

NCRO HIGHLIGHTS

Duke
Neuroscience

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



August 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	Coordination	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
Sharon Dowell, Administrative Manager	Kristen Linney 668-2843	linne003@mc.duke.edu
Lisa Gauger, Clinical Research Administrator	Sarah Moore 668-2842	moore016@mc.duke.edu
JoAnn Jones, Regulatory Administrator	Sarah Wyne 668-2837	wyn0001@mc.duke.edu

Because of the increasing growth of the NCRO, a number of changes have been made in the last quarter. In an effort to streamline communication, we have created four contact points, and hope that any investigator will contact us directly. Carmen Graffagnino and Mark Stacy are available and happy to speak with you regarding any concern, and encourage all calls. For **Regulatory, Contract and IRB** issues, please call JoAnn Jones; **Study Administration and Budget concerns**, Sharon Dowell; and **Trial Coordination and Monitoring**, the assigned coordinator or Lisa Gauger.

As a result of the last Divisional faculty meeting, a number of new recruitment procedures are being considered. We are reviewing a process to screen clinic visits on a regular basis. Potential subjects will be assessed by trial inclusion/exclusion criteria, and if these criteria appear to be met, the attending physician will be contacted to see if the subject may be recruited. We are also exploring methods to distribute study detail to Neurology faculty electronically either through the Duke intranet or by email an updated document monthly for dragging to desktop. Finally, the entire collection of NCRO SOP's will be reviewed and presented to the NCRO Advisory Board. This Advisory Board will meet on a quarterly basis to improve NCRO operations and communication and voice with Division Faculty.

“REGULATORY NEWS”

IRB TIMELINES:

What happens to your study once it gets submitted to the IRB?

- Received in the IRB Office
- In about 4 weeks is placed on IRB full board meeting agenda and Primary Reviewer assigned
- In about 2 weeks is reviewed by convened IRB full board
- In 1-3 business days, the IRB distributes IRB-requested modifications to NCRO for processing

With the addition of a fourth full board meeting each month, the above timelines are decreasing and we will update this section in the future as the IRB continues to make great strides to reduce time from submission to full board review. During the above review process by the IRB, the NCRO Regulatory Group is working with IRB primary reviewers, IRB specialists, CROs and sponsors to expedite final approvals.

ASCERTAINMENT/RECRUITMENT OF POTENTIAL PARTICIPANTS – Review Preparatory to Research (RPR) vs. Request for Waiver of Consent and HIPAA Authorization

For IRB new study submissions, the NCRO Regulatory Group submits a RPR on all studies. However, if your ascertainment/recruitment process involves writing down or recording a person's individually identifiable health information PRIOR to obtaining consent, a PI will need to complete the Request for Waiver of Consent and HIPAA Authorization found on the IRB webpage @ <http://irb.mc.duke.edu/> and submit to JoAnn Jones when you submit the research summary. See below for more information.

For ascertainment/recruitment of POTENTIAL subjects for research PRIOR to obtaining consent:

Review Preparatory to Research (only if PHI will NOT leave DUHS) AND where you REVIEW a person's PHI or other identifiable private information but DO NOT RECORD it for research purposes (name or initials only can be recorded WITHOUT any other identifiable private information) PRIOR to obtaining consent

OR

Request for Waiver or Alteration of Consent and HIPAA Authorization (if PHI WILL leave DUHS) And/Or you WRITE or RECORD individually identifiable health information (PHI) or other identifiable private information for the purpose of research (regardless of whether the recorded information will leave DUHS) PRIOR to obtaining consent (other than name OR initials ONLY). This also includes recording any PHI onto a telephone script on people who call in answering a study advertisement.

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 **38** active studies. This list includes only those studies that are actively enrolling.

DEMENTIA STUDIES

PI	SPONSOR	INDICATION	STUDY-ID	COORD.	TARGET / # PTS ENROLLED-7/31/04
WHITE, Heidi	NIH	Mild cog. Impairment	Nicotine Tr of MCI	Cook 684-0865	25 / 1

GENERAL

Hurwitz, Barrie	Berlex	RR-Multiple Sclerosis	Beyond	Beck 668-2278	15 / 2
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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 / 4
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 / 433
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 43
SCOTT, Burt	Wyeth Pharm	PD-ERT	POETRY	Moore 668-2842	5 / 0
SCOTT, Burt	Wyeth Pharm	PD-ERT	POEMS	Moore 668-2842	20 / 11

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 / 2
GOLI, Veeraindar	UCB Pharma	Postherpatic 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 / 123
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 / 5
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 / 323
LASKOWITZ, Danny	Merck & Phys Funded	Aneurismal SAH	Simvastatin-SAH	B. Blessing 970-4888	120 / 32
LYNCH, John	Physician Funded	Traumatic brain injury	Simvastatin-TBI	B. Blessing 970-4888	100 / 2

**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	Preparing for FDA Inspections
October 4, 2004	Protocol Deviations
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.

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