be rating scales to measure your ability to function in day to day life. A brain scan, heart rhythm test, chest Xray, spinal tap, and blood tests will be scheduled to make sure there are no underlying medical problems that would make it unsafe for you to participate. These tests will be repeated at 6 month intervals. You will be enrolled in the study for 12-18 months.

### **What are the risks associated with participating?**

- Some people experience emotional discomfort when being observed for symptoms of HD
- Some people feel claustrophobic having a brain scan
- There may be minor pain and the possibility of bruising from blood draws, and the lumbar puncture
- There is the potential for a headache after a spinal tap
- Exposure to a minimal amount of radiation from the chest Xray

### **What are the benefits to me if I decide to participate in PRE-CELL?**

There will be no direct benefit to you in this observational trial, however you will be contributing to the growing knowledge of Huntington's Disease. Subjects who successfully complete PRE-CELL and meet future study eligibility criteria will be considered for a planned stem cell therapy trial in HD.

### **How do I learn more about PRE-CELL?**

**Contact:**

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