NIH Grants Overview: Scientific Review and Grants Management

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NIH Community

NIH

Extramural Research

Intramural Research

Management
The NIDCR Extramural Team

Scientific Review

Program

Grants Management
Life Cycle of an NIH Grant Application
A Grant Application Starts with a Great Idea

- **Who?**
  Scientists at Colleges, Universities, Research Institutes, Small Businesses, Others

- **What?**
  Research relevant to human health: Basic, applied, behavioral, translational, clinical
Examples of NIH Funding Mechanisms

- **Research Projects (R type)**
  - Unsolicited (R01, R21, R03)
  - Individual, multiple PI, or consortium

- **Cooperative Agreements (U type)**
  - Partnership with NIH and an Institution

- **Small Business Grants**
  - Small business innovation research (SBIR)
  - Small business technology transfer (STTR)

- **Training and Career Development (F, K, T)**
  - Predoctoral, postdoctoral, mentored career development
  - Individual or Institutional
Preparing an Application

- Interacting with NIDCR Program Staff
  - Does the proposed research support the mission of the institute?
  - Is the topic a high priority for the institute?

Office of Extramural Research

http://grants1.nih.gov/grants/oer.htm

- Funding Opportunity Announcement
  - Requests for Applications (RFAs)
  - Program Announcements (PAs)
  - Parent Announcements (unsolicited applications)
## Parent Announcements

The following Parent Announcements are available (sorted by Activity Code):

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<th>Announcement Number</th>
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<td>R41/R42</td>
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<td>R43/R44</td>
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Funding Opportunity Announcement

- Instructions for registration & electronic submission are available online
  - Grants.gov requires Institutional registration
  - NIH eRA Commons requires Institutional and individual registration
  - Applicants are highly encouraged to start the registration process at least four weeks prior to the grant submission date.
Preparing an Application

Forms and Instructions
http://grants1.nih.gov/grants/forms.htm

- Standard Form 424 Research and Related electronic application SF424 (R&R)
- PHS 398 (paper) for: Research Grants, Career Awards (K Series), Institutional NRSA (Training) grants, complex mechanisms (U)

Contents

- Face page
- Budget and budget justification
- Personnel
- Research plan
Submitting an e-Application

http://www.grants.gov

Find. Apply. Succeed.

NIH eRA Commons: https://commons.era.nih.gov/commons/

Center for Scientific Review,
Division of Receipt and Referral

Assigned to IC or CSR Review
Electronic Submission www.grants.gov

Applicant organization must register in Grants.Gov and eRA.

Application must be signed and submitted by an Authorized Organizational Representative at the applicant organization.
Receipt and Referral

Center for Scientific Review (CSR) at NIH receives all NIH Applications (~80,000 per year)

- Determines locus of peer review: CSR or Institute
- Assigns CSR Integrated Review Group & Study Section
NIH Peer Review

- Study Section: standing committees and Special Emphasis Panels
- Panel of experts in appropriate scientific areas
- Applications assigned for critique and discussion
- Evaluation of scientific and technical merit
- Meets in person, teleconference, or internet
Role of the Scientific Review Administrator

- Contact for applicant prior to review
- Administrative review of applications for completeness, responsiveness to the FOA
- Selects and assigns qualified reviewers
- During the review meeting, makes sure members of the study section adhere to policy and procedures
- Prepares Summary Statements
Institute Review – NIDCR
NIDCR Special Grants Review Committee:
Special Emphasis Panels (SEP) ZDE1

- Mechanisms used by only one or a few ICs, or mechanisms used by multiple ICs in highly varied ways (examples include)
  - all Ks, Ts, Ps, Us, some R21s

- Requests for Applications (RFAs)

- Multi-site clinical trials
NIDCR Review

- R03 PAR-06-211 NIDCR Small Research Grants for Data Analysis and Statistical Methodology
- R21 PAR-06-219 International Collaborative Oral Health Research Planning Grant
- R21 PAR-06-246 NIDCR Exploratory and Developmental Grants in Clinical Research
- R21 PAR-06-244 NIDCR Clinical Pilot Data Grant
- R21 PAR-06-245 NIDCR Clinical Trial Planning Grant
- R21 PAR-06-213 Clinical Trials: Oral Complications of Cancer Therapy
- R21 PAR-06-556 Clinical Studies of Bisphosphonate Therapy and Osteonecrosis of the Jaws
NIH Peer Review

- Review criteria
  - Significance
  - Approach
  - Innovation
  - Investigator
  - Environment

- Investigators receive a priority score and summary statement
Priority Scores

Each scored grant application is assigned a single score that reflects the overall impact that the project could have on the field based on consideration of the review criteria with the emphasis on each criterion varying from one application to another, depending on the nature of the application and its relative strengths. The best possible priority score is 100 and the worst is 500.
Outcome of Initial Peer Review

- **Priority score**: a numerical rating that reflects the scientific and technical merit of the proposed research relative to the "state of the science"

- **Summary statement**: the reviewers' written comments and the SRA's summary of the discussion during meeting
  - recommendations of the study section
  - comments on Human Subjects (if appropriate)
  - administrative notes of special considerations
  - a recommended budget
Post Peer Review

- Scores are recorded and released within one or two business days
- Summary Statements are available approximately 8 weeks after the meeting
- Accessible from the NIH eRA Commons
- https://commons.era.nih.gov/commons/
Secondary Review

- National Advisory Dental and Craniofacial Research Council (NADCRC)
  - Scientific and public representatives chosen for their expertise, interest, or activity in matters related to oral, dental, and craniofacial health and disease
  - Membership:
    - 2 non-voting ex officio (DOD, VA)
    - 13 scientists/clinicians/public
    - 4 year term
  - Advises, consults, makes recommendations
  - Applications can only be funded after review by NADCRC and concurrence with initial review outcome
Funding Decisions

- **Factors:**
  - Scientific Merit – score, reviewer comments
  - Contribution to the mission of NIDCR
  - Program priorities and portfolio balance
  - Availability of funds

- **Variables:**
  - Award period
  - Total amount of award
  - Specific budget items
Other Post-Review Activities

- Awards administered by an NIDCR Grants Management Officer
- Annual progress reports and financial status reports
- End of award/competing renewal

- If Not Funded:
  - Discussions between Applicant and NIDCR Scientific Program Staff
    - Review issues
    - Programmatic issues
    - Resubmission of revised application (up to 2 resubmissions)
    - Three cycles per year for unsolicited applications
      - Receipt date, review date, council date each cycle
http://www.nidcr.nih.gov/

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Roles & Responsibilities
Grants Management Officer

- The GMO is the only NIH official authorized to obligate NIH to the expenditure of funds - or to change funding amounts, budget/project period dates, or other terms and conditions of a grant award
- Monitors administrative and fiscal aspects of the project
- Assures compliance with federal laws and regulations, and NIH administrative policies and procedures
- GMOs are responsible for maintaining the official grant files for grant awards
Grants Management Specialist

- Assures compliance with Federal law and NIH policies and procedures - are costs requested allocable, allowable and reasonable?
- Analyzes grant applications prior to award
- Provides technical assistance, interprets NIH policies and Institute procedures
- Awards grant funds
- Reviews and responds to grantee prior approval and rebudgeting requests
- Assures documentation of official grant files
- The Grants Management Specialist acts as an agent of the GMO
Grantee Institution

- Award made to institution
- Legally responsible for proper conduct and execution of the project
- Provides fiscal management of the project
- Oversight on allocation decisions
- Assures compliance with Federal laws and regulations, as well as NIH policies and procedures
Authorized Organizational Representative (AOR)

- Designated representative of the grantee organization
- Accountable for information presented in grant application, signs all official correspondence.
- 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 proposal
- Assures compliance with Federal laws and regulations, and NIH policies and procedures - maintains contact with Grants Management Specialist
- Assures scientific compliance by maintaining contact with Program Administrator
Principal Investigator

Should work with designated officials within grantee organization to:

- Create and maintain necessary documentation, both technical and administrative
- Prepare justifications
- Ensure Federal support is acknowledged in publications
- Comply with organizational and Federal requirements
Who to Call?

- Call Program Official for programmatic issues (i.e. which grant mechanism) or scientific issues (specific areas of research NIDCR supports)
- Call Grants Management Specialist for administrative matters (next receipt date, budgetary questions, etc.)
- Issues often overlap and will be discussed between staff
Where to find help …

- General info on Electronic Submission & the SF424 (R&R)

- Grants.gov registration, submission and PureEdge behavior questions:
  - Visit: [http://www.grants.gov](http://www.grants.gov)
  - Grants.gov Customer Service
    - E-mail: support@grants.gov
    - Phone: 1-800-518-4726

- eRA Commons registration and post submission questions on Commons functionality
  - eRA Commons Help Desk
    - E-mail: commons@od.nih.gov
    - Phone: 1-866-504-9552 OR 301-402-7469
Additional Help …

- Forms transition and questions on NIH’s overall plan for electronic receipt
  - NIH Grants Information
    - Office of Extramural Research Home Page
      [http://grants1.nih.gov/grants/oer.htm](http://grants1.nih.gov/grants/oer.htm)
    - E-mail: grantsinfo@nih.gov
    - Phone: 301-435-0714

- NIDCR Grants Management Branch
  - Amy McGuire
  - Email: am366z@nih.gov
  - Phone: (301) 594-4836
  - Main Phone: (301) 594-4800
Type of Applications

- New - Type 1
- Renewal - Type 2
- Revision - Type 3
  - Competitive - outside original scope
  - Administrative - within the original scope
- Extension - Type 4
- Continuation - Type 5
- Successor-In-Interest/Name Change – Type 6
- Change of Grantee Institution – Type 7
- Change of Institute – Type 8 (noncompeting)
- Change of Institute – Type 9 (competing)
Points of Consideration in the Review of R21 Applications

- Justification for the proposed work can be provided through literature citations, data from other sources, or investigator-generated data.

- Less emphasis on methodological detail, supportive preliminary data.

- Preliminary data are not required, may be included if available.
Applicant’s Access to Information/Status

https://commons.era.nih.gov/commons/

Status Information

**Study Section**
Init Review: ZDE1 LK (01)
Meeting Date: 05/05/07
Study Roster: [View Roster Member Details](web link active 30 days before meeting)

**Contacts**
Scientific Review Administrator (SRA) Name, Telephone
Grants Management Specialist (GMS)
Program Official (PO)