A Guide to NIH Funding

Steven O. Moldin, Ph.D.
DC Office of Research Advancement
Office of the Vice President for Research

March 6, 2014
Course Objectives

- Understand federal R&D budget process
- Learn NIH organizational structure
- Identify NIH research priorities
- Understand NIH funding ("mechanisms")
- Navigate submission & review processes
- Develop grant writing skills
- Improve advocacy skills
Federal Spending as a Percent of GDP, 1962 - 2018

Source: Budget of the U.S. Government FY 2014.
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obligations in billions of constant FY 2012 dollars

"Other" includes research not classified (includes basic research and applied research; excludes development and R&D facilities). Life sciences are split into NIH support and other agencies' support.


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in billions of constant FY 2012 dollars

Source: AAAS Report: Research & Development series. FY 2012 and FY 2013 figures are latest estimates. Basic research only.
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Select R&D Agencies in the FY15 Base Budget (Preliminary)

percent change from FY14 discretionary budget authority, nominal dollars

DOE EERE
ARPA-E
NIST
USDA - NIFA
NNSA
NSF
DOE Science
NIH
NASA
USDA - ARS
DOE Nuclear Energy
DOE Fossil R&D

NIH FY15 Budget

• $30.4 billion requested
• Increase of $211 million (0.7%) over FY14
• 34,197 grants to be funded
• Only 9,326 new grants to be funded
• Harder to get funded - dropping pay lines (<10%)
• ‘Big Science’ will flourish
Challenge of Rising U.S. Health Expenditures

Biomedical Research Must Deliver

National Health Expenditures as a Percent of GDP

Actual
Projected

Percent of U.S. GDP

$4.1 trillion
NIH Organizational Structure

- Largest agency of Department of Health & Human Services (DHHS)
- Headquarters: Office of the Director
- NIH organized into 27 institutes & centers
  - One center conducts most NIH peer reviews
  - Two centers support intramural activities
  - 24 institutes provide extramural research support - each with specific research priorities
NIH Institutes & Centers

- NCI – Cancer
- NHLBI – Heart, Lung & Blood
- NIDDK – Diabetes & Digestive & Kidney Diseases
- NIDA – Drug Abuse
- NIAAA – Alcohol Abuse & Alcoholism
- NIBIB – Biomedical Imaging & Bioengineering
- NINR – Nursing Research
- NIA – Aging
- NICHD – Child Health & Human Development
- NIDCD – Deafness & Other Communication Disorders
- NIAID – Allergy & Infectious Diseases
- NEI – Eye Institute
- NHGRI – Human Genome Research
- NIMH – Mental Health
NIH Institutes & Centers

• NIAMS – Arthritis & Musculoskeletal & Skin Diseases
• NIDCR – Dental & Craniofacial Research
• NINDS – Neurological Disorders & Stroke
• NIEHS – Environmental Health Sciences
• NIGMS – General Medical Sciences
• FIC – Fogarty International Center
• NLM – National Library of Medicine

• NIMHD - National Institute on Minority Health & Health Disparities
• NCCAM – National Center for Complimentary & Alternative Medicine
• NCATS – National Center for Advancing Translational Sciences
• CSR – Center for Scientific Review
• CC – Clinical Center
• CIT – Center for Information Technology
• OD – Office of the Director
NIH Director - Francis Collins

• Research directions set by Director – not Congress or President

• Tension between investigator-initiated and ‘big science’
Broad Scientific Areas of Interest to NIH

• Research of direct or strong indirect relevance to understanding and preventing disease

• Research on basic biological and psychological processes of potential interest if there is disease relevance
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<td>Fogarty International Center</td>
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<td><strong>30,151</strong></td>
<td><strong>30,362</strong></td>
<td><strong>+211</strong></td>
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</table>
NIH Research Priorities, FY15

• Investing in Today’s Basic Science for Tomorrow’s Breakthroughs
  - Unlocking the mysteries of the brain: Human Connectome Project, optogenetics, innovative neurotechnologies (BRAIN initiative)
  - Single cell biology
  - Epigenomics

• Taking Advantage of Big Opportunities in Big Data
  - Focus on increasingly larger and more complex biomedical data sets, e.g., high resolution medical images, recorded physiological signals, complete DNA sequences - in large numbers of individuals
NIH Research Priorities, FY15

• Investing in Precision Medicine
  - New targets for therapeutic intervention
  - Tailoring treatments to individual characteristics
  - NCATS - re-engineer process of translating discoveries into new diagnostics & therapeutics
  - Cures Acceleration Network - ‘high need cures’
  - Accelerating Medicines Partnerships (AD, Type 2 diabetes, RA & lupus)

• Nurturing Talent & Innovation
  - Enhancing Diversity in the Biomedical Research Workforce
  - Encouraging Innovation: NIH Director’s Early Independence, New Innovator, Pioneer & Transformative Research Award Programs

• Disease focus
  - HIV/AIDS - $3 billion
  - Alzheimer’s disease - $566 million
Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative

• Part of Presidential focus aimed at revolutionizing understanding of human brain
• Development and application of innovative technologies
• revolutionary new dynamic picture of the brain
NIH BRAIN Initiative

• Launched with $100 M in FY14 budget - funded by NIH, DARPA, NSF

• Private Sector Partners
  - Allen Institute for Brain Science
  - Howard Hughes Medical Institute
  - Kavli Foundation
  - Salk Institute for Biological Studies

• Strong academic leadership from high-level working group: co-chairs, C. Bargmann & W. Newsome
  - Define detailed scientific goals
  - Develop multi-year scientific plan - timetables, milestones & cost estimates

Big Data to Knowledge (BD2K)

- Facilitate broad use & sharing of large, complex biomedical data sets
- Develop & disseminate new analytical methods & software
- Enhance training of data scientists, computer engineers, bioinformaticians
- Establish centers of excellence to develop generalizable approaches that address important problems in biomedical analytics, computational biology, & medical informatics
- ~$40 million investment - each Big Data Center of Excellence will be funded at $2-5M/year for 3–5 years
Opportunity, Growth & Security Initiative

- Multi-agency initiative
- Grow economy & create opportunities
- Additional $970 million to NIH
  - Increase new grants
  - Increase resources - BRAIN Initiative
  - Improve sharing & analysis of complex biomed. data sets
  - Expand Alzheimer’s disease research
  - Expand vaccine development
  - Accelerate partnerships to develop new drug targets
NIH Grants & Contracts
Solicited Applications

• Request For Applications (RFA)
  – Set-aside $$
  – Special review
  – Special deadline

• Program Announcements (PA)
  – Typically no set-aside
  – Typically regular receipt dates apply
  – Typically review is by standing committees
  – PAS: $$ for some grants above payline
  – PAR: specific review

• Cooperative Agreements (U’s)
  – “Significant government participation”
  – Clinical Trials, Translational grants

• Request for Proposals (RFP)
  – Contract solicitation
  – Acquisition; gov’t buys a product
Funding Opportunities (RFAs, PAs) & Notices - NIH Guide for Grants and Contracts

The NIH Guide for Grants and Contracts is the official publication for NIH medical and behavioral research grant policies, guidelines and funding opportunities. Definitions and More Information...

Search the NIH Guide for:
- Active RFAs (Requests for Applications)
- Active PAs (Program Announcements)
- Recent Notices (Released in Last 12 Months)
- Inactive & Active Announcements (use Advanced Search)

With Announcement # or Keywords: (Optional) Search Advanced Search

Browse Active Funding Opportunities
- Requests for Applications (RFAs)
- Program Announcements (PAs)
- Parent Announcements (unsolicited applications)

Browse Recent Policies and Guidelines
- Notices (Released in last 12 months)

Recovery Act Funding
- Current NIH Funding Opportunities and Notices
- Grant Funding Opportunities Web Page

NIH Guide for Grants and Contracts Updates
- New Announcements This Week - Current Weekly Table of Contents (TOC)
- Subscribe or Unsubscribe to Weekly Update via E-mail LISTSERV
- RSS Format - NIH Funding Opportunities now available in RSS (Really Simple News Syndication) format.
- Follow NIH Funding Opportunities on Twitter

Other Funding Opportunities and Notices Listings

NIH Grants and Contracts
Unsolicited Applications

• Traditional “bread & butter” NIH grant support
• Regular receipt deadlines
• Review by pre-existing (“standing”) review committees (typically CSR)
• Increased likelihood of success if fits in with Institute priorities
• NIH permission needed if budget exceeds $500K in any one year
## R01 Review and Award Cycles

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<td>June 5</td>
<td>October 5</td>
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<td>Scientific Merit Review</td>
<td>June - July</td>
<td>October - November</td>
<td>February - March</td>
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<tr>
<td>Advisory Council Review</td>
<td>September - October</td>
<td>January - February</td>
<td>May - June</td>
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<tr>
<td>Earliest Project Start Date</td>
<td>December</td>
<td>April</td>
<td>July</td>
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Demand for Grants Surges at End of Doubling Period, Success Rates Fall

- Success Rate: 31%
- Applications: 24,154
- Applicants: 19,663
- Number of Applications/Applicants (in thousands): 51,007
- Number of Applications/Applicants (in thousands): 35,975

Demand for grants surges at the end of the doubling period, causing success rates to fall.
Submitting an Unsolicited Grant Application

• Assignment to Institute for funding consideration

• Assignment to particular review committee
Managing the Process

• Receipt and Referral
  - All NIH grant applications sent to CSR
  - CSR assigns them to Institutes and peer review committees
    - Based on “referral guidelines” &/or PI request in a cover letter
      &/or an ARA from Program staff

• You can request which Institute & program you want to be assigned for funding consideration
  - Letter to CSR; contact with Program official

• You can request which committee you want to conduct the peer review
  - Letter to CSR; contact with Program official
Popular Grant Mechanisms

- **Fellowship Programs**
  - F31: Predoctoral Individual National Research Service Award
  - F32: Postdoctoral Individual National Research Service Award

- **Research Career Programs**
  - K01/K02: Research Scientist Development Awards
  - K05: Research Scientist Award
  - K07: Academic/Teacher Award
  - K08: Clinical Investigator Award
  - K12: Physician Scientist Award
  - K18: Career Enhancement Award
  - K20/K21: Senior Development Awards
  - K22: Career Transition Award
  - K23: Mentored Patient-Oriented Research Career Development Award
  - K24: Midcareer Investigator Award in Patient-Oriented Research
NIH Career Development Awards

• Grant to do research on small scale and obtain training in scientific area
• Mentored v. nonmentored awards
• Basic v. clinical research
• Traditionally easier to get than traditional Research Project (R01) award BUT…

• http://grants1.nih.gov/training/careerdevelopmentawards.htm
NIH Grant Mechanism Timetable

Approx. Stage of Research Training and Development

- GRADUATE/MEDICAL STUDENT
- POST DOCTORAL
- EARLY
- MIDDLE
- SENIOR

Mechanism of Support

- Predoctoral Institutional Training Grant (T32)
- Predoctoral Individual NRSA (F31)
- Predoctoral Individual MD/PhD NRSA (F30)
- Postdoctoral Institutional Training Grant (T32)
- Postdoctoral Individual NRSA (F32)
- Mentored Research Scientist Development Award (K01)
- Mentored Clinical Scientist Development Award (K08)
- Mentored Patient-Oriented RCDA (K23)
- Mentored Quantitative RCDA (K25)
- Independent Scientist Award (K02)
- Midcareer Investigator Award in Patient-Oriented Research (K24)
- Senior Scientist Award (K05)
Grant Mechanisms

- **Research Program Projects & Centers**
  - P01: Research Program Projects
  - P20: Exploratory Grants
  - P30: Center Core Grant
  - P50: Specialized Center

- **Research Projects**
  - R01: Research Project
  - R03: Small Research Grant
  - R21: Exploratory/Developmental Grants
  - R41/R42: Small Business Technology Transfer (STTR) Grants
  - R43/R44: Small Business Innovation Research Grants (SBIR)
NIH Research Projects

- **R01 grants**: Unsolicited (investigator-initiated) grants from one or more labs
  - Cornerstone of NIH funding
  - Reflect scientists’ interests, assessment of the field, and feasibility
- **R03 grants**: Small, self-contained research projects; feasibility
- **R21 grants**: High-risk / high-return
  - Time and dollar limits; Institutes differ
  - Less stringent need for preliminary data
- **R41/R42, R43/R44 grants**: Small businesses
  - SBIR: small business, commercialization
  - STTR: same, with a university component
  - Phases (1, 2, fast-track)
FY 2015 NIH Budget
$30.4 Billion – Estimated Percent Total by Mechanism

- Research Project Grants: 53.4%
- Research Centers: 9.0%
- Intramural Research: 11.3%
- Research & Development Contracts: 10.0%
- Other Research, Superfund, Office of the Director: 8.3%
- Facilities Construction: 0.5%
- Research Training: 2.5%
- Research Management and Support: 5.1%
How Does an Application Get Funded?

• Application submitted to CSR
  - Regular receipt date (unsolicited apps)
  - “Special” receipt date (solicited apps)
• Application assigned to Institute for funding consideration
• Application assigned to peer review committee
• Multiple levels of review
• Grants Management Office of Institute collects necessary information
Multiple Levels of Evaluation

- **Peer review, scientific review committee**
  - Members drawn from extramural scientific community
  - Major effect on probability of being funded
- **Approval of review, Scientific Advisory Council**
  - Each institute has its own Council
  - Members drawn from extramural scientific community
  - Nonscientific members
  - Typically, minimal effect on probability of being funded
- **Program evaluation**
  - Evaluation for agreement with Institute priorities
  - Greatest effect on probability of being funded
National Institutes of Health

School or Other Research Center

Center for Scientific Review

- Assigns to IRG/Study Section & IC

Study Section

- Evaluates for Scientific Merit

Institute

- Evaluates for Program Relevance

Advisory Councils and Boards

- Recommends Action

Institute Director

- Takes final action for NIH Director

Research Grant Application

- Initiates Research Idea

- Submits Application

- Allocates Funds

- Conducts Research
NIH Research Plan

- Specific Aims – 1 page
- Research Strategy - 12 pages
  - Significance
  - Innovation
  - Approach
  - Preliminary Studies (New Applications) or
  - Progress Report (Renewal/Revision Applications)
Specific NIH Review Criteria

• **Overall Impact** - After considering all of the review criteria, briefly summarize the significant strengths and weaknesses of the application and state the likelihood of the project to exert a sustained powerful influence on the field.

• **Significance** - Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

• **Investigators** - Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project.
Specific NIH Review Criteria

- **Innovation** - Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

- **Approach** - Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

- **Environment** - Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?
Additional Considerations

Significance

• **New Investigator**: An NIH research grant Program Director/Principal Investigator (PD/PI) who has not yet competed successfully for a substantial, competing NIH research grant is considered a New Investigator. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. However, a PD/PI who has received a Small Grant (R03) or an Exploratory/Developmental Research Grant Award (R21) retains his or her status as a New Investigator. A complete definition of a New Investigator along with a list of NIH grants that do not disqualify a PD/PI from being considered a New Investigator can be found at [http://grants1.nih.gov/grants/new_investigators/resources.htm](http://grants1.nih.gov/grants/new_investigators/resources.htm).

• **Early Stage Investigator (ESI)**: An individual who is classified as a New or First-Time Investigator and is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent) is considered an Early Stage Investigator (ESI). The 10 year period after completion of the terminal degree or residency may be extended to accommodate special circumstances including various medical concerns, disability, pressing family care responsibilities, or active duty military service. If an extension has been approved, the SRO will bring this to the reviewers’ attention.
Additional Considerations

- **Protection for Human Subjects**
- **Inclusion of Women, Minorities & Children**
- **Vertebrate Animals**
- **Biohazards**
- **Budget & Period Support**
- **Resource Sharing Plans**
Ranking and Priority Scores

- 2-3 assigned reviewers discuss a grant, and may be the only ones who read it
  - The primary reviewer by far has the greatest impact on the score!
  - All reviewers (~30) vote on all grants, based on discussion at the meeting
  - If it’s not in the research strategy, they don’t have to read it (appendices, and last minute data)

- Grants are scored from 1 (exceptional) - 9 (poor) for the overall impact/priority score as well as the individual review criteria. Ratings are provided only in whole numbers, not decimals

- Applications judged unanimously by the peer reviewers as less competitive, based on preliminary impact/priority scores (roughly the bottom half of applications for that review meeting), will not be discussed and will not receive a final impact/priority score.
# NIH Grant Application Scoring System

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<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
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<tbody>
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<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
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<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
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<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
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<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
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<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
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<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
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<td>Low</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
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<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
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**Non-numeric score options:** NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed

**Minor Weakness:** An easily addressable weakness that does not substantially lessen impact

**Moderate Weakness:** A weakness that lessens impact

**Major Weakness:** A weakness that severely limits impact
A Few Last Points on Review

• Program staff can attend reviews, but can’t influence reviewers

• You will be sent a score and percentile after review; SROs release summary statements in 4-6 wks
  – (They are NOT available to Program till then, either)
  – USE https://commons.era.nih.gov/commons/!!

• You can request (with good reason) that someone not review your grant, but can’t suggest reviewers
First Major Independent Research Support Occurs at an Ever-Later Age

Average Age of Initial Type 1 R01/R23/R29 Award for Different Degrees Held
Percentage of New Investigators in Competing R01 Awards Continues to Decrease
FY 1962 - FY 2003

Established Investigator

New Investigator
Advice: Writing the Proposal

• Abstract and Specific Aims: clearly state what you propose to do - why and how, *without* distracting detail
• State hypotheses clearly and design clear answers from your experiments
  - Address interesting and significant issues
  - Make the design win-win by assuming the worst
  - Develop alternative strategies for potential problems
• Preliminary Data: prove you can do the work, analyze the results, and draw sound conclusions
• Avoid being overly ambitious
How to Write Your Proposal

• There are several outstanding Web sites devoted to tips
• Carefully develop a strategy -
• Don’t jump the shark!

• Publish the papers--submit the best application you can
  - Have funded colleagues read your drafts
  - Look for & cite relevant Program Announcements
  - If you have questions, ask Program Staff
Advice: Writing the Proposal

• Make it easy for the primary reviewer
  - S/he will present your case
  - Clear significance, fair literature review
  - Clear and sound hypotheses
  - Demonstrate productivity and feasibility
  - Logical experimental design
    - Avoid Aims that may make next step impossible
  - Don’t assume they know what you mean, *tell them*
  - *Make it “sexy”*
  - Present it in readable, attractive format
    • Spell check; avoid too many acronyms
Helpful Websites

- http://www.usc.edu/research/for_researchers/funding/federal/
- NIH - www.nih.gov
- NIH peer review
  - www.csr.nih.gov/review/peerrev.htm
  - www.csr.nih.gov/review/irgdesc.htm
- NIH Guide for Grants & Contracts
  - grants.nih.gov/grants/guide/index.html
More Helpful Websites

http://grants2.nih.gov/grants/grant_tips.htm
http://www.niaid.nih.gov/ncn/grants/
http://www.nigms.nih.gov/funding/tips.html
http://www.nigms.nih.gov/funding/moregrant_tips.html
http://deainfo.nci.nih.gov/EXTRA/EXTDOCS/gntapp.htm
http://12.46.245.173/cfda/cfda.html
http://cpmcnet.columbia.edu/research/writing.htm
Building Key Relationships

- Critical difference between program and review staff [firewall between them]
  - Program staff make funding decisions
    - Former scientists, specific areas of expertise
    - Based at individual Institutes
    - Take Institute priorities, review scores into account
    - Attend review meetings
  - Review staff: Scientific Review Administrators (SRAs)
    - Former scientists who coordinate study sections at CSR or within Institutes
    - Oversee standing review committees or special emphasis panels (SEPs)
    - Based at CSR or individual Institutes
Advocacy Tips

• Make sure there is close match between your research & institute priorities
• Work with Program Staff early
  - Find a ‘champion’
  - ‘Light touch’ - avoid at all costs pressure, manipulation, shameless self-promotion
  - Identify right person
  - Respect hierarchy
  - Get advice
  - Build enthusiasm – enlist him/her as your advocate
  - Send papers, data
Summary

• NIH is ‘crown jewel’ of fed R&D agencies
• Institute R&D priorities matter!
• NIH director has influence but institute priorities & programs persist for years
• Find homes for your research - both review & funding (‘champion’)
• Write best proposal you can – tightly focused, “sexy,” with “A-List” personnel
• Be patient and tenacious
DC Office for Research Advancement

Additional questions, advice:
Dr. Steven Moldin
moldin@usc.edu
202-824-5860