



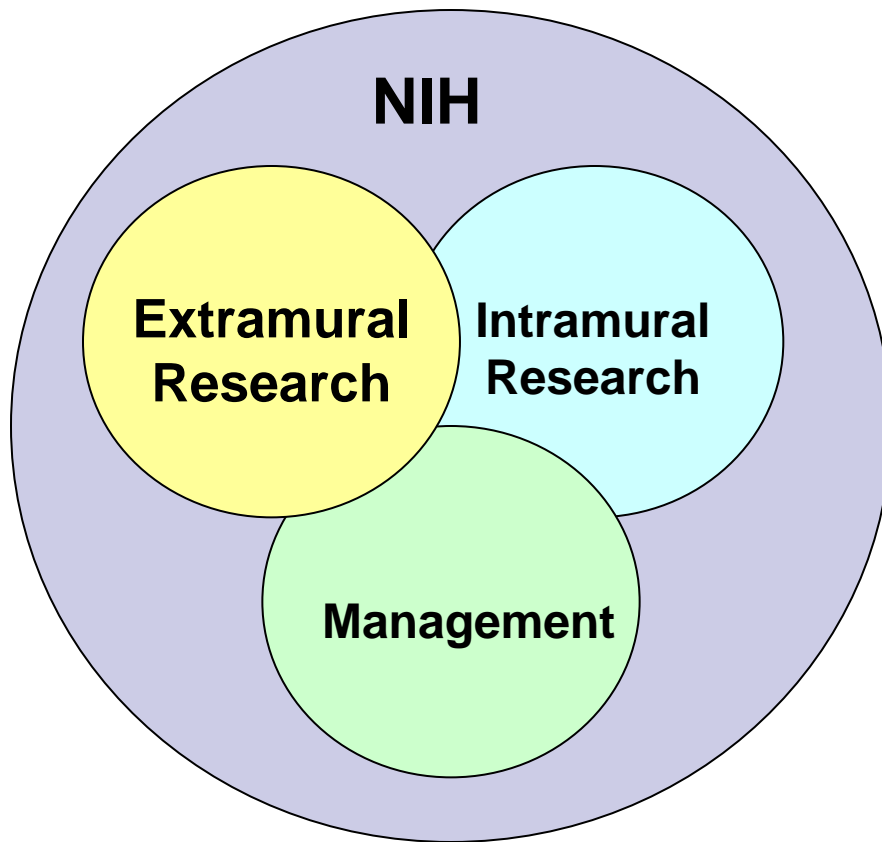
NIH Grants Overview: Scientific Review and Grants Management

Lynn Mertens King, PhD
Chief
Scientific Review Branch
Division of Extramural Activities
NIDCR

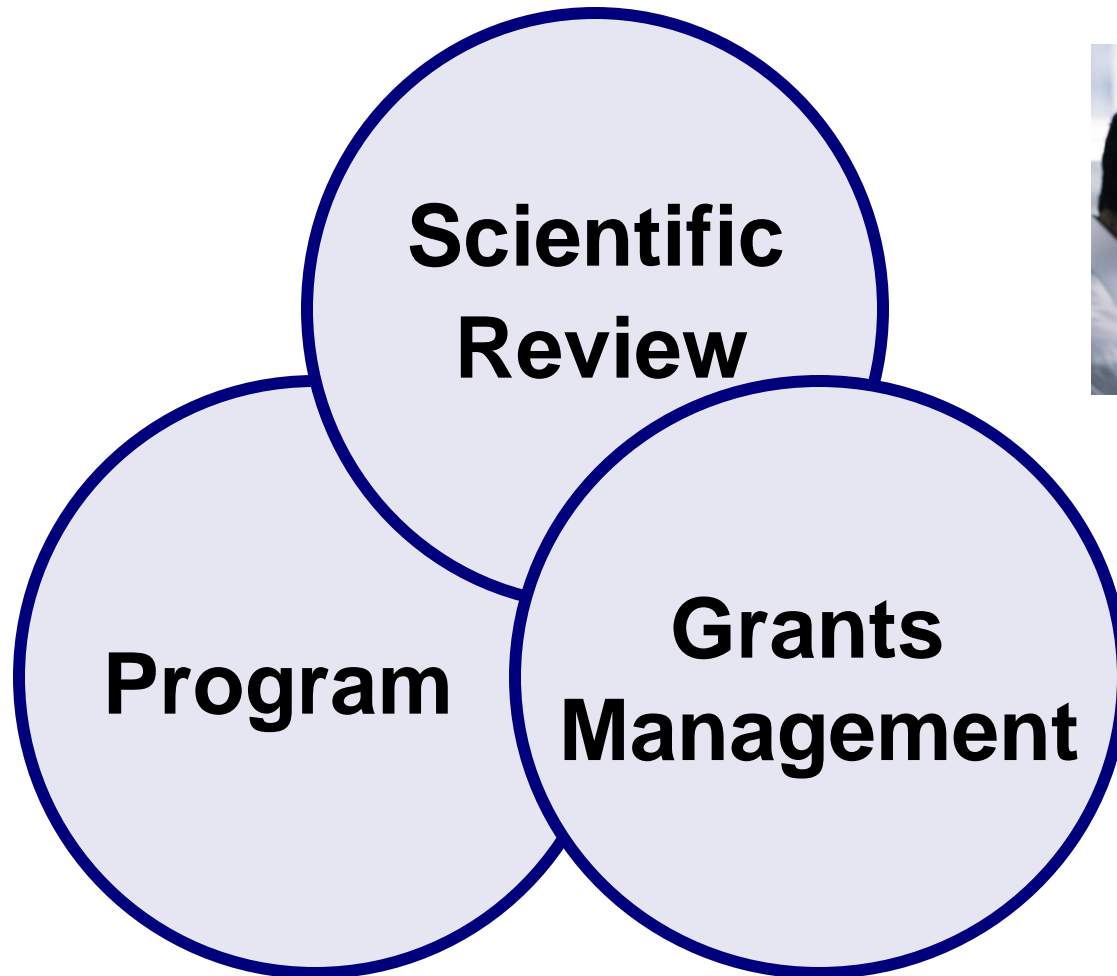
Amy McGuire
Grants Management Specialist
Grants Management Branch
Division of Extramural Activities
NIDCR



NIH Community



The NIDCR Extramural Team





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?

NATIONAL INSTITUTES OF HEALTH
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)

Office of Extramural Research

Parent Announcements (For Unsolicited or Investigator-Initiated Applications)

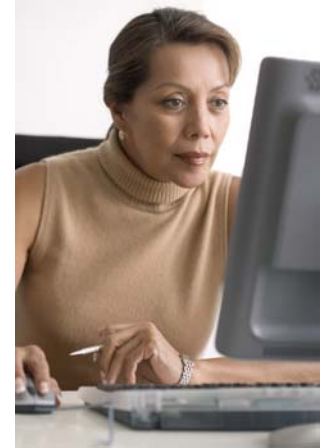
The following Parent Announcements are available (sorted by Activity Code):

Activity Code(s)	Title	Announcement Number	Issuing Organization	Release Date	Opening Date (SF424 Only) 	Expiration Date
R01	Research Project Grant (Parent R01)	PA-07-070	NIH	11/20/2006	01/05/2007	01/03/2010
R03	NIH Small Research Grant Program (Parent R03)	PA-06-180	NIH	03/02/2006	05/02/2006	05/02/2009
R13, U13	NIH Support for Conferences and Scientific Meetings (Parent R13/U13)	PA-06-041	NIH	10/26/2005	11/21/2005	09/02/2008
R15	Academic Research Enhancement Award (Parent R15)	PA-06-042	NIH	10/26/2005	01/17/2006	01/03/2009
R21	NIH Exploratory/Developmental Research Grant Program (Parent R21)	PA-06-181	NIH	03/02/2006	05/02/2006	05/02/2009
R41/R42	PHS 2007-02 Omnibus Solicitation of the NIH for Small Business Technology Transfer Grant Applications (Parent STTR [R41/R42])	PA-07-281	NIH	01/16/2007	02/05/2007	01/03/2008
R43/R44	PHS 2007-02 Omnibus Solicitation of the NIH, CDC, and FDA for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44])	PA-07-280	NIH	01/16/2007	02/05/2007	01/03/2008

http://grants1.nih.gov/grants/guide/parent_announcements.htm

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

Get Electronic



Submitting an e-Application



<http://www.grants.gov>



Find. Apply. Succeed.



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



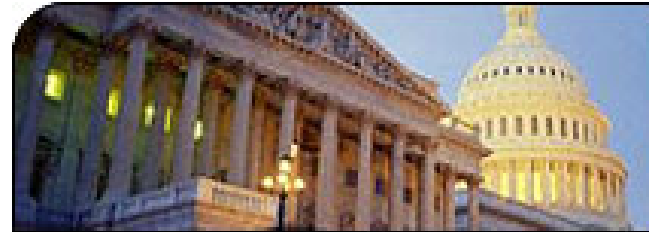
**Center for Scientific Review,
Division of Receipt and Referral**



Assigned to IC or CSR Review



Electronic Submission www.grants.gov



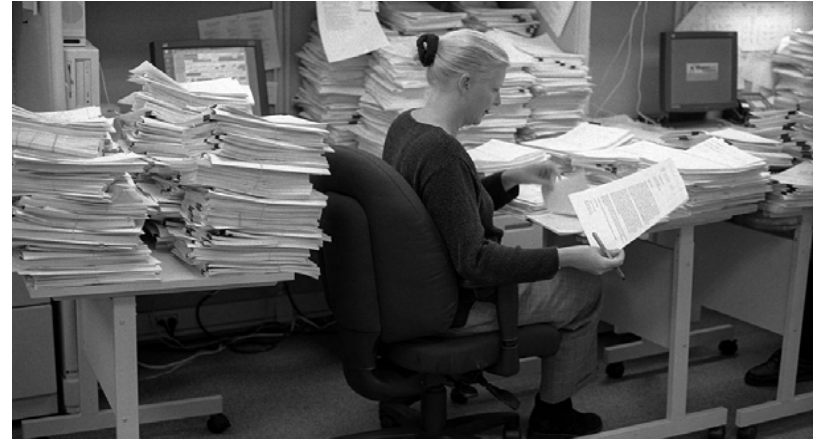
Applicant organization must register in Grants.Gov and eRA.

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



Priority Score Range	Description
1.0 - 1.5	Outstanding
1.6 - 2.0	Excellent
2.1 - 2.5	Very Good
2.6 - 3.0	Good
3.1 - 5.0	Acceptable



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:

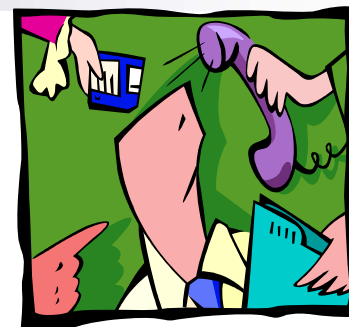
- Scientific Merit – score, reviewer comments
- Contribution to the mission of NIDCR
- Program priorities and portfolio balance
- Availability of funds

■ Variables:

- Award period
- Total amount of award
- Specific budget items



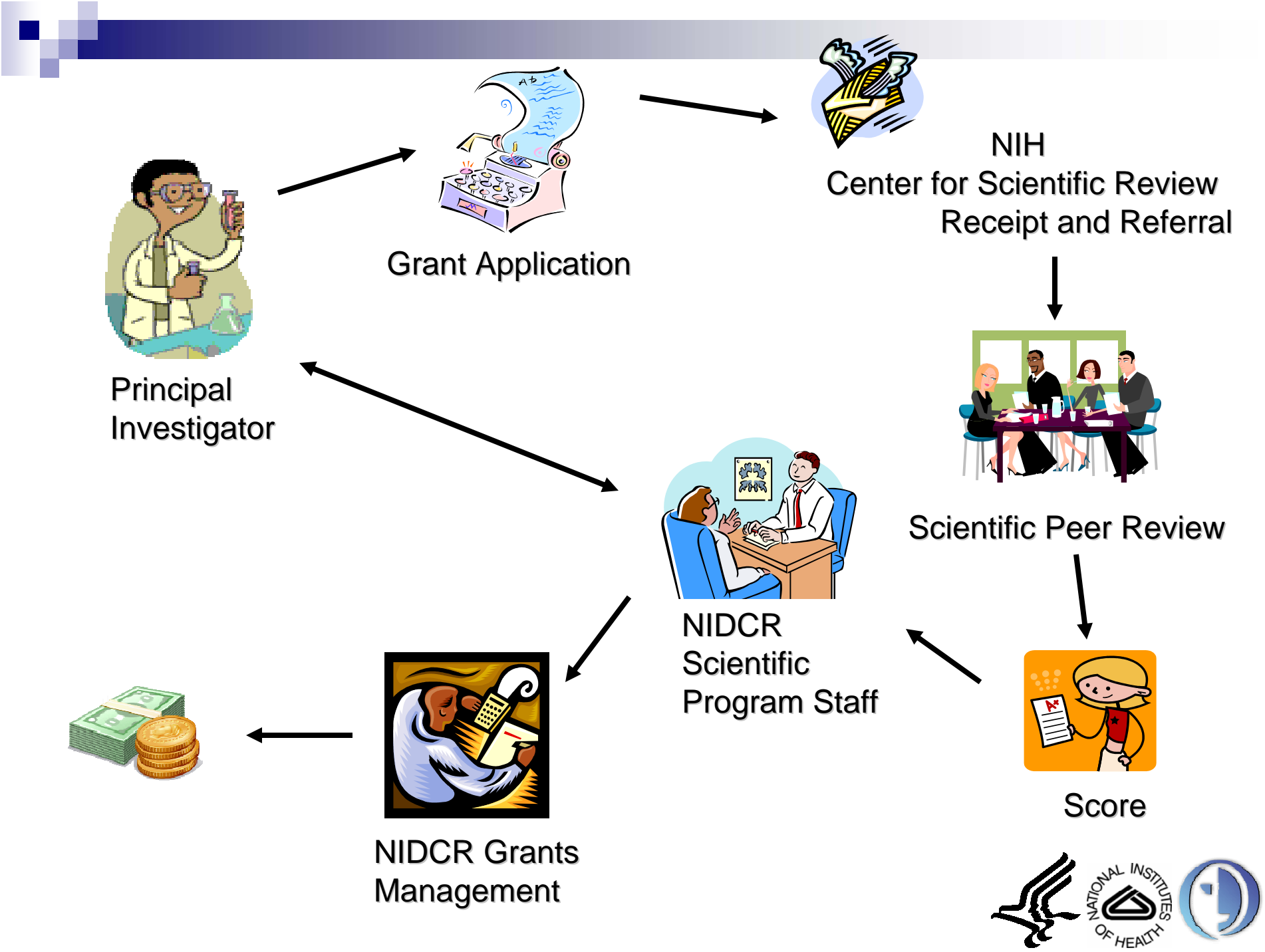
Other Post-Review Activities



- 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





Principal Investigator



Grant Application



NIH
Center for Scientific Review
Receipt and Referral



Scientific Peer Review



Score



NIDCR
Scientific
Program Staff



NIDCR Grants
Management





NIDCR National Institute of
Dental and Craniofacial Research

Improving the Nation's Oral Health



NATIONAL INSTITUTES OF HEALTH

Text Size:

<http://www.nidcr.nih.gov/>

Lynn Mertens King, PhD
Chief, Scientific Review Branch
National Institute of Dental and Craniofacial Research
45 Center Drive, Room 4AN 32F
Bethesda, MD 20892-6402
Lynn.King@NIH.gov





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)
 - <http://era.nih.gov/ElectronicReceipt>

- Grants.gov registration, submission and PureEdge behavior questions:
 - Visit: <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
 - Support Page: <http://era.nih.gov/commons>
 - eRA Commons Help Desk
 - Web support: <http://ithelpdesk.nih.gov/eRA/>
 - 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>
 - 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)

