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Welcome to the fourth edition of the Duke Clinical Research Institute (DCRI) Neurosciences Medicine quarterly newsletter. This newsletter is designed to help you, our sponsors and colleagues, stay up to date on our exciting research news, publications, events, and faculty activities.

DCRI Neurosciences Medicine conducts psychiatry- and neurology-focused phase I-IV clinical trials. The thought leadership and guidance from Duke University faculty, who are also practicing physicians, sets us apart. [Click here to learn more about our faculty and expertise.](#)

COMING IN SPRING 2018:

EEG as a Biomarker in Neuroscience Clinical Trials—a DCRI Webinar
[Let us know if you are interested in attending virtually!](#)

A PEDIATRIC PARTNERSHIP

Meet Dr. Linmarie Sikich



On the heels of receiving [the National Institutes of Health Autism Center of Excellence award](#) a few months ago, the DCRI's Neurosciences team continues to make strides in improving pediatric patient care through research. Drs. Scott Kollins and Linmarie Sikich lead DCRI's global Pediatric Neurosciences team. They have over 50 years

combined experience in treating patients with ADHD and autism, and between them have conducted over 100 clinical trials for new products, therapeutics, and, most recently, a game to treat pediatric attention deficit.

Dr. Sikich is a child and adolescent psychiatrist and associate director of the Duke Center for Autism and Brain Development. She earned her undergraduate degree, master's degree in developmental neurobiology, and her medical degree from Washington University in St. Louis. Prior to completing her residency, she completed a postdoctoral fellowship focused on basic neurodevelopment. She attended Yale University for her general psychiatry and child psychiatry residencies. She was on the faculty at the University of North Carolina for 19 years before joining the Duke



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Center for Autism and Brain Development as associate director. At UNC, she founded the TEACCH Medical Consultation Clinic, whose goal is to facilitate the integration of biomedical, behavioral and educational treatments for individuals with autism spectrum disorders (ASDs), and led a research program focused on the development and evaluation of treatments for youth with psychiatric and developmental problems.

She has previously participated in NIH, Cure Autism Now, and Autism Speaks conferences examining appropriate outcome measures for autism intervention trials and emerging intervention strategies for ASD and Fragile X syndrome. She has served as a reviewer of research proposals to the MIND Institute, Thrasher Institute, and Autism Speaks, and was the chair of the National Institute of Mental Health Interventions for Children (ITVC) Study Section from 2010 to 2013. She is a member of the Autism

Speaks Autism Treatment Network research advisory board and the data safety and monitoring board for the NICHD rare diseases network. She has participated in many psychopharmacologic clinical trials for individuals with ASD, Fragile X, pediatric bipolar disorder, and early onset psychosis funded by foundations, the federal government, and individual pharmaceutical companies. She also has conducted behavioral intervention studies designed to improve functioning in youth with psychosis and to help African-American parents advocate more effectively for their children with special needs.

At Duke, she is involved in research focused on treatments for autism, provides clinical care to individuals with autism and early onset psychosis, and provides training to physicians, social workers, and psychologists interested in neurodevelopmental disorders. She is also PI of a study in autism to improve reciprocal social behaviors (SOARS-B).

SPOTLIGHT ON NEUROSCIENCES CLINICAL OPERATIONS

Meet April Clayton



What are your top three priorities as associate director for clinical operations in Neurosciences Medicine? Support the NSM faculty, generate quality proposals with a competitive budget for win/award, and oversee current NSM studies to ensure a positive client relationship is maintained.

Do you have any hobbies? Kids' soccer games, dance competitions, and spending time at the beach.

Within Neurosciences Medicine, what types of indications are your favorite? Can you get any better than stem cell studies for neurological conditions and games for ADHD kids?

NEUROSCIENCES MEDICINE PARTNERS WITH EARLY PHASE RESEARCH

The [Duke Early Phase Clinical Research team](#) held an open house for sponsors and friends on October 23. Neurosciences Medicine's Drs. Daniel Laskowitz and Jeffrey Guptill were in attendance, along with former FDA Commissioner Dr. Robert Califf, to show support for early phase neurosciences research at Duke.

For more information regarding our phase I unit and capabilities, please [contact Jen Hart](#).



WHAT'S NEXT? UPCOMING CONFERENCES, MEETINGS, AND SPEAKING ENGAGEMENTS

[CNS Summit– Boca Raton, Florida](#)

November 16–19, 2017

Richard Keefe, PhD—To present on “Technology and the Future of Cognition.” Others from DCRI’s Neurosciences team, including Daniel Laskowitz, MD, Jeff Guptill, MD, and Jennifer Hart, assistant director for business development, will be in attendance.

[American Professional Society of ADHD and Related Disorders \(APSARD\)— Washington, D.C.](#)

January 12–14, 2018

Scott Kollins, PhD—To present: “Technology and Cognitive Training Using the Akili Data.”

NEW PUBLICATIONS

[Jeffrey Guptill, MD, MA, MHS](#)

Juel VC, Sanders DB, Hobson-Webb LD, Massey JM, **Guptill JT**, O’Brien F, Wang JJ, Howard JF. Marked clinical and jitter improvement after eculizumab in refractory myasthenia. *Muscle Nerve*. 2017;56:E16-8. (PMID: 28214342)

Sanders DB, **Guptill JT**, Aleš KL, Hobson-Webb LD, Jacobus DP, Mahmood R, Massey JM, Pittman MM, Prather K, Raja SM, Yow E, Juel VC. Reliability of the triple timed-up-and-go (3TUG) test [published online May 25, 2017]. *Muscle Nerve*. doi: 10.1002/mus.25700. (PMID: 28545168)

Thakkar N, **Guptill JT**, Aleš K, Jacobus D, Jacobus L, Peloquin C, Cohen-Wolkowicz M, Gonzalez D; DAPPER Study Group. Population pharmacokinetics/pharmacodynamics of 3,4-diaminopyridine base in patients with Lambert-Eaton Myasthenic Syndrome (LEMS). *CPT Pharmacometrics Syst Pharmacol*. 2017;6:625-34. (PMID: 28623849)

Yi JS, **Guptill JT**, Stathopoulos P, Nowak R, O’Connor K. B cells in the pathophysiology of myasthenia gravis [published online September 20, 2017]. *Muscle Nerve*. doi: 10.1002/mus.25700. 2017. (PMID: 28940642)

Shakhnovich V, Smith B, **Guptill JT**, James L, Collier D, Wu H, Livingston C, Zhao J, Kearns G. Lean body weight dosing of pantoprazole is most appropriate for obese children with gastroesophageal reflux disease. *J Pediatrics*. In press.

Howard JF Jr, Utsugisawa K, Benatar M, Murai H, MD, Barohn RJ, Illa I, Vissing JS, Burns EM, MD, Kissel JT, Muppidi S, Nowak RJ, O’Brien F, Wang JJ, Mantegazza R;

REGAIN Study Group. Safety and efficacy of eculizumab in anti-acetylcholine receptor antibody-positive refractory generalised myasthenia gravis (REGAIN): a phase 3, randomised, double-blind, placebo-controlled, multicentre study. *Lancet Neurol*. In press.

Guptill JT, Raja S, Narayanaswami P, Sanders DB. Comparative effectiveness research to advance treatment of myasthenia gravis. Presented at: 13th International Conference on Myasthenia Gravis and Related Disorders; May 16, 2017; New York, NY.

Li K, Russo M, Liu W, Raja S, **Guptill JT**, Yi JS. Immune profiling of circulating follicular helper T cells in MuSK-MG patients. Presented at: 2017 AANEM annual meeting; September 2017; Phoenix, AZ.

Sanders DB, Small M, Budinger S, **Guptill JT**. A Redcap database for the MG clinic and multicenter collaborations. Presented at: 2017 AANEM annual meeting; September 2017; Phoenix, AZ.

Noveck R, **Guptill JT**, Foss C, Hauser B, Suffredini AF. Safety and tolerability of a new clinical lot of reference endotoxin [LPS (CCRE Lot 94332B10)] in healthy subjects. Presented at: 2017 Annual Meeting of the American College of Clinical Pharmacy; October 2017; Phoenix, AZ.

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Richard Keefe, PhD

The Genetics of Endophenotypes of Neurofunction to Understand Schizophrenia (GENUS) consortium: A collaborative cognitive and neuroimaging genetics project [published online October 3, 2017]. *Schizophr Res*. doi: 10.1016/j.schres.2017.09.024. (PMID: 28982554)

The impact of medication anticholinergic burden on cognitive performance in people with schizophrenia. *J Clin Psychopharmacol*. 2017;37:651-56. (PMID: 29016375)

Genetic correlates of insight in schizophrenia [published online October 17, 2017]. *Schizophr Res*. doi: 10.1016/j.schres.2017.10.021. (PMID: 29054485)

Bradley Kolls, MD, PhD, MMCI

Kolls BJ, Mace BE, Dombrowski KE. Implementation of continuous video-electroencephalography at a community hospital enhances care and reduces costs [published

online October 24, 2017]. *Neurocrit Care*. doi: 10.1007/s12028-017-0468-6. (PMID: 29067633)

Scott Kollins, PhD

Lee CT, McClernon FJ, **Kollins SH**, Fuemmeler BF. Childhood ADHD symptoms and future illicit drug use: the role of adolescent cigarette use [published online July 17, 2017]. *J Pediatr Psychol*. doi: 10.1093/jpepsy/jsx098. (PMID: 29049706)

of a neuroimaging study with methylphenidate challenge [published online October 20, 2017]. *Neuropsychopharmacology*. doi: 10.1038/npp.2017.248. (PMID: 29052617)

Sweitzer MM, **Kollins SH**, Kozink RV, Hallyburton M, English J, Addicott MA, Oliver JA, McClernon FJ. ADHD, smoking withdrawal and inhibitory control: results

Improving recognition and management of ADHD in adults. Presented at: Georgia Academy of Family Physicians Annual M; October 26, 2017; Atlanta, GA.

Daniel Laskowitz, MD, MHS

Terrell T, Kelapport, Abramson R, Bennett ER, Cantu R, Sloan G, **Laskowitz DT**, McKeag D, Nichols G, Verle V. Genetic polymorphisms associated with the risk of concussion in 1056 college athletes: a multi-center prospective cohort study. *BMJ*. In press.

outcomes in ischemic stroke. *Ann Clin Transl Neurol*. 2017;4:246-65. (PMID: 28382306)

El-Husseini, N, Bennett ER, Goldstein L, Li YJ, Taylor R, **Laskowitz DT**, James ML. Association of IL6ST (gp130) polymorphism with functional outcome following spontaneous intracerebral hemorrhage [published online September 27, 2017]. *J Stroke Cerebrovasc Dis*. doi: 10.1016/j.jstrokecerebrovasdis.2017.08.017. (PMID: 28964648)

Xian Y, Federspiel JJ, Hernandez AF, **Laskowitz DT**, Schwamm LH, Bhatt DL, Smith EE, Fonarow GC, Peterson ED. Use of intravenous tPA in patients with acute ischemic stroke who take non-vitamin K antagonist oral anticoagulants before stroke. *Circulation*. 2017;135:1024-35. (PMID: 28119380)

Berger M, Ponnusamy V, Greene N, Cooter M, Nadler J, Friedman A, McDonagh D, **Laskowitz DT**, Newman MF, Shaw L, Warner DS, Matthew J, James ML. The effect of propofol versus isoflurane anesthesia on postoperative changes in CSF cytokine levels: results of a randomized trial. *Front Immunol*. In press.

Sharma R, Rosenberg A, Bennett ER, **Laskowitz DT**, Acheson SK. A blood based biomarker panel to risk-stratify mild traumatic brain injury. *PLoS One*. 2017;12:e0173798. (PMID: 8355230)

Tu TM, Wang H, Dawson H, Kolls B, **Laskowitz DT**. Apolipoprotein E mimetic peptide, CN-105, improves

Laskowitz DT, Wang H, Chen T, Lubkin DT, Cantillana V, Tian-Ming T, Kernagis D, Zhou G, Macy G, Kolls BJ, Dawson HN. Neuroprotective pentapeptide CN-105 is associated with reduced sterile inflammation and improved functional outcome in a traumatic brain injury murine model. *Sci Rep*. 2017;7:46461. (PMID: 28429734)

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Daniel Laskowitz, MD, MHS (cont'd)

Terrell TR, Bostick R, Barth J, Sloane R, Cantu RC, Bennett E, Galloway L, **Laskowitz DT**, Erlanger D, McKeag D, Valentine V, Nichols G. Multicenter cohort study on association of genotypes with prospective sports concussion: methods, lessons learned, and recommendations. *J Sports Med Phys Fitness*. 2017;57:77-89. (PMID: 25242101)

Wilkinson D, Ade K, Rogers L, Attix DK, Margatha K, Smith L, **Laskowitz DT**, Freeman MC, Hoffer ME, Saper JR, Scott DL, Sakel, M, Calhoun A, Black R. Preventing episodic migraine with caloric vestibular stimulation: a randomized controlled trial. *Headache*. 2017;57:1065-87. (PMID: 28656612)

El Hussein N, Goldstein LB, Peterson ED, Zhao X, Olson DM, Williams JW Jr, Bushnell C, **Laskowitz DT**. Depression status is associated with functional decline over a 1 year period following stroke. *J Stroke Cerebrovasc Dis*. 2017;26:1691-4. (PMID: 28389192)

Wang X, Wang Y, Patel UD, Xie Barnhart H, Li Z, Li H, Wang C, Zhao X, Liu L, Wang Y, **Laskowitz DT**. Comparison of associations of reduced estimated glomerular filtration rate with stroke outcomes between hypertension and no hypertension. *Stroke*. 2017;48:1691-4. (PMID: 28438908)

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