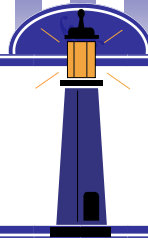


PHAROS



SPOTLIGHT

This newsletter is dedicated to our PHAROS participants and their families.



PHAROS...A Roadmap to the Future for HD

Volume 5

August 2006

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Dear PHAROS Participants and Families,

On July 1, 2006 we submitted an application to the National Institutes of Health (NIH) seeking funds to continue PHAROS through 2010. In order to achieve the aims of the study a longer period of observation is necessary. The resulting knowledge will facilitate the design and conduct of clinical trials aimed at postponing the onset of HD.

Other exciting news we would like to share with you is the recent publication on the baseline characteristics of the PHAROS population in Archives of Neurology (63:991-998). This is a chapter in the story you have helped to write. It is the first of several reports we plan to publish as the study proceeds. A reprint of the actual publication will be given to you either in person or by mail.

The investigator and coordinator at your research site are prepared to answer any questions you may have about the continuation of PHAROS and its research procedures and the publication. We extend our appreciation to you for your continued dedication to this important study of persons at risk for HD.

Sincerely,

*Ira Shoulson, MD
Principal Investigator*

*Anne B Young, MD, PhD
Co-Principal Investigator*

Recent Publication

The Huntington Study Group PHAROS Investigators. At Risk for Huntington Disease. The PHAROS (Prospective Huntington At Risk Observational Study Cohort Enrolled). *Archives of Neurology* 63:991-998.

The Huntington Study Group (HSG) PHAROS (Prospective Huntington At Risk Observational Study) investigators reported on the baseline characteristics of this remarkable cohort in the July 2006 issue of the *Archives of Neurology* (63:991-998). PHAROS is a multi-site, multi-year project that aims to gain knowledge about the early signs of Huntington's disease (HD) onset and their relationship to environmental and genetic factors. PHAROS is also examining the psychosocial, ethical and practical issues involved in long-term study of adults at 50:50 risk to develop HD who have chosen not to undergo predictive genetic testing to learn of their gene carrier status.



**PHAROS Spotlight
Newsletters can now be
found online at:**

**[http://www.huntington-study-group.org/
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Topics of Interest (cont)

The PHAROS cohort of 1001 adults at risk for HD is mostly women (65%), well educated, and gainfully employed. At the start of the study, enrolled research participants were characterized as highly functional with minimal, if any, impairment of movement or intellect. Participants have enrolled in PHAROS mindful that the knowledge from this long-term study will help shape the efficient design and appropriate conduct of future clinical trials aimed at delaying the onset of illness in gene carriers who have not yet developed signs of HD. The knowledge from PHAROS will also inform us about how persons at high risk to develop a disabling genetic disease deal with lingering uncertainties about their future health and complex choices about their participation in research.

“You are part of the special PHAROS group which has been the focus of our recent publication in Archives of Neurology.”

Meet The Researchers

This issue features the members of the PHAROS project team at the Clinical Trials Coordination Center who oversee the conduct of the PHAROS study.

What is the Clinical Trials Coordination Center?

The Clinical Trials Coordination Center (CTCC), a research unit of the University of Rochester’s Department of Neurology in Rochester NY, operates to support multi-institutional academic research through the development, management, and reporting of hypothesis-driven, controlled clinical trials.



PHAROS CTCC Team

Top Row (l-r): Connie Orme, Elaine Julian-Baros, Lisa Lang, Joe Weber

Bottom Row (l-r): Megan Romer, Letty Laskowski, Elise Kayson, Ira Shoulson

The CTCC has been in operation since 1986 and has conducted and managed over 80 clinical trials in the US, Canada, Europe and Australia including all of the Huntington Study Group research efforts.

Each study at the CTCC has a dedicated research team that oversees all aspects of running the study. This ranges from design of research studies and data collection tools, oversight of the study sites conducting the trial where subjects are seen for visits, recruitment and retention, answering study specific questions, receiving data from the study sites, clarifying the data for any problems, analyzing the data and publishing the results. So when your study coordinator says “I’ll have to ask the Rochester team if we can do that in this study” they are referring to the PHAROS CTCC team at the University of Rochester overseeing the study.

The primary responsibility of the study team is to ensure that the study is running properly, the wellbeing of the participants is maintained and the data that is collected is accurate.

PHAROS Study Team

The PHAROS team composition includes the Principal Investigator (Ira Shoulson, MD), Project Manager (Elise Kayson), Project Coordinator (Elaine Julian-Baros), Assistant Coordinator (Letty Laskowski), Statistician (Megan Romer), Database Programmer (Joe Weber), Information Analyst (Connie Orme), and Data Control Clerk (Lisa Lang). Many members of the team have been working on the study since 1999 and are vested to ensure the confidentiality and accuracy of your information.

Why do we need so many people on the PHAROS team?

As you can imagine with the study running since July 1999, and having responsibility for 42 sites and 1001 participants we have received a ton of questions and data. Since the inception of the study there have been over 5200 study visits, we have processed over 95,000 data forms, generated 16,000 clarification questions and fielded over 2000 questions from the sites via phone, fax or email.

What does each person do?

Project Management: *Ira Shoulson*, the Principal Investigator is responsible for the scientific integrity, safety and well being of the participants. *Elise Kayson* the Project Manager of the team with the assistance of *Elaine Julian-Baros* and *Letty Laskowski* are the central communication center for the study sites, the team and Steering Committee members. They are responsible for helping to design the study and data collection tools, answer site questions about the study, track and maintain recruitment and retention, collect and review all necessary regulatory documents and ensure that the study is running efficiently.

Data Management: *Joe Weber* starts the data management process by designing and developing the database where all the study information is stored. *Lisa Lang* receives, reviews and tracks all of the data forms including the survey booklets! *Connie Orme* reviews all of the data for accuracy and generates clarifications to the sites. Once the data is clean and there are no further corrections *Megan Romer* helps the other biostatisticians on the steering committee analyze the data.

Of note we are sad to report at the publication of this newsletter Letty has left to attend Law School and Megan is also going back to earn her PhD in Biostatistics.

We hope the overview of the HSG CTCC is helpful to you in understanding the process of managing such an important study and what happens to all of your data that is collected, processed and transformed into valuable information that will help pave the way for future studies.

Huntington's Disease Society of America Conference 2006

The HDSA held their 21st Annual Convention for patients, families and health care professionals on the beautiful shores of Lake Michigan in Milwaukee WI on June 9-11, 2006. There were more than 500 participants in attendance. The theme of the meeting was "The Cure Starts Here...The Caring Never Stops." Many of the workshops focused on the family, coping with the disease, genetic testing, promoting better health and current therapeutic trials.

Ira Shoulson, MD the PI of PHAROS presented at the Saturday Research Forum on "Translating Promising Drugs into Treatments for Huntington's Disease." He also conducted a workshop

on "Getting Involved in Clinical Trials." Many of our PHAROS participants were present to provide first hand information on their involvement with this observational study.

The meeting as usual was busy and informative with reunions of families and friends all coming to learn about the latest developments in treatments that make a difference for HD.



For more information on eligibility criteria and the location of HSG participating sites in the U.S. and Canada, please call the HSG at 1-800-487-7671 or visit the HSG website at www.huntington-study-group.org.

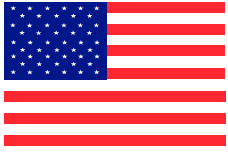
New HSG Studies

As we learn more about the course of HD, new drugs are being developed to target the pathways in the brain affected by the expanded CAG repeat length. We are pleased to announce the initiation of two clinical research studies for people at risk or with manifest HD, conducted by the Huntington Study Group investigators and coordinators.

DOMINO (A Multi-Center, **D**ouble-Blind, Pilot Study of **M**inocycline in Huntington's Disease) is a study of minocycline supported by the Food and Drug Administration (FDA).

COHORT (**C**ooperative **H**untington's Disease **O**bservational **R**esearch **T**rial) is a study to collect information in order to learn more about HD, potential treatments, and plan for future research studies of experimental drugs.

Upcoming Events



U.S. Events

The 22nd Annual Huntington's Disease Society of America (HDSA) Convention will be held **June 15-17, 2007** in Oklahoma City, Oklahoma. If you have any questions, please contact HDSA at hdsainfo@hdsa.org or toll free at **1-800-345-4372**.



Canadian Events

The Huntington Society of Canada will hold its bi-annual conference in Vancouver in the **fall of 2006**. For more information call the HSC toll free in Canada **1-800-998-7398** or email info@hsc-ca.org

For more information on national or local events visit:
www.hsc-ca.org/english/events.htm



World Events

World Congress on Huntington's Disease (WCHD) will hold its bi-annual conference in Dresden, Germany. The conference will take place **September 8-12, 2007** at the International Congress Center. The WCHD is a joint meeting of the World Federation of Neurology Research Group on Huntington's Disease and the International Huntington Association (IHA).

For more information see the WCHD website at:
www.worldcongress-hd.net

For More Information



"Huntington Study Group"
www.huntington-study-group.org or contact the HSG toll free at **1-800-487-7671**

"PHAROS Spotlight" newsletter online
<http://www.huntington-study-group.org/PHAROSNewsletterVolumes.htm>

"Huntington's Disease Society of America" www.hdsa.org or contact HDSA toll free at
1-800-345-HDSA (1-800-345-4372)

"Huntington Society of Canada"
www.hsc-ca.org or contact HSC at
1-800-998-7398

"Huntington Project"
<http://www.huntingtonproject.org>

"Hereditary Disease Foundation"
www.hdfoundation.org

"International Huntington Association"
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