DC Office for Research Advancement

Developing and Submitting an NIH Grant Application

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40 years in S&T with Federal Agencies
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
  – Organized according to disease focus
What are NIH’s Research Priorities?

- Before you start writing, is what you want to do of interest to NIH?
- What science *is* of interest to NIH?
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
NIH’s Major Opportunities
Five Themes

• Applying high throughput technologies to understand fundamental biology, and to uncover the causes of specific diseases
• Translating basic science discoveries into new and better treatments
• Putting science to work for the benefit of health care reform
• Encouraging a greater focus on global health
• Reinvigorating and empowering the biomedical research community
NIH Grant Mechanism Timetable

Approx. Stage of Research Training and Development

- GRADUATE/MEDICAL STUDENT
  - Predoctoral Institutional Training Grant (T32)
  - Predoctoral Individual NRSA (F31)
  - Predoctoral Individual MD/PhD NRSA (F30)
  - Postdoctoral Institutional Training Grant (T32)
  - Postdoctoral Individual NRSA (F32)

- POST DOCTORAL
  - Mentored Research Scientist Development Award (K01)
  - Mentored Clinical Scientist Development Award (K08)
  - Mentored Patient-Oriented RCDA (K23)
  - Mentored Quantitative RCDA (K25)

- EARLY
  - Independent Scientist Award (K02)

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

- SENIOR
  - Senior Scientist Award (K05)
NIH Informatics

The Biomedical Information Science and Technology Initiative  http://www.bisti.nih.gov/
BISTI Funding Announcements  http://www.bisti.nih.gov/funding/index.asp

BISTI is a consortium of representatives from each of the NIH institutes and centers. BISTI was established in May 2000 to serve as the focus of biomedical computing issues.

The mission of BISTI is to make optimal use of computer science and technology to address problems in biology and medicine by fostering new basic understandings, collaborations, and transdisciplinary initiatives between the computational and biomedical sciences.

In support of this mission, the BISTI coordinates research grants, training opportunities, and scientific symposia associated with biomedical computing. Regular monthly meetings are conducted to discuss program status, future needs and directions, and topics of interest to the bioinformatics community.

Biomedical Informatics Network  http://www.birncommunity.org/

OECD-NSF Workshop
Begin Supplemental Charts
Deciphering NIH Grant Mechanisms

- Over a hundred different types of grant programs ("mechanisms")
- Several have Institute-specific criteria
- Major categories
  - Fellowship Programs
  - Research Career Programs
  - Research Program Projects & Centers
  - Research Projects
  - Institutional Training Programs
  - Cooperative Agreements
  - Research and Development-Related Contracts
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
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.
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
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
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
University of Southern California

National Institutes of Health
- 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
You Have Control

- 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
How to Write Your Proposal

• There are several outstanding Web sites devoted to tips
• Develop your strategy carefully - don’t rush the application
  – 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

• 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*
Advocacy Tips

• Make sure there is close match between your research & Institute priorities
• Work with Program Staff early
  – Identify right person
  – Respect hierarchy
  – Get advice
  – Build enthusiasm – enlist him/her as your advocate
  – Send papers, data
  – Avoid at all costs pressure, manipulation, shameless self-promotion