

# NCRO HIGHLIGHTS

Duke  
Neuroscience

## Neuroscience Clinical Research Organization

Division of Neurology  
Department of Medicine  
Duke University Health System



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

August 2006

### 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>
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Cathy O'Neill, Finance Manager		

### 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).

#### DEMENCIA STUDIES

PI	SPONSOR	INDICATION	STUDY-ID	COORDINATOR	TARGET / # PTS ENROLLED-8/31/06
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 / 21

#### GENERAL

Hurwitz, Barrie	Serono	RR-Multiple Sclerosis	25643 (Cladribine)	Wyne 668-2837	9 / 0
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#### MOVEMENT DISORDERS

MORGENLANDER, J	Private Investors	Restless Legs	RLS	N/A	20 / 18
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	25 / 8
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 / 49
BEDLACK, Rick	UCB Pharma	Motor neuron disease	Levetiracetam	Heydt 668-2843	20 / 16
BEDLACK, Rick	NIH, Columbia University	Combination Therapy Selection Trial	Minocycline/creatine vs. celecoxib/creatine comb.	Grace 668-2844	3-6 / 0

#### VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	10 / 17
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 / 688
LASKOWITZ, Danny	Merck & Phys Funded	Aneurysmal SAH	Simvastatin-SAH	M. Scism 668-1429	120 / 59
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin	M. Scism 668-1429	25 / 0

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).

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

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

**R. Bedlack (PI) – Combination Therapy Selection Trial in Amyotrophic Lateral Sclerosis (ALS)**

**“A multi-center, randomized, double-blind, phase II selection trial of combination therapy in 120 subjects with ALS”**

The primary objective of this study is to determine which of two drug combinations (minocycline/creatine vs. celecoxib/creatine) best slows deterioration as measured by the ALS functional rating scale-revise (ALSFRRS-R) and to establish whether the combinations are safe and well tolerated in conjunction with riluzole, the only currently FDA-approved medication for ALS. Subjects who pass screening will be randomized at the baseline visit, have labs checked every two weeks during the study, and report for study visits every month for six months. Subjects who are currently on riluzole treatment for ALS may participate and must be on a stable dose for at least 30 days prior to entering this study. Potential participants will be recruited from the Muscular Dystrophy Association website, the ALS Association website, the Duke Neurology website, the Duke Neurology and ALS clinics and outside referrals. Minimum PHI used for screening includes: diagnosis, medical history, DOB, medication history, medication allergies, and social history. We expect to recruit 3-6 subjects here at DUHS. Contact Dr. Rick Bedlack or Karen Grace (668-2844) 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>Date</b>	<b>Topic</b>	<b>Speaker</b>
September 18	Consent with Special Populations and Legally Authorized Representatives	Warren Taylor, M.D.
October 16	Making the Protocol Your Guide	Sheda Moori
November 20	Angiogenesis and Gene Therapy	Debra Hunt
December 18	Monitoring	TBD
January 8	E-IRB and IRB Forms	Mina Pak Debbie Reddoch
February 12	TBD	TBD
March 12	TBD	TBD
April 9	TBD	TBD
May 14	TBD	TBD
June 11	TBD	TBD

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 .10 CONTINUING EDUCATION UNITS.**

BRING YOUR LUNCH, THE COMPLIANCE OFFICE WILL PROVIDE DRINKS AND DESSERTS!!

FOR THOSE WHO WILL BE COMING FROM OFF CAMPUS, DRIVING DIRECTIONS AND PARKING INFORMATION CAN BE FOUND AT THE FOLLOWING LINK: <http://neuro.duke.edu/Links/map.htm>

**PLEASE REGISTER FOR THE SERIES BY E-MAILING [CTQA@MC.DUKE.EDU](mailto:CTQA@MC.DUKE.EDU)**

**CHECK OUR WEB SITE FOR UPDATES: <http://medschool.duke.edu/compliance>**