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?

- Sponsored Programs Office
- IRB
- IACUC
- Research
- Compliance
- Technology
- Biosafety
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
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)?
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.
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)

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
IRB Decision Aid:

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) 613-8388
- Executive Director, Kevin Nellis at (718) 613-8461
- IRB Staff at (718) 613-8480
For additional guidance, see: [http://www.hhs.gov/chrp/policy/checklists/decisioncharts.html](http://www.hhs.gov/chrp/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

IRB Decision Aid: Does a SUNY DMC project need a SUNY DMC IRB Application or an SUNY DMC IRB Determination Letter?

03.31.2015
Page 1
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](http://www.hhs.gov/ohrp/policy/engage08.html)
Activities That DO NOT Require IRB Review

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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)
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.
<table>
<thead>
<tr>
<th>IRB Contacts</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phyllis G. Supino, EdD, IRB Chair, Boards A, B and E</td>
<td>(718) 613–8355</td>
</tr>
<tr>
<td>Daniel Cukor, PhD, Vice Chair, Board A</td>
<td>(718) 270–2077</td>
</tr>
<tr>
<td>Stanley Friedman, MD, Vice Chair, Board B</td>
<td>(718) 270–1335</td>
</tr>
<tr>
<td>Kevin L. Nellis, MS, CIP, Executive Director, Human Research Protection &amp; Quality Assurance</td>
<td>(718) 613–8461</td>
</tr>
<tr>
<td>Diann Johnson, MPH, Associate IRB Administrator</td>
<td>(718) 270–4341</td>
</tr>
<tr>
<td>Angela Cartmell, PhD, CIP, Associate IRB Administrator</td>
<td>(718) 270–4454</td>
</tr>
<tr>
<td>Nakih Gonzales, IRB Assistant</td>
<td>(718) 270–4372</td>
</tr>
<tr>
<td>IRB Office</td>
<td>(718) 613–8480</td>
</tr>
</tbody>
</table>
IACUC Fundamentals

Julie M. Sharp, DVM, CPIA, DACLAM
Director
Office of Animal Welfare
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 FCR (72 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

PI revises submission
PRE-REVIEW – OAW vet, Primary IACUC Reviewer

2° REVIEWS
Training, IBC, Radiation Safety, Grant Congruency

Modifications Required to Secure Approval

IACUC MEETING *

APPROVAL

* Decision Options FCR:
  • Approve
  • DMR – see below
    o Approve
    o FCR
  • FCR
  • Disapprove

DCM VET (USDA)
DRAFT
REVIEWS
Training, IBC, Radiation Safety, Grant Congruency

PI revises submission

Modifications Required to Secure Approval

DRAFT
DCM VET (USDA)

Designated IACUC Reviewer, Vet*

2º REVIEWS Training, IBC, Radiation Safety, Grant Congruency

APPROVAL

* Decision Options
DMR:
• Approve
• FCR

IACUC Review Process – DMR
### Animal Program Contacts

<table>
<thead>
<tr>
<th>Email – <a href="mailto:IACUC@Downstate.edu">IACUC@Downstate.edu</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Diana Dow-Edwards, PhD</td>
</tr>
<tr>
<td>• IACUC Chair</td>
</tr>
<tr>
<td>Julie M. Sharp, DVM, CPIA, DACLAM</td>
</tr>
<tr>
<td>• Director, OAW</td>
</tr>
<tr>
<td>Meagan Eastman, CPIA, LATG</td>
</tr>
<tr>
<td>• Assistant Director, OAW</td>
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<tr>
<td>Lydia Bailey</td>
</tr>
<tr>
<td>• IACUC Coordinator</td>
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</table>
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.
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
Box 0128
SUNY Downstate Medical Center
450 Clarkson Avenue
Brooklyn, NY 11203
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

- NIH
- DOD
- NSF
- HRSA
- AHA
- American Cancer Society
- FDA
- CDC
- AHRQ
- SAMHSA
- DARPA
- Simons Fdtn.
- Alzheimer's Assoc.
- NYS DOH
- NYC DOE
- NYC DOH
- American Cancer Society
- Autism Speaks
- Susan G. Komen Breast Cancer Fdtn
- Brain and Behavior Research Fdtn. (NARSAD)
- Epilepsy Fdtn.
- Cystic Fibrosis Fdtn.
- OREF
- Simons Fdtn.
- Autistic Speaks Brain and Behavior Research Fdtn. (NARSAD)
- Susan G. Komen Breast Cancer Fdtn
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).
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](http://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.
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.

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](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](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

NIH Research Project Grant (Parent R01)

Reissue of PA-15-302

- July 30, 2016: NIMDS Policy for Submission of Applications Containing Clinical Trials. See Notice NOT-MDS-16-034.
- NOT-MDS-16-005: Update to NIMDS Policy Regarding Submission of Clinical Trials Applications.
- NOT-MDS-16-030: Notice of Information: Parallel Funding Initiative for Collaborative Research Between Investigators in the USA and in the State of Sao Paulo, Brazil.
- NOT-MD-16-007: NIH Policy for Submission of Applications Containing Clinical Trials.
- NOT-MH-16-003: Change in R33 policy. R01 and R03 Activity Codes will no longer be used to support investigation-initiated Phase II clinical trials for medical interventions and cancer imaging modalities.
- NOT-DK-16-012: Clarification of NEIDC Policy: Investigation-Initiated Multi-Center Clinical Studies.
- NOT-AOD-16-004: NID & NIMH Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015).

PA-16-160

None

See Section III. Additional Information on Eligibility.

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 (IC) 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-ADD applications allowed for this FOA. Consult application instructions on these dates.
### Key Dates

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>Posted Date</td>
<td>March 31, 2016</td>
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<tr>
<td>Open Date (Earliest Submission Date)</td>
<td>May 5, 2016</td>
</tr>
<tr>
<td>Letter of Intent Due Date(s)</td>
<td>Not Applicable</td>
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<tr>
<td>Application Due Date(s)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>AIDS Application Due Date(s)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Scientific Merit Review</td>
<td>Standard dates apply</td>
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<td>Advisory Council Review</td>
<td>Standard dates apply</td>
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<td>Earliest Start Date</td>
<td>Standard dates apply</td>
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<tr>
<td>Expiration Date</td>
<td>May 8, 2016</td>
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<tr>
<td>Due Dates for E.O. 12372</td>
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</table>

### Required Application Instructions

- All applicants must follow the instructions in the SF-424 (SRV) 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 diverge 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 also 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 systems in your system 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

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 scientific and research 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 NIH-IC Inventory of 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 the 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 VII: 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
Recompetition
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
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. Eligibility Information

1. Eligible Applicants

**Eligible Organizations**

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

- Historically Black Colleges and Universities (HBCUs)
- Tribal Colleges and Universities (TCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education
- Nonprofit 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
- Indigenous American Tribal Governments ( Federally Recognized)
- Indigenous 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/Education 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.

Foreign components, as defined in the NIH Grants Policy Statement, are allowed.

**Required Registrations**

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.
Section III, Parts 2 & 3

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 initial 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 instructions...
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

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.

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 sections supplement 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.
   - Appendices: do not use the Appendix to circumvent page limits. Follow all instructions for Appendices 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 Foreign Grantee 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)
   Managing the requirements for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management
Section IV – Parts 3 – 7: SAM, Submission Dates, Review, Restrictions & Other Requirements

3. Unique Entity Identifier and System for Award Management (SAM)
   See Part II, Section II.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
   Applicants are responsible for submitting their application before the due date 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 full awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grant Policy Statement. Pre-award costs are allowable only as described in the NIH Grant Policy Statement.

7. Other Submission Requirements and Information
   All full applications must be submitted electronically, following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

   Important reminders:
   - All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Delegated Signing Official Component of the SF424(R&R) Application Package. Failure to include the Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section II.B.2b. of the SF424 (R&R) Application Guide.
   - The applicant organization must ensure that the EKNS 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 any year (excluding consortium F&A) must contact a Scientific/Research Contact at least 6 weeks before submitting the application and follow the Policy for 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-13-008.
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 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 are state of the field?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If the project involves early-stage investigators or new investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishment that has advanced their field(s)? If the project’s collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise, if needed? 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? Are the investigator’s proposed strategies and methodologies adequate to accomplish the specific aims? 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: (1) protection of human subjects from research risks, and (2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and/or ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Is the scientific environment in which the work will be done conducive to the probability of success? Are the institutional support, equipment and other physical resources available to the investigator 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 to 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.

Protection for Human Subjects

For research that involves human subjects and 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) potential benefits to the subjects and others, 3) importance of knowledge to be gained, 4) 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

If the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for inclusion (or exclusion) of individuals on the basis of age, sex, sex/gender, race, ethnicity, and/or disability.
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 stated review 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 Grant Application, Grant and Progress Report. 
Section VI – Award Information

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 NIH Commons. Refer to Part I for details 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 “live-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 is signed by the grants management officer of the funding institute and will be sent via email to the grantee's business office.

Applicants must comply with any funding restrictions described in Section IV.C. 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 applicant's risk. These costs may be reimbursed only to the extent considered allowable in advance of the NoA.

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 are highlighted on this website.

2. Administrative and National Policy Requirements

All NIH grants 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, Grants, and Activities. Additional information is provided at Award Conditions and Information for NIH Grants.

Applicants of financial assistance (FAA) from NIH must administer their programs in compliance with federal civil rights law. This means that recipients of NIH funds must ensure equal access to their programs without regard to 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. NIH 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 limitations, 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 Office of Civil Rights (OCR) of the Department of Health and Human Services (HHS). OCR enforces civil rights laws that prohibit discrimination in HHS's grant programs. For more information, see http://www.hhs.gov/ocr/hipaa/index.html. If you have any questions about the policies described in this Notice of Award, please contact the NIH Grants Management Office at nihgrants@nih.gov.

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.


The Federal Funding Accountability and Transparency Act of 2006 (FOIA Act), includes a requirement for awardees of Federal grants to report information about financial 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 opportunity and welcome the opportunity to answer questions from potential applicants.
Section VII – Agency Contacts

Application Submission Contacts

- eRA Service Desk (Questions regarding eRAHESE, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission due to the date, (post submission issues).
- Telephone: 314-402-7489 or 866-554-5552 ( Toll Free )
- Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
- Contact Center Telephone: 800-115-4726
- Web-based system: https://grants.gov/apsyjgrants.gov/ContactUs.aspx
- Email: support@grants.gov
- Grants.gov (Questions regarding application instructions and process, finding NIH-grant-eligible resources)
- Email: GrantsInfo@nih.gov (preferred method of contact)
- Telephone: 314-402-0077

Scientific/Research Contact(s)

Participating NIH-Institute and Centers are listed in “Components of Participating Organizations” in Part 1. Overview. Scientific/Research Contact Information is listed on the RFA 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-Institute and Centers are listed in “Components of Participating Organizations” in Part 1. Overview. Financial/Grants Management Contact Information is listed on the RFA IC-Specific Scientific Interests and Contact website.

Section VIII. Other Information

Recently issued 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 USG 244 and 244) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Weekly TDC for this Announcement

NIH Funding Opportunities and Notices

NIH – Turning Discovery Into Health

National Institutes of Health
Office of Extramural Research

[Image of NIH logo and USA.gov logo]
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
Please contact Kalilah O’Gwin at x 2680

- Kalilah.o’gwin@downstate.edu