

NCRO HIGHLIGHTS

**Duke
Neuroscience**

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



April 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	beck0002@mc.duke.edu
Carmelo Graffagnino, Co-Medical Director	Gail Cook 684-0865	cook0007@mc.duke.edu
Ron Beauvais, Administrator	Joanne Field 668-2842	joanne.field@duke.edu
Donna Carnes, Regulatory Assistant	Karen Grace 668-2844	karen.grace@duke.edu
Lisa Gauger, Clinical Research Administrator	Debra Heydt 668-2843	debra.heydt@duke.edu
JoAnn Jones, Regulatory Administrator	Rene Link 970-1648	link0002@mc.duke.edu
Tina Long, Regulatory Assistant	Sarah Wyne 668-2837	wyne0001@mc.duke.edu
Cathy O'Neill, Financial Manager		

We are pleased to announce Tina Long has joined the NCRO Regulatory Staff! Please join us in welcoming her to our group. She is located in Rm. 233 at Morreene Road.

ACTIVE ENROLLING STUDIES

The NCRO currently supports **45** 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-4/30/06
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 / 16

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 / 499
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 63
SCOTT, Burt	Teva Pharmaceuticals	Early PD	Rasagiline (Adagio)	Field 668-2842	8-10 / 1
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

NEUROMUSCULAR

BEDLACK, Rick	NEALS/CytRx Corp.	ALS	Arimoclomol	Grace 668-2844	10 / 11
BEDLACK, Rick	NIH, MDA, ALS Assoc.	ALS-motor neuron diseases	DNA Banking Repository	Heydt 668-2843	50 / 0
BEDLACK, Rick	UCB Pharma	Motor neuron disease	Levetiracetam	Heydt 668-2843	20 / 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 / 12
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 / 11
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	450 / 621
LASKOWITZ, Danny	Merck & Phys Funded	Aneurysmal SAH	Simvastatin-SAH	M. Scism 668-1429	120 / 52
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.

STUDY SPOTLIGHT

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

R. Bedlack (PI) – ALS DNA Banking Repository

“Amyotrophic Lateral Sclerosis Research Group [ALS RG] Collection of Data and Biomaterial for Repository Banking to Facilitate Research into the Etiology of ALS and Related Motor Neuron Diseases”

The primary purpose of this study is to participate in the collection and banking of DNA and cell lines from patients with motor neuron diseases and from controls in a collaborative effort of ALS care with research centers across the US and Canada for submission to the NINDS Human Genetic Repository. The samples and data in the repository will be available to qualified researchers for use into causes of ALS and other diseases. We anticipate collection of 2000 samples from ALS subjects as well as 2000 samples from control subjects across all sites. Participants will be asked to provide information on their health and family history and provide an approximately 20 cc blood sample. We expect to recruit 25 subjects and 25 controls here at Duke. Minimum PHI used for screening includes: DOB, diagnosis, medical history, and family history. Contact Dr. Rick Bedlack or Deb Heydt (668-2843) if you have a patient who may be interested in this study.

R. Bedlack (PI) – Pilot Levetiracetam

“A Pilot Trial of Levetiracetam for Cramps, Spasticity and Neuroprotection in Patients with Motor Neuron Disease”

The primary purpose of this study is to test levetiracetam in reducing the severity and frequency of painful cramps, spasticity and disease progression due to motor neuron diseases. This is an open-label, repeated-measures design that will last for 24 months. We anticipate recruiting 20 subjects. Study length for each enrolled subject will be 12 months. There will be an initial three month drug-free period to establish data followed by nine months on levetiracetam. Minimum PHI used for screening includes: diagnosis, DOB, medical history, medication history, and social history. Contact Dr. Rick Bedlack or Deb Heydt (668-2843) if you have a patient who may be interested in this study.

D. Laskowitz, (PI) – Albumin in Acute Stroke (ALIAS)

“A Phase III Randomized Multicenter Clinical Trial of High-Dose Human Albumin Therapy for Neuroprotection in Acute Ischemic Stroke”

The primary purpose of this study is to ascertain whether high-dose human albumin therapy confers neuroprotection in acute ischemic stroke, specifically whether human albumin therapy increases the proportion of acute ischemic stroke patients with favorable outcome compared to placebo. Favorable outcome is defined as either an NIHSS score of 0 or 1, or a mRS of 0 or 1, or both, measured at 3 months from randomization. Separate randomization to human albumin or placebo will be carried out in two cohorts: 1) a cohort that receives standard-of-care treatment with IV tPA and 2) a cohort that does not receive tPA therapy. Determination of tPA therapy will be based on clinical judgment. Subjects will be followed for 12 months from randomization to determine the durability of the effect of human albumin therapy. Minimum PHI used for screening includes: DOB, diagnosis, time of stroke onset, medical history, and medication history. We expect to recruit 25 subjects here at Duke. It is expected the majority of recruitment will occur in the Duke ED. Neurology residents will be made aware of the study. Triage and emergency room nursing staff and physicians will be in-serviced about the study. Potential stroke subjects will be identified by the Emergent Stroke Code system at Duke. If an acute stroke is suspected, the Stroke Code Pager will be initiated and a neurology resident or fellow immediately called to evaluate the patient within 10 minutes. Potentially eligible subjects will be reviewed by the Stroke Team and study coordinator. Contact Dr. Danny Laskowitz or Monica Scism (668-1429) if you would like more information about 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.

May 12
June 6

Humanitarian Use Devices
TBD

John Falletta, M.D.
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 1.0 CONTINUING EDUCATION UNITS.**

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