

NIH Agency Specifics

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NIH Pre-Award

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What is the NIH?

The National Institutes of Health is the primary federal agency for conducting and supporting medical research in the United States. The NIH is comprised of 27 institutes and centers and is part of the U.S. Department of Health & Human Services.



NIH Mission

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to **enhance health, lengthen life, and reduce illness and disability.**

Agency Goals:

- Foster fundamental creative discoveries, innovative research strategies,
- Develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease
- Expand the knowledge base in medical and associated sciences and ensure a continued high return on the public investment in research
- Exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science

In realizing these goals, the NIH provides leadership and direction to programs designed to improve the health of the Nation by conducting and supporting research in:


- Causes, diagnosis, prevention, and cure of human diseases
- Processes of human growth and development
- Biological effects of environmental contaminants
- Understanding of mental, addictive and physical disorders
- Directing programs for the collection, dissemination, and exchange of information in medicine and health, including the development and support of medical libraries



NIH Institutes

- [National Cancer Institute \(NCI\)](#) — Est. 1937
- [National Eye Institute \(NEI\)](#) — Est. 1968
- [National Heart, Lung, and Blood Institute \(NHLBI\)](#) — Est. 1948
- [National Human Genome Research Institute \(NHGRI\)](#) — Est. 1989
- [National Institute on Aging \(NIA\)](#) — Est. 1974
- [National Institute on Alcohol Abuse and Alcoholism \(NIAAA\)](#) — Est. 1970
- [National Institute of Allergy and Infectious Diseases \(NIAID\)](#) — Est. 1948
- [National Institute of Arthritis and Musculoskeletal and Skin Diseases \(NIAMS\)](#) — Est. 1986
- [National Institute of Biomedical Imaging and Bioengineering \(NIBIB\)](#) — Est. 2000
- [Eunice Kennedy Shriver National Institute of Child Health and Human Development \(NICHD\)](#) — Est. 1962
- [National Institute on Deafness and Other Communication Disorders \(NIDCD\)](#) — Est. 1988
- [National Institute of Dental and Craniofacial Research \(NIDCR\)](#) — Est. 1948
- [National Institute of Diabetes and Digestive and Kidney Diseases \(NIDDK\)](#) — Est. 1950
- [National Institute on Drug Abuse \(NIDA\)](#) — Est. 1974
- [National Institute of Environmental Health Sciences \(NIEHS\)](#) — Est. 1969
- [National Institute of General Medical Sciences \(NIGMS\)](#) — Est. 1962
- [National Institute of Mental Health \(NIMH\)](#) — Est. 1949
- [National Institute on Minority Health and Health Disparities \(NIMHD\)](#) — Est. in 1993
- [National Institute of Neurological Disorders and Stroke \(NINDS\)](#) — Est. 1950
- [National Institute of Nursing Research \(NINR\)](#) — Est. 1986
- [National Library of Medicine \(NLM\)](#) — Est. 1956

For more information: <http://www.nih.gov/icd/>



NIH Funding

NIH funds [grants](#), [cooperative agreements](#), and [contracts](#) that support the advancement of fundamental knowledge about the nature and behavior of living systems to meet the NIH Mission of extending healthy life and reducing the burdens of illness and disability.

http://grants.nih.gov/grants/grant_basics.htm



NIH Grant Process

Submit Application

Applicant organization submits most applications to NIH through Grants.gov.

Receipt & Referral: Months 1-3

- Applications compliant with NIH policies are assigned for review by the Division of Receipt and Referral in the Center of Scientific Review (CSR).
- CSR assigns application to an NIH Institute/Center (IC) and a Scientific Review Group (SRG).
- Scientific Review Officer (SRO) assigns applications to reviewers and readers.

Peer Review: Months 4-8

Initial Level of Review: SRG members review and evaluate applications for scientific merit

Impact Scores: Available to Principal Investigator on eRA Commons


Summary Statement: Available to Principal Investigator on eRA Commons

Second Level of Review: Advisory council/board reviews applications

Award: Months 9-10

Pre-Award Process: IC grants management staff conducts final administrative review and negotiates award. **JIT TIME!*

Notification of Award: NIH Institute/Center (IC) issues and sends Notice of Award (NoA) to applicant institution/organization.



NIH Participants

- **Center for Scientific Review (CSR):** Portal for NIH grant applications and their review for scientific merit. CSR organizes the peer review groups or study sections.
- **Scientific Review Officer (SRO):** NIH officer who serves as the designated Federal official having legal responsibility for managing the peer review meeting, the procedures for evaluating the applications assigned to the Scientific Review Group and the determinations and management of conflicts of interest.
- **Grants Management Officer (GMO):** Signs the Notice of Award (NoA) and is the NIH official who is responsible for the business management and other non-programmatic aspects of the award. GMOs ensure that the NIH and grantee staffs fulfill requirements of laws, regulations, and administrative policies.
- **Grants Management Specialist (GMS):** Works with the GMO on day-to-day management of the grant. The name and contact information of the GMS assigned to a particular grant appears on the NoA.
- **Program Official (PO):** Responsible for programmatic, scientific, and/or technical aspects of assigned applications and grants. Develop research initiatives and research training programs; coordinate with Center for Scientific Review and IC Scientific Review Officers and work in partnership with grants management on post-award administration (review of progress reports, participation in site visits, and other activities).
- **Office of Extramural Research (OER):** Provides corporate framework for NIH research administration, ensuring scientific integrity, public accountability, and effective stewardship of the NIH extramural research portfolio.



Finding NIH Funding

- Grants.Gov:
http://www.grants.gov/applicants/find_grant_opportunities.jsp
- OER: <http://grants.nih.gov/grants/oer.htm>
- NIH Weekly Funding Opportunities Listserv:
<http://grants.nih.gov/grants/guide/index.html>

3 kinds of solicitations or FOAs:

- 1) Parent Announcement:** Most common; Investigator Initiated, Standard Deadlines: <http://grants.nih.gov/grants/funding/submissionschedule.htm>
- 2) Program Announcement:** Normally on the standard receipt dates. Usually for a specific scientific need and investigator initiated.
- 3) Request for Applications (RFA):** Specified receipt date. For a well defined scientific area. Specifies number of awards.



Selecting the right type of grant

- Identify an institute within NIH that would possibly fund your research:
<http://www.nih.gov/icd/>
- Contact that Institute's PO to discuss your research
- If investigator initiated, review & select from the NIH funding mechanisms or reply to a specific PA or RFA.

Here are the main three research mechanisms that NIH funds:

R01 – Research Project Grant Program

- Used to support a discrete, specified, circumscribed research project
- Most commonly used grant program
- No specific dollar limit unless specified in FOA
- Advance permission required for \$500K or more (direct costs) in any year
- Generally awarded for 3 -5 years
- All ICs utilize
- Parent FOA: <http://grants.nih.gov/grants/guide/pa-files/PA-13-302.html>



Selecting the right type of grant

R21 - NIH Exploratory/Developmental Research Grant Award

- Encourages new, exploratory and developmental research projects. Sometimes used for pilot and feasibility studies.
- Limited to up to 2 years of funding
- Combined budget for direct costs for the 2-year project period usually may not exceed \$275,000
- No preliminary data is generally required
- Most ICs utilize
- Parent FOA: <http://grants.nih.gov/grants/guide/pa-files/PA-13-303.html>

R03 - Small Grant Program

- Provides limited funding for short time period to support a variety of types of projects
- Limited to 2 years of funding
- Direct costs generally up to \$50,000 per year
- Not renewable
- Utilized by more than half of the NIH ICs
- Parent FOA: <http://grants.nih.gov/grants/guide/pa-files/PA-13-304.html>

For more mechanisms please visit: http://grants.nih.gov/grants/funding/funding_program.htm



Selecting the right type of grant

CAREER GRANTS - <http://grants.nih.gov/training/careerdevelopmentawards.htm>

Purpose: To provide support and “protected time” for an intensive, career development experience which leads to research independence or to expand their potential to make significant contributions to their field of research. Examples include:

- K01: Mentored Research Development Award
- K02: Independent Scientist Award
- K05: Senior Scientist Award

TRAINING GRANTS - <http://grants.nih.gov/training/nrsa.htm>

For the institution to provide training funds for a fixed number of predoctoral and/or postdoctoral positions to learn and be trained in research. Examples:

- T32 : Most common; For year-round appointments of predoctoral and/or postdoctoral trainees; 2-year minimum commitment usually required for MDs. (For detailed instructions, see PA-14-015.)
- T35 - Short Term Institutional NRSA; Usually funds summer research for medical students, minority students, or for a special class; Only offered by some institutes. (For detailed instructions, see PA-14-016.)



Selecting the right type of grant

FELLOWSHIP GRANTS - <http://grants.nih.gov/training/nrsa.htm>

Awards made to the institutional on behalf of a predoctoral or postdoctoral scholar for the purpose of facilitating their research education and training. These grants are mentored grants.

Examples:

- F30: Individual **Predoctoral** NRSA for MD/PhD. Fellowships - Individual fellowships for training that leads to the combined MD/PhD . For more info, see PA-14-150.
- F31: **Predoctoral** Individual National Research Service Award - To provide supervised research training in specified health and health-related areas leading toward the research degree (e.g., PhD). For more info, see PA-14-147.
- F32: **Postdoctoral** Individual National Research Service Award - To provide research training to broaden their scientific background and extend their potential for research in specified health-related areas. For more info, see PA-14-149.



Selecting the right type of grant

Program Project/Center Grants (P series)

Large, multi-project efforts that generally include a diverse array of research activities.

Examples:

- **P01:** Research Program Project Grant
 - Support for integrated, multi-project research projects involving a number of independent investigators who share knowledge and common resources
 - Each project contributes or is directly related to the common theme of the total research effort, thus forming a system of research activities and projects directed toward a well-defined research program goal
 - Specific dollar limit unless specified in FOA
- **P30:** Center Core Grants
 - To support shared resources and facilities for categorical research by a number of investigators from different disciplines who provide a multidisciplinary approach to a joint research effort or from the same discipline who focus on a common research problem.
 - The core grant is integrated with the center's component projects or program projects, though funded independently from them.



NIH Grant Award Types

The first digit on the Proposal/Award Number is known as the Application Identification Number, also known as “Types”:

- **Type 1:** New — Provides PHS support for a new grant
- **Type 2:** Renewal — Extends a project period that would otherwise expire for one or more grant budget periods; applications are peer reviewed and compete for funding
- **Type 3:** Supplement — Provides additional funds to grant as administrative supplement or revision (*aka competing supplement*)
- **Type 4:** Extension — Provides time and funds beyond the recommended level; used only for a few award types
- **Type 5:** Noncompeting Continuation — Continues support in the out years of a grant; does not compete for funds
- **Type 6:** Change of Grantee — Transfers a grant only when one organization buys out another, also called successor of interest
- **Type 7:** Change of Grantee — Transfers a grant from one institution to another (other than Type 6).
- **Type 8:** Change of NIH Institute — Transfers a grant from one institute to another
- **Type 9:** Change of institute—continues support for grant transferred from one institute to another.

Examples: 5 R01 CA012345-02

2 R01 CA012345-06



Grants Policy and Guidance

- SF 424 R&R Instructions
 - Provides guidance for the preparation and submission of proposals
 - <http://grants.nih.gov/grants/funding/424/index.htm>
- NIH Grants Policy Manual
 - General terms and conditions for all NIH awards
 - <http://grants.nih.gov/grants/policy/policy.htm>
- eRA Commons User Guide
 - http://era.nih.gov/commons/user_guide.cfm



Proposal Process

- Review Solicitation
- Prepare Budget
- Download Proposal Package (or Paper Forms)
- Complete Proposal Package
- Submit Proposal
- Review Proposal in eRA Commons
- Submit Just In Time (JIT) Materials



Solicitation Review

1. Ask for the solicitation & read carefully!
2. Key Items:
 - a) Eligibility Requirements
 - b) Paper vs. Electronic Submission
 - c) Deadline Dates – See handout
 - d) Budget Restrictions
 - e) Page Limitations – See handout
 - f) Contact for Questions
3. Sample Solicitation Review – See Handout



Budget Preparation

Salary Cap - NIH will not pay requested salary above the annual salary cap

- AN Faculty = \$183,300
- AY Faculty = \$137,475 AY; \$45,825 SU
- Modular Budgets: Determine which module to request using the salary cap
- Detailed Budgets: Include the actual salary and NIH will cut at the time of award

**Exception – If we are running up to a direct cost cap, we should use the salary cap amount*



Budget Preparation

- Person Months

- List effort in person months rather than percentages of effort in both the detailed budget and budget justification
 - AN Faculty: 5% effort = .6 Calendar months ($.05 \times 12$ mos.)
 - AY Faculty:
 - 5% Effort in Academic Year = .45 Academic Months ($.05 \times 9$ mos.)
 - 5% effort in Summer = .15 Summer Months ($.05 \times 3$ mos.)
- FAQs and Converter Calculator

http://grants.nih.gov/Grants/policy/person_months_faqs.htm



Budget Preparation

- Modular Budget
 - Designed to focus the attention of investigators and NIH staff on science rather than budget details
 - **Required** on new, competing continuation, and revised applications that request up to a total of \$250,000 Direct Costs (less consortium F&A) and fall in one of the following mechanisms: R01, R03, R15, R21, R34, and some RFA/PAs
 - Request Total Direct Cost in modules of \$25,000



Budget Preparation

- Module Calculation
 - $\text{Total Direct Cost} / \# \text{ of yrs requested} = \text{Avg. Direct Cost per yr}$
 - $\text{Avg. Direct Cost per yr} / \$25,000 = \# \text{ of modules to be requested}$
 - Request total direct cost in modules of \$25,000
 - Must use salary cap when determining modules
 - Large equipment purchases should be taken into consideration when determining # of modules in a given year
 - Typical modular applications will request the same number of modules for each year



Budget Preparation


- Modular Budget Justifications
 - Justification required for:
 - All personnel including position, role and level of effort (**in person months**)
 - “To be appointed” positions
 - Consultants
 - Separate justification explaining the difference in the number of modules requested between yrs, if applicable
 - Separate justification for consortium costs, if applicable.



Budget Preparation

- R&R Budget Component
 - Detailed budget including sections A through K
 - A. Senior/Key Personnel
 - All senior/key persons who are at the applicant organization and are included in the project in that budget year
 - B. Other Personnel
 - List all other persons requesting pay on the project that weren't included in section A

* *Note: For detailed budgets with individuals paid over the NIH salary cap, please include their actual salary and NIH will cut it before making an award*



Budget Preparation

- R&R Budget Component

- C. Equipment

- All items over \$5,000 and placed in service for over one year

- D. Travel (foreign and domestic listed separately)

- Include details such as persons traveling, destinations and dates in budget justification

- E. Participant Support Costs

- Unless included in a specific program announcement, this category isn't used by NIH and should be left blank



Budget Preparation

- R&R Budget Component

- F. Other Direct Costs

- 1. Materials & Supplies

- Explain general categories in budget justification, including an amount for each category

- 2. Publication Costs

- 3. Consultant Services

- Include name and organizational affiliation for all consultants in budget justification, as well as services to be performed



Budget Preparation

- R&R Budget Component
 - F. Other Direct Costs
 - 4. ADP/Computer Services
 - 5. Subaward/Consortium Costs - Total of all subs included in budget (direct and indirect costs)
 - 6. Equipment or Facility Rental/User Fees
 - 7. Alterations & Renovations
 - 8. Other
 - Grad Tuition & Fees
 - Patient Care Costs



Budget Preparation

- R&R Budget Component
 - G. Total Direct Costs (Sum of A-F)
 - H. Indirect Costs
 - Most allow MSU's full negotiated rate of 53.5% (55%)
 - I. Total Direct & Indirect (Sum of G and H)
 - J. Fees - Typically not allowed in a Grant or Cooperative Agreement
 - K. Budget Justification
 - Justify all categories of expenses included in your budget
 - Subaward/Consortium – Included with their own budget attachment and are not included here



Proposal Preparation

Paper vs. Electronic Forms

- Paper: <http://grants1.nih.gov/grants/forms.htm>
 - PHS 398 – Paper competing grant application
- Electronic Application
 - Download package from Grants.gov
 - Sharing the proposal package between users – one at a time
 - Let's go through the proposal forms together – **See handout**



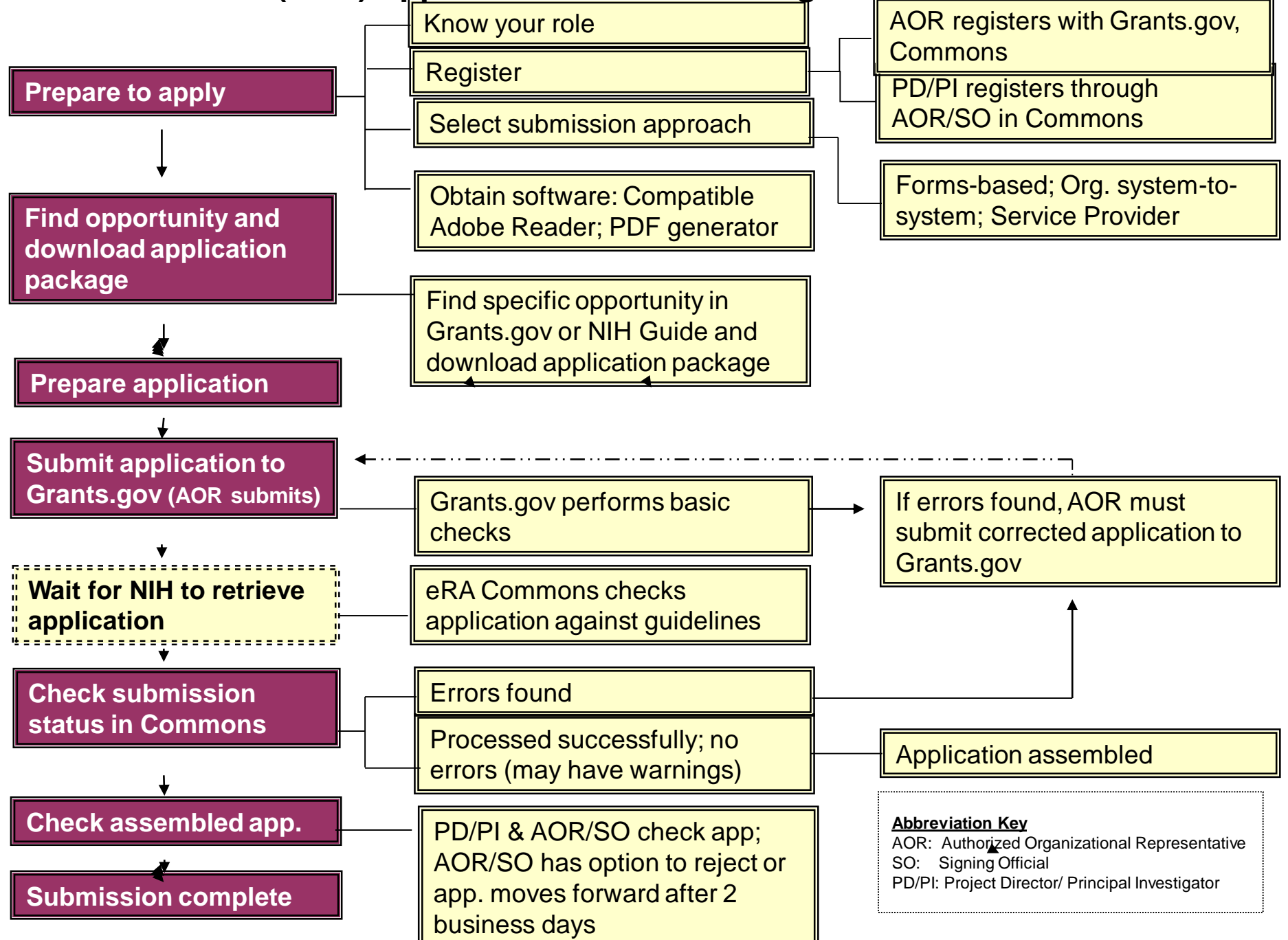
Proposal Submission

Submitting Electronic Application

1. OSP submits to Grants.gov
2. Proposal package retrieved by NIH and loaded into eRA Commons
3. PI has **2** business days to review proposal package in eRA Commons – only if **prior** to the deadline



Electronic SF424 (R&R) Application Process Through Grants.gov



What is eRA Commons?

NIH's electronic proposal and grant processing system, which supports the full grant life cycle from proposal submission to grant close-out

To Register:

- Email your OSP Proposal Team to request access
- Faculty registration required in order to submit application with PI role
- Administrators are registered with the ASST role
- Trainees and Fellows must also be registered



Proposal Review in eRA Commons

- Only PIs have access to review their proposals in eRA Commons
- If you are assigned with the ASST role in eRA Commons, the PI may designate you with “view access”
- View the proposal as it will be seen by reviewers
- Two working days (as long as it is submitted before the deadline) to review proposal before it is passed on for review



Other pre-award tasks in eRA Commons

- Supplement requests
- Proposal withdrawals

*ASSIST – separate system-to-system service required for large proposal submissions.



Peer Review Process

- Level 1 – Carried out by Scientific Review Group (SRG)
 - Scientific Review Officer (SRO) assigned, as well as SRG Chair and Review Panel
 - Scoring utilizes a 9 point rating scale (*1=exceptional; 9=poor*)
 - NRFC = Not Recommended for Further Consideration (Not passed on to second level of review)



Peer Review Process

High Impact Table

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses

Medium Impact Table

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses

Low Impact Table

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses

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

Peer Review Process

- Level 2 – Institute and Center (IC) National Advisory Councils or Boards
 - Composed of scientists from the extramural research community and public representatives
 - IC director makes final funding decisions based on staff and Advisory Council/Board advice
 - NRFC = Not Recommended for Further Consideration (Not passed on to the second level of review)



Just in Time (JIT) Process

- Following the peer review process, applications that may be funded are typically reviewed for the following additional components:
 1. Other Support Document
 - Must be submitted for all senior/key personnel
 - Reviewing to ensure the following:
 - Sufficient levels of effort are committed to the project
 - No scientific, budgetary, or commitment overlap
 - Commitment must be listed in person months
 2. IRB Approval
 3. IACUC Approval
 4. Evidence of compliance with education in the protection of human research participants requirement
- 

Just in Time (JIT) Process

- PI will be notified (primarily by e-mail) when JIT information is needed
- May have 2 weeks (or less) from the date they were notified to submit the materials
- In most cases, JIT information is uploaded by the PI in eRA Commons. OSP reviews and submits the JIT request
- Please work with your OSP Proposal Team if an extension of time is needed to submit JIT



Just in Time (JIT) Process

To submit **Just in Time** information

- Log into eRA Commons as a Signing Official (SO)
- Click the **Status** tab at the top of the screen
- Click the **Just In Time** hyperlink on the left side of the screen under Status
- Enter any known information (PI Name, Grant Number, etc.) into any of the available data fields and click **Search**
- From the *Status Result – Just In Time* screen, select the **JIT** hyperlink in the *Action* column for the desired grant
- Upload the required Support , Budget and/or Other file
- Click Import
- Click Browse and select the document you wish to upload
- Click Upload File
- Once the file has been uploaded the *Just In Time* screen appears



Award Received

- Award notifications are emailed to your OSP Contract Team
- OSP Contract Team reviews for the following:
 - Terms and conditions
 - Final budget must matches awarded amount
 - All necessary compliance information (IRB, IACUC, etc.)
- Once review is complete, award will be passed to CGA for account setup. PI and administrator are copied on this email to CGA Awards Group.



Other NIH Policies to be Aware of:

- New Investigator and Early Stage Investigator
 - http://grants.nih.gov/grants/new_investigators/
- Post Submission Application Materials
 - NOT-OD-10-115
- Prior Approval Required for \$500,000+ Direct Costs
 - Must seek approval from IC at least 6 weeks prior to submission
 - Doesn't apply to proposals submitted in response to RFA's that include specific budgetary limits



Other NIH Policies to be Aware of:

- Modified Submission Policy
 - Available for certain applications submitted listing as PD/PI individuals serving as appointed members of NIH chartered standing study sections.
 - http://grants.nih.gov/grants/peer/continuous_submission.htm
- Late Applications
 - You may not request permission to submit a late application
 - If you submit late, your proposal must include a cover letter explaining the reasons for the delay
 - Late applications are reviewed on an individual basis to determine whether or not the proposal will be reviewed



Other NIH Policies to be Aware of:

- Resubmission Policy
 - NIH will not accept a Resubmission that is submitted later than 37 months after the date of receipt of the initial New, Renewal, or Revision application
 - Only one resubmission allowed (NOT-OD-10-140)
 - The same idea may also be submitted as a new application (NOT-OD-14-074)
- Grants.gov Application Packages (FORMS-C)



Post-Award Management for NIH Grants



Presented By:

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Key Points of NIH Grants

- Award Types
- Prior Approvals
- Re-Budgeting
- eRA Commons
- RPPR
- Financial Reporting
- Closeout

Award Types

Grant Number: 1R21EB017881-01A1
FAIN: R21EB017881

Principal Investigator(s):

- Grant Number Defines:
 - Type of Award
 - Year
 - Type of Funding
 - “Standard Years”
 - Supplemental Funding

Prior Approvals

- Partial Listing of the Most Common:
 - Grantee approved no-cost extension
 - No-cost extensions requested after the budget period end
 - No-cost extensions beyond the initial or 12 months
 - Carryover of Unobligated Balances (authority is outlined in the NoA)
 - Change in Scope
 - Change in Key Personnel or significant reduction of effort
 - Key personnel are only those listed on the NoA
 - Addition of a Foreign Component

NIH Grants Policy Statement, Section 8.1.2 Prior Approval Requirements

Prior Approvals – Grantee Approved No-Cost Extensions

- How do I request an initial No-Cost Extension?
 - Must be submitted prior to current budget period end for Grantee Authority
 - PI must provide the following information via email to awards@cga.msu.edu:
 - The Grant Number (NIH Grant Number)
 - The date to which to extend the agreement
 - A technical justification as to why the justification is necessary
 - A brief description of what will be done during the extension period
 - A comment about the work that is being performed during the extension period is within the original scope of work
 - If effort is reduced more than 25% during this time we'll need to seek agency approval of the reduced effort on the project

Prior Approvals – NIH Approved No-Cost Extensions

- NIH approval is required if submitted after the end date or 2nd or beyond no-cost extension
 - Provide the following information to submit to NIH:
 - Memorandum, on department letterhead, addressed to the Grants Management Specialist, referencing the NIH grant number – must include a scientific justification for the extension as well as identifying the unspent balance and plans for expenditure
 - A budget for the unspent balance – ideally on the PHS 2590 form (Page 2 (Budget), Page 3 (Justification), and Page 6 (Checklist – IDC))
 - Once complete – please have the PI sign and send to awards@cga.msu.edu for review, countersignature, and submission

Prior Approvals - Carryover

- Carryover authority defined in Section 3 of the NoA
- Carryover requests are submitted after the Annual FFR is submitted – CGA will notify the FO and PI of the unspent balance
 - The following information is necessary to request carryover:
 - Memorandum, on Department Letterhead, Addressed to the Grants Management Specialist, referencing the NIH Grant number – must include a scientific justification for the unspent balance and plans for expenditure
 - A budget for the unspent balance – ideally on the PHS 2590 form (Page 2 (Budget), Page 3 (Justification), and Page 6 (Checklist – IDC))
 - Once complete – please have the PI sign and send to awards@cga.msu.edu for review, countersignature, and submission

Prior Approvals – Change in Key Personnel

- NIH considers only those listed as the Principle Investigator or in Section 4 of the NoA as Key Personnel requiring prior approval
 - In order to request a change in key personnel:
 - Memorandum, on department letterhead, addressed to the Grants Management Specialist, referencing the NIH grant number – must include a justification for the change in key personnel (also note if change in scope, any budget implications, etc.)
 - Biographical sketch and other support information for the replacement key personnel must be included
 - Once complete – please have the current and newly proposed PI sign and send to awards@cga.msu.edu for review, countersignature, and submission

Prior Approvals – Significant Reduction of Effort

- Effort as included in the proposal is in effect for all Key Personnel over the course of the project unless a significant reduction is approved
 - What is a significant reduction?
 - Absence of 3 months or more
 - Reduction of 25% or more of proposed effort
 - How to request a reduction in effort:
 - Memorandum, on Department Letterhead, Addressed to the Grants Management Specialist, referencing the NIH Grant number – must include a justification for the reduction of effort as well as indicating if there will be any change to the scope or any significant budget implications
 - Once complete – please have the PI sign and send to awards@cga.msu.edu for review, countersignature, and submission

Re-Budgeting

- When can I re-budget?
 - Most NIH awards do not have re-budgeting restrictions. Common ones are the standard research awards such as R01's.
 - Prior approval will need to be sought if the budget change causes a change in scope
 - If acquiring a large piece of equipment, not previously budgeted – contact the Awards (awards@cga.msu.edu) Group for further guidance
 - Training Grants and Fellowship Awards do have re-budgeting restrictions
 - Cannot re-budget Stipends or Tuition/Fees on a Training Grant
 - Cannot re-budget Stipends or Tuition/Fees on a Fellowship Award
 - Institutional Allowance is restricted for re-budgeting into Tuition/Fees only for Fellowship Award

Always consult the Grants Policy Statement and Funding Opportunity Announcement (FOA) for further guidance.

Case Study #1

Dr. John Smith currently has an R01 which he'd like to add Dr. John Doe from the University of Michigan as an NIH recognized Co-PI on. Is this possible and, if so, what would he need to do?

- First, check the Request for Applications (RFA) which is referenced on the NoA to see if there are any constraints
- If no constraints, prepare the following for submission:
 - Memorandum addressed to the GMS, referencing the Grant Number and include a scientific justification for the change, leadership plan, designation of a contact PI who is located at the grantee institution, biographical sketches and other support information for additional PIs, budgetary implications of the change, and proposed changes in scope
 - Once complete, both the current PI and proposed PI need to sign the memorandum and send to awards@cga.msu.edu for review, countersignature and submission
- A revised NoA confirms that the change has been recorded

Case Study #2

Dr. Tom Smith currently has a P42 and wishes to add a subaward with the University of Peru which was not previously budgeted. Is prior approval necessary?

- Yes! The addition of a foreign component requires prior approval.
 - Prepare a memorandum, on department letterhead, addressed to the Grants Management Specialist, referencing the NIH grant number – must include a justification for the addition of the subaward as well as indicating if there will be any change to the scope or any significant budget implications. Include a budget, justification, and statement of work for the Subrecipient
 - Once complete, have the PI sign and send to awards@cga.msu.edu for review, countersignature, and submission

Case Study #3

Dr. Harold Finch has a T32 and would like to appoint several Pre- and Postdoctoral students to the project. He has had his Administrator process their appointment thru the MSU system. Is this all he needs to do?

- No, Trainees must also have a completed Statement of Appointment form thru eRA Commons. This must be submitted prior to the start of each trainee's appointment or reappointment, but no earlier than the issuance of the NoA
- Once their appointment has been completed, a Termination Notice (TN) must be submitted within 30 days. The TN needs to route PI to Trainee to PI to Business Official (CGA)

eRA Commons

- Go to Award Management System
 - xTrain Appointments (T's, F's, K12's, etc.)
 - Research Performance Progress Report (RPPR's)
 - Due 45 days prior to current budget period end date
 - Should be referenced upon receipt of award for reporting due dates
 - Annual Financials
 - Grantee Approved No-Cost Extensions
 - Closeout Documents
 - Financials
 - Final Progress Report
 - Final Invention Statement

Research Performance Progress Report (RPPR)

- Due Annually 45 days prior to current budget period end date – thru eRA Commons
 - Also called a non-competing continuation application
 - Initiates additional year of funding to be received
 - Contains scientific and administrative information

RPPR Requirements

- October 2013: PMCID's become mandatory for all publications which are:
 - Peer Reviewed
 - Accepted for Publication in a Journal on or after April 7, 2008
 - And, arises from:
 - Any direct funding from an NIH grant or cooperative agreement active in FY 2008 or beyond; or,
 - Any direct funding from an NIH contract signed on or after April 7, 2008; or,
 - Any direct funding from the NIH Intramural Program; or,
 - An NIH Employee
- Check compliance thru MyNCBI
www.ncbi.nlm.nih.gov/sites/myncbi

RPPR Requirements

- As of October 17, 2014 Commons IDs for all individuals in graduate and undergraduate student roles who participate in NIH-funded projects for at least 1 person month or more are required.
 - If an Undergraduate Student, Graduate Student, or Postdoctoral Researcher, the following profile fields must be completed:
 - Date of Birth
 - Gender
 - Race
 - Ethnicity
 - Disabilities
 - US Citizenship Status and/or Country of Citizenship

Financial Reporting

- Most NIH awards only require a final financial
- Awards with carryover restrictions always require an annual financial
 - Annual financials are due 90 days after the current budget period end
 - Upon completion of the Annual, an email will be sent to the PI and Department Contact providing directions on requesting carryover

Award Closeout

- All final reports are due 120 days after award end
 - Reports Include:
 - Final Financial Statement
 - Final Invention Statement
 - Final Progress Report
 - Only required if a renewal has not been submitted
 - Who initiates the closeout?
 - CGA will send an email to the PI within 30 days after the award end requesting the completion of the closeout memorandum. The return of the memorandum allows for the completion of the Final Invention Statement by MSUT
 - CGA will review expenditures and request clarification from the FO and/or PI if necessary
 - Once expenditures are settled, CGA will submit the final financial and complete the final draw or return of funds

Thank You for Attending!

All ERA course materials are posted on the SPROUT site:

<https://sprout.vprgs.msu.edu/training/electives/>