PSG NEWSLETTER

PSG ANNUAL MEETING/PSG SYMPOSIUM

In May, the PSG will hold their 22nd Annual meeting. The PSG was founded in 1986 by Ira Shoulson and Stan Fahn and celebrated its 20th Anniversary in 2006. To think we are fast approaching its 25th anniversary in 2011 is pretty amazing! Over the years PSG members have enjoyed coming together in person at various venues all across the U.S. and Canada.

On May 13-15 we hope to bring together most of our members and welcome invited guests from various organizations like the Parkinson's Disease Foundation, Michael J. Fox Foundation, and people with Parkinson's who have participated in the PDF’s Clinical Research Learning Institute.

The meeting will be very busy with study meetings, working group meetings, eClinical training, etc. PSG members will have the opportunity to attend all six working group meetings as there is no overlap this year. Every year we offer a “New Members Workshop” for the newly credentialed investigators and their coordinators and anyone who has not attended a meeting. This workshop is even a good update for members who have been in the PSG a while and they are welcome to attend.

At the PSG Membership Meeting on Friday, May 14th members will hear research presentations from Marian Evatt, Katrina Paumier and Amie Peterson. Marian Evatt is an Assistant Professor of Neurology at Emory University and was awarded a datamining grant to study “Vitamin D Insufficiency: Prevalence and Clinical Correlates in the DATATOP Cohort”; Katrina Paumier is a PHD candidate under Dr. Timothy Collier’s direction and they were awarded a datamining grant to study “Antidepressant Induced Delay of Motor Symptoms in PD (AIDS-PD)”; and Amie Peterson is a Movement Disorders Fellow at Oregon Health & Science University who is the current Mentored Clinical Research Awardee who will present her research on “A Pilot Study of Balance and Vitamin D in Persons with PD”. Also, brief reports on the status of the PSG, the recent election, finances, Scientific Review Committee and Mentoring Committee will be given.

A special lunchtime training module, hosted by the PSG Mentoring Committee facilitated by Joel Perlmutter, will take place on Friday on “Training Mentors to be Mentors”. This was brought back this year and we would like to have all PSG investigators attend. The PSG is committed to providing mentors with the skills they need to become better and more effective mentors.

Most members agree that the most enjoyable part of the annual meeting is coming together in person and meeting people whom you have only known through email, conversing with new colleagues that may lead to a collaborative project, networking for a young investigator that may benefit his or her research career, sharing ideas on how trials are conducted at other sites and many other invaluable experiences. The “human” part of the meeting is rewarding and creates bonds with people you work with every day and, in some cases, forms lasting personal and professional relationships. The meeting wraps up with a reception in honor of coordinators hosted by the Executive Committee. This is a chance for members to kick back and enjoy each other and celebrate all their hard work!

On Saturday, May 15th the 24th annual PSG Symposium will be held. This is a full day program that encompasses the Third Shults Symposium and the PSG Symposium. It is the first time the symposium will be combined with the PSG annual meeting. As one, the Genetics and Environmental Risk Working Group and the PSG Symposium Organizing Committee have worked together to develop the morning session on “Current Issues in Genetic and Environmental Contributions to Parkinson’s Disease and Other Movement Disorders” and the afternoon session featuring guest speaker Dr. Christopher Gomez on “Genetics of Ataxia” with 6 platform presentations to follow. Throughout the day 18 posters will be displayed with Andrew Feigin highlighting them at 11:45 with author formal presentations to follow from 12:00-1:00. A total of 24 abstracts were accepted by the committee and cover a variety of topics on Parkinson's disease and other movement disorders.

New this year will be exhibitors from pharmaceutical companies, publication companies, medical labs and non-profit organizations. They will be exhibiting all day in a dedicated exhibit room.
Study Updates

SPIN-PD
by Jennifer Harman

SPIN-PD (Spectroscopy in Parkinson Disease Diagnosis). We enrolled our 100th subject on February 5th, 2010 and continue working towards activating the remaining few sites. Our goal is to enroll a total of 500 subjects by the end of October 2010. Once we reach 160 subjects milestone, we will begin our first phase of analysis geared towards validating and perfecting the analysis parameters. The research goal of the SPIN-PD project is to analyze blood samples from people with PD as well as healthy subjects to determine if spectroscopy can differentiate between the two. These research participants will be followed for an additional 2 years to evaluate if spectroscopy can predict any outcomes. This study is funded by Molecular Biometrics, Inc. which obtained a grant from the Michael J. Fox Foundation.

SURE-PD
by Alice Rudolph

SURE-PD (A randomized, double-blind, placebo-controlled, dose-ranging trial of oral inosine to assess safety and ability to elevate urate in early Parkinson’s disease) has a goal of enrolling 90 subjects. Since June, seven subjects have been enrolled at five sites. Three of the original nine sites have had to withdraw due to staffing issues. So with the goal of increasing enrollment and meeting revised milestones, nine new sites are in the process of joining the study, bringing the total number of sites to 17. The Steering Committee offers their thanks and congratulations to John Goudreau and Doozie Snider at Michigan State University for so quickly getting through their IRB and subcontracting practices and enthusiastically beginning to recruit for SURE-PD. Despite recruitment challenges, the rationale for the trial has only grown with recent findings strengthening the link between higher urate and better outcomes in PD and other neurodegenerative diseases. For example, the University of Rochester’s Peggy Auinger, Karl Kieburtz and Mike McDermott recently reported that higher urate levels amongst Huntington disease subjects was a predictor of slower clinical progression (Mov. Disorders 2010). The SURE-PD trial is funded by the Michael J. Fox Foundation.

STEADY-PD
by Cheryl Deeley

STEADY-PD (Safety, Tolerability, and Efficacy Assessment of Dynacirc CR for PD) is well underway. All 17 sites are up and running. We have had 38 enrollments thus far. Our enrollment goal is 10 subjects/month to reach 100 enrolled subjects by the targeted end-date of August 2010. STEADY-PD is a pilot Phase II double-blind, placebo-controlled tolerability 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. This study is funded by the Michael J. Fox Foundation.

QE3
by Rory Doolan

QE3 (Effects of Coenzyme Q10 on Early Parkinson Disease) enrolled its 400th subject in December 2009 on its way to enrolling 600 subjects at 68 sites. We are still seeking new subjects and want to get the word out to the PSG and the entire Parkinson’s community that we will be actively enrolling at least into the summer months. The objective of the QE3 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 are followed every four months over a 16 month period, must be diagnosed with PD within the last 5 years and not have been on dopaminergic therapy for more than 90 days. This study is funded by the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH). Further details of the study may be found on the PSG website.

More study updates on the following page...
PostCEPT and PROBE
by Emily Flagg

PostCEPT (A Longitudinal Observational Follow-up of the PRECEPT Study Cohort) continues with the third year of follow up visits. In addition to the baseline report noted in the last newsletter (Mov Disord. 2009;24(14):2081-2090), the data obtained from this cohort has generated three more abstracts by K. Marek and R. Kurlan (to be presented at May 2010 PSG annual meeting) and by C. Tanner (to be presented at AAN in April). The cohort continues to maintain a high retention rate (about 88%) and will continue to be followed through the end of this year. With the recent February 5th submission of a grant application to NIH, our goal is to continue with an additional 5 years of follow up as part of the Longitudinal and Biomarker Studies in Parkinson Disease (LABS-PD) project.

PROBE (Blood α-Synuclein, Gene Expression, and Smell Testing as Diagnostic and Prognostic Biomarkers in Parkinson’s Disease) is continuing into the analyses phase of the study, with sample reconciliation completed. High-quality RNA has been extracted from 191 of the 206 samples eligible for analyses (93% yield). We anticipate completing the initial diagnostic analyses by the end of the first quarter. Follow up and data collection for the PD subjects is ongoing under the PostCEPT study. This study was funded by the Department of Defense.

Information regarding PSG clinical trials can be found on the PSG web site or www.clinicaltrials.gov.

Also, the PSG Research Site Map is a great resource for referral contact information: PSG Research Site Map. If you notice that your site contact information is not listed on the map, please notify us and we will make sure it is posted.

Kudos to Sites!

Nita Gardiner wants to extend “kudos” to Katie Kompoliti and Luci Blasucci at Rush University and David Grimes and Jennifer Conway at Ottawa for being outstanding recruiters for the STEADY-PD trial.

We hope PSG members have enjoyed hearing about “kudos”. If you have any news to share for future newsletters, please contact Roseanna Battista.

PSG ELECTION IS IN PROGRESS! We encourage all PSG members to cast their vote for one investigator and one coordinator member for the PSG Executive Committee.

Congratulations to the candidates! The winners will be announced at the PSG Annual Meeting.

Investigator Member (listed alphabetically):
Karen Blindauer, MD, Medical College of Wisconsin
Andrew Feigin, MD, Hofstra University, North Shore-LIJ Health System
Daniel Weintraub, MD, University of Pennsylvania

Coordinator Member (listed alphabetically):
Lorelei Derwent, RN, University of Calgary
Cathi Thomas, MS, RN, CNRN, Boston University
Marguerite Wieler, BA, BScPT, MSc, University of Alberta
A Comprehensive Review of Movement Disorders for the Clinical Practitioner
St. Regis Resort, Aspen, Colorado
July 26-29, 2010

Karen Hodgeman, CCRA

Every year Stan Fahn, Joe Jankovic, and Mark Hallett direct a comprehensive CME course on Parkinson’s disease and other movement disorders. Movement disorder fellows apply and about 20 are selected to receive a stipend to attend the course. The faculty also offers three fellowships for coordinators.

This year, Karen Hodgeman was nominated and selected to participate. Karen works at the Clinical Trials Coordination Center at the University of Rochester as a Senior Clinical Project Manager. She has been involved in clinical research for over 20 years and worked on many PSG trials. Congratulations Karen!

For further information about the course you can contact any of the faculty or visit: http://ColumbiaCME.org

Credentials Committee

The Credentials Committee has credentialed 6 new investigators to the PSG since last report. One credentialed investigator moved to a new site and credentialing for that site was approved. We welcome the following investigators:

Rohit Dhall, MD, MSPH, Barrow Neurological Clinics at St. Joseph’s Hospital & Medical Center, Phoenix, AZ

Joseph M. Ferrara, Jr., MD, University of Louisville, Louisville, KY

Rebecca W. Gilbert, MD, PhD, NYU Langone Medical Center, New York, NY

Ariane Park, MD, MPH, Madden Center for PD and Related Disorders, Columbus, OH

Tiffini Voss, MD, University of Virginia, Charlottesville, VA

Michele K. York, PhD, Neuropsychologist, Baylor College of Medicine, Houston, TX

PSG investigators at new sites approved:
Butler Hospital, Providence, Rhode Island
PSG Investigator: Joseph H. Friedman, MD

You must be credentialed in order to participate in PSG studies. **If you are a PSG credentialed investigator and move to a non-PSG site, that site must be reviewed by the PSG Credentials Committee.** The Credentials Committee reviews applications about 4 times per year. The next meeting of the committee will be at the PSG Annual Meeting on Friday, May 14, 2010. We encourage anyone interested in becoming a credentialed PSG investigator to contact Donna Moszkowicz donna.moszkowicz@ctcc.rochester.edu for application materials.

The Credentials Committee consists of Karen Marder, Chair, Amy Colcher, Deborah Hall, Claire Henchcliffe, Christine Hunter, Stuart Isaacson, Mark Lew, Johan Samanta, Cathi Thomas and Lin Zhang. We have just recruited new members to the committee because a few of our members term their service on this committee this year. We are pleased to welcome Stacy Horn, DO, Alex Rajput, MD and Thyagarajan Subramanian, MD.
Mentoring Committee Program in Toronto
Monday, April 12, 2010, 12:00-1:30 p.m.
The Strathcona Hotel, 60 York Street

The PSG Mentoring Committee is hosting a program entitled “Parkinson Study Group Presents: Starting a Clinical Research Career – Clues for Success” during the AAN Annual Meeting this year on Monday, April 12, 2010 from 12:00-1:30 p.m. in Toronto at The Strathcona Hotel, 60 York Street, in the York Street Café Room. The hotel is a short walk of two blocks away from the Metro Toronto Convention Centre main meeting venue.

This lunch time program is designed specifically for early career investigators including neurology residents, fellows and those within 5 years of completing fellowship training and is provided at no charge to the participants. The objective is to provide a forum for discussion of methods, opportunities and obstacles for developing a clinical research career and to familiarize the participants with the PSG. Topics will include identifying educational opportunities, selecting the right fellowship, negotiating a junior faculty position, and obtaining research funding. The role of mentoring and interactions with CTSAs will be covered.

Dr. Joel Perlmutter, Chair and Dr. Jon Stoessl, Co-chair of the PSG Mentoring Committee will facilitate the program. Dr. Wendy Galpern, Program Director in the Office of Clinical Research at NIH/NINDS is our special guest. To register, contact Roseanna Battista at mailto:roseanna.battista@ctcc.rochester.edu. Walk-ins are welcome. This meeting has been made possible through the Parkinson's Disease Foundation's Advancing Parkinson’s Treatments Innovations Grant.

Need help with your research?

The PSG Advisor Program is available for new investigators who are initiating a research career or continuing an existing research area. This valuable resource is managed by the PSG Mentoring Committee and they established a bank of advisors who are willing to help you find a local mentor in your area (both research and geographic) or help you find specific research funding sources (foundations, etc.) for your research.

If you would like to participate in this program, please complete the application form on the PSG website (www.parkinson-study-group.org).

Both the advisor and advisee will keep confidential any information received or obtained as a result of participating in the program that is identified as, or would be reasonably expected to be, confidential, unless they agree otherwise.

“My mentor was exceedingly generous with his time and advice. He gave me invaluable information that can only be imparted from someone who has negotiated the system and has a lot of personal experience in what works and what doesn’t as well as an “insider’s” understanding of what it takes to succeed. He gave me information regarding funding opportunities or how to complete research even without funding. I would recommend this program to a colleague.” – Galit Kleiner-Fisman, MD, advisee; Bernard Ravina, MD, MSCE, advisor.
Researchers in the News

In this issue, we dedicate the “Researcher in the News” section to the PSG Scientific Review Committee (SRC). Throughout the year the SRC reviews many applications either requesting funding, seeking approval to be a PSG study, or proposing a collaborative project. This demands a dedicated committee of experts who provide quality reviews and meet together to discuss proposals and make recommendations to the PSG Executive Committee. Often there are times when reviews need to be expedited for pending grant submissions.

Dr. Carlie Tanner and Dr. Web Ross lead this notable committee which includes: Statistics: Yuko Palesch, Steven Piantadosi, David Oakes; General Clinical: Stanley Fahn, Lisa Gauger, Carol Moskowitz, Ronald Pfeiffer, Kelly Lyons, Marian Evatt; Basic Science: Jeff Bronstein; Genetics/Genetic Epidemiology: Tatiana Foroud, Joseph Savitt, Martha Nance, David Simon; Epidemiology: Connie Marras; Psychiatry: Laura Marsh, Matthew Menza; Neuropsychology: Bonnie Levin, Peter Como; and Neurosurgery/Surgical Clinical Trials: Aviva Abosch, William Marks.

Besides the 15 research proposals reviewed this past year, the SRC has adapted the new NIH-style scoring system and written guidelines for reviewers that are posted on the PSG website. Improvements to the on-line “toolkit” continue to be made with templates added to use when needed to write a proposal protocol or schedule of activities, and templates for the reviewers to use when writing up a report. For those members who are new to the PSG, we encourage you to check the toolkit out at: PSG Toolkit.

With generous support from the Parkinson’s Disease Foundation we have been able to fund two datamining awards. Xuemei Huang, MD, PhD, Associate Professor of Neurology at Penn State Hershey Medical Center, was awarded a grant for her datamining project entitled “Serum cholesterol level as a predictor of progression in PD” and Un Kang, MD, Professor of Neurology at the University of Chicago Medical Center, was awarded a grant for his datamining project entitled “The role of motor learning in dopaminergic therapy of PD”.

Other projects approved as PSG studies that are seeking or have received alternative funding this year are: Metabolomic Analysis of PD CSF, Peter LeWitt, PI, funded by Michael J. Fox Foundation; Exercise as Disease Modifying Treatment in Early PD, Roger Kurlan, PI, submitted to NIH; Evaluation of Blood Biospectroscopy as a Novel Biomarker of Idiopathic PD (SPIN-PD), Bernard Ravina and Tony Lang, PIs, funded by Molecular Biometrics, Inc., which obtained a grant from Michael J. Fox Foundation, to name a few. At times the SRC seeks help from the PSG Mentoring Committee to do reviews. The PSG Mentoring Committee consists of Joel Perlmutter, Chair, Jon Stoessl, Co-chair, Alberto Ascherio, Julie Carter, David Edelberg, Xiang Gao, Cindy Lawler, Mike McDermott, Amie Peterson, and Gregory Pontone. They also assist PIs in resubmissions or in guiding the development of a research idea.

The SRC and Biomarkers Working Group have also recently been involved in helping the PSG Repository Subcommittee come up with a long-term plan for the handling and storage of PSG biospecimens. This precious resource needs to be centralized and modernized to ensure optimal use for future research.

Recent publications from completed research include:


SECOND CLINICAL RESEARCH LEARNING INSTITUTE
by Nicole Rabin and Roseanna Battista

On October 15th through 17th, 2009, more than 40 people living with Parkinson’s disease (PD) from around the country came to Florham Park, New Jersey to participate in the Parkinson’s Disease Foundation’s (PDF) second Clinical Research Learning Institute. The three-day program educated participants about the ways in which people living with PD can contribute to the development of new treatments and a cure for PD by becoming advocates within the clinical research process.

PDF’s Learning Institute is based on the premise that all too often, the perspectives and experiences of people with Parkinson’s are excluded from the decision-making that advances new therapies. This includes not just participation in trials – where it is estimated that less than one percent of the one million people in the United States living with Parkinson’s currently participate at all – but also active roles in advising investigators on clinical trial implementation and evaluation.

To prepare for new roles as PDF Clinical Research Liaisons, this year’s participants – a diverse group of business leaders, scientists and educators hailing from 24 states – attended educational sessions led by national experts, including researchers, study coordinators, and industry representatives. The courses focused on such topics as the clinical research process and current therapies development, bioethics, analysis and evaluation of clinical research and the protection of clinical study participants.

Advocates have returned to their home communities ready to engage in a range of activities that include educating the broader community about the importance of clinical research and study participation through support group and conference presentations and serving on clinical study oversight and advisory committees. All graduates also take part in PDF’s ongoing educational and networking opportunities, where they will regularly share information and compare best practices.

The following PSG Members participated in the Clinical Research Learning Institute as planning committee members and/or faculty:

Joohi Jimenez-Shahed, M.D., Maureen Cook, R.N., Patricia Kavanagh, M.D., Christine Hunter, R.N., C.C.R.C., Lin Zhang, M.D., Ph.D., Bernard Ravina, M.D., M.S.C.E, Claire Henchcliffe, M.D., D.Phil., Mike McDermott, Ph.D., and Scott Kim, M.D., Ph.D.

Robin Elliott, PDF Executive Director, commented on the training, “The Parkinson’s Disease Foundation believes that inclusion of the perspective and experiences of people with Parkinson’s has the potential to benefit the clinical research process and therapies development. We are committed to providing the tools and resources necessary to make this happen – in the hope that the Clinical Research Learning Institute provides the foundation for these motivated consumers to become engaged and involved in a process that directly impacts their current quality of life and strives to find a cure for this debilitating disease.”

As participant Diane Cook said, “The Learning Institute curriculum provided an interactive and effective learning environment, where I could debate issues critical to treatment development with other people with Parkinson’s whose experience with the disease has been very different from mine. I think we are all ready to share our knowledge – both to increase the community’s understanding about clinical trials and to hopefully affect change in the way that Parkinson’s clinical research is conducted.”

People with Parkinson’s were not the only beneficiaries of the Learning Institute. “It was eye opening for me to realize that people who live with PD have a “take” on the research process that is often so different from that of the scientists and doctors. I was surprised by how much risk the participants said they would be willing to take within a clinical trial. Sometimes, as doctors, we tend to be overprotective of our patients. Maybe I need to be more aware of my own patients’ attitudes toward clinical research” commented Claire Henchcliffe, M.D., who was on the Clinical Research Learning Institute faculty. “The Learning Institute experience has expanded the way that I think about the role of the person with PD in research and the insight that he or she has to offer the scientific community. I think there should be much more communication among doctors, researchers and people with PD.”

Participant Elke Ballweg noted that “Nobody is in a better position than a person with Parkinson’s to empower another person with PD and to strengthen his or her belief in the role that clinical research can play in finding treatments and a cure for PD.” Elke further

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expressed her goals upon leaving the Learning Institute, “I would like to take on a more proactive role in the PD community. Since I feel comfortable in a medical environment and with clinical trial information, I would like to be a source of clinical study information for other people who are still wrestling with the implications of the diagnosis and are contemplating participating in clinical research. I’ll start with my local support group, working with one of last year’s Learning Institute graduates.”

In five short months, the 2009 Clinical Research Learning Institute graduates have embraced their roles as PDF Clinical Research Liaisons. For example, Jim Wong, Ph.D., of Orange, CA, has been named as the patient advisor/representative to the Longitudinal Assessment and Biomarkers Study (LABS-PD) Steering Committee; Diane Cook of Denver, CO and David Zook, Ph.D. of Golden Valley, MN have reached out to nearly 70 individuals about the Parkinson’s Associated Risk Study (PARS); and Paul Zimmet, D.D.S., of Washington, D.C. has been appointed as a member of an Institutional Review Board (IRB) focusing on neurology projects at the Georgetown University School of Medicine in Washington, DC.

If you would like to learn more the Clinical Research Learning Institute and the ways that graduates can contribute to your work in Parkinson’s clinical research, please contact Ronnie Todaro, M.P.H., PDF Director of National Programs at rtodaro@pdf.org or (800) 457-6676.
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1351 Mt. Hope Avenue, Suite 223
Rochester, New York 14620
585-275-1642
Fax: 585-273-1074
www.parkinson-study-group.org

PSG EXECUTIVE COMMITTEE
Karl Kieburtz, MD, MPH, Chair
Karen Marder, MD, MPH, Co-chair
Jeana Jaglin, RN, CCRC
Michael McDermott, PhD
Janis Miyasaki, MD
Joel Perlmutter, MD
Bernard Ravina, MD, MSCE
Michael Schwarzschild, MD, PhD
Caroline Tanner, MD, PhD
Frederick Wooten, MD

Ex-officio:
Roseanna Battista, BS
Donna Moszkowicz
Karen Rabinowitz, JD

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.

PSG Newsletter

Calendar of Events

April 12, 2010, 12:00-1:30 p.m.
PSG PRESENTS: STARTING A CLINICAL RESEARCH CAREER – CLUES FOR SUCCESS, hosted by the PSG Mentoring Committee, Strathcona Hotel, 60 York Street, Toronto, Canada. No fee to register and lunch is provided. Visit the PSG web site at www.parkinson-study-group.org to obtain a registration form – walk-ins are welcome. Contact Roseanna Battista with any questions at: mailto:roseanna.battista@ctcc.rochester.edu.

May 13-15, 2010
PSG 22nd ANNUAL MEETING, Four Seasons, Irving, Texas. Contact Donna Moszkowicz for registration information at: donna.moszkowicz@ctcc.rochester.edu. 24th ANNUAL PSG SYMPOSIUM on PD and Other Movement Disorders, Saturday, May 15, 2010.

September 28-October 1, 2010
WORLD PARKINSON CONGRESS, Glasgow, Scotland. Learn more at: www.worldpdcongress.org or contact Elizabeth “Eli” Pollard, Congress Manager, at info@worldcongress.org. PSG is proud to be an organizational partner of this event.

May 12-14, 2011
PSG 23rd ANNUAL MEETING and 25TH ANNUAL PSG SYMPOSIUM. Location: TO BE DETERMINED.

Comments? Questions?

Please let us know...your comments and questions will be kept confidential. We also welcome your feedback on the newsletter and your ideas for topics for future newsletters.

Please send all correspondence to Roseanna Battista, mailto:roseanna.battista@ctcc.rochester.edu or contact Karl Kieburtz at mailto:karl.kieburtz@ctcc.rochester.edu or Karen Marder at mailto:ksm1@columbia.edu. Thank you!