

**Invitation to Participate:
A New Measure for Tracking Thinking Skills & Behavior for PTEN**

Dear Participant,

Dr. Charis Eng invites you to participate in an upcoming research project that might be of interest to you and your family.

It is often difficult for people with genetic syndromes, such as PTEN Hamartoma Tumor Syndrome (PHTS), to travel to specialty care clinics for evaluation and treatment by expert clinicians. We are seeking participants to assist in the development of online evaluation tools that can be completed from the comfort of home to track important information before and during clinical care.

There will be two kinds of evaluation tools completed through this project.

1. The first evaluation tool being studied will ask individuals diagnosed with PTEN (or an unaffected sibling as a healthy control) to watch an online video on your home computer with a built-in video camera (webcam). The webcam computer software will watch your reaction while viewing the video, which will be saved as pieces of data that will be analyzed. Each online video will take approximately 15 - 20 minutes to complete. No verbal or physical responses will be required. This will be done three times, at baseline (first time), at 1-month (one month after baseline) and at 4-months (four months after baseline).
2. The second evaluation tool will ask a parent or close informant to complete a set of questions in a survey on your home computer that asks about the participants' behavior and their ability to complete daily activities. The link to this survey will arrive in your email at the same time as the link to the online video measure and the survey will take approximately 20 – 25 minutes to complete. This will be done three times, at baseline (first time), at 1-month (one month after baseline) and at 4-months (four months after baseline). Some questions in the survey may involve sensitive or personal information and you may choose not to answer all questions.

There is a potential risk of loss of confidentiality of your data, however, every effort will be made to keep your information confidential through the use of a unique identification code to identify your data, and password protected computers/databases accessible only by research staff. You may not receive direct benefit from being in this study. However, taking part may help patients with PTEN Hamartoma Tumor Syndrome receive better care in the future. No results will be reported to participants or supporting informants. A research stipend will be paid to the participant and the informant for each study measure completed (please see stipend explanation below).

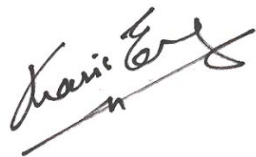
Both the individual with PHTS (participant) and their informant will receive a \$30 stipend at the completion of each measure, for a possible total of \$180 for each enrolled pair.

This project is a strong first step toward developing a series of evaluation tools that can be used to enhance future clinical and research assessments for people with PHTS and other genetic and neurodevelopmental syndromes.

A member of the research staff will contact you in five (5) days to see if you are interested in participating. If you do not wish to receive a call, please feel free to call 216-445-5850 and leave a message that you do not wish to be contacted.

If you are interested in participating in this research, you may contact the research coordinator, Beth Crouser, at crouseb2@ccf.org or by telephone at (216) 445-5850. Participation in this study is completely voluntary, and your decision not to participate will in no way affect your current or future medical care at Cleveland Clinic. You may also contact the Cleveland Clinic Institutional Review Board Office at 216-444-2924 if you have questions about your rights as a research subject. We look forward to hearing from you!

Sincerely,

A handwritten signature in black ink, appearing to read "Sondra J. and Stephen R. Hardis". The signature is written in a cursive style and is positioned above a horizontal line.

Principal Investigator
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