Research at Western

Introduction to the Granting Process with the U.S. Federal Granting Agencies

January 11th, 2017
Today’s Agenda

1) Finding Funding Opportunities
2) Differences – Canadian vs U.S. Funding
3) NIH – Grants and Contracts
4) Funding Opportunity Announcements (FOA)
5) Review Processes and Program Staff Roles
6) Peer Review and Funding Decisions
7) U.S. Regulations
8) Website Links to Resources
9) Q&A
Welcome to the New NIH Grants and Funding Website...Take a Tour!

About Grants

Navigate the NIH grants process from finding a funding opportunity to monitoring your award.

- Grants Basics
- Grants Process Overview
- How to Apply
- Pre-Award Process
- Post Award Monitoring and Reporting
- Forms Library

Policy and Compliance

Learn about the policy and compliance obligations of your grant award and find helpful resources on select policy topics.

- NIH Grants Policy Statement
- Notices of Policy Changes
- Compliance and Oversight
- Select Policy Topics

Information for...

Find key resources just for you.

- Researchers
- Research Administrators
- Reviewers
- Small Businesses
- Foreign Applicants
- Media and the Public
- NIH Staff

https://report.nih.gov/
Research Funding
Pivot.cos.com
Canadian vs U.S. Federal Funding

• Funding Sponsor guidance and assistance
• Review Processes
• National Center for Biotechnology Information
Case Western Reserve University
Case Western Reserve University
Requested NIH funds for a boat
Moving an NIH grant from US to Canada is a bit like finding the right taxi in Uganda
You need the right attitude...
Be realistic of what lies ahead.....
Get back to your research and making an impact

NIH – my definition: Research without boundaries and focused on the best science and improving care for all humanity
Lots of differences between the Canadian Institutes of Health Research.....

.... and the National Institutes of Health
Major Differences

Conflict of interests:

1. NIH - clear regulations that have to comply with US Government rules on COI. Requires written policy at the university.

2. All key personnel and their immediate family are required to file a COI with the funded institution and this COI must be filed and reviewed annually.
Human subjects:

1. All studies working with humans or human material require IRB approval or clear exemptions. IRB approvals must be reviewed and renewed yearly. All IRB approvals must be performed with an IRB with a FWA number.

2. Exemptions are standard for most blood or samples acquired from an NIH recognized specimen repository.

3. All personnel (not just “key”) working with or associate with human samples/protocols must have attended an NIH-approved human subjects training program and must have passed a test.
Effort reporting:
All key personnel must report their work effort for various activities as a fraction of calendar months/year. This reporting must take in account effort on all other NIH or US federal grants, CIHR/tricouncil grants, teaching, service, and administrative effort. Must be reported annually.
Publication policy

All publications associated with or supported by the grant must be open access as defined by NCBI.
NIH Award Mechanisms

• **Grants**
  – Investigator initiated
  – Program Announcement (PA) or Request for Applications (RFA)

• **Cooperative agreements**
  – Substantial NIH staff involvement
  – Solicited – RFA

• **Contracts**
  – Solicited – Request for Proposals (RFP), Broad Agency Agreement (BAA), other contract mechanisms
 NIH Guide for Grants and Contracts

Official publication listing NIH funding opportunities and policy notices – web page: http://grants.nih.gov

- Published weekly
- List grants and contracts
  - Request for Applications (RFA)
  - Program Announcements (PA)
  - Request for Proposals (RFP)

**Non-U.S. Institutions, questions to consider:**

- Does the application/proposal
  - Present **special** opportunities for furthering research programs?
  - Describe use of **unusual** talent, resources, populations, or environmental conditions?
  - Propose research **not readily available in the United States** or that augments existing U.S. resources as well as your local population?
Examples of Research Project Budgets

<table>
<thead>
<tr>
<th>Research Project Grant (R01)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Used to support a discrete, specified research project</td>
</tr>
<tr>
<td>• NIH most commonly used grant program</td>
</tr>
<tr>
<td>• Budget – costs appropriate for the project, typically &lt;$500K/year</td>
</tr>
<tr>
<td>• Generally awarded for 3-5 years</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exploratory/Developmental Research Grant Award (R21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• New, exploratory &amp; developmental projects, supports early stages of project</td>
</tr>
<tr>
<td>• Limited to up to two years of funding</td>
</tr>
<tr>
<td>• Budget for direct costs for the two year project period up to $275,000.</td>
</tr>
<tr>
<td>• No preliminary data is generally required</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Small Grant Program (R03)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Limited funding for a short period of time to supports various types of projects, including: pilot or feasibility studies, collection of preliminary data</td>
</tr>
<tr>
<td>• Direct costs generally up to $50,000 per year</td>
</tr>
<tr>
<td>• Limited to two years of funding</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research Project Cooperative Agreement (U01)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Supports discrete, specified projects to be performed by investigator(s) in an area representing specific interests and competencies</td>
</tr>
<tr>
<td>• Substantial NIAID program staff involvement</td>
</tr>
<tr>
<td>• No specific dollar limit – amount and years specified in FOA</td>
</tr>
</tbody>
</table>

Other opportunities including Program projects P01 and R21/R23 transitional grants.
Funding Opportunity Announcements (FOA)

- All grant applications must be submitted in response to a FOA
- NIH simultaneously posts FOAs on:
  - Grants.gov for Grants, and
  - Funding Opportunities and Notices Web Page - NIH Guide for Grants and Contracts
- Identify FOA of interest and check application due date
- Read Eligibility Section – ensure non-U.S. entities are eligible to apply
- Download FOA application and instructions

NOTE: Prior to submitting a grant application, researchers may need to register or affiliate eRA Commons accounts to Western. This is done through Research Services (researchoffice@uwo.ca).
Funding Opportunity Announcements


FOA Examples

• **RFA-DE-16-006**: Oral HIVacc: Oral Mucosal Immunization Approaches for HIV Prevention (R01)
  – Application due dates: Not Applicable
  – FOA Expiration date: November 24, 2016

• **RFA-MH-16-406**: Exploratory Clinical Trials of Novel Interventions for Mental Disorders (R21/R33)
  – Application due dates: July 27, 2015; October 14, 2015; February 17, 2016; June 15, 2016; October 14, 2016, by 5:00 PM local time of applicant organization
  – FOA Expiration date: October 15, 2016
NIH Grant Application and Review Process

1. **Plan Content**
2. **Write the Application**
3. **Submit Application via Grants.gov**
4. **Peer Review Process**
   - Center for Scientific Review Study Section
   - Or
   - NIH Institute Scientific Review Panel
5. **Decision To Fund**
6. **NIH Institute Advisory Council**
7. **NoA**

From application submission to award may take... 9 months

**Western**
The Center for Scientific Review (CSR) is the gateway for NIH grant applications and their review for scientific merit. We organize the peer review groups or study sections that evaluate the majority (75%) of the research grant applications sent to NIH. We also receive all grant applications for NIH, as well as for some other components of the U.S. Department of Health and Human Services (DHHS).

Our Mission
Since 1946, we have worked to see that NIH grant applications receive fair, independent, expert, and timely reviews—free from inappropriate influences—so NIH can fund the most promising research.

The Power of Peer Review
Our peer review system has enabled NIH to fund fundamental, cutting-edge research that years later led to new treatments which have allowed millions to leave their doctor’s office with new drugs and cures for diseases that afflicted their parents or grandparents.

- 70% of major drugs were developed or made possible by NIH-funded research
- 80% of the Nobel Prizes in Physiology/Medicine were awarded to or shared by NIH scientists since 1964
- 1.35 million deaths are prevented each year due to NIH research advances in treating or preventing cardiovascular disease, stroke, cancer and diabetes.

Why Has NIH Peer Review Been So Successful?
- It is transparent to the applicant.
- The focus is on funding ideas or people not institutions.
- Ideas spring from independent researchers across the country.

http://public.csr.nih.gov/aboutcsr/Pages/default.aspx
Program Officer

• Responsible for the scientific and/or technical aspects of grants
• **Important contact for PIs**
• 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
Program Officer can help:

• Find the right program and Institute;
• Suggest the most appropriate mechanism;
• Provide technical assistance as the researcher develops the application; and,
• Navigate information on study sections
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

• Is the only NIH official authorized to obligate the NIH to funds or other terms and conditions of award
• 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
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
The Grants Specialist can help:

• Answer questions about completing the SF424 (Application form)

• Provide guidance on administrative and fiscal aspects of applications and awards; and,

• Navigate NIH grants management information on the Web
Peer Review: Evaluation Criteria

• Review of applications based on NIH standard review criteria
  – Significance, Investigator, Innovation, Approach, Environment

• Also initiative specific review criteria, when applicable

• Additional review criteria – (HS, Animals, Biohazards, resubmission, renewal)

• Additional review considerations:
  – Applications from Foreign Organizations
  – Select Agent
  – Resource Sharing Plans
  – Budget and Period Support
  – Foreign Justification
After Peer Review …

• Application receives an overall impact/priority score

• Summary statement is written – provides a summary of the reviewers discussion and recommendations

• Priority score and summary statement are available to the applicant in the NIH eRA Commons system

To Fund or Not To Fund?

• Funding decisions
  – Details documented in each institute’s procedures.

• Review products used in funding decisions
  – Impact score and percentile
  – Summary statement
  – Criterion scores

• Program factors in funding decisions
  – Relevance to institute’s mission and priorities
  – Council recommendations
  – New PI status
  – Other Institute specific identified factors

• Institute final funding decisions based on advice from staff and the Advisory Council/Board

• Successful applicants receive a Notice of Award from the funding institute’s Grants Management Officer
Two Systems Working Together

**Grants.gov**
The Federal government’s single online portal to find and apply for Federal grant funding.

Used by all 26 Federal grant-making agencies.

**eRA Commons**
Allows applicants, grantees, and Federal staff to access, share and transmit information related to applications and awarded grants.

Used by NIH and other HHS components

**IMPORTANT:**
Each system has its own registration and application requirements.
- All publications require a PMCID #
- PMID # is **not** sufficient
- Public access by a journal without a PMCID # is **not** sufficient
- Public access provided by your university library without a PMCID # is **not** sufficient.
Charges to a grant....

Get help!
Simple rules for R series grants!

- Don’t purchase office supplies on any R series grant
- Don’t purchase computers unless they were part of the original request
- No renovations or anything deemed mortar/brick infrastructure
- Purchases under $5000 per unit are considered supplies, over that is equipment. All equipment purchases must be in the original budget request (but equipment purchases are possible and recommended)
- All budgets in grants can be spent with considerable flexibility in categories (except equipment)
- Budget in specific categories can be altered (e.g. for equipment) with permission from the Program Officer
Track your application to eRA Commons…

Application → Successfully submitted to NIH

Submitting to Grants.gov is NOT the last step in the process!
Navigating eRA Commons for grant information and non-competitive renewals

Welcome to the Commons

System Notification Message

Update your browser by Nov. 30 to continue using eRA Commons and IAR

eRA is strengthening the security of its modules on Nov. 30 by moving to the 'https only' secure connection mandated for all federal agencies. You may need to update your browser to access Commons. Check this message to see a list of browser versions that will continue to work after the security upgrade.

Scheduled Commons Maintenance: For maintenance information, see the eRA Scheduled Maintenance Calendar.

Support Related Resources

- Electronic Submission: Learn about the most frequent application errors at Avoiding Common Errors.
- Electronic Application Submission: To learn about completing and submitting an electronic grant application and access helpful resources, visit the Applying Electronically website.
- eRA Home Page: To find Commons FAQs, User Guides, training materials, and step-by-step instructions for performing tasks in Commons, visit the eRA website.

Commons Related Resources

- Reference Letters: To submit a reference letter when requested by an applicant, please follow this link: Submit Reference Letter.
- Demo Facility: Demo Facility allows you to try most of the capabilities of the NIH eRA Commons in a sample environment.

Privacy Act Statement

This is a U.S. Government computer system, which may be accessed and used only for authorized Government business by authorized personnel. Unauthorized access or use of this computer system may subject violators to criminal, civil, and/or administrative action. Use of the eRA Commons website requires gathering personal information as part of the NIH grant proposal submission and administration process. Grant proposals are treated as confidential until awards are made. Upon award, the title, principal investigator name(s), abstracts, and award amount are disclosed publicly. Other information may be made available within and outside the NIH through routine uses, as described in OCR 09-25-0038, or, subject to the provisions of the Freedom of Information Act 5 U.S.C. 552. Your activity while using this site is not anonymous. To protect the site, NIH tracks the IP address and login information that is used for access, as well as the individual pages you visit. The IP address is used to help verify user ID and to provide information specific to the user's interest and to respond to user queries. More detailed notice is provided here.
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Commons allows you to perform the following activities below based on the privileges associated with this profile:

- Administration - Allows you to assign a delegate to perform system and accounts maintenance
- Institution Profile - Enables you to view and update institution information
- Personal Profile - Allows you to update your personal information. Please periodically review your profile to ensure accuracy of information submitted
- Status - Allows you to check the status of grants and applications that have been submitted
- RPFR - Allows you to review the information needed to complete a progress report. See RPFR Information and Submitting Progress Reports
- xTrain - Enables you to assign a Trainee or SO role to confirm the information that you have submitted for a Trainee role
- Internet Assisted Review (IAR) - Allows reviewer to submit critiques and preliminary scores for applications they are reviewing

What's New

- New in RPFR
- New Service Desk System

Commons Resources

- Frequently Asked Questions
- Latest Release Notes
- Commons Login Tutorial
- Commons Support Page
- eRA Training
- User Guides
- Grantee Organization Registration
- eRA Website
- Applying Electronically

Additional Links

- eRA Contacts
- eRA PORT
- Grants.gov
- iEdison
- National Institutes of Health
- Public Access Policy Page
- Loan Repayment Program
- Like Us
- Multiple Affiliations
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- **Status** - Allows you to check the status of grants and applications that have been submitted [more...]
- **RPPR** - Allows you to review the information needed to complete a progress report. See [RPPR Information] and [Submitting Progress Reports]
- **xTrain** - Enables you in a Trainee or SO role to confirm the information that you have submitted for a Trainee role type [more...]
- **Internet Assisted Review (IAR)** - Allows reviewer to submit critiques and preliminary scores for applications they are reviewing [more...]

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- Frequently Asked Questions
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Additional Links

- eRA Contacts
- BePORT
- Grants.gov
- iEdison
- National Institutes of Health
- Public Access Policy Page
- Loan Repayment Program
- Like This
- Multiple Affiliations
Status: PI Search

The Status screens have been updated. If you have any questions about the new Commons Status look and feel please contact the eRA Service Desk.

The following list of applications represents a result of the search by Grants.gov Tracking # or a list of all Recent/Pending eSubmissions. If you do not see a complete list of your Recent/Pending eSubmissions, please click Recent/Pending eSubmissions menu tab again.

Recent/Pending eSubmissions

- Applications that require action (e.g., to view errors/warnings) prior to submission completion
- Applications that are available to view (during two business day correction window) prior to submission completion
- Applications that have been rejected by Signing Official

List of Applications/Grants

- Funded Grants
- Successfully submitted applications, both paper and electronic
- Review assignment status, review results, summary statements, and Notices of Award
- Other Commons features (e.g., Just In Time, eSNAP, Closeout, Financial Status Report) for previously submitted applications/grants

Search by Grants.gov Tracking Num

Enter the Grants.gov Tracking Number into the following box for easy access to a specific grant application

Tracking Number Search
<table>
<thead>
<tr>
<th>Application ID</th>
<th>Start Date</th>
<th>End Date</th>
<th>PI</th>
<th>Co-PI</th>
<th>Project Title</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01AI084616</td>
<td>09/23/2009</td>
<td>08/31/2019</td>
<td>GAO, YONG (PD/PI)</td>
<td></td>
<td>Explore the Optimal Vaccination Strategy with a Polyvalent Anti-HIV Vaccine</td>
<td>Administered Withdrawn by IC</td>
</tr>
<tr>
<td>R01AI108547</td>
<td>07/01/2013</td>
<td>06/30/2018</td>
<td>ARTS, ERIC J (PD/PI)</td>
<td></td>
<td>Analysis of a Genomic RNA Packaging Enhancer (GRPE) Element</td>
<td>Administered Withdrawn by IC</td>
</tr>
<tr>
<td>P01AI102829</td>
<td>07/01/2013</td>
<td>06/30/2018</td>
<td>ARTS, ERIC (PD/PI)</td>
<td></td>
<td>Eliminating Latent HIV with Heterogenous Therapeutic HIV-1 Vaccines</td>
<td>Administered Withdrawn by IC</td>
</tr>
<tr>
<td>D43TW006591</td>
<td>04/01/2013</td>
<td>03/31/2018</td>
<td>ARTS, ERIC (PD/PI)</td>
<td></td>
<td>Basic HIV/TB Science Training Program for Uganda</td>
<td>Withdrawn</td>
</tr>
<tr>
<td>R56AI070090</td>
<td>03/01/2006</td>
<td>12/31/2017</td>
<td>VARANI, GABRIELE (PD/PI)</td>
<td></td>
<td>New Inhibitors of HIV replication</td>
<td>Administered Withdrawn by IC</td>
</tr>
<tr>
<td>R01GM106669</td>
<td>03/01/2006</td>
<td>07/31/2017</td>
<td>VARANI, GABRIELE (PD/PI)</td>
<td></td>
<td>New Inhibitors of HIV replication</td>
<td>Awarded: Non-Fellowships Only</td>
</tr>
<tr>
<td>R01AI049170</td>
<td>12/01/2000</td>
<td>07/31/2017</td>
<td>ARTS, ERIC J (PD/PI)</td>
<td></td>
<td>Impact of HIV-1 fitness on disease progression</td>
<td>Awarded: Non-Fellowships Only</td>
</tr>
<tr>
<td>Application ID Not Yet Assigned</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R01AI070090</td>
<td>03/01/2006</td>
<td>05/31/2017</td>
<td>VARANI, GABRIELE (PD/PI)</td>
<td></td>
<td>New Inhibitors of HIV replication</td>
<td>Administered Withdrawn by IC</td>
</tr>
<tr>
<td>R01AI100772</td>
<td>04/01/2012</td>
<td>03/31/2017</td>
<td>ARTS, ERIC J (PD/PI)</td>
<td></td>
<td>Characterization and inhibition of a second HIV RNA packaging element</td>
<td>Administered Withdrawn by IC</td>
</tr>
</tbody>
</table>
Western Process and Contacts

As soon as you know you intend to apply for U.S. federal funding (3-4 months in advance, or sooner):

• Your Faculty Research Officer, and

• Research Development & Services

researchoffice@uwo.ca
How to Navigate for U.S. Information?

• Following slides provide a number of links to US funding website resources
Website Resources
- Research Funding Opportunities -

• U.S. Department of Health and Human Services
  http://www.hhs.gov/grants/

• Grants.gov (grants)
  http://www.grants.gov/

• FedBizOps (contracts)
  https://www.fbo.gov/

• NIH: Office of Extramural Research (OER)
  – http://grants.nih.gov/grants/oer.htm
  – http://grants.nih.gov/grants/foreign/
Website Resources
- e-Submission and Peer Review -

• Electronic submission of grant applications (OER)
  http://era.nih.gov/ElectronicReceipt/

• e-Submission: Contact support for International applicants

• e-Submission: Tips for International Applicants

• Video of a Peer Review Meeting
Website Resources
- General NIH Guidance for Applicants -

- NIH Guide for Grants and Contracts
  http://grants.nih.gov/grantsguide/index.html

- eRA Commons
  http://commons.era.nih.gov/

- Multiple PIs

- New and Early Stage Investigators

- Rigor and Reproducibility
  http://grants.nih.gov/reproducibility/index.htm
Website Resources

- NIAID Specific Guidance for Applicants -

• NIAID
  http://www3.niaid.nih.gov/

• NIAID All About Grant Tutorials

• NIAID Grants Policy and Management Training for Foreign Investigators
  http://www.niaid.nih.gov/ncn/grants/int/grantspolicy/default.htm
Website Resources
- Finding Help -


Website Resources
- Finding Help -

– NIH Applying Electronically website:

– eRA Commons:
  [https://commons.era.nih.gov/commons/](https://commons.era.nih.gov/commons/)