

NCRO HIGHLIGHTS

Duke
Neuroscience

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



July 2004

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

Who's Who in NCRO

Management	Coordinators	Email:
Carmelo Graffagnino, Medical Director	Kate Beck 668-2278	beck0002@mc.duke.edu
Mark Stacy, Director of Operations	Yong Choi 668-2844	choi0001@mc.duke.edu
Ron Beauvais, Administrator	Gail Cook 684-0865	cook0007@mc.duke.edu
Donna Carnes, Regulatory Assistant	Rene Link 970-1648	link0002@mc.duke.edu
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JoAnn Jones, Regulatory Administrator	Sarah Moore 668-2842	moore016@mc.duke.edu
Sarah Wyne, Clinical Research Administrator		

“IN THE NEWS”

CONSENTING – DEFINING PI / COORDINATOR ROLES

Due to recent discussion, it is felt that the following information would be helpful to better define PI/CRC roles in the consenting process:

PI role – identify a candidate for a study and educate the potential participant to the science, advantages and reasons for study enrollment.

Coordinator role – discuss the consent form with the potential participant and answer any questions. If potential participant then declines to provide consent based on the consent document and discussion with the coordinator, the coordinator should then discuss the concern with the PI. The PI may then elect to discuss the issue with the potential participant.

STUDY SPOTLIGHT

NEW IRB-Approved Study

A Fourteen-Week, Placebo-Controlled, Dose-Response Efficacy and Safety Study of NS 2330 in Early Parkinson's Disease Patients (Study for Proof of Concept in Early Parkinson's Disease of a Triple Reuptake Inhibitor, SCEPTRE) – Mark Stacy, M.D. – PI

The primary objective of this proof of concept study is to demonstrate efficacy and dose-response of NS 2330 vs. placebo in patients with early Parkinson's disease in 14 weeks of treatment, and to investigate the safety and tolerability of NS 2330 in these patients.

The eligibility criteria are as follows: 1) male or female (age \geq 40 at time of diagnosis) with idiopathic Parkinson's disease, less than 5 years diagnosed; 2) Hoehn & Yahr stage 1 – 3; 3) willing and able to comply with scheduled visits, treatment plan, laboratory tests and other study procedures; 4) written informed consent in accordance with GCP and local legislation obtained at screening visit, prior to any study-related procedures.

Contact: Lisa Gauger / Mark Stacy at 919-668-2493 if you have any potential candidates you'd like to refer for consideration in this study.

ACTIVE ENROLLING STUDIES

The NCRO currently supports **38** active studies. This list includes only those studies that are actively enrolling.

DEMENTIA STUDIES

PI	SPONSOR	INDICATION	STUDY-ID	COORD.	TARGET / # PTS ENROLLED-6/30/04
WHITE, Heidi	NIH	Mild cog. Impairment	Nicotine Tr of MCI	Cook 684-0865	25 / 0

GENERAL

Hurwitz, Barrie	Berlex	RR-Multiple Sclerosis	Beyond	Beck 668-2278	15 / 0
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MOVEMENT DISORDERS

HUSAIN, Aatif	Boehringer Ingelheim	Restless Legs	RLS	Beck 668-2278	8 / 0
MASSEY, Janice	Elan	Cervical dystonia	CD-AN072-401	R. Hall 684-5422	15 / 3
MORGENLANDER, J	Private Investors	Restless Legs	RLS	N/A	20 / 0
STACY, Mark	Boehringer Ingelheim	Movement disorder	SCEPTRE	Gauger	8 / 0
SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 429
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 43
SCOTT, Burt	Wyeth Pharm	PD-ERT	POETRY / POEMS	Moore 668-2842	5 / 0

NEUROMUSCULAR

BEDLACK, Rick	Carolinas Med Ctr	ALS	ALS-Creatine	Choi 668-2844	15 / 15
MASSEY, Janice	FDA	Myasthenia Gravis	MG-Cellcept	Provided by Physician	10 / 5

PSYCHIATRY

GOLI, Veeraindar	Celgene	Fibromyalgia	Thalidomide	Choi 668-2844	30 / 3
GOLI, Veeraindar	Elan	Chronic severe pain	Chronic Pain-ZEST	Linney 668-2843	4 / 0
GOLI, Veeraindar	UCB Pharma	Postherpetic neuralgia	Levetiracetam PHN	Linney 668-2843	5 / 0
GOLI, Veeraindar	UCB Pharma	Fibromyalgia syndrome	Keppra	Choi 668-2844	60 / 0

VASCULAR

BUSHNELL, Cheryl	NIH	Stroke	Hormone Repl. Therapy	Link 970-1648	140 / 121
GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	10 / 2
GOLDSTEIN, Larry	Boehringer Ingelheim	Recurrent strokes	PRoFESS	Link 970-1648	30 / 0
GRAFFAGNINO, C	AstraZeneca-	Acute ischemic stroke	Stroke-SA-NXY-0007	Stoner 668-5275	10 / 4
GRAFFAGNINO, C	Centocor	Acute ischemic stroke	AbESTT II	Stoner 668-5275	12 / 0
LASKOWITZ, Danny	Biosite	Biomarker-brain injury	Triage Stoke Panel	B. Blessing 970-4888	450 / 193
LASKOWITZ, Danny	Merck & Phys Funded	Aneurismal SAH	Simvastatin-SAH	B. Blessing 970-4888	120 / 25
LYNCH, John	Physician Funded	Traumatic brain injury	Simvastatin-TBI	B. Blessing 970-4888	100 / 1

ANY PHYSICIANS INTERESTED IN ACTING AS AN INVESTIGATOR IN ANY FUTURE STUDIES, CONTACT JOANN JONES AT 668-2847.

**CTQA LUNCH AND LEARN SERIES
2004-2005 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 19, 2004	Development of a Study Regulatory Binder
September 13, 2004	Protocol Deviations
October 4, 2004	Preparing for FDA Inspections
November 1, 2004	Subject Recruitment
December 06, 2004	The Consenting Process
January 10, 2005	Recognizing and Reporting Research Misconduct
February 14, 2005	Handling Monitoring Visits
March 14, 2005	Preparing Research Budgets
April 11, 2005	Basics of INDs
May 09, 2005	TBA
June 6, 2005	TBA

ALL SESSIONS ARE FROM 12:00-1:00pm AND HELD IN ROOM 103 BRYAN RESEARCH BUILDING. SEATING IS ON A FIRST COME, FIRST SERVED BASIS FOR THOSE WHO HAVE REGISTERED FOR THE SERIES. BRING YOUR LUNCH, THE COMPLIANCE OFFICE WILL PROVIDE DRINKS AND DESSERTS!! **PLEASE REGISTER FOR THE SERIES BY E-MAILING ctqa@mc.duke.edu**