Supporting research that is the foundation for disease diagnosis, treatment, and prevention

NIH 101
Boston – January 2012

Michael Bender, Ph.D., *Program Director*
Division of Genetics and Developmental Biology
AND
Mona Trempe, Ph.D., *Scientific Review Officer*
Office of Scientific Review
National Institute of General Medical Sciences

NIH 101

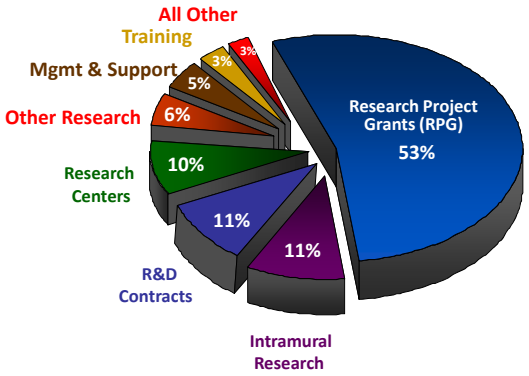
1. NIH and NIGMS Mission
2. Grant Mechanisms
3. Forms & Information
4. Grantsmanship and Resources
5. Review Process and Funding

Mission and Budget

NIGMS

NIH is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.

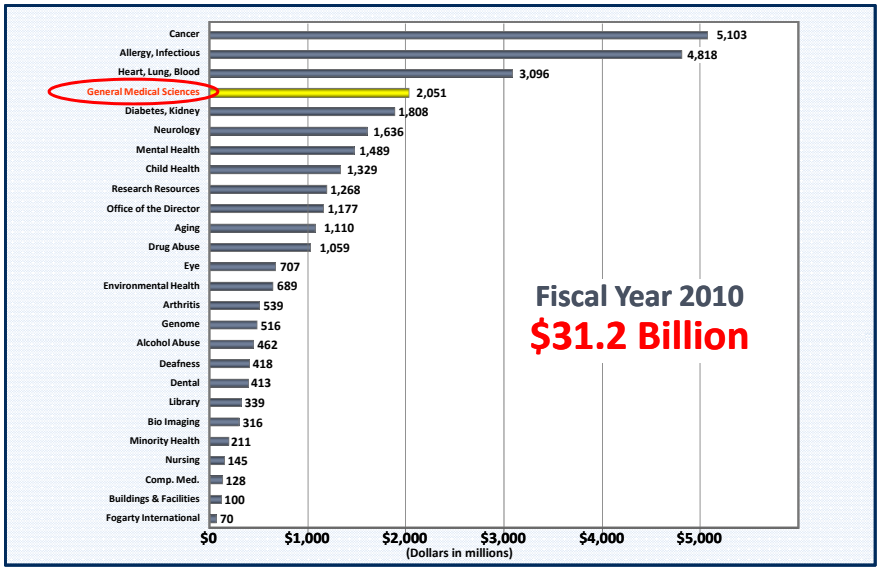
Annual Budget
$31.2 Billion
Fiscal Year 2010



Institute Funding (2010)

NIGMS

Direct responsibility for funding research and training relevant to their mission.

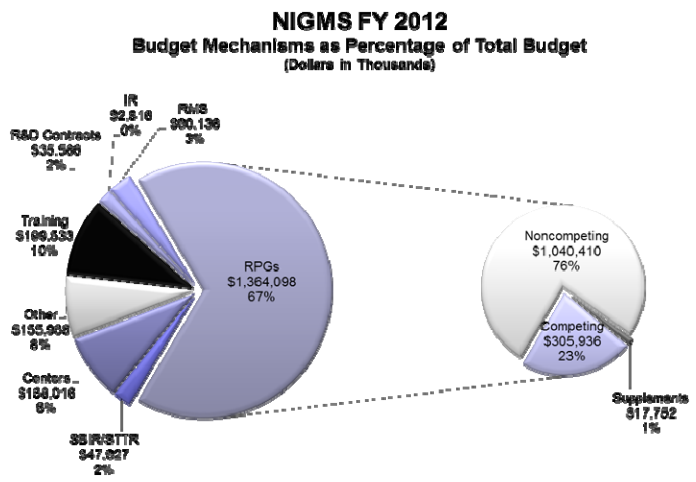


NIGMS Mission

The NIGMS mission is to support research that increases understanding of life processes and lays the foundation for advances in disease diagnosis, treatment, and prevention.

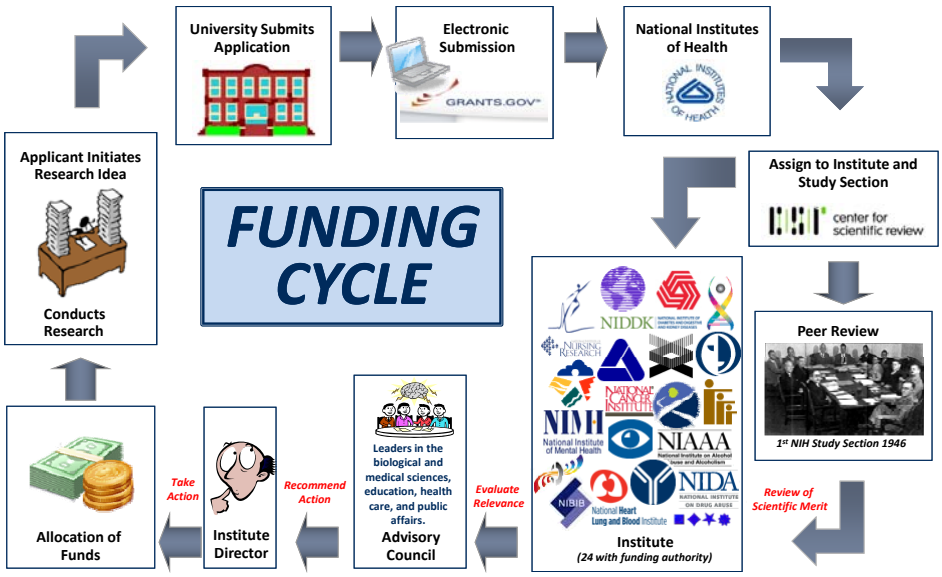
NIGMS also provides leadership in training the next generation of scientists to assure the vitality and continued productivity of the research enterprise.

NIGMS Budget Distribution



Submission & Award Process

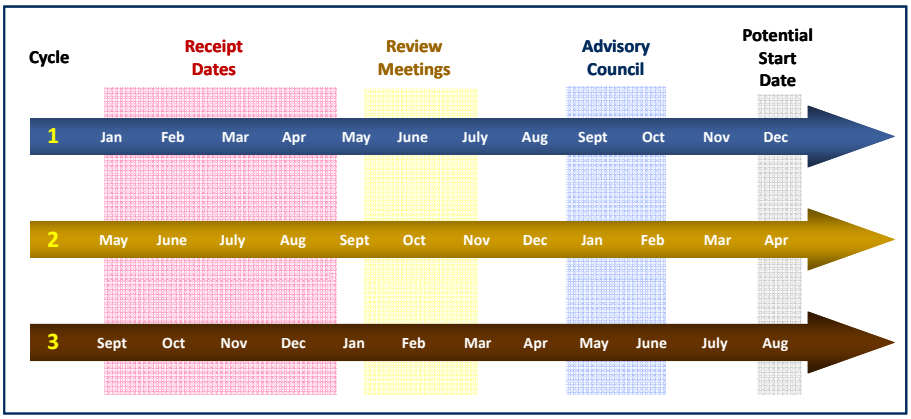
NIGMS



Receipt, Review & Award Cycles

NIGMS

3 Overlapping Funding Cycles Per Year



"F" Mechanism

NIGMS

NRSA Fellowship Awards

F30	**Individual Predoctoral Fellowship for MD/PhD** *8 participating institutes*
F31	**Predoctoral Fellowship to Promote Diversity** *21 participating institutes* *To support doctoral candidates from underrepresented groups (ethnic, disabilities, disadvantaged)*
F31	**Individual Predoctoral Fellowship** *8 participating institutes*
F32	**Individual Postdoctoral Fellowship** *21 participating institutes*
F33	**Individual Senior Fellowship** *15 participating institutes*

Characteristics:

- Not all Institutes participate in each mechanism
- Apply with mentor/sponsor
- Eligibility: U.S. Citizen or permanent resident
- Length: Up to 5 years support pre-doctoral; 3 years postdoctoral
- Stipend, tuition and institutional allowance
- Payback Service Obligation

"K" Mechanism

NIGMS

Career Development Awards

K01	**Mentored Research Scientist Development Award** *16 participating institutes* *Usually for Ph.D.'s in basic research*
K02	**Independent Scientist Award** *11 participating institutes*
K05	**Senior Scientist Award** *Additional time & effort support for researcher with R01 award*
K07	**Academic Career Award**
K08	**Mentored Clinical Scientist Development Award** *For clinicians to get basic laboratory research training*
K12	**Mentored Clinical Scientist Program Award**
K22	**Career Transition Award**
K23	**Patient-Oriented Research Career Development Award**
K24	**Mid-Career Patient-Oriented Research Award**
K99/R00	**Pathway to Independence Award** *22 participating institutes* *1-2 year mentored phase followed by 3 year independent phase*

"R" Mechanism

NIGMS

Research Awards

R01 Research Project Grant
- *Primary funding mechanism for investigator initiated research*
- *Up to 5 years and $500K per year* (prior required approval for projects greater than $500K).
- Transformative R01s (T-R01) – Special Roadmap Program

R03 Small Research Grant Project
- *Up to 2 years and $50K per year*
- *Not all ICs support this mechanism*

R15 Academic Research Enhancement Award (AREA)
- *Small-scale health-related research projects at eligible domestic institutions*
- *Up to 3 years and $300K total direct costs*

R21 Exploratory Development Research Grant
- *Foster the introduction of novel scientific ideas, model systems, tools, agents, targets and technologies*
- *Break new ground or extend previous discoveries toward new directions or applications*
- *Up to 2 years and $275K total direct costs*

R41/R42 Small Business Technology Transfer Grant (STTR)

R43/R44 Small Business Innovation Research Grant (SBIR)

Mechanisms of Interest to New Investigators

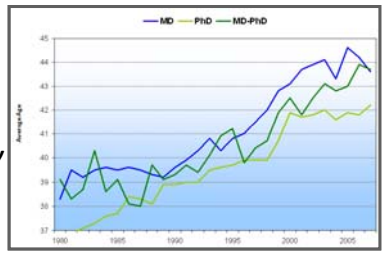
NIGMS

- **K awards (K01, K08, K22, K23, K25)**
- **Small grant (R03)**
- **Exploratory/developmental grant (R21)**
- **NIH Director's New Innovator Award (DP2, $1.5M/5 years)**
  - Exceptionally innovative research with potential for significant impact
  - Open to new investigators within 10 years of terminal degree (early stage investigators)
  - Preliminary data optional
- **NIEHS Outstanding New Environmental Scientist Award (ONES, R01, $1.625M/5 years)**
  - Outstanding early stage scientists who are committed to research in the mission of NIEHS
  - Open to new investigators within 10 years of terminal degree (early stage investigators)
  - One application per school or college within a university

New Investigators

NIGMS

- **New and Early Stage Investigator Policies**
  grants.nih.gov/grants/new_investigators
- **Definition**
  A principal investigator who has not previously competed successfully for a significant NIH independent research award.



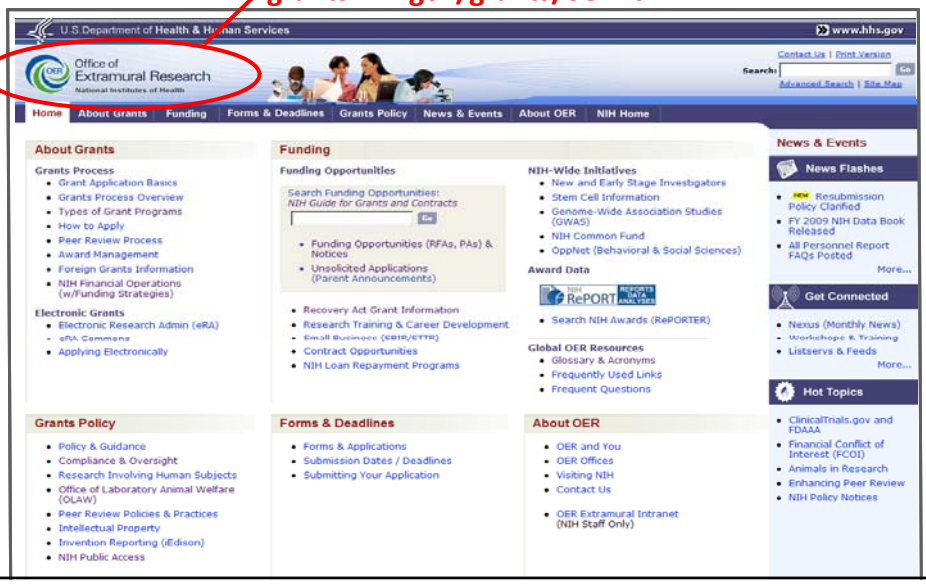
Average age of first R01 award

- **Designations**
  - Early Stage Investigator (ESI): Within 10 years of receiving terminal degree
  - New Investigator (NI): No record of significant independent support
- **Commitment to New Investigators**
  - Over the past three years about 20% of all R01 awards have gone to new investigators.
  - Institutes maintain success rates for new investigators - better paylines
  - Requested award length may be given to new investigators by institutes
  - Separate clustering during review

Everything is here, *but you may still want to try* Google

NIGMS

grants.nih.gov/grants/oer.htm



NIH Guide for Grants and Contracts

NIGMS

- ***Official notification of NIH policies, notices and availability of funds***
- ***Contains all Funding Opportunity Announcements (PAs/RFAS) for new or ongoing interest from one or more Institutes in supporting research, training or resources.***
- ***Sign up to receive weekly NIH Guide updates***

grants.nih.gov/grants/oer.htm

Program Announcement (PA)

- Addresses a broad category of research
- No set-aside budget
- Submit on regular receipt dates
- Regular review criteria for mechanism of application

Request for Applications (RFA)

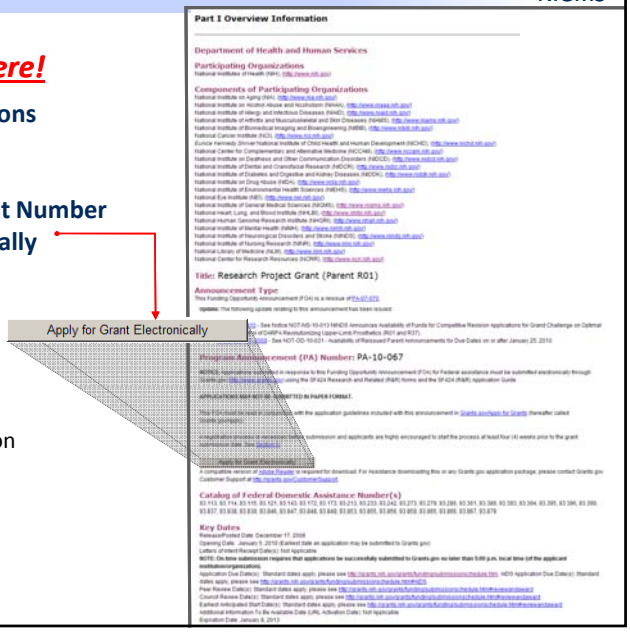
- Addresses a well defined area of research
- Set-aside budget
- Submit on special, one-time receipt date
- Often special eligibility and/or review criteria
- Often special application format and/or submission instructions

Funding Opportunity Announcements

NIGMS

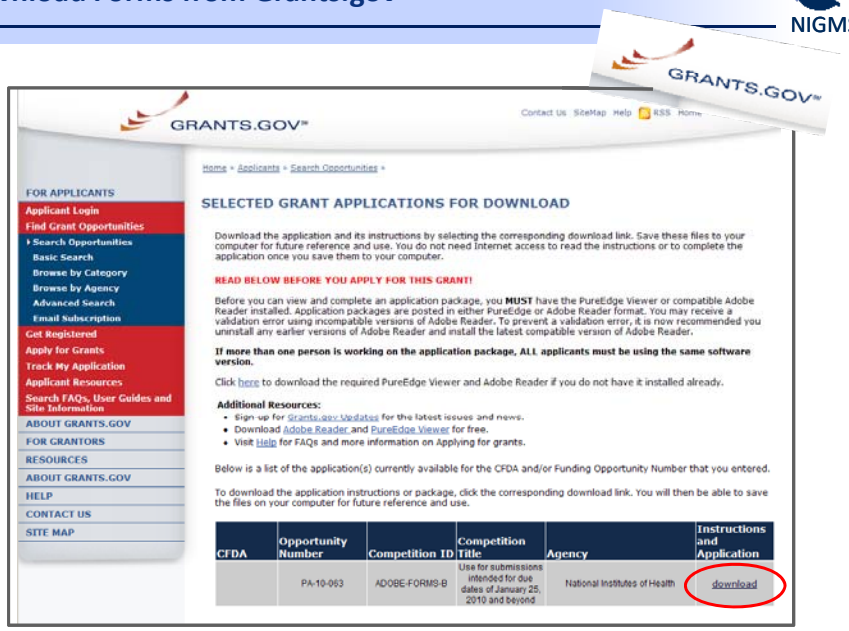
All the details are here!

- **Participating Organizations**
- **Title**
- **Announcement Type**
- **Program Announcement Number**
- **Link to Apply Electronically**
- **Key Dates**
- **Summary / Overview**
- **Specifics**
  - Objectives
  - Award Information
  - Eligibility
  - Application / Submission
  - Review Information
  - Award Administration
  - Agency Contacts



Download Forms from Grants.gov

NIGMS



Preparing Your Application

NIGMS

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 idea.

Dr. William Raub
Past Deputy Director, NIH

Choosing a Research Project

NIGMS

What makes a research project outstanding?

- **Addresses an important problem clearly**
- **Potential to lead to seminal new observations or new ways of thinking**
- **Lays the foundation for further research in the field**
- **Addresses a difficult problem in a way that seems simple in retrospect.**
  Makes reviewers wonder why they didn't think of the idea themselves!
- **All aspects of the project are clearly linked**

What's Your Strategy

NIGMS

Preparing to Write a Grant Application

Assess the potential for your idea

- What has already been done, reported and funded in your area?
- What are the "gaps"?
- How can you take it a step farther?

Assess the competition

- Who are the important contributors to the field?
- What have they accomplished?
- Search the literature and the NIH RePORTER database (www.projectreporter.nih.gov) of funded grants in the field

Critically assess yourself

- Do you have the necessary expertise, resources, personnel and preliminary data to be competitive?

Consider the review criteria

NIGMS

Overall Impact
- Is this project likely to exert a sustained, powerful influence on the research field(s) involved based on consideration of the review criteria?

Significance
- Does this study address an important problem or barrier to success in the field?
- How will scientific knowledge, technical capability or clinical practice be improved?

Investigators
- Are the PIs, collaborators and other researchers well suited to the project?
- If ESIs or NIs, do they have appropriate experience and training?
- If established, do they have an ongoing record of accomplishments?

Innovation
- Does the application challenge and seek to shift current paradigms?
- Are the concepts, approaches, or instrumentation novel or applied in new ways?

Approach
- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims?
- Are potential problems, alternative strategies, and benchmarks presented?
- Will feasibility be established and will risky aspects be managed?

Environment
- Will the scientific environment contribute to the probability of success?
- Are the institutional support and physical resources adequate?
- Will the project benefit from unique features (e.g. subject populations, collaborations)?

Know Your Audience

NIGMS

Know Your Audience

NIGMS

Two audiences of reviewers:

- a small number familiar with your techniques or field
- the majority who have more general expertise

Reviewers are
- Informed strangers
- Inherently skeptical and critical
- Extremely busy

Make their job easier
- Write a well organized, clear and concise application
- Guide reviewers with graphics - flow diagrams, charts, figures – and clear timelines
- Demonstrate enthusiasm with strong active verbs
- Sell your application - show why NIH should fund your application

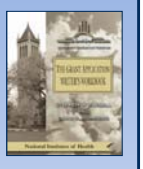
Avoid things that irritate
- Exceeding page limits, small margins, and/or font too small
- Information in the wrong section
- Omitting or mislabeling references/figures
- Spelling, grammar, math errors

Grant Writing Resources

NIGMS

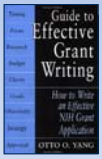
Manuals & Books

"The Grant Application Writer's Workbook"★ available at GrantCentral.com



"Writing the NIH Grant Proposal: A Step-by Step Guide"
by William Gerin

"Grant Application Writers Handbook" (4th Ed)
by Liane Reif-Lehrer



"Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application" by Otto O. Yang

"How to Succeed in Academics"★
by Edward R. B. McCabe and Linda McCabe

Grant Writing Resources

NIGMS

NIH Websites

NIH Central Resource Site	grants.nih.gov/grants/grant_tips.htm
NIGMS	www.nigms.nih.gov/Research/Application/Tips.htm
NCI	http://deainfo.nci.nih.gov/extra/extdocs/gntapp.pdf
NIAID*	http://www.niaid.nih.gov/researchfunding/grant/pages/aag.aspx
NINDS	www.ninds.nih.gov/funding/grantwriting.htm
NIMH	http://www.nimh.nih.gov/research-funding/grants/writing-approval-process/index.shtml

Grant Writing Resources

NIGMS

People

NIH Program Officers

- Advice on appropriate Institute/Center, Funding Opportunity, and Grant Mechanism
- Targeting appropriate study section

Your Colleagues

- Is your application understandable and readable, especially by those that are not in your specific field?
- Have you clearly addressed all of the review criteria?
- Is your timeline for submission realistic based on your existing preliminary data and current draft of the application?
- How long does it REALLY take for the sponsored projects office to approve and submit your application?

When your application arrives at NIH

NIGMS

THEN

NOW

Grants.gov
http://www.grants.gov/

→

eRA Commons
http://era.nih.gov/

eRA Commons

NIGMS

Electronic Research Administration
eRA Commons
Sponsored by National Institutes of Health

Where the NIH exchanges application information

- **Errors/warnings associated with electronic submissions**
  - ***NO error correction after due date!***
- **View of submitted application transmitted from Grants.gov**
  - ***If YOU can't see it NIH can't see it!***
- **Assignment and Contact Information**
  - ***– Institute, Study Section, Program Director, Scientific Review Officer***
- **Overall Impact Score and Percentile**
- **Summary Statement**
- **Notice of Grant Award**

Requires individual account provided by your Office of Sponsored Programs!

Application Number

NIGMS

2 R01 GM063815-09A1

type — *mechanism* — *institute* — *serial* — *year* — *suffix*

Application Type
1 - New
2 - Competing Continuation
5 - Noncompeting Continuation

Mechanism
R01, R03, R15, K01, F32, etc . . .

Institute
GM (NIGMS), CA (NCI), etc . . .

Serial Number
Sequential numbering of applications submitted to particular Institute

Support Year
All new applications start at -01

Suffix – *additional identifier*
A1 - amended application
S1 - supplement

What Happens After Submission?

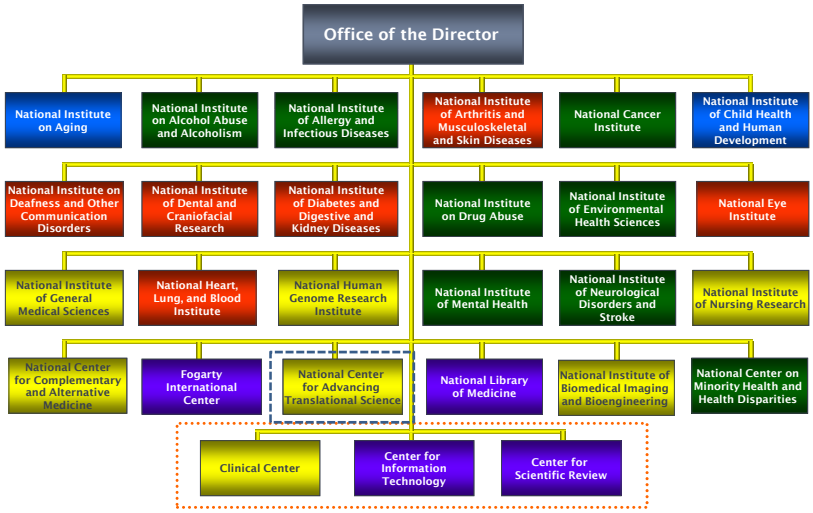
NIGMS

Center for Scientific Review (CSR)

- **Central receipt point for all applications for the NIH**
- **Annually ca. 76,000 applications received of which 52,000 are reviewed in 2000 meetings**
- **Assigns applications to NIH Institute/Center as potential funding component; multiple assignments possible**
- **Assigns applications for peer review**
  - **Ca. 200 Initial Review Groups ("Study Sections") managed by CSR**
  - **Institute Review Offices**

27 Institutes and Centers

NIGMS



Different Missions, Responsibilities and Constituencies

Cover Letter

NIGMS

You may provide information to assist CSR in assigning your application

Example

[Date]

Suzanne Fisher, Ph.D., Director
Division of Receipt and Referral
Center for Scientific Review
National Institutes of Health
6701 Rockledge Dr., Suite 2030
Rockledge II MSC 7720
Bethesda, MD 20892-7720

Dear Dr. Fisher:

Enclosed for your consideration is a grant application entitled *[Title as it appears on the application]*. I believe that the subject of the study *[elaborate, as necessary]* would be of interest to the *[name of NIH institute(s)]*. The scope of the science proposed *[elaborate, as necessary]* matches best the expertise represented on the *[name(s) of study section(s)]*.

If you should need any additional information, please contact me at *[telephone number and email address]*.

Thank you for your consideration.

Sincerely,
[PI signature and name]

Review Process

NIGMS

Prior to Review Meeting

- Each application assigned to at least 3 primary reviewers
- Reviewers submit preliminary overall impact scores, core criteria scores, and written comments

At Review Meeting

- Persons with conflicts of interest excused
- Primary reviewers provide preliminary overall impact scores (1 to 9)
- Discussion of application's scientific and technical merit as well as human subjects and vertebrate animal research
- Restatement of scores by assigned reviewers
- All present panel members score privately
- Consideration of budget and any additional review criteria

About 50% of applications will be streamlined = **ND,** *not discussed*

Feedback from Review

NIGMS

Overall Impact Score & Percentile

- Available in eRA Commons 1 – 2 days after review group meeting
- Impact score is average reviewer score (1 – 9) times ten (10 – 90)
- Percentile = relative ranking of application with prior three meetings of study section

SRG Action: Impact/Priority Score: 20 Percentile: 6
Human Subjects: 10-No human subjects involved
Animal Subjects: 10-No live vertebrate animals involved for competing appl.

Summary Statement

- Available in eRA Commons 4 – 6 weeks after review group meeting
- Summary of discussion written by Scientific Review Officer
- Core criteria scores and written reviewer comments →

Significance: 2
Investigator(s): 1
Innovation: 1
Approach: 3
Environment: 1

- Budget recommendations, administrative notes including acceptability of human subjects and vertebrate animal research plans

Resubmission ?

NIGMS

Deciding whether and when to resubmit:

- **Only one resubmission allowed!**
- **Digest your summary statement**
- **Talk with your program officer**

The Funding Decision

NIGMS

What factors determine funding?

Scientific Merit

- **Percentile ranking (priority score)**
- **Each Institute sets its own "paylines"**
- **Paylines vary for different types of grants**
- **Extra consideration for "New Investigators" and "Early Stage Investigators**

Programmatic Considerations

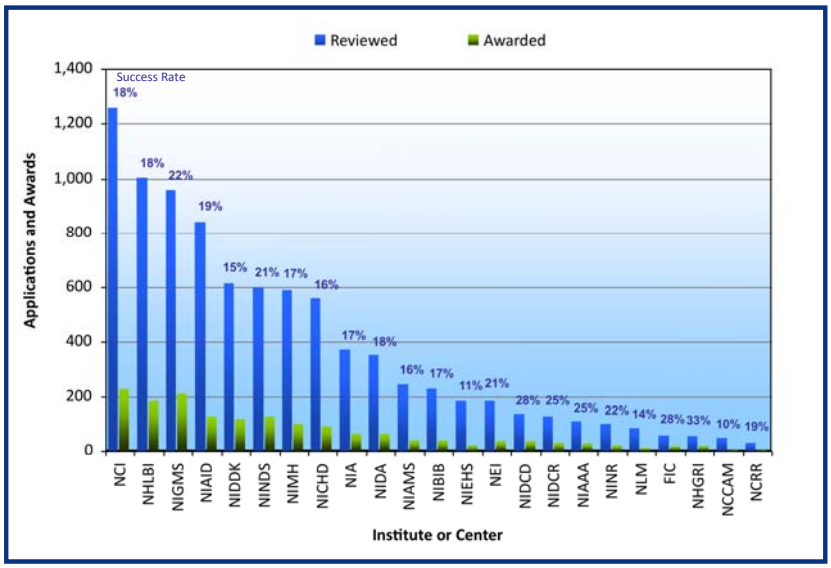
- **A balance of science, geographic sites, approaches, etc. in portfolio**

Availability of Funds

- **Most of budget already committed to continuing grants and programs**
- **A "flat" NIH budget means tighter paylines**

New Investigator R01 Applications & Success Rates

NIGMS



When and Who to Contact

NIGMS

When	Who
Pre-application	Colleagues, Institute Staff, CSR Staff
Submission	Your Office of Sponsored Research, eRA Helpdesk
Receipt & Referral	Scientific Review and Program Officers
Review	***Only*** Scientific Review Officer
Summary Statement Advisory Council Funding Decision Resubmit - or not?	Program Director
Award	Program Director or Grant Specialist

RePORTER *replaces CRISP*

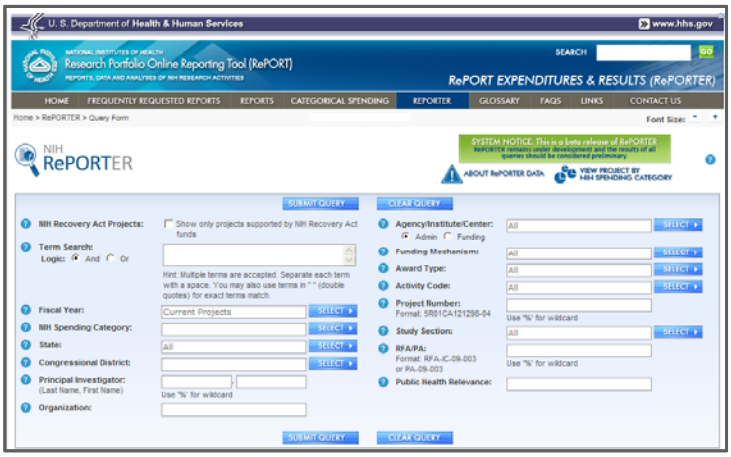
NIGMS

Expenditures and Results of NIH-Funded Research

projectreporter.nih.gov

Search Many New Categories

- ***Over 200 disease categories***
- ***Keywords***
- ***RFA/PA***
- ***Investigator***
- ***Organization***
- ***Funding mechanism***
- ***Recovery Act***
- ***Location***
- ***Study Section***



Thanks to Miles Fabian, Ph.D.
National Institute of General Medical Sciences
Program Director
Division of Pharmacology, Physiology & Biological Chemistry