

Introduction to the NIH Grants Application Process

Courtesy of the staff of
National Human Genome Research Institute

- **Roles and Definitions**
- **Required Registrations**
- **Developing the Budget**

NIH Defined Roles

At the Applicant Organization:

- Principal Investigator (PI)
- Authorized Organization Representative/Signing Official (AOR/SO)

At NIH:

- Program Official (PO)/Program Officer/Project Officer
- Scientific Review Officer (SRO)
- Grants Management Officer (GMO)

Principle Investigator - PI

- A PI is an individual designated by the applicant organization to direct the project or program supported by the award.
- PI works with his/her organization to prepare the application, and passes the completed application on to the Authorized Organization Representative/Signing Official for submission to NIH.

Authorized Organization Representative/Signing Official– AOR/SO

- **The AOR/SO is the designated representative of the applicant organization in matters related to the award and administration of its NIH grants, including those that require NIH approval.**
- **Only AOR/SOs have the authority to submit a grant application to NIH.**

Program Officer - PO

- NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant or cooperative agreement.

Scientific Review Officer – SRO

- NIH official 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

- NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions.
- Only GMOs are authorized to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH.

Definitions

- **Grant** - A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever NIH anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

Definitions

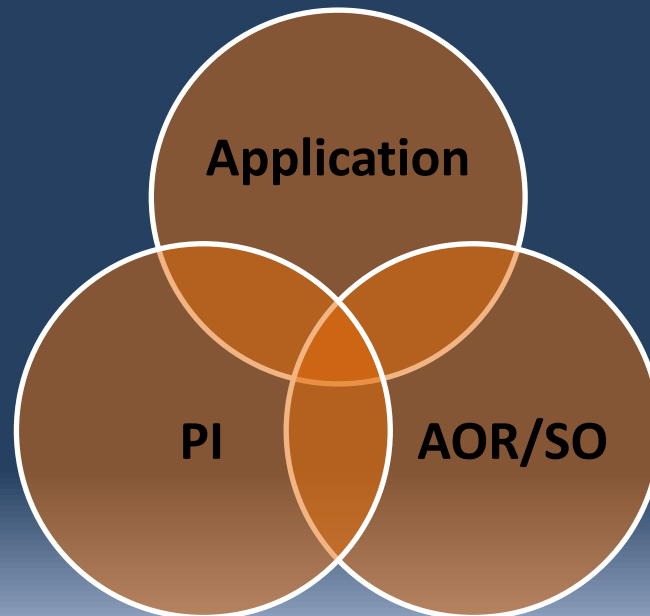
- **Cooperative Agreement** - A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

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Getting Started – PI and AOR/SO

- AOR/SO completes all required registrations.
- PI writes the application.
- Actions are concurrent – AOR/SO registers while the PI writes the application.



The entire application process is FREE

- Registrations are required.
- Registrations are free.
- Registrations take time – begin the process as soon as possible!

Allow Adequate Time

- 8 weeks to complete all required registrations.
- It is strongly advised that the AOR/SO begin the registration process no later than September 26 to allow adequate time to complete the registrations in time for the December 2 application receipt deadline.

Registrations – Before you begin

- Check online to see if your organization is already registered in **eRA Commons**
http://era.nih.gov/commons/quick_queries/index.cfm#commons
- If NOT already registered in eRA Commons the following registrations **MUST** be completed before an application can be submitted to NIH.

Required Registrations

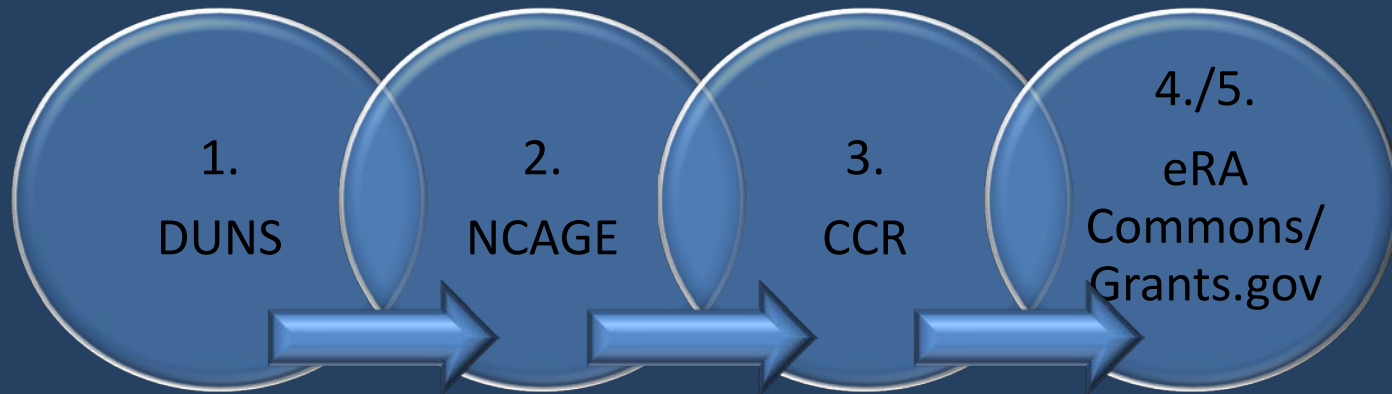
Role - AOR

- 4/5 Required Registrations
- Registrations are sequential and must be completed in the following order:
 1. DUNS number
 2. NCAGE code
 3. CCR registration
 4. eRA Commons
 5. Grants.gov*

eRA Commons and Grants.gov may be completed at the same time.

*Required for applicants to RFA-RM-11-009

Registration Sequence



Registration 1. DUNS Number

Data Universal Numbering System (DUNS)

- The Federal government requires that all applicants for Federal grants and cooperative agreements have a DUNS number.
- To find out if your institution already has a DUNS number check here
<http://fedgov.dnb.com/webform/CCRSearch.do?val=1>
- **Register** If a DUNS is needed apply online at
<http://fedgov.dnb.com/webform/index.jsp>

Registration 2. NCAGE code

NATO Commercial and Governmental Entity (NCAGE) Code.

- All applicants outside of the U.S. need this number, not just NATO country applicants.
- The Code is a five-character ID number used by the federal government to provide identification.
- **Register** online at [http://www.dlis.dla.mil/Forms/Form AC135.asp](http://www.dlis.dla.mil/Forms/Form_AC135.asp)

Registration 2.

NCAGE Code, cont. (2) – Need Assistance?

- Access may be blocked for technical or security reasons. If you cannot access the web site, send an e-mail to the NATO CAGE Code team at NCAGE@dla.mil asking them to review your situation. Include the following in your email:
- Your organization's name and the Internet Protocol (IP) address from which you are trying to access the Defense Logistics Agency Logistics Information Service web site.
- Include specific information about funding opportunity you will apply for including the RFA number and program officer.
- Send a copy of the e-mail to the program officer so that they are aware of your difficulty.

Registration 3.

CCR

- Central Contractor Registration is the official on-line registrant database for the U.S. Federal Government. CCR collects, validates, stores and disseminates data in support of federal acquisition and award missions.

Registration 3.

CCR cont. (2)

- Prior to registering in CCR, insure that your newly assigned NCAGE is listed on the Business Identification Number Cross- Reference System (BINCS) at http://www.dlis.dla.mil/bincs/begin_search.aspx
- If the assigned NCAGE is not listed in BINCS send an email to NCAGE@dla.mil.
- **Register** at <https://bpn.gov/ccr/international.aspx>

Registration 3.

CCR, cont. (3) – Need Assistance?

- CCR Assistance Center
Hours of Operation are 9 a.m. to 5 p.m. Eastern Standard Time, Monday through Friday.
International Phone:1-269-961-5757
E-mail: dls-support@dls.dla.mil

Registration 4.

Electronic Research Administration

eRA Commons

- The NIH online interactive system for the receipt, review, monitoring and administration of NIH grants.
- Java Script is required for registration.
- **View** the online registration tutorial at http://era.nih.gov/virtualschool/external/c101_GranteRegistrationProcess.htm
- **Register** online at <https://commons.era.nih.gov/commons/>

Registration 4. eRA Commons cont. (2) – Need Assistance?

- Contact the eRA Commons Help Desk:
Email: commons@od.nih.gov
Hours: Mon-Fri, 7 a.m. to 8 p.m. U.S. Eastern
Time, (closed on U.S. Federal holidays)

Registration 5.

Grants.gov

- Grants.gov is the Federal-wide portal to find and apply for Federal grant funding
- **View** the Organization Registration tutorial at http://www.grants.gov/assets/Organization_Registration_Overview.html
- **Register** the Organization online at http://grants.gov/applicants/get_registered.jsp
- (Note - Spaces in the URL addresses are underscores “_”.)

Registration 5.

Grants.gov cont. (2) – Need Assistance?

- Check the Grants.gov Self Service Portal at <https://grants-portal.psc.gov/Welcome.aspx?pt=Grants>
- Contact the Grants.gov Contact Center: support@grants.gov Hours of Operation: 24 hours a day, 7 days a week. Closed on U.S. [Federal holidays](#).

Registrations Complete!

- ✓ DUNS number
- ✓ NCAGE code
- ✓ CCR registration
- ✓ eRA Commons
- ✓ Grants.gov

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- Required Registrations
- **Developing the Budget**

Budget costs

- Three types of costs included in NIH budgets
 1. Direct costs (DC)
 2. Facilities and Administrative costs (F&A)
 3. Total costs
- Direct Costs + Facilities & Administrative Costs = Total Costs

Direct Costs

- Costs that can be identified specifically with a particular project and that directly benefit that project.
 - Personnel costs
 - Supplies
 - Equipment
 - Travel

Facilities and Administrative Costs – F&A

- Funded at 8% of direct costs for international organizations.
 - \$100,000 direct costs x 8% = \$8,000 F&A costs
 - Funded to support compliance with applicable U.S. public policies:
 - Protection of Human Subjects
 - Animal welfare
 - Financial conflict of interest
 - Invention reporting
- Equipment costs are excluded from the F&A calculation.

Total Costs

- Calculated by adding the Direct Costs and Facilities and Administrative Costs

\$375,000 Direct

+ \$30,000 Facilities & Administrative

- \$405,000 Total

Developing the budget

- Principal Investigator and Department Administrator or other Organization Official meet to discuss budget needs.
- Consider printing out blank budget pages from the 424 electronic application or the PHS 398 detailed budget page to act as a guide during the discussion.

Developing the budget – Personnel costs

- Who will work on the project?
 - Technicians, Post docs, Data managers, etc.
- How much effort for each individual?
- Same individuals in each year of the project?
- New positions created for this project?

Developing the budget – Personnel costs, cont.

- NIH uses Person Months to define effort
 - Person months - Is the metric for expressing the effort (amount of time) PI(s), faculty and other senior personnel devote to a specific project. The effort is based on the type of appointment of the individual with the organization; e.g., calendar year (CY), academic year (AY), and/or summer term (SM); and the organization's definition of such. For instance, some institutions define the academic year as a 9-month appointment while others define it as a 10-month appointment.

Calculating Person Months

- Conversion of percentage of effort to person months is straight-forward. To calculate person months, multiply the percentage of your effort associated with the project times the number of months of your appointment. For example:

25% of a 9 month academic year appointment equals 2.25 (AY) person months ($9 \times .25 = 2.25$)

10% of a 12 month calendar appointment equals 1.2 (CY) person months ($12 \times .10 = 1.2$)

35% of a 3 month summer term appointment equals 1.05 (SM) person months ($3 \times .35 = 1.05$)

Another example:

If the regular pay schedule of an institution is a 9 month academic year and the PI will devote 9 months at 30% time/effort and 3 months summer term at 30% time/effort to the project, then 2.7 academic months and .9 summer months should be listed in the academic and summer term blocks of the application ($9 \times 30\% = 2.7$ person months; $3 \times 30\% = .9$)

Person Months Calculator

- Go Here
http://grants.nih.gov/grants/policy/person_months_faqs.htm#1039
- Scroll down to question #2 and see:
- Percent of Time & Effort to Person Months Calculator (Excel spreadsheet)

Developing the budget - Consultant costs

- Individual with specific expertise
- Participates at a limited level
- Not paid a salary by the institution
- Include the details of their reimbursement
of hours x \$xx amount

Developing the budget - Equipment costs

- Equipment – NIH definition: An item costing more than \$5,000 with a useful life of more than one year
 - Is new equipment necessary?
 - Costs for each individual type of equipment should be itemized
 - Example: Thermalcyclers (2 x \$7,500)
Nanopipettors (1 x \$139,850)
- NOT:**
- Equipment \$154,000

Developing the budget - Supplies costs

- Supplies include different categories, such as chemicals, reagents, glassware, plasticware, etc.
- Decide what supplies are necessary for the project.
- Will they remain the same in each year?

Developing the budget – Other costs

- Publication costs
- Service contracts
- Long distance telephone call costs (that can be assigned to the project, provide details about the number of anticipated calls, *e.g.* weekly teleconferences with NIH)
- Animal research costs
- Miscellaneous costs
- Will these costs vary from year to year?

Developing the budget – Consortium/Contractual costs

- Consortium: A collaborative partner involved in the project research.
- A complete detailed budget must be submitted for each consortium organization.
- Application must also include a list of all the performance sites.
- A letter of commitment or intent signed by the AOR/SO of each consortium organization.

Developing the budget – Justifications

- Provide a justification for each budget category requested.
- Justifications should include enough detail to give a reviewer a clear understanding of the reason for the request.

Developing the budget – Justifications - Samples

- Personnel

Principal Investigator: Colin R. Parrish (1 .8 calendar months), John M. Olin Professor of Virology. He will oversee all of the work in this project, and will directly supervise that which is conducted at Cornell. He will be responsible for the administration of the program and any necessary reporting, and will ensure that the various combined projects are carried out between the workers at Cornell and Penn State, as well as with the laboratories of the collaborators on this project.

Postdoctoral Fellow: 6.0 calendar months) will be involved in studies of the protease sensitivity of the case as well as carrying out the studies in the laboratory using yeast expression and mutagenesis to identify the residues in the antibodies and receptors that interact with the capsid surface, and to alter the affinities.

Developing the budget – Justification samples, continued

- Personnel, continued

Postdoctoral Associate: TBD (7.2 calendar months) will be responsible for the studies that involve the analysis of the capsid structures through mutagenesis, and the biochemical and biophysical analysis of the resulting viruses. This person would also prepare materials for analysis of the receptor and antibody binding to the wild type or mutant capsids that are uncleaved, or treated with proteases.

Research Support Specialist: 6 calendar months). supports the various projects in the laboratory, and provides support for this project including preparation of the tissue culture cells, antibodies, and general laboratory maintenance. She is an expert in the production of monoclonal antibodies from hybridomas, and would carry out those parts of the project.

Paper Submission

Scientific Merit Review	February/March, 2012
Advisory Council Review	May, 2012
Earliest Start Date(s)	July, 2012
Expiration Date	December 3, 2011
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the [PHS398 Application Guide](#) except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts](#)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. While some links are provided, applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

Looking ahead: NIH is committed to transitioning all grant programs to electronic submission using the SF424 Research and Related (R&R) format and is currently investigating solutions that will accommodate NIH's multi-project programs. NIH will announce plans to transition the remaining programs in the [NIH Guide to Grants and Contracts](#) and on NIH's Applying Electronically [website](#).

Note: A new version of the paper PHS 398 application form and instructions (revised 6/2009) must now be used. Download the new application form and instructions from <http://grants.nih.gov/grants/forms.htm>.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

Low- and middle-income nations suffer over ninety percent of the world's burden of premature mortality, as measured in lost years of life. These countries, constituting three-quarters of the world's population, now must deal with a triple burden: the persistent cluster of infectious diseases, malnutrition, and a growing incidence of chronic disease and disabilities due to increased life spans and new risk exposures that accompany it. The NIH has a long-standing commitment to address both communicable and non-communicable diseases around the world through health research and training, and one of NIH's stated priorities is enhancing efforts in global health. Genomics and other large-scale biological studies provide cutting-edge approaches to research on the genetic and environmental contributors to health and disease, the understanding of which will lead to unimagined advances in medical science and powerful new ways for improving human health. To maximize the impact on the health of people globally, advances in the fields of genetics/genomics/environmental studies must be integrated into the research conducted in developing countries, as well as into their medical education and health services. Notably, however, African