

NCRO HIGHLIGHTS

**Duke
Neuroscience**

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



August 2005

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
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Lisa Gauger, Clinical Research Administrator	Rene Link 970-1648	link0002@mc.duke.edu
JoAnn Jones, Regulatory Administrator	Sarah Wyne 668-2837	wyn0001@mc.duke.edu

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.

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-8/31/05
BURKE, Jim	GlaxoSmithKline	Mild to Moderate AD	Rosiglitazone XR	Heydt 668-2843	15 / 7
WHITE, Heidi	NIH	Mild cog. Impairment	Nicotine Tr of MCI	Cook 684-0865	25 / 12

EPILEPSY

HUSAIN, Aatif	Schwarz	Epilepsy-partial seizures	SPM 927 (SP 754)	Beck 668-2278	5 / 6
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MOVEMENT DISORDERS

MORGENLANDER, J	Private Investors	Restless Legs	RLS	N/A	20 / 10
SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 464
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 54
SCOTT, Burt	Wyeth Pharm	PD-ERT	POETRY	Gauger 668-1538	5 / 3
SCOTT, Burt	Kyowa	PD-motor response complications	KW-6002 (6002-US-018)	Cook 684-0865	8 / 9
SCOTT, Burt	Boston Life Sciences	Altropane	PD – tremors	Wyne 668-2837	20 / 6
STACY, Mark	Novartis	PD requiring levodopa	Stride PD (Stalevo)	Beck 668-2278	15 / 12
STACY, Mark	Inst Neurodeg Disorder	Early PD	SPECT imaging	Gauger 668-1538	8 / 1
STACY, Mark	Boehringer Ingelheim	PD eye safety study	Pramipexole vs. Ropinirole	Field 668-2842	10 / 0

NEUROMUSCULAR

BEDLACK, Rick	Columbia / NINDS	ALS	Minocycline	Grace 668-2844	15-20 / 15
MASSEY, Janice	Hoffman LaRoche-Aspreva	Myasthenia Gravis	Mycophenolate mofetil	Provided by Physician	6 / 0
MASSEY, Janice	FDA	Myasthenia Gravis	MG-Cellcept	Provided by Physician	10 / 12

VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	10 / 13
GOLDSTEIN, Larry	Boehringer Ingelheim	Recurrent strokes	PRoFESS	Link 970-1648	30 / 11
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 / 10
GRAFFAGNINO, C	AstraZeneca	Acute ICH	CHANT-SA-NXY-0012	Stoner 668-5275	3-6 / 2
LASKOWITZ, Danny	Biosite	Biomarker-brain injury	Triage Stoke Panel	B. Blessing 970-4888	450 / 529
LASKOWITZ, Danny	Merck & Phys Funded	Aneurismal SAH	Simvastatin-SAH	B. Blessing 970-4888	120 / 48
LYNCH, John	Physician Funded	Traumatic brain injury	Simvastatin-TBI	B. Blessing 970-4888	100 / 6

****NCRO Advisory Board Meeting Reminder****

October 12, 2005

5:30 p.m. – 2nd Floor Conference Room
Morreene Road Clinic

If you have particular items of interest you would like discussed, please call or email JoAnn Jones for placement on the meeting agenda (668-2847 / jones018@mc.duke.edu).

Human Subject Research Annual Re-Certification

ATTENTION: KEY PERSONNEL

(“Research Personnel who are directly involved in conducting research with human subjects, or who are directly involved with the handling of protected health information related to those subjects in the course of a research project”)

From The DUHS IRB Office

A new certification year will begin on October 1, 2005 for all DUHS Key Personnel. All Key Personnel who are conducting research with human subjects at any time during the period October 1, 2005 - September 30, 2006 must fulfill annual re-certification requirements by completing two (2) research ethics modules. The modules can be found on the Duke Research Ethics website at: <http://researchethics.mc.duke.edu>

There has been a temporary shortage of new modules in the past year. If you have completed all available modules, but need re-certification, you may repeat previously taken modules. However, you must choose modules other than those you have completed in the last 12 months. As new modules become available, an e-mail notice will be sent to all DUHS Key Personnel.

In addition, the Accessible Genetics Research Ethics Education (AGREE) modules may now be used to satisfy the certification requirements. AGREE modules can be found at: <http://agree.mc.duke.edu/>. Keep in mind that this is a separate website with its own account and password requirements.

The DUHS IRB website (<http://irb.mc.duke.edu>) provides direct links to both sets of modules as well as complete information on DUHS certification requirements.

If you have lost or forgotten your password: follow the instructions on the research ethics web site to have a new password emailed to you. If you have not received a password within a few hours following your request, call Duke Media Services at 684-6159 and request a password over the phone.

OIT ACCEPTABLE USE:

Please be aware that you may not give your user id and password to another person nor may you allow another person to use your account. Your user id and password constitute your electronic signature for any activity on your account. Complete details on OIT acceptable use and policies can be found at <http://www.oit.duke.edu/oit/policy/CompNet.html>

**Duke University School of Medicine
CTQA LUNCH AND LEARN SERIES
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.

September 22
October 24
November 7
December 8

Source Documentation
Research and Animal Welfare
What is Exempt Research?
AE Reporting

Sam Beavers
Ron Banks
John Harrelson
Ken Mahaffey

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 1.0 NURSING CONTACT HOURS AND .08 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!!