

## 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.*

December 2007

#### Who's Who in the NCRO

Management	Coordination	Email:
Mark Stacy, Medical Director	Kate Beck 668-2278	<a href="mailto:beck0002@mc.duke.edu">beck0002@mc.duke.edu</a>
Ron Beauvais, Administrator	Joanne Field 668-2842	<a href="mailto:joanne.field@duke.edu">joanne.field@duke.edu</a>
Donna Carnes, Clinical Trials Assistant	Karen Grace 668-2844	<a href="mailto:karen.grace@duke.edu">karen.grace@duke.edu</a>
Lisa Gauger, Clinical Research Administrator	Debra Heydt 668-2843	<a href="mailto:debra.heydt@duke.edu">debra.heydt@duke.edu</a>
JoAnn Jones, Regulatory Administrator	Rene Link 970-1648	<a href="mailto:link0002@mc.duke.edu">link0002@mc.duke.edu</a>
Cathy O'Neill, Finance Manager	Peggy Perry-Trice 684-0865	<a href="mailto:peggy.perrytrice@duke.edu">peggy.perrytrice@duke.edu</a>
Jackie Woody, Clinical Trials Assistant	Sarah Wyne 668-2837	<a href="mailto:wyne0001@mc.duke.edu">wyne0001@mc.duke.edu</a>

#### 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).

#### EPILEPSY

PI	SPONSOR	INDICATION	STUDY-ID	COORDINATOR	TARGET / # PTS ENROLLED-12/31/07
HUSAIN, Aatif	EISAI	Refractory partial seizures	Rufinamide (E2080-A001-301)	Beck 668-2278	6 / 2

#### GENERAL

SKEEN, Mark	Novartis (CFTY720D2309)	Relapsing Remitting MS	Fingolimod (FTY720)	Wyne 668-2837	5 / 0
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#### MOVEMENT DISORDERS

SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 532
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 79
SCOTT, Burt	Boehringer Ingelheim	PD tx'd with Mirapex / other anti-PD agents	BI 248.619 Dominion	Field 668-2842	75-225 / 108
SCOTT, Burt	NIH/NINDS	PD – early treated	Creatine (LS-1)	Grace 668-2844	36 / 11
STACY, Mark	Novartis	PD	Quest	Field 668-2842	10 / 2
			PD(CELC200AUS11)		
STACY, Mark	Ceregene	Idiopathic PD	Cere-120-02	Gauger 668-1538	12 / 12
STACY, Mark	Merz Pharmaceuticals	Blepharospasm	MRZ 60201-0433	Heydt 668-2843	10 / 0
STACY, Mark	Schering Plough	Moderate-to-severe PD	SCH420814 (P04501)	Perry-Trice 684-0865	5-6 / 0

#### NEUROMUSCULAR

BEDLACK, Rick	Physician Funded	ALS, Myopathy & Healthy Controls	HDAC Expression in Muscle	N/A	12 / 14
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#### VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	45 / 35
LASKOWITZ, Danny	Physician funded	Biomarker-brain injury	Stroke Panel of Biomarkers	E. Bennett 668-1429	1000 / 795
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin	E. Bennett 668-1429	25 / 6

#### GERIATRICS

WHITE, Heidi	Amgen	Observational-Anemia & Chronic Kidney Ds	20050239	Perry-Trice 684-0865	25 / 17
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#### NON-NCRO TRIALS

BROWNDYKE, Jeff	Ortho-McNeil Neurologics, Inc.	Mild AD	GAL-EMR-4026	Wyne 668-2837	36 / 4
GRAFFAGNINO, C	NIH / Wash Univ	Carotid occlusion - COSS	Surgery vs stan med care	Stoner 668-5275	30 / 4
GRAFFAGNINO, C	PhotoThera	Acute Ischemic Stroke	NEST-2-NeuroThera Laser System	Stoner 668-5275	12 / 5
MASSEY, Janice	NIH/UAB	Myasthenia w/o thymoma	Thymectomy	Lipscomb 684-5422	6 / 0

## REGULATORY NEWS

\*\*\*Revised DUHS IRB Research Ethics Credentialing\*\*\*

### Duke Medicine IRB Research Ethics Education Standard November 1, 2007

**Requirement:** Two modules per year for everyone working on a study

**Effective Date:** January 1, 2008

- All researchers must take 2 modules between July 1 and December 31, 2007 to fulfill the education requirement and be considered current on January 1, 2008
- Delinquent notices will be sent on January 2, 2008 from the Occupational & Environmental Safety Office (OESO) to those not current.

**Module choices:**

- Duke Research Ethics Modules
- CITI Modules will be added as a choice in 2008
- VA education requirements will be accepted for Duke Faculty in lieu of other modules

**Module Order:**

- New faculty/staff must first take the two Orientation Modules—Protecting Research Subjects and What Counts as Research
- Additional annual modules are your choice of any of the offerings, but the pair must be from either the Duke site or the CITI site. You are not permitted to mix choices.

**Reminders:**

- OESO will send reminders to researchers when their IRB credentialing update is due, at 30 and 7-days prior to termination date.
- The eIRB will check the status of each key personnel member and if delinquent or within the 30-day window, it will send an email to the individual and the PI.
- Researchers will continue to do the modules and check their status on the Research Ethics site: <http://researchethics.mc.duke.edu/>

## \*\*\*Revised ClinicalTrials.gov Registration Information\*\*\*

New information provided by Dr. Wesley G. Byerly, Associate Dean, Research Support Services at a recent Lunch & Learn Series (12/10/07) notes the following information for those with investigator-initiated trials that need to register their trials on ClinicalTrials.gov.

Send an email request to [Rebeka.Branagan@duke.edu](mailto:Rebeka.Branagan@duke.edu)

The subject line should state "ClinicalTrials.gov Protocol Registration"

Include the name, telephone number and email address of the individual who will be completing the listing

Within two business days, you will receive an email message from ClinicalTrials.gov containing your login name and temporary password

You will also be provided information to proceed with registering your trial on the website

### Duke University School of Medicine Clinical Research Support Office (CRSO)

#### LUNCH AND LEARN SERIES

\*\*\*CHANGE IN VENUE NOTED BELOW\*\*\*

#### *Lunch & Learn Series*

#### Lunch and Learns are held the 2nd Monday of each Month

Time: Noon - 1:00 pm

**NEW LOCATION:** School of Nursing

Room 1014 (Peter and Ginny Nicholas Auditorium and Learning Center)  
307 Trent Drive

No registration necessary

Beverages and desserts are provided. Please feel free to bring your lunch.

#### Scheduled Topics:

February 11, 2008

**Topic:** Human Subject Protections Program (HRPP)

**Presenters:** Jennifer Holcomb (CRSO Operations Director) and John Falletta, MD (IRB Chair)

If you have questions, please contact Sue Avery at [sue.avery@duke.edu](mailto:sue.avery@duke.edu) or 668-8685.