

NCRO HIGHLIGHTS

**Duke
Neuroscience**

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



March 2007

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
Ron Beauvais, Administrator	Gail Cook 684-0865	cook0007@mc.duke.edu
Donna Carnes, Clinical Trials Assistant	Joanne Field 668-2842	joanne.field@duke.edu
Lisa Gauger, Clinical Research Administrator	Karen Grace 668-2844	karen.grace@duke.edu
JoAnn Jones, Regulatory Administrator	Debra Heydt 668-2843	debra.heydt@duke.edu
Cathy O'Neill, Finance Manager	Rene Link 970-1648	link0002@mc.duke.edu
Jackie Woody, Clinical Trials Assistant	Sarah Wyne 668-2837	wyne0001@mc.duke.edu

We are pleased to announce Jackie Woody 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 **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-3/31/07
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 / 23

MOVEMENT DISORDERS

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	Boehringer Ingelheim	PD tx'd with Mirapex / other anti-PD agents	BI 248.619 Dominion	Field 668-2842	75-225 / 41
SCOTT, Burt	EISAI	PD	E2007-A001-302	Heydt 668-2843	25 / 1
SCOTT, Burt	Merz Pharmaceuticals	Cervical Dystonia	MRZ 60201-0408	Heydt 668-2843	6-8 / 0
SKEEN, Mark	Opexa Therapeutics	Clin Isolated Syndrome or Relapsing Remitting MS	Tovaxin/TERMS 2005-00	Wyne 668-2837	5 / 0
STACY, Mark	Novartis	PD	Quest	Field 668-2842	10 / 1
STACY, Mark	Ceregene	Idiopathic PD	PD(CELC200AUS11) Cere-120-02	Gauger 668-1538	6-8 / 0

NEUROMUSCULAR

BEDLACK, Rick	NIH, MDA, ALS Assoc.	ALS-motor neuron diseases	DNA Banking Repository	Heydt 668-2843	120 / 82
BEDLACK, Rick	UCB Pharma	Motor neuron disease	Levetiracetam	Heydt 668-2843	20 / 21

VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	40 / 24
GRAFFAGNINO, C	CoAxia, Inc.	Acute ischemic stroke	SENTIS-CD-0125	Stoner 668-5275	10 / 0
LASKOWITZ, Danny	Physician funded	Biomarker-brain injury	Stroke Panel of Biomarkers	M. Scism 668-1429	1000 / 786
LASKOWITZ, Danny	Merck & Phys Funded	Aneurysmal SAH	Simvastatin-SAH	M. Scism 668-1429	120 / 63
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin	M. Scism 668-1429	25 / 2

GERIATRICS

WHITE, Heidi	Amgen	Observational-Anemia & Chronic Kidney Ds	20050239	Cook 684-0865	25 / 0
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NON-NCRO TRIALS

BUSHNELL, Cheryl	Hazel K. Goddess Fund	Pregnant women with pre-eclampsia	Transcranial Doppler & Biomarker Pilot	CBusnell 684-5650	50 / 3
GRAFFAGNINO, C	NIH / Wash Univ	Carotid occlusion - COSS	Surgery vs stan med care	Stoner 668-5275	30 / 3

******ADVISORY BOARD MEETING******

The next Advisory Board meeting is scheduled for Wednesday, April 11, 2007 at 5:30 p.m. in the 2nd floor conference room at 932 Morreene Road.

**REGULATORY NEWS
eIRB
New Scientific Review process**

Beginning February 15, 2007, all new research studies submitted for IRB review must be submitted electronically using eIRB.

As a result of eIRB implementation at DUHS, since eIRB does not provide an electronic mechanism for the Department-mandated scientific review of all new research studies, please note the new process defined below for Division of Neurology prior to sending the study for Dr. Strittmatter's signature in eIRB.

For those PIs submitting studies through eIRB (without NCRO involvement), you will need to bring a hard copy of the appropriate IRB submission documents (protocol, research summary, consent forms, etc.) to JoAnn Jones for scientific review to be obtained. Once completed, JoAnn will stamp the package as "Approved by Neurology Advisory Board" and call you for pick up. The PI's office will need to take these stamped approved documents to Dr. Strittmatter's office. Once the PI notifies Dr. Strittmatter a study has been sent to him through eIRB for signoff, Dr. Strittmatter will be able to match the eIRB submission with the hard copy you provide to know scientific review has been completed.

**Duke University School of Medicine
Clinical Research Support Office (CRSO)
LUNCH AND LEARN SERIES
2007 Schedule
CHANGES NOTED BELOW**

The Clinical Research Support Office (CRSO) is now in charge of the Lunch/Learn Series and a revised schedule is noted below. More information will follow as the schedule is updated.

Lunch & Learn Series

All Lunch & Learns are held in Room 103 of the Bryan Research Building on Research Drive (not Bryan Center) from Noon until 1:00 PM with no registration necessary. Beverages and desserts are provided - please feel free to bring your lunch.

April 9, 2007	PRMO Update	Speaker - Karen Perera
May 14, 2007	TBD	
June 11, 2007	TBD	

If you have questions please contact Pam Riley at pam.riley@duke.edu or 668-5928.

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.