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Global Expertise in Neural Engineering

MOVEMENT RESTORATION

> AUTONOMIC SYSTEM

> > BRAIN HEALTH

> > > PAIN

TOOLS & TECHNOLOGY

# **Cleveland FES Center**

Report to the Community 2015

Executive Summary	1
Who We Are	3
Investigators	4
Research Thrusts	7
Movement Restoration	8
Hand Therapy Video Games	10
Pain	12
Brain Health	14
Creating the Next Generation	
of DBS Technology	16
Autonomic System	18
Focusing on Pelvic Health	20
Helping Prevent	
Lung Infections	22
Tools & Technology	24
Neuroprosthetic Devices	26
Clinical and Regulatory Affairs	28
Industrial Relations	30
Education	32
Institutional Partners & Facilities	4(
By the Numbers	42
Publications	44
Funding Portfolio	



Robert Kirsch, PhD Executive Director



Ronald Riechers, MD Medical Director

# Dear Friends and Colleagues

The Cleveland Functional Electrical Stimulation (FES) Center has seen significant progress over the past year and has developed a strong plan for the future in our recent VA Office of Rehabilitation Research and Development (RR&D) Center proposal. We are excited that over the past 25 years we have received core support for the FES Center to drive FES research, technologies, and translational opportunities.

The FES Center is a global leader in Neurostimulation and Neuromodulation research that addresses the unmet rehabilitation needs of individuals with spinal cord injuries and neurological disorders. The FES Center consists of individuals who perform and support cutting edge research projects focused on the development and clinical translation of a wide spectrum of rehabilitation interventions based on functional electrical stimulation (FES).

The FES Center broadly facilitates the research of its investigators by nurturing a trans-disciplinary research community and providing unique, shared resources and infrastructure. The FES Center attracts and maintains top research talent, strategically guides research directions and facilitates institutional synergies and individual collaborations.

#### **FES Center Advocates**

Our advocates come in all shapes and sizes – individuals including research participants and families, sponsors, and institutions that have led to our successes along the way. Due to the support and passion of so many we are closer to realizing our goal!

We encourage you to share our research and stories and to connect with us to continue to strengthen and support the drive of the Cleveland FES Center.

Sincerely,

1. find

Robert Kirsch, PhD Executive Director

Ronald Riechers, MD Medical Director



# Kernel Who We Are

A trans-disciplinary **alliance** of active, passionate and committed professionals, in science and medicine, specializing in the fields of biomedical and neural research, engineering, medicine and rehabilitation. We embrace an open-door, collaborative, compassionate, and inquisitive engagement.

> Together, we translate academic knowledge, neural technology, and clinical practice into *hope and progress.*

## **Redefining FES**

Functional electrical stimulation (FES) is the use of small, artificially generated electrical currents that are safely and selectively applied to the central or peripheral nervous system to replace the actions of neurons that have been damaged by injury or disease. When applied appropriately, FES can "speak the language of the nervous system" and evoke desired actions by both activation and inactivation of various elements of the nervous system (e.g., peripheral nerves, spinal cord, brain). Because virtually all body functions are directly controlled or indirectly influenced by the nervous system, FES is thus a powerful, broadly applicable technique for evoking functional muscle contractions, reducing pain, and restoring balance in autonomic, spinal, and brain circuits. The FES Center is the most comprehensive and cohesive program in the world performing FES investigation that spans from basic to applied, and our investigators work on many different applications.

# Investigators

Ajiboye, A Bolu, PhD Case Western Reserve University Louis Stokes Cleveland VA Medical Center

Alberts, Jay, PhD Cleveland Clinic

Audu, Musa, PhD Case Western Reserve University

Bhadra, Narendra, MD, PhD Louis Stokes Cleveland VA Medical Center Case Western Reserve University

Bhadra, Niloy, MD, PhD MetroHealth Medical Center Case Western Reserve University

Bourbeau, Dennis, PhD Louis Stokes Cleveland VA Medical Center MetroHealth Medical Center Case Western Reserve University

Brose, Steven, DO Louis Stokes Cleveland VA Medical Center Case Western Reserve University Clinical Professor, Ohio University Heritage College of Osteopathic Medicine

Calabrese, Joseph, MD University Hospitals of Cleveland Case Western Reserve University Capadona, Jeffrey, PhD Louis Stokes Cleveland VA Medical Center Case Western Reserve University

Chae, John, MD MetroHealth Medical Center Case Western Reserve University

Chen, Peijun, MD, PhD Louis Stokes Cleveland VA Medical Center University Hospitals of Cleveland Case Western Reserve University

Cornwell, Andrew, PhD Louis Stokes Cleveland VA Medical Center Case Western Reserve University

Crago, Patrick, PhD Case Western Reserve University

DiMarco, Anthony F, MD MetroHealth Medical Center Case Western Reserve University

Durand, Dominique, PhD Case Western Reserve University

Fu, Michael, PhD MetroHealth Medical Center Case Western Reserve University

Furlan, Anthony, MD University Hospitals of Cleveland Case Western Reserve University Geertman, Robert, MD, PhD MetroHealth Medical Center Case Western Reserve University

Gustafson, Ken, PhD Case Western Reserve University Louis Stokes Cleveland VA Medical Center

Hardin, Elizabeth, PhD Louis Stokes Cleveland VA Medical Center

Hdeib, Alia, MD University Hospitals of Cleveland Case Western Reserve University

Hoyen, Harry, MD MetroHealth Medical Center Case Western Reserve University

Jacono, Frank, MD Louis Stokes Cleveland VA Medical Center Case Western Reserve University

Jurjus, George, MD Louis Stokes Cleveland VA Medical Center Case Western Reserve University

Keith, Michael, MD MetroHealth Medical Center Case Western Reserve University Louis Stokes Cleveland VA Medical Center

Kilgore, Kevin, PhD MetroHealth Medical Center Case Western Reserve University Louis Stokes Cleveland VA Medical Center Kirsch, Robert, PhD

Executive Director, Cleveland FES Center Case Western Reserve University Louis Stokes Cleveland VA Medical Center MetroHealth Medical Center

Knutson, Jayme, PhD MetroHealth Medical Center Case Western Reserve University

Kowalski, Krzysztof E, PhD MetroHealth Medical Center Case Western Reserve University Louis Stokes Cleveland VA Medical Center

Lempka, Scott, PhD Louis Stokes Cleveland VA Medical Center Cleveland Clinic

Lewandowski, John, PhD Case Western Reserve University

Lewis, Stephen J, PhD Case Western Reserve University

Lhatoo, Samden, MD, FRCP University Hospitals of Cleveland Case Western Reserve University

Machado, Andre, MD, PhD Cleveland Clinic

Makowski, Nathan, PhD MetroHealth Medical Center Case Western Reserve University Marsolais, Byron, MD, PhD University Hospitals of Cleveland Case Western Reserve University Louis Stokes Cleveland VA Medical Center

Mchaourab, Ali, MD Louis Stokes Cleveland VA Medical Center Case Western Reserve University

McIntyre, Cameron, PhD Louis Stokes Cleveland VA Medical Center Case Western Reserve University

Megerian, Cliff, MD University Hospitals of Cleveland Case Western Reserve University

Mejia, Melvin, MD MetroHealth Medical Center Case Western Reserve University

Miller, Jonathan, MD University Hospitals of Cleveland Case Western Reserve University

Moynahan, Megan, MS Case Western Reserve University

Nemunaitis, Gregory, MD MetroHealth Medical Center Case Western Reserve University

Onders, Raymond, MD University Hospitals of Cleveland Case Western Reserve University Peckham, Hunter P, PhD Case Western Reserve University Louis Stokes Cleveland VA Medical Center MetroHealth Medical Center

Plow, Ela, PhD Cleveland Clinic Louis Stokes VA Medical Center Cleveland State University

Pundik, Svetlana, MD Louis Stokes Cleveland VA Medical Center Case Western Reserve University

Rhee, Douglas, MD University Hospitals of Cleveland Case Western Reserve University

Richmond, Mary Ann, MD Louis Stokes Cleveland VA Medical Center Case Western Reserve University

Riechers, Ronald, MD Medical Director, Cleveland FES Center Louis Stokes Cleveland VA Medical Center Case Western Reserve University

Ronis, Robert, MD Case Western Reserve University University Hospitals of Cleveland

Schearer, Eric, PhD Cleveland State University Schiefer, Matthew, PhD Louis Stokes Cleveland VA Medical Center Case Western Reserve University

Selkirk, Stephen, MD, PhD Louis Stokes Cleveland VA Medical Center Case Western Reserve University

Selman, Warren, MD University Hospitals Case Western Reserve University

Shaikh, Aasef, MD, PhD University Hospitals of Cleveland Case Western Reserve University

Strohl, Kingman P, MD University Hospitals of Cleveland Case Western Reserve University

Sweet, Jennifer, MD University Hospitals of Cleveland Case Western Reserve University

Tabbaa, Kutaiba, MD MetroHealth Medical Center Case Western Reserve University

Taylor, Dawn, PhD Cleveland Clinic Louis Stokes Cleveland VA Medical Center Case Western Reserve University MetroHealth Medical Center Tyler, Dustin, PhD Louis Stokes Cleveland VA Medical Center Case Western Reserve University MetroHealth Medical Center

Vaidya, Punit, MD Louis Stokes Cleveland VA Medical Center Case Western Reserve University

Van Acker, Gustaf, MD, PhD MetroHealth Medical Center

Veizi, Elias, MD, PhD Louis Stokes Cleveland VA Medical Center Case Western Reserve University

Vrabec, Tina, PhD Case Western Reserve University

Walker, Mark, MD Louis Stokes Cleveland VA Medical Center Case Western Reserve University

Walter, Benjamin, MD Case Western Reserve University University Hospitals of Cleveland

Williams, Matthew, PhD Louis Stokes Cleveland VA Medical Center Case Western Reserve University

Wilson, Richard, MD MetroHealth Medical Center Case Western Reserve University



## **Research Thrusts**

The scope of the Cleveland FES Center and applications of "functional electrical stimulation" have grown significantly over the past several years. The FES Center has been a significant engine of this expansion. The scope of research of the FES Center has correspondingly evolved and expanded.

The FES Center has five research thrusts:

MOVEMENT RESTORATION Restoring limb and other body movements

AUTONOMIC SYSTEM Autonomic nervous system stimulation for restoration and/or regulation of internal body and visceral functions

BRAIN HEALTH Brain stimulation for movement disorders, stroke and traumatic brain injuries, epilepsy and neuropsychiatric disorders

PAIN Pain mitigation through stimulation of peripheral nerves and the spinal cord

TOOLS & TECHNOLOGY Development of implantable systems and electrodes, modeling & simulation tools and other rehabilitation approaches complementary to FES

## **Movement Restoration**



### **Program Overview**

The restoration of limb, respiratory, and other functional movements to individuals with spinal cord injury, stroke, and several other patient populations through the use of electrical stimulation was the original motivation for the establishment of the FES Center. Work in this area over the past 25 years has been prolific, with major scientific and clinical impacts. Early work has motivated additional research that has developed into greater research programs within the FES Center. Movement Restoration research continues to be highly innovative, and the FES Center continues to be a leader in translating laboratory discoveries into commercial products and clinical adoption.

The FES Center enables the Movement Restoration research by promoting collaborations between complementary investigators from disparate disciplines and institutions, in particular between engineers and physicians. The FES Center provides key infrastructure, such as shared engineering and surgical expertise, access to electrical stimulation devices, clinical trial and outcome assessment experience, and regulatory oversight and support. FES Center investigators have led clinical trials of several FES-based functional movement applications, as well as the commercialization of technology including Neurocontrol Corp. for hand grasp, Synapse Biomedical for diaphragm pacing, and Institute for Functional Restoration for upper extremity applications.

Left: Jen participates in the Stand & Transfer Program for Spinal Cord Injury and is able to walk short distances using a walker.

## **Accomplishments**

- The first implant of a new, Networked Neuroprosthetic (NNP) System for upper extremity movement restoration and seated posture control was performed in a Veteran with SCI in February 2016.
- The first system that combines FES-based arm and hand functional restoration with a user interface based on an intracortical braincomputer interface was implemented in 2015 and is undergoing testing.
- Clinical assessment of a gait-assist FES system for stroke is underway.
- A clinical feasibility trial for FES-evoked cough is underway for individuals with SCI.

Being able to hold a cup so that nobody else has to hold it for you, that's wonderful.

Hand Grasp Participant

## **Upper Extremity**

The **FES hand grasp system** stimulates muscles and nerves to produce movement of the paralyzed hand. Programmed to activate the muscles in a coordinated manner, the stimulation can provide a variety of functional grasp patterns.





(Top) Chris likes to keep an active lifestyle by using his system to hold hand weights and grasp other exercise equipment to stay physically fit.

(Bottom) Maria uses her system to play tennis, apply her make-up, and cook for her family.

## **Using Video Games to Foster Pediatric Hand Function**

Motivating kids with physical disabilities to do occupational therapy exercises at home can be challenging. It got a little easier this summer for one of Cleveland Clinic Children's occupational therapists, Anna Curby, MS, OTR/L. For six weeks, Curby helped two children with hemiplegia caused by cerebral palsy gain motor skills using a homebased treatment of hand therapy video games in combination with Contralaterally-Controlled Functional Electrical Stimulation (CCFES).

"We can give kids all the exercises and checklists in the world, but they have school and friends and other things that distract them," says Curby. "But when we say, 'Your home exercise program is to play video games twice a day,' that's appealing!"

Curby utilized an intervention developed by Michael Fu, PhD, an investigator with the Cleveland FES Center, a research assistant professor at Case Western Reserve University and a member of the bioscientific staff at MetroHealth Medical Center. "There aren't a lot of intervention options for kids with cerebral palsy who have hand hemiparesis to improve their motor skills and hand function," says Fu. "Our goal was to take what we've learned from working with stroke patients and try to impact other forms of hemiplegia."

Fu's research, funded by a training grant from the National Institutes of Health, initially focused on rehabilitation for adult stroke patients. As a postdoctoral researcher, Fu joined a group at the FES Center led by Jayme Knutson, PhD, associate director of regulatory affairs at the center, an assistant professor in Case Western Reserve University's School of Medicine, a senior staff scientist at MetroHealth Medical Center and the director of research at MetroHealth Rehabilitation Institute of Ohio. The group is using CCFES, a novel neurotherapeutic application of surface electrical stimulation, to help stroke survivors recover voluntary hand function and ankle dorsiflexion.

Fu's contribution to the group was to develop custom therapy video games that could be used in conjunction with CCFES. The games, which are played by opening and closing the paretic hand, facilitate motor practice based on learning principles such as goal-oriented movement, intense repetition and task variation.

Curby first heard about the intervention during an in-service educational session led by Knutson at Cleveland Clinic Children's rehabilitation hospital. "I sat in the presentation thinking, 'Oh, my goodness! I could use this for my kids," recalls Curby. "I was excited about the possibilities." She contacted Fu that day and proposed they work together.

Throughout the summer, Curby met with two cerebral palsy patients with hemiplegia twice a week for two hours during the first three weeks, then once a week for a two-hour session the remaining three weeks. CCFES enabled the children to open their paretic hand by stimulating finger and thumb extensors with surface electrodes. The stimulation was proportional to the degree of the unimpaired hand opening as detected by an



Right-impaired feasibility trial participant plays the marble maze using CCFES

instrumented glove worn on that hand. Volitional opening of the non-paretic hand produces stimulated opening of the paretic hand. The games the children played included paddle ball, skee ball, sound tracker (following a moving track generated by different songs) and marble maze (guiding marbles out of a maze and into a bucket).

"It was really fun to sit in a treatment session with the kids," says Curby. "Six weeks is a fairly short treatment period, but we saw improvements in both kids." One of the patients had a moderate level disability. Prior to the CCFES-mediated video game intervention, he didn't use his paretic hand. By the end of the summer, he was using that hand to pick up things. "Because he was able to play video games that were exciting to him, he figured out really quickly how to use his unaffected hand to help move his affected hand," says Curby. "It was amazing to watch him gain awareness of that whole limb!"

The other patient is more severely affected by his disability. Though he still doesn't independently open his hand without stimulation, he has begun using his arm, shoulder and elbow in ways he never has before, says Curby. He recently picked up a ball using two arms during an occupational therapy session, something he never did before the intervention. "I can only imagine the benefits if we're able to use this treatment over a longer period of time with kids with a moderate disability" says Curby. "For any kid, there's big potential."

Fu agrees that the results are encouraging. He is currently applying for grants to conduct a larger, controlled study to ascertain why they are getting results and how they can design and optimize the treatment for a more general population of cerebral palsy patients. "We have some ideas on why the stimulation is helping, but we really need to do more experiments," says Fu. "If we can figure it out, maybe we can provide targeted therapies for kids with impaired hand function."

For more information on Hand Therapy Video Games research contact: info@FEScenter.org | (216) 231-3257

## Pain

## **Program Overview**

Effective treatment of pain is a high priority across all areas of clinical practice. Although pharmaceuticals have historically been the primary treatment option for pain, the use of neuromodulation and neurostimulation techniques has increased significantly over the past few decades. Research on the use of neuromodulation for the treatment of pain has also grown rapidly within the FES Center because of the world-class expertise of its investigators regarding the effects of electrical current on neural structures, collaborations with top clinical partners and the clear clinical imperative.

Ongoing research in post-stroke shoulder pain began with the application of electrical stimulation to reverse shoulder subluxation. However, researchers discovered that the applied electrical stimulation likely alleviated pain directly via nerve activation rather than indirectly by improving shoulder biomechanics. Ongoing research into methods for electrical nerve conduction block was originally developed for the control of muscle spasticity in spinal cord injury and stroke. Since then, the potential to use these developing techniques to treat pain became clear and has led to a significant interest from the field of neuromodulation. Both of these approaches have resulted commercial translation – via SPR Therapeutics and Neuros Medical, respectively – and are already finding multiple clinical applications. Furthermore, these successes have attracted a number of additional clinicians and researchers with a direct focus on acute and chronic pain.

The work being performed by investigators in the FES Center in the area of pain includes fundamental experimental studies, development of new technologies, computational modeling of existing and proposed concepts, clinical feasibility studies, and clinical trials.

Right: Rich Wilson, MD evaluates a patient for the shoulder pain program



## Accomplishments

- Demonstrated the effective use of peripheral FES in the treatment of shoulder pain following stroke and for (nonstroke) musculoskeletal pain, such as lower back pain.
- Developed several new approaches for using electrical stimulation for blocking neural responses, and began applying these techniques for amputee pain and several other acute and chronic pain applications.
- Developed a new research program on neural modeling of spinal cord stimulation to improve the effectiveness of this established technique and reduce or eliminate its side effects.
- Initiated new FES collaborations for facial pain, migraines, and several other applications.

### **Spinal Cord Stimulation**

Spinal cord stimulation (SCS) applies electrical pulses to a patient's spinal cord to help mask the patient's pain. Computer models can be used to calculate the electric fields generated during SCS and to study how neurons respond to the stimulation.

Right: Computer model of the voltage distribution generated during SCS (image by Scott Lempka, PhD)



## **Brain Health**



Bolu Ajiboye, PhD running a program developed by his students to learn how to interpret brain waves from an able-bodied subject for BrainGate research.

## **Program Overview**

Neurological disorders related to brain mechanisms, such as stroke, TBI, epilepsy, parkinson's disease, and some psychiatric conditions, may be mitigated through the use of electrical stimulation. Rehabilitation techniques can employ brain plasticity to retrain neural mechanisms to mitigate the chronic impact of stroke, TBI, and other brain disorders. Computational modeling of brain circuits can now be used to understand the mechanisms of various brain disorders to develop tools that accurately and selectively target structures, and to devise stimulation patterns improving efficacy. While FES Center investigators have developed FES-based stroke rehabilitation techniques and Deep Brain Stimulation (DBS) for motor disorders for many years, we have more recently established a major human Brain-Computer Interface (BCI) activity. These are the mainstays of our Brain Health program.

## Accomplishments

- Completed a RCT of 80 chronic (>6 mo) stroke patients and showed that Contralaterally Controlled FES improved hand dexterity and function more than conventional cyclic electrical stimulation.
- Demonstrated that stroke patients can self-administer video game therapy integrated with FES at home.
- Showed that contralesional regions play an important role in supporting sensory-motor recovery post-stroke, and that stimulating higher motor regions enhances outcomes, especially for severe impairment.
- Began a Phase II clinical trial to test the efficacy and safety of low frequency stimulation for epilepsy.
- Demonstrated that people with SCI can control the movements of cursors and robots via a brain computer interface (BCI).
- · Commercialized a clinical DBS software system (GUIDE DBS).



Contralaterally-Controlled Functional Electrical Stimulation (CCFES) subject practicing picking up a glass.

## Non-Invasive, Innovative FES Treatments for Stroke

Stroke commonly results in loss of hand function. Contralaterally-Controlled Functional Electrical Stimulation (CCFES) is a rehabilitation technique developed by FES Center investigators to improve recovery of hand function after stroke. With CCFES, stroke patients control stimulation to their paretic finger and thumb extensors with an instrumented glove worn on the unaffected, contralateral hand and practice using it in therapy sessions to incorporate principles that are important for driving neuroplasticity and motor relearning. To address proximal arm paresis in severely impaired stroke patients, FES Center investigators are combining FES with robotics to reduce effort-related hypertonia and thus provide full upper limb function. For lower limb function after stroke, FES Center investigators are implementing multi-channel implantable stimulators targeting hip, knee, and ankle impairments to augment retained gait capabilities.

Virtual reality environments and interactive video games are being used more and more in neurorehabilitation. FES Center investigators have developed a unique set of hand therapy video games specifically for integration with CCFES to create the first integrated FES videogame therapy in which the two approaches are working synergistically and simultaneously on the patient. FES Center investigators also create and use virtual reality environments to train SCI participants to modulate cortical activity in BCI control of FES systems.

Non-invasive brain stimulation with repetitive transcranial magnetic stimulation (rTMS) has been increasingly used for investigating the neuroanatomy and effects of therapeutic interventions as well as a therapeutic modality itself. Transcranial direct current stimulation (tDCS) is another non-invasive method to activate cortical networks and facilitate beneficial neuroplastic changes. FES Center investigators use these methods along with fMRI, diffusion tensor imaging (DTI), cortical thickness analyses, EEG-based assessments, and functional near-infrared spectroscopy to enhance gait training in stroke patients and to individualize and optimize brain stimulation treatment for stroke patients. rTMS is also being used by investigators to enhance recovery of sensory function, an important issue in stroke rehabilitation.

FES Center investigators are active participants in the national StrokeNet program sponsored by the NIH National Institute of Neurological Disorders and Stroke (NINDS). Case Western Reserve University became a StrokeNet site in 2013. Currently, we are conducting a StrokeNet study investigating the efficacy of telerehabilitation. FES Center participation in StrokeNet provides greater opportunities for nation-wide collaboration, as well as for development of multi-site studies to disseminate FES Center expertise.

## **Creating the Next Generation of DBS Technology**



Dr. McIntyre working with Sr. Research Associate, Angela Noecker, on patient-specific visualization software, developed in his lab. The left side monitor shows the tissue volumes that are activated by the electrode on a standardized brain, the right side monitor shows those volumes applied to a specific patient's brain images.

## **Deep Brain Stimulation**

Cameron McIntyre, PhD, has spent the last 10 years looking at how electrical fields interact with the circuitry of the brain, trying to figure out the best way to interrupt dysfunctional circuits and provide relief for patients with Parkinson's disease, movement disorders and, most recently, neuropsychiatric disorders.

Deep brain stimulation (DBS) is improving the quality of life for patients with Parkinson's disease and shows great promise for epilepsy. Still, many questions remain about its efficacy, delivery, and side effects. Successfully engineering DBS technologies requires a multi-disciplinary approach.

"Our group is integrating imaging, neurophysiology,

neuroanatomy, and computational modeling to increase our understanding of precisely how DBS works," says McIntyre, associate director of industrial relations at the FES Center, a biomedical engineering professor at Case Western Reserve University and a biomedical engineer with the Louis Stokes Cleveland VA Medical Center. "Deep brain stimulation is a complex technology, and we're working to better engineer the next generation of these devices to help patients receive even better outcomes."

Basic science work is being conducted through the Human Connectome Project, a large-scale, multi-center project funded by the National Institutes of Health to develop a circuitry map of the human brain. "We want to figure out how to take advantage of that map and use it in our clinical practice," says McIntyre. "We're calling it 'connectomic neuromodulation.' If we know what the maps say and we know what circuits in a given disorder are dysfunctional, we can then use that information to tell us where we should put electrodes to best treat a particular disease."

McIntyre's team is developing therapies based off the research that basic science has previously done and tailoring it to neurological diseases and patients. "The map helps us see pathways in the brain that are affected by these diseases, and we use that 'connectomic-based' philosophy to tailor it to one patient and their anatomy," says McIntyre.

His research group is creating clinical software technologies that can be used by neurosurgeons in the DBS surgical planning process as well as by neurologists who manage patients after surgery. The technology allows clinicians to see a model of the patient's brain and helps them target where to place DBS electrodes and how and where to stimulate the brain to receive the best estimated outcome.

The impetus for the research team's work comes from observing clinicians implement current neuromodulation technologies. Some parts of current commercial systems aren't user-friendly to the patient or clinician. "When we as scientists observe clinicians using the technology, then we can find ways to make it better," says McIntyre. "Our motivation comes from finding the little nuggets that we can tweak that would totally change the way the clinician interfaces with a very expensive piece of technology."

Ultimately, those little tweaks may lead to big changes in practice that benefit both clinicians and patients.



Illustration of a DBS system with an electrode implanted in the brain and the pulse generator located under the clavicle.

For more information on Deep Brain Stimulation research contact: info@FEScenter.org | (216) 231-3257

## **Autonomic System**



## **Program Overview**

The autonomic nervous system is involved in the control/regulation of almost all internal body functions, including glucose and electrolyte concentrations, blood pressure, inflammatory responses, appetite, bladder and bowel function, autonomic dysreflexia, and many others. The use of electrical stimulation, particularly of the vagus nerve and sensory nerve pathways, has become a popular approach for treating disorders associated with these functions. These approaches are termed "electroceuticals" and "bioelectric medicine" because they avoid systemic drug applications, can be quite selective for specific fascicles (or nerve branches) of the vagus nerve, and can be easily modulated (or even turned off). This is an exciting and rapidly growing area for the use of FES.

The fundamental techniques long used by FES Center investigators to devise peripheral motor applications (e.g., electrical activation for spinal cord injury movement restoration) can be directly applied to applications in the autonomic nervous system. The FES Center is leading the development of stimulation techniques to down-regulate or block nerve conduction. The FES Center has expertise in characterizing neuroanatomy and developing the needed neural interfacing approaches, and there is a significant need to achieve corresponding understanding of the neuroanatomy of the autonomic nervous system, with sufficient detail and resolution to accurately model the fascicular structure of the vagus nerve and sympathetic chain/ganglia, the myelination characteristics along these nerves, and the branching patterns of these nerves as they near their target organs. Simulations using these neuroanatomical data can then be used to optimize electrode geometries and simulation parameters that provide maximum and natural effectiveness.

Over the last 5 years, the FES Center has greatly expanded our projects and expertise in autonomic physiology and clinical disorders and related research areas. We have expanded into areas of hypertension, nerve block, bowel function and afferent nerve stimulation, sleep disorders, gastric function, and ventilation and pulmonary care.

## Accomplishments

- Demonstrated the efficacy of afferent stimulation to improve bladder function, both continence and emptying, in SCI and other disorders.
- Established a FES-based research activity to improve bowel motility following SCI and other disorders.
- Developed new FES approaches for addressing challenges in sleep disorders, pulmonary care, cardiac arrhythmias, hypertension, and post-stroke swallowing to prevent aspiration.
- Have begun to develop FES interventions for gastric function and autonomic dysreflexia.

A hallmark of our research activities has been collaboration. We've always had teams of whatever the mix of expertise was needed in order to address the clinical problem at hand.

Robert Kirsch, PhD

## **Focusing on Pelvic Health**



Left: Dennis Bourbeau, PhD and Steven Brose, DO; Right: Pelvic model showing surface stimulation

People with spinal cord injury or other neurological disorders have many

**Bladder/Bowel Research** 

health concerns, but one that is often overlooked is pelvic health. "Individuals with diminished bladder and bowel function have few options for managing their care. Their needs are incompletely met, and they report that restoring these functions is a high priority," says Dennis Bourbeau, PhD, an investigator at the Cleveland FES Center and a biomedical engineer with the Louis Stokes Cleveland VA Medical Center.

Bourbeau is spearheading research to develop devices using electrical stimulation to restore pelvic autonomic function, providing alternatives to surgeries or drugs. "I am particularly interested in the mechanisms of sensory feedback to control these functions," he says. "I envision an interface with the nervous system that provides access for stimulating sensory neurons to activate or inhibit spinal reflexes to control autonomic functions. This strategy would take advantage of existing spinal reflex circuits that remain following spinal cord injury."

Bourbeau began working with fellow investigators Ken Gustafson, PhD, and Steven Brose, DO, in 2011 to study restoration of bladder function. Together, they are conducting studies on the effectiveness of genital nerve stimulation to inhibit unwanted bladder activity and improve urinary continence. The work is funded by a Merit Review and a CDA-1 award from the U.S. Department of Veterans Affairs.

The researchers are completing a short-term chronic test of genital nerve stimulation (GNS) to improve bladder control in human subjects. "We are beginning to look ahead at testing this approach for longer periods of time in more subjects and move toward an implantable system," says Bourbeau. The team also is collaborating with Margot Damaser, PhD, a biomedical engineer with Cleveland Clinic, to couple its approach with her implantable bladder sensor technology for closed-loop control.

During the bladder control research, many study participants reported that they also experience bowel dysfunction, so Bourbeau and his peers began to study bowel function restoration as well. People with neurogenic bowel dysfunction use digital rectal stimulation – a gloved finger inserted into the rectum – to evoke a colon reflex that promotes emptying of the bowel. The team of researchers are conducting preclinical experiments to develop and validate an electrical stimulation approach to improve colonic motility, which is severely slowed in people with spinal cord injury. Their work is funded by a CDA-2 award from the VA.

The ultimate goal of both the bladder and bowel research is to improve quality of life for people with SCI or other neurological disorders. "If our approaches are successful, we hope to improve confidence, independence and dignity for these individuals as well as significantly reduce costs and burdens related to care," says Bourbeau.



## **Pulmonary Research**

Tucked away on the 5th floor of Cleveland's MetroHealth Medical Center is the Respiratory Physiology Lab. While the lab's wooden medicine cabinets, piles of books and mountains of research papers may seem old-fashioned, the research and clinical trials conducted here are at the forefront of helping patients worldwide.

Anthony DiMarco, MD, principal investigator, and Krzysztof Kowalski, PhD, lead co-investigator, are developing pulmonary procedures devoted to increasing the quality of life of patients with respiratory muscle paralysis. Their work has led to a significant decrease in pneumonia – the greatest cause of mortality among patients with spinal cord injury.

In addition to serving as an investigator at the Cleveland FES Center, DiMarco is a CT physician at MetroHealth and a professor at Case Western Reserve University's School of Medicine. Kowalski is a neurophysiologist at MetroHealth, an associate professor at Case's School of Medicine and a research health scientist at the Louis Stokes Cleveland VA Medical Center.

Their 20-year collaboration has resulted in several distinct and successful procedures, including a clinical trial involving the actor Christopher Reeve, who was ventilator-dependent. DiMarco and Kowalski work alongside a dedicated team, including University Hospitals' Ray Onders, MD (who operated on Reeve), Case Western Reserve University biomedical engineers and Veterans Administration rehabilitation therapists.

Their work focuses on a seemingly simple reflex -

coughing. Typically, the cough of a person with spinal cord injury is barely audible, explains Kowalski. To be productive, patients' coughs need to be forceful enough to help clear out the lungs.

In 2010, Damien Nickle, a former NASA engineer, was among the first group of patients in a clinical trial to achieve this goal. Nickle, who has the use of his arms and hands, was paralyzed from a fall off a ladder. After he attended a meeting about spinal cord injury at MetroHealth, Nickle signed up for the clinical trial with the Respiratory Physiology Lab. "Why not?" he thought. "I wasn't going to let fear of the unknown hold me back."

During a procedure that lasted seven hours, Nickle was implanted with a disk the size of a dime and provided a hand-held remote control to stimulate the nerves on the spinal cord. The stimuli produced a muscular contraction in the diaphragm that produced a cough – something Nickle was unable to do on his own. Nickle also was susceptible to pneumonia. But that was before the implant.

Today, Nickle presses a button to help expel foreign objects caught in his throat or to produce a cough. Each night, Nickle exercises his diaphragm by pressing the remote control 20 times to produce 20 coughs. "Since my hands and arms are 'my legs,' this is how I operate the device that produces cough, something I can't do without the implant and the remote control," he says.

It's a tiring routine that often leaves him drained, but it's necessary for conditioning muscles. "All muscles need



Left: Anthony DiMarco, MD; Right: Krzysztof Kowalski, PhD

exercise to prevent atrophy. Each time I press a button on the remote control to produce an effective cough, it's exercising the muscles," says Nickle.

The participation of Nickle and other patients in research projects at the lab helps lead to new advancements. This year marks a milestone for the Respiratory Physiology Lab. The team introduced a pioneering clinical trial procedure still aimed at the goal of reducing susceptibility to upper respiratory tract infection in qualified patients. The new outpatient procedure, which takes no more than an hour and a half, utilizes wire electrodes threaded through a needle to restore a cough to mid-diaphragm and recapture a primary defense against infection. Thanks to the lab, patients (such as Reeve) who are ventilator-dependent now have access to outpatient procedures where electrodes can be placed via laparoscopic surgery. Patients like Nickle with paralyzed respiratory muscles can undergo life-enhancing outpatient procedures, eliminating long hospital stays or extra home care.

Patients used to be dependent upon suctioning, insufflation-exsufflation or abdominal compression. Today, thanks to the Respiratory Physiology Lab, these practices have been supplanted by more adaptable technologies aimed at greater ease of use among patients. In fact, patients participating in the Respiratory Physiology Lab's newest research study already demonstrate reduced susceptibility to life-threatening respiratory tract infection.

Improving patients' quality of life is paramount to DiMarco and Kowalski. "When I first started looking at the lungs, paralyzed individuals barely survived on mechanical ventilation requiring 24-hour assistance," says DiMarco. "Not enough was being done."

A picture of Reeve hangs on a wall in the lab, a reminder of more than two decades of demonstrated successes aimed at improving the quality of life of patients. While DiMarco and Kowalski know that more work still needs to be done, they both remain focused on the ultimate goal: It's the "lives being saved" that count.

## **Tools & Technology**

## **Technology Vision**

The Cleveland FES Center has the ability to conceive, fabricate, test, and produce advanced technologies addressing clinical applications. Our technological capabilities are divided into two segments; **innovation** and **technical**.

The innovation group is charged with identifying the cutting edge techniques, materials and concepts from across the industry for possible inclusion into neural applications.

The technical production group is charged with fabricating small quantities of implantable and external devices to a quality level fit for clinical use.

It's been a long road, it's a lot of work to get from the point of things scribbled on napkins to an FDA approved device that can be put into humans.

Kevin Kilgore, PhD







Implantable electrode designs. More information on page 27.

### **The Technical Development Laboratory**

Established 1991, the FES Center's Technical Development Laboratory (TDL) facilitates the design, development, and fabrication of prototypes for implantable research devices. These medical devices are intended for use in clinical feasibility studies conducted under Investigational Device Exemptions (IDEs).

To discuss potential collaborations regarding FES technologies contact: **Technical Development Laboratory (TDL)** info@FEScenter.org | (216) 368-3153

## **Neuroprosthetic Devices**

Neuroprosthetic devices are powerful tools providing life sustaining and functional enhancement for individuals with central nervous system disorders.

In general, a neuroprosthetic system should provide:

- · The robust functions that users deserve
- Understandable and intuitive tools that clinicians need to implement those functions
- The technical transparency for surgeons to implant the system
- The power, flexibility, and upgradeability to meet the demanding and changing needs of researchers for continued development of new and improved functionality and control

#### Implantable Stimulator Telemeter (IST)



This device is used as a 10, 12, or 16 channel implantable pulse generator (IPG). It is inductively powered and controlled via an external coil which is placed on the skin over the coil. Communication is bidirectional and can accommodate up to 2 bipolar EMG signals.

#### Networked Neuroprosthetic (NNP) System



The Networked Neuroprosthetic (NNP) System is based on a network of small implanted modules – "neuroprosthetic building blocks." Modules are distributed throughout the body and each one is dedicated to a specific function. They are linked to a centralized power source via a network cable, through which they all communicate.

There are many advantages to the NNP System: Neuroprosthesis capacity can be tailored to the individual's needs, hardware is scalable from simple to complex applications, multiple needs can be addressed in a single individual, the system is upgradeable – in hardware and/or software – to accommodate new technologies (upgrades), and it is adaptable to the changing needs of the user (functional enhancements.) Lastly, it frees the user of external components, which means that neuroprosthesis function is available spontaneously in any environment.



### Implantable Electrode Design

#### **Epimysial & Intramuscular Electrodes**

Both electrodes have a tandem conductor close coiled lead wire from the connector, covered with a silicone tube ("closed helix"). The epimysial electrode terminates in a Pt-10 Ir disc mounted in a silicone backing reinforced with dacron. The intramuscular electrode has a stainless steel stimulating area wound around the lead's distal end.

#### Cuff Electrode

This automatic spiraling electrode is designed to form to the natural shape of the nerve. The cuff electrode has four contracts that can be grouped together to create a stimulation that will activate groups of muscles.

#### **Myoelectric Signal (MES) Electrode**

The MES electrodes are bipolar epimysial electrodes surgically implanted on the fascia of the target muscle. They are made of two 4mm diameter Pt-10 Ir discs mounted on a medical grade Dacron reinforced silicone backing. The discs are positioned 10mm apart. The distal lead wires for the bipolar MES electrodes begin with a Y-junction and run together to the distal recording electrode pair, with an impedance of 2 Ohms/cm.

To place an order or for more information on electrodes contact:

#### **Ardiem Medical**

(866) 349-0855 | info@ardiemmedical.com | ardiemmedical.com



None of us possesses all the knowledge that we need to get the best outcome for our patients. We all have to work with other people that have other expertise. And we work together to come up with the best possible solutions for patients.

Jayme Knutson, PhD

It is understood that there is no greater statement of trust and clinical need than when a person enrolls in research.

## **Clinical and Regulatory Affairs**

The overall goal of the research taking place at the Cleveland FES Center is to improve the function and quality of life in individuals with disabilities by developing new technologies and methods, performing clinical evaluation and feasibility testing, and promoting the widespread deployment of the new technologies into clinical practice. This requires that the research programs address significant needs in a manner that ensures safety and efficacy. The safety and protection of our participants is the foundation of our clinical research protocols and regulatory processes. It is understood that there is no greater statement of trust and clinical need than when a person enrolls in research.

The FES Center adheres to the principles of good clinical practices (GCPs), including adequate human

subject protection (HSP). These principles are universally recognized as a critical requirement to the conduct of research involving human subjects.

Within each of our active clinical protocols, real human needs are being addresses to bring research and technology advances into the clinic. Regulatory and clinical oversight is addressed through dedicated team members working with the individual investigators. Leading the charge with the research community, the FES Center continues to expand and work closely with the Associate Medical Directors and the University Hospitals Case Medical Center - Clinical & Translational Science Collaborative for guality, consistency, safety and significance.



### **Industrial Relations & Partnerships**

Much of the mission of the Center is to bring technologies to those who need it, and this work is accomplished through partnerships with existing industry partners or through formation of new companies. By partnering early with prospective partners, the Center can de-risk the technology transfer process by designing solutions to regulatory, documentation, and reimbursement hurdles. Tackling these problems early in the development cycle greatly facilitates the adoption of university technology by new or established industry partners.

In addition, the FES Center can leverage years of device expertise and neural technology research to de-risk early stage research for companies. Differing from a traditional sponsored project, these types of explorations combine industrial development, academic research, and federal funding opportunities to answer specific questions relevant to both the academic investigator and the industrial partner. These types of collaborations have been enormously successful and represent a new model for rapid advances and transfer of academic research.



For more information and to discuss strategic collaborations or industrial partnerships contact:

Andrew Cornwell, PhD Director of Strategic and Industrial Collaborations info@FEScenter.org | (216) 231-3257 | Twitter: @andy\_cornwell The goal of everyone in the FES Center is to positively impact the lives of patients with neurological disorders using advanced neuromodulation technologies. While academic research can initiate new concepts for clinical care, we need to work together with the neuromodulation industry to turn those concepts into clinical reality.

Cameron McIntyre, PhD

### **Strategic Collaborations**

The FES Center believes strongly in collaborative research, and works closely with many groups across the country on a wide variety of research projects centered around neuromodulation, neural rehabilitation, neural prostheses, brain-computer interfaces, deep brain stimulation, and more. We strive to stay at the front of new fields of neural stimulation research and frequently partner with other groups where our collective expertise might dovetail.

FES Center investigators regularly compete successfully for major funding initiatives from federal sources, such as NIH and DARPA, as well as industrial and philanthropic agencies. The most successful of these projects are those with content experts from worldwide institutions, and we actively seek– and are responsive to– outside collaborations.

## **Collaborative Partners**



## Education

## **Spreading the Word**

Developing technology and advanced science is most valuable if it is communicated effectively. The Cleveland FES Center is dedicated to the dissemination of information related to our work through hosting cutting edge scientific and community-based conferences, participation in presentations, professional publications, popular media features and community programs. Widespread deployment of new technologies is achieved through professional, educational and commercial partnerships.



John Chae, MD on the moderating panel at Concussion 2015

## **CONCUSSION** A NATIONAL CHALLENGE

*Concussion, A National Challenge* was designed to bring experts from engineering and medicine together to identify and discuss emerging methods of detection, prevention and treatment of concussion. Discussion topics included understanding the problem, tissue injury, biomechanics of the concussive impact, and detection and prevention.

### **Speakers**

Jay L Alberts, PhD Christopher M Bailey, PhD Jeffrey J Bazarian, MD, MPH Dwayne Bray David L Brody, MD, PhD Thomas F Budinger, MD, PhD Robert C Cantu, MD Jeffrey A Claridge, MD

Charles L Emerman, MD, FAAEM Col. Dallas C Hack, MD, MPH Brian W Hainline, MD S Alan Hoffer, MD Susan M Joy, MD Geoffrey SF Ling, MD, PhD Susan S Margulies, PhD Ann C McKee, MD Jeffrey Michael, EdD Daniel P Perl, MD Raul A Radovitzky, PhD Robert L Ruff, MD, PhD Douglas H Smith, MD Thomas M Talavage, PhD Mary M Vargo, MD

#### An NAE-IOM Regional Meeting Global Center for Health Innovation, Cleveland Ohio | Concussion2015.org













## **CLEVELANDNEW** NEURAL ENGINEERING WORKSHOP

### What is ClevelandNEW?

ClevelandNEW is a facilitated, participant-driven workshop. Instead of passive listening, all attendees and organizers are participants, with discussion leaders providing moderation and structure for attendees. This non-traditional format is centered on integrated working groups identifying opportunities; preparation and participation are essential.

### **Workshop Objective**

Bring the neural engineering leaders from industry, academia, and government together as a resource and forum committed to providing the neural technology solutions for individuals with neurological disorders or injury. The workshop is an effort to identify the opportunities and roadblocks for improving clinical care, bolster the neural engineering community, and develop a cohesive vision and plan for the field to best advance neural technology for the next century.

Visit **ClevelandNEW.org** for more information about ClevelandNEW 2017







## **Neural Prosthesis Seminar Series**

The Neural Prosthesis Seminar Series debuted in 1988. Since its debut, this series has sponsored numerous distinguished clinicians and scientists, working in areas that include functional neuromuscular & electrical stimulation, cortical prosthesis, neuromodulation, brain computer & machine interfaces, simulation & modeling, and other related areas.

The Neural Prosthesis Seminar Series is a public educational forum with prominent presenters active in all areas of research. The series brings together researchers, scientists, clinicians and students in the Greater Cleveland Research Community to encourage the exchange of scientific information on global emerging neuromodulation and neurostimulation topics.

The Neural Prosthesis Seminar Series is sponsored by the Cleveland FES Center in partnership with our seminar co-hosts.

Visit FEScenter.org/seminar to check out the 2016-17 series.

34



Philip Sabes, PhD Associate Professor, Physiology University of California, San Francisco *"A Learning-Based Approach to Artificial Proprioception"* 



Leo Cohen, MD Chief, Human Cortical Physiology and Stroke Neurorehabilitation Section National Institute of Neurological Disorders and Stroke *"Learning, Reward and Brain Stimulation in Neurorehabilitation"* 



**D Michael Ackermann, PhD** President and CEO Oculeve Incorporated

"Oculeve Incorporated: Neurostimulation Therapy for Dry Eye & Spinning Out a Med-Tech Start-up from a University"



Nicholas Hatsopoulos, PhD Associate Professor Chair Committee on Computational Neuroscience University of Chicago *"Learning and Plasticity Associated With Long-Term Exposure of a* 



#### David J Reinkensmeyer, PhD Professor:

Brain-Machine Interface"

Anatomy & Neurobiology, Mechanical and Aerospace Engineering, Biomedical Engineering, and Physical Medicine and Rehabilitation University of California, Irvine

"Robotics and Wearable Sensors for Neurorehabilitation"



Polina Anikeeva, PhD Assistant Professor Department of Materials Science and Engineering Massachusetts Institute of Technology

"Interrogating Neural Circuits with Electronic, Optical and Magnetic Materials"



#### Lena Ting, PhD

Professor, Wallace H. Coulter Department of Biomedical Engineering Emory University and Georgia Institute of Technology Co-Director, Innovations for Neural Technology and Engineered Neural Therapies (INTENT) "Neuromechanical Principles Underlying Sensorimotor Modularity: Implications for Rehabilitation"

## **Seminar Co-Hosts**





Orthopaedic Rehabilitation Association presents

## Rehabilitation into the 21st Century

CLEVELAND CONFERENCE

## About the Conference

This comprehensive program brought together leaders in the field of joint preservation, joint replacement, traumatology, neuro-restorative care, and neuro-spine surgery to provide practical scientific information, advances in medicine, research, and cutting-edge innovative technology in the fields of:

- Reconstructive Neurosurgery
- Cutting-edge Joint Replacement
- Joint Preservation
- Reanimation
- · Caring for Injuries of our Wounded Warriors

## **Speakers**

Jay Alberts, PhD Gary Calabrese, PT Ryan Carr, MD John Chae, MD, MS Robin C Crandall, MD Dominique Durand, PhD Ryan Farris, PhD Mark Froimson, MD, MBA Levi Hargrove, PhD Salim Hayek, MD John D Hsu, MD Kevin Kilgore, PhD Glenn Klute, PhD Jayme Knutson, PhD Rudi Kobetic, MS Lisa L Lattanza, MD Kevin Malone, MD Cameron McIntyre, PhD Jonathan Miller, MD Joseph Ruzbarsky, MD Dustin Tyler, PhD Ronald Triolo, PhD Seth Vilensky, MBA Richard Wilson, MD



The Cleveland FES Center continues to actively support the regional VA Wheelchair Games, through the planning committee, administrative tasks, and volunteering in teams for events. Nearly 60 athletes enjoyed competitions in air rifle, billiards, boccia ball, bowling, slalom, table tennis, track and field events, swimming, and weightlifting.





## Health Success HPAC Tours the VA Labs

Northeast Ohio Medical University Health Professions Affinity Community (NEOMED HPAC) toured the FES Center labs at the Louis Stokes Cleveland VA Medical Center to learn about careers in biomedical engineering.



## **Great Lakes Science Center |** *Engineering Careers Day*



The FES Center adapted a robotic toy *Hexapod* to demonstrate how FES technology works. EMG signals are detected by surface electrodes and used to control the hexapod, similar to the activation of an FES system in a clinical application.



## **Cleveland State University Visits the Buckeye Wellness Center**

Anne Bryden, OTR/L led an FES demonstration for Cleveland State occupational therapy students at the Buckeye Wellness Center (BWC), a facility specific to spinal cord injury recovery and wellness. Chris, BWC Founder and Owner and FES Center research participant, along with Maria, demonstrated their respective FES Hand Grasp Systems.











#### Louis Stokes Cleveland VA Medical Center

Susan M Fuehrer, MBA Medical Center Director

Murray Altose, MD Chief of Staff

The Louis Stokes Cleveland VA Medical Center (LSCVAMC) provides clinical care to veterans with complications due to spinal cord injuries, head injuries, or stroke, among other illnesses. Along with significant support of individual research projects, the Louis Stokes Cleveland VAMC provides the core infrastructure to further this veteran relevant mission.

#### **Research Laboratories**

Louis Stokes Cleveland VAMC B-E210 10701 East Boulevard Cleveland, Ohio 44106 (216) 231-3257



#### Case Western Reserve University

Barbara R Snyder President

The Cleveland FES Center's inclusion at Case Western Reserve University (CWRU) in the Schools of Engineering and Medicine enables access to leading academic, clinical and engineering expertise, facilities and a rich learning environment result in a dynamic element for FES research and development.

#### **Technical Development Laboratory**

Bingham Building, Room 306 2104 Adelbert Road Cleveland, Ohio 44106 (216) 368-3153

#### **Research Laboratories**

Wickenden Building 2071 Martin Luther King Jr. Drive Cleveland, Ohio 44106 (216) 231-3257

#### School of Medicine

Health Sciences Campus 2109 Adelbert Road Cleveland, Ohio 44106 (216) 368-3450



#### MetroHealth Medical Center

Akram Boutros, MD, FACHE President, CEO

Bernard Boulanger, MD Executive Vice President Chief Clinical Officer

Integration into the accomplished Rehabilitation Services of MetroHealth Medical Center (MHMC) enables valuable access to patient care and clinical expertise in Orthopaedics & Orthopaedic Surgery, Neurosciences & Neurosurgery, and Physical Medicine and Rehabilitation.

MetroHealth Main Campus 2500 MetroHealth Drive Cleveland Ohio 44109-1998 (216) 957-3368

Old Brooklyn Health Center 4229 Pearl Road Cleveland, Ohio 44106 (216) 957-3368



## University Hospitals of Cleveland

Daniel Simon, MD President

University Hospitals of Cleveland (UHC) joined the FES Center as a consortium member in 2015. UHC is a medical affiliate of Case Western Reserve University, and has strong clinical interactions with the LSCVAMC. The UHC Neurological Institute has major capabilities in neurosurgery, neurology, epilepsy, and psychiatry that complement and expand the expertise available from the LSCVAMC and MHMC.

University Hospitals of Cleveland 11100 Euclid Avenue Cleveland, OH 44106 (216) 844-1000



## <sup>2015</sup> Innovation Statistics



## **Economic Impact**

Job Creation











Alabama 4 Arizona 3 Arkansas 1 California 13 Colorado 3	Delaware 1 Florida 14 Georgia 3 Illinois 1 Indiana 8	Kansas 1 Kentucky 1 Louisiana 2 Maryland 4 Massachusetts 2	Minnesota 6 Mississippi 2 Missouri 4 Nevada 1 New Jersey 2	New York 15 N Carolina 6 N Dakota 1 Ohio 819 Oklahoma 4	Pennsylvania 13 Rhode Island 2 S Carolina 6 Tennessee 2 Texas 6	Virginia 7 Washington 4 W Virginia 1 Wisconsin 2	Australia 2 Brazil 1 Canada 6 Columbia 1 India 2	Isreal 1 Jordan 1 Persia 1 Republic of Panama 1 United Kingdom 1
Colorado 3 Connecticut 3	lowa 1	Massachusetts 2 Michigan 11	New Jersey 2 New Mexico 1	Oregon 1	Vermont 1		India 2 Ireland 1	United Kingdom I



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