SUNY RF
The Research Foundation for
The State University of New York
Downstate Medical Center

Fundamentals of Research Administration

Office of Research Administration
Sharon Levine-Sealy, Pre-Award Director
Elliot Feder, Post-Award Director

Agenda

- What is Research Administration?
- What offices are involved?
- Meet the Folks behind the scenes
- Types of Funding
- Funding Opportunities – What are they? Where are they? How to find them?
- Funding Opportunity Announcements (FOAs) – What to look for
- Eligibility Requirements
- Deadline Dates

What is Research Administration?

- Research Administration involves the development, management, and implementation of research initiatives.

Who are Research Administrators?

- People working in Research Administration who provide:
  - Services to enhance a researchers success
  - Management support for the institution's research missions
  - Support to sponsors to achieve their goals to ensure their regulations are enforced

Who are Research Administrators?

- According to Garrett Sanders, previous EVP and COO of the Research Foundation for SUNY (RF), "these professionals assist faculty, students, and staff members through every step of the research grant process, allowing them to focus on their work and ensuring their compliance with university, grant sponsor, and government requirements."
  - "Our research administration professionals contribute directly to SUNY's mission by helping faculty members find, apply for, and manage funding for their research, training, and public service projects."

Who's Involved?

Who is Involved?

- Office of Research Administration
  - Pre-Award
  - Post-Award
- IRB
- IACUC
- Biosafety / IBC
- Technology and Commercialization
- Compliance Office

IRB Fundamentals

Kevin L. Nellis, MS, CIP

Executive Director

SUNY Downstate Medical Center

Institutional Review Board (IRB)

- Protects the rights and welfare of research participants.
- Empowered to approve, require modifications, or disapprove Human Research.
- Ensures Human Research is scientifically/scholastically valid, ethical, and in compliance with all requirements.
- Ensures compliance through oversight functions.

Activities Requiring IRB Review

- Clinical Trials (21 CFR Parts 50, 56, 312, 812)
- Research involving Protected Health Information (PHI) from patients or employees (45 CFR Parts 160, 162, and 164)
- Human (Subjects) Research (Common Rule:45 CFR Part 46)
  - Ask the following question, in order:
    1) Is it Research?
    2) Does it involve Research Participants (Human Subjects)?

Is IRB Review Required for Human Research? (Under the Common Rule)

1) Is it research ?

- YES

2) Does it Involve Research Participants (Human Subjects)?

- YES

Submit IRB Application

- If "NO" to either question, consult "IRB Decision Aid" or call IRB @ X8480

Is it Research?
(Under the Common Rule)

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

Generalizable Knowledge

Investigations designed to develop or contribute to **generalizable knowledge** are those designed to draw general conclusions (i.e., knowledge gained from a study) that may be applied to populations outside of the specific study population.

Generalizable Knowledge

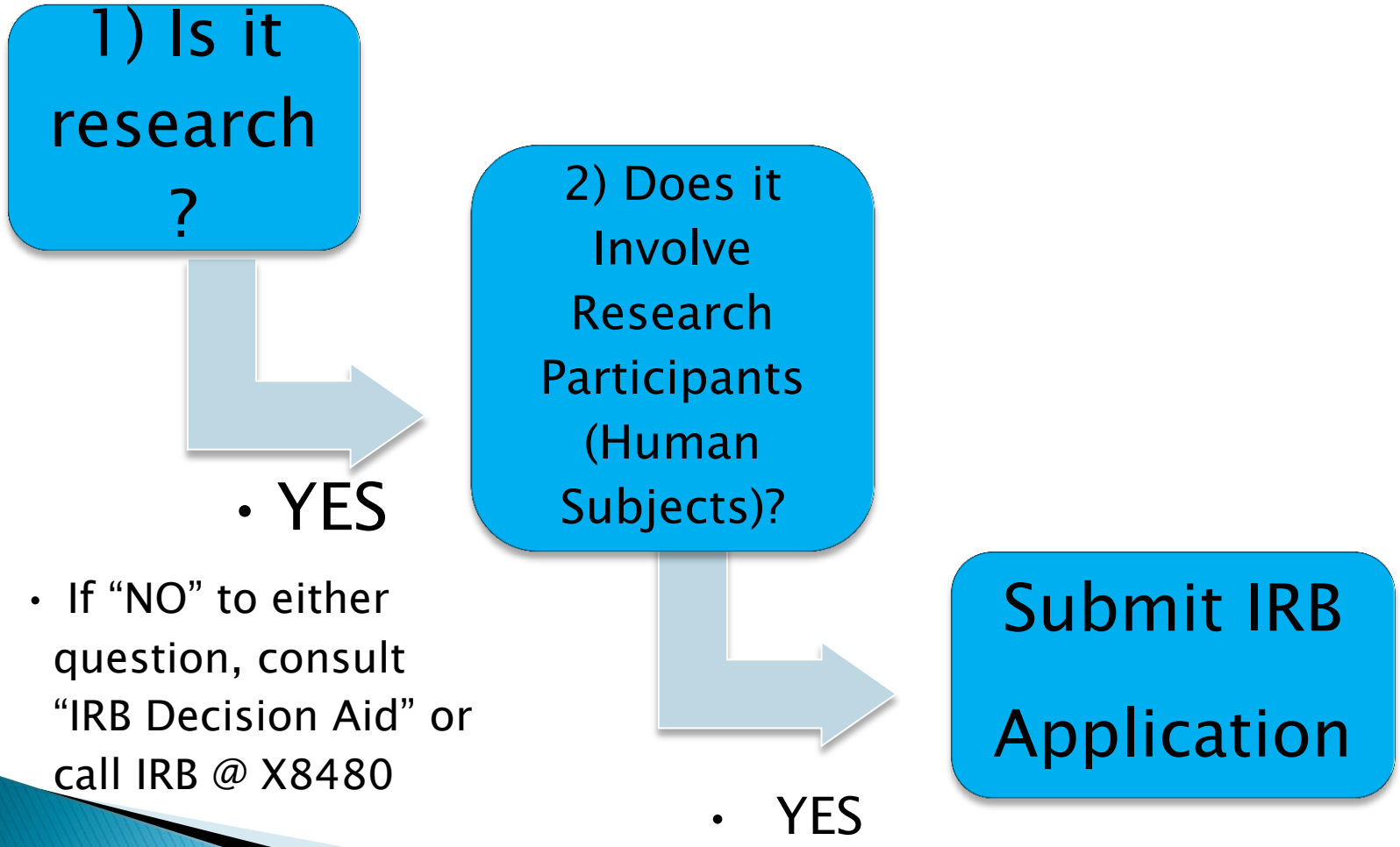
Examples:

- The findings from the activity involving a patient population at SUNY Downstate Medical Center can be applied to a population outside of the SUNY Downstate Medical Center.
- The findings from a population within a healthcare network can be applied to a population outside of the network.
- The findings of a student research project can be applied to other students in another school.

Does it Involve Research Participants (Human Subjects)? (Under the Common Rule)

- *Living* individuals *about whom* an investigator conducting research, obtains either…
  - Data through intervention or interaction with the individual
  - Individually identifiable private information
    - including identifiable specimens

Is IRB Review Required for Human Research? (Under the Common Rule)



- If "NO" to either question, consult "IRB Decision Aid" or call IRB @ X8480

IRB Decision Aid

SUNY Downstate Medical Center	**SUNY Downstate Medical Center** **University Hospital of Brooklyn** **College of Medicine** **College of Health Related Professions** **College of Nursing** **School of Graduate Studies** **Graduate Program in Public Health**	**IRB Decision Aid: Does a SUNY DMC project need a SUNY DMC IRB Application or an SUNY DMC IRB Determination Letter?**

Whenever you are not sure how to answer a question, contact the IRB for help. Questions may be directed initially to:

- **IRB Chair, Phyllis G. Supino, EdD** at **(718) 613-8355**
- **Executive Director, Kevin Nellis** at **(718) 613-8461**
- **IRB Staff** at **(718) 613-8480**

For additional guidance, see: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Three Key Definitions:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research participant means a living individual about whom an investigator (whether professional or student) conducting research obtains

1. data through intervention or interaction with the individual, or
2. identifiable private information.

Human Research (also known as Human Subjects Research) means any activity that involves a *research participant* in a *research* activity. *An IRB application is required for all Human Research.*

This guidance incorporates the above HHS regulatory definitions as well as HIPAA, FDA, and other Federal and NY state regulations.

The following are "examples" that require IRB approval when the activities meet the definition of ***Human Research***, *but this list does not include all activities that require IRB approval*:

- An activity that involves observation of, or interaction with, individuals to gather information for research
- Collection of pilot data

Activities That DO NOT Require IRB Review

- Emergency use of an investigational drug, device, or biologic (must notify IRB within 5 days of use).
- Off-label use of approved drug (requires Pharmacy approval)
- Internal Healthcare Operations Activities (e.g., performance improvement; not intended for research).
- Case Reports/Series (up to 3 individuals, living or deceased).
- Research with de-identified data set (based on IRB definitions).
- Preparatory to Research Activities (with Certification Form)
- When SUNY DMC is "not engaged" in Human Research.
  - See: http://www.hhs.gov/ohrp/policy/engage08.html

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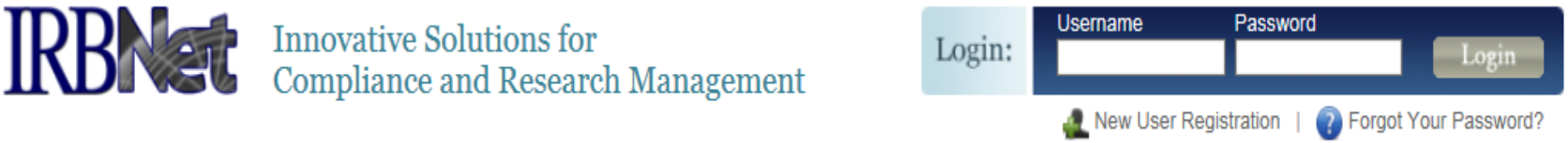
Types of IRB Review

- Determination Letter (indicates IRB review is NOT required)
- Exempt Review
- Expedited Review
- Convened (Full) IRB Review
- External IRB Review (some multi-site research)

IRB Net



Step 1: Create an IRBNet user account

- Go to www.irbnet.org and click the "New User Registration" link.
- Follow the online instructions. Complete all items with red asterisk (*).
- When asked to identify your "organization," type SUNY in the text box and then select SUNY Downstate Medical Center, Brooklyn, NY.
- Remember to click on the "Register" button in order to finalize your "New User Registration."
- Press the "Continue" button on the "Registration is Complete" page and follow **"Step 2"** to activate your IRBNet user account.

Step 2: Activate your IRBNet user account

- After successful completion of **"Step 1,"** the User will receive an activation email to the registered email address.
- Click on the link within that email to activate your IRBNet account.
- You may begin using IRBNet as soon as activation is complete.

IRB Contacts

Phyllis G. Supino, EdD, IRB Chair, Boards A, B and E	(718) 613-8355
Daniel Cukor, PhD, Vice Chair, Board A	(718) 270-2077
Stanley Friedman, MD, Vice Chair, Board B	(718) 270-1335
Kevin L. Nellis, MS, CIP, Executive Director, Human Research Protection & Quality Assurance	(718) 613-8461
Diann Johnson, MPH, Associate IRB Administrator	(718) 270-4341
Angela Cartmell, PhD, CIP, Associate IRB Administrator	(718) 270-4454
Nakih Gonzales, IRB Assistant	(718) 270-4372
IRB Office	(718) 613-8480

IACUC Fundamentals

Julie M. Sharp, DVM, CPIA, DACLAM
Director
Office of Animal Welfare

SUNY Downstate Medical Center

Institutional Animal Care & Use Committee (IACUC) Functions

- Protects the welfare of research animals.
- Reviews and approves, requires modifications, or disapproves animal research proposals.
- Conducts semi-annual program and facility reviews.
  - Documents deficiencies & corrective action plans
- Ensures all animal users are skilled and qualified.
- Ensures occupational health oversight of all personnel working with animals.
- Ensures compliance through oversight functions.
  - Post-Approval Monitoring
  - Review of Animal Welfare Concerns

IACUC.Welfare@Downstate.edu

External Oversight

- Office of Laboratory Animal Welfare, NIH
  - PHS Assurance
- United States Department of Agriculture, APHIS
  - USDA Registration
- AAALAC, Int.
  - Accreditation
- New York State Dept. of Health
  - Registration
- Federal and State Drug Enforcement Agencies
  - Registration for Controlled Drugs

IACUC FORMS

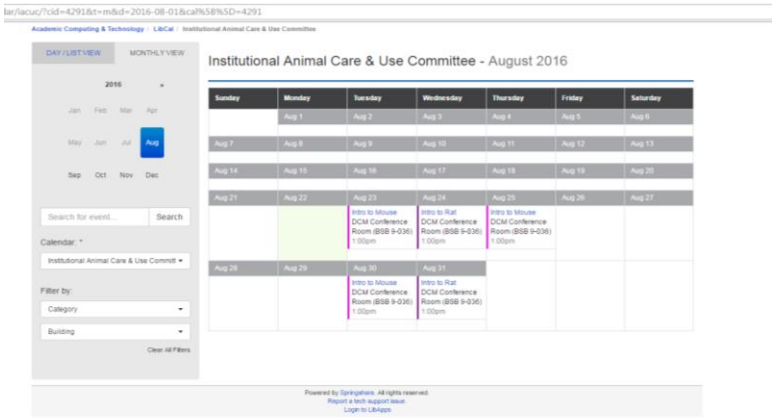
- http://research.downstate.edu/iacuc/iacuc-forms.html
- Animal Protocol
- Annual Renewal
- Protocol Amendment
- Personnel Amendment
  - New Scientist Questionnaire

Types of IACUC Review

- Full Committee Review (FCR)
  - All new and 3-year renewal protocols
  - Any submission that has been called for FCR
  - Convened meetings held once a month

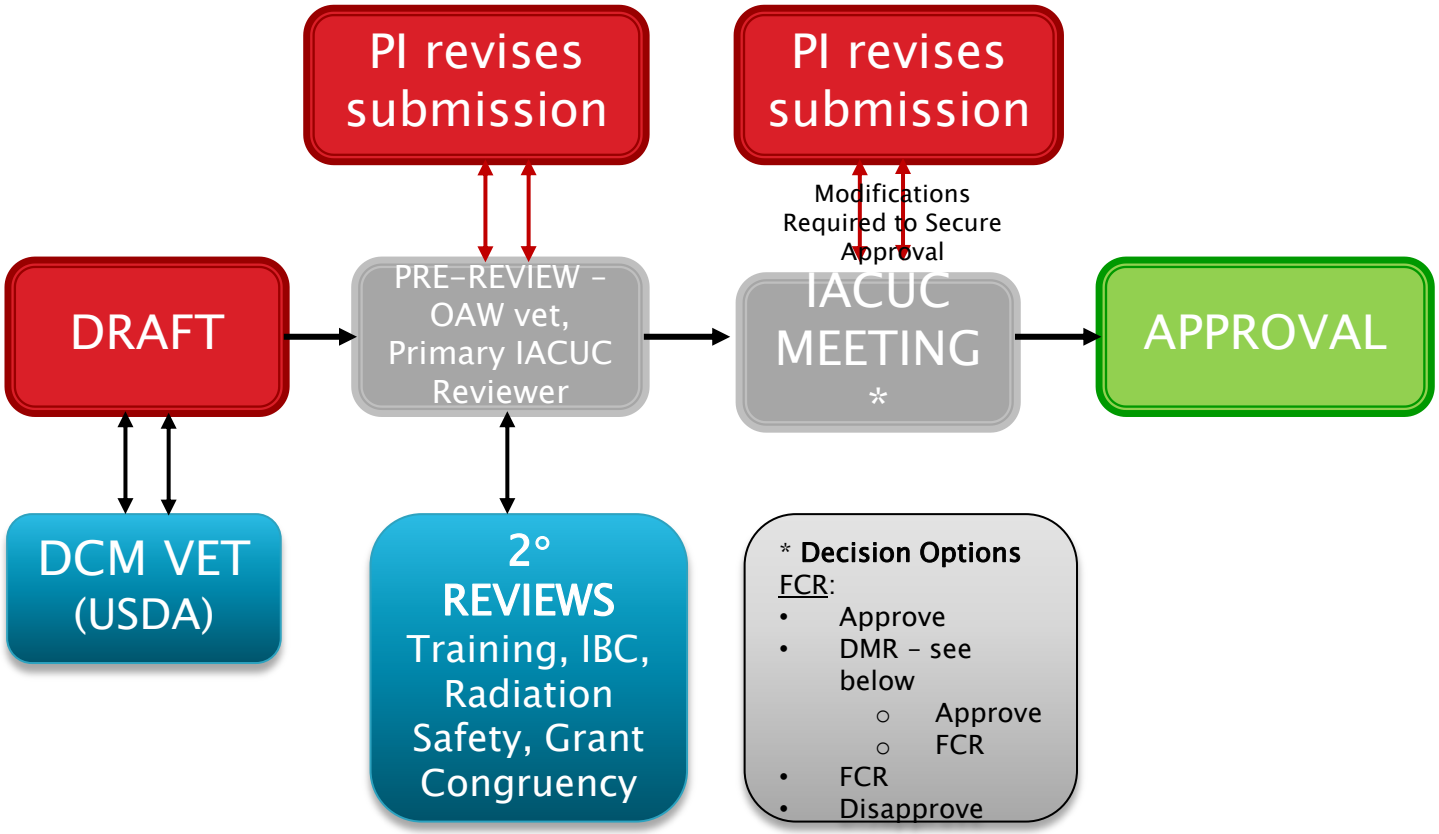
- Designated Member Review (DMR)
  - Protocols subsequent to FCR
  - Protocol Amendments
    - Reviewers are designated by the IACUC Chair
    - All members have the opportunity to call for  hours from notification)
    - Can be approved once all clarifications are resolved if not called for FCR
- Administrative Amendments
  - VVC – Veterinary Verification & Consultation
  - Personnel
  - Can be approved once all clarifications are resolved

Types of IACUC Review

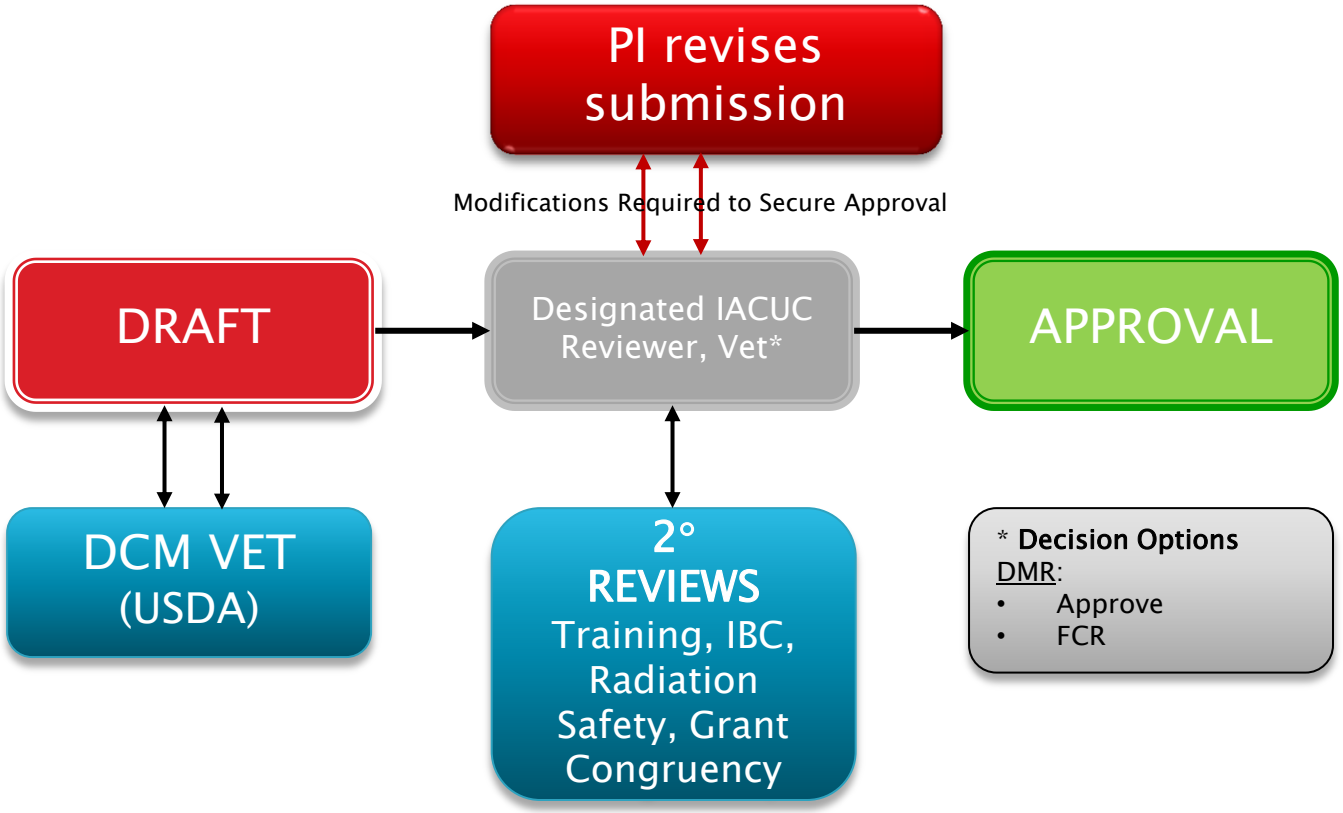


- Secondary Reviews
  - Training Requirements
    - Online CITI Training
    - Wetlab Training – can register online
    - Environmental Health & Safety
  - Institutional Biosafety Committee (IBC)
  - Radiation Safety
  - Grant Congruency

IACUC Review Process – FCR



IACUC Review Process – DMR



Animal Program Contacts

Email – IACUC@Downstate.edu	
Diana Dow-Edwards, PhD • IACUC Chair	718-270-3987
Julie M. Sharp, DVM, CPIA, DACLAM • Director, OAW	718-270-4645
Meagan Eastman, CPIA, LATG • Assistant Director, OAW	718-330-5568
Lydia Bailey • IACUC Coordinator	718-270-3912

The Office of Technology Commercialization (OTC) at SUNY Downstate Medical Center: A Brief Overview

Fundamentals of Research Administration-Training
Office of Research Administration
SUNY Downstate Medical Center
September 7, 2016

Presenter: David Schoenhaut, Ph.D.
Director, Office of Technology Commercialization
SUNY Downstate Medical Center

http://research.downstate.edu/administration/tech-transfer.html

Technology Transfer

Technology transfer is the process of transferring scientific findings [and proprietary Intellectual Property (IP)] from one organization to another for the purpose of further development and commercialization.

[Note: SUNY Owns Inventions & Other IP made by investigators in the scope of their SUNY research]

The process includes:

-Identifying & evaluating new technologies (e.g at a given University)

-Protecting and promoting the technologies through patents and copyrights

-Negotiating technology licensing contracts with existing private sector companies or creating new startup companies based on the technology

Industrial Liaison

⊙**Our office manages pro-active efforts to engage industry and biotech investors to promote Downstate technologies based on our investigators' research** (Business Development).

⊙**Our office is involved in any contractual agreement or industry engagement where Downstate's investigators' IP is involved or may be created or used in the corporate relationship.**

Some exceptions include:
-Industry-Initiated/Sponsored Clinical Trial Agreements,
-Most Govt basic research grants

Compliance

-Federal Govt. regulations with respect to IP developed under research grants (e.g. Bayh-Dole Act of 1980)

-IP reporting to research sponsors (e.g. NIH, Disease Foundations, State Agencies, Industry Sponsors)

-SUNY Patents and Inventions Policy

-Conflict-of-Interest Policy

Key Tasks & Transactions

- Material Transfer Agreements
- Non-Disclosure or Confidential Disclosure Agreements (NDA or CDA)
- Industry Sponsored Research Agreements (pre-award office primary)
- Technology Licensing Agreements with Industry
- Collaborative Research Agreements (sharing or co-development of IP)
- Inter-Institutional IP management and revenue sharing agreements
- Faculty Revenue Sharing Agreements
- Commercial Development Award Proposals (e.g SUNY-TAF, Bioaccelerate)

- New Technology Disclosures-Evaluations

- Review and response, with outside counsel, to Patent Office actions. Decisions to continue to prosecute the patents and the scope of coverage of claims.

- Individual Meetings with Faculty to Discuss Research & Technology Prospects

- Outreach/meetings with venture cap and angel investors, research executives and research “scouts” from pharmaceutical and biotech companies

Interactions with other Campus Offices

Pre-award:

⊙MTA requests coming through Pre-award office

⊙CDA requests involving investigator research programs or intellectual property terms of either party

⊙ Review of IP terms of sponsored research agreements, and certain awards which focus on technology commercialization or IP sharing among different institutions.

⊙Updating compliance records for grant closeouts etc.

Post-award:

⊙OTC payments to vendors, especially patent law firms.

⊙OTC payments to investigators for their share of revenue derived from licensing of inventions

IRB:

⊙Verify IRB approval or review waiver for any transaction involving human materials, usually in connection with MTA (Material Transfer Agreements)

Downstate Counsel:

⊙occasional liability issues or inquiries on Downstate licensing or IP transactions.

Downstate Technology Incubator:

⊙Incubator startup companies, educational programs.

DMC Office of Technology Commercialization (OTC)
Current Staffing
2 FTE

Director:
-Ph.D. Molecular Biology
-14 yrs Pharma/Biotech R&D (Roche, Abbott, Pfizer)
-10 yrs Tech Transfer/Licensing (Nucleonics, Albert Einstein C.of M., SUNY)

Licensing Associate:
-B.S. Chem E.
-4 yrs Tech Transfer (U. Rochester, SUNY)

Licensing Assistant (position pending final approval)

OTC Contacts:

David Schoenhaut, Ph.D.
Director, Office of Technology Commercialization
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450 Clarkson Avenue
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718-613-8514

david.schoenhaut@downstate.edu

Alexandra Dudman
Senior Licensing Associate
Office of Technology Commercialization
Box 0128
SUNY Downstate Medical Center
450 Clarkson Avenue
Brooklyn, NY 11203
718-613-8524

alexandra.dudman@downstate.edu

http://research.downstate.edu/administration/tech-transfer.html

Compliance

- COI
  - Annual Disclosure
  - Transactional Questionnaire
  - Training
- HIPAA

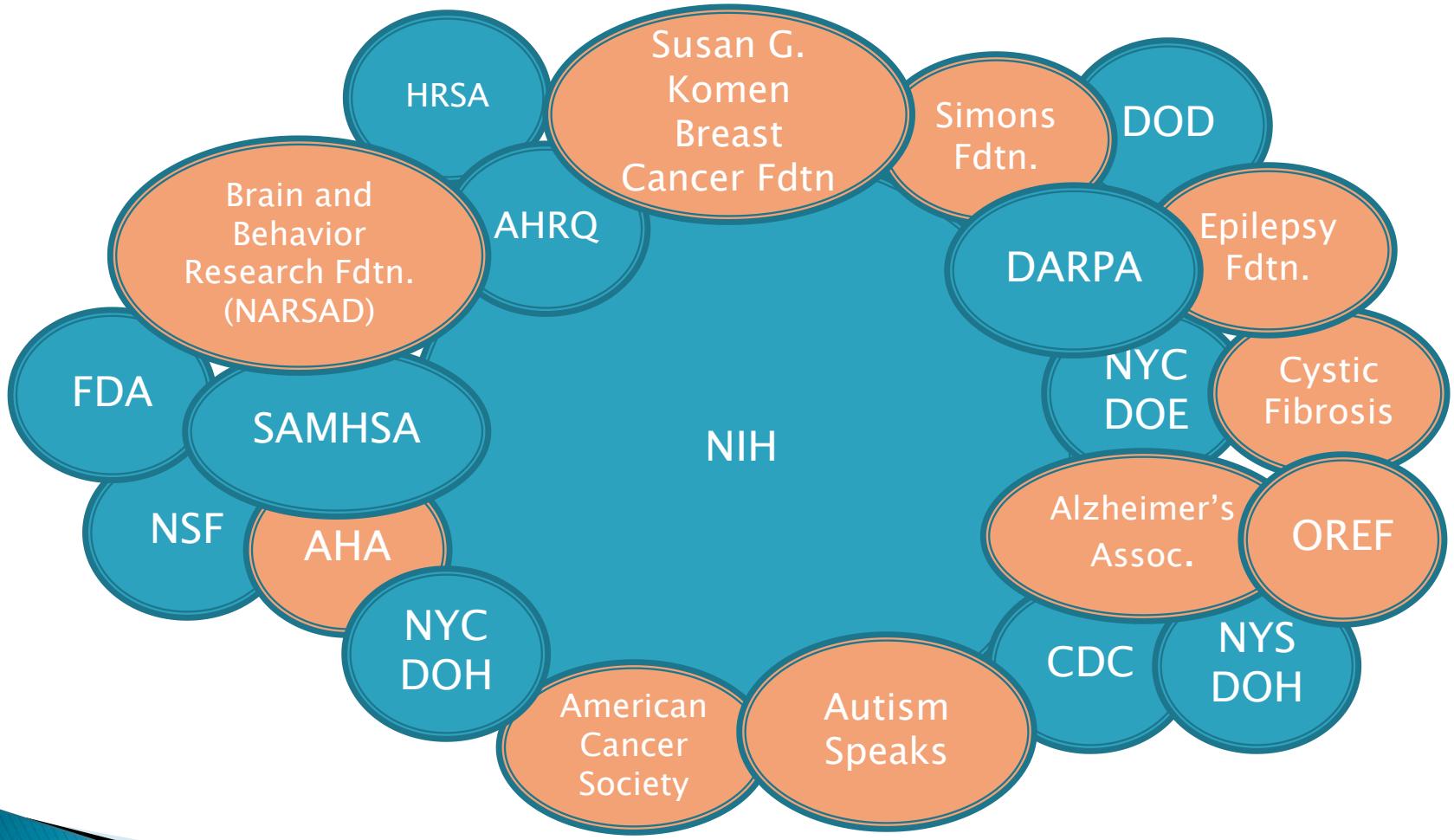
The role of the AVP of Compliance is to oversee all the compliance offices: IRB, IACUC, IBC and COI

Who are the key players?

- Principal Investigator (PI)
- Department Chairs
- School Deans
- Office of Research Administration (Pre & Post)
- IACUC
- IRB
- Compliance
- Biosafety

and YOU!!

The list goes on…Some of the many extramural sponsors



Types of Funding Available: Grants, Contracts & Cooperative Agreements

- Grants:
  - Financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
  - The PI is responsible for developing the concepts, methods, and approach for a research project. The sponsor is interested in the productivity of the study vs. the product.
  - Grants may or may not be in response to a specific funding announcement. Some sponsors have ongoing standard deadlines several times a year.

Types of Funding Available: Grants, Contracts & Cooperative Agreements

- Contract:
  - An award instrument establishing a binding legal procurement relationship between the sponsor and a recipient obligating the latter to furnish a product or service.
  - The sponsor is responsible for establishing the detailed requirements. The principle purpose of the study is to acquire a specific service or end product for the direct benefit of that sponsor.
  - Usually in response to a Request for Proposal (RFP).

Types of Funding Available: Grants, Contracts & Cooperative Agreements

- Cooperative Agreements:
  - 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.
  - Both the sponsor and the PI have substantial responsibility.
  - Solicitation in response to a specific Program Announcement (PA) or Request for Application (RFA).

Sponsors

- The National Institutes of Health (NIH) – The Nation's Medical Research Agency – includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov

Funding Opportunity Announcements (FOAs)

- A publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds.

- FOAs may be known as:
  - Program Announcements
  - Requests for Applications
  - Notices of Funding Opportunities
  - Solicitations
  - or other names depending upon the Agency and type of program.

NIH Specific:
Parent Announcement / Unsolicited / Investigator-Initiated Grants

- NIH-wide FOA enabling applicants to submit an electronic investigator-initiated grant application for a single grant mechanism, e.g., Research Project Grant (Parent R01).

- Go to Parent Announcements for Unsolicited or Investigator-Initiated Applications.

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

NIH Specific:
Solicited Applications

- Program Announcement (PA) – An announcement by an NIH Institute or Center requesting applications in the stated scientific areas. PAs are published in the NIH Guide for Grants and Contracts.
- Request for Applications (RFA) – The official statement inviting grant or cooperative agreement applications to accomplish a specific program purpose. RFAs indicate the amount of funds set aside for the competition and generally identify a single application receipt date.
- Request for Proposals (RFP) – Announces that the sponsor would like to award a contract to meet a specific need, such as the development of an animal model. RFPs have a single application receipt date. Contracts are based on deliverables and milestones.

- http://grants.nih.gov/grants/guide/index.html?CFID=10110956&CFTOKEN=5eab9058129fd544-BF2F1820-5056-9439-7E005170B2465609

NIH Specific (but similar across other sponsors): NIH Staff and Functions

- Scientific Review Officer (SROs) – A Federal Scientist who presides over a scientific review group and is responsible for coordinating and reporting the review of each application assigned to it. The SRO serves as an intermediary between the applicant and reviewers and prepares summary statements for all applications.

- Program Officer (PO) – The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant.

- Grants Management Specialists (GMS) – A NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations and guidelines; negotiating grants; providing consultation and technical assistance to grantees; and administering grants after award.

NIH Specific: Types of Announcements

- NIH Notices
  - Notice (NOT)
    - announces policy and procedures
    - announces changes to RFA or PA announcements
    - announces changes to RFP's
    - other general information items

    http://grants.nih.gov/grants/guide/search_results.htm?year=active&scope=not

NIH Specific: Numbering System

- PA numbering (e.g. *PA-12-241*): Indicates a Program Announcement issued in 2012 or for funding in 2012 (12) with an associated serial number (241).
- RFA numbering (e.g. *RFA-HL-13-013*): Indicates an RFA issued by NHLBI (HL) in 2012 for funding in 2013 (13) with an associated serial number (013).
- Notice Numbering (e.g. *NOT-OD-12-157*): Indicates a Notice issued by the Office of Director (OD) in Fiscal Year 2012 (12) with an associated serial number (157).

Where do you find these Announcements?

- Grants.gov is your source to FIND and APPLY for federal government grants.
  - http://www.grants.gov
- All discretionary grants offered by the 26 federal grant making agencies can be found on Grants.gov
- DO NOT REGISTER ON GRANTS.GOV
- *ORA is authorized on behalf of RFSUNY and Downstate Medical Center to submit all proposals and accept all awards on behalf of the institution.*

http://research.downstate.edu/funding/funding-opportunities.html

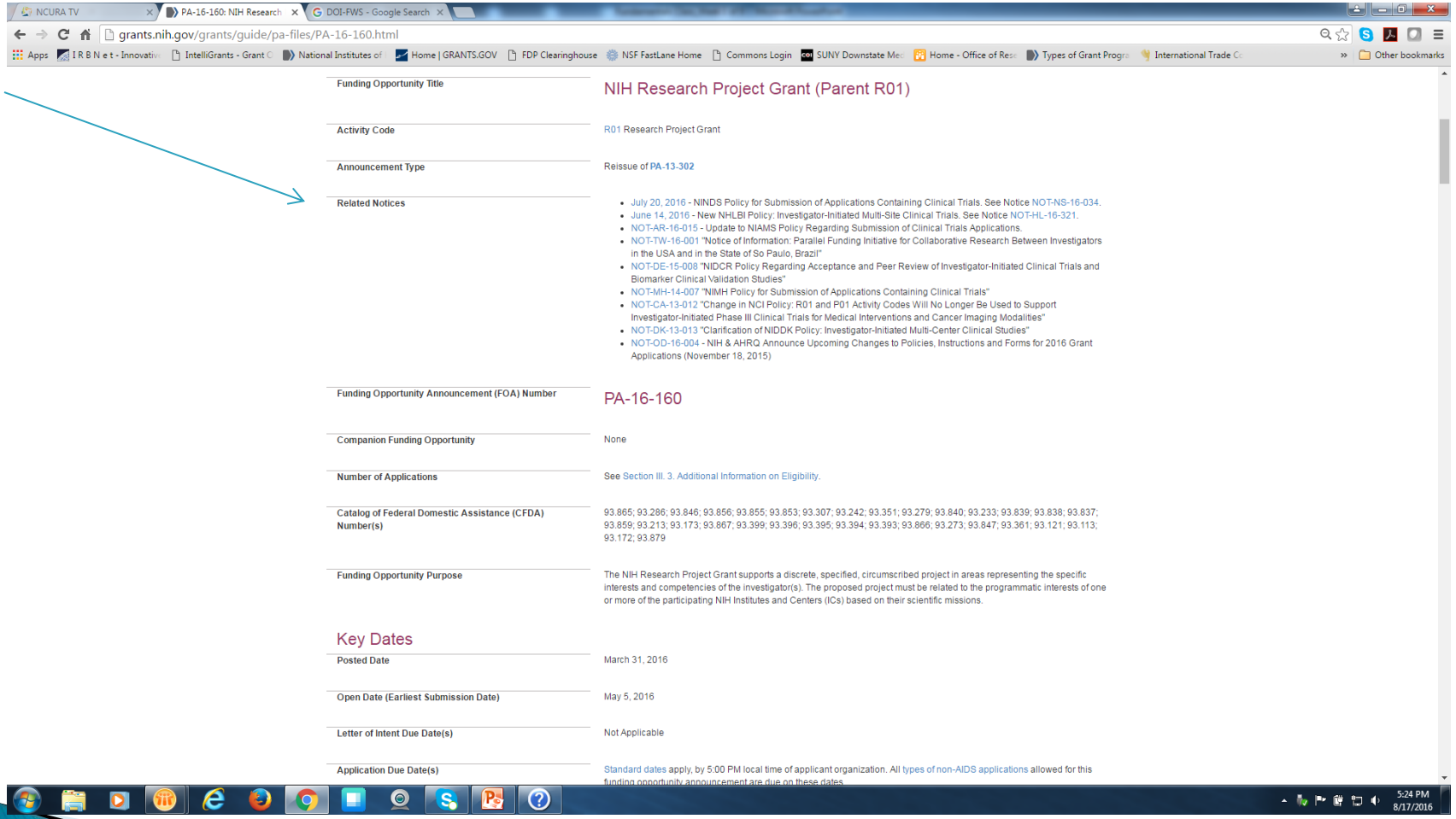
Components of the Funding Announcement – NIH example

Part I – Overview:

1. Participating Organizations – link in FOA
2. Related NOTs and Purpose of FOA
3. Key Dates: VITAL INFORMATION
4. Required Application Instructions

How to apply? Use the correct forms !!

Parent FOA – Part I – Overview



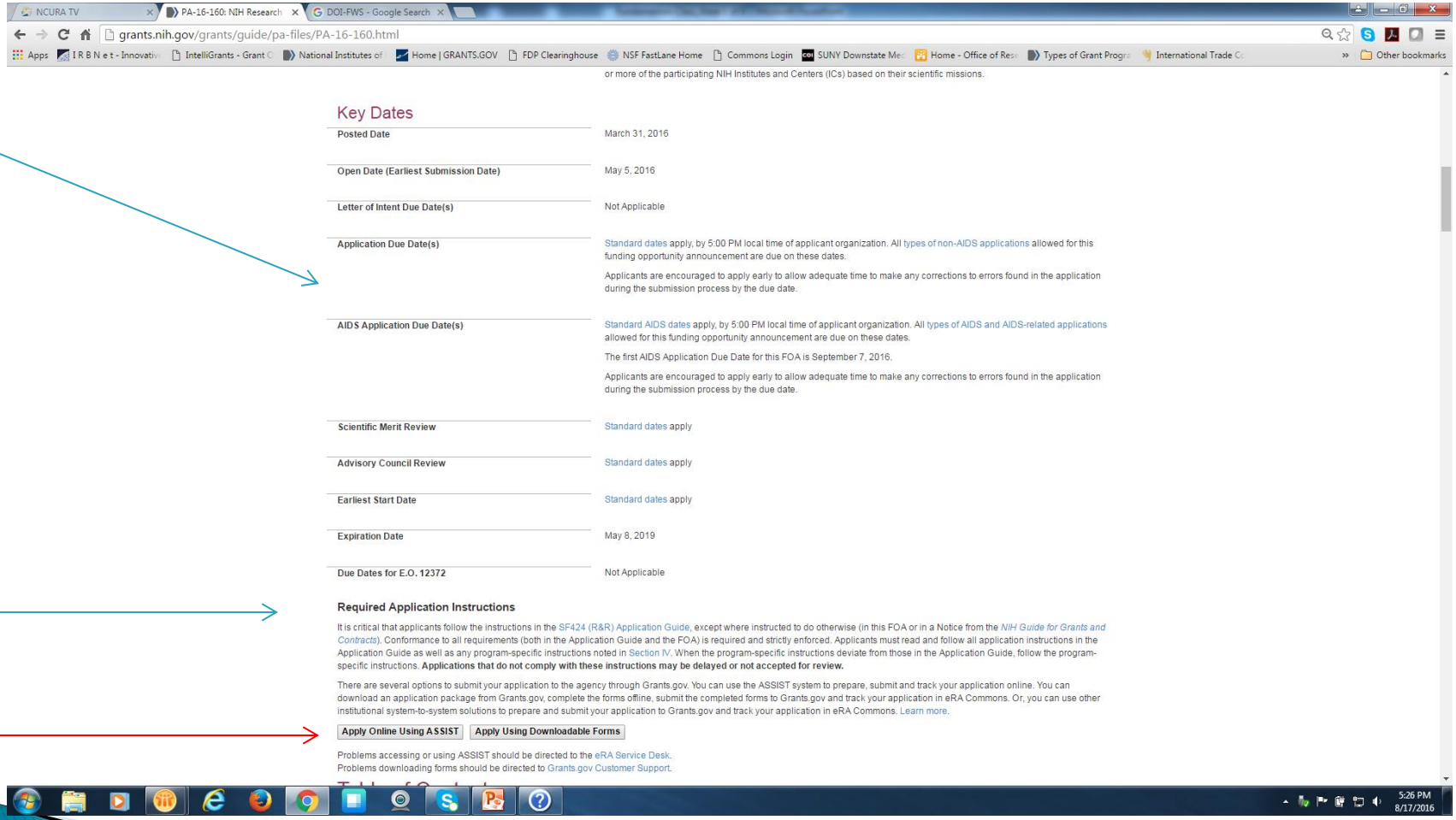
grants.nih.gov/grants/guide/pa-files/PA-16-160.html

Funding Opportunity Title	NIH Research Project Grant (Parent R01)
Activity Code	R01 Research Project Grant
Announcement Type	Reissue of PA-13-302
Related Notices	• July 20, 2016 - NINDS Policy for Submission of Applications Containing Clinical Trials. See Notice NOT-NS-16-034. • June 14, 2016 - New NHLBI Policy: Investigator-Initiated Multi-Site Clinical Trials. See Notice NOT-HL-16-321. • NOT-AR-16-015 - Update to NIAMS Policy Regarding Submission of Clinical Trials Applications. • NOT-TW-16-001 "Notice of Information: Parallel Funding Initiative for Collaborative Research Between Investigators in the USA and in the State of So Paulo, Brazil" • NOT-DE-15-008 "NIDCR Policy Regarding Acceptance and Peer Review of Investigator-Initiated Clinical Trials and Biomarker Clinical Validation Studies" • NOT-MH-14-007 "NIMH Policy for Submission of Applications Containing Clinical Trials" • NOT-CA-13-012 "Change in NCI Policy: R01 and P01 Activity Codes Will No Longer Be Used to Support Investigator-Initiated Phase III Clinical Trials for Medical Interventions and Cancer Imaging Modalities" • NOT-DK-13-013 "Clarification of NIDDK Policy: Investigator-Initiated Multi-Center Clinical Studies" • NOT-OD-16-004 - NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015)
Funding Opportunity Announcement (FOA) Number	PA-16-160
Companion Funding Opportunity	None
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.865; 93.286; 93.846; 93.856; 93.855; 93.853; 93.307; 93.242; 93.351; 93.279; 93.840; 93.233; 93.839; 93.838; 93.837; 93.859; 93.213; 93.173; 93.867; 93.399; 93.396; 93.395; 93.394; 93.393; 93.866; 93.273; 93.847; 93.361; 93.121; 93.113; 93.172; 93.879
Funding Opportunity Purpose	The NIH Research Project Grant supports a discrete, specified, circumscribed project in areas representing the specific interests and competencies of the investigator(s). The proposed project must be related to the programmatic interests of one or more of the participating NIH Institutes and Centers (ICs) based on their scientific missions.

Key Dates

Posted Date	March 31, 2016
Open Date (Earliest Submission Date)	May 5, 2016
Letter of Intent Due Date(s)	Not Applicable
Application Due Date(s)	Standard dates apply, by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates.

Overview, cont.



or more of the participating NIH Institutes and Centers (ICs) based on their scientific missions.

Key Dates

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AIDS Application Due Date(s)	Standard AIDS dates apply, by 5:00 PM local time of applicant organization. All types of AIDS and AIDS-related applications allowed for this funding opportunity announcement are due on these dates. The first AIDS Application Due Date for this FOA is September 7, 2016. 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	May 8, 2019
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the SF424 (R&R) 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. 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.**

There are several options to submit your application to the agency through Grants.gov. You can use the ASSIST system to prepare, submit and track your application online. You can download an application package from Grants.gov, complete the forms offline, submit the completed forms to Grants.gov and track your application in eRA Commons. Or, you can use other institutional system-to-system solutions to prepare and submit your application to Grants.gov and track your application in eRA Commons. Learn more.

Apply Online Using ASSIST | Apply Using Downloadable Forms

Problems accessing or using ASSIST should be directed to the eRA Service Desk.
Problems downloading forms should be directed to Grants.gov Customer Support.

Components of the Funding Announcement – NIH example

Part II – Full text of the announcement

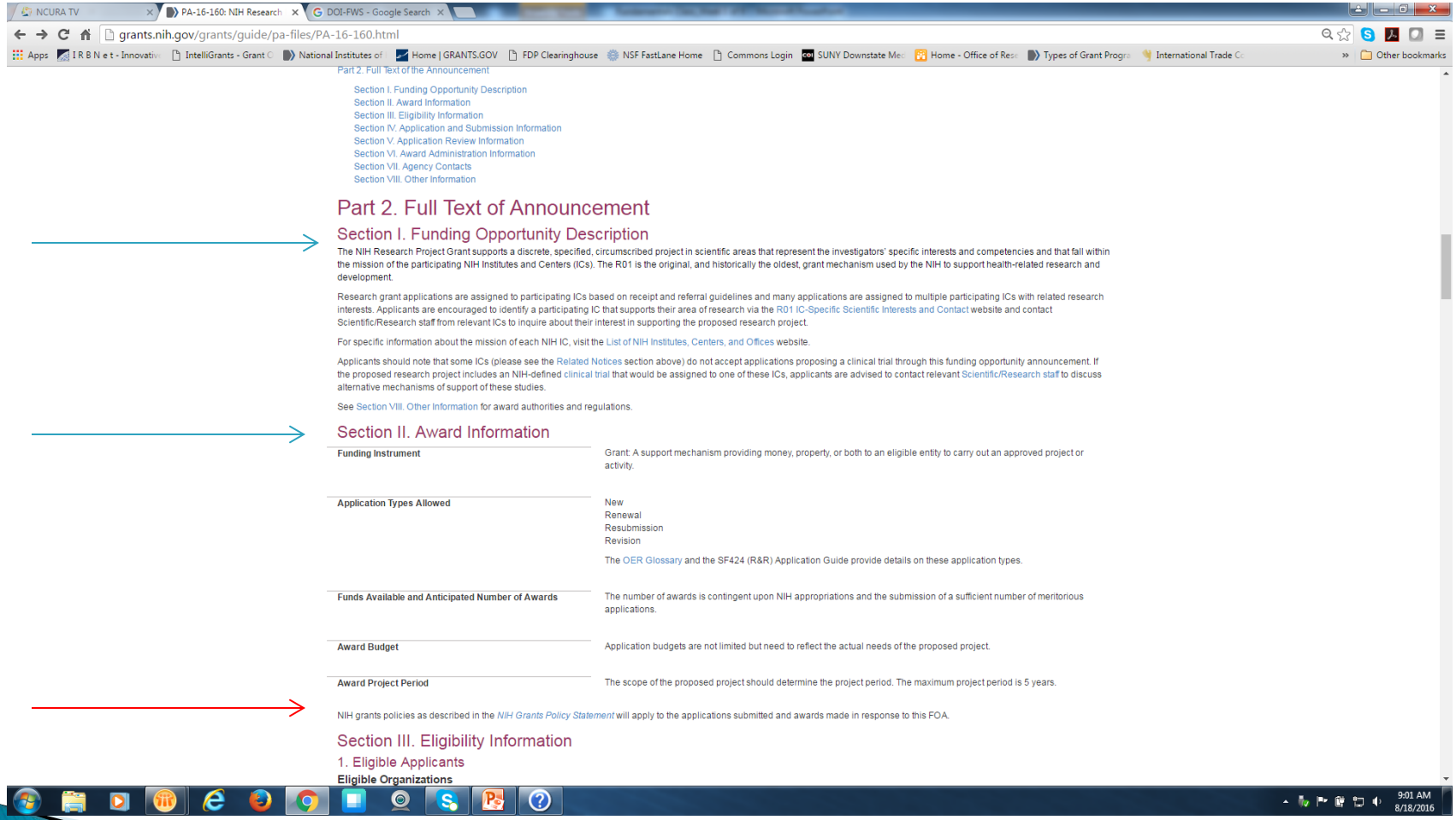
Section I – Funding Opportunity Description

- Research Objectives

Section II – Award Information

- Mechanisms of Support
- Funds Available

Part II – Announcement



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Part 2. Full Text of the Announcement

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The NIH Research Project Grant supports a discrete, specified, circumscribed project in scientific areas that represent the investigators' specific interests and competencies and that fall within the mission of the participating NIH Institutes and Centers (ICs). The R01 is the original, and historically the oldest, grant mechanism used by the NIH to support health-related research and development.

Research grant applications are assigned to participating ICs based on receipt and referral guidelines and many applications are assigned to multiple participating ICs with related research interests. Applicants are encouraged to identify a participating IC that supports their area of research via the R01 IC-Specific Scientific Interests and Contact website and contact Scientific/Research staff from relevant ICs to inquire about their interest in supporting the proposed research project.

For specific information about the mission of each NIH IC, visit the List of NIH Institutes, Centers, and Offices website.

Applicants should note that some ICs (please see the Related Notices section above) do not accept applications proposing a clinical trial through this funding opportunity announcement. If the proposed research project includes an NIH-defined clinical trial that would be assigned to one of these ICs, applicants are advised to contact relevant Scientific/Research staff to discuss alternative mechanisms of support of these studies.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument	Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
Application Types Allowed	New Renewal Resubmission Revision The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.
Award Budget	Application budgets are not limited but need to reflect the actual needs of the proposed project.
Award Project Period	The scope of the proposed project should determine the project period. The maximum project period is 5 years.

NIH grants policies as described in the *NIH Grants Policy Statement* will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

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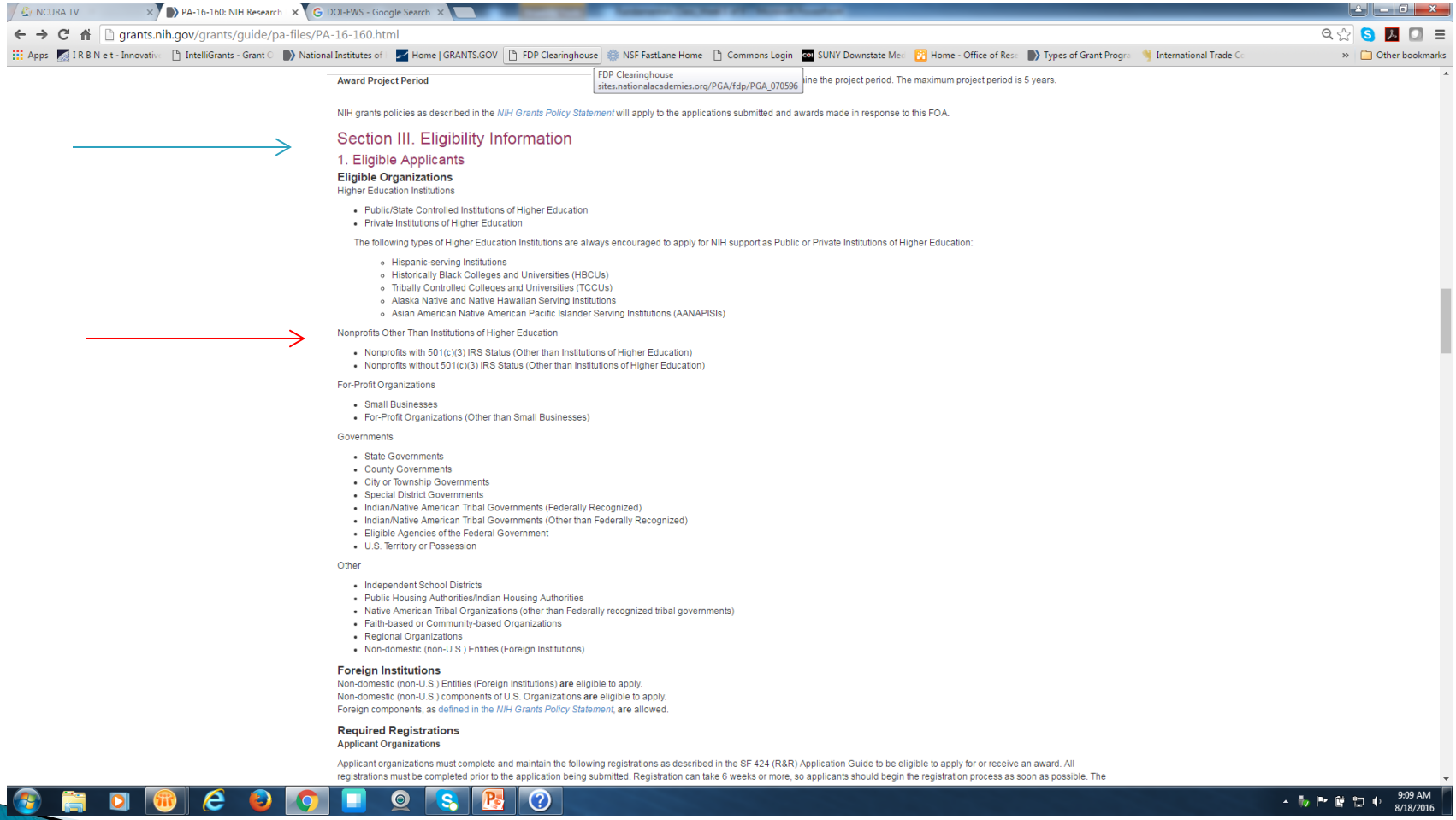
Components of the Funding Announcement – NIH example

Section III, Part 1 – Eligibility Information

1. Institutional Eligibility: STOP: if the Institution can only submit a certain number of applications (Limited Submission). Contact your sPA immediately.

2. PI Eligibility: STOP: if the PI doesn't have an Institutional Base Salary. Contact your sPA immediately

Section III, Part 1 – Eligibility



Award Project Period

FDP Clearinghouse
sites.nationalacademies.org/PGA/fdp/PGA_070596

...ine the project period. The maximum project period is 5 years.

NIH grants policies as described in the *NIH Grants Policy Statement* will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Institutions)

Foreign Institutions

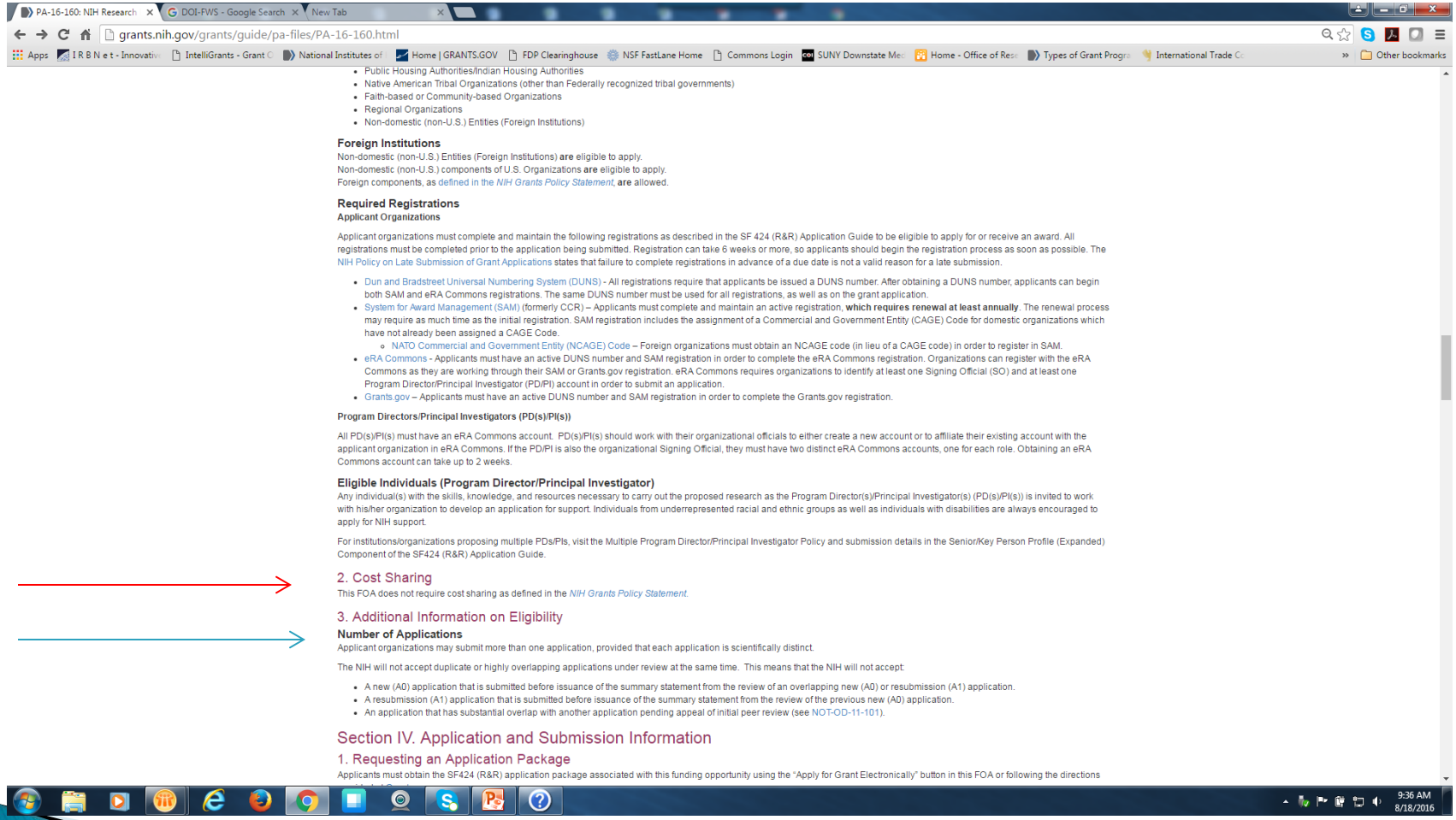
Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.
Foreign components, as defined in the *NIH Grants Policy Statement*, **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The

Section III, Parts 2 & 3



- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Institutions)

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Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
  - NATO Commercial and Government Entity (NCAGE) Code – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the *NIH Grants Policy Statement*.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101).

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must obtain the SF424 (R&R) application package associated with this funding opportunity using the "Apply for Grant Electronically" button in this FOA or following the directions

Components of the Funding Announcement – NIH Example

Part IV – Application and Submission Information

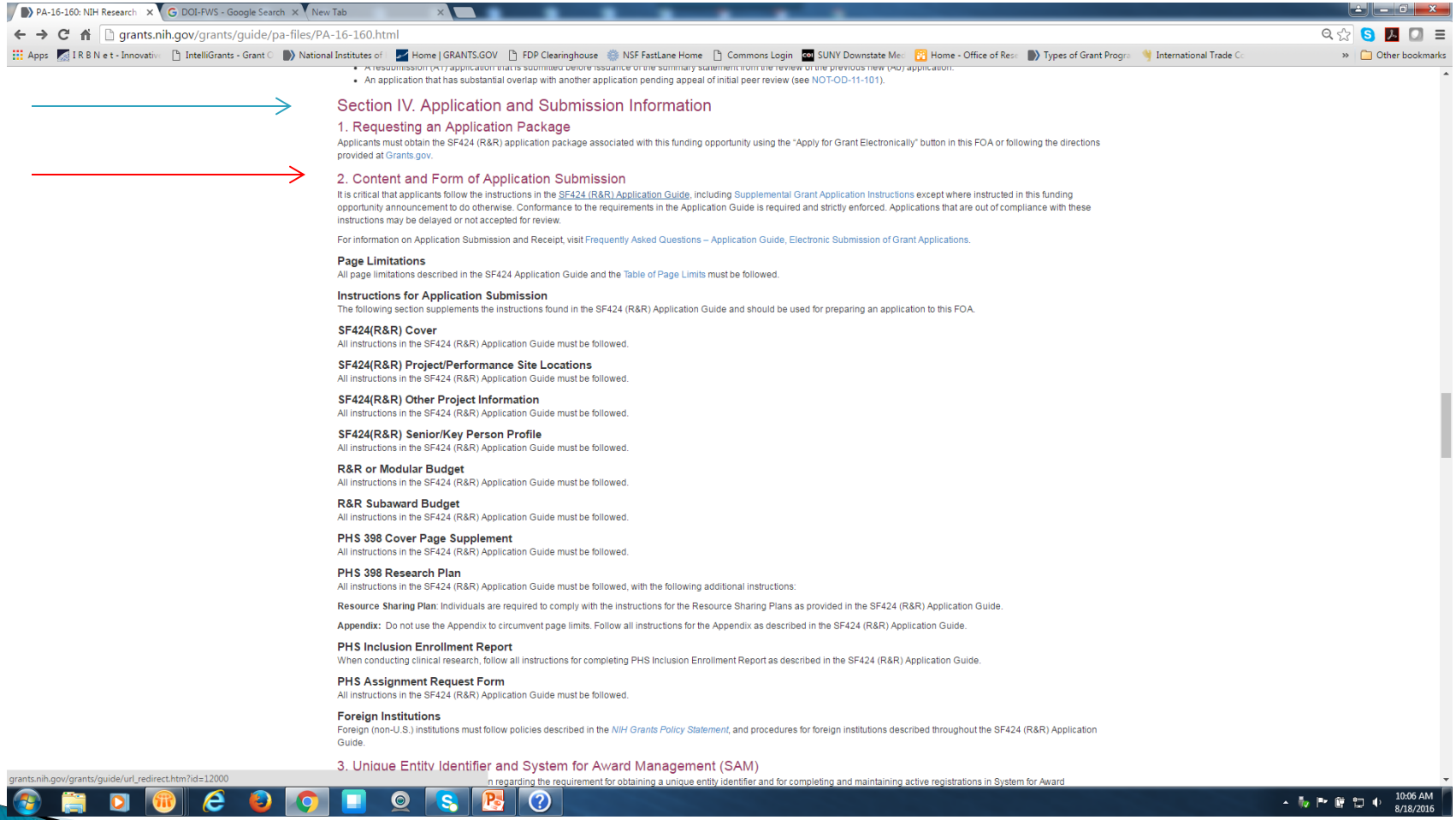
Part V – Application Review Information

Part VI – Award Administration Information

Part VII – Agency Contacts

Part VIII – Other Information

Section IV – Parts 1 & 2: Application and Submission Information



- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101).

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must obtain the SF424 (R&R) application package associated with this funding opportunity using the "Apply for Grant Electronically" button in this FOA or following the directions provided at Grants.gov.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, including Supplemental Grant Application Instructions except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.

Page Limitations
All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed.

Instructions for Application Submission
The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover
All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations
All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information
All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile
All instructions in the SF424 (R&R) Application Guide must be followed.

R&R or Modular Budget
All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Subaward Budget
All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement
All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan
All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Inclusion Enrollment Report
When conducting clinical research, follow all instructions for completing PHS Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

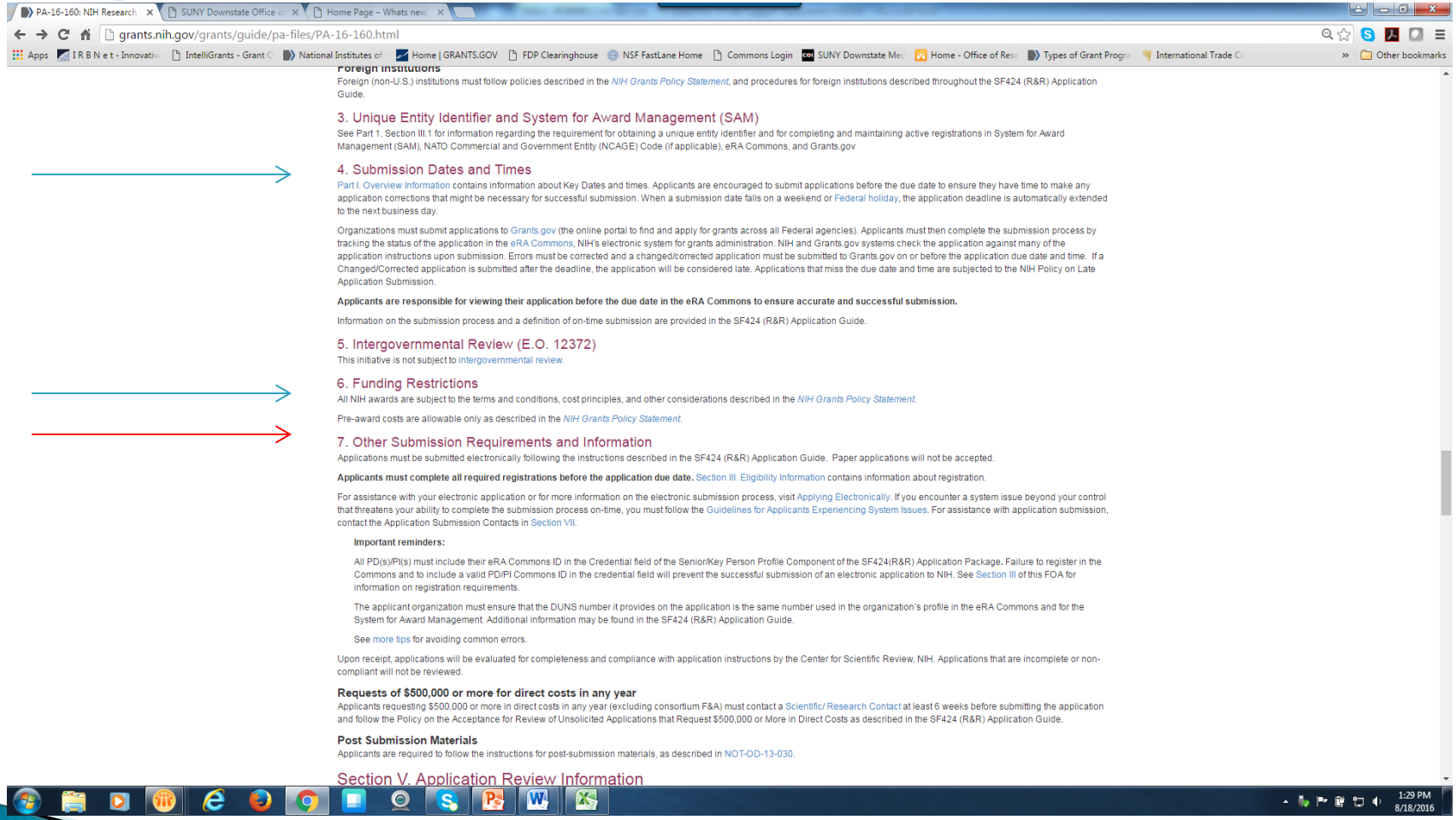
PHS Assignment Request Form
All instructions in the SF424 (R&R) Application Guide must be followed.

Foreign Institutions
Foreign (non-U.S.) institutions must follow policies described in the *NIH Grants Policy Statement*, and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

3. Unique Entity Identifier and System for Award Management (SAM)

n regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award

Section IV – Parts 3 – 7: SAM, Submission Dates, Review, Restrictions & Other Requirements



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grants.nih.gov/grants/guide/pa-files/PA-16-160.html

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Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the *NIH Grants Policy Statement*, and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday, the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement*.

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement*.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Guidelines for Applicants Experiencing System Issues. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Requests of $500,000 or more for direct costs in any year

Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-13-030.

Section V. Application Review Information

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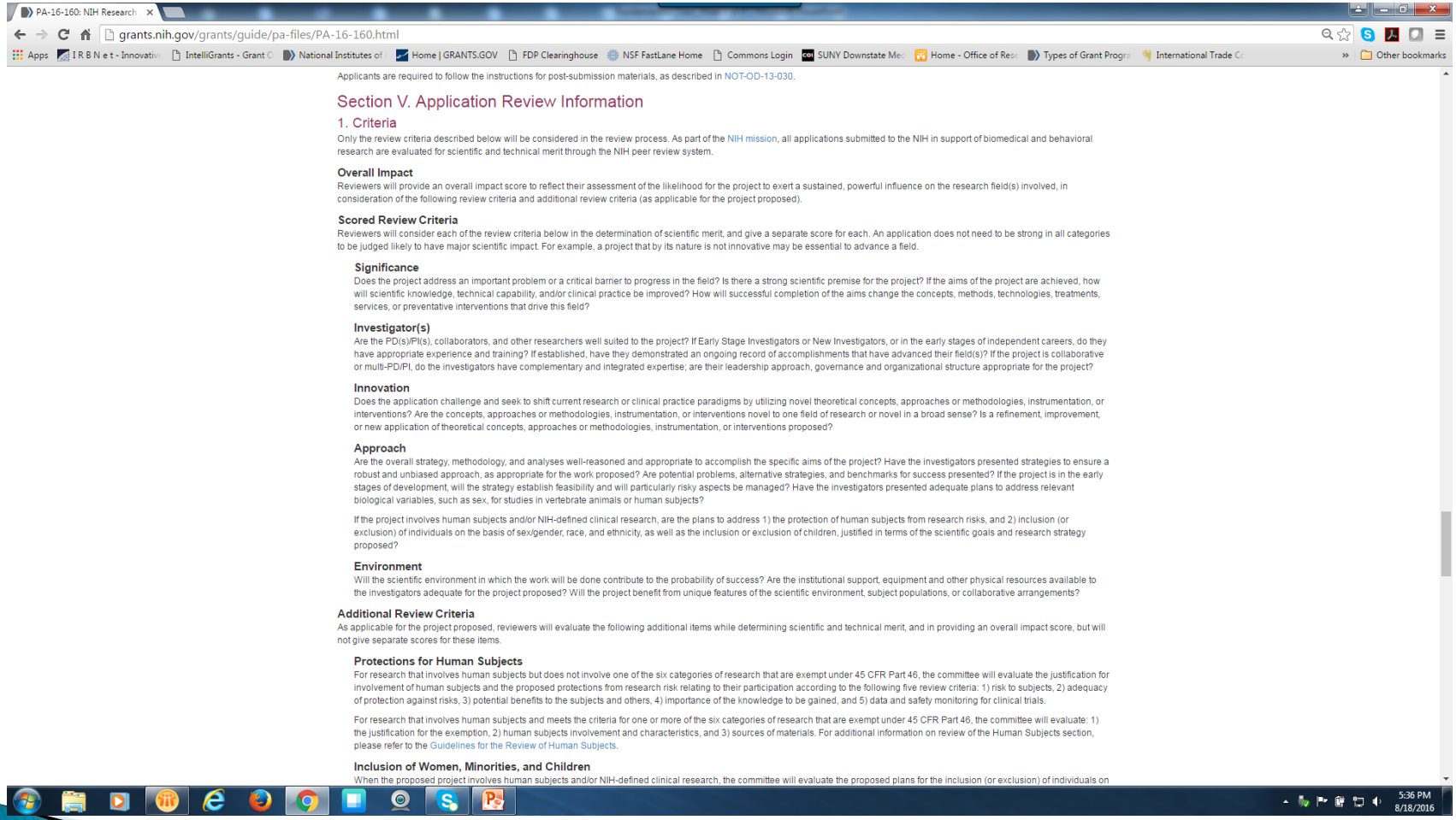
Section V – Application Review



PA-16-160: NIH Research

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Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-13-030.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the NIH mission, all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

Inclusion of Women, Minorities, and Children

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on

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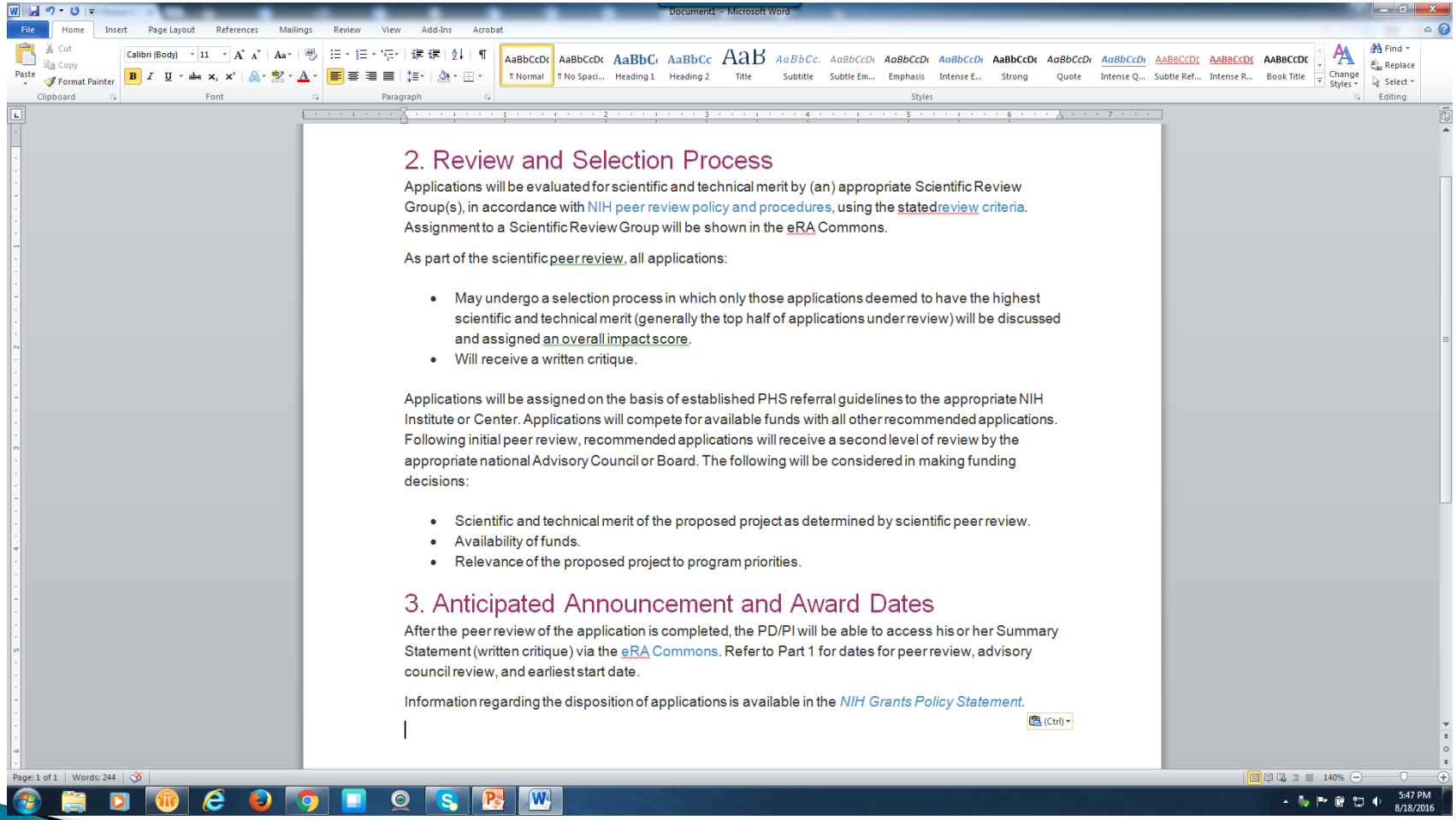
Section V – Parts 2 & 3 –



2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), in accordance with NIH peer review policy and procedures, using the statedreview criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

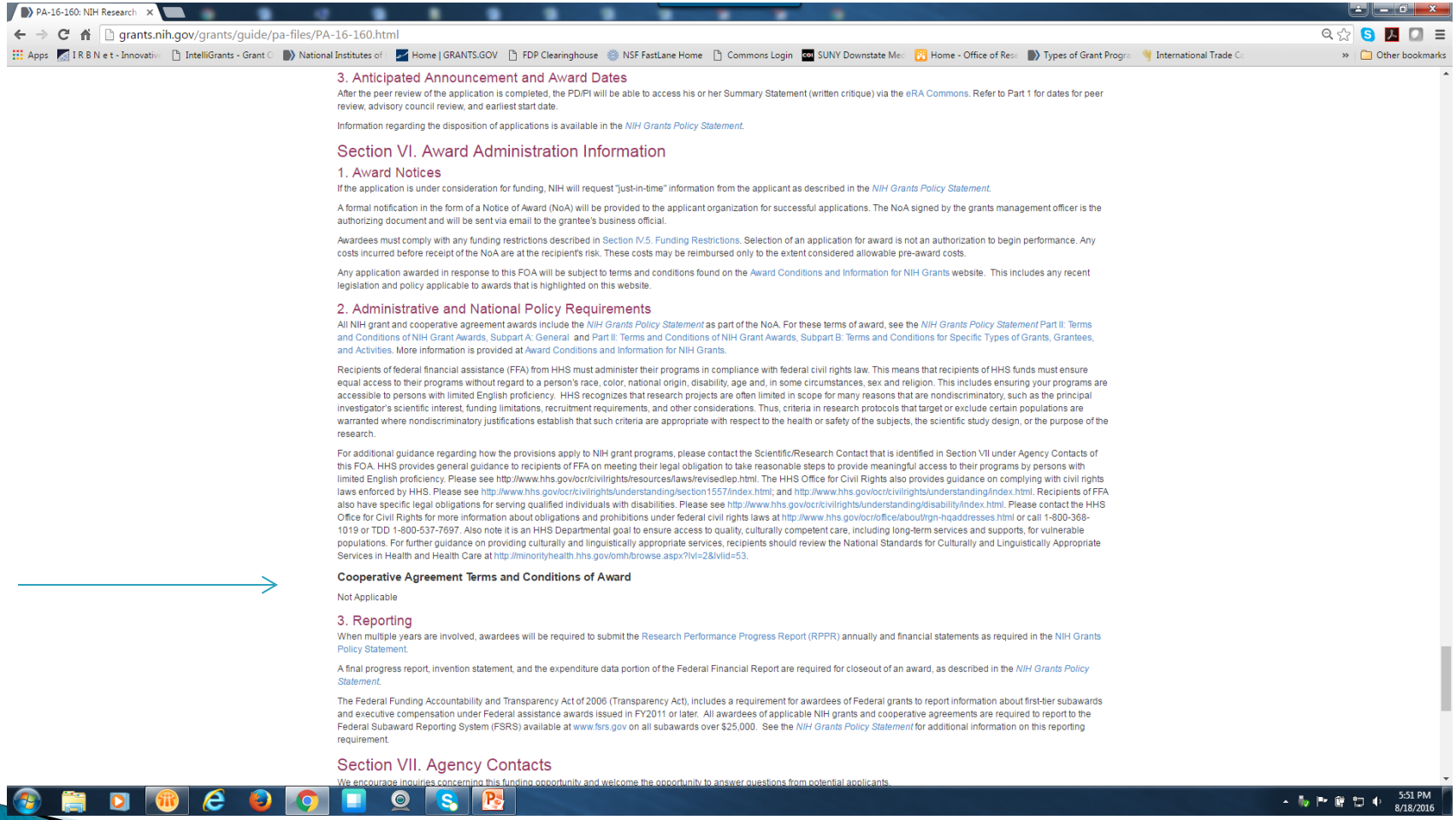
- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons. Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the *NIH Grants Policy Statement.*

Section VI – Award Information



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After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons. Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the *NIH Grants Policy Statement*.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the *NIH Grants Policy Statement*.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities. More information is provided at Award Conditions and Information for NIH Grants.

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html; and http://www.hhs.gov/ocr/civilrights/understanding/index.html. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html. Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the NIH Grants Policy Statement.

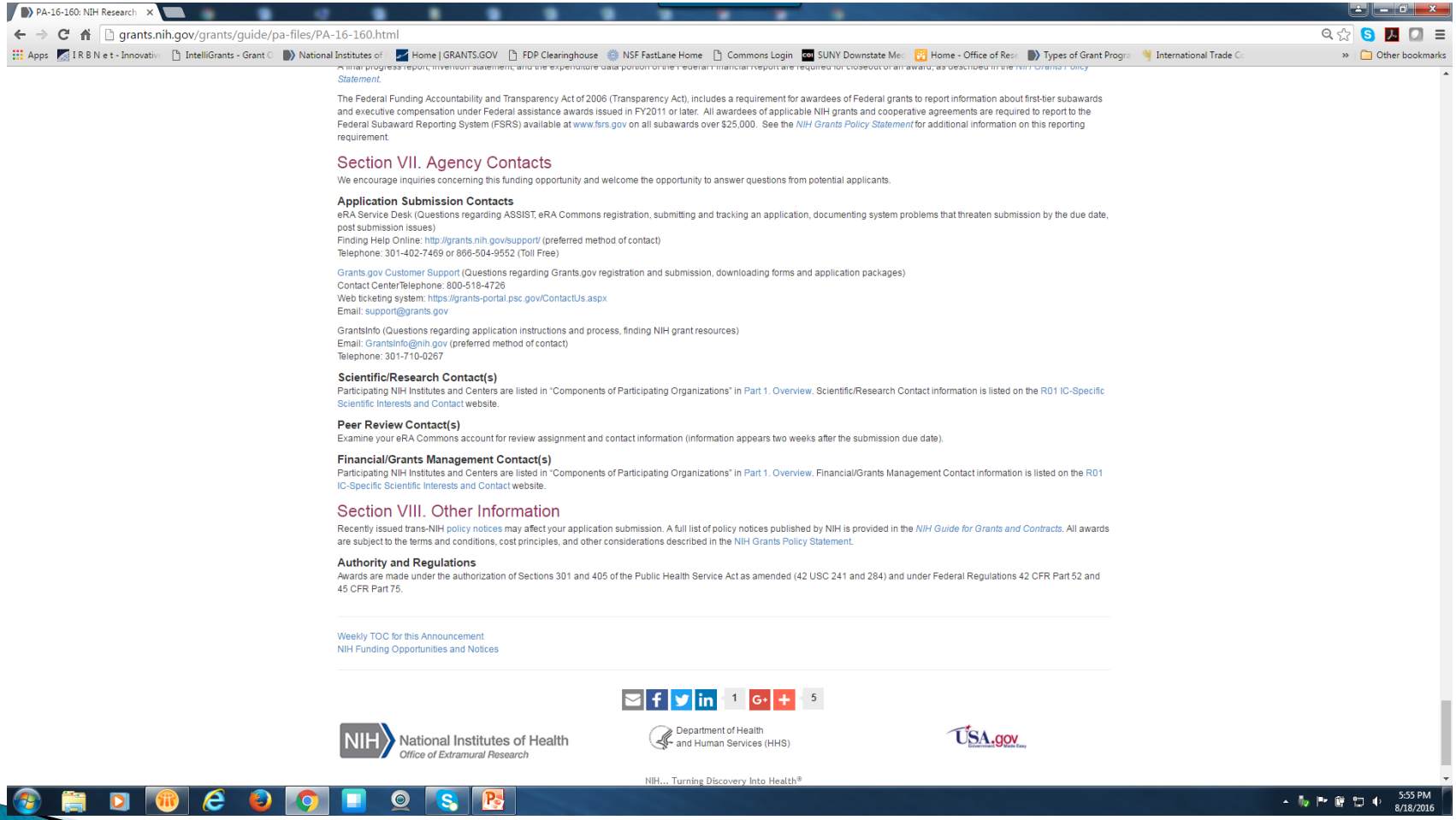
A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the *NIH Grants Policy Statement*.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the *NIH Grants Policy Statement* for additional information on this reporting requirement.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Section VII – Agency Contacts



PA-16-160: NIH Research

grants.nih.gov/grants/guide/pa-files/PA-16-160.html

Statement.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the *NIH Grants Policy Statement* for additional information on this reporting requirement.

Section VII. Agency Contacts

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Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Finding Help Online: http://grants.nih.gov/support/ (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact CenterTelephone: 800-518-4726
Web ticketing system: https://grants-portal.psc.gov/ContactUs.aspx
Email: support@grants.gov

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)
Email: GrantsInfo@nih.gov (preferred method of contact)
Telephone: 301-710-0267

Scientific/Research Contact(s)

Participating NIH Institutes and Centers are listed in "Components of Participating Organizations" in Part 1. Overview. Scientific/Research Contact information is listed on the R01 IC-Specific Scientific Interests and Contact website.

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

Participating NIH Institutes and Centers are listed in "Components of Participating Organizations" in Part 1. Overview. Financial/Grants Management Contact information is listed on the R01 IC-Specific Scientific Interests and Contact website.

Section VIII. Other Information

Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts*. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

NIH National Institutes of Health Office of Extramural Research
Department of Health and Human Services (HHS)
USA.gov
NIH... Turning Discovery Into Health®

5:55 PM 8/18/2016

Funding Requirements in FOA

- Know your limits! Carefully read the FOA for budget criteria. Look out for limits on types of expenses (e.g. no construction allowed), spending caps on certain expenses (e.g. travel limited to $10,000), and overall funding limits (e.g. total costs cannot exceed $300,000 per year). Relevant sections include:

  - II.1 (Mechanisms of Support)
  - II.2 (Funds Available)
  - III.2 (Cost Sharing or Matching), and
  - IV.5 (Funding Restrictions)

Contact Us

- Joseph Barabino, AVP of Research Administration
  - Joseph.barabino@downstate.edu
- Sharon Levine-Sealy, Director of Pre-Award
  - Sharon.levine-sealy@downstate.edu
- Elliot Feder, Director of Post-Award
  - Elliot.feder@downstate.edu

http://research.downstate.edu/administration/pre-award.html

ORA Listserv

- Please contact Kalilah O'Gwin at x 2680
  - Kalilah.o'gwin@downstate.edu