

# 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 2008

### Who's Who in the NCRO

Management	Coordination	Email:
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### ACTIVE ENROLLING STUDIES

The NCRO currently supports **39** active studies. This list includes only those studies that are actively enrolling. Please help us reach our targets (column 6).

<b>DEMENTIA</b>					
PI	SPONSOR	INDICATION	STUDY-ID	COORDINATOR	TARGET / # PTS ENROLLED-11/30/08
BURKE, Jim	Eli Lilly	Mild to Moderate Alzheimer's Disease	LY450139 (H6L-MC-LFAN)	Heydt 668-2843	20 / 2
BURKE, Jim	Toyama Chemistry Co, Ltd	Mild to Moderate Alzheimer's Disease	T-817MAa (AA4437420)	Heydt 668-2843	13 / 2
<b>EPILEPSY</b>					
HUSAIN, Aatif	Schwarz Biosciences	Partial onset seizures	Lacosamide monotherapy (SP 902)	Beck 668-2278	6 / 1
<b>GENERAL</b>					
SKEEN, Mark	Novartis (CFTY720D2309)	Relapsing Remitting MS	Fingolimod (FTY720)	Wyne 668-2837	20 / 9
<b>MOVEMENT DISORDERS</b>					
SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 548
SCOTT, Burt	NIH/NINDS	PD – early treated	Creatine (LS-1)	Grace 668-2844	36 / 29
SCOTT, Burt	HP Therapeutics	Huntington's Disease	Observational (COHORT)	Wyne 668-2837	25 / 18
SCOTT, Burt	Juvantia Pharma Ltd / Santhera Pharmaceuticals	Parkinson's Disease	Fipamezole oromucosal tablet (SNT-11-004)	Gauger 668-1538	12 / 2
SCOTT, Burt	Mass General (NINDS)	Huntington's Disease	Coenzyme Q10 (2CARE)	Wyne 668-2837	8 / 3
STACY, Mark	Novartis	Non-motor symptoms in idiopathic PD	CELC200AUS14 (Stalevo vs. IR carbidopa/levodopa	Field 668-2842	8 / 0
STACY, Mark	Weill Cornell	Parkinson's Disease	Coenzyme Q10 (QE3)	Field 668-2842	12 / 0
<b>NEUROMUSCULAR</b>					
BEDLACK, Rick	Avanir Pharmaceuticals	Tx of pseudobulbar affect in ALS	AVP-923 (Zenvia) 07-AVR-123 (STAR)	Grace 668-2844	12 / 8
BEDLACK, Rick	Amyotrophic Lateral Sclerosis Association (ALSA)	Validation of ALS Biomarkers	BIO ALS-01	Grace 668-2844	36 / 7
<b>VASCULAR</b>					
GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	White-Tong 668-2905	55 / 38
GOLDSTEIN, Larry	Schering Plough	Atherosclerotic Disease	SCH 530348 with standard of care (TRA 2°P – TIMI 50)	White-Tong 668-2905	75 / 0
GRAFFAGNINO, C	The Medicines Company	Acute hypertension & ICH	Clevidipine IV infusion (TMC-CLV-07-02)	Stoner 668-5275	6 / 2
KOLLS, Bradley	Astute Medical, Inc.	Biomarker for AKI in ICU patients	Prot AST-103	E. Bennett 668-1429	300 / 9
LASKOWITZ, Danny	Physician funded	Biomarker-brain injury	Stroke Panel of Biomarkers	E. Bennett 668-1429	1200 / 844
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin	E. Bennett 668-1429	25 / 6
<b>NON-NCRO TRIALS</b>					
MASSEY, Janice	NIH/UAB	Myasthenia w/o thymoma	Thymectomy	Lipscomb 684-5422	6 / 1

**\*\*\*STUDY SPOTLIGHT\*\*\***

**New Approved Studies Ready for Recruitment!!**  
Please see further details below – Thank you for your Support!

**Bradley Kolls (PI) – Astute Medical, Inc. (Prot AST-103)**

**“Sample Collection Study to Evaluate Novel Biomarkers from Acutely Ill Patients at Risk for Acute Kidney Injury”**

The objective of this study is to discover novel biomarkers in blood and urine from subjects at risk for acute kidney injury (AKI), including biomarkers that are sensitive and specific for AKI and can identify AKI prior to current methods (i.e., increases in serum creatinine) in acutely ill patients. Identification of early AKI, before changes in existing markers of kidney function occurs, may identify a target population for the development of prevention and treatment strategies. This study will enroll 300 subjects from an acute care setting (including the Emergency Dept, Neuroscience Intensive Care Unit, Medical Intensive Care Unit, and Coronary Care Unit) here at DUHS. You may contact Dr. Bradley Kolls or Ellen Bennett (668-1429) for more information.

**An update from the Duke IRB**

**Any new submissions or continuing reviews (renewals) initiated in the eIRB on or after November 1, 2008 will automatically include the DUHS Investigator’s Agreement. This Agreement consists of 22 statements to which the PI must attest before formally submitting the protocol. The statements outline the agreement of the PI to adhere to Institutional Human Subject Protection policies and IRB oversight under Duke’s Federal-Wide Assurance (FWA #00009025). The DUHS PI agreement can be found on the Duke IRB website (under the ‘Forms/Standard Language’ tab).**

**New requirements for Human Subjects Protection Certification**

**Beginning January 1, 2009, Duke Medicine is adopting the web-based modules available at the Collaborative Institutional Training Initiative (CITI) website ([www.citiprogram.org](http://www.citiprogram.org)) for certification in Human Subjects Protection. Duke Medicine will transition from the IRB online ethics training modules to CITI. The Clinical Research Support Office (CRSO) will be responsible for tracking module completion. Please go to the CRSO website for more information ([www.crso.som.duke.edu](http://www.crso.som.duke.edu)).**

**Duke University School of Medicine  
Clinical Research Support Office (CRSO)  
LUNCH AND 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.

If you have questions, please contact the CRSO at [CRSO.Help@notes.duke.edu](mailto:CRSO.Help@notes.duke.edu) or 681-6665.

**We would like your suggestions for topics in future issues of the NCRO Newsletter! Please send your suggestions to: Donna Carnes @ [donna.carnes@duke.edu](mailto:donna.carnes@duke.edu).**