

# NCRO HIGHLIGHTS

**Duke  
Neuroscience**

## Neuroscience Clinical Research Organization

Division of Neurology  
Department of Medicine  
Duke University Health System



January 2006

*The mission of the NCRO is to foster the development of a world-class neuroscience clinical trials center.*

### Who's Who in the NCRO

| Management                                   | Coordination          | Email:   |
|--|-----------------------|--|
| Mark Stacy, Medical Director                 | Kate Beck 668-2278    | <a href="mailto:beck0002@mc.duke.edu">beck0002@mc.duke.edu</a>   |
| Carmelo Graffagnino, Co-Medical Director     | Gail Cook 684-0865    | <a href="mailto:cook0007@mc.duke.edu">cook0007@mc.duke.edu</a>   |
| Ron Beauvais, Administrator                  | Joanne Field 668-2842 | <a href="mailto:joanne.field@duke.edu">joanne.field@duke.edu</a> |
| Donna Carnes, Regulatory Assistant           | Karen Grace 668-2844  | <a href="mailto:karen.grace@duke.edu">karen.grace@duke.edu</a>   |
| Lisa Gauger, Clinical Research Administrator | Debra Heydt 668-2843  | <a href="mailto:debra.heydt@duke.edu">debra.heydt@duke.edu</a>   |
| JoAnn Jones, Regulatory Administrator        | Rene Link 970-1648    | <a href="mailto:link0002@mc.duke.edu">link0002@mc.duke.edu</a>   |
|  | Sarah Wyne 668-2837   | <a href="mailto:wyn0001@mc.duke.edu">wyn0001@mc.duke.edu</a>     |

**We would like your suggestions for topics in future issues of the NCRO Newsletter! Please send your suggestions to: JoAnn Jones @ [jones018@mc.duke.edu](mailto:jones018@mc.duke.edu).**

### ACTIVE ENROLLING STUDIES

The NCRO currently supports **39** active studies. This list includes only those studies that are actively enrolling. Please help us reach our targets (column 6).

#### DEMENTIA STUDIES

| PI           | SPONSOR         | INDICATION           | STUDY-ID           | COORDINATOR    | TARGET / # PTS ENROLLED-1/31//06 |
|--------------|-----------------|----------------------|--------------------|----------------|----------------------------------|
| BURKE, Jim   | GlaxoSmithKline | Mild to Moderate AD  | Rosiglitazone XR   | Heydt 668-2843 | 15 / 9                           |
| WHITE, Heidi | NIH             | Mild cog. Impairment | Nicotine Tr of MCI | Cook 684-0865  | 25 / 15                          |

#### MOVEMENT DISORDERS

|                 |                         |                       |                            |                 |                 |
|-----------------|-------------------------|-----------------------|----------------------------|-----------------|-----------------|
| MORGENLANDER, J | Private Investors       | Restless Legs         | RLS                        | N/A             | 20 / 16         |
| SCOTT, Burt     | Physician Funded        | Movement disorder     | Visual Documentation       | N/A             | No Target / 499 |
| SCOTT, Burt     | Physician Funded        | Movement disorder     | Tetrabenazine              | N/A             | No Target / 63  |
| SCOTT, Burt     | Boston Life Sciences    | Tremor                | Altropane                  | Wyne 668-2837   | 20 / 9          |
| STACY, Mark     | Novartis                | PD requiring levodopa | Stride PD (Stalevo)        | Beck 668-2278   | 15 / 17         |
| STACY, Mark     | Inst Neurodeg Disorder  | Early PD              | SPECT imaging              | Gauger 668-1538 | 8 / 3           |
| STACY, Mark     | Boehringer Ingelheim    | PD eye safety study   | Pramipexole vs. Ropinirole | Field 668-2842  | 10 / 0          |
| STACY, Mark     | Ovation Pharmaceuticals | Psychosis in PD       | Melperone OV-1003          | Gauger 668-1538 | 6 / 0           |

#### NEUROMUSCULAR

|               |                   |     |             |                |        |
|---------------|-------------------|-----|-------------|----------------|--------|
| BEDLACK, Rick | NEALS/CytRx Corp. | ALS | Arimoclomol | Grace 668-2844 | 10 / 0 |
|---------------|-------------------|-----|-------------|----------------|--------|

#### VASCULAR

|                  |                      |                                |                          |                      |           |
|------------------|----------------------|--------------------------------|--------------------------|----------------------|-----------|
| GOLDSTEIN, Larry | AGA Med Corp         | Cryptogenic stroke             | RESPECT                  | Link 970-1648        | 10 / 17   |
| GOLDSTEIN, Larry | Boehringer Ingelheim | Recurrent strokes              | PRoFESS                  | Link 970-1648        | 30 / 11   |
| GRAFFAGNINO, C   | NIH / Wash Univ      | Carotid occlusion              | Surgery vs stan med care | Stoner 668-5275      | 30 / 3    |
| GRAFFAGNINO, C   | AstraZeneca-         | Acute ischemic stroke          | Stroke-SA-NXY-0007       | Stoner 668-5275      | 10 / 10   |
| GRAFFAGNINO, C   | Novo Nordisk         | Acute intracerebral hemorrhage | F7ICH-1641               | Stoner 668-5275      | 5 / 1     |
| LASKOWITZ, Danny | Biosite              | Biomarker-brain injury         | Triage Stoke Panel       | B. Blessing 970-4888 | 450 / 573 |
| LASKOWITZ, Danny | Merck & Phys Funded  | Aneurismal SAH                 | Simvastatin-SAH          | B. Blessing 970-4888 | 120 / 51  |
| LYNCH, John      | Physician Funded     | Traumatic brain injury         | Simvastatin-TBI          | B. Blessing 970-4888 | 100 / 6   |

\*\*\*STUDY SPOTLIGHT\*\*\*

**New Approved Study Ready for Recruitment!!**  
Please see further details below– Thank you for your Support!

**M. Stacy (PI) – OV-1003**

**“Safety and Efficacy of Melperone in the Treatment of Patients with Psychosis Associated with Parkinson’s Disease”**

The primary objective of this study is to assess the safety and efficacy of 20, 40 and 60 mg per day of melperone in syrup formulation (5 mg/ml) in approximately 90 subjects (30 placebo & 20 per active dose group) with psychosis associated with Parkinson’s Disease. Maximum study duration will be 10 weeks including a 1-2 week screening/washout period, 5 week titration phase, 1 week maintenance phase, and 2 week taper/followup period. Subjects will have the option of continuing in an open-label extension study. Minimum PHI used for screening includes: diagnosis, medical history, medications, medication history, & social history. We estimate to recruit 6 subjects here at DUHS. Contact Dr. Mark Stacy or Lisa Gauger (668-1538) if you have a patient who may be interested in this study.

**Duke University School of Medicine  
Clinical Trials Quality Assurance (CTQA)  
LUNCH AND LEARN SERIES  
2005/2006 Schedule**

The lunch and learn series are one hour **coordinator centric educational sessions** with the primary goal of providing useful, hands on knowledge to build a stronger research work force. These sessions will also provide the members of the CTQA office an opportunity to present themselves as a resource to the research community.

|                   |                                     |                              |
|-------------------|-------------------------------------|------------------------------|
| <b>February 6</b> | <b>Investigational Drug Service</b> | <b>Sharon Ellison, R.Ph.</b> |
| <b>March 20</b>   | <b>Clinical Trials Litigation</b>   | <b>Kim Wilson, J.D.</b>      |
| <b>April 6</b>    | <b>Clinical Trials Billing</b>      | <b>Donna Morris</b>          |
| <b>May 12</b>     | <b>Humanitarian Use Devices</b>     | <b>John Falletta, M.D.</b>   |
| <b>June 6</b>     | <b>TBD</b>                          | <b>TBD</b>                   |

THE CTQA LUNCH AND LEARN SERIES IS FREE AND OPEN TO THE PUBLIC – DUKE UNIVERSITY HEALTH SYSTEM AFFILIATION IS NOT REQUIRED. SEATING IS ON A FIRST COME, FIRST SERVED BASIS FOR THOSE WHO HAVE REGISTERED FOR THE SERIES.

ALL SESSIONS ARE SCHEDULED FOR 12:00-1:00 PM IN ROOM 103 OF THE BRYAN RESEARCH BUILDING (NOT THE BRYAN CENTER). **SESSIONS HAVE BEEN APPROVED FOR 1.2 NURSING CONTACT HOURS AND 1.0 CONTINUING EDUCATION UNITS.**

PLEASE REGISTER FOR THE SERIES BY E-MAILING [CTQA@MC.DUKE.EDU](mailto:CTQA@MC.DUKE.EDU)  
BRING YOUR LUNCH, THE COMPLIANCE OFFICE WILL PROVIDE DRINKS AND DESSERTS!!

**Clinical Trials Quality Assurance (CTQA)  
Coordinator Training Session**

**New Coordinator Training Session on February 20th, 2006**

On February 20, 2006, Clinical Trials Quality Assurance will offer a day-long Coordinator Training Session. This training is appropriate for coordinators who are new to clinical research, administrative staff who may be involved in some aspect of clinical research, and for individuals who would like to become clinical research coordinators.

Enrollment is limited to Duke employees. Current research coordinators should have 2 years or less of experience. The training session is free. Nursing contact hours or continuing education units will be available to attendees completing the training.

Registration is limited to 75. Additional sessions will be offered throughout the year, with the next session currently scheduled for May 22, 2006.

Please contact [ctqa@mc.duke.edu](mailto:ctqa@mc.duke.edu) to register. Registrants must provide the following information:

|                         |  |
|-------------------------|--|
| <b>Name:</b>            | <b>Years of experience as a study coordinator:</b> |
| <b>E-mail address:</b>  | <b>Current job title:</b>                          |
| <b>Mailing address:</b> | <b>Duke Unique ID:</b>                             |