

## **Genetic Disease Investigators**

Colleyville, Texas

*Consent Form for Participation in a Clinical Research Study*

**TITLE: Head Circumference Growth in Ehlers-Danlos Children Who Develop POTS (Postural Orthostatic Tachycardia Syndrome) – a Retrospective Analysis**

**INVESTIGATORS:** Diana Driscoll, O.D. (Study Director), Richard Driscoll, O.D. (Investigator) Genetic Disease Investigators

*This is an important form. Please read it carefully. It tells you what you need to know about this research study. If you agree to take part in this study, you need to sign this form. Your signature means that you have been told about the study and the potential risks. Your signature on this form also means that you want to take part in this study.*

### **Why is this research study being done?**

This study is being done to get a better understanding of cause of the numerous neurological complications of Ehlers-Danlos patients, with particular focus on the cognitive decline and “brain fog” experienced by these patients. Preliminary analysis indicates “Benign External Communicating Hydrocephalus” may play a role in the development of POTS. If hydrocephalus is found from birth, these results may also point us toward effective treatments for the condition, or may allow us to prevent it entirely.

### **How many people will take part in this research study?**

The plan is to include 25 patients with Ehlers-Danlos/POTS.

### **What will happen in this research study?**

Patients need not travel for this study. Potential participants with a diagnosis of Ehlers-Danlos and POTS (or a suspicion of POTS by an evaluation of symptoms) must provide head circumferences, weights, and lengths for approximately the first 15 months of life (generally in intervals of 2-3 months).

Participants can provide this information to the Investigators on-line – no travel is necessary. Patients will be asked to complete a questionnaire concerning their symptoms.

### **May I leave the study if I desire to do so?**

Taking part in this research study is your decision. You may decide to stop at any time. Additionally, the doctors may stop you from taking part in this study at any time if it is discontinued for any reason.

### **Is there any cost to participating in the study?**

**Genetic Disease Investigators**

Head circumference - EDS

Form approved: June 1, 2011

There is no cost to you for participating in the study. There is no remuneration to you for participating in the study, either, but we will provide for you, at no cost, a copy of our research results.

**Will my identity be protected?**

As is true with any medical record, your test results will remain strictly confidential. Your profile and results will be identified by a number, rather than your name for evaluation (the doctor evaluating the results will not know who you are). If you allow your results to be used for further research, your results may be stored indefinitely and confidentially at Genetic Disease Investigators.

There is a very small chance that some commercial value may result from the use of your sample. If that would happen you will not be offered a share in any profits.

**Are there any risks to participation?**

There are no risks to participation in this study.

A copy of this form will be placed in your medical record.

**I have had an opportunity to have my questions answered. I have been given a copy of this form. I agree to take part in this research study.**

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Participant (or Legal Guardian)

\_\_\_\_\_  
Signature of Participant (or Legal Guardian)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Individual Obtaining Consent

\_\_\_\_\_  
Signature of Individual Obtaining Consent