

# NCRO HIGHLIGHTS

**Duke  
Neuroscience**

## Neuroscience Clinical Research Organization

Division of Neurology  
Department of Medicine  
Duke University Health System



July 2005

*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>
Sharon Dowell, Administrative Manager	Debra Heydt 668-2843	<a href="mailto:debra.heydt@duke.edu">debra.heydt@duke.edu</a>
Lisa Gauger, Clinical Research Administrator	Rene Link 970-1648	<a href="mailto:link0002@mc.duke.edu">link0002@mc.duke.edu</a>
JoAnn Jones, Regulatory Administrator	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 **41** 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-7/31/05
BURKE, Jim	GlaxoSmithKline	Mild to Moderate AD	Rosiglitazone XR	Heydt 668-2843	15 / 4
WHITE, Heidi	NIH	Mild cog. Impairment	Nicotine Tr of MCI	Cook 684-0865	25 / 9

#### EPILEPSY

HUSAIN, Aatif	Schwarz	Epilepsy-partial seizures	SPM 927 (SP 754)	Beck 668-2278	5 / 5
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#### MOVEMENT DISORDERS

MORGENLANDER, J	Private Investors	Restless Legs	RLS	N/A	20 / 10
SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 464
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 54
SCOTT, Burt	Wyeth Pharm	PD-ERT	POETRY	Gauger 668-1538	5 / 3
SCOTT, Burt	Kyowa	PD-motor response complications	KW-6002 (6002-US-018)	Cook 684-0865	8 / 7
SCOTT, Burt	Boston Life Sciences	Altoprane	PD – tremors	Wyne 668-2837	20 / 4
STACY, Mark	Novartis	PD requiring levodopa	Stride PD (Stalevo)	Beck 668-2278	15 / 11
STACY, Mark	Inst Neurodeg Disorder	Early PD	SPECT imaging	Gauger 668-1538	8 / 1
STACY, Mark	Merck KgaA	PD with tx dyskinesias	Sarizotan	Gauger 668-1538	12 / 9
STACY, Mark	Boehringer Ingelheim	PD eye safety study	Pramipexole vs. Ropinirole	Field 668-2842	10 / 0

#### NEUROMUSCULAR

BEDLACK, Rick	Columbia / NINDS	ALS	Minocycline	Grace 668-2844	15-20 / 12
BEDLACK, Rick	Dainippon AS-3201-253	Diabetic sensorimotor polyneuropathy	AS-3201	Grace 668-2844	20 / 8
MASSEY, Janice	Hoffman LaRoche-Aspreva	Myasthenia Gravis	Mycophenolate mofetil	Provided by Physician	6 / 0
MASSEY, Janice	FDA	Myasthenia Gravis	MG-Cellcept	Provided by Physician	10 / 10

#### VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	10 / 12
GOLDSTEIN, Larry	Boehringer Ingelheim	Recurrent strokes	PROFESS	Link 970-1648	30 / 10
GRAFFAGNINO, C	NIH / Wash Univ	Carotid occlusion	Surgery vs stan med care	Stoner 668-5275	30 / 0
GRAFFAGNINO, C	AstraZeneca-	Acute ischemic stroke	Stroke-SA-NXY-0007	Stoner 668-5275	10 / 10
GRAFFAGNINO, C	Centocor	Acute ischemic stroke	AbESTT II	Stoner 668-5275	12 / 1
GRAFFAGNINO, C	AstraZeneca	Acute ICH	CHANT-SA-NXY-0012	Stoner 668-5275	3-6 / 2
LASKOWITZ, Danny	Biosite	Biomarker-brain injury	Triage Stoke Panel	B. Blessing 970-4888	450 / 522
LASKOWITZ, Danny	Merck & Phys Funded	Aneurismal SAH	Simvastatin-SAH	B. Blessing 970-4888	120 / 47
LYNCH, John	Physician Funded	Traumatic brain injury	Simvastatin-TBI	B. Blessing 970-4888	100 / 6

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

**New Approved Study Ready for Recruitment!!**

If you have patients who may be interested in participating in the below-referenced study, please contact the individuals listed below – Thank you for your Support!

**M. Stacy (PI) – Boehringer-Ingelheim (BI 248.538)**

**“A Two Year Open Label, Randomized, Parallel Group, Blinded Assessment Ophthalmologic Safety Study of Pramipexole IR versus Ropinirole in Early Parkinson’s Disease (PD) Patients”**

The purpose of this study is to determine if there is any difference in the presence of retinal deterioration in PD patients treated with Pramipexole IR vs. Ropinirole as monitored by an overall review of all components of comprehensive ophthalmology assessments from baseline to the end of study at two years. Minimum PHI used for screening includes: gender, date of birth, diagnosis, medications, medical and social histories. Subjects will be randomized to receive either Pramipexole or Ropinirole. Subject participation in the trial will last for a total of two years. We estimate to recruit 10 subjects here at Duke. Contact Dr. Mark Stacy or Lisa Gauger (668-1538) if you have a patient who may be interested in this study.

**NCRO Advisory Board**

The next NCRO Advisory Board meeting is scheduled for Wednesday, October 12, 2005 from 5:30 – 6:30 p.m. in the second floor conference room at Morreene Road Clinic. The agenda for this meeting will include:

**Old Business:**

- 1) Review of Profit and Loss (P/L) data from FY 2001-2005
- 2) Review Board Approved Policies for:
  - a. Coordination costs
  - b. PDC trial activity

**New Business:**

- 1) NCRO personnel
- 2) NCRO Database of trial activity
- 3) Discussion of PI responsibilities and reimbursement policies

Please contact an Advisory Board member if you have any other agenda concerns. Members of the Board include: Rick Bedlack, Jim Burke, Tim Collins, Larry Goldstein, Carmen Graffagnino, Barrie Hurwitz, Danny Laskowitz, Rod Radtke, Don Sanders and Burt Scott.

**Regulatory News**

**Confidentiality Agreements (CDAs)**

When a PI is contacted by a sponsor expressing interest in receiving information about a potential clinical trial, the sponsor will provide a CDA to the PI to evaluate/determine the feasibility of the PI/site conducting the trial before any trial-related material is sent out. These CDAs must be forwarded on to the Duke Legal Office (Office of Corporate Research Relations) for review. If only the PI signs the CDA, the CDA is valid only for the PI. No other Duke personnel, nor the University itself, are obligated to keep anything confidential nor are they liable if they don't. The PI bears the complete liability for the obligations in the CDA. Duke Legal will review and negotiate CDAs with the appropriate sponsor contacts. This removes the liability from the PI and puts it on the University and will also ensure that the terms of the CDA are consistent with Duke policies.

For PIs who intend to utilize the NCRO for their studies, the CDA can be forwarded to JoAnn Jones @ [jones018@mc.duke.edu](mailto:jones018@mc.duke.edu) for processing. For those who wish not to utilize the NCRO, the CDA should be forwarded directly to the Duke Office of Corporate Research Relations – Fax #919-684-4595.

**NCRO New Study Reviews**

The NCRO is implementing a new policy for receipt of documents needed from the PI before the NCRO can proceed with administrative and scientific reviews of new proposed studies. The PI will have 30 days from date of request to return the: 1) Memorandum of Understanding (MOU), 2) Request for Clinical Trial Support and 3) Research Summary to JoAnn Jones. This will help the NCRO avoid undue delays in processing of new proposed studies. Thank you for your support.

Duke University School of Medicine  
CTQA LUNCH AND LEARN SERIES  
2005 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.

August 5	IRB Nomenclature	Minna Pak Debbie Reddoch
September 22	Source Documentation	Sam Beavers
October 24	Research and Animal Welfare	Ron Banks
November 7	What is Exempt Research?	John Harrelson
December 8	AE Reporting	Ken Mahaffey

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 1.0 NURSING CONTACT HOURS AND .08 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!!