

NCRO HIGHLIGHTS

**Duke
Neuroscience**

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



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

September 2005

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
Sharon Dowell, Administrative Manager	Debra Heydt 668-2843	debra.heydt@duke.edu
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 **40** 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-9/30/05
BURKE, Jim	GlaxoSmithKline	Mild to Moderate AD	Rosiglitazone XR	Heydt 668-2843	15 / 8
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 / 4
SCOTT, Burt	Boston Life Sciences	Altopane	PD – tremors	Wyne 668-2837	20 / 7
STACY, Mark	Novartis	PD requiring levodopa	Stride PD (Stalevo)	Beck 668-2278	15 / 13
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 / 1
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 / 533
LASKOWITZ, Danny	Merck & Phys Funded	Aneurismal SAH	Simvastatin-SAH	B. Blessing 970-4888	120 / 50
LYNCH, John	Physician Funded	Traumatic brain injury	Simvastatin-TBI	B. Blessing 970-4888	100 / 6

REGULATORY NEWS

Research Summary

Subject Identification & Recruitment Procedures PRIOR to Consenting

HIPAA requires valid authorization for the use of protected health information (PHI) for research purposes. PRIOR to consenting subjects in a research study, there must be appropriate measures in place to document use of PHI during the identification and recruitment of potential participants in research. Additionally, measures must be in place for the destruction of PHI obtained on potential participants who do not consent. The Principal Investigator (PI) must detail in the Research Summary the procedures for ascertainment/recruitment of potential participants into a research study under Section 6 "Subject identification, recruitment and compensation." The two vehicles that permit research use of PHI PRIOR to consenting include:

- Review Preparatory to Research (RPR)
PHI is reviewed but NOT written down or recorded (other than name or initials only with no other identifiers) and information does NOT leave DUHS
- Request for Waiver or Alteration of Consent and HIPAA Authorization
PHI IS written down or recorded whether or not it will leave DUHS (includes information recorded from a recruiting telephone script)
PHI will leave DUHS (i.e., to sponsor)

For more information on the RPR vs. the Wavier, please visit the DUHS IRB website: <http://irb.mc.duke.edu/forms.htm>.

The ONE Exception: When the PI is recruiting his/her own patients ONLY into a study and no new PHI will be collected prior to consenting, then neither a RPR or Waiver is required. The PI should simply state this information in the Research Summary so the IRB will have this information during review of the study.

Information a PI must address in Section 6 of the Research Summary include:

- Complete description of method(s) of identification of potential participants (i.e., medical records, clinic schedules)
- Recruitment procedures the PI has identified for potential participants (i.e., clinic, telephone, mail, advertisements)
- Individual(s) responsible for approaching potential participants about the study
Individual must be listed as Key Personnel
Initial contact must be healthcare personnel known to the potential subject (no cold calling)
Contact by an unknown healthcare personnel can ONLY occur with the patient's prior permission
- Plans of how and where consenting will be obtained
- Plans to ensure equitable subject selection (justify any exclusions)

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.

October 24
November 7
December 8

Research and Animal Welfare
What is Exempt Research?
AE Reporting

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!!