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Director's Message

So far, this year at NCMRR has been marked by three major themes: An improvement in pay lines for investigator-initiated applications; continued interest by the rehabilitation community in applying for grants; and persistence by applicants to NCMRR. The pay line for R01 grants this year is at the 15th percentile, a considerable improvement from last year's 10th percentile. In a significant policy shift, the pay line for R21 grants (i.e., high-risk, exploratory grants) is now identical to that for the R03s (i.e., small grants). Because the R21 mechanism is well suited to many pilot projects in rehabilitation research, applicants to NCMRR who have used this mechanism have done well this year. Although the pay lines for next year are not yet known and depend on congressional appropriations and NIH budget issues, we expect that the differential between R01 and R21 pay lines will continue, meaning

investigators will have a continued incentive to develop applications for the R21 mechanism. R21 grants provide \$275,000 in support of the



Michael Weinrich, M.D., Director, NCMRR

direct costs for research during a two-year period. The NIH has also placed particular emphasis on the need to fund new investigators, especially those submitting R01 applications; therefore the NICHD and other Institutes have established procedures to accomplish this goal.

The NCMRR received more than 600 applications for grant support so far this year, a figure comparable to last year's application level. It is particularly gratifying to see the success of investigators who resubmitted applications. The

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Hello Again!

We hope you have had an opportunity to read our first two e-updates (Fall-Winter 2005 and Summer-Fall 2006), which the Center created in response to requests for periodic updates. These e-updates help to further the NCMRR mission of fostering the development of scientific knowledge needed to enhance the health, productivity, independence, and quality-of-life of persons with disabilities. The NCMRR accomplishes this goal by supporting research on the daily functioning of people with disabilities. These e-updates provide a means of recognizing progress and disseminating information about the many funding opportunities and advances made in the field of medical rehabilitation as a result of NICHD funding.

This special installment of *Innovations* reviews some of the funding opportunities and resources available for new investigators, particularly rehabilitation clinicians and those interested in pursuing a research career in medical rehabilitation. This *Innovations* also highlights individual career development grant mechanisms, provides brief "How To" tips for submitting a grant application, and offers descriptions of some NICHD funding mechanisms. We also touch on institutional training grants and NCMRR networks. We hope that you will find this information helpful – Your feedback is appreciated (sheredoc@mail.nih.gov).

—Carol A. Sheredos, P.T., M.A., NCMRR

Director's Message

NCMRR staff enjoys working with investigators, providing feedback on ideas for new projects and helping them interpret the reviewers' critiques when their applications must be resubmitted. We expect that the number of targeted new initiatives issued by the NICHD will continue to be very limited in the coming years, and that funding for investigator-initiated research will continue to be the priority. NCMRR staff continue to work very closely with our colleagues at NIH to ensure that applications are assigned to the most appropriate Institutes and to develop co-funding plans whenever appropriate.

Please do not hesitate to call or e-mail NCMRR staff if you would like to discuss an idea for a grant application, if you have questions about the application or review process, or if we can help you in any way. The success of the NCMRR depends upon your success in writing applications.

Other significant items this year have included:

- ❖ An interesting meeting on the rehabilitation plateau, organized by Dr. Nitkin (see *A Research Agenda for Getting Beyond the Plateau: Promoting Recovery Through the Chronic Phase*); and
- ❖ The publication of a notice in the NIH Guide as part of a collaboration with the Centers for Medicare and Medicaid Services (CMS) (see *Information for Investigators Engaged in Medical Rehabilitation Research* in sidebar).

The report recently released by the Institute of Medicine (IOM), *The Future of Disability in America*, is also of note to those in the medical rehabilitation field and those interested in the NCMRR. Of the 14 members of the IOM committee that authored the report, six were current or past members of the National Advisory Board on Medical Rehabilitation Research (NABMRR), the NCMRR advisory body. In addition, Dr. Alan Jette, who is currently member of the NABMRR, chaired the committee.

—Michael Weinrich, M.D., Director, NCMRR

IN OTHER NEWS

Special Announcement: Information for Investigators Engaged in Medical Rehabilitation Research

The NCMRR, in conjunction with the Centers for Medicare and Medicaid Services (CMS), held a *Workshop to Develop a Research Agenda on Appropriate Settings for Rehabilitation* in February 2005. This notice (visit link above) resulted from the workshop and from discussions among CMS and NIH staff.

What is this notice and why is it important?

The intent of the notice is to inform investigators that CMS is genuinely interested in working with them to help enhance the rehabilitation evidence base. A designated CMS contact is interested in hearing your ideas about clinical studies; this contact will also advise you on designs for studies so that, to the extent permitted by law, the costs of participation are covered by the Medicare benefit. The NCMRR believes that its collaboration with CMS will be very useful for investigators as they develop ideas for research studies. Although the CMS is most interested in promoting randomized controlled trials, it is also willing to discuss any study design appropriate to clinical problems under investigation.



NCMRR 101

This section reviews the basics of the NCMRR, including its operating principles and research priorities.

Public Law 101-613 established the NCMRR in 1990 as a Center within the NICHD. The Center has its own advisory board—the National Advisory Board on Medical Rehabilitation Research (NABMRR)—consisting of 18 members who are clinicians, advocates, and researchers in the field of medical rehabilitation.

The Center is guided by its Research Plan, which was developed by the NABMRR in 1993. The Research Plan includes seven (7) priority areas of focus. These priority areas and examples of some funded grant topics are included below. In addition, the Center went through a planning process to develop its future directions as part of its latest report to the National Advisory Child Health and Human Development (NACHHD) Council, the NICHD's advisory body; you can view the Center's report at http://www.nichd.nih.gov/publications/pubs_details.cfm?from=&pubs_id=5049.

Improving Functional Mobility

- ❖ Coordination and control of movement
- ❖ Gait analysis and gait training
- ❖ Microbiological factors in contracture, recovery from injury
- ❖ Physical agents, surgical, and pharmaceutical treatments
- ❖ Body strength, flexibility, and endurance
- ❖ Respiratory control

Promoting Behavioral Adaptation to Functional Losses

- ❖ Psychosocial adjustment to disability
- ❖ Health promotion, wellness, and exercise
- ❖ Impact of disability on caregivers and family members
- ❖ Special issues for women with disabilities
- ❖ Aging with a disability
- ❖ Community participation of children and adults with disabilities
- ❖ Compensatory strategies for memory and cognitive deficits associated with some disabling conditions
- ❖ Sexuality

Assessing Efficacy and Outcomes of Medical Rehabilitation Therapies and Practices

- ❖ Outcomes Measures
- ❖ Interventions for urinary tract infections and bladder dysfunction
- ❖ Neuroimaging in stroke and traumatic brain injury (TBI)
- ❖ Treatment decision-making and access to health care
- ❖ Economic and social constraints
- ❖ Rehabilitation and recovery from hip fracture or total joint replacement

Developing Improved Assistive Technology

- ❖ Wheelchairs, seat cushions, and other durable medical equipment
- ❖ Development and application of virtual reality and other computer tools
- ❖ Improved design, fitting, and monitoring of orthotics and prosthetics
- ❖ Design of specialized recreational equipment and accessible facilities
- ❖ Neuroprostheses and microsensors for brain, peripheral nerves, or joints
- ❖ Functional electric stimulation (FES)
- ❖ Therapeutic footwear
- ❖ External control of bowel and bladder function
- ❖ Communication aids and computer interfaces
- ❖ Improved environmental controls

Understanding Whole-Body System Responses to Physical Impairments and Functional Changes (Including Secondary Conditions Relating to Medical Rehabilitation)

- ❖ Motor cortex changes associated with stroke and brain injury
- ❖ Spinal cord plasticity and regeneration
- ❖ Muscle atrophy, dysfunction, and decreased bone density
- ❖ Causes of pain and potential treatment strategies

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NCMRR 101

Understanding Whole-Body System Responses to Physical Impairments and Functional Changes (Continued)

- ❖ Cognitive and behavioral changes (e.g., attention, memory)
- ❖ Reproductive function and sexual response
- ❖ Comorbidities and mortality
- ❖ Skin ulceration and tissue healing
- ❖ Tissue/biomaterial interface
- ❖ Sympathetic and parasympathetic function
- ❖ Training strategies involving robotics and computers

Developing More Precise Methods to Measure Impairments, Disabilities, and Societal and Functional Limitations

- ❖ Demographics
- ❖ Archives of disabilities
- ❖ Brain imaging for diagnostics, prognoses, and functional mapping
- ❖ Improved measures of well-being, satisfaction, and quality-of-life
- ❖ Special assessments for children and women with disabilities
- ❖ Measurement of musculoskeletal function and dysfunction
- ❖ Risk factors associated with disability
- ❖ Ethnographic and socioeconomic analyses

Training Research Scientists in the Field of Medical Rehabilitation

- ❖ Individual fellowships for postdoctoral fellows
- ❖ Institutional training grants for graduate students and postdoctoral scientists
- ❖ Mentored awards specifically targeted to those in rehabilitation fields
- ❖ Mentored awards to expose clinicians to research opportunities
- ❖ National development and training program for Physical Medicine and Rehabilitation (PM&R) departments

It is the last priority area on which this issue of *Innovations* is focused.

The NCMRR uses the following disability model:



Based on this model, the Center assigns its applications to five major programs:

- ❖ Behavioral Sciences and Rehabilitation Technology (BSRT)
- ❖ Biological Sciences and Career Development (BSCD)
- ❖ Traumatic Brain Injury and Stroke Rehabilitation (TSR)
- ❖ Pediatric Critical Care and Rehabilitation (PCCR)
- ❖ Spinal Cord and Musculoskeletal Disorders and Assistive Devices (SMAD)

Although the greatest training and career development responsibility rests in the BSCD Program, all of the Center's programs offer career development awards and awards to new investigators.

To view the NCMRR's projects for the last two fiscal years, select a link below:

- ❖ [NCMRR Projects for Fiscal Year 2007](#)
- ❖ [NCMRR Projects for Fiscal Year 2006](#)

National Network of Medical Rehabilitation Research Infrastructure Cores

The NCMRR supports a network of regional centers or cores to provide research infrastructure for young faculty at the formative stage of their careers. The six centers, supported by R24 grants, provide state-of-the-art research facilities, mentorship, pilot grants, and other opportunities. These networks are particularly useful for junior investigators who are seeking collaborations in the following areas: Robotics and engineering; genomics and proteomics; muscle physiology; neuroregeneration; and cognitive rehabilitation and brain imaging.

More details about the infrastructure program are available at <http://www.ncmrr.org> and at <http://www.nichd.nih.gov/research/supported/rehabinfra.cfm>.

What's Hot in Rehabilitation Research?

Some research topics that are particularly common in medical rehabilitation research are listed below.

Disorders & Conditions

- ❖ Neurotrauma (e.g., TBI, spinal cord injury, amputation)
- ❖ Stroke & other hypoxic/ischemic insults
- ❖ Neurodevelopmental disorders (e.g., cerebral palsy, post-polio syndrome)
- ❖ Neurodegenerative disorders (e.g., multiple sclerosis, parkinsonism, muscular dystrophy)
- ❖ Non-neuromuscular disorders (e.g., arthritis, cancer)

Clinical Issues

- ❖ Weakness & paralysis, spasticity, tremors
- ❖ Movement disorders: Balance, coordination, gait
- ❖ Pain & sensory dysfunction
- ❖ Autonomic dysreflexia
- ❖ Bowel & bladder dysfunction

Secondary Conditions & Complications

- ❖ Musculoskeletal changes: Muscle atrophy, osteoporosis
- ❖ Skin ulceration & breakdown
- ❖ Connective tissue dysfunction
- ❖ Increased susceptibility to infection
- ❖ Increased morbidity & mortality
- ❖ Risk of recurrence

Cognitive & Behavioral Issues

- ❖ Executive function (decision making)
- ❖ Attention (both temporal and spatial)
- ❖ Cognition & memory
- ❖ Visuospatial perception
- ❖ Communication disorders
- ❖ Aggression
- ❖ Depression
- ❖ Drug addiction & alcoholism

Neurological Strategies & Mechanisms

- ❖ Prevention & reducing recurrence
- ❖ Improved diagnosis & prognosis
- ❖ Reducing initial pathology
- ❖ Minimizing collateral damage
- ❖ Reducing inflammation & scarring
- ❖ Promoting regeneration & neuroplasticity
- ❖ Adaptation & activity-mediated changes

Therapeutic Approaches

- ❖ Addition of exogenous genes, cells, tissues
- ❖ Trophic factors & pharmacological agents
- ❖ Activity-mediated changes
- ❖ Promoting angiogenesis
- ❖ Therapeutic exercise & cardiovascular fitness
- ❖ Gender differences & role of hormonal factors

Children & the Developing Brain

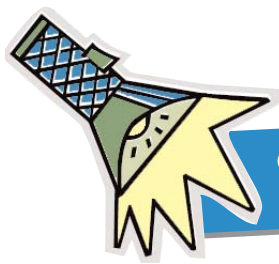
- ❖ Increased vulnerability, as well as increased potential for plasticity & recovery
- ❖ Growth trajectory: Effects of rapidly changing physical & behavioral repertoire
- ❖ Disorders as impediment to future development; concept of “Critical Periods”
- ❖ Children's reactions to trauma & how they differ from adult reactions: Physically, psychologically, emotionally
- ❖ Unique sensitivity to & effects from pharmacological & other therapeutic approaches

Bioengineering Research

- ❖ Orthotics, prosthetics, other assistive devices
- ❖ Neuroprosthetic devices
- ❖ FES & transcranial magnetic stimulation
- ❖ Brain imaging (e.g., fMRI, PET)
- ❖ Robotics to improve therapy, improve diagnoses, & assist mobility
- ❖ Wheelchairs & other mobility aids, seating technology
- ❖ Environmental controls
- ❖ Speech, language, & communication aids

Assessments & Outcomes

- ❖ Importance of working across the domains of pathology, function, and/or disability
- ❖ Improved diagnostic & prognostic measures
- ❖ Assessment of function & disability
- ❖ Participation (family, community, employment, education, sports & recreation)
- ❖ Quality-of-life measures
- ❖ Goals of the person with a disability may differ from those of the family, caregiver, and/or clinician; these goals may change over time
- ❖ Healthcare constraints & policy issues



Spotlight: For New Researchers

Pathways to Becoming a New Researcher in Medical Rehabilitation

Why Rehabilitation Research?

The medical rehabilitation research field has an acute need for new ideas and new investigators that result from several issues unique to the field. For example, rehabilitation research:

- ❖ Currently lacks evidence-based studies to justify therapeutic and other treatment approaches, a fact that is especially troubling in light of today's managed care environment.
- ❖ Includes unknown or unsubstantiated opportunities for progress, even in the chronic phase.
- ❖ Needs to coordinate multidisciplinary teams and resources, as demonstrated by the financial and budgetary implications of disability and chronic disease.
- ❖ Needs to focus on the individual person, rather than on the cell/tissue/organ that are the focus of other research endeavors.
- ❖ Addresses longer time frames than other systems research.
- ❖ Considers functional outcomes, participation, and quality-of-life issues in a way that other fields do not.
- ❖ Investigates the interactions among subjects with their environments.
- ❖ Generally involves more complex relationships among several levels of conceptual analysis and studies that cross professional disciplines.
- ❖ Can provide guidance and goal-setting direction to address the often-conflicting goals among the person with a disability, the family, the caregiver, the children, etc.
- ❖ Assists in developing treatments in real-world settings (e.g., home, community)—*Ecological Validity*, meaning it is appropriate to real-world settings.
- ❖ Includes analyses that tend to cross the domains of pathology, impairment, function, and/or disability.

How can a clinician develop his or her research career?

Research is VERY different from Clinical Practice! In research, the investigator must go beyond associative links and confirmatory links to seek causative, not just correlative, relationships and opportunities to control/isolate variables. (S)he must learn to develop mechanistic hypotheses and

predictions and be able to design experiments that critically challenge those hypotheses to acquire conclusive results. The successful researcher should be able to consider other interesting patient populations in which (s)he can contrast treatments and outcomes.

A clinician (e.g., therapist, physician) who is considering a career in research should ask him/herself the following:

- ❖ What skills do you possess and in what skills are you proficient? What does your *Curriculum Vitae* project?
- ❖ Who do you want to be as a researcher? What additional skills will get you there?
- ❖ What types of training experiences (e.g., courses, research skills, patient work, assessments) will get you there?
- ❖ What mentorship do you need?

Rehabilitation Clinicians Make Good Researchers

Rehabilitation clinicians often make good researchers because of several characteristics, listed below, that are desirable in addressing issues unique to the rehabilitation field:

- ❖ Clinicians in the rehabilitation field treat “function” and “disability” rather than specific diseases or organ systems.
- ❖ Clinicians know how to integrate material from the psychosocial, physiological, and clinical fields—They see the “bigger picture.”
- ❖ Clinicians understand the role of environmental factors as supports or barriers to the goals of rehabilitation.
- ❖ Clinicians already focus on clinically significant and ecologically relevant goals.
- ❖ Clinicians are motivated, collaborative, and persistent.

Practical Considerations

Once you have decided to pursue a research career, it is important to:

- ❖ Understand the expectations of your academic department and institution.
- ❖ Think realistically about productivity (i.e., publications), especially early in your career.
- ❖ Develop a mixed portfolio: mostly sure-fire studies with a few high-risk excursions.
- ❖ Develop a stable base of grant funding.
- ❖ Guard your time and collaborate effectively.

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Pathways to Becoming a New Researcher in Medical Rehabilitation

Grantsmanship and Peer Review

Developing a Career Development Research Proposal

(See The Career Development Program for more information on these types of awards.)

The career development application (“K” award) is like an autobiography. Use it to show that you are a good candidate. Articulate your career goals, both short- and long-term. Discuss the appropriateness and commitment of your mentor(s). Discuss your experiences and needs as an investigator, and propose additional didactic experiences, such as courses, workshops, and sabbaticals. Discuss your research project (and develop it with your mentor). Remember that it is important to focus on the operating process rather than on a technique, patient population, or therapeutic approach. A few general topic examples:

- ❖ GOOD: Focus is on a specific mechanism or goal of the research.
 - ◆ Enhancing compliance in gait therapy
 - ◆ Exercise therapies to reduce obesity
 - ◆ Developing ecologically valid measures of support and longitudinal change
- ❖ BAD: Subjects are too broad.
 - ◆ Reducing disability in stroke
 - ◆ Upper-limb function in the workplace
 - ◆ Improving participation for people with spinal cord injury
 - ◆ Revising the SF-36® and the Functional Independence Measure (FIM)

The Importance of Preliminary Studies

Preliminary studies:

- ❖ Demonstrate your competence, commitment, and standards.
- ❖ Demonstrate the feasibility of your approach.
- ❖ Potentially address theoretical hurdles.
- ❖ Demonstrate your familiarity with patient populations, which enhances an impression of your competence.
- ❖ Documents your success with difficult or highly specialized techniques, demonstrates your personal mastery, and shows support from collaborators with appropriate expertise.

Hypotheses and Aims

It is important to understand that an empirical comparison of two or more treatments merely establishes which one is better, but provides little guidance on why and how to improve that treatment. A hypothesis-driven comparison suggests a dimension along which the better treatment could be further modified and improved.

The hypothesis should define *who* should benefit most from *which* treatment “ingredients” with respect to *what* procedures and under what circumstances or conditions.

Most rehabilitation treatments are multifaceted. What is the “active ingredient” in the proposed therapy and how does it act? Set up your experimental design to isolate that particular “ingredient.” Contrast that “ingredient” with appropriate alternative or control treatments. Justify dosing (e.g., frequency, intensity, and duration). Standardize the delivery of the treatment or intervention. Control for heterogeneity and other variables.

Subject Population

Given the research question, what is the most appropriate subject population(s)? Are the subjects defined by the pathology or the resulting disability? Provide explicit inclusion and exclusion criteria.

What are appropriate contrast or control groups? Justify the number of subjects: **Power calculation!**

Discuss recruitment strategies and management of attrition. Address the relevant aspects of human subjects research (e.g., informed consent, risks, privacy, diversity, etc.)

Confounding Variables

- ❖ Beware: Subjects may be concurrently seeking other treatments or medications!
- ❖ Be sure to address subject compliance—Are they following protocols?
- ❖ Outside activities may affect outcomes.
- ❖ Consider possible natural recovery processes.
- ❖ If yours is a retrospective study, self-selection of subjects to particular treatment groups may bias your outcomes.

Assessments and Outcomes

- ❖ Evaluators should be blinded to experimental treatment of the subjects.
- ❖ Outcome measures should be appropriate to the level of the intervention.
- ❖ Use measures that are clinically significant, validated, and meaningful.
- ❖ Avoid ceiling or floor effects.
- ❖ Consider follow-up assessments to evaluate persistence of treatment effects.

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Pathways to Becoming a New Researcher in Medical Rehabilitation

Do's and Don'ts

- ❖ DON'T wait for a specific Request for Application (RFA) if you have a good idea, but
- ❖ DO look for any RFAs or program announcements (PAs) that may apply to your idea.
- ❖ DO contact program officers at NIH for advice on your idea.
- ❖ DO check Institute research priorities to choose the best "home" for your application.
- ❖ DO write a cover letter specifying the range of expertise you feel is necessary to review your application.
- ❖ DO review Study Section rosters.
- ❖ DO express your ideas clearly and concisely in your proposal.
- ❖ DO address protection of human subjects and inclusion of both sexes, as well as of minorities and children.
- ❖ DO use your pilot data to its best advantage.
- ❖ DO write your specific aims with great care.
- ❖ DO organize your application so reviewers can easily read it.
- ❖ DO document availability of required specialized expertise.
- ❖ DO ask colleagues to review your proposal. If possible, find a colleague who has served on an NIH Study Section to critique your proposal.
- ❖ DO find an appropriate mentor.
- ❖ DON'T GIVE UP!

(Thanks to Nancy Shinowara, Ph.D., and Ralph Nitkin, Ph. D., for their input and assistance in developing *Pathways to Becoming a New Researcher in Medical Rehabilitation* topic.)



From the Desk of the NIH Director

Elias A. Zerhouni, M.D., Director, NIH

In his latest newsletter—From the desk of the NIH Director—Dr. Zerhouni highlights the NIH's efforts and focus on new investigators, including:

- ❖ The NIH will maintain a level of new investigators in 2007 at a level comparable to the average of the most recent five years.
- ❖ The NIH will support, at a minimum, 1,500 first-time investigators on competing R01 awards in fiscal year 2007. NIH will devote \$91 million to this effort.
- ❖ Awards will be selected based on the scientifically creative and innovative approaches that meet the mission of the Institute or Center.
- ❖ The NIH established a new award within the Roadmap called the Director's New Innovator Award to support new investigators who propose highly innovative research projects with the potential for exceptionally great impact on biomedical or behavioral science.
- ❖ The NIH expects to make at least 14 Director's New Innovator Awards, each for five years and up to a total of \$1.5 million in direct costs, in September 2007.
- ❖ The NIH offers the NIH Director's Bridge Award (NDBA) to provide continued but limited funding for established grantees who have submitted a competing renewal grant application that describes a highly meritorious project, but that has fallen below the pay line. The NDBA provides one year of additional support to enable the PI to continue research while strengthening a resubmission application. Eligible applications were nominated by the Institute; applications were not accepted. All NICHD nominations were funded.

To read the entire newsletter, visit

<http://www.nih.gov/about/director/newsletter/Spring2007.htm>.

Other Resources for New Rehabilitation Researchers

- ❖ The Enhancing Rehabilitation Research in the South (ERRIS) workshops. These workshops include five days of lectures, mentoring, and small group discussions, as well as one-on-one access to some of the NCMRR's known investigators and mentors. The most recent workshop was held January 17-21, 2007.
- ❖ NIH New Investigators Web site
- ❖ The Center for Scientific Review (CSR) has a video depicting a Study Section (peer review) on its Web site at <http://www.drg.nih.gov/Video/Video.asp>.

NIH Funding 101

NOTE: This section is meant to consolidate information regarding NICHD funding for the edification of new investigators. It is not a complete accounting of NICHD funding. Official policies and details regarding all NIH funding mechanisms are available at <http://grants1.nih.gov/grants/oeer.htm>.

The Training Program

Training awards are designed to support the research training of scientists for careers in the biomedical and behavioral sciences, and to help professional schools to establish, expand, or improve programs of continuing professional education. Training awards include individual fellowships (F) and institutional training grants (T).

Fellowships

- ❖ Individual Pre-doctoral Kirschstein National Research Service Award (NRSA) Fellowships (F31). At the NICHD, this award is reserved for promoting diversity in health-related research. It is meant to support graduate (doctoral) training, but only for applicants who are from under-represented minority populations or who have a disability.
- ❖ Individual Postdoctoral Kirschstein NRSA Fellowships (F32). This award is, as it says, for those applicants who are at the postdoctoral level.
- ❖ NIH National Research Service Awards for Senior Fellows (F33). This award is for experienced scientists who wish to make major changes in the direction of their research careers, or who wish to broaden their scientific backgrounds by acquiring new research capabilities.

Institutional Training Grants

These awards are for educational institutions who train and mentor current and future scientists. New investigators may want to explore the various institutions that receive NIH support for training programs.

- ❖ Ruth L. Kirschstein NRSA Institutional Research Training Grants (T32). These awards are for institutions that are mentoring graduate students and/or postdoctoral fellows. The objective of the NRSA program is to provide pre-doctoral and postdoctoral research training opportunities for institutions to support individuals interested in pursuing research careers in biomedical, behavioral, and clinical research. The awards are renewable and last for up to five years.

The Career Development Program

The NICHD supports career development through various “K” mechanisms, which provide salary and minimal laboratory support for individuals who need “protected time” at critical periods of their research careers. Most of these mechanisms are for new clinical investigators and require 75-percent commitment to research activities, but there is also support for mid-level investigators who are “re-tooling” their careers.

K Mechanisms (Individual)

(For information on all K mechanisms, visit <http://grants2.nih.gov/training/careerdevelopmentawards.htm>.)

- ❖ K01: Mentored Research Scientist Development Award. Applicant must have an advanced clinical degree (e.g., M.D.). This award is for those seeking an additional period of sponsored support in a targeted area (e.g., medical rehabilitation), especially if their career has been interrupted by family obligations or illness. Funding is for three to five years.
- ❖ K02: Independent Research Scientist Development Award. This mechanism is intended to help develop the careers of independent scientists who already have NIH research grants. The mechanism provides for a period of intensive research focus not longer than five years.
- ❖ K08: Mentored Clinical Investigator Award. The award focuses on investigators who are clinically trained (e.g., M.D.) and who are getting into basic research careers (versus the K23 mechanism below, which focuses on patient-oriented research).
- ❖ K22: Career Transition Award. This mechanism is for investigators who spend at least two years in research training in the NICHD Division of Intramural Research to facilitate their successful transition to an extramural institution as independent investigators with two years of research support.
- ❖ K23: Mentored Patient-Oriented Research Development Award. Like the K08 award, this mechanism focuses on investigators who are clinically trained (e.g., M.D.). But this award is intended for those who work in patient-oriented research, i.e., research conducted with human subjects or on materials of human origin.
- ❖ K25: Mentored Quantitative Research Career Development. This mechanism applies to quantitative scientists, engineers, or mathematicians who are changing their focus to life science research.

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K Mechanisms (Individual) (Continued)

- ❖ **K25: Mentored Quantitative Research Career Development.** This mechanism applies to quantitative scientists, engineers, or mathematicians who are changing their focus to life science research.
- ❖ **K99/R00: NIH Pathway to Independence (PI) Award.** This newly established opportunity enables promising postdoctoral scientists to receive both mentored and independent research support from the same award. This mechanism provides up to five years of support consisting of two phases: The initial phase provides one to two years of mentored support; the second phase includes up to three years of independent support, contingent upon securing an independent research position. (Award recipients are expected to compete successfully for independent R01 support from the NIH during the career-transition award period.) For more information, visit the New Investigators Program Web site, or the Pathway to Independence Award Web site.
- ❖ **K12: Multidisciplinary Clinical Research Career Development Programs.** In addition to the individual “K” career development mechanisms discussed above, the NCMRR has two national programs that support career development in specific fields. These programs use the K12 mechanism. Dr. John Whyte leads a program to mentor researchers trained in PM&R; Dr. Jonathan Dean leads a program to mentor pediatric intensivists. The NCMRR is about to launch two additional K12 programs, which will be targeted to emerging researchers in allied health fields.
- ❖ **Academic Research Enhancement Award (AREA) Grants (R15).** Intended for schools that have not been major recipients of NIH funds, especially when projects engage undergraduate students. Budgets are up to \$150,000 direct costs plus applicable Facilities & Administrative (F&A)/indirect costs for the entire project period of up to three years; the award is renewable.
- ❖ **Research Project Awards (R01).** Support investigator-initiated applications, which constitute the majority of basic and clinical research at NIH. Focus is on a specific set of aims of the study. Budgets are typically \$150,000 to 250,000 annual direct costs. Investigators may request up to five years funding; the award is renewable.
- ❖ **Small Business Grants: Small Business Technology Transfer (STTR) Grants (R41/R42, Fast Track) & Small Business Innovation Research (SBIR) Grants (R43/R44, Fast Track).** Support innovative research that has potential for commercialization. For Phase I, budget is approximately \$100,000 (one year); for Phase II, \$750,000 (two years). SBIR and STTR eligibility criteria differ for Principal Investigators (PI) versus small businesses.

For additional information regarding specific career development grants, visit

<http://www.nichd.nih.gov/funding/position/index.cfm>.

Additional information is also available at

<http://www.nichd.nih.gov/funding/mechanism/index.cfm#career>

or by contacting Dr. Ralph Nitkin at rn21e@nih.gov.

Research Grants (R Awards)

New investigators should also consider the development of research applications, especially in the later stages of their K awards. Some of the more common NIH grant mechanisms are included below. The choice of which mechanism might be most appropriate can be discussed with a Program Officer. For more information on these or other grant mechanisms, visit the NIH Office of Extramural Research (OER) Home Page or the Funding Mechanisms used by the NICHD page.

- ❖ **Small Research Grants (R03).** Support pilot studies (feasibility), innovative research, high-risk studies, or development of new methodology or technology. New investigators especially encouraged. A total project period of up to two years and a budget for direct costs of up to two \$25,000 modules or \$50,000 per year may be requested. Not renewable and not to be used to supplement funded projects
- ❖ **Exploratory/Developmental Grants (R21).** Support development of novel research activities in categorical program areas. Studies should break new ground or extend previous discoveries toward new directions or applications. Budgets are up to a total direct cost of \$275,000 for a combined two-year award period.

Special Funding Opportunity: Promoting Diversity in Health-Related Research

To promote diversity, the NIH provides for supplements to already-funded research grants to support qualified individuals at *any* career level (i.e., high school, undergraduate, graduate, postdoctoral, or beginning investigators).

These grants are intended for individuals who:

- ❖ Are from an underrepresented minority
- ❖ Come from disadvantaged backgrounds
- ❖ Have disabilities

Supplements cannot be used to support individuals who are already on research grants; candidates must be a U.S. citizen or green card. Contact the NIH Project Officer of the already-funded research grant for more information.

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

Featured in each issue of *Innovations*, this section normally focuses on specific SBIR/STTR (R41, R43, R44) projects funded by the NICHD through the NCMRR. In keeping with the theme of this special installment, this section features some SBIR and STTR projects that are supported by grants awarded to new investigators across all NCMRR programs. Narrative project descriptions are excerpted from applications or progress reports.

SBIR/STTR Projects by New Investigators

- ❖ Johnson, Richard D. – R41HD053159 – Long-Distance Nerve Regeneration via Processed Allografts in a Caprine Model
Program: BSCD

Every year in the United States, several million people suffer serious peripheral nerve injury, which is a major source of disability, impairing the ability to move muscles or to feel normal sensations. To treat these problems, more than 1 million procedures were performed in the United States in 2002, totaling more than \$10 billion in medical costs. Peripheral nerve injuries are undertreated primarily because repair options are limited and ineffective. The overall aim of this project is to determine the feasibility of testing nerve allografts in a novel goat animal model to allow for functional and histomorphometric assays of axon regeneration efficacy.

- ❖ Levi, Daniel S. – R41HD047495 – Pediatric Thin-Film Nitinol (TiNi) Catheter-Based Heart Valve
Program: PCCR

Heart-valve replacement in pediatric patients continues to require an invasive surgical approach, including cardiopulmonary bypass, a midline sternotomy, and significant rehabilitation. The recovery after these surgeries creates a disruption in the socialization and development of affected children. The development of a heart valve amenable to placement in children with transcatheter technology, rather than with surgery, could allow children to avoid this process. Although percutaneous valve replacement has become a reality in adults and teenagers, transcatheter heart valves suitable for use in neonates and younger children do not exist. TiNi, a titanium-nickel alloy, has shape-memory and super-elastic characteristics. It is biocompatible, very strong, and resists fatigue. An expertise in the production of very thin-film TiNi suitable for use in catheter-based artificial heart valves has been developed. An entirely nitinol catheter-based heart valve will be designed for use in small children and tested in vitro and in an animal model. (*Levi D. A Thin-Film Nitinol Covered Stent. United States Patent and Trademark Organization Provisional Patent, 2004. US 60/643,407.*)

- ❖ Varghese, Oomman K. – R44HD049233 – A Transcutaneous Gas Sensor for Non-Invasive Diagnosis of Necrotizing Enterocolitis (NEC)
Program: PCCR

The outcome of this work will be a non-invasive, real-time sensor system for detecting certain diseases that can be diagnosed by monitoring the variation in excreted transcutaneous gases. Such a sensor system could prove to be of tremendous utility for improving early diagnosis and, hence, care management of diseases such as acidosis and NEC.

- ❖ Deutsch, Judith E. – R41HD054261 – Virtual Reality-Augmented Cycling for Post-Stroke Mobility Rehabilitation
Program: SMAD

The project is relevant to post-stroke individuals who have experienced inactivity and a loss of walking ability. It will allow post-stroke individuals to exercise in a safe way to reverse the deficits produced by the stroke that interfere with their ability to fully participate in their societal roles that require efficient walking. The company is developing virtual reality-augmented systems to help clinicians convert their existing exercise equipment to provide intensive, task specific functional re-training. The concept is to build tools that will enhance existing clinical resources, rather than requiring the purchase of new equipment. The Virtual Reality-Augmented Cycling Kit (VRACK), being developed for this Phase I application, includes advances in the integration of hardware, software, and existing equipment with current knowledge of neural plasticity and motor learning.

- ❖ Snyder, Geoffrey – R43HD055777 – Spring-Loaded Assistive Devices for Locomotor Therapy
Program: SMAD

This research explores the feasibility of using simple spring-loaded devices to help patients who have gait disorders re-learn how to walk during treadmill locomotor therapy. The devices replace the manual assistance with leg movements that is currently provided by physical therapists. These devices may allow patients to receive more extensive and, thus, effective treadmill walking therapy at a greatly reduced financial cost.

Do you have any questions for NCMRR staff?

For example, do you need assistance identifying an appropriate funding mechanism for your application? If so, please e-mail us at sheredoc@mail.nih.gov. Thank you!

NCMRR WORKSHOP

A Research Agenda for Getting Beyond the Plateau: Promoting Recovery through the Chronic Phase

To challenge the concept of a recovery “plateau,” the NCMRR held a workshop titled, A Research Agenda for Getting Beyond the Plateau: Promoting Recovery Through the Chronic Phase, on March 6-7, 2007. The workshop included presentations from 11 distinguished speakers from the rehabilitation community. The Interagency Committee on Disability Research (ICDR) also contributed support for this workshop.

While current biomedical research and health services focus primarily on the acute phase of recovery, increasing evidence suggests that significant treatment opportunities and functional recovery can occur in the months or even years following traumatic injury or the onset of a chronic disease state. Moreover, the notion of a “plateau” may be inappropriate because recovery is not just a linear process, but rather a continuous effort to manage a trajectory, which is challenged by episodes of disability, secondary conditions, and relapse.

The framework for the workshop and subsequent discussion called attention to moving beyond support primarily focused on the acute phase toward support for recovery throughout the chronic phase.

Initial background presentations, listed below, encouraged participants to consider some of the physiological, behavioral, and psychosocial substrates that may interact with therapeutic strategies, environmental factors, outcome measures, and health service constraints to promote functional recovery:

- ❖ Neurological and musculoskeletal substrates of recovery
- ❖ Clinical issues of the acute phase
- ❖ Promoting cognitive and behavioral rehabilitation
- ❖ Assessing outcomes
- ❖ Cardiovascular fitness and health
- ❖ Environmental factors and trajectories of recovery
- ❖ Community support and health promotion
- ❖ Community neurorehabilitation
- ❖ Preventing secondary conditions
- ❖ Health policy perspective
- ❖ The CMS perspective

Pathology, plasticity, recovery, and adaptation are overlapping processes, and research in these areas seeks key windows of opportunity to advance functional recovery. In some neurological conditions, the cellular and molecular level events following injury may create a “sick” neuron, tottering on the brink of programmed cell death or apoptosis. The acute phase of neurological injury and this prolonged time-course of secondary pathologies may provide opportunities for long-term interventions and other biomedical therapies. Processes such as sprouting, generation of new neurons, induction of growth-inhibiting and growth-promoting environments, involvement of cytokines, and reorganization processes are all potential targets to facilitate systemic improvements. At the functional level, further research may build on theories of re-learning, pharmacological interventions, and other integrated therapies to promote recovery.

The ability to recover is influenced not only by the internal cascade of injury, but also by the external environment and available resources. Cognitive and behavioral deficits can also impact delivery of therapy and participation. The workshop also explored clinical treatment strategies, appropriate outcome measures, environmental supports and barriers, and health service constraints such as policy, management, and medical economics. External influences that may impact recovery include: Complexity of managing clinical care and changing trends, in the length of stay, including the cost effectiveness of extending recovery versus re-admission. These influences may constrain the ability to deliver appropriate therapies, possibly even shifting the strategy to providing compensatory rather than restorative therapy. In addition, some conventional care strategies may provide inadequate task repetition, which may not exploit the ideal timing or capacity for learning.

Exercise and general health are necessary to maintain fitness; unfortunately, conventional care approaches may not provide enough opportunity for exercise and aerobic conditioning. Cardiovascular de-conditioning and poor metabolic health may contribute to poor recovery and further functional limitations, compounding the risks for secondary disabilities and recurrent events. Therefore, a rehabilitation setting or environment that encourages community outreach and promotes exercise across all phases of recovery may be advantageous by improving access to resources, promoting physiological and psychological health, and, most importantly, supporting individual empowerment. Psychological factors, such as perceived self-efficacy, social support, and cultural, political, and economic resources, also affect recovery, compliance, and participation.

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A Research Agenda for Getting Beyond the Plateau: Promoting Recovery through the Chronic Phase

Proper outcome measures are essential for assessing progress and functional recovery. The workshop participants emphasized the differences between statistically significant versus clinically meaningful outcomes, as well as the varying perspectives of patients, clinicians, and third-party payers. Patient perception is driven by personal progress rather than clinical meaningfulness; clinicians tend to focus on empirical and evidence-based measures; third-party payers are attentive to quantifiable outcomes, costs, and quality-of-life. The workshop also highlighted treatment variables, such as age, duration of the condition, dose, timing, and intensity, and relevant outcome measures, all of which suggest a need to integrate primary care and rehabilitation approaches with state and federal policies and also to build social and community networks.

The NCMRR was pleased to have participation of CMS in this workshop to provide insight on the acute-care medical model in which payments differ depending on the treatment setting (e.g., a nursing home, in-patient rehabilitation facility, or an outpatient program). CMS staff expressed the desire to provide the care that people need, instead of paying primarily based on the recovery setting. They indicated that they hope to partner with the research community to gather the evidence that could substantiate better patient placement, more appropriate care, and improved fund allocations and health care utilization.

Understanding the time course and complexities of recovery and adjustments to chronic conditions would have significant value in the design of clinical trials, rehabilitation outcomes, and assessing the appropriate levels of care. A research agenda that supports rehabilitation throughout the chronic phase of recovery would reduce secondary conditions, enhance health maintenance, and promote recovery in individuals with chronic disabilities.

*- Johnalyn Lyles, Ph.D.
Program Analyst, NCMRR*



NCMRR Conference Calendar

- ❖ The Medical Home Model for Children after Life-Threatening Illness or Injury—March 13-14, 2007.
- ❖ NCMRR Training Meeting—October 4-6, 2007, in conjunction with the American Congress of Medical Rehabilitation/American Society of Neuroradiology meeting in Washington, D.C. Contact: Ralph Nitkin at NitkinR@mail.nih.gov. For information on past training meetings conducted by the NCMRR, visit: http://www.nichd.nih.gov/about/meetings/2002/ncmrr_leadership.cfm or http://www.nichd.nih.gov/about/org/ncmrr/program_bscd/index.cfm.
- ❖ The Medical Home Model for Children after Life-Threatening Illness or Injury Working Group—March 11-12, 2008. Contact: Tammara Jenkins, (301) 435-6837

In the next *Innovations*

- ❖ *The SBIR/STTR Corner*
- ❖ *In the News*
- ❖ *Conference Calendar*
- ❖ *Special Section on Rehabilitation Engineering*

