

# NCRO HIGHLIGHTS

Duke  
Neuroscience

## Neuroscience Clinical Research Organization

Division of Neurology  
Department of Medicine  
Duke University Health System



June 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>
Tina Long, Regulatory Assistant	Sarah Wyne 668-2837	<a href="mailto:wyne0001@mc.duke.edu">wyne0001@mc.duke.edu</a>
Cathy O'Neill, Financial Manager		

### ACTIVE ENROLLING STUDIES

The NCRO currently supports **43** 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-6/30/06
BURKE, Jim	GlaxoSmithKline	Mild to Moderate AD	Rosiglitazone XR	Heydt 668-2843	15 / 11
WHITE, Heidi	NIH	Mild cog. Impairment	Nicotine Tr of MCI	Cook 684-0865	25 / 17

#### MOVEMENT DISORDERS

MORGENLANDER, J	Private Investors	Restless Legs	RLS	N/A	20 / 17
SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 502
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 61
SCOTT, Burt	Teva Pharmaceuticals	Early PD	Rasagiline (Adagio)	Field 668-2842	8-10 / 4
STACY, Mark	Inst Neurodeg Disorder	Early PD	SPECT imaging	Gauger 668-1538	8 / 3
STACY, Mark	Ovation Pharmaceuticals	Psychosis in PD	Melperone OV-1003	Gauger 668-1538	6 / 0
STACY, Mark	Novartis	PD	Quest PD(CELC200AUS11)	Field 668-2842	10 / 0
STACY, Mark	GE Healthcare	Parkinsonian Syndrome	99mTc-NC100697 Injection	Field 668-2842	4-6 / 0

#### NEUROMUSCULAR

BEDLACK, Rick	NIH, MDA, ALS Assoc.	ALS-motor neuron diseases	DNA Banking Repository	Heydt 668-2843	50 / 26
BEDLACK, Rick	UCB Pharma	Motor neuron disease	Levetiracetam	Heydt 668-2843	20 / 9

#### 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 / 12
GRAFFAGNINO, C	NIH / Wash Univ	Carotid occlusion	Surgery vs stan med care	Stoner 668-5275	30 / 0
GRAFFAGNINO, C	Novo Nordisk	Acute intracerebral hemorrhage	F7ICH-1641	Stoner 668-5275	5 / 1
GRAFFAGNINO, C	CoAxia, Inc.	Acute ischemic stroke	SENTIS-CD-0125	Stoner 668-5275	10 / 0
LASKOWITZ, Danny	Biosite	Biomarker-brain injury	Triage Stoke Panel	M. Scism 668-1429	700 / 657
LASKOWITZ, Danny	Merck & Phys Funded	Aneurysmal SAH	Simvastatin-SAH	M. Scism 668-1429	120 / 54
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin	M. Scism 668-1429	25 / 0
LYNCH, John	Physician Funded	Traumatic brain injury	Simvastatin-TBI	M. Scism 668-1429	100 / 6

**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).**

**\*\*\*\*Advisory Board Meeting Reminder\*\*\*\***

The next Advisory Board meeting is scheduled for Wednesday 7/12/06 at 5:30 p.m. in the 2<sup>nd</sup> floor conference room at Morreene Road Clinic.

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

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

**M. Stacy (PI) – TR0202**

**“An Open-Label, Phase 2 Study to Assess the Safety and Efficacy of <sup>99m</sup>Tc-NC100697 Injection in Detecting or Excluding Striatal Dopaminergic Deficits in Subjects with 1 or More Signs of a Parkinsonian Syndrome”**

The primary objective of this study is to estimate the sensitivity and specificity of <sup>99m</sup>Tc-NC100697 Injection with SPECT brain imaging in detecting or excluding striatal dopaminergic deficits in subjects with suspected Parkinsonian Syndrome (PS) based on combined visual and quantitative image assessments conducted by blinded independent readers. This is a multicenter, open –label study with a 6 month followup period. Potential participants will undergo a screening visit. Eligible patients will be scheduled for SPECT imaging within 21 days of screening. Followup visits will occur at month 3 and month 6 after imaging. Patients referred by a non-movement disorder specialist with one or more clinical signs suggestive of PS will be screened. The clinical findings and tentative diagnosis of the non-movement disorder specialist will be documented. Potential participants will then be consented, ensure eligibility criteria and undergo screening assessments. Minimum PHI used for screening includes: diagnosis, medical history, DOB and medications. We expect to recruit up to 6 subjects here at DUHS. Contact Dr. Mark Stacy or Joanne Field (668-2842) 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.

**Next session scheduled for July 17, 2006**

**Speaker: Sam Beavers**

**Subject: Corrective Action/Preventive Action (CAPA) Systems**

**The FDA is encouraging researchers to apply CAPA systems to clinical research to maintain quality and integrity of data. Such systems are common to Good Laboratory Practice Regulations and to Pharmaceutical and Medical Device Good Manufacturing Practice. This session will discuss how to translate these systems to a clinical research setting.**

**Look for the new CTQA Lunch/Learn schedule to be posted in an upcoming issue of the newsletter once the CTQA office finalizes.**

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!!