

Overview of NIH, Peer Review and Support of Medical Rehabilitation

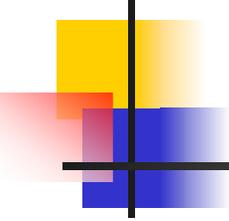
Ralph Nitkin, Ph.D.

National Center for Medical
Rehabilitation Research (NCMRR)

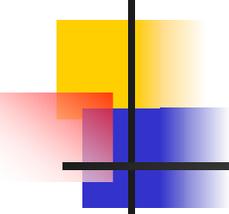
National Institute of Child Health and
Human Development (NICHD)

National Institutes of Health (NIH)



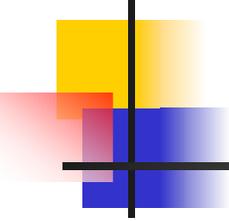


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- Overview of the NIH and NCMRR
 - The NIH application and review process
 - Winning over Reviewers
 - NIH Grant Mechanisms
 - Research Resources and NIH contacts



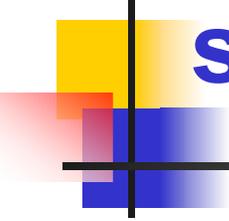
The NIH is made up of 28 Institutes, Centers, Divisions:

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)

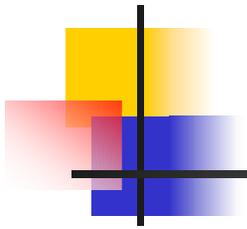
NCI (Cancer)

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

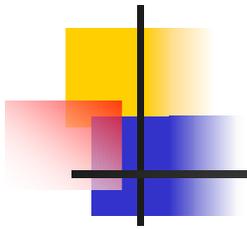
Majority of funds go to *investigator-initiated* proposals - rather than applications developed in response to program initiatives

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

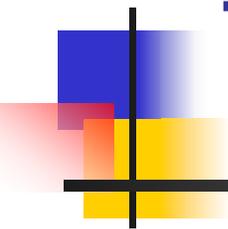


Applying to the NIH, continued

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

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

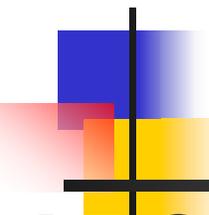
Each Institute has a limited amount of funds to
support research in their areas of interest



Therefore . . .

Life is tough.

But, we are here to help you.



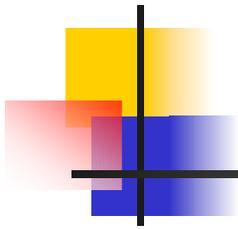
How an Application becomes a Grant – or at least tries

**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?

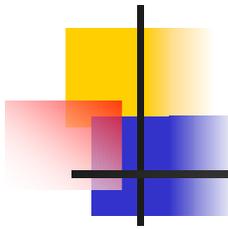


Center for Scientific Review (CSR)

The “Judiciary Branch” of the NIH

Over 100 standing study sections in following areas:

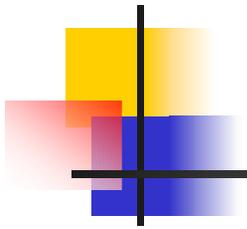
- | | |
|--|--|
| AIDS and Related Research | Behavioral and Biobehavioral Processes |
| Biochemical Sciences | Biology of Development and Aging |
| Biophysical and Chemical Sciences | Bioengineering Sciences and Technologies |
| Brain Disorders and Clinical Neuroscience | Cardiovascular Sciences |
|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



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):

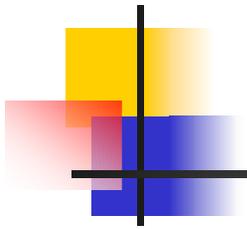
Checks applications for administrative issues

Makes reviewer assignments

Avoids “conflicts of interest” both +/-

Typical workload for study section:

50-80 applications per round



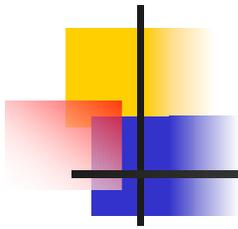
Prior to the Review Meeting

**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

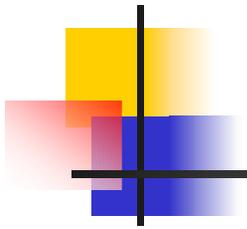
For “upper half” applications:

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.**

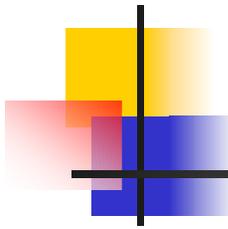
Outcomes:

Award notice

Revise

Back to the drawing board

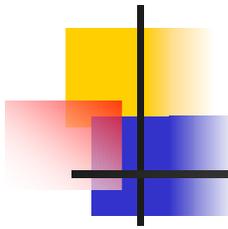
Talk to your Program official!



Grantsmanship

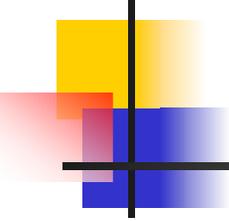
"There is no amount of grantsmanship that will turn a bad idea into a good one, but there are many ways to disguise a good one."

- William Raub, former Deputy Director, NIH



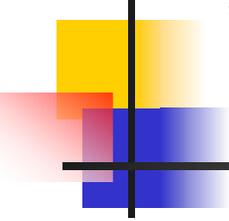
Winning over Reviewers

- **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**



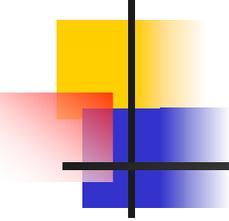
Winning over Reviewers

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



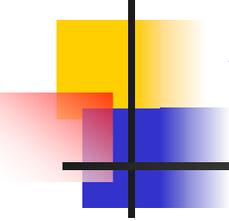
Winning over Reviewers

- **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**



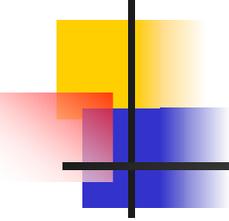
Winning over Reviewers

- **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**



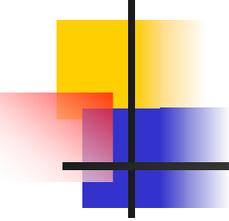
Grantsmanship: Making your Case in Peer Review

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



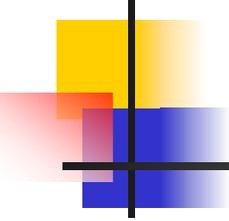
NIH Review Criteria

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



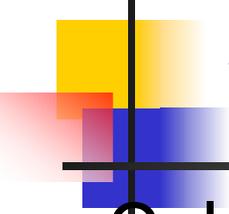
Preparing the NIH Application

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



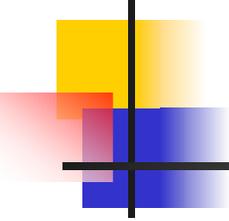
Cover letters

- **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)**



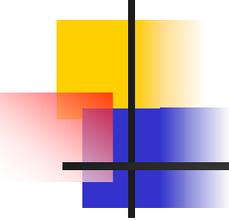
Resubmission: if at first you don't succeed . . .

- 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



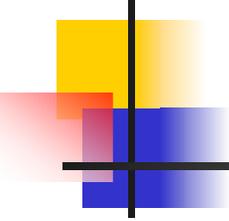
NIH Grant Mechanisms

- **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**



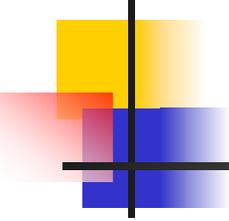
Small Grants: R03 and R21

**Pilot studies (feasibility); innovative research;
high-risk; new methodology or technology**

New investigators especially encouraged

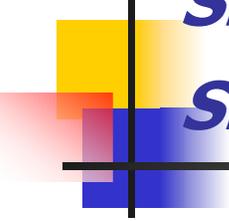
**Budgets \$100,000/ \$275,000 per year
(direct costs) over two years**

**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**

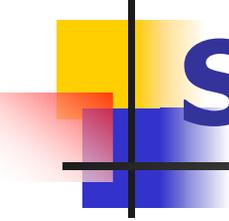


Small Business Tech Transfer (STTR, R41/42)

Small Business Innovation Res (SBIR, R43, R44)

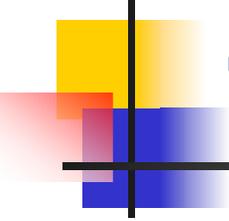
Innovative research, potential for commercialization

- **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

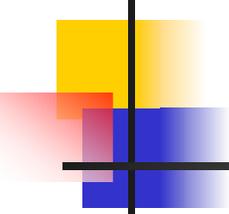
- **Career Development Mechanisms**

 - New investigator in specific fields or

 - Clinician getting into research

 - Mentored research (3-5 yrs @ 75% effort)

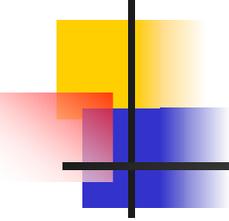
 - Application process may vary across Institutes



Mentored Research Scientist Development Award (K01)

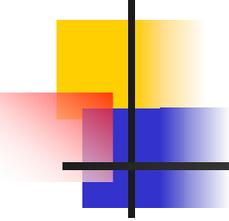
**Clinical trained in targeted area*
and have advanced degree (e.g., PhD)**

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



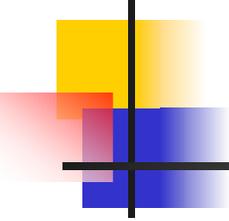
Mentored Clinical Scientist (K08)

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



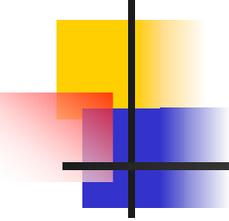
***Mentored Patient-oriented Research
Career Development Award (K23)***

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



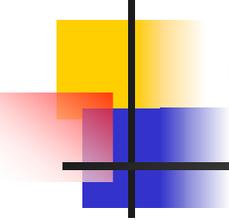
***Midcareer Investigator Award in
Patient-Oriented Research (K24)***

**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**

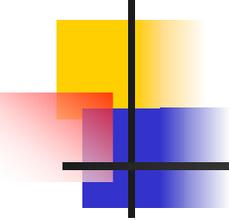


Supplements to already funded NIH grants

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



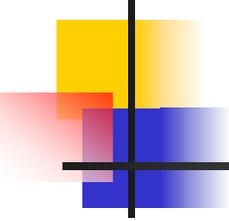
Useful NIH Web sites

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.commonscit.nih.gov/crisp/



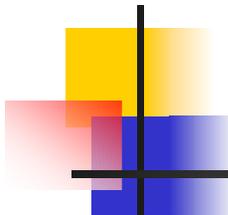
Useful NIH Web sites

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”

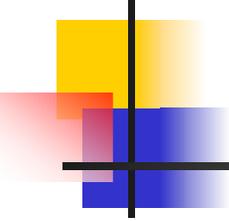
<http://grants1.nih.gov/grants/funding/giofaq.htm>

“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**

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

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

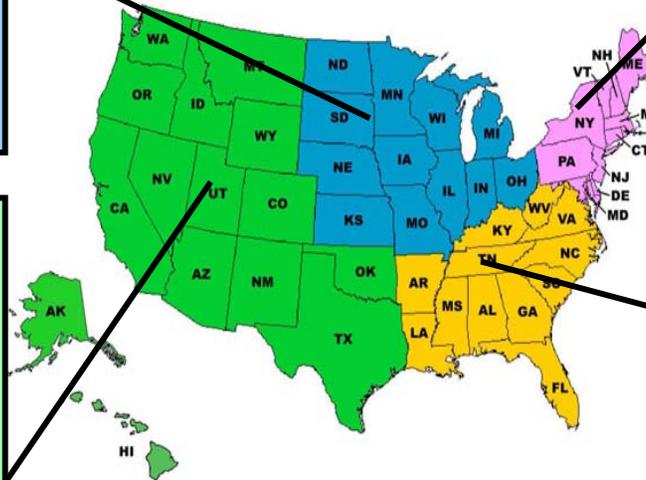
Website:

<http://rehabnetwest.washington.edu>

Email: rehabw@u.washington.edu

Tel: (206) 543-3674

Medical Rehabilitation Research Networks



Funded by NCMRR to enhance the quality of rehabilitation research

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

Enhancing Rehabilitation Research in the South (ERRIS)

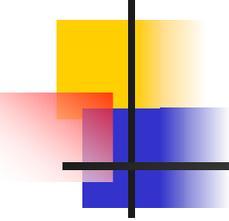
- Expertise in quantification methodologies
- Facilitation of inter-institutional research
- Assistance in development, design, and funding
- Application of technology for research collaboration

Website:

<http://erris.med.virginia.edu>

Email: ERRIS@virginia.edu

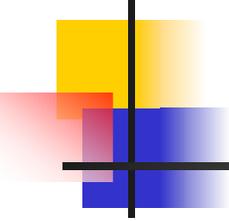
Tel: (434) 924-0245



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

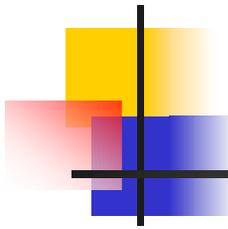
NCI (Cancer)
Ann O'Mara, 301-402-5336 email: ao45s@nih.gov

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 . . .