

NCRO HIGHLIGHTS

**Duke
Neuroscience**

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



June 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
Sharon Dowell, Administrative Manager	Kristen Linney 668-2843	linne003@mc.duke.edu
JoAnn Jones, Regulatory Administrator	Sarah Moore 668-2842	moore016@mc.duke.edu
Sarah Wyne, Clinical Research Administrator	Carroll Wilcox 668-2841	wilco001@mc.duke.edu

Roles of PI and Study Coordinator

PI

- Meet with study coordinator and PI staff assistant prior to study start up
- Complete knowledge of protocol especially inclusion/exclusion criteria
- Refer potential study patients to coordinator based on inclusion/exclusion criteria
- Present for all required study visits
- Review of labs, CRFs, source documents, and other study related documents in agreed upon timeframe

Study Coordinator

- Assist with patient recruitment
- Correspond with drug company
- Correspond with study patients
- Patient follow-up (lab results, track AEs, medication changes, study compliance)
- Present at all study visits
- Present at all sponsor related visits
- Complete knowledge of protocol

ACTIVE ENROLLING STUDIES

The NCRO currently supports **37** active studies. This list includes only those studies that are actively enrolling.

DEMENTIA STUDIES

PI	SPONSOR	INDICATION	STUDY-ID	COORD.	TARGET / # PTS ENROLLED-5/31/04
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
MASSEY, Janice	Elan	Registry	CD-MIND	R. Hall* 684-5422	N/A
MORGENLANDER, J	Private Investors	Restless Legs	RLS	N/A	20 / 0
SCOTT, Burt	NIH	Parkinson, early untx'd	PD-FS-TOO	Wilcox 668-2841	5 / 3
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	Moore 668-2842	5 / 0

NEUROMUSCULAR

BEDLACK, Rick	Carolinas Med Ctr	ALS	ALS-Creatine	Choi 668-2844	15 / 11
SANDERS, Don	FDA	Myasthenia Gravis	MG-Cellcept	Provided by Physician	10 / 5

PSYCHIATRY

PI	SPONSOR	INDICATION	STUDY-ID	COORD.	TARGET / # PTS ENROLLED-5/31/04
GOLI, Veeraindar	Celgene	Fibromyalgia	Thalidomide	Choi 668-2844	30 / 1
GOLI, Veeraindar	Elan	Chronic severe pain	Chronic Pain-ZEST	Linney 668-2843	4 / 0
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	200 / 118
GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	10 / 0
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
GRAFFAGNINO, C	Pfizer	Post-stroke depression	Sadbrain	Stoner* 668-5275	75 / 34
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

*Coordinators not included in above Who's Who list.

SERVICES PROVIDED BY THE REGULATORY OFFICE

REGULATORY START-UP DOCUMENT PACKAGES TO SPONSOR

Required by sponsor before shipment of study drug

- Compile and process documents according to Sponsor's Instructions which include but not limited to: FDA Form 1572; CVs for PI and sub-Is (signed/dated); medical licenses; IRB Membership Roster; Protocol Signature page; Investigator Brochure receipt page; Authorized Study Site Personnel Signature List; Site Delegation of Responsibilities Log; Confidentiality statement; Financial Disclosures at site initiation, yearly, and Study Completion; JCAHO Accreditation, CLIA, CAP and Laboratory Director CV and NCML, local laboratory information and reference ranges (when local laboratory used); Statement of IRB ICH-GCP compliance
- Obtain appropriate signatures from PI and staff
- Submit to Sponsor
- Maintain documents in Regulatory Binder and update as appropriate

REGULATORY DOCUMENT MAINTENANCE

- IRB submissions (new, amendments, advertisements, annual renewals, study closures)
- Obtain IRB and Departmental required signatures for IRB submissions
- Communicate with IRB from submission to approval and handle IRB-requested modifications with limited PI involvement
- Keep study staff informed of all updates/changes to studies
- Communicate with CRO/Sponsor throughout study
- Amendments include but not limited to:
Revised Investigator Brochures; amendments to protocol/consent; DSMB reports)
- Prepare site-specific Consent to meet IRB, ICH, HIPAA requirements
- Consent negotiation with CRO/Sponsor
- IND Safety Reporting (Duke subjects and outside site subjects) to DUHS IRB
- Receive and Process Study Correspondence from CRO/Sponsor
- Maintain documents in Regulatory Binder
- Submit to Sponsor as appropriate when documents renewed / updated

MONITOR VISITS

- Ensure site regulatory compliance
- Meet with monitor and f/u as needed

STUDY CLOSE-OUT

- Process IRB Study Closure Report
- Submit IRB acknowledgement to Sponsor