Mentoring Committee

The PSG Mentoring Committee (MC) was established in 2006 under the leadership of Cynthia Comella, MD and Joel Perlmutter, MD and has four main roles:

- To solicit, review, and select candidates to receive the Parkinson's Disease Foundation supported mentored clinical research award (MCRA). This is a major award in support of a project that is a practical training ground for individuals to acquire new skills and expertise in clinical research.
- To serve as a resource for individuals who need assistance in formulating and developing protocols to the point ready for review by the Scientific Review Committee. The Committee may provide direct guidance or refer to appropriate individuals within the PSG for provision of that guidance. In some circumstances individuals may need a limited amount of mentoring or guidance, and direct assistance can be provided. In other circumstances that require more detailed mentorship, a list of potential mentors or mentoring services are supplied to the proposing investigator. The proposing investigator will be responsible for implementation of these suggestions and arranging the appropriate relationship with the individual or groups contacted.
- To develop and organize innovative programs to promote interest in Parkinson’s disease research, facilitate mentorship relationships, and increase awareness of the PSG. The program is called “Training Initiative for New Clinical Investigators” and has been held as an affiliate meeting at the AAN Annual Meeting since 2007. Special guests over the years have been Stan Fahn and Robert Griggs. This year the program will be held on April 27th, 12:00-1:30 p.m. at the Sheraton Seattle Hotel, with Joel Perlmutter facilitating the program and special guest William Weiner.
- To assist the Scientific Review Committee in reviewing research proposals submitted.

Over the years, the MC has been called upon to assist individuals in formulating and developing protocols. In 2008, the MC started developing a more formal program, and we are now developing the PSG Advisor Program to create a bank of advisors who are willing to help investigators. Once that is established, we will open the program up to individuals to apply for help from an advisor. The MC will match that individual up with an appropriate advisor and provide contact information to the advisee.

Since inception, the MC has held 4 programs to promote interest in Parkinson’s disease research, facilitate mentorship relationships, and increase awareness of the PSG. The program is called “Training Initiative for New Clinical Investigators” and has been held as an affiliate meeting at the AAN Annual Meeting since 2007. Special guests over the years have been Stan Fahn and Robert Griggs. This year the program will be held on April 27th, 12:00-1:30 p.m. at the Sheraton Seattle Hotel, with Joel Perlmutter facilitating the program and special guest William Weiner.

The MC has carried out this mission with the expertise of its members Alberto Ascherio, Julie Carter, David Eidelberg, Xiang Gao, Cindy Lawler, Mike McDermott, Gregory Pontone and Vicki Shanker. We thank Connie Marras and Barbara Vickrey for previously serving from 2006-2008.

This year the MC received 11 applications in response to the request for proposals for the MCRA. These are in review and applicants will be notified in May. All previous awardees are mentioned on the PSG web site with a brief abstract of their work. http://www.parkinson-study-group.org/AwardAnnouncements.asp.

Cynthia Comella, MD, Chair and Joel Perlmutter, MD, Co-chair, PSG Mentoring Committee
Mentoring Committee, continued from front page...

Last June, the MC hosted a new program with the MDS at its annual meeting in Chicago. It was called “Pearls from junior and senior mentors for new investigators: Opportunities and obstacles”. Cindy Comella welcomed two international panels with Stan Fahn moderating the discussion. The junior mentors consisted of Connie Marras, Christine Klein, Ray Dorsey, and Birgit Högl and the senior mentors consisted of Oscar Gershanik, Tony Lang, Karl Kieburtz, Yoshikuni Mizuno, Eduardo Tolosa, and Kimberly Gray. The audience enjoyed this interactive program and gained useful information.

In addition to these programs, Joel Perlmutter has presented a training module on “Training Mentors to be Mentors” at the PSG Annual Meeting. This developed out of feedback received from the training programs and a needs assessment done in 2007. The needs assessment suggested that residents, fellows and junior faculty did not always have mentorship available to them nor did all faculty know how to be mentors. This was so well received at last year’s meeting that Dr. Perlmutter plans on presenting this again at this year’s annual meeting.

The MC’s newest responsibility has been to help the SRC in research proposal reviews. To date, they have been involved in about a dozen proposal reviews and have been a tremendous help.

Cindy Comella is completing her term as Chairman of the committee and Joel Perlmutter will assume the chair. Jon Stoessel of the Pacific Parkinson’s Research Centre in British Columbia will serve as Co-chair. We would like to thank Cindy for her work, and look forward to the next years under the leadership of Joel and Jon.

None of this would be possible if not for the generous annual support of the Parkinson’s Disease Foundation’s Advancing Parkinson’s Treatments Innovations Grant to the PSG. The MC looks forward to continuing their work on their important mission.

Scientific Review Committee

The SRC recently awarded a $25,000 grant to Timothy Collier, PhD and Katrina Paumier, BS for their data-mining project entitled “Antidepressant Induced Delay of Motor Symptoms in PD (AIDS-PD)”. This project will be coordinated with the PSG Genetics and Environmental Working Group funded project on “Impact of commonly prescribed medications on PD progression” led by Andrew Siderowf, MD, MSCE. Dr. Collier’s abstract is posted on the PSG web site for more information.

We would like to thank the committee members who recently rotated off the SRC for their hard work and dedication to this committee: Bruce Levin, Glenna Dowling, Ergun Uc, Timothy Greenamyre (past Chair), Mark Mehler, Bill Scott, Steve Chin, Dan Weintraub, Bob Heaton, Alex Troster. We want to welcome new committee members: Steven Piantadosi, Carol Moskowitz, Ronald Pfeiffer, Kelly Lyons, Jeff Bronstein, David Simon, Connie Marras, Matthew Menza, Bonnie Levin, and Peter Como.

Nominating Committee

Last fall, the Nominating Committee consisting of William Weiner, Chair, Karen Blindauer, Brad Racette, and Oksana Suchowersky set forth to solicit the membership for nominees to run for the investigator position on the PSG Executive Committee as William Weiner is rotating off in 2009. From this solicitation and other criteria, the committee met and came up with 3 candidates: Irene Litvan, Michael Schwarzschild, and David Simon. A write-in period where members could further nominate someone if they had the support of 7 other members was conducted and no other nominee was identified. The voting ensued for 30 days and the results of the election will be announced at the PSG Annual Meeting. We thank the Nominating Committee for their hard work on this important task.

Publications Committee

Under the leadership of David Grimes with members Andrew Feigin and Michel Panisset, the PSG Publication Committee is responsible for assisting the Executive Committee in the adjudication of problems or conflicts arising out of implementation of the PSG publication policy. PSG members should familiarize themselves with these policies when submitting a manuscript for publication to ensure they are following authorship policies and procedures. This is posted on the PSG web site as well as a list of all PSG publications to date. Members should remember to use the appropriate acknowledgements when presenting platforms or posters at professional meetings.
Study Updates

STEADY-PD
by Cheryl Deeley

STEADY-PD (Safety, Tolerability, and Efficacy Assessment of Dynacirc CR for PD) will soon be enrolling subjects at 17 sites throughout the US and Canada. STEADY-PD is a pilot Phase II safety and dose finding study of isradipine CR in subjects with early Parkinson’s disease. Isradipine CR is a dihydropyridine calcium channel blocker, approved for treatment of hypertension. This class of calcium channel blocking agents may provide neuroprotection and may reduce the risk of developing PD and slow disease progression. One hundred subjects with early PD will participate in this 12-month trial. Secondary endpoints include the impact of isradipine CR on motor disability, blood pressure, cognition, PD quality of life and PD-related disabilities. Dr. Tanya Simuni at Northwestern University and Dr. Kevin Biglan at the University of Rochester lead this study.

APLIED
by Emily Flagg

The APLIED (A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Three Doses of Aprindore MR 1, 3, and 6mg BID in Patients with Early Parkinson Disease) study is being conducted to evaluate safety, efficacy and tolerability of aprindore in the treatment of early-stage PD. The study was initiated with the first enrollment on March 19, 2009. There are 40 participating PSG sites and we are working towards getting all sites actively recruiting and enrolling. The enrollment period for this study is relatively short and our goal is to have all 168 subjects enrolled by the end of this summer.

The study is being sponsored by Neurogen Corporation and is being led by Dr. Ira Shoulson and Dr. Karen Marder.

SURE-PD
by Alice Rudolph

The SURE-PD study (Safety of URate Elevation in Parkinson’s Disease) is pleased to announce that IND approval was received in January. Subcontracting is underway between the 11 participating sites and Mass General Hospital, which is the home institution of the study PI, Michael Schwarzschild. In March sites will receive the protocol and model study and repository consent forms and begin their IRB process. Ninety participants with early PD who are not expected to need treatment for at least 3 months will be enrolled in this phase II randomized, double-blind, placebo-controlled, dose-ranging trial of oral inosine. This study is unique in that the treatment groups are not based on study drug dosages, but rather on target levels of serum urate elevation. The unprecedented availability of clinical data to define the relationship between urate levels and specific rates of disease progression from the PRECEPT and DATATOP studies simplified the selection of dosing targets.

QE3
by Rory Doolan

We are very pleased that after a number of delays, the QE3 study is now underway. 60 of a planned 70 sites across the U.S. and Canada have been opened and are ready to enroll. Since recruitment began on January 12th, 2009, the study has enrolled 62 of 600 planned subjects. The objective of this study is to evaluate the safety and effectiveness of high dosages of CoQ (2400 mg and 1200 mg vs placebo) in slowing clinical decline in patients with early PD. Participants, who will be followed every four months over a 16 month period, must be diagnosed with PD within the last 5 years and not yet receiving dopaminergic therapy.

PramiBID
by Alice Rudolph

The PramiBID database was locked in December, allowing the study analyses to begin. During the upcoming PSG Annual Meeting, the PramiBID Investigators and Coordinators will convene for a closeout meeting to learn the study results and discuss publication of an abstract and manuscript. Plans are being developed to invite the 311 PramiBID subjects to be informed of the results as a group via telephone audio conference with Karl Kieburtz, the study PI.

PROGENI
by Cheryl Halter

Dr. Tatiana Foroud from Indiana University reports that since the annual PSG meeting in 2008 the PROGENI study has added 7 new and 5 returning PSG sites into the study. Enrollment of subjects has increased following the expansion of criteria to include any individual with PD who also has at least one first degree relative (parent, sibling, child) with PD. With 59 PSG sites now participating, 1801 Study Visits have been conducted since 1998. An additional 53 visits are being scheduled. The study continues to perform analyses to identify novel genes contributing to the risk for PD and has published several manuscripts describing these efforts. These manuscripts will be discussed at the 2009 annual PSG meeting in San Diego. Dr. Foroud has recently submitted a grant for renewal of the study to NIH. This will be reviewed this summer.
Credentials Committee

The Credentials Committee has credentialed 5 new investigators to the PSG since last report. We welcome the following investigators and coordinators:

**Pravin Khemani, MD**, Stanford University Medical Center, Stanford, CA
Stephanie Louie, Coordinator

**Punit Agrawal, MD**, Ohio State University Medical Center, Columbus, OH
Paige Pancake, Coordinator

**Xuemei Huang, MD, PhD**, Hershey Brain Analysis Research, Penn State – Hershey Medical Center, Hershey, PA
Eleanore Hernandez, Coordinator

**Cenk Sengun, MD**, University of Miami, Miami, FL
Monica Quesada, Coordinator

**Ludy C. Shih, MD**, Harvard Medical School/Beth Israel Deaconess Medical Center, Boston, MA
Peggy Rose, Coordinator

A new site was approved since last report:

**John Bertoni, MD, PhD**, The Nebraska Medical Center, Omaha, NE
Carolyn Peterson, Coordinator

You must be credentialed in order to participate in PSG studies. The Credentials Committee reviews applications about 4 times per year. The next meeting of the committee will be at the PSG Annual Meeting on May 29, 2009. We encourage anyone interested in becoming a credentialed PSG investigator to contact Roseanna Battista for application materials. We hope to have information regarding the credentialing process and how to apply posted on the PSG web site in the near future.

The Credentials Committee consists of Karen Marder, Chair, Amy Colcher, Deborah Hall, Christine Hunter, Stuart Isaacs, Mark Lew, Kelly Lyons, Wayne Martin, Jay Nutt, and Lin Zhang. Kelly, Wayne and Jay will be finishing up their term this May. We thank them for their dedication and hard work on the committee. We will welcome 3 new members to the committee: Claire Henchcliffe, Johan Samanta, and Cathi Thomas who will begin their term at the PSG Annual Meeting in May.

---

Study Updates (Con’t)

**PostCEPT, PROBE and LABS-PD**

by Emily Flagg

**PostCEPT** (A Longitudinal Observational Follow-up of the PRECEPT Study Cohort) is finishing up the second year of follow-up visits. The clinical data collected from Baseline, Year 01 and Year 02 visits have been posted to the PD-DOC website for access by approved researchers. In addition, we are working to have the 380 DNA sample submissions finalized and catalogued in the NINDS Human Genetics DNA and Cell Line Repository at Coriell Institute for Medical Research, so that they can be made available to other researchers. Subjects are also continuing on now to their fourth imaging scan, being conducted by the team at the Institute for Neurodegenerative Disorders in New Haven, CT.

**PROBE** (Blood α-Synuclein, Gene Expression, and Smell Testing as Diagnostic and Prognostic Biomarkers in Parkinson’s Disease) completed enrollment at the end of 2008 and we will soon be locking the database for analysis. The study enrolled a total of 102 PD, 27 MSA, 26 PSP and 54 Healthy Control subjects. Analyses of the biomarker research labs are planned to take place over the next year. Data will continue to be collected from the PD subjects via PostCEPT over the next two years for further longitudinal analyses.

**LABS-PD** (Longitudinal and Biomarker Study in PD) project background and objectives are being developed by the Steering Committee in preparation of a grant application planned for submission by the end of 2009. Funding for this project is being sought to support future biomarker and longitudinal studies utilizing other cohorts such as PostCEPT, PROBE, FOUND and QE3.

Information regarding PSG clinical trials can be found on the PSG web site. Also, the PSG Research Site Map is a great resource for referral contact information: [http://www.parkinson-study-group.org/PSGResearchSites.asp](http://www.parkinson-study-group.org/PSGResearchSites.asp)
From time to time we hear about outstanding work or accomplishments done by PSG investigators and coordinators, but it is very seldom shared with the membership. This new feature to the newsletter hopes to open the door to recognizing sites and staff accomplishments and to share ideas on how they do what they do in conducting clinical trials so others can apply new ideas for their site.

In this issue, the University of Toledo and the University of Tennessee Health Science Center get kudos for the PROGENI study! Tatiana Foroud (PI) and Cheryl Halter are very impressed with all the investigators and coordinators in the PROGENI study.

University of Toledo (Formally Medical University of Ohio): Investigator Lawrence Elmer, Coordinators Stephanie Wilson and Kathy Davis, and additional staff Mary Scott and Julia Spears.

Dr. Elmer reports “We’re trying to set new records for PROGENI Cares visits up here in Ohio! Stephanie Wilson is the designated coordinator for our PROGENI Cares - but Kathy Davis (the previous coordinator) is helping to see patients also. In the past year we have seen almost 40 PROGENI Cares patients.”

“We try to let patients know that participating in research can be a rewarding experience, even when it doesn’t involve a new drug study. Many of our patients are interested in participating in clinical trials but don’t always qualify for actively recruiting drug trials. PROGENI Cares has been an excellent way for those patients without a family history of Parkinson’s disease to get involved. In addition, many of our previous research participants were interested in this genetic research and have volunteered to be a part of the PROGENI studies. We’ve used our conversations during these studies to further build our database of potential patients who could then be contacted about future clinical trials. We also add people to this database as we see them in clinic or as the patients visit our research table during our annual Parkinson’s disease symposium. We then can contact these patients whenever appropriate research opportunities arise.”

“PROGENI and PROGENI Cares are straightforward and simple studies. Most patients state that they’ve enjoyed participating in this study, which opens the door for their participation in future studies. Needless to say, the coordinators are the key to all of our studies, but in the case of the PROGENI studies, they actually make these visits ‘fun’ for our patients. My coordinators are outstanding and they make our research program a real success!!”

Stephanie Wilson with patient, Robert DuBois

University of Tennessee Health Science Center: Investigator Ron Pfeiffer, Coordinator Brenda Pfeiffer.

This husband and wife team has logged many miles traveling to evaluate PROGENI subjects in the hinterlands. Whenever Cheryl Halter has a potential subject who is too debilitated to travel to their PSG site for evaluation, she knows that Ron and Brenda are likely to be willing to drive to the subject’s house. With Brenda as chief navigator and Ron at the wheel, the longest excursion they have made has been over 700 miles round trip. In addition to enjoying the scenic countryside, the Pfeiffers have been unfailingly impressed with the tremendous warmth and hospitality they invariably receive from the patients and their family members during these home visits. Perhaps taking long car rides together is the secret to a long and happy marriage as well as high study enrollment.

Ronald Pfeiffer, MD with patient

We want to thank Alice Rudolph for bringing these kudos to our attention and coming up with the idea to add this new feature to the newsletter! If you would like to send kudos or tell "your story", please send to Roseanna Battista so she can include in future newsletters. Thank you!
I was always fascinated by the complexity of the clinical phenomenology and pharmacological management of movement disorders which were the driving force for my decision to pursue a fellowship in that area. I consider myself a clinician investigator with a majority of the research questions and projects stemming from the clinical interaction with patients and a commitment to improve the lives of courageous people living with these diseases. I remain perplexed by the multi-faceted nature of Parkinson's and other movement disorders and variety of my research questions that stem from daily interaction with patients.

In 1996 I completed a fellowship in movement disorders at the Pennsylvania Hospital, University of Pennsylvania under the mentorship of Drs. Matthew Stern and Howard Hurtig. After completing fellowship I stayed on faculty at Penn being in charge of the surgical program. My early research interests were impact of deep brain stimulation surgery on PD disability. We published a number of articles reporting outcomes of the DBS surgery.

In 2000 I moved to Northwestern University to establish a new movement disorders program. Northwestern has been a wonderful place to develop multidisciplinary collaborations that resulted in a number of research projects. The most exciting one is the translational work on potential disease modifying effect of isradipine, a dihydropyridine calcium channel blocker, in early PD. The work stems from the data reported by Dr. James D. Surmeier (Chan et al, Nature 2007), Director of the Udall Center at Northwestern, demonstrating neuroprotective effect of isradipine in preclinical models of parkinsonism. His work is based on a novel data demonstrated by his laboratory of selective vulnerability of dopaminergic neurons in the substantia nigra pars compacta potentially responsible for their accelerated cell death and leading to the cardinal motor manifestations of PD. His data suggests that this selective vulnerability may be due to the reliance of these neurons on L-type Ca_{1.3} Ca^{2+} channels. Blocking these channels with isradipine protects these neurons in \textit{in vitro} and \textit{in vivo} models of parkinsonism. Isradipine is an FDA approved agent for the treatment of hypertension but has not been systematically evaluated in PD. Our group completed a pilot open label dose escalation safety and tolerability study of isradipine in 20 normotensive subjects with early PD. That study, the results of which were presented at the 22nd annual PSG symposium in Salt Lake City, demonstrated acceptable tolerability of isradipine in PD population and provided pilot data for further investigation of isradipine in PD. In July 2007, in collaboration with Kevin Biglan, MD and David Oakes, PhD, we submitted a proposal to the PSG Scientific Review Committee to conduct a Phase II randomized placebo controlled dose finding and early efficacy study of isradipine in patients with early PD. The proposal was accepted in January 2008 after revisions that incorporated Committee feedback, at which point we started the “funding journey”. We received funding from Michael J. Fox Foundation to conduct Phase II dose selection tolerability study. The STEADY-PD study will be conducted by PSG as a 17 site multicenter project to be launched in spring 2009. We are in the process of resubmitting the proposal to NIH for the next phase of the isradipine studies.

PSG contribution to the development of the isradipine projects has been invaluable. While I have been the site principal investigator on multiple multicenter studies, this is my first experience in the role of National Principal Investigator on a multicenter study. It has been a tremendously educational journey starting with the discussions on conceptual study design with Karl Kieburtz and Bernard Ravina to protocol development with Kevin Biglan, to invaluable contribution of David Oakes on statistical data analysis, to budgetary “university” work with Pat Donaghue, to incredible commitment and expertise of the whole Clinical Trials Coordination Center Team. The lessons learned on this journey are invaluable and teach multi-faceted meaning of translational research and what it takes to translate the scientific concept into practical aspects of the clinical trial. \textit{The journey has just started and hopefully will be fruitful at the end but I would use this as an example of the true commitment of the PSG leadership to promote collaborations with the PSG investigators.}

I also enjoy involvement in various aspects of PSG activities. I currently serve on the PSG annual symposium committee; I am a member of the PSG cognitive and classical motor symptoms working groups. I would strongly encourage junior investigators to use the PSG resources such as Mentoring Committee and Scientific Review Committee to advance their research projects and interests.

Tanya Simuni is an Associate Professor of Neurology at Northwestern University’s Feinberg School of Medicine, and Medical Director of the PD and MD Center. Dr. Simuni has been a PSG member since 1997.
PSG ANNUAL MEETING in San Diego

We are gearing up for the PSG Annual Meeting in San Diego on May 27 through May 29. Invitations have been sent out, so please remember to register if you have not done so already. This year the Cognitive/Psychiatric Working Group will host the Second Clifford W. Shults Symposium on Cognitive & Psychiatric Aspects of PD. The planning committee, Ergun Uc, Kelvin Chou, John Growdon, Marsha Tennis and Karen Marder, have planned an excellent program which will strike a good balance between presenting up-to-date complex scientific information and its accessibility to all audience members with diverse backgrounds ranging from seasoned, pioneering PD experts to coordinators who are attending the meeting for the first time.

New this year will be a poster session on Friday, May 29, 2009. Researchers from the past 3 years have been asked to present a poster of their work whether it be completed or in progress. This incorporates about 25 posters and we have opened the opportunity for a few others to submit abstracts for poster consideration.

During the PSG Membership Business Meeting, research reports will be given by Greg Pontone, 2008-2009 MCRA awardee, on his research “Prevalence and familial aggregation of panic disorder in patients with PD”, Robert Hauser on his research “Determination of Minimally Clinically Important Change in Early and Advanced PD”, and Andrew Siderowf on his research “Impact of commonly-prescribed medications on PD progression”. A special presentation will be given by Roger Kurlan on how to use PD-DOC effectively and what it can offer PSG members.

The 6 working groups have separate meeting times this year. The only overlap is with the Genetics/Environmental Risk group and the Cognitive/Psychiatric group. We hope this will give everyone a chance to attend more working group meetings this year. Each working group will “workshop” proposals predetermined to take advantage of the SRC and MC members present at their meetings. There will be opportunities for members to present new ideas also.

The meeting will also cover study-specific meetings, eRT training, a mentorship training module, new members meeting, and committee meetings. The investigators and coordinators will have a designated 2-hour meeting for each group to discuss topics of interest. The meeting will conclude with a reception for all meeting attendees hosted by the Executive Committee in honor of Coordinators.

PSG PD and OTHER MOVEMENT DISORDERS SYMPOSIUM at ANA ANNUAL in Baltimore, Maryland

The PSG Symposia Committee and the HSG Symposia Committee have met and have started planning the fall symposium on Etiology, Pathogenesis, and Treatment of Parkinson’s Disease (PD) and Other Movement Disorders (OMD) to be held on Sunday, October 11, 2009 at the ANA Annual Meeting in Baltimore. The two keynote speakers this year will be Dr. Nicolaas Bohnen, on “Imaging in Parkinson’s Disease” and Dr. Elan Louis, on “Epidemiology and Pathology of Essential Tremor”. The PSG Executive Committee conducted a needs assessment survey with the PSG members and past attendees of the symposium to help with future planning of the program and meet CME requirements. We anticipate having CME credit for attendees and the program is still offered at no charge. We encourage PSG members to submit abstracts on Parkinson’s disease and other movement disorders. A Call for Abstracts form can be obtained on the PSG web site. Deadline for abstracts is June 1, 2009 with late-breaking research abstracts due June 22, 2009.
The Parkinson Study Group (PSG) is a non-profit, cooperative group of Parkinson's disease experts from medical centers in the United States and Canada who are dedicated to improving treatment for persons affected by Parkinson's disease.