Introduction to the National Institutes of Health

Speakers

Krista Montgomery & Jason Darby

Research Funding Managers, US & International Agencies, Research Services Office

Guest Speaker

Professor Timothy Hughes

Donnelly Centre for Cellular & Biomolecular Research

NATIONAL INSTITUTES OF HEALTH

Outline

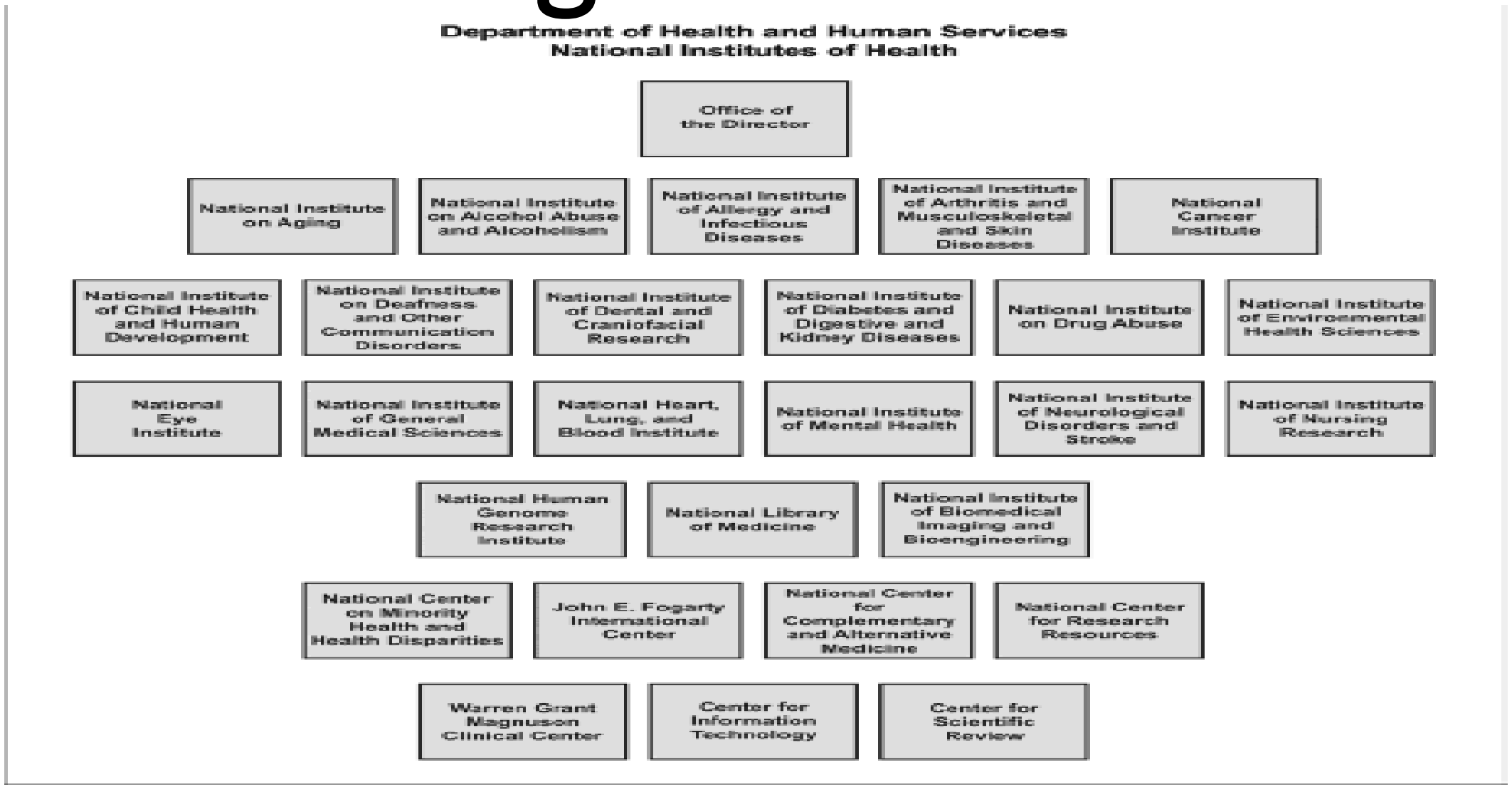
- NIH Overview
- Prior to Applying
- The Application
- Submission Process
- Review Criteria & Process

NIH Overview

- Agency of the U.S. Department of Health and Human Services
- 27 Institutes and Centers
- Operations are based in Bethesda, Maryland
- $32.9 billion invested FY2016 toward medical research

- 80% of the NIH's funding is awarded through 50,000 grants institutions in and outside the US.
- In FY 2015 NIH awarded 502 grants with a funding in the amount of 246 million to Non-US institutions - Representing 1% of the total NIH funding awarded in FY2015

NIH Organization Chart



Mission & Goals

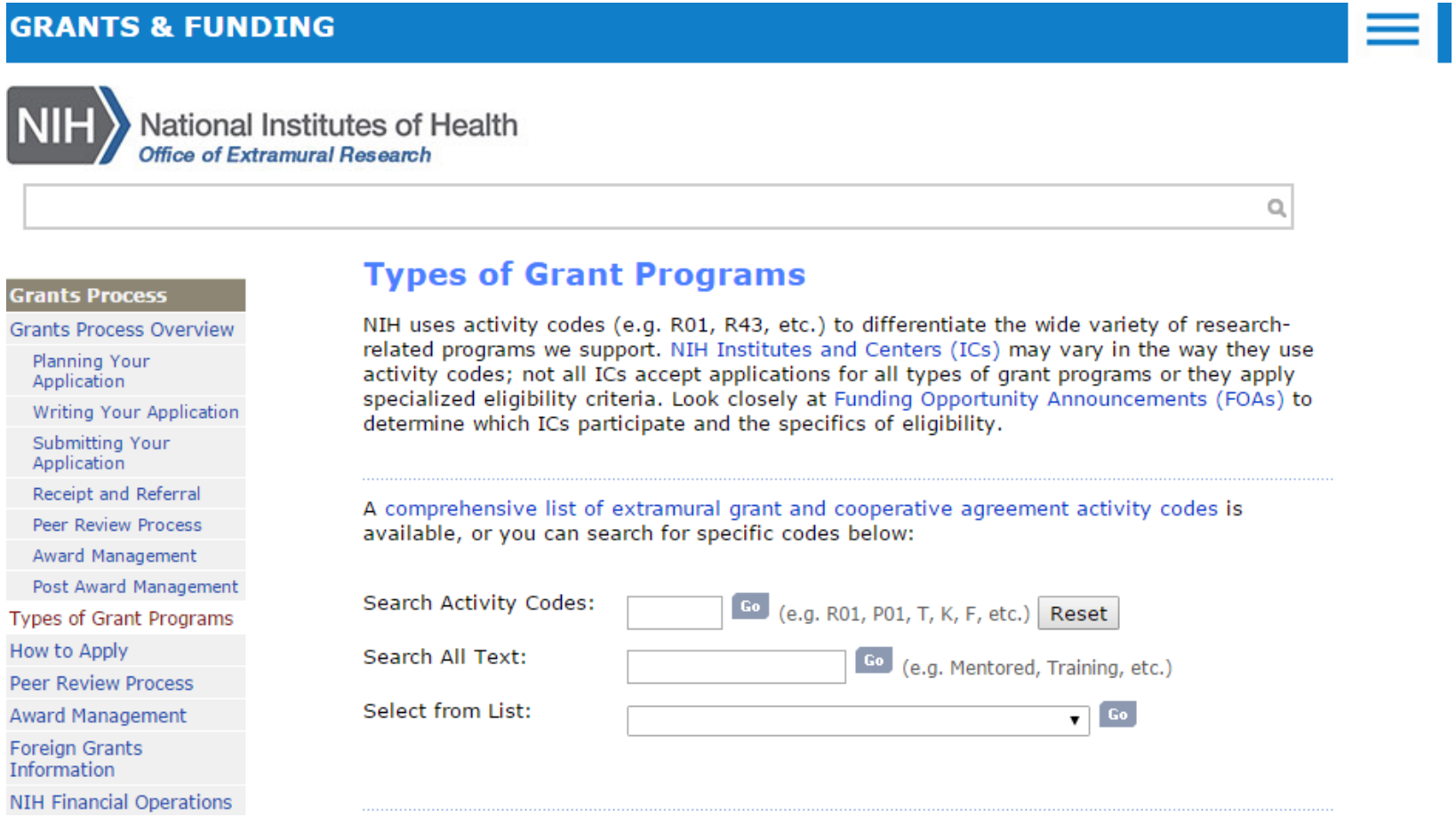
NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability

- to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health;
- to develop, maintain, and renew scientific human and physical resources that will ensure the **Nation's capability to prevent disease**;
- to expand the knowledge base in medical and associated sciences in order to enhance the **Nation's economic well-being** and ensure a continued high return on the public investment in research; and
- to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

Finding Funding

www.grants.gov

Finding Funding



http://grants.nih.gov/grants/funding/funding_program.htm

Finding Funding

Weekly NIH Funding Opportunities and Notices

NIH Guide for Grants and Contracts
February 26, 2016
Table of Contents (TOC)
Web Version

Notices

- NIHs Implementation of the Federal Awardee Performance and Integrity Information System (FAPIIS) Requirements (NOT-OD-16-067) National Institutes of Health

- Notice of Correction of AIDS Application Due Date in PAR-16-093 "Improvement of Animal Models for Stem Cell-Based Regenerative Medicine (R01)"
(NOT-OD-16-069) Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs
National Institute of Allergy and Infectious Diseases
National Institute of Dental and Craniofacial Research
National Institute of Environmental Health Sciences

https://grants.nih.gov/grants/guide/listserv.htm

Finding Funding

UNIVERSITY OF TORONTO | RESEARCH ALERTS

National Institutes of Health - Weekly Funding Announcements

February 16, 2016 • Reply to Krista Montgomery

The National Institutes of Health has released the following requests for applications and program announcements:

https://alerts.research.utoronto.ca/index.php/alert/public_alerts

Funding Opportunity Announcement

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Cancer Institute (NCI) National Eye Institute (NEI) National Heart, Lung, and Blood Institute (NHLBI) National Human Genome Research Institute (NHGRI) National Institute on Aging (NIA) National Institute on Alcohol Abuse and Alcoholism (NIAAA) National Institute of Allergy and Infectious Diseases (NIAID) National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) National Institute of Biomedical Imaging and Bioengineering (NIBIB) *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) National Institute on Deafness and Other Communication Disorders (NIDCD) National Institute of Dental and Craniofacial Research (NIDCR) National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) National Institute on Drug Abuse (NIDA) National Institute of Environmental Health Sciences (NIEHS) National Institute of General Medical Sciences (NIGMS) National Institute of Mental Health (NIMH) National Institute on Minority Health and Health Disparities (NIMHD) National Institute of Neurological Disorders and Stroke (NINDS) National Institute of Nursing Research (NINR) National Library of Medicine (NLM) National Center for Complementary and Integrative Health (NCCIH, formerly NCCAM) Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP)
Funding Opportunity Title	**Research Project Grant (Parent R01)**
Activity Code	R01 Research Project Grant
Announcement Type	Reissue of PA-11-260
Related Notices	• January 12, 2016 - Notice of Information: Parallel Funding Initiative for Collaborative Research Between Investigators in the USA and in the State of So Paulo, Brazil . See Notice NOT-TW-16-001. • NOT-OD-16-004 - NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015) • NOT-OD-16-006 - Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals (November 18, 2015) • NOT-OD-16-011 - Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications (November 18, 2015) • April 16, 2015 - Notice of Information: NIMH High-Priority Areas for Research on Women's Mental Health During Pregnancy and the Postpartum Period . See Notice NOT-MH-15-013. • September 25, 2014 - See Notice NOT-MH-14-033. Notice of Information on High-Priority Research Areas to Understand and Reduce Mental Health Disparities . • September 4, 2014 - Notice Announcing Updates to NHLBI Topics of Special Interest (TOSI). See Notice NOT-HL-14-236. • August 29, 2014 - See Notice NOT-AR-14-021. NIAMS Policy for Submission of Applications Containing Clinical Trials. • August 06, 2014 - See Notice NOT-MH-14-007. Notice of change to application requirements. • July 10, 2014 - Notice of National Institute on Minority Health and Health Disparities (NIMHD) Participation in PA-13-302. See Notice NOT-MD-14-003. • June 10, 2014 - Notice of NICHD's Interest in Supporting Research on Contraception, Long-Term Outcomes of Assisted Reproductive Technologies, and Intrauterine Assessment of Placental and Fetal Function. See Notice NOT-HD-14-020. • June 4, 2014 - Notice NOT-14-074 supersedes instructions in Section III. 3 regarding applications that are essentially the same. • November 25, 2013 - See Notice NOT-HL-13-201. Notice Announcing NHLBI Topics of Special Interest (TOSI). • August 21, 2013: Removed reference to ASSIST in section IV.3, since ASSIST is currently only available for multi-project applications. • NOT-DK-13-013 "Clarification of NIDDK Policy: Investigator-Initiated Multi-Center Clinical Studies" • August 7, 2013 - Use this funding opportunity announcement for due dates of September 25, 2013 and beyond.
Funding Opportunity Announcement (FOA) Number	PA-13-302
Companion Funding Opportunity	None
Number of Applications	See Section III. 3. Additional Information on Eligibility
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.361, 93.233, 93.839, 93.838, 93.837, 93.113, 93.859, 93.879, 93.286, 93.273, 93.172, 93.173, 93.866, 93.853, 93.847, 93.856, 93.855, 93.121, 93.351, 93.867, 93.213, 93.242, 93.846, 93.865, 93.399, 93.307, 93.396, 93.395, 93.394, 93.393, 93.279
Funding Opportunity Purpose	The Research Project Grant (R01) supports a discrete, specified, circumscribed project to be performed by the named investigator(s) in areas representing the specific interests and competencies of the investigator(s). The proposed project must be related to the programm descriptions of their programs.

Key Dates

Posted Date	August 2, 2013
Open Date (Earliest Submission Date)	August 7, 2013
Letter of Intent Due Date(s)	Not Applicable
Application Due Date(s)	Standard dates apply, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.
AIDS Application Due Date(s)	Standard AIDS dates apply, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.
Scientific Merit Review	Standard dates apply
Advisory Council Review	Standard dates apply
Earliest Start Date	Standard dates apply
Expiration Date	September 8, 2016

Types of Funding Announcements

- **Parent Announcement**
  - Investigator initiated
- **IC-Specific Program Announcement (PA)**
  - Investigator Initiated
    - Specific research area relevant to IC
- **Request for Applications (RFA)**
  - Specified amount of funding and # of awards
  - NIH requested research area

Reviewing FOA

	Cycle I	Cycle II	Cycle III
Application Due Dates	January 25 - May 7	May 25 - September 7	September 25 - January 7
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Round	August or October *	January	May
Earliest Project Start Date	September or December *	April	July

- **Eligibility**
  Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.
- **Foreign Institutions**
  Special Requirements
- **Funding Restrictions**
  Limits/items cannot be Funded
- **Other Submission Requirements & information**
  Letter of Intent or Resource Sharing

Funding Activity Codes

Activity Code Mechanism	Duration	Funding Amount	Characteristics	Parent Announcement
R03 Small Research Grant Program	1-2 yrs	50k	Non-renewable, most IC use	PA-13-304
R21 Exploratory Development Research Grant	1-2 yrs	275k	Most ICs Non-renewable	PA-13-303
R01 Research Project Grant Program	3-5 yrs	No Limit*	All ICs Renewable	PA-13-302
U01 Research Project Cooperative Grants	3-5 yrs	No Limit*	Involvement by ICs Renewable*	None - RFA

Funding Activity Codes

Activity Code Mechanism	Duration	Funding Amount	Characteristics	Parent Announcement
R03 Small Research Grant Program	1-2 yrs	50k	Non-renewable, most IC use	PA-13-304

Provides funding to support short term projects

- Limited to two years of funding
- Direct costs up to $50,000 per year
- Not renewable
- Used by more than half of the NIH ICs

Funding Activity Codes

Activity Code Mechanism	Duration	Funding Amount	Characteristics	Parent Announcement
R21 Exploratory Development Research Grant	1-2 yrs	275k	Used by most ICs Non-renewable	PA-13-303

Provides funding for new, exploratory and developmental research projects

- Limited to up to two years of funding
- Combined budget for direct costs for the two year project period may not exceed $275,000.
- Most ICs utilize

Funding Activity Codes

Activity Code Mechanism	Duration	Funding Amount	Characteristics	Parent Announcement
R01 Research Project Grant Program	3-5 yrs	No Limit*	Used by all ICs Renewable	PA-13-302

Provides funding to support a specified research project

- No specific dollar limit unless specified*
  *$500K or more (direct costs) in any year requires prior approval
- Awarded for 3 - 5 years
- All ICs use

Funding Activity Codes

Activity Code Mechanism	Duration	Funding Amount	Characteristics	Parent Announcement
U01 Research Project Cooperative Grants	3-5 yrs	No Limit*	Involvement by ICs Renewable*	None-RFA

Supports specific scientific area to accomplish specific research objectives.

- Used when programmatic involvement is expected by the awarding Institute or Center
- No specific dollar limit unless specified
- Cooperative agreement

Preparing to Apply

- ❑ Determining Proposal a Good Fit
- ❑ Finding Application Form & Instructions
- ❑ Electronic Requirements
- ❑ Involving Other Institutions
- ❑ NIH FCOI Requirements

Is Proposal a Good Fit?

- RePORT
- IC Research Priorities
- Funding Announcement
- Contact Program Officer

NIH Match Maker

- Enter Abstract or Scientific Text
- Similar projects funded
- Breakdown of Activity Codes, IC and SRG

Locating the Application

1. Download PDF Application & Instructions

   Apply Using Downloadable Forms

   - Grants.gov
     - Form C or Form D (deadline May 25 or later)
       - Sign-up for e-mail notification

2. Application Submission System & Interface for Submission Tracking (ASSIST)

   Apply Online Using ASSIST

   - Web-based Application System
   - eRA Credentials

Electronic Requirements

- **Supported Adobe Reader Version**
  - Opening with unsupported version can corrupt application.
- **Adobe Converter**
  - Application attachments
- **eRA Commons Account**
  - Post Submission & Award System
  - All PD/PI listed on application need an Account
  - Contact Research Services Office to initiate account set-up

Involving Another Institution

- Subawardee
  - ❑ Budget
  - ❑ Endorsement
  - ❑ Institutional Information
  - ❑ Administrative Requirements
  - ❑ Other (Biosketch. etc)

Start Early & Contact RSO

Financial Conflict of Interest

- NIH Requirement
  - Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F)
    - All UofT Key Personnel
      - Training (5 years)
      - Financial Interests Report (Annually)

http://www.research.utoronto.ca/faculty-and-staff/secure-research-funding/find-funding/nih-financial-conflict-of-interest-fcoi-requirements/

The Application

Important Note for All Applicants:

Applicants MUST Follow ALL Application Guidance

Conformance to all instructions documented in the following is required and strictly enforced:

- Funding Opportunity Announcement
  - Pay special attention to FOA-specific notices in the Related Notices section and to FOA-specific requirements in section IV
- Notices in the NIH Guide for Grants and Contracts
- Application guides and supplemental instructions

Registrations in Multiple Federal Systems are Required to Submit

See Registrations for details.

All registrations must be completed and active to apply. System for Award Management (SAM) registration must be renewed annually. We urge you to complete all registrations and renewals as soon as possible.

Proceed to Grants.gov to Download Application

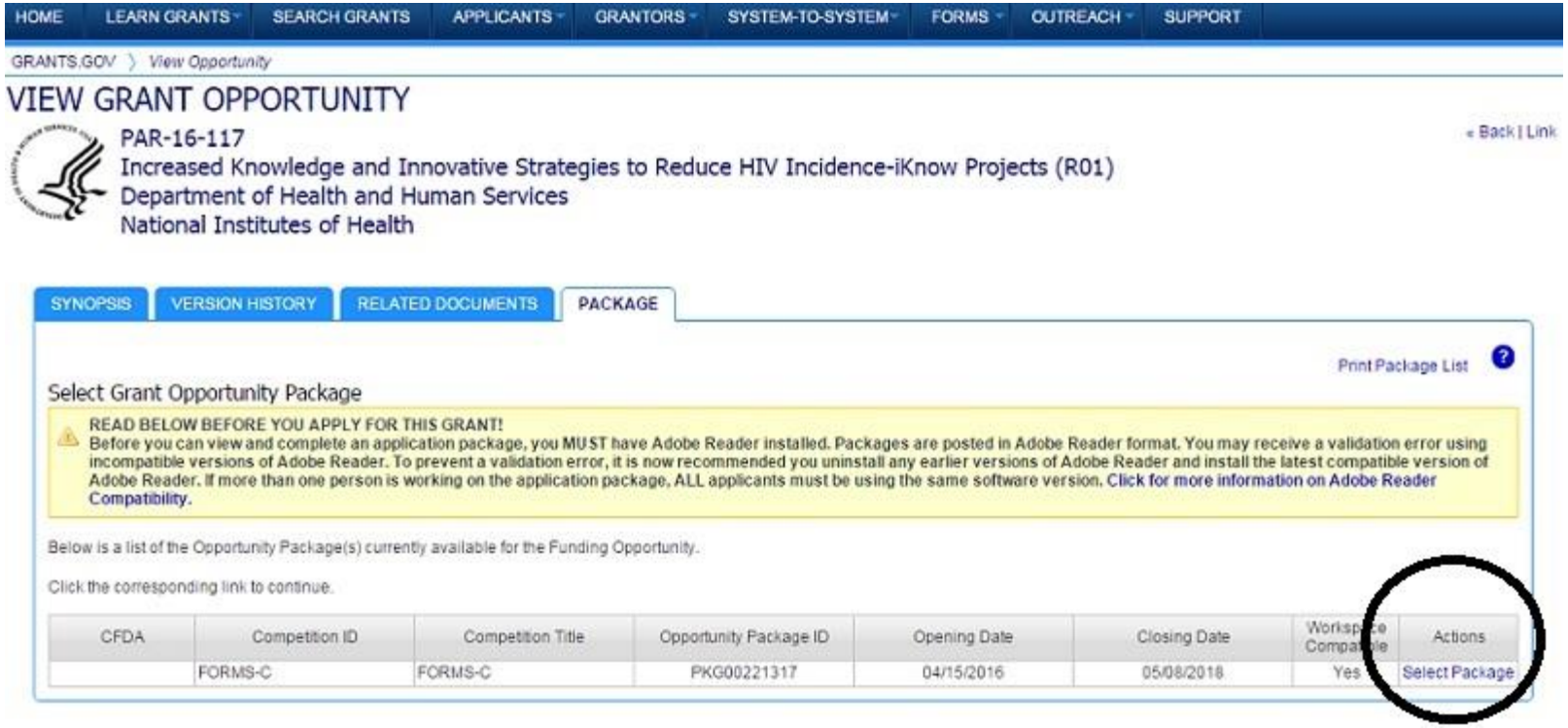
http://grants.nih.gov/grants/guide/ApplyButtonSplash.cfm

Ready to download the application…

- Grants.gov – online portal for submission of PHS applications
- Synopsis – reviews all the detail related to this opportunity
    - Relevant dates
    - Eligibility
    - Relevant Information
    - Agency
    - Contact information – important to establish a rapport with relevant contacts.
- Version History – provides updates to this opportunity – relevant in resubmissions.
- Related Documents – where applicable supplemental documentation would be available here.

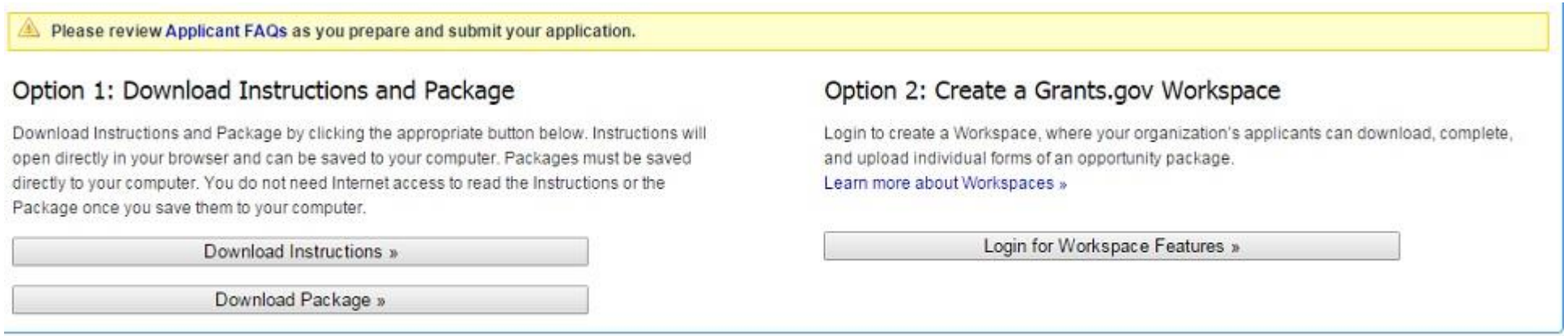
Ready to download the application

- "The Application Package"
  - Shows all the application packages related to the opportunity
- You are now ready to download your application!



Downloading the Application, cont…

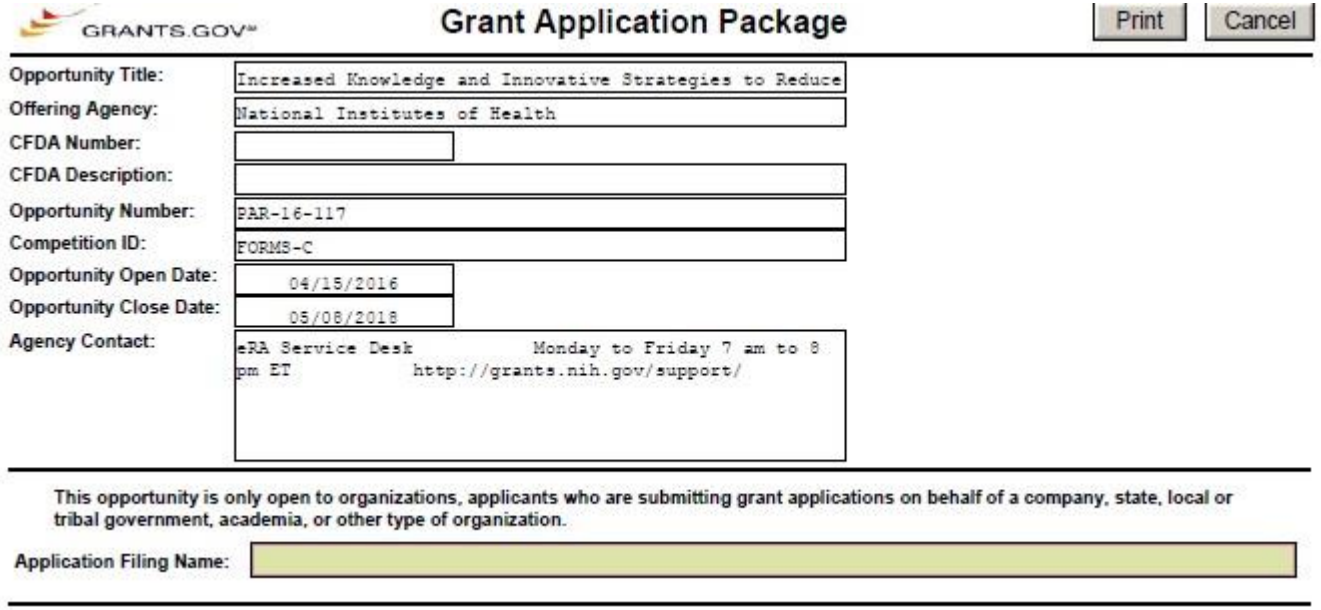
- Choose to enter your email address.
  - This will notify you of any changes to the opportunity/submission process



- Select Option 1.
- You should also download the instructions as it contains information relevant to your specific opportunity.

Time to complete the Application!

- Application will auto-populate the relevant information relating to the Funding Opportunity



GRANTS.GOV

Grant Application Package

Print Cancel

Opportunity Title:	Increased Knowledge and Innovative Strategies to Reduce
Offering Agency:	National Institutes of Health
CFDA Number:	
CFDA Description:	
Opportunity Number:	PAR-16-117
Competition ID:	FORMS-C
Opportunity Open Date:	04/15/2016
Opportunity Close Date:	05/08/2018
Agency Contact:	eRA Service Desk Monday to Friday 7 am to 8 pm ET http://grants.nih.gov/support/

This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.

Application Filing Name:

You will need to complete the filing name

Application Components

Select Forms to Complete

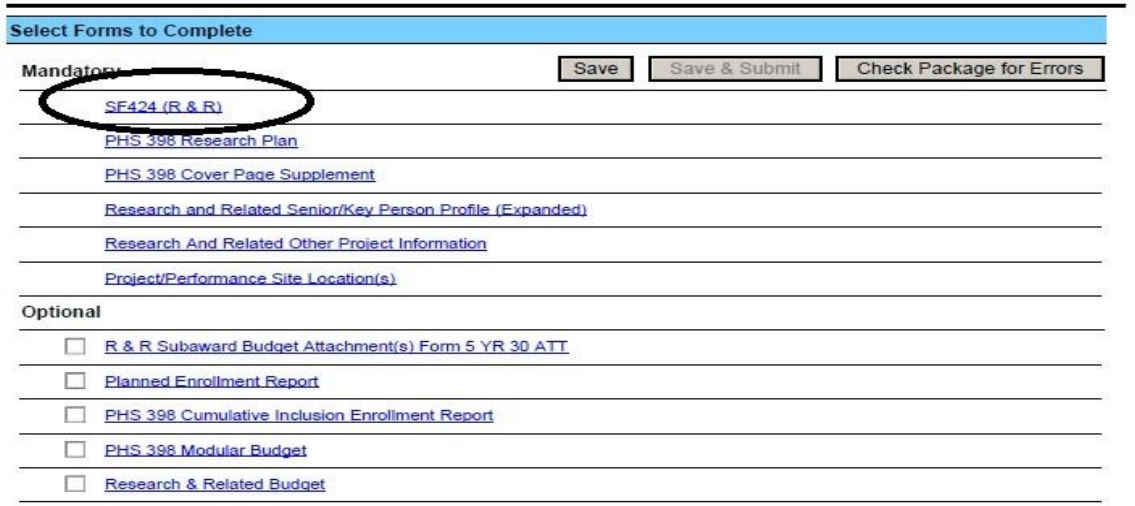
Mandatory | Save | Save & Submit | Check Package for Errors

- SF424 (R & R)
- PHS 398 Cover Page Supplement
- Research And Related Other Project Information
- Project/Performance Site Location(s)
- Research and Related Senior/Key Person Profile (Expanded)
- PHS 398 Research Plan

Optional

- ☐ Research & Related Budget
- ☐ R & R Subaward Budget Attachment(s) Form 5 YR 30 ATT
- ☐ PHS 398 Modular Budget
- ☐ PHS 398 Inclusion Enrollment Report
- ☐ PHS Assignment Request Form

Application Step 1 – SF424 (R&R)



- This area is where you will enter all the administrative information relating to your award
- Refer to U of T NIH Guide as it provides you with all relevant information for each area of this initial overview.

A few helpful tips on SF424

- Which RSO contact will you be working with?
  - Divided by faculty
  - Faculty of Medicine is separated by last name
- All uploads MUST be in PDF Format
- Although not required it is always advisable to include a cover letter
  - Refer to I-55 in the application guidelines.
  - Outlines key ideas to include.

PHS 398 Cover Page Supplement

- Please complete all sections relevant to your application
  - Is this a Clinical Trial?
  - Agency- Defined Phase III Clinical Trial?
  - Program Income?
  - Use of Human Embryonic Cells
  - Inventions and Patents? (Renewals)
  - Change of Investigator

R&R Other Project Information

- Item 1a & 2a – Human Subjects Assurance Number & Animal Welfare Assurance Number
  - Refer to U of T NIH guide
- Item 4 – Environmental impact?
- Item 7 – Project Summary/Abstract
  - No more than 30 lines, suitable for dissemination to the public
  - Serves as a stand alone succinct & accurate description of proposed work
- Item 8 – Project Narrative
  - Prepare in accordance with the announcement and/or agency specific instructions
  - General, it should describe the relavance of this proposed work to public health

R&R Other Project Information

- Item 9 - Bibliography & Works Cited

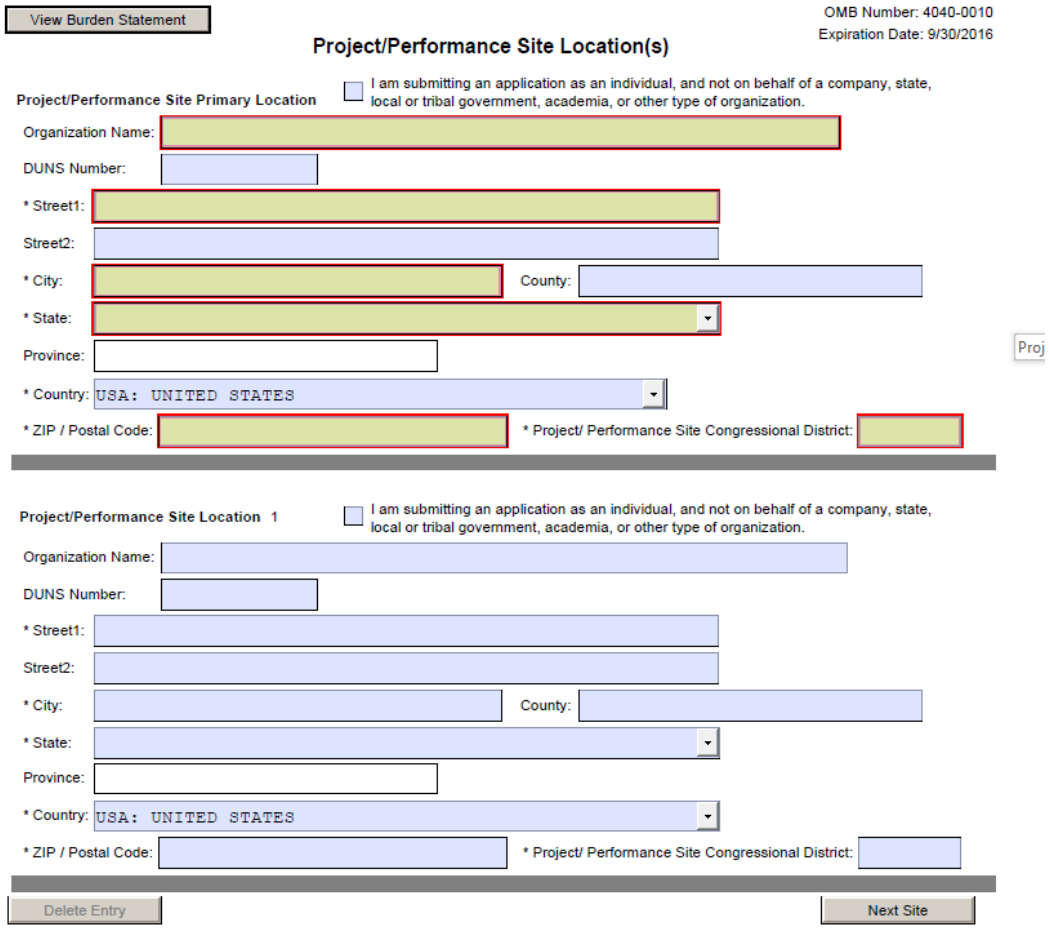
- Item 10 - Facilities & Other Resources
  - Used to assess the capability of the Organizational resources available to perform the proposed work

- Item 11 - Equipment
  - List major items of equipment ALREADY available for this project.

R&R Other Project Information

- **Item 12 - Other Attachments**
  - Attach files only to provide any other key information not covered under any of the other sections or in accordance with the specific announcement and/or agency specific instructions
- **Foreign Justification**
  - MUST be included with all applications originating from U of T & Must describe:
    - Specific relevance to mission and objectives of NIH
    - Potential to advance health sciences in the US
    - Is similar research underway in the US and a need for additional research in area?

Project/Performance Site Location(s)



View Burden Statement

OMB Number: 4040-0010
Expiration Date: 9/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:
DUNS Number:
* Street1:
Street2:
* City: County:
* State:
Province:
* Country: USA: UNITED STATES
* ZIP / Postal Code: * Project/ Performance Site Congressional District:

Project/Performance Site Location 1

☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:
DUNS Number:
* Street1:
Street2:
* City: County:
* State:
Province:
* Country: USA: UNITED STATES
* ZIP / Postal Code: * Project/ Performance Site Congressional District:

Delete Entry Next Site

R&R Senior Key Personnel

- Each PD/PI will need an eRA Commons user name
  - Your RSO liaison will create for you

- You must list each individual identified as key personnel
  - attach a PDF Bio-Sketch for each Key Personnel
    - Should not exceed 5 pages and it is critical to follow the instructions using the most recent forms
  - include all sub-awardees

Always open each PDF as you upload to ensure they are viewable

PHS 398 Research Plan

- Specific Aims
  - It is advisable to tailor your aims to the opportunity you are applying to. As Krista indicated “fit” is a key to success with NIH

- Research Strategy
  - In this area you would map out your aims in greater detail and tie in how funding through this mechanism would allow you to meet these aims. Focus on methodology, significance of your work, the impact, its innovative nature

ALWAYS adhere to page limits - Verifying these with FOA

PHS 398 Research Plan

- Item 11 – Multiple PD/PI Leadership plan

- Item 12 – Consortium/Contractual Agreements
  - Facepage or a letter of intent from Subawardee institution; this confirms participation

Only add items to the relevant fields

The R&R Budget

- All foreign applicants MUST use the R&R Budget Form regardless of what the funding announcement states
  - Must be in USD
  - Note exchange rate in budget Justification

- Budget Periods may only be 12 months
  - If your require additional periods, please use the “add period”.

The R & R Budget

- **Section A & B – Personnel**
  - Always indicate the PI as a PD/PI
  - Include all calendar month effort even if no salary requested
    - U of T is on a 12 month appointment basis – 10% effort equals 1.2 months
  - Please ensure your are adhering to NIH's salary cap
    - http://grants.nih.gov/grants/policy/salcap_summary.htm
  - Include all appropriate Fringe Benefits
    - Staff & Faculty- 24.75%, PDFs – 10% + $50/month, Students – 0%
    - http://www.finance.utoronto.ca/services/benefits.htm

The R & R Budget

- Section C – Equipment
- Section D – Travel – Fly America Act
- Section E – Participant/Trainee Support
- Section F – Other Direct Costs*
- Section G – Direct Costs (Total Direct Costs)

The R & R Budget

- **Section H – Indirect costs**
  - NIH IDC rate for foreign institutions is 8%
  - IDC cost base is all direct costs MINUS equipment
- **Section I – total direct & Indirect costs**
  - Calculates automatically
- **Section K – Budget Justification**
  - Currency Conversion
  - Description of each expense
  - PI roles and responsibilities – salaries and benefits
  - How did you arrive at these costs?
  - PDF attachment – open the attachment after you upload to make sure it is viewable

The R & R Budget – Subawards

- You must include a separate budget attachment for each subsite
- You would input the total of all subsites into Section F under #5, Subawards/Consortium/Contractual Costs.
- Subsites indirect costs DO NOT count against the direct cost limit

Submission Process

- 4 Business Days in advance of NIH DEADLINE
  - Start your MRA
- Administrative review – 1 day turnaround
- Return to Research Services 2 days in advance of the deadline
- Errors & Warnings
- Assembled Package

The Submission Process

Submit to RSO (4 days prior to deadline)

Administrative Review (1 Day)

Returned back to the PI with comments

The Submission Process

Submitted by RSO

eRA Commons Valildation

-errors & warnings

-Assembled Package

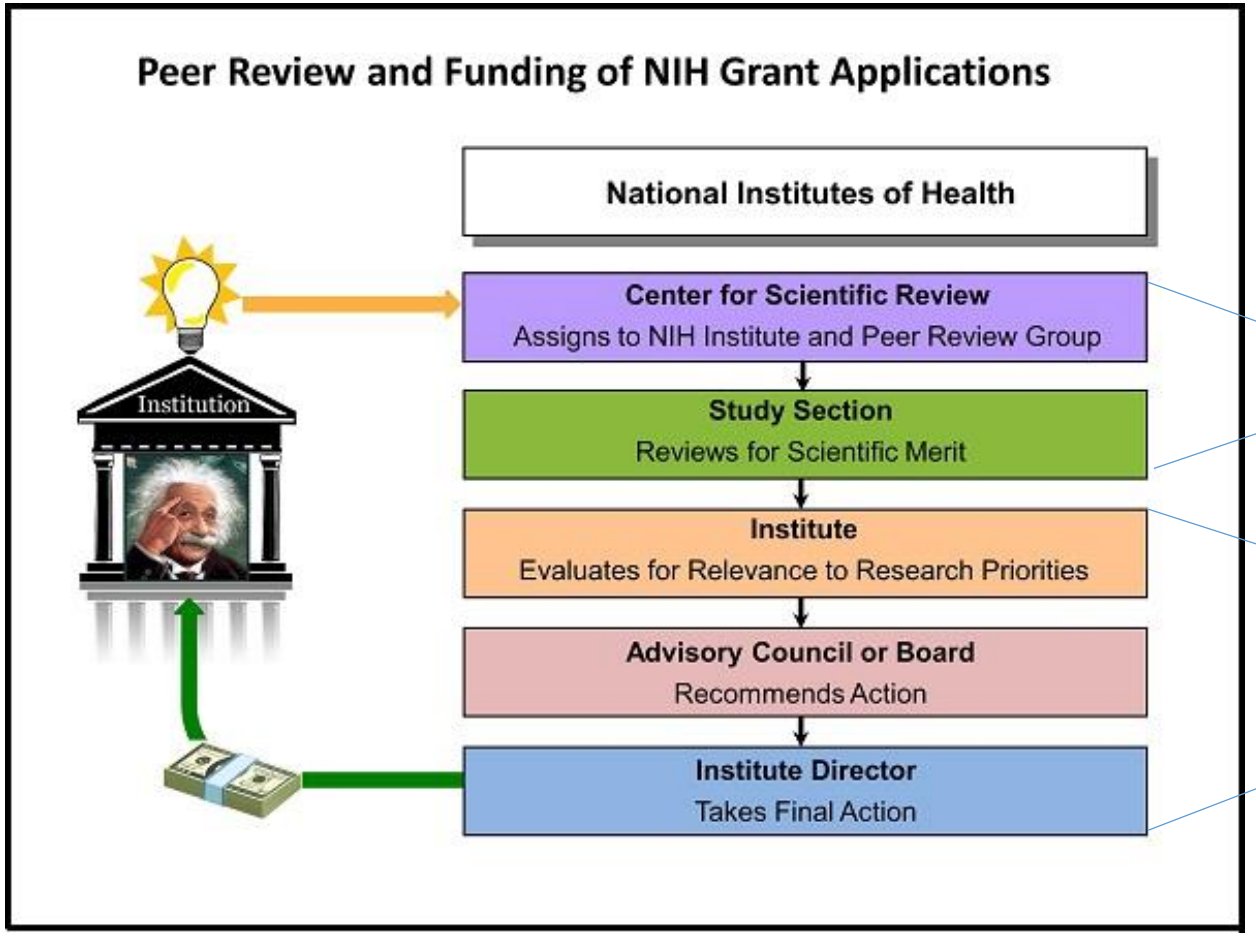
Grants.gov tracking number assigned

Application Submission System & Interface for Submission Tracking (ASSIST)
Sponsored by the National Institutes of Health

ASSIST

- **Application Submission System & Interface for Submission Tracking**
  - Online version of the PDF application
  - eRA Commons ID & Password
- **Benefits**
  - Multiple User Access
  - Lockout
  - Research Office – Review
  - Live Error Checking

Review Process



LEVEL 1

LEVEL 2

http://public.csr.nih.gov/aboutcsr/NewsAndPublications/PeerReviewNotes/Pages/USBiomedicalResearchNIHFormulaSuccess.aspx

Review Process

Level 1: Scientific Review Group

Evaluation for Scientific Merit

- Reviewed by Center for Scientific Review (CSR) or IC*
  - Review Application against NIH Policy & FOA
  - Recruit Reviewers
  - Assign to Scientific Review Groups (SRG)
    - academic experts in area
  - Coordinate review by SGR

Scoring

- **Overall Impact**
  - Likelihood influence research field
- **Scored Review Criteria**
  - Score for each criteria
  - Scale: 1 (best) - 9 (poor)
- **Final Overall Impact Score**
  - Mean of all scores then multiplied by 10
  - Final score between 10 and 90
  - Summary Statement

Review Criteria

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

Overall Impact or Criterion Strength	Score	Descriptor
High	1	Exceptional
	2	Outstanding
	3	Excellent
Medium	4	Very Good
	5	Good
	6	Satisfactory
Low	7	Fair
	8	Marginal
	9	Poor

Review Criteria

- **Additional Review Criteria**
  - Ethics, Biohazard & Application type
  - Overall Impact Score
- **Additional Review Considerations**
  - Foreign, Select Agent, Budget & Period
  - Noted but not scored

Review Process

Level 2: Advisory Council or Board

- Specific IC
  - Members both academic and public
  - Review applications against IC needs and goals
  - Advise IC Director
  - IC Director final decision on funding

Advice from Reviewer & Awardee

Professor Timothy Hughes
Donnelly Centre for Cellular & Biomolecular Research

Tips for Success

- Becoming a Reviewer
- Getting to know Institute/Center & Program Officer
- Foreign Justification
- Link with US based Collaborator

Next

Information Session

Post-Review and Award Process

May 2016

Watch for the Research Alert

Questions ???

Krista.Montgomery@utoronto.ca

Dalla Lana, Applied Sci & Eng, Dentistry, Forestry, Kinesiology & PE, Nursing, Pharmacy, UTM, and Medicine (last names A-M only).

or

J.Darby@utoronto.ca

Architecture, Arts & Science, Law, Rotman, Information, Social Work, OISE, UTSC, Music, and Medicine (last names N-Z only)