

NIH Fundamentals

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NCURA Region IV Meeting
27 April 2003

The Agenda

- # Agency Overview
- # Roles and Responsibilities
- # Award Mechanisms
- # Proposal Submission and Review
- # Notice of Grant Award
- # Post Award Administration

Who Is Eligible for an NIH Grant?

- # Qualified scientist at institution that can provide the needed resources
- # Except for fellowships and career awards, grants are to institutions, not individuals
- # Awards to foreign institutions for projects not having comparable research in the U.S.
- # For most training and career awards, person needs U.S. permanent residency

Essential Documents

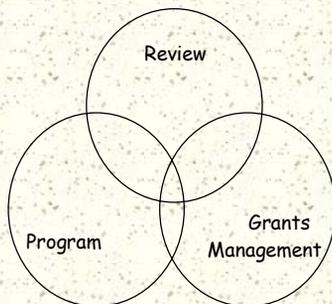
- # *NIH Guide*
- # *NIH Grants Policy Statement*
- # *PHS 398 Application*
- # *PHS 2590 Application*
- # *Notice of Grant Award*
- # *PHS 416-1 Application*

<http://www.grants.nih.gov/grants/oer.htm>

NIH Institutes and Centers

National Institute on Aging	National Eye Institute	National Institute of Mental Health	National Institute on Drug Abuse	National Cancer Institute
National Institute of Allergy and Infectious Diseases	National Institute of Child Health and Human Development	National Institute on Alcohol Abuse and Alcoholism	National Institute of Environmental Health Sciences	National Human Genome Research Institute
National Institute of Nursing Research	National Library of Medicine	Fogarty International Center	National Heart, Lung and Blood Institute	National Center for Research Resources
National Institute for Neurological Disorders and Stroke	National Center for Complementary and Alternative Medicine	National Center for Minority Health and Health Disparities	National Institute of General Medical Sciences	National Institute of Biomedical Imaging and Bioengineering
National Institute of Dental and Craniofacial Research	National Institute of Arthritis and Musculoskeletal and Skin Diseases	National Institute of Diabetes and Digestive and Kidney Diseases	National Institute on Deafness and Other Communication Disorders	‡Center for Scientific Research
‡Clinical Center		‡Center for Information Technology		

The NIH Extramural Team



Program Officer

Responsible for the scientific and/or technical aspects of grants

- ✦ Initiates and encourages interest in scientific area of importance to match that of Institute's mission
- ✦ Is familiar with the peer review process
- ✦ Prepares funding recommendations
- ✦ Reviews annual progress of grants

Scientific Review Administrator

Performs administrative & technical review of applications

- ✦ Selects reviewers
- ✦ Manages study sections and project site visits
- ✦ Prepares summary statements
- ✦ Provides any requested information about study section requirements

Grants Management Officer

Monitors administrative and fiscal aspects of the grant

- ✦ Assures compliance with Federal laws and NIH administrative policies and procedures
- ✦ Responsible for maintaining the official grant files for grant awards
- ✦ Is the only NIH official authorized to obligate the NIH to funds or other terms and conditions of award

Grants Management Specialist

Acts as an agent of the *GMO*

- # Assures compliance with Federal laws and NIH policies and procedures
- # Analyzes grant applications prior to award
- # Prepares award for *GMO* release
- # Reviews and responds to grantee prior approval and rebudgeting requests
- # Assures documentation of official grant files

Grantee Institution

- # Award made to institution
- # Legally responsible for proper conduct and execution of the project
- # Oversight on allocation decisions
- # Assures compliance with Federal laws and regulations, and NIH policies and procedures

Authorized Institutional Official

- # Designated representative of the grantee organization
- # Accountable for information presented in grant application, signs it and all official correspondence with NIH
- # Assures compliance with Federal laws and regulations, and NIH policies and procedures

Principal Investigator

- ✦ Designated by grantee institution
- ✦ Responsible for scientific and technical aspects of the grant
- ✦ Assures fiscal and administrative compliance—maintains contact with Grants Management Specialist
- ✦ Assures scientific compliance—maintains contact with Program Officer

Key Personnel

- Those individuals who contribute in a substantive way to the scientific development or execution of the grant
- ✦ Typically have doctoral/professional degrees
 - ✦ May include those from consortia institutions
 - ✦ May include consultants

Award Mechanisms-Grants

- ✦ Research Project Grants
 - Traditional - R01
 - Exploratory/Development Grants- R21
 - Program Project - P01
 - Small Business - R41, R42, R43, R44
 - Usually investigator initiated

Award Mechanisms-Grants

#Research Center Grants

- Established by ICs to meet special needs
- Research and core facility
- Examples
 - Specialized - P50, U54
 - Core grants - P30
 - General clinical - M01

Award Mechanisms-Grants

#Other Research

- Small grants - R03
- Conferences - R13
- AREA - R15

Research Training and Career Awards

#Training Grants - T32

- Institutional
- Predoctoral and postdoctoral

#Fellowships - Kirschstein NRSA's

- Individual
 - Predoctoral (F31)
 - Postdoctoral (F32)

#Career Awards (Ks)

Award Mechanisms

- # Cooperative Agreements (U01, U10, U13, U19, U24, U54)
 - Assistance as opposed to acquisition
 - Substantial programmatic involvement
 - Generally referred to as a "grant"
 - Usually initiated by NIH

Award Mechanisms

- # Contracts (N01, N02, N41, N42, N43, N44)
 - Acquisition or purchase of services or supplies for the direct use or benefits of the federal government
 - Initiated by NIH
 - FEDBIZOPPS (formerly *CBD & NIH Guide*)

When Do I Have to Submit a Modular Grant?

- # Research project grant mechanisms (R01, R03, R15, R21, R41, & R43) and RFAs with no more than \$250,000 direct costs/year.
- # Requested total direct costs in modules of \$25,000 reflecting appropriate support for project. There will be no future year escalations in the traditional sense.

I have to contact NIH *before* I submit a proposal?

- # IC staff must agree to accept the application prior to a submission for any investigator-initiated competitive applications with \geq \$500,000 direct cost for any single year
- # Request must be six weeks before deadline
- # Refer to NIH Guide dated 10/16/2001

When Are Applications Due?

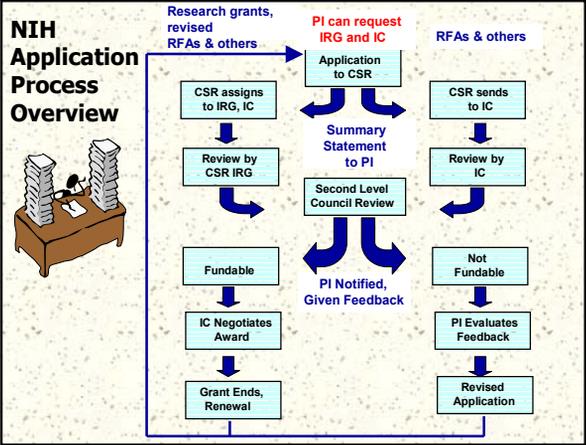
- ALL NIH competitive applications are submitted to CSR
- # Unsolicited Applications:
 - Considered on time if received by or mailed on or before the published receipt date
 - # Solicited Applications:
 - Must be received by the specified date (or the following business day if a weekend or holiday)

Where Are Applications Reviewed?

<u>GROUPS</u>	<u>APPLICATIONS REVIEWED</u>
CSR Study Sections Special Emphasis Panels	Research projects Academic Research Enhancement Awards Postdoctoral Fellowships Small Business Innovation Research
Institutes Scientific Review Committees	Shared Instrumentation Program Projects Centers Institutional Training Grants Conference Grants Career Awards Small Grants RFAs
Contract Review Committees	Contracts

What happens when CSR receives a grant?

- * Assessed for completeness and eligibility
- * Referral Officer
 - Assigns to a SRG for initial peer review
 - Assigns to a primary and multiple secondary IC for potential funding and secondary review (advisory council/board)
- * Application number assigned
- * Notice of assignment sent in 4-6 weeks



Who reviews grants?

- * Scientific Review Administrator recruits and selects reviewers
- * Some reviewers charter; others ad hoc or temporary
- * Reviewers are scientists with appropriate expertise
- * Specific grant review assignments based on expertise of reviewers and their knowledge of the field

What Review Criteria Are Used?

Depends upon mechanism...for R01 applications, NIH uses five review criteria

- Significance
- Innovation
- Approach
- Investigator
- Resources and Environment

Based upon these, each reviewer assigns a preliminary score of 1 (best) to 5 (worst) to each application assigned to him/her

What is Streamlined Review?

The process by which applications judged by the reviewers to be in the lower half of those assigned for review are not discussed at the SRG meeting.

Any member can object to the streamlining of an application

Streamlined applications receive written critiques from the reviewers

How is a priority score determined?

✦ The best possible priority score is 100 and the worst is 500.

✦ Individual reviewers mark scores to two significant figures, e.g., 2.2,

✦ The individual scores are averaged and then multiplied by 100 to yield a single overall score for each scored application, e.g., 253.

✦ All fellowships and career applications are scored.

How and when is a grant percentiled?

- # Research grants reviewed by CSR are percentiled. Other applications--e.g., fellowships, SBIRs/STTRs--are not percentiled.
- # The conversion of priority scores to percentile rankings is based on scores assigned to applications reviewed during the current plus past two review rounds.

How and when is a grant percentiled? (con't)

- # Applications reviewed by SEPs are percentiled against the parent study section if at least 30% of the reviewers are current or recent regular members of that study section.
- # Applications reviewed by SEPs where fewer than 30% of the reviewers are current or recent members are given a percentile based on the distribution of scores assigned by all CSR study sections.

Study Sections Do Not Fund

INSTITUTES AND CENTERS FUND!

- # Study sections judge application's scientific and technical merit
- # Institutes takes these evaluations very seriously
- # Institutes also consider the relevance of the application to the Institutes priorities

What Does Council Do?

- # Conducts second level peer review
- # Selected Pay (HPPs, foreign grants, human subjects/animal welfare concerns, PI appeals)
- # En bloc approval of all other applications
- # Approval of new program initiatives and concept clearances
- # Consideration of policy issues

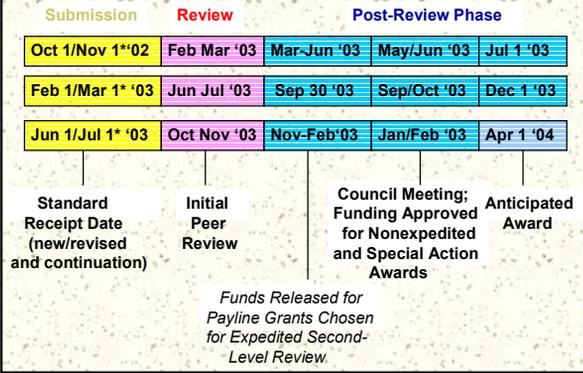
Funding Factors Institute Considers In Making Awards

- # Scientific Merit
- # Contribution to the Mission of the Institute
- # Program Balance
- # Availability of Funds/Funding Strategy

What Is An Expedited Award?

- # NIH initiative designed to shorten the time from receipt of application to notification of award for the most meritorious applications
- # Most IC's are actively participating in this initiative

Funding Timeline



Are There Limits on Resubmitting a Proposal?

- # Maximum of two revisions
- # Submission within two years of following submission of the original, unamended application

<http://grants.nih.gov/grants/guide/notice-files/not97-011.html>

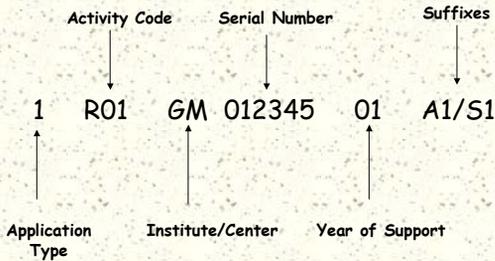
Helpful Hints

- # Use proper font; observe margins, page limits
- # Follow directions
- # After checking website roster, self-refer to IRG
- # Suggest reviewers (+/-) to SRA
- # Persist—revise and resubmit

What Funds Are Available for New Awards?

- ✦ Depends on the Appropriation
- ✦ Commitment Base (~75%) off top
- ✦ Political Concerns/Guidelines
 - earmarks, taps, new salary caps
- ✦ Set-Asides
 - PAs, RFAs, Select Pays
- ✦ Number of New Grants

Sample Application Number



Types of NIH Grants

- ✦ Competing - Type 1
- ✦ Competing Continuation - Type 2
- ✦ Supplement - Type 3
- ✦ Non-competing Continuation - Type 5
- ✦ Change of Grantee Institution - Type 7
- ✦ Change of Institute, Noncompeting - Type 8
- ✦ Change of Institute, Competing - Type 9

Just-In-Time Information

- # Other Support of Key Personnel
- # IACUC Approval Within 3 Years
- # IRB Approval Within 1 year
- # Certification of Education on Human Subjects

Scientific Monitoring

- # Scientific Overlap
- # Budgetary Overlap
- # Commitment Overlap

Scientific Overlap

- # Substantially the same research is proposed in more than one application submitted to two or more different funding sources
- # A specific research objective and research design are the same or closely related in two or more applications or awards, regardless of the funding source

Budgetary Overlap

Duplicate or equivalent budgetary items requested in an application are already funded or provided for by another source.

Commitment Overlap

Any project personnel who have a time commitment exceeding 100 percent

What Is In the Notice of Grant Award?

- # Legally Binding Document
 - Establishes funding level
 - Establishes period of support
 - Sets forth terms and conditions
 - NIH Contact Information
 - Program Director
 - Grants Management Specialist

What Is In the Notice of Grant Award? (con't)

Notice of Grant Award Letter:

- # Identifies name of institution, PI, budget period, project period, amount of award, issue date, title of project
- # Sent to the business official
- # Specifies that the award terms are accepted once funds are drawn or obtained from the payment system

What Is In the Notice of Grant Award? (con't)

NGA Section I:

- # Award Data
 - Provides a categorical breakdown of the budget (unless modular or SNAP award) for current and future years
 - Indicates whether an unobligated balance has been applied to the award amount

What Is In the Notice of Grant Award? (con't)

NGA Section I

- # Fiscal Information

NGA Section II:

- # Grant Payment Information
- # OIG Hotline Information

What Is In the Notice of Grant Award? (con't)

NGA Section III: Terms and Conditions

- # Grant program legislation and regulations
- # Restrictions on the expenditure of funds in appropriation acts
- # 45 CFR 74 or 92 as applicable
- # NIH Grants Policy Statement
- # The award notice, including terms and conditions

Standard Terms and Conditions

- # Included or excluded from carryover or the FDP as appropriate
- # Streamlined Noncompeting Award Process (SNAP)
- # Program Income

Special Terms and Conditions

- # Revised award
- # Supplemental award
- # Cooperative agreement
- # Restrictive terms

Grants Covered by Expanded Authorities

- # R series
- # P01s
- # K (Career Awards)
- # Not Fs
- # Not grants that require closer monitoring

To SNAP or Not to SNAP

- # Awards typically *not* SNAPed (Streamlined Non-Competing Award Process)
 - Cooperative Agreements
 - Clinical Trials
 - Program Projects (P01's)
 - Centers
 - Training Grants
 - Grants for a Large Dollar Amount

Administrative and Fiscal Monitoring

- SNAP (Streamlined Non-Competing Award Process)**
 - # Award in total direct and indirect costs
 - # Total costs as commitment base
 - # Modified financial reporting - FSR only due at the end of the competitive segment
 - # Three questions in noncompeting applications

Administrative and Fiscal Monitoring

SNAP Questions

- # Change in "Other Support" key personnel?
- # Change in the level of effort for key personnel?
- # Estimated unobligated balance greater than 25% of current year's total budget?

Administrative and Fiscal Monitoring

Traditional/ Non-SNAP

- # Submit complete non-competing continuation application (PHS 2590)
 - detailed budget and updated other support
- # Categorical awards
- # Total Costs as commitment base
- # Annual Financial Status Reports

What Can Slow Down the Award Process...

- # Lack of or Slow Response to Inquiries
- # Delays Sending JIT Info
 - IRB approvals
 - IACUC approvals
 - Certification of Education on Human Subjects
 - Other Support
- # Information Sent Without Identification
- # Lack of Institutional Signatures

What Can Slow Down the Award Process ...

- # Key Personnel that Aren't Key Personnel
- # Budgets with Inadequate Justification
- # Other Support for an Individual that Adds Up to More than 100%
- # Checklist F&A that Doesn't Make Sense
- # Being on Continuing Resolution

What Can Slow Down the Award Process ...

- # Substantial Carryover Without Justification
- # A Noncompetitive Renewal Missing Interim Required Prior Approvals
- # Sending Change of Institution in August or September

After award, when do we need to contact to NIH?

- # Change in Scope
- # Preaward Costs >90 Days Prior to Effective Date of New or Competing Award
- # Change in Key Personnel
- # Change in Grantee Institution
- # Addition of a Foreign Component
- # Changes in Grantee Organizational Status

After award, when do we need to contact to NIH?

- # Changes to Award Terms and Conditions or Undertaking Any Activities Disapproved or Restricted as a Term of Award
- # Second No-Cost Extension
- # Retention of Research Grant Salary/Fringe Benefit Funds When a K Award is Made
- # Transferring Costs from Trainee Costs

Examples of Change of Scope

- # Change in specific aims
- # Substitution of one animal model for another
- # Change from approved use of animals or human subjects
- # Shift in research emphasis to a different disease area
- # Application of new technology -- i.e., changing to a different type of assay

More Examples of Change in Scope

- # Change in Key Personnel
- # Significant Rebudgeting—i.e., when expenditures in a single direct cost budget category deviate by >25% of the total costs awarded (current year budget + supplements)
- # Transfer of the performance of substantive work to a third party
- # Patient care costs not previously approved

Items that Do NOT Require Prior Approval, Unless Change in Scope

- ✦ Under Expanded Authority/FDP
 - Equipment Purchases >\$25,000
 - Transferring Performance of Substantive Programmatic Work to a Domestic Third Party
 - Incurrence of Patient Care Costs... particularly rebudgeting

Award Closeout

Final Reports - Grantees are required to submit **90 days after the end of the project period**

- ✦ Final Financial Status Reports
- ✦ Final invention statement and certification
- ✦ Final Progress Report

Why Doesn't NIH Do Things One Way?

NCRR NLM NINR FIC NIDDK
NIA NIMH NIBIB NIGMS
NIDCR NCI NIAMS NIEHS
NINDS NHGRI NHLBI
NICH NEI NIDA NCMHD
D NCCAM NIAAA NIAID NIDCD
