

NCRO HIGHLIGHTS

Duke
Neuroscience

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



June 2008

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

Who's Who in the NCRO

Management

Mark Stacy, Medical Director
Ron Beauvais, Administrator
Donna Carnes, Clinical Trials Assistant
Lisa Gauger, Clinical Research Administrator
JoAnn Jones, Regulatory Administrator
Cathy O'Neill, Finance Manager
Jackie Woody, Clinical Trials Assistant

Coordination

Kate Beck 668-2278
Joanne Field 668-2842
Karen Grace 668-2844
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ACTIVE ENROLLING STUDIES

The NCRO currently supports **38** 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-6/30/08
HUSAIN, Aatif	EISAI	Refractory partial seizures	Rufinamide (E2080-A001-301)	Beck 668-2278	6 / 4
HUSAIN, Aatif	Schwarz Biosciences	Partial onset seizures	Lacosamide monotherapy (SP 902)	Beck 668-2278	5-6 / 0

GENERAL

SKEEN, Mark	Novartis (CFTY720D2309)	Relapsing Remitting MS	Fingolimod (FTY720)	Wyne 668-2837	5 / 3
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MOVEMENT DISORDERS

SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 548
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 91
SCOTT, Burt	NIH/NINDS	PD – early treated	Creatine (LS-1)	Grace 668-2844	36 / 23
SCOTT, Burt	HP Therapeutics	Huntington's Disease	Observational (COHORT)	Wyne 668-2837	25 / 3
SCOTT, Burt	Juvantia Pharma Ltd / Santhera Pharmaceuticals	Parkinson's Disease	Fipamezole oromucosal tablet (SNT-11-004)	Gauger 668-1538	12 / 1
SCOTT, Burt	Mass General (NINDS)	Huntington's Disease	Coenzyme Q10 (2CARE)	Wyne 668-2837	8 / 0
STACY, Mark	Schering Plough	Moderate-to-severe PD	SCH420814 (P04501)	Perry-Trice 684-0865	5-6 / 4
STACY, Mark	Novartis	Non-motor symptoms in idiopathic PD	CEL200AUS14 (Stalevo vs. IR carbidopa/levodopa)	Field 668-2842	8 / 0

NEUROMUSCULAR

BEDLACK, Rick	Avanir Pharmaceuticals	Tx of pseudobulbar affect in ALS	AVP-923 (Zenvia) 07-AVR-123 (STAR)	Grace 668-2844	8-10 / 6
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VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Gauger 668-1538	45 / 38
GRAFFAGNINO, C	NIH / Wash Univ	Carotid occlusion - COSS	Surgery vs stan med care	Stoner 668-5275	30 / 5
GRAFFAGNINO, C	The Medicines Company	Acute hypertension & ICH	Clevidipine IV infusion (TMC-CLV-07-02)	Stoner 668-5275	6 / 1
LASKOWITZ, Danny	Physician funded	Biomarker-brain injury	Stroke Panel of Biomarkers	E. Bennett 668-1429	1200 / 815
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin	E. Bennett 668-1429	25 / 6

NON-NCRO TRIALS

MASSEY, Janice	NIH/UAB	Myasthenia w/o thymoma	Thymectomy	Lipscomb 684-5422	6 / 0
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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.

******REGULATORY NEWS******
IRB ANNOUNCEMENT
NEW DUHS PRINCIPAL INVESTIGATOR AGREEMENT

The DUHS IRB announced at its recent workshop on June 17, 2008 implementation of a DUHS Principal Investigator Agreement form in the very near future for all new study submissions. The agreement will include 23 statements and will require PI signature for all new study submissions to the IRB and at each Annual Renewal.

The PI's signature will indicate commitment of a DUHS PI to Institutional Human Subject Protection Policies and IRB oversight under Federal-Wide Assurance, FWA #00009025.

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

M. Stacy (PI) – Novartis (CELC200AUS14)

“An 8-week, prospective, randomized, double-blind, double-dummy, active-controlled, multi-center comparison study of the effects of Stalevo® versus immediate release carbidopa/levodopa on non-motor symptoms in patients with idiopathic Parkinson’s disease and demonstrating non-motor symptoms of wearing off”

The primary objective of this study is to compare the effects of Stalevo® vs. IR carbidopa/levodopa on the non-motor symptoms in patients with idiopathic PD and non-motor symptoms of wearing off. Eligible subjects (between the ages of 30-85) meeting all eligibility criteria [including a clinical diagnosis of idiopathic PD and exhibiting at least 2 of 3 PD symptoms (rigidity, resting tremor & bradykinesia) who demonstrate non-motor symptoms of end-of-dose wearing off, MMSE score of at least 25, receiving treatment with a stable dose of IR carbidopa/levodopa (up to 600 mg/day of levodopa) and not experiencing disabling dyskinesias] will be randomized to either Stalevo® plus IR carbidopa/levodopa placebo or IR carbidopa/levodopa plus Stalevo® placebo. Trial participation for subjects is up to 14 weeks (6 week maximum screening period and 8 week treatment period). The study will recruit approximately 172 subjects. We anticipate recruiting 8 subjects at DUHS. You may contact Dr. Mark Stacy or Joanne Field (668-2842) for more information about this study.

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.

[Future Lunch & Learn and Advanced Lunch & Learn Dates and Topics.](#) 

Scheduled Topics:

July 14, 2008

Topic: The Role of Contracts in Protecting Study Participants

Presenter: H. Gilbert Smith, Ph.D.,

Managing Director, Office of Corporate Research Collaborations

August 11, 2008

Topic: Privacy vs. Confidentiality: Impacts on Research

Presenter: Wesley Byerly, Pharm.D.

Associate Dean, Research Support Services

If you have questions, please contact the CRSO at CRSO.Help@notes.duke.edu or 681-6665.