INNOVATIONS
Future Solutions Now An NCMRR Update

Fall—Winter 2008

Inside This Issue

Hello again!

Welcome to the Winter 2008 installment of *Innovations*: An E-Update from the NCMRR. The NCMRR, within the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), continues to support a sizable portfolio of projects and resources in the field of medical rehabilitation research. The purpose of these electronic updates is to communicate to our constituents some of the many activities and scientific discoveries that have been taking place as a result of NICHD funding, and to call attention to the many opportunities and resources available to medical rehabilitation researchers. We are pleased to share some of the new and innovative technologies and treatment interventions that are continually being developed, improved upon, and made ready for clinical trials and/or the marketplace. In this *Innovations*, Dr. Michael Weinrich, NCMRR director, addresses fiscal issues at NIH and discusses opportunities for investigators in medical rehabilitation research despite difficult economic times (see Director's Message below).

This *Innovations* takes a closer look at the various research networks within the NCMRR portfolio that operate as a result of NICHD funding and collaborative efforts. We are pleased to be able to bring these resources, technologies, ventures, and challenges to your attention.

We hope that you find the information in this e-update interesting, informative, and helpful. If by chance you have missed previous *Innovations*, you may access them at:

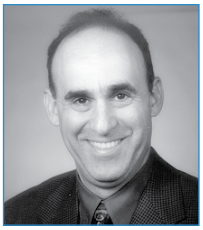
- *Winter 2007-Spring 2008*
- *Spring-Summer 2007*
- *Summer-Fall 2006*
- *Fall-Winter 2005*

Carol A. Sheredos, P.T., M.A., NCMRR

Director's Message

We do not yet have an appropriation for the fiscal year beginning October 1, 2008, so it is difficult to predict Institute pay lines with any confidence. Based upon current projections, this next year is likely to be very competitive for investigators seeking new and renewed funding. However, there are several opportunities that I would like to bring to the attention of the rehabilitation research community.

First, the NIH will continue its commitment to bringing new investigators into biomedical research. For the last few years, Institutes have met their established targets for funding specific percentages of new investigators out of the total pool of new and competing R01 applications funded. The specific mechanics of how the commitment toward funding new investigators will be met over the coming years is still under discussion, but there should be no doubt that this remains a serious priority. Investigative teams that can anoint a credible new



Michael Weinrich, M.D., Director, NCMRR

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Do you have any questions for NCMRR staff?

For example, do you need help identifying an appropriate funding mechanism for your application? Is there a topic you would like to see in a future *Innovations*?

If so, please e-mail us at *sheredoc@mail.nih.gov*.

Thank you!

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Director's Message (Cont.)

investigator (i.e., appropriate experience and publication record) as a principal investigator (PI) should take advantage of these opportunities.

Second, the NIH recently issued its next NIH Roadmap Initiative, the *Roadmap Transformative R01 Program, or T-R01 (RFA-RM-08-029)*. To quote directly from the Request for Application (RFA), "a major goal of the NIH is to foster bold and creative investigator-initiated research…to provide a more flexible and engaging avenue for support of investigators testing novel concepts and truly transformative ideas. The primary objective of the T-R01 initiative is to create a program that is specifically designed to support exceptionally innovative, high risk, original and/or unconventional research with the potential to create new or challenge existing scientific paradigms." The T-R01 program, deemed a High Risk/ High Reward Demonstration Project, is supported by the NIH Common Fund, through which novel approaches to peer review and program management are also piloted.

Two highlighted areas of special interest to the rehabilitation community are described below.

Understanding and Incenting Behavior Change

Even though behavior change is critical to the prevention, management, and treatment of many important health conditions, initiating and maintaining behavior change can be very difficult; even interventions that succeed in controlled clinical trials do not always scale well. Therefore, transformative advances in behavior change, especially those that can unify disease-specific efforts, are urgently needed. To address this challenge, the T-R01 program invites proposals from investigators and interdisciplinary teams working to understand basic mechanisms of behavior change at the biological, behavioral, and social levels and to develop innovative approaches to intervention. Questions of particular interest include how the interaction between neural, biological, behavioral, psychological, and social factors results in initial and sustained behavior change. See the RFA for more specific information.

Transitions from Acute to Chronic Pain

Although more than 30 million Americans suffer from unrelieved chronic pain, pain management strategies often fail, in part, because an individual's susceptibility to chronic pain is highly variable, identifying those who may transition from acute to chronic pain is difficult, and, once pain has become chronic, physiological changes may have occurred that cannot be easily reversed. Well-defined phenotypes reflecting the cellular, molecular, genetic, psychological, cognitive, and behavioral changes that occur as individuals transition to chronic pain are also lacking, resulting in a major barrier to personalized intervention approaches. The T-R01 program seeks proposals to transform how we view the pain state of individuals and to revolutionize the current empirically based analgesic approaches to those based upon objective and predictive measures.

The *RFA* also explains that responsive studies will likely involve innovative partnerships including interdisciplinary and multidisciplinary teams to adequately address the topic and achieve the intended goals. To be sure, competition for these large grants will be very intense. Only investigative teams with substantial experience and well-established track records are likely to succeed in this competition; the announcement clearly calls for bold, new approaches. Nonetheless, these issues are at the heart of practice in rehabilitation, and I encourage the field to respond to this RFA.

For investigators who are not ready to apply for this Roadmap initiative, we have another opportunity. In 2004, the NIH Rehabilitation Coordinating Committee released *PAR-04-077: Research Partnerships for Improving Functional Outcomes*. This announcement solicited R01 applications from investigators interested in rehabilitation or management of chronic disease. To apply, investigators were to partner with researchers from outside their usual clinical collaborations to attack problems in novel ways. Although most investigators identified interesting problems, the majority of applications did not use the multidisciplinary team approach successfully and were not funded.

The new announcement, *PAR-08-207: Meetings, Conferences, and Networks for Research Partnerships to Improve Functional Outcomes (R13)* targets the same broad set of problems, but provides investigators with more modest funds (up to $25,000 a year for two years in direct costs) to bring investigators together, perform preliminary analyses, and conduct workshops, meetings, and other activities necessary to lay the foundation for a successful R01 application. Applicants will still have to identify an important problem and an interesting approach and will also need to identify likely collaborators from other disciplines. However, for this solicitation, the emphasis is on the ideas and the investigators' plans to develop their investigative teams, rather than on the experimental methods. We hope that this announcement will be useful to investigators who wish to develop new methods in rehabilitation.

Michael Weinrich, M.D., director, NCMRR

Innovations Spotlight: NCMRR Research Networks and Partnerships

This issue of *Innovations* looks more closely at NCMRR's networks and partnerships. Increasingly, the medical rehabilitation research field has recognized the value of utilizing research networks. The concept of a network, in its structure and associations, can be very advantageous in building research capacity and can be further optimized by a range of resources, expertise, and translational opportunities across a spectrum of multi-site, multi-investigator settings. Networks are beneficial for facilitating the collection of evidence regarding the efficacy of a variety of rehabilitation interventions.

Clinical studies of rehabilitation treatments and interventions are particularly enabled by the use of networks. Research networks allow investigators to enroll a broad range of the population, with the purpose of coordinating protocols (such as standardized patient-inclusion criteria, standardized and quantitative measurement of treatment outcomes) needed to draw scientific conclusions about the efficacy of various treatment interventions.

The *NIH Roadmap for Medical Research* also notes the importance of research networks for conducting clinical studies and for enhancing research infrastructure, stating that the bench-to-bedside translation of discoveries is often best accomplished through "networks of investigators who are equipped with tools to facilitate collaboration and information sharing." The leaders of the NIH Roadmap add that improving access to data, using standardized data reporting, sharing samples, and reducing duplication not only within networks, but also across networks, can further efforts to address research questions.

The next few sections of this e-update describe the NCMRR's efforts in building and sustaining research networks and partnerships to further medical rehabilitation research.

Research Infrastructure Projects

Medical rehabilitation research involves basic and clinical studies in several domains, primarily those of pathophysiology, impairment, functional limitation, disability, and societal interaction. Increasingly, research breakthroughs and potential therapeutic strategies are the result of integrating expertise from allied fields, as well as of building up a core understanding of rehabilitative mechanisms and clinical outcomes.

Access to technologies and approaches from allied fields is key to promoting multidisciplinary collaborations and developing research opportunities. To encourage these types of collaborations, the NCMRR has joined with the National Institute of Biomedical Imaging and Bioengineering (NIBIB) and the National Institute for Neurological Disorders and Stroke (NINDS) to fund six grants under the R24 mechanism. These Resource-Related Research Projects are used in a variety of ways to provide resources that address problems for which multiple expertise is needed to focus on a single complex problem in biomedical research or to enhance research infrastructure.

By providing state-of-the-art research facilities, mentorship, pilot grants, and other collaborative opportunities, as well as expertise in bioengineering and robotics, cognitive rehabilitation and brain imaging, neurorehabilitation and regeneration, genetics and genomics, and muscle physiology, this program demonstrates that a centralized research infrastructure will enhance the capability of medical rehabilitation investigators, particularly young faculty at the formative stage of their careers. The program is designed to assist the medical rehabilitation research field in understanding the mechanisms of functional recovery, in the development of therapeutic strategies, and in the improvement of the lives of people with disabilities.

Centers currently participating in the program include the following:

- Medical Rehabilitation Research Infrastructure Program in Muscle: University of California, San Diego; Richard Lieber, Ph.D.
- National Capital Area Rehabilitation Research Network: Georgetown University and National Rehabilitation Hospital, Washington, D.C.; Barbara Bregman, P.T., Ph.D., and Joseph Hidler, Ph.D.

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Research Infrastructure Projects (Cont.)

- Integrated Molecular Core for Rehabilitation Medicine: Children's National Medical Center, Washington, D.C.; Eric Hoffman, Ph.D., and Susan Knoblach, Ph.D.
- Engineering for Neurologic Rehabilitation: Rehabilitation Institute of Chicago; William Zev Rymer, M.D., Ph.D.
- Center for Experimental Neurorehabilitation Training: University of Pennsylvania and University of California, Los Angeles (UCLA); Michael Selzer, M.D., Ph.D., and Bruce Dobkin, M.D., F.R.C.P.
- Research Methods for Cognitive Rehabilitation: Moss Rehabilitation Research Institute and University of Pennsylvania; John Whyte, M.D., Ph.D.

For more information on these centers and their projects, visit the NCMRR Research Infrastructure Web site at *http://www.ncmrr.org/*.

The NICHD Collaborative Pediatric Critical Care Research Network (CPCCRN)

Modern critical care medicine has introduced a number of management principles and innovative methodologies without rigorous use of the controlled observation necessary for their objective evaluation. As a result, the balance between assuring prompt implementation of new technologies, procedures, treatments, and drugs, and evaluation of their safety, efficacy, and cost/risk/benefit ratios continues to be an issue. The longer-term sequelae of critical illness and/or injury in childhood are also not well studied, neither in terms of the consequences for individual children and their families, nor for the larger communities into which they are re-integrated. As the mortality of critical illness in childhood has decreased, the morbidity of surviving children and their access to specialized medical care have become increasingly significant issues. For example, approximately one-fourth of admissions to pediatric intensive care units represent children with congenital neurodevelopmental disabilities who are especially technology-dependent[1]. Children with special health care needs are at increased risk for physical, mental, and behavioral problems; multiple unmet health-care needs; increased hospital readmissions; and over-burdened families.

The NICHD CPCCRN, which the NCMRR began funding in April 2005, serves as a national resource for studying the scientific bases of pediatric critical care medicine. The Network consists of six clinical centers, chosen on the basis of proposed scientific work, patient ethnicity, and concordance with programmatic objectives. A Data Coordinating Center supports the Network using cutting-edge informatics to manage the complexities of the emerging collaborative research.

A recently published funding opportunity announcement, *RFA-HD-08-025: Collaborative Pediatric Critical Care Research Network (U10)*, a reissue of RFA-HD-04-004, continues support for the CPCCRN with the intention of funding a substantial range of research activities reaching across traditional disciplinary lines and transcending customary thinking and organizational structures to achieve innovative research in the care of critically ill children.

The goal of the CPCCRN is to develop an infrastructure to pursue well-designed collaborative clinical trials and meaningful descriptive studies in pediatric critical care medicine. The Network seeks to reduce morbidity and mortality in pediatric critical illness and injury, and to provide a framework for the development of the scientific basis of pediatric critical care practice. A particular objective of the Network is to evaluate the link between acute interventions and chronic illness and disability. The NICHD project scientist, Carol Nicholson, M.D., M.S., and Program officer, Michael Weinrich, M.D., are responsible for the overall administration of the CPCCRN.

The current six participating clinical sites are:

- Arkansas Children's Hospital, Little Rock, Arkansas
- Children's Hospital, Los Angeles, California
- Children's Hospital of Michigan, Detroit, Michigan
- Children's National Medical Center, Washington, D.C.
- Mattel Children's Hospital at UCLA, Los Angeles, California
- Seattle Children's Hospital, Seattle, Washington
- University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania

The Data Coordinating Center, currently located at the University of Utah Health Sciences Center, Salt Lake City, Utah, includes a PI, biostatisticians, research assistants, programmers, consultants, and support staff. For more information, visit the National *Collaborative Pediatric Critical Care Research Network Web site*.

[1]Graham RJ, Dumas HM, O'Brien JE, Burns JP. Congenital neurodevelopmental diagnoses and an intensive care unit: Defining a population. *Pediatr Crit Care Med*, 2004; 5(4):321-8.

The Traumatic Brain Injury (TBI) Clinical Trials Network

Researchers have much to learn about the underlying damage and pathophysiology of the deficits associated with TBI and the links among acute care, rehabilitation, and long-term patient outcomes.

To learn more about the complex topic of TBI, the NCMRR established a multicenter TBI Clinical Trials Network, whose sites are working together to design clinical intervention protocols and measures of outcome for TBI and its related conditions.

The TBI Clinical Trials Network is discussed in more depth and detail in the *NCMRR Staff in the Limelight* interview with Program director Dr. Beth Ansel.

Intra- and Extra-NIH Collaborations

Public-Private Partnerships (PPPs)

The NCMRR participates in the NIH PPP Program, which is designed to facilitate collaborations to improve public health through biomedical and behavioral research. The PPP Program represents an important aspect of the NIH Roadmap; visit *http://ppp.od.nih.gov* for more information.

What is a Public-Private Partnership?

PPPs involve the NIH in collaboration with any of a wide range of other organizations, including patient advocacy groups, foundations, pharmaceutical or biotechnology industry members, and academic institutions. Partnerships may take many forms and range widely in size and scope. Partnership activities center not only on the shared goals and mandates of the partners, but also on leveraging knowledge, skills, resources, and services to achieve synergy. All NIH PPPs are science-driven, aim to improve the public health, and are structured to uphold the principles of transparency, fairness, inclusiveness, scientific rigor, and compliance with federal laws and NIH policies.

In which PPPs does the NCMRR participate?

The NCMRR has an active collaboration with Health Authority #11 in Tuscany and with the Italian equivalent of the NIH, the Istituto Superiore di Sanitá (ISS) of the Italian Republic. The Center has provided technical assistance under the auspices of the NIH/ISS Memorandum of Understanding (MOU). The NCMRR project leaders are also planning a contract solicitation to expand some of this work, specifically to collect stroke outcomes data across Tuscany that will link to a health services database.

In 2007 and in 2008, the NCMRR, through a contract mechanism, conducted training sessions at the Annual American Congress of Rehabilitation Medicine Conferences. These sessions discussed the importance of discovering and articulating an area of interest within a broader discipline in early career development and described how to develop research questions and clarify areas of interest in order to translate these questions into "specific aims" for research proposals. The sessions also explained how to best seek out and work with an appropriate mentor(s) to obtain ongoing feedback and guidance early in a researcher's career. A similar activity is planned for fiscal year 2010.

The NCMRR has also provided small amounts of funding to a variety of organizations to help plan and carry out meetings, such as its support, with the National Science Foundation (NSF), for a Rehabilitation Research Networking Session at the 38th Annual Society for Neuroscience meeting, scheduled for November 15-19 in Washington, D.C. This workshop, *NIH and NSF Funding for Your Research Training and Career Development*, discusses NIH and NSF funding opportunities for graduate students, postdoctoral fellows, and junior faculty at all stages of training and career development. Program and review staff from NIH and NSF will discuss fellowships and career development grants, the "Do's and Don'ts" of how to apply, good grantsmanship, selecting the appropriate mentor/sponsor, picking the appropriate grant mechanism, what to expect from peer review, and other issues.

U.S.-Japan Brain Research Cooperative Program (BRCP)—U.S. Component

The NICHD supports basic, clinical, and behavioral research in the neurosciences, particularly as the research relates to normal and abnormal nervous system development, reproduction, promotion of healthy development as a way to prevent disability, and using rehabilitation to improve the health, function, and quality-of-life of persons with chronic physical and/or cognitive disabilities.

The NIH is once again accepting applications for the *U.S. component of the U.S.-Japan BRCP*. The purpose of the BRCP is to promote scientist exchange, training, and research collaborations between neuroscientists from the U.S. and Japan. The U.S. component of the BRCP supports U.S. scientists' visits to Japanese institutions to conduct collaborative research and/or to acquire advanced research skills, and joint workshops to exchange scientific information and to foster collaborations.

To be eligible, applicants at a U.S. institution must have a currently active NIH grant from one of the participating NIH Institutes (see the *Notice* for a listing of Institutes). The BPRC Travel Fund (supplements the travel and lodging expenses of the U.S. scientist's visit to Japan) and Workshop Fund (provides partial support for joint workshops) are provided as administrative supplements to the applicant's parent grant. The goals of the collaborative research/training and workshop must be related to the research areas of the parent grant. Each component (U.S. or Japanese) of the BRCP is expected to supplement travel and lodging expenses of the joint workshop participants from their own countries.

Approval from program staff at the respective participating NIH Institute is required prior to the submission of applications. All applications must be received by the Neuroscience Center on or before September 15* of each participating year.

*Note that the deadline is September 15 for 2008, but that another opportunity is open until September 15, 2009.

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Intra- and Extra-NIH Collaborations (Cont.)

Collaboration with the National Institute of Biomedical Imaging and Bioengineering (NIBIB)

[Adapted from Minutes, National Advisory Council for Biomedical Imaging and Bioengineering, May 16, 2007]

The NIBIB and the NICHD share a strong relationship in the rehabilitation research field, as evidenced by NIBIB's collaborations with NICHD's NCMRR.

Among these collaborative efforts is co-funding for two contracts tasked with developing robots for the rehabilitation of stroke patients, including those who have upper-arm impairments, conducted by **Dr. David Reinkensmeyer**, at University of California, Irvine, and **Dr. Jiping He**, at Arizona State University. Another co-funded grant led by **Dr. William Zev Rymer**, Rehabilitation Institute of Chicago, which serves as a resource for investigators to learn techniques and scientific methods for pilot studies in robotics research, has also resulted from the collaboration between the two Institutes. In addition, **Dr. Richard Weir**, Rehabilitation Institute of Chicago, is leading a co-funded Bioengineering Research Partnership to develop a prosthetic arm controlled through remote circuitry using implanted myoelectric sensors.

The NICHD/NCMRR and the NIBIB are pleased with the progress and caliber of these projects and look forward to possibly adding to these collaborations in the future.

Research Partnerships to Improve Functional Outcomes

In the context of the Research Partnerships Program, a "partnership" is a multidisciplinary research team that applies an integrative, systems approach to developing knowledge and/or methods to improve functioning, promote health, and increase participation in community life. The partnership includes appropriate individuals who have clinical expertise related to rehabilitation in combination with biomedical, psychosocial-behavioral, engineering, epidemiological, and/or health services researchers. Two examples of such research partnerships are:

- R01HD053793: Novel Strategies to Enhance Motor Function After Stroke; Celnik, Pablo; Johns Hopkins University, Baltimore, Maryland; Program: TBI and Stroke Rehabilitation
- R01HD050439: Improving Outcomes in Acute Rehabilitation for TBI; Horn, Susan; Isis, Inc., Salt Lake City, Utah; Program: Behavioral Sciences and Rehabilitative Technologies

Visit *http://grants.nih.gov/grants/guide/pa-files/PAR-04-077.html* for more information about the Research Partnerships Program.

Did You Know?

Federal Conflict of Interest (FCOI) Tutorial

The NIH Office of Extramural Research recently posted a Web-based tutorial about complying with the FCOI regulations at *http://grants.nih.gov/grants/policy/coi/index.htm*. Current and potential NCMRR grantees are encouraged to take the tutorial to ensure the most up-to-date knowledge of and compliance with FCOI regulations.

NCMRR Staff in the Limelight

Beth Ansel, Ph.D.

Director, TBI and Stroke Rehabilitation (TSR) Program

Each *Innovations* focuses on one of the NCMRR's staff and his or her program(s). It is hoped that this section will assist you to learn more about NCMRR program staff and particularly about the Center's specific programs.

This *Innovations* highlights the *TBI and Stroke Rehabilitation (TSR) Program* and its Program officer, Dr. Beth Ansel.

Innovations: Where did you receive your education? In what subjects/fields were your degrees, and what were your areas of concentration?

Dr. Ansel: My undergraduate training was in biology/biochemistry at the State University of New York at Stony Brook, where I earned a bachelor of science degree. I received my master of science degree in communication sciences and disorders from the University of Wisconsin-Madison. I also completed my doctorate at the University of Wisconsin-Madison. My graduate training included both research and clinical practice in the areas of communicative and cognitive aspects of adult neurogenic disorders. My postdoctoral fellowship in pediatrics at the Kennedy Krieger Institute for Handicapped Children (Johns Hopkins University) in Baltimore, Maryland, complemented the adult emphasis of my doctoral education. Following my postdoctoral education, I joined the faculty at Purdue University in West Lafayette, Indiana.

Innovations: When and why did you join the staff at the NCMRR?

Dr. Ansel: The NIH seemed like an ideal place to incorporate my background in research, teaching, and clinical practice. I joined the NCMRR in 2000 as the Center was beginning to expand its research focus. I was asked to develop the Clinical Practices Research Program, the initial goal of which was to promote research in pediatric rehabilitation and TBI. We were fortunate during this time to have dedicated funding, which allowed us to promote this research via a series of targeted research initiatives.

The first of these initiatives was a Pilot Clinical Trials Grant for Pharmacological Intervention in Pediatric TBI. The objective of this initiative was to promote clinical trials research to evaluate the efficacy of pharmacological interventions for the physiological and behavioral sequelae of TBI in children. A number of successful projects resulted, including studies that evaluated the:

- Efficacy of hypertonic saline to treat intracranial pressure in children with severe TBI
- Pharmacological intervention to improve arousal and recovery
- Most effective pharmacological agents for attention, memory, and other behavioral sequelae of TBI in children

A second research initiative, Clinical Trials Planning Grants for Pediatric Rehabilitation, aimed to support clinical trials of rehabilitation interventions that focused on pediatric injury and trauma. Planning grants were issued to support the assembly of an effective research team, and to develop elements necessary for a successful subsequent clinical trial. For example, such grants supported plans for patient recruitment, research design, intervention strategies, and outcome measures. This initiative was broad, inclusive of a variety of etiologies in the pediatric population. Research projects that refined rehabilitation approaches for the clinical care of children in a spectrum of areas were developed from this proposal, including:

- Study of impact of assistive technology devices for children with disabilities
- Development of standardized management approaches following spinal cord injury
- Rehabilitation models for newborn children with disabilities
- Studies of gait parameters in children with cerebral palsy and in pediatric rehabilitation generally

The third of these initial research initiatives was the Cooperative Multicenter TBI Clinical Trials Network. The goal of the TBI Network was and still is to identify the intervention variables that result in improvements in long-term outcome. (This Network is discussed in more detail later in this interview.)

Innovations: The TSR Program involves funding for projects related to TBI and stroke rehabilitation. Please tell us about your Program, and how it fits in to the field of rehabilitation.

Dr. Ansel: A large proportion of disabilities result from injury to or diseases of the nervous system; these include stroke, Parkinson's disease, multiple sclerosis, spinal cord injury, and TBI. Much of a rehabilitation team's efforts during inpatient and outpatient therapy for such neurologic disorders focus on restoring the ability to maintain independence in daily activities. The companion role of medical rehabilitation research is to develop interventions that lead to post-acute functional recovery, which can be maintained throughout the individual's life. One broad goal of the research supported by the TSR Program relates neurologic changes to reductions in functional limitations and disabilities.

The TSR Program (previously called the Clinical Practices Research Program) supports research and training within the broad discipline of basic and applied rehabilitation sciences. The majority of the research projects supported through this Program are extramural, or investigator-initiated, projects. One

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NCMRR Staff in the Limelight (Cont.)

important component of each NCMRR Program is to develop and implement a strategic plan that addresses area(s) of research need through targeted research initiatives that stimulate research to evaluate the efficacy of rehabilitation methods and to refine rehabilitation approaches in clinical practice.

Let me give you some examples of TSR Program initiatives:

- *Clinical Trial Planning Grants to Guide Timing, Intensity and Duration of Rehabilitation for Stroke and Hip Fracture (RFA HD-01-022)*—Stroke and hip fracture are the leading health care problems requiring rehabilitation services in older Americans; they account for the majority of days spent and are responsible for the largest expenditure of Medicare dollars spent in rehabilitation. Both are common, enduring, and expensive in terms of medical costs, rehabilitation costs, caregiving costs, and lost productivity. Current medical practice has evolved in response to reimbursement guidelines, rather than based on clinical evidence. The purpose of this initiative was to support clinical research studies to evaluate models for providing rehabilitation that consider timing, intensity, and duration of treatment for these patients.
- *Augmentative and Alternative Communication (ACC) Strategies for Treatment of Acquired Cognitive-Linguistic Disorders (RFA-HD-02-002)*—Traditionally, AAC strategies were designed for individuals who had severe motor impairment; however, clinical practice has also extended AAC use as a tool for cognitive remediation. Although technological developments offer the potential for vastly improved communication and inclusion, technology alone does not result in successful communication. While AAC interventions have become increasingly common across the lifespan, the research base underlying the design of AAC technology, intervention strategies, and treatment potential across communication disorders remain quite limited. This initiative funded projects that addressed three interrelated areas of research: use of AAC strategies as a research tool to provide theoretical insights into the nature of normal and impaired language and cognition; development of AAC methods as treatment tools to facilitate language recovery and use; and the efficacy of applying AAC as communication modalities for individuals with acquired cognitive/linguistic communication disorders.
- *Multi-Drug Combinations to Promote Recovery in TBI (RFA-HD-08-003)*—The potential to capture the earliest recovery window via early neuroprotection is a priority for TBI rehabilitation, and recent attention has focused on a number of pharmacological agents evaluated in experimental TBI models. These studies suggest improved motor and cognitive outcomes as well as a decrease in the loss of brain tissue. Although these studies have shown promising preclinical efficacy in clinically relevant experimental models, most large, multicenter, phase III clinical trials have failed to demonstrate the robust and significant improvement in patient outcome necessary for clinical application. This initiative invites applications to develop preclinical data on multiple-drug combination interventions as a precursor to motivate clinical research in humans who have had TBI and stroke. We anticipate that the result will lead to the development of laboratory evidence, which will demonstrate neuroprotective effects and will provide pilot research to assess the safety and potential benefit of administration of combinational pharmacotherapies to patients with TBI.

Innovations: You are responsible for developing and administering the TBI Clinical Trials Network, the first clinical trials network funded by the NCMRR. Can you please tell us about that Network?

Dr. Ansel: TBI is a leading cause of death and disability in children and adults worldwide. Survival after TBI has increased significantly in the United States during the past 25 years with improvements in early and specialized emergency care, treatment at the accident scene, "trauma team" and neuro-critical care evaluation and treatment, and radiographic technologies. Further, understanding of the basic pathophysiology of TBI has contributed to a better understanding of the injury and recovery process. The implementation of the TBI Guidelines prepared by the Brain Trauma Foundation has also helped standardized care and increased survival. Despite these advances, a large percentage of TBI survivors have persistent physical, cognitive, behavioral, and social deficits which may compromise their quality-of-life. Increases in survival results in an increasing number of patients who need effective treatments to help them attain a satisfactory long-term life adjustment and improved quality-of-life.

Despite the long history of TBI and the advances in the field, few large, multicenter, prospective randomized control trials (RCTs) have been completed in TBI populations. Therefore, the NCMRR established this cooperative multicenter RCT research network to provide infrastructure for supporting collaborative clinical trials in TBI populations and to evaluate the relationship between acute care practice and rehabilitation strategies in regard to the long-term functional outcome of TBI patients.

Innovations: How is the NCMRR TBI Clinical Trials Network different from other TBI projects?

Dr. Ansel: The TBI Clinical Trials Network represents a tremendous accomplishment in TBI research. Past experience has taught us that, in order for multicenter research in TBI to be successful, the research needs to be coordinated, carried out to completion, and include proper follow-up. By having the Network members reach consensus to determine what is to be studied and what protocols to follow, we believe we can assure the coordinated treatment of all study participants. This collaborative effort among health care providers and clinical researchers has established precise treatment protocols at each stage of patient care.

In addition, the Network is the first to link clinical protocols in the acute and post-acute care settings. Network researchers have

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NCMRR Staff in the Limelight (Cont.)

also refined a series of outcome measures that we believe will help detect meaningful behavioral differences for those with TBI. We feel confident that the Network has made significant progress toward developing a broad spectrum of deliverable treatment trials, which will provide long-term benefits for individuals with TBI.

Innovations: What is the current makeup of the TBI Clinical Trials Network, and what have been some if its successes?

Dr. Ansel: The Network is currently composed of eight academic clinical centers, a data coordinating center, and me as the NIH project scientist. All investigators function in collaboration to design clinical intervention protocols, establish outcome measures, recruit patients into clinical studies, and evaluate and treat participants in all of the Network's clinical studies. Through rigorous patient evaluation using common protocols and interventions designed for multiple points of care (e.g., the accident scene, emergency room, intensive care unit, rehabilitation, and long-term follow-up), we are able to study the required numbers of patients and provide answers more rapidly than individual centers acting alone. In coordinating care, the Network has employed a consensus-based approach to determine what should be studied, as well as how TBI patients should be treated upon presentation and throughout hospitalization and rehabilitation. Consensus in care considerably reduces the discrepancy between centers.

There have been a number of major achievements to date, including the following:

- Network researchers developed a profile of patients to determine those who had different clinical features eligible for future studies and to estimate recruitment times that might be necessary for full enrollment.
- Network researchers developed clinical treatment guidelines and procedures for all points in the continuum of care. These include pre-hospital and acute care, surgical guidelines, systems-based protocols for moderate and severe TBI patients, deep-vein thrombosis prophylaxis procedures, as well as rehabilitation guidelines for physical therapy, speech-language pathology, occupational therapy, and neuropsychology. By developing a set of unique outcome measures and using them in conjunction with strict adherence to the guidelines and procedures, researchers were able to form the basis of clinical care for all patients randomized into each Network trial.
- Researchers successfully developed the first Network clinical trial protocol, including a manual of procedures, and completed the initial enrollment of patients into the Citicoline Brain Injury Trial (COBRIT).
- The Network has worked to develop acute intervention, genetics, behavioral rehabilitation, and depression protocols.

Innovations: You mention COBRIT—can you please tell us more about the trial?

Dr. Ansel: The Network has enrolled more than 450 patients into its first multicenter trial—COBRIT— which will evaluate the effect of 90 days of citicoline on functional outcomes in patients with complicated mild, moderate, and severe TBI. Citicoline, an endogenous compound found throughout the body, has been shown to have neuroprotective properties. Its safety and role as a neuroprotective agent in humans has been demonstrated in literature related to stroke. This two-arm, double-blind, placebo-controlled, phase III, multicenter trial employs stringent neuroimaging and clinical criteria to assure accurate enrollment. Functional outcomes are assessed at 30, 90, and 180 days after injury. Researchers are also conducting a parallel study evaluating the role of genetic markers to establish a TBI genetics database.

Innovations: How can people learn more about the TBI Clinical Trials Network?

Dr. Ansel: Those interested should check out the *Network Web site* or the *Web site for Networks related to clinical research*. Or, they can contact me at 301.402.2242 or at *anselb@mail.nih.gov*.

Hot Topics...

...in Medical Rehabilitation Research

Repairing the Human Brain After Stroke

I. Mechanisms of Spontaneous Recovery

II. Restorative Therapies

The author, Steven C. Cramer, M.D., received funding from the NICHD (K08HD001219), as well as from NINDS and NIBIB.

Animals in Research

A "Story of Discovery" from a medical rehabilitation colleague, Donald Stein, Ph.D.

The Hormonal Cycle of Female Rats Provides Clues to a New Treatment for Brain Injury

Note: The content of these articles is solely the responsibility of the author and does not represent the official views of the NICHD, the NIH, or the DHHS.

Of Interest to Investigators

Patient-Reported Outcomes Management Information System™ (PROMIS), the NIH Roadmap Initiative: Re-engineering the Clinical Research Enterprise

The NCMRR encourages its investigative community to become familiar with and consider applying for the second funding phase of the PROMIS initiative, announced through the NIH Roadmap for Medical Research. This funding opportunity is a continuation of a trans-NIH initiative that seeks to foster the advancement, development, and application of new technologies to measure patient-reported symptoms, such as pain and other aspects of health-related quality-of-life, across a wide variety of chronic diseases and conditions. The NCMRR has an interest in this research area as a means of building evidence for medical rehabilitation interventions. Please access the links below for detailed information on this initiative.

- *PROMIS Network Center (U54) (RFA-RM-08-022)*—To provide overall coordination, management, infrastructure, and leadership for the PROMIS Network and planning and implementation of the transition from the first to the second funding phase. Application Receipt/Submission Date: March 3, 2009.
- *PROMIS Research Sites (U01) (RFA-RM-08-023)*—To develop, test, and evaluate new domains as per PROMIS item bank development procedures and/or validate new or existing PROMIS item banks in various clinical populations as part of the PROMIS Network. Application Receipt/Submission Date: March 3, 2009.
- *PROMIS Technology Center (U54) (RFA-RM-08-024)*—To research, develop, and provide computer administration services, including computer-adaptive testing (CAT), Web access to short forms, and other administration modalities. Application Receipt/Submission Date: March 3, 2009.
- *PROMIS Statistical Center (U54) (RFA-RM-08-025)*—To conduct collaborative research on statistical and psychometric aspects of Patient-Reported Outcomes, coordinate data collection from the PROMIS Research Sites, manage data quality, assist in general population sampling for new item bank testing, provide psychometric and statistical support for the PROMIS Network, as well as develop PROMIS-approved translations of new and extant domains. Application Receipt/Submission Date: March 3, 2009.

Other Announcements of Interest

In addition, the following RFAs and Program Announcements (PAs) may be of interest to researchers in the medical rehabilitation field.

- *Research on Emergency Medical Services for Children (R01) (PAR-08-261)*—Application Receipt/Submission Date(s): January 15, 2009, September 19, 2009, and September 15, 2010. Contact *Carol Nicholson* for more information.
- *Collaborative Pediatric Critical Care Research Network (U10) (RFA-HD-08-025)*—Application Submission/Receipt Date: March 31, 2009. Contact *Carol Nicholson* for more information.
- *Data Coordinating Center for the Collaborative Pediatric Critical Care Research Network (U01) (RFA-HD-08-027)*—Application Submission/Receipt Date: March 31, 2009. Contact *Carol Nicholson* for more information.
- Nanoscience and Nanotechnology in Biology and Medicine (Contact *Michael Weinrich* for more information.)
  - *R01 (PA-08-052)*—Application Submission/Receipt Date: January 8, 2011.
  - *R21 (PA-08-053)*—Application Submission/Receipt Date: January 8, 2011.
- Ruth L. Kirschstein National Research Service Award (NRSA)
  - *Institutional Research Training Grants (T32) (PA-08-226)*—Applicable to all NCMRR Programs. Application Submission/Receipt Date: September 8, 2011.
  - *Short-Term Institutional Research Training Grants (T35) (PA-08-227)*—Applicable to all NCMRR Programs. Application Submission/Receipt Date: September 8, 2011.
- Mechanisms of Functional Recovery After Stroke (NINDS is the primary Institute on these PAs; contact *Beth Ansel* for more information.)
  - *R01 (PA-08-099)*—Application Submission/Receipt Date: May 8, 2011.
  - *R21 (PA-08-100)*—Application Submission/Receipt Date: May 8, 2011.

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IN THE NEWS

New! Transformative R01 Program

As discussed in Dr. Weinrich's *Director's Message*, the NIH recently announced a new program, conducted through the NIH Roadmap, designed to stimulate disruption of existing paradigms or creation of paradigms where none exists. The Transformative R01 Program (T-R01s) will allow support of highly creative, "out-of-the-box" projects. The NIH recognizes that new paradigms are needed in certain Highlighted Areas (listed below) and will particularly encourage research that addresses these areas:

- Understanding and incenting behavior change
- 3-D tissue models
- Functional variation in mitochondria
- Transition from acute to chronic pain
- Formulation of novel protein capture reagents
- Evidence for pharmacogenomics clinical studies

This unusual research opportunity will make available up to 60 grants, in any scientific area, of $25 million a year for five years. There is no limit, however, on the amount of the grant award, so theoretically one grant could be funded for $25 million. The eligibility criteria are detailed in the announcement, but the overall goal for the NIH is to fund research that is either paradigm disrupting or that creates paradigms where none previously existed. Visit *http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-08-029.html* for more information.

NIH to Fund "Best Science"

Peer review is an element critical to ensuring that the NIH funds the best research, including rehabilitation research. The *NIH recently announced* that it will commit $1 billion over the next five years to make critical changes to improve the peer-review system. The announcement marks the end of a year-long effort, which brought internal and external communities together to determine ways to further enrich the peer-review process. These consultations resulted in the creation of a comprehensive framework, and implementation will be carried out over the next 18 months.

The Implementation Plan consists of four main priorities for the NIH to: engage the best reviewers, improve quality and transparency of reviews, ensure balanced and fair reviews across scientific fields and career stages, and develop a permanent process for continual review of the peer-review process.

For more information about enhancing peer review at NIH and to learn about the Implementation Plan, visit *http://enhancing-peer-review.nih.gov*.

NICHD Fiscal Year 2008 Funding Strategies

The NICHD distributes its resources among many diverse programs and uses various mechanisms. The Institute is committed to funding the largest number of meritorious projects possible, while allowing the flexibility needed to support selected program priorities and respond to emerging scientific opportunities. For more information on how the NICHD plans to balance these priorities, visit *http://www.nichd.nih.gov/funding/newsflash/020608.cfm*.

Final Dates for Transition to Electronic Submission

Transition dates for training and career development applications to go to electronic submission are now posted. All applicants must use electronic submission by the following dates:

- Career Development (K) Awards: February 2009
- Fellowship (F) Awards: April 2009
- Training Grant (T32) Awards: September 2009 (*But note that the NICHD has only a single annual submission date of May 25, 2009)

Report on Disability Released

The National Center for Health Statistics, Centers for Disease Control and Prevention, released a new report Disability and Health in the United States, 2001–2005. The report is available at: *http://www.cdc.gov/nchs/data/misc/disability2001-2005.pdf*.

Disability and Business Technical Assistance Centers (DBTAC)

The DBTAC is a national network of ten regional Americans with Disabilities Act (ADA) Centers that provides the most complete and experienced service for up-to-date information, referrals, resources, and training on the ADA to businesses, employers, government entities, researchers, and individuals with disabilities, as well as members of the media. For more information, visit the DBTAC Web site at *http://www.adata.org/*. This project is funded by the National Institute on Disability and Rehabilitation Research (Grant Number H133A060087-01).

NIH Disability Employment Program (DEP)

The DEP, run by the NIH Office of Equal Opportunity and Diversity Management, works to promote the hiring and advancement of people with disabilities and to educate the NIH community about workplace issues that people with disabilities confront every day. Visit *http://oeodm.od.nih.gov/dep/* for more information.

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NOW RECRUITING!

NCMRR-Supported Clinical Trials

(Alphabetical by title)

- A Randomized Controlled Trial on Preventing Pressure Ulcers with Wheelchair Seat Cushions
  - PI: David M. Brienza, Ph.D., University of Pittsburgh (Grant number R01HD04109); contact: Margo B. Holm, Ph.D. (*mholm@pitt.edu*); Program: BSRT
- Constraint-Based Therapy to Improve Motor Function in Children with Cerebral Palsy
  - PI: Edward Taub, Ph.D., University of Alabama, Birmingham (Grant number R01HD040692); contact: Edward Taub, Ph.D. (*etaub@uab.edu*); Program: PCCR
- Effects of Spinal Cord Injury on Female Sexual Response
  - PI: Marca L. Sipski, M.D., University of Alabama, Birmingham (Grant number R01HD03014); contact: Paula Spath (*pspath@uab.edu*); Program: SMAD
- Electrical Stimulation After Total Knee Arthroplasty
  - PI: Lynn Snyder-Mackler, P.T., Sc.D., University of Delaware (Grant number R01HD041055); contact: Lynn Snyder-Mackler, P.T., Sc.D. (*smack@udel.edu*); Program: SMAD
- Exercise Study for People with Parkinson Disease
  - PI: Margaret L. Schenkman, P.T., Ph.D., University of Colorado at Denver and Health Sciences Center, Aurora (Grant number R01HD043770); contact: Jaime C. Salay (*jaime.salay@uchsc.edu*); Program: BSCD
- Functional Electrical Stimulation (FES) for Footdrop in Hemiparesis
  - PI: John M. Chae, M.D., Case Western Reserve University (Grant number R01HD044816); contacts: Cathy Corrigan, R.N. (*ccorrigan@metrohealth.org*), or Peggy Maloney, R.N. (*mmaloney@metrohealth.org*); Program: TSR
- FES for Upper Extremity Recovery in Stroke
  - PI: John Chae, M.D., MetroHealth Medical Center; Case Western Reserve University (Grant number R01HD049777); contacts: Peggy Maloney, R.N. (*mmaloney@metrohealth.org*), or Catherine Corrigan, R.N. (*ccorrigan@metrohealth.org*); Program: TSR
- Improving Memory in Patients with Multiple Sclerosis
  - PI: Lauren B. Krupp, M.D., State University New York, Stony Brook (Grant number R01HD38107); contact: P atricia Melville, R.N. (*Pmelvill@neuro.som.sunysb.edu*); Program: TSR
- Physical Work Capacity after TBI
  - PI: Kurt A. Mossberg, P.T., Ph.D., University of Texas Medical Branch, Grant number R01 HD046570); contact: Paula Skinkis, M.Ed. (*pskinkis@utmb.edu*); Program: TSR
- Prevention of Urinary Tract Infection in Persons with Spinal Cord Injury
  - PI: Rabih O. Darouiche, M.D., Baylor College of Medicine, Grant number R01HD043943); contact: Colleen Cerra-Stewart, R.N. or Rabih Darouiche, M.D. (*rabih.darouiche@med.va.gov*); Program: SMAD
- Relaxation Training to Decrease Pain and Improve Function in Adolescents with Cerebral Palsy
  - PI: Joyce M. Engel, O.T., Ph.D., University of Washington (Grant number P01HD033988); contacts: Joyce M. Engel, O.T., Ph.D. (*knowles@u.washington.edu*), or Amy J. Hoffman (*ajulian@u.washington.edu*); Program: BSRT
- Respiratory Muscle Training in Ventilator-Dependent Patients
  - PI: Anatole D. Martin, P.T., Ph.D., University of Florida (Grant number R01HD042705); contact: Anatole D. Martin, P.T., Ph.D. (*dmartin@phhp.ufl.edu*); Program: TSR
- Shoulder, or Elbow, or Wrist: What Should We Train First After a Stroke?
  - PIs: Bruce T. Volpe, M.D., Burke Medical Research Institute, New York, & Hermano I. Krebs, Ph.D., Massachusetts Institute of Technology (Grant number R01HD045343); contacts: Avrielle Rykman, O.T.R. (*arykman@burke.org*), or Bruce T. Volpe, M.D. (*bvolpe@burke.org*); Program: BSRT
- SIRROWS: Stroke Inpatient Rehabilitation Reinforcement of Walking Speed
  - PI: Bruce Dobkin, M.D., University of California, Los Angeles (Grant number R01HD046740); contacts: Study Coordinator, Prudence Plummer-D'Amato (*pdamato@ucla.edu*), or Dr. Dobkin (*bdobkin@mednet.ucla.edu*); Program: BSRT

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NCMRR-Supported Clinical Trials (Cont.)

- Strength Training Using Neuromuscular Electrical Stimulation for Children with Cerebral Palsy
  - PI: Samuel C.K. Lee, P.T., Ph.D., Shriners Hospital for Children, Philadelphia (Grant number R01HD043859); contacts: S amuel C.K. Lee, P.T., Ph.D. (sclee@shrinenet.org), or Ann M. Tokay, D.P.T. (atokay@shrinenet.org); Program: PCCR
- Stress Management for Patients with Multiple Sclerosis
  - PI: David C. Mohr, Ph.D., University of California, San Francisco (Grant number R01HD043323); contacts: Claudine Catledge (claudine.catledge@va.gov), or Yuriko Courtney (nycourt@u.washington.edu); Program: BSRT
- Study of Citicoline for the Treatment of Traumatic Brain Injury (COBRIT) Cooperative agreement; PIs and sites are listed below; Program: TSR; for more information, visit the COBRIT Web site.
  - PI: Thomas Novak, Ph.D., University of Alabama at Birmingham; contact Olivia Hogue (olivia.hogue@ccc.uab.edu)
  - PI: Howard Eisenberg, M.D., University of Maryland, Baltimore; contact: Charlene Aldrich, M.S.N. (caldrich@smail.umaryland.edu)
  - PI: Jack Jallo, M.D., Ph.D., Temple University, Philadelphia; contact: Tessa Hart, Ph.D. (thart@einstein.edu)
  - PI: Joseph H. Ricker, Ph.D., University of Pittsburgh; contact: Tina Harrison (harrisonta@upmc.edu)
  - PI: Shelly Timmons, M.D., Ph.D., University of Tennessee Health Sciences Center, Memphis; contact: Inge Fine (ifine@utmem.edu)
  - PI: Ramon Diaz-Arrastia, M.D., Ph.D., University of Texas, Southwestern Medical Center, Dallas; contact: Carol Moore, M.A. (carol.moore@UTSouthwestern.edu)
  - PI: M. Ross Bullock, M.D., Ph.D., Virginia Commonwealth University, Richmond; contact: Randall Merchant, Ph.D. (rmerchan@hsc.vcu.edu)
  - PI: Nancy Temkin, Ph.D., University of Washington, Seattle; contact: Nancy Temkin, Ph.D. (temkin@u.washington.edu)
- Study of Hand Therapy 3 to 24 Months After Stroke
  - PI: James B. Koeneman, Ph.D., Kinetic Muscles, Inc. (Grant number R44HD041805); contacts: *(Phoenix, Arizona)* Lisa Orozco (lisa.orozco@bannerhealth.com), or Richard Herman, M.D. (richard.herman@bannerhealth.com); *(Atlanta, Georgia)* Veronica Rowe, M,S., O.T.R./L. (vrowe@emory.edu), or Steven L. Wolf, P.T., Ph.D. (swolf@emory.edu); Program: SMAD
- Subacromial Corticosteroid Injection for Hemiplegic Shoulder Pain
  - PI: John Chae, M.D., MetroHealth Medical Center, Case Western Reserve University (Grant number K24HD054600); contacts: Peggy Maloney, R.N. (mmaloney@metrohealth.org), or Catherine Corrigan, R.N. (ccorrigan@metrohealth.org); Program: TSR
- Therapy for Reading Problems in Adults After Brain Injury
  - PI: Rhonda B. Friedman, Ph.D., Georgetown University (Grant number R01HD036019); contacts: Sarah F. Snider, M.A., S.L.P. (sfs24@georgetown.edu), or Nora L. Watson (nlw9@georgetown.edu); Program: BSRT
- Transfer of Grasp Control Across Hands After Stroke
  - PI: Preeti Raghavan, M.D., Mount Sinai School of Medicine (Grant number K23HD049472); contacts: Eddie Li (212-241-7182), or Preeti Raghavan, M.D. (preeti.ragahavan@mountsinai.org); Program: TSR
- Treadmill Training with Body-Weight Support in Patients with Spinal Cord Injury
  - PI: Blair M. Calancie, Ph.D., University of Miami Project to Cure Paralysis (Grant number U01HD37460); contact: Blair M. Calancie, Ph.D. (bcalancie@miamiproj.med.miami.edu); Program: SMAD
- Treatment for Movement Problems in Elderly Stroke Patients
  - PI: Edward Taub, Ph.D., University of Alabama, Birmingham (Grant number R01HD34273); contact: Edward Taub, Ph.D. (etaub@uab.edu); Program: TSR
- Treatments for Recovery of Hand Function in Acute Stroke Survivors
  - PI: Jayme S Knutson, Ph.D., Case Western Reserve University (Grant number R21HD054749); contacts: Peggy Maloney, R.N. (mmaloney@metrohealth.org), or Catherine Corrigan, R.N. (ccorrigan@metrohealth.org); Program: SMAD

For a full listing of all NICHD-sponsored clinical trials, visit http://www.nichd.nih.gov/health/clinicalresearch/index.cfm.

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Of Interest to Investigators (Cont.)

Other Announcements of Interest (Cont.)

- *Research Supplements to Promote Diversity in Health-Related Research (PA-08-190)*—Applicable to all NCMRR Programs. Application Submission/Receipt Date: September 30, 2011.
- *Meetings, Conferences, and Networks for Research Partnerships to Improve Functional Outcomes (R13) (PAR-08-207)*—Application Submission/Receipt Date: September 8, 2011. Contact *Michael Weinrich* for more information.
- *Pediatric Critical Care Scientist Development Program (K12) (RFA-HD-08-022)*—Application Submission/Receipt Date: November 20, 2008. Contact *Carol Nicholson* for more information.
- *Multi-Drug Combinations to Promote Neurological Recovery in TBI (R01) (RFA-HD-08-003)*—Application Submission/Receipt Date: November 29, 2008. Contact *Beth Ansel* for more information.
- *2009 NIH Director's Pioneer Awards (PAR-09-012)*—Pioneer Awards, part of the NIH Roadmap for Medical Research, provide up to $2.5 million in direct costs over five years and are open to scientists at any career stage. The Pioneer Award competition begins with a proposal submission period from November 17 to December 17, 2008. See the announcement for instructions and *http://nihroadmap.nih.gov/pioneer/* for more information. Send questions to *pioneer@nih.gov*.
- The *2009 New Innovator Award* competition begins with a proposal submission period from December 15, 2008, to January 15, 2009. See the announcement for instructions and *http://nihroadmap.nih.gov/newinnovator/* for more information. Send questions to *newinnovator@nih.gov*.

NCMRR Conference Calendar

- Trauma Spectrum Disorders: The Role of Gender, Race & Other Socioeconomic Factors—October 1-2, 2008

  As we know from history, health innovations developed in the civilian and military contexts are synergistic; what is learned in each context has relevance to the other and contributes greatly to improved health of all citizens. The NIH Office of Research on Women's Health collaborated with the NINDS, the National Institute of Mental Health, the NICHD, the Defense Centers of Excellence for Psychological Health and TBI, and the U.S. Department of Veterans Affairs on this two-day scientific conference. Conference participants reviewed the best existing science on trauma spectrum disorders related to military deployment, such as post-traumatic stress disorder and TBI. In addition to exploring how research could lead to improved care, the conference sought to help identify evidence-based strategies to better assess and treat psychological health issues and TBI. During the conference, invited speakers and guests explored gender and other factors specific to psychological health needs of populations exposed to high stress, traumatic events, and deployment; TBI; and treatment outcomes. For information, please visit *http://www.dcoe.health.mil/events.htm*.

- In Vivo Imaging in Recovery After Neural Injury: From Microimaging in Animal Models to Functional Imaging in Man—October 15, 2008.

  The University of Pennsylvania Center for Experimental Neurorehabilitation Training, funded by the NCMRR, sponsored this day-long symposium held immediately before the 2008 American Congress of Rehabilitation Medicine/ American Society of Neurologic Rehabilitation Joint Educational Conference, in Toronto, Ontario, Canada. For additional information, contact *cent@uphs.upenn.edu* or visit *http://www.acrm.org*.

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Small Business Innovative Research (SBIR)/Small Business Technology Transfer (STTR) Corner

Featured in each issue of *Innovations*, this section focuses on a few SBIR/STTR (R41, R42, R43, R44) projects that are currently or recently funded by NICHD under NCMRR. The descriptions below are adapted from project abstracts.

- DeWald, Julius – R42HD049923 – LAM Design Management, Orchard Park, New York – A 3-D Robot to Overcome Arm Dysfunction in Stroke
  Program: Spinal Cord and Musculoskeletal and Assistive Devices (SMAD)

  Disturbances in movement coordination are the least understood but often the most debilitating effects with respect to functional recovery following stroke. These deficits are expressed in the form of abnormal muscle synergies and result in limited and functionally disabling stereotypic movement patterns. The result is an abnormal coupling between shoulder abduction and elbow flexion, significantly reducing reaching range of motion or workspace when an individual lifts the weight of the impaired arm against gravity. In Phase I of this STTR, the investigator developed and tested the first prototype of the Arm Coordination Training 3-D system (ACT3D), which consists of a force-controlled robot combined with a Biodex System 3 seating system and a compact liquid crystal display (LCD). As part of Phase I, it was demonstrated that the ACT3D could be used to completely eliminate the weight of the arm or provide partial support of the limb during active reaching. The project also demonstrated that individuals with chronic stroke can be trained to overcome gravity-induced discoordination subsequently increasing the workspace of the paretic arm. During Phase II of this STTR, the results obtained in Phase I will be expanded upon by developing and building a greatly improved commercial product. Visit *http://www.devicelink.com/mpmn/archive/06/05/018.html* for more information.

- Hartman, Eric – R44HD055019 – customKYnetics, Inc., Versailles, Kentucky – Adaptive High Intensity Electrical Stimulation for Post-Surgical Rehabilitation
  Program: SMAD

  Recovery of quadriceps muscle force following post-surgical knee immobilization is a significant therapeutic goal associated with quality of gait and the ability to perform activities of daily living. Several studies from various research groups have shown that neuromuscular electrical stimulation (NMES), used in conjunction with a comprehensive post-surgical rehabilitation program, is a safe and highly effective method for achieving quadriceps strengthening. The most profound results have been demonstrated with use of a high-intensity NMES technique in which a few very strong isometric contractions of the quadriceps muscle were performed several times per week during a physical therapy session while the patient was seated on a biomechanical dynamometer. Efficacy of this technique has been demonstrated for individuals undergoing rehabilitation following surgical reconstruction of the anterior cruciate ligament; however, widespread clinical acceptance of the technique has been limited. This project is developing a novel rehabilitation system indicated for quadriceps strengthening during post-surgical knee immobilization; the system stabilizes the knee joint using an instrumented post-surgical knee brace and delivers stimulation by a high-output, portable NMES unit with autonomous, adaptive stimulation control capabilities.

- Veatch, Bradley – R44HD054091 – ADA Technologies, Inc., Littleton, Colorado – A Low-Cost Upper-Extremity Prosthesis for Underserved Populations
  Program: Behavioral Sciences and Rehabilitation Engineering Technologies (BSRT)

  The objective of this three-phase SBIR program is to create a complete upper-extremity prosthesis which can be manufactured and distributed on a large scale to enable disadvantaged amputees for whom few or no other viable rehabilitative options exist. Visit *http://www.adatech.com/default.asp* for more information.

- Greenwald, Richard – R44HD055715 – SIMBEX, LLC, Lebanon, New Hampshire – A Device to Monitor Toe Walking in Children with Cerebral Palsy
  Program: SMAD

  This project involves the development of a means for continuous monitoring and analysis of simple gait parameters in children with Cerebral Palsy outside the clinical laboratory and during normal daily activities. This device is intended to provide clinically useful outcomes data that are not currently available as well as critical diagnostic data for determining intervention timing. The proposed technology will supply objective, quantitative data to assess the severity of toe walking and its progression over time as the child develops. These data will also inform intervention strategies, which can be implemented to improve a patient's mobility. The key innovation is the development of a miniature, extremely low-power data acquisition/recording device, which can be worn unobtrusively by children with Cerebral Palsy during activities of daily living to measure ankle angle and center of pressure trajectories during ambulation.

For a complete listing of NCMRR-supported SBIR/STTR projects, visit:

- *NCMRR-supported projects for fiscal year 2007*
- *NCMRR-supported projects for fiscal year 2008*

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IN THE NEWS

Pediatric Medical Devices Workshop

Dr. Steven Hirschfeld, associate director for clinical research for NICHD, co-organized a workshop in partnership with other NIH Institutes, the Agency for Healthcare Research and Quality (AHRQ), the Food and Drug Administration (FDA), and about 20 professional and advocacy societies. The Pediatric Medical Devices: Development and Challenges workshop, held July 23, 2008, featured presentations and discussions from a wide range of stakeholders including patients, manufacturers, clinicians, regulators, scientists, and engineers.

Participants identified and discussed the following major issues: barriers and challenges, proposals for resources and process, clinical research needs, stakeholder sharing, and training and education.

The outcome of the workshop is a three-part plan with components from and activities for NIH, AHRQ, and FDA; the plan was be submitted to Congress in September 2008 in response to provisions of the Pediatric Medical Device Safety and Improvement Act of 2007. Dr. Hirschfeld is the formal NIH point of contact for pediatric device development and co-chairs a trans-NIH Pediatric Device Working Group. You can contact him at *hirschfs@mail.nih.gov*.

Support for Early Stage Investigators

Maintaining its robust biomedical research workforce is essential to helping the NIH achieve its mission of raising healthcare standards worldwide. Early stage investigators bring innovation and new perspectives into the research endeavors that enable the NIH to continue its groundbreaking work.

The agency's longstanding commitment to attracting and retaining the best new investigators, defined as someone who has not previously competed successfully for a significant NIH independent research award, led to the development of *New Investigator Programs* geared toward cultivating talent and allowing individuals to mature into world-class researchers. These programs have resulted in the recruitment of more than 1,600 new investigators in fiscal year 2007, more than 25 percent of all NIH-funded competing R01-equivalent awards.

In the future, the NIH will also focus attention on encouraging the transition into independent research careers by further developing these programs with a special focus on early stage investigators (those researchers who are within a set number of years of their terminal degree). This approach, patterned after the *NIH Director's New Innovator Award*, both supports singularly creative new investigators at an early career stage and stimulates highly innovative research that has the potential for significant impact. Visit *http://grants1.nih.gov/grants/new_investigators/pathway_independence.htm* for more information on one type of mechanism that focuses on transitioning new investigators to independent research careers.

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NCMRR Conference Calendar (Cont.)

- National Medical Rehabilitation Research Advisory Board—December 8-9, 2008

  The Board reviews and assesses federal research priorities, activities, and findings in rehabilitation research and makes recommendations to the director of the NCMRR and the Director of NICHD. The Board has a unique role in working with NCMRR staff to evaluate the relevance and effectiveness of existing research programs and in identifying opportunities for new directions. The Board is composed of clinicians, researchers, and consumer advocates with a broad range of expertise in medical rehabilitation and in the promotion of opportunities for people with disabilities, as well as ex-officio members from relevant federal agencies. Contact: Ralph Nitkin, Ph.D., (301) 402-4206. For further background, visit *http://www.nichd.nih.gov/about/overview/advisory/nmrrab/index.cfm*.

- ERRIS Grant Writing Workshop—January 13-17, 2009

  Unlike passive seminars on grant writing, participants selected for this workshop will come prepared to complete a grant proposal for submission to the NIH. The target audience for this workshop includes junior and mid-level faculty, in all medical rehabilitation disciplines, who are on the cusp of success in NIH-funded research. This workshop will provide the expertise and support to be successful at the national level in obtaining research grant support. Visit *http://erris.med.virginia.edu/workshop.htm* for additional information.

In the next *Innovations*