Overview of NIH, Peer Review and Support of Medical Rehabilitation

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National Center for Medical Rehabilitation Research (NCMRR)

National Institute of Child Health and Human Development (NICHD)

National Institutes of Health (NIH)

- Overview of the NIH and NCMRR
- The NIH application and review process
- Winning over Reviewers
- NIH Grant Mechanisms
- Research Resources and NIH contacts

The NIH is made up of 28 Institutes, Centers, Divisions:

OD	NIDA	NCI	NIEHS
NEI	NIGMS	NHLBI	NIMH
NHGRI	NINDS	NIA	NINR
NIAAA	NLM	NIAID	CIT
NIMAS	CSR	NIBIB	FIC
NIDCR	NCRR	NIDDK	CC

National Center for Medical Rehabilitation Research (NCMRR)

- Established 1990 by Public Law 101-613
- MISSION: To foster development of scientific knowledge needed to enhance the health, productivity, independence, and quality of life of persons with disabilities
- Located within the National Institute of Child Health and Human Development (NICHD)

Other NIH Institutes that support Medical Rehabilitation

NINDS (Neurological Disorders & Stroke) e.g., spinal cord & brain injury, cerebral palsy

NIAMS (Arthritis & Musculoskeletal & Skin) e.g., muscle physiology, bone & skin

NIA (Aging) e.g., geriatric populations

NINR (Nursing Research)

NCI (Cancer)

NHLBI (Heart, Lung & Blood) e.g., exercise, cardiovascular

NIDCD (Deafness & Communication Disorders) e.g., speech, balance

NCCAM (Complementary and Alternative Medicine)

NIBIB (Biomedical Imaging and Bioengineering)

Applying to the NIH

Majority of funds go to *investigator-initiated* proposals - rather than applications developed in response to program initiatives

Funding for medical rehab research is largely driven by the number of quality applications NIH receives

NIH accepts proposals in three annual cycles, typically: February 1, June 1, October 1

From submission to funding: at least 9 months

Support is provided to *institutions* in name of investigator

Applying to the NIH, continued

The NIH gets over 15,000 applications per round (three rounds per yr)

Funding of research is largely driven by the peer-review system

Each Institute has a limited amount of funds to support research in their areas of interest

Therefore . . .

Life is tough.

But, we are here to help you.

How an Application becomes a Grant – or at least tries

15,000 applications arrive at NIH Central:

"Receipt and Referral"

Which Institute(s) is interested in this area of research?

Which study section has the most appropriate expertise?

Cover letters?

Center for Scientific Review (CSR)

The “Judiciary Branch” of the NIH

Over 100 standing study sections in following areas:

AIDS and Related Research
Biochemical Sciences
Biophysical and Chemical Sciences
Brain Disorders and Clinical Neuroscience
Cell Development and Function
Endocrinology and Reproductive Sciences
Hematology
Infectious Diseases and Microbiology
Molecular, Cellular, & Developmental Neurosci
Nutritional and Metabolic Sciences
Respiratory Sciences
Renal and Urological Sciences
Surgery, Radiology and Bioengineering;
Behavioral and Biobehavioral Processes
Biology of Development and Aging
Bioengineering Sciences and Technologies
Cardiovascular Sciences
Digestive Sciences
Genetic Sciences
Immunological Sciences
Integrative, Functional, & Cognitive Neurosci
Musculoskeletal, Oral and Skin Sciences
Oncological Sciences
Risk, Prevention and Health Behavior
Health of the Population

Also Institute Peer-review

Some study sections also in Institutes to review:

- **Requests for Applications (RFAs) and other one-time initiatives**
- **Training and career-development applications**
- **Other specialized support mechanisms**

Function similar to peer-review panels of CSR

Application gets assigned to a Study Section

Study section has about two dozen reviewers,
plus ad hoc expertise as needed
Scientific Review Administrator (SRA):
Checks applications for administrative issues
Makes reviewer assignments
Avoids “conflicts of interest” both +/-
Typical workload for study section:
50-80 applications per round

Prior to the Review Meeting

Each application assigned to three reviewers:
primary, secondary, reader

But other unassigned reviewers also read applications

Sometimes, additional outside opinions sought

Assigned reviewers prepare detailed written critiques prior to the meeting (which become part of the “summary statement”)

At the Review Meeting

Triage process: Which applications are in the "upper half" and merit further discussion?

Triaged applications do not receive a priority score, but still get full benefit of written critiques

For "upper half" applications:

- **Assigned reviewers discuss their critiques**
- **Rest of committee joins in discussion**
- **Assign priority score: 100 (best) – 500 (worst)**

Later, priority score gets translated into percentile

Meanwhile, back at the Institutes . . .

Applications with summary statements get second level of review from Institute Advisory Councils

Limited amount of funds to support applications:

- **based on percentiles, program priorities, etc.**

Outcomes:

- **Award notice**
- **Revise**
- **Back to the drawing board**

Talk to your Program official!

Grantsmanship

"There is no amount of grantsmanship that will turn a bad idea into a good one, but there are many ways to disguise a good one."

- William Raub, former Deputy Director, NIH

Winning over Reviewers

- **Write to your likely peer-review audience; Use a style that is interesting and readable**
- **Raise an interesting question (basic or clinical) and propose a potential solution**
- **Develop a focused application, with explicit goals**

Winning over Reviewers

- **Provide a mechanistic basis or theoretical framework for your approaches**
- **Discuss your proposal in the context of previous studies, current practice**

Winning over Reviewers

- Include sufficient detail on techniques, outcome measures, plans for analysis
- If appropriate, describe collaborations and include letters
- Include appropriate statistical expertise, even in the planning stages

Winning over Reviewers

- **Define your subject population (inclusion/exclusion criteria)**
- **Include power calculation to justify numbers of subjects (or animals) in each group**
- **If research involves Human Subjects:**

  Approval from your local Initial Review Board (IRB)

  NIH policies on inclusion of women, of minorities, and of children

Grantsmanship: Making your Case in Peer Review

- **Make sure your application is neat, accurate, and complete**
- **Follow NIH guidelines for page limits, type size, margins, etc.**

NIH Review Criteria

- **Significance**
- **Approach**
- **Innovation**
- **Investigator**
- **Environment**

Preparing the NIH Application

- **Abstract**
- **Background/Introduction**
- **Specific Aims**
- **Progress and Preliminary Data**
- **Experimental Design**
- **Significance**
- **Other assurances**
- **Budget**

Cover letters

- One-page letter addressed to the NIH Referral Officer
- Briefly state goals of your proposal
- Requested Institute(s) Assignment
- Appropriate study section (visit the CSR web site for expertise and rosters)

Resubmission: if at first you don't succeed . . .

- Only two more revisions after initial submission
- Make sure you understand the message in the summary statement; talk to NIH staff?
- Three pages of Introduction for your response; address each concern raised by reviewers
- Do not expand the proposal, unless you were directed to add experiments by the critique
- Keep the overall tone polite and collegial; maybe you were not clear enough
- No grant is perfect, use this as opportunity to improve and update your application

NIH Grant Mechanisms

- **Research grants**
- **Training and Career Development**

Research Project Award: R01

- **Investigator-initiated applications**
  (majority of basic and clinical NIH funding)
- **Focus on specific set of aims**
- **Budget: no boundaries**
  but typically $150-250,000 per year
- **May request up to 5 years; Renewable**

Small Grants: R03 and R21

- **Pilot studies (feasibility); innovative research; high-risk; new methodology or technology**
- **New investigators especially encouraged**
- **Budgets $100,000 / $275,000 per year (direct costs) over two years**
- **Not renewable; not to be used to supplement funded projects**

AREA (Academic Research Enhancement Award): R15

- **Schools that have not been major recipients of NIH funding**
- **Especially projects that engage undergraduate students**
- **Up to 3 years, aggregate budgets up to $100,000 direct costs, Renewable**

Small Business Tech Transfer (STTR, R41/42)
Small Business Innovation Res (SBIR, R43, R44)

Innovative research, potential for commercialization

- **STTR: Phase I: $100,000 (1 year)**
  Phase II: $500,000 (2 years)
- **SBIR: Phase I: $100,000 (6 months)**
  Phase II: $750,000 (2 years)

Special Research Initiatives

- **Program Announcements (PA)**
  Highlights Institute(s) interest in specific area
- **Request for Applications (RFA)**
  One-time set aside for applications in specific area
- **Request for Proposals (RFP)**
  One time set aside for specific product (contract)

Training & Career Development

- **Individual Fellowships**
  Graduate students (F31) or Postdoc (F32)
- **Institutional Training Grants (T32)**
  Department Support graduate and/or Postdocs
- **Career Development Mechanisms**
  New investigator in specific fields or
  Clinician getting into research
  Mentored research (3-5 yrs @ 75% effort)
  Application process may vary across Institutes

Mentored Research Scientist Development Award (K01)

**Clinical trained in targeted area*
and have advanced degree (e.g., PhD)**

***NICHD is currently targeting:**
Medical Rehabilitation
Population research
Child abuse and neglect

Mentored Clinical Scientist (K08)

Clinically trained individual (e.g., MD), getting training in *basic* research

Mentored Patient-oriented Research Career Development Award (K23)

Clinically trained individual (e.g., MD), getting training in *clinical* research

Midcareer Investigator Award in Patient-Oriented Research (K24)

Supports mentoring of clinical researchers

(To make someone a better mentor)

Mentored Quantitative Research Career Development Award (K25)

Quantitative or Engineering background getting into biomedical Research

Supplements to already funded NIH grants

To add qualified individuals at any level (high school through investigator) who:

- **are from under-represented minorities**
- **have disabilities**
- **re-entering research after family obligations**

Contact NIH program director of funded grant

Useful NIH Web sites

NIH Home page: www.nih.gov

National Center for Medical Rehab (in NICHD) www.nichd.nih.gov/about/ncmrr/ncmrr.htm

Neuroscience at the NICHD: www.nichd.nih.gov/neuroscience/funding.cfm

CRISP (searchable database of all NIH-funded grants): www.commons.cit.nih.gov/crisp/

Useful NIH Web sites

NIH Guide (research initiatives, policy): www.grants.nih.gov/grants/guide/index.html

Center for Scientific review (study section descriptions and rosters): www.csr.nih.gov

The HIPAA Privacy Rule and Research: http://privacyruleandresearch.nih.gov/

NIH Loan Repayment Program: http://www.lrp.nih.gov/

Info on grant writing, peer review, and funding

"Everything you wanted to know about the NCI Grant process but were afraid to ask"

http://www3.cancer.gov/admin/gab/02gpb/nci_grants_bk.pdf

"Answers to Frequently asked Questions about NIH Grants"

http://grants1.nih.gov/grants/funding/giofaq.htm

"Tips for New Applicants" from NIGMS: http://www.nigms.nih.gov/funding/tips.html

Specific information for bioengineers: http://www.nibib.nih.gov/research/investigators.htm

NCMRR Research Networks

- **Four regional research networks**
- **Multidisciplinary research cores, information transfer, new project development**
- **Help with networking and developing proposals**

Medical Rehabilitation Research Networks

Midwest: Center for Advanced Research in Neurorehabilitation (CARN)

- Consultations to support studies of rehabilitation in CNS dysfunction
- Training in robotics, biomechanics, and human-machine interaction

Website: http://marvin.smpp.nwu.edu/

Email: w-rymer@nwu.edu

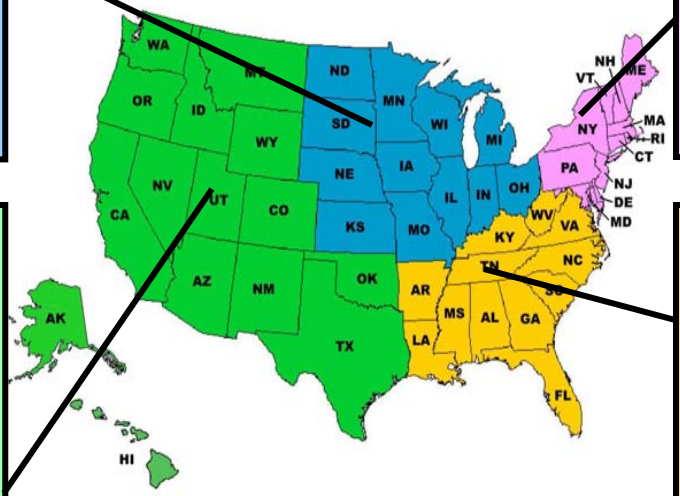
Tel: (312) 238-3919

Northeast: Cognitive Rehabilitation

- Clinical trials core to centralize subject recruitment and screening
- Consultation and methodological development of functional neuroimaging in cognitive rehabilitation research
- New research outpatient clinic to host cognitive rehabilitation studies

Email: jwhyte@aehn2.einstein.edu

Tel: (215) 456-5925



RehabNet-West: Experimental Design and Functional Imaging

- Workshops and Consultations on Experimental Design and Statistics
- Consultation and Pilot studies in Functional Neuroimaging at UCLA
- Funding for Pilot Projects in the West

Website: http://rehabnetwest.washington.edu

Email: rehabw@u.washington.edu

Tel: (206) 543-3674

Enhancing Rehabilitation Research in the South (ERRIS)

- Expertise in quantification methodologies
- Facilitation of inter-institutional research
- Assistance in development, design, and funding
- Application of technology for research collaboration

Website: http://erris.med.virginia.edu

Email: ERRIS@virginia.edu

Tel: (434) 924-0245

Funded by NCMRR to enhance the quality of rehabilitation research

You are encouraged to contact NCMRR Staff . . .

- Behavioral Sciences & Rehabilitation Technologies - Louis Quatrano, PhD
- Biological Sciences and Career Development - Ralph Nitkin, PhD
- Traumatic Brain Injury and Stroke Rehabilitation - Beth Ansel, PhD CCC SLP
- Pediatric Critical Care and Rehabilitation - Carol Nicholson, MD, FAAP
- Spinal Cord and Musculoskeletal Disorders and Assistive Devices - Nancy Shinowara, Ph.D.
- Director, NCMRR: Michael Weinrich, M.D.

Other NIH Institutes supporting Medical Rehabilitation

NINDS (Neurological Disorders and Stroke) e.g., spinal cord & brain injury, cerebral palsy
Daofen Chen, 301-496-1917 email: dc342b@nih.gov
NIAMS (Arthritis & Musculoskeletal & Skin Diseases) e.g., muscle physiology, bone & skin
James Panagis, 301-594-5055 email: jp149d@nih.gov
NIA (Aging) e.g., geriatric populations
Chhanda Dutta, 301-435-3048 email: cd23z@nih.gov
NINR (Nursing Research)
Claudette Varricchio, 301-402-6423 email: cv9h@nih.gov
NCI (Cancer)
Ann O'Mara, 301-402-5336 email: ao45s@nih.gov
NHLBI (Heart, Lung & Blood) e.g., exercise, cardiovascular
Denise Simons-Morton, 301-435-0377 email: ds56h@nih.gov
NIDCD (Deafness & Communication Disorders) e.g., speech, balance
Jeffery Sklare, 301-496-1804 email: ds104i@nih.gov
NCCAM (Complementary and Alternative Medicine)
Richard Nahin, 301-496-4792 email: rn8p@nih.gov
NIBIB (Biomedical Imaging and Bioengineering)
John Haller, 301-451-4780 email: jh586j@nih.gov

And Beyond the NIH

National Institute on Disability & Rehabilitation Research (NIDRR)

e.g., disability and societal interactions

Joel Mykelbust 202-401-2071 email: joel_myklebust@ed.gov

Center for Disease Control and Prevention (CDC)

e.g., prevention, secondary complications

Donald Lollar, 770-488-7094 email: DCL5@CEHOD1.em.cdc.gov

Veterans Affairs (VA)

e.g., treatment of Veterans: stroke, SCI, psychosocial issues

Patricia Dorn, 202-254-0261 email: patricia.dorn@hq.med.va.gov

Dept of Defense, e.g., bioengineering, assistive devices, robotics

Ravi Athale, 703-696-2237 email: rathale@DARPA.MIL

And Foundations . . .