Agenda

- Determine the 4 W’s
- The Application – A glimpse into the SF424
- Overview of the other types of applications
- The Review – what does your Sponsored Project Associate (sPA) look for?
- Adhering to Federal and University regulations (as part of proposal preparation)
Gather the Facts

Who, What, When, and Where – Plus 1

- **Who** – is going to be the Principal Investigator?
- **What** – announcement are you responding to?
- **When** is this proposal due?
  - to the sponsor
  - to ORA
- **Where** – is this proposed research going to be conducted?

PLUS 1 – Notify your sPA
Who?

- Who is the PI?
- Will there be Multiple PI’s?
- Is this a collaborative project?
- Are multiple institutions involved?
- Consultants?
- Postdocs, Graduate Students?
- Nurses, Lab Techs?
- Who are the Key Personnel?
Definition of Key Personnel

The PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition. Senior/key personnel must devote measurable effort to the project whether or not salaries or compensation are requested. "Zero percent" effort or "as needed" are not acceptable levels of involvement for those designated as Senior/Key Personnel.

http://grants.nih.gov/grants/glossary.htm#Senior/KeyPersonnel
What?

- What is the scope of work?
- What resources will the PI need in order to meet the scope of work?
- What are the sponsor requirements, both in terms of general federal guidelines and expectations outlined in the funding announcement?
  - For example, does the sponsor require cost sharing or matching of funds?
- What must the PI commit to?
When?

- When is the proposal due?
- When were the latest forms and sponsor policies published?
- When will the research be completed?
- When will funding be determined?
Where?

- Where will the work be performed?
- Consortium sites?
- Foreign institutions?
- Travel for conferences, meetings?
  - Foreign or Domestic
  - Export Control
  - Fly American Act [http://www.gsa.gov/portal/content/103191](http://www.gsa.gov/portal/content/103191)
Back at the FOA...let's start!

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
Continue to follow the links...

Important Note for All Applicants:

Applicants MUST Follow ALL Application Guidance

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

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

Registrations in Multiple Federal Systems are Required to Submit

See Registrations for details.

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

Proceed to Grants.gov to download Application
Continue to follow the links...
Almost there...
Download the Application
The Application...

Grants.gov

Grant Application Package

Opportunity Title: NIH Research Project Grant (Parent R01)
Offering Agency: National Institutes of Health
CFDA Number: 
CFDA Description: 
Opportunity Number: PA-16-160
Competition ID: FORMS-D
Opportunity Open Date: 04/17/2016
Opportunity Close Date: 05/07/2019
Agency Contact: eRA Service Desk Monday to Friday 7 am to 8 pm ET http://grants.nih.gov/support/

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

Application Filing Name: 

Print | Cancel
SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

**Page 2**

### I. PROJECT DIRECTOR/PRIOR PRINCIPAL INVESTIGATOR CONTACT INFORMATION
- **Name:**
- **Title:**
- **Organization:**
- **Street:**
- **City:**
- **State:**
- **ZIP Code:**
- **Email:**

### IV. ESTIMATED PROJECT FUNDING
- **Total Federal Funds Requested:**
- **Total Non-Federal Funds:**
- **Total Non-Federal Funds:**
- **Total Federal & Non-Federal Funds:**

### VI. AUTHORIZED REPRESENTATIVE
- **Name:**
- **Title:**
- **Organization:**
- **Street:**
- **City:**
- **State:**
- **ZIP Code:**
- **Email:**

### VII. SIGNATURE OF AUTHORIZED REPRESENTATIVE
**Signature:**
**Date Signed:**

Note: The form contains multiple sections and fields for additional information that are not fully visible in the provided image.
Where to find grant information?

http://research.downstate.edu/resources/information.html
PHS 398 Cover Page Supplement

5. Inventions and Patents Section (RENEWAL)
*Inventions and Patents: Yes □ No □
*Previously Reported: Yes □ No □

6. Change of Investigator / Change of Institution Section

- Change of Project Director / Principal Investigator
  - Name of Former Project Director/Principal Investigator:
    - Prefix: __________
    - First Name: __________
    - Middle Name: __________
    - Last Name: __________
    - Digits: __________

- Change of Current Institution
  - Name of Current Institution: __________
Other Project Information
Performance site locations
Senior/Key Person Profile

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

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To ensure proper performance of this form, after adding 20 additional Senior/Key Persons, please save your application, check the Adobe.
The Biosketch

http://grants.nih.gov/grants/forms/biosketch.htm
Research Plan
The end ... Just kidding!
Detailed vs. Modular Budget Determination

- Do your direct costs (minus any consortium/subcontract F&A costs) equal less than $250,000 per year?
  - No: Use detailed budget (SF424 (R&R) Budget Form)
  - Yes: Are you applying for an R01, R03, R15, R21, or R34 grant?
    - No: Is the applicant organization based in the United States?
      - Yes: Use modular budget (PHS398 Modular Budget Form)
        - http://grants.nih.gov/grants/funding/modular/modular.htm
Internal Budget Template

Tips for Preparing Your Budget:

1. Only information in yellow highlighted areas should be entered.
2. Gray shaded areas are auto-populated; please do NOT delete any rows or columns.
3. Please do NOT delete any rows or columns.
4. The Fiscal Year runs from July 1 through June 30.
5. Enter the Project Period first to determine the number of months in each Fiscal Year.
6. Depending on project period, enter the number of months in cell M4 and M5.
7. REMEMBER: This number must equal 12.
8. FTE is strongly discouraged and cannot be applied to RF personnel.
9. The rows of personnel are suggestions only. Please change to fit your project.
10. The salaries listed in the Base Salary column are examples only and should be revised to match the Institutional Base Salary (IBS) of your project.
11. If you do not know these numbers, please ask your Sponsored Programs Associate or PI to provide them.
12. Professional Fees should be included in the "other" category.
13. The cost of equipment should fit the actual equipment only. Maintenance fees, installation, and software costs should be included in the "other" category.
14. Graduate Students do not take fringe.
15. WAFS assumes 1 subcontract; (i.e., $25,000 if no subcontracts) add $25,000 for each subcontract per institution.
The Budget

- What is considered direct vs indirect?
- What are fringe benefit rates?
- What F&A should be used?
- Is there a budget cap in the FOA?
- Will the direct costs be $500,000 or more?
  - Will prior approval be required from NIH?

http://research.downstate.edu/resources/information.html
http://research.downstate.edu/policies–downstate.html
The Budget (cont.)

- Should identify all costs necessary and reasonable

- Should define all allowable costs
  - Research Costs vs. Standard of Care
  - Patient Care Costs vs. Subject related Costs
  - Research Personnel vs. Professional Fees
  - Consortium vs. Contractor
  - Research Pharmacy
  - Data Safety Monitoring Board members and travel

http://research.downstate.edu/resources/information.html
Budget Items and Preparation

- Salary and Fringe
- Consultants
- Equipment & Supplies
- Animals
- Travel
- Consortium / Subawards
- Patient Care Costs
- Other Costs, includes:
  - Study Subject Costs
  - Pharmacy
  - Publication costs
  - Advertising
  - Professional Fees
- Facilities & Administrative (F&A)
Personnel Costs -- Institutional Base Salary (IBS)

- Institutional Base Salary (IBS) consists of:
  - Base Salary plus
  - Guaranteed additional “Also- Receives”

- Salaries are maintained and updated in Human Resources
  - State salaries
  - Research Foundation salaries

- The amount of salary that can be compensated from sponsored projects cannot exceed an individual’s guaranteed annual salary, the IBS
Personnel -- Effort

Overall Effort

http://research.downstate.edu/policies-downstate.html
Personnel Costs
Cost Share or Matching Funds

- When an institution shares a portion of the cost of a sponsored project
  - Mandatory
  - Voluntary Committed
  - Voluntary Uncommitted (VUCS)

- Matching Funds – when an institution is required to solicit additional project costs by a third-party, as identified in the FOA

http://research.downstate.edu/policies-downstate.html
Personnel Costs Cost Share or Matching Funds

- **Mandatory cost share:**
  - Proposals should include the **minimum** amount of cost sharing necessary, in order to meet the sponsor’s requirements.

- **Voluntary committed cost share:**
  - Is strongly discouraged.

- As you develop your budget, keep cost sharing in mind.

http://research.downstate.edu/policies-downstate.html
Equipment – each individual item must be $5,000 or more. These items are excluded from the MTDC base when calculating F&A

Supplies – each item must be project specific, e.g. binders, study materials, etc. The purchase of pens, paper and the like should not be requested from a sponsored project

http://research.downstate.edu/policies-downstate.html
The consultant must be a non-University employee

A consultant agreement should be put in place

The consultant will need to provide confirmation of FCOI prior to award
An agreement typically issued through Sponsored Projects, whereby the research project is carried out by the grantee and one or more other organizations. The grantee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties.

- Research Foundation Central issues subcontracts for DMC
- Budget consists of DC & IC
- Grantee collects IC on the 1st $25,000
Contract / Service Agreement

- An agreement typically issued through Procurement whereby the grantee is purchasing a service from another institution (i.e. assays, scans, etc)
  - Research Foundation Central issues service agreements for DMC
  - Budget consists of a total cost, inclusive of IC
  - Grantee collects IC on the entire amount
The Decision Tree ... and the UG
Facilities & Administrative Costs / Indirect Costs

- Costs incurred by the Grantee for joint or common objectives and cannot be identified specifically to a grant or project

- Rate is based on a negotiated DHHS rate agreement

http://research.downstate.edu/resources/information.html
Consists of all direct costs except for:

- equipment
- capital expenditures
- patient care costs (e.g. tests not SOC in hospital setting)
- participant costs (for NSF applications only)
- tuition reimbursement
- rental costs of off-site facilities
- scholarships, fellowships (mostly NSF)
- the portion of each subcontract in excess of $25,000
Back to the Budget pages...

Personnel

- Project Subaward/Consortium
- Add Additional Key Person
- Add Attachment
- Add Senior/Other Personnel
- Add Additional Other Personnel
- Total Salary, Wages and Fringe Benefits (A+B)
Budget ... Equipment, Travel & Participant Support Costs
Budget ... Other Direct Costs (plus our Indirect)

<table>
<thead>
<tr>
<th>F. Other Direct Costs</th>
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<tbody>
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<td>2. Publication Costs</td>
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<td>3. Consultant Services</td>
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<td>4. ADP/Computer Services</td>
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<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
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<tr>
<td>6. Equipment or Facility Rental/Usage Fees</td>
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<td>7. Alterations and Renovations</td>
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<td>Indirect Cost Base ($)</td>
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<th>K. Budget Justification</th>
<th>Add Attachment</th>
<th>Delete Attachment</th>
<th>View Attachment</th>
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The Budget Justification

- Is a detailed narrative of the budget
- Every line item should be justified
- It should follow in the same order as the budget
- It should only include DMC costs, except for the consortium
Other grant budgets...

- Every sponsor is slightly different though all are similar
- Follow the FOA and download the application package and instructions
- All sponsor instructions are online
Plan way ahead of sponsors deadline

- Must get the proposal to ORA at least five business days before the sponsor’s deadline!

- Must have the Proposal Tracking form from PI and approvals from all academic offices involved with the proposal (science, resources, space, faculty)

- Must have Cost Share documentation from PI for self and all other faculty where cost share is applicable, as well as approvals from all academic offices involved with the proposal

- All Financial Conflict of Interest (FCOI) annual disclosures must be filed annually in COI–SMART, effective October 2014, for your sPA to submit the proposal. A transactional questionnaire must be filed for each application.

  - [http://research.downstate.edu/compliance.html](http://research.downstate.edu/compliance.html)
What the sPA reviews...

- All the components of the grant application
- The FOA
- The consortium paperwork (if applicable)
- FCOI documentation
- Internal paperwork: The Signature Worksheet and Cost Share Template
"The public trust in what we do is just essential, and we cannot afford to take any chances with the integrity of the research process."

— Dr. Francis Collins, Director, NIH
FCOI – The Ruling

- Public Health Service (PHS) regulations govern:
  - Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F)
  - Responsible Prospective Contractors (45 C.F.R. Part 94)
2011 Key Changes to FCOI policy

- Definition of Significant Financial Interest (SFI)

- Extent of Investigators’ disclosure of information to Institutions regarding their SFIs;

- Institutions’ management of identified Financial Conflicts of Interest (FCOI);

- Information reported to the PHS funding component (e.g., NIH);

- Information made accessible to the public (i.e., Institutions’ FCOI policy and FCOIs of Senior/Key personnel)

- Investigator training
FCOI – what it really means

- Must have a policy publicly available
- Must have ALL investigators complete an annual FCOI disclosure
- Must have ALL investigators complete an additional FCOI disclosure for each new research project
- Must report to any conflicts and management plans to the federal government

http://downstate.edu/coi/
Communicate with your Sponsored Programs Associate (sPA)

- Ask for help
  - Need assistance with the requirements of an FOA?
  - Need salary and fringe costs for budget personnel?
  - Need help determining subcontract compliance?
  - Need help with the budget?
  - With anything else? CALL US, we’re here to help
Resources

- Office of Research Administration
  - [http://research.downstate.edu/](http://research.downstate.edu/)
- Pre-Award division
  - [http://research.downstate.edu/administration/pre-award.html](http://research.downstate.edu/administration/pre-award.html)
- Post-Award division
  - [http://research.downstate.edu/administration/post-award.html](http://research.downstate.edu/administration/post-award.html)
- Forms
  - [http://research.downstate.edu/resources/forms.html](http://research.downstate.edu/resources/forms.html)
- Policies
  - [http://research.downstate.edu/policies-downstate.html](http://research.downstate.edu/policies-downstate.html)
- Funding Opportunities
  - [http://research.downstate.edu/funding/funding-opportunities.html](http://research.downstate.edu/funding/funding-opportunities.html)
- Institutional Information
  - [http://research.downstate.edu/resources/information.html](http://research.downstate.edu/resources/information.html)
External Resources

- CDC – List of Select Agents
  - [http://www.cdc.gov/od/sap/docs/salist.pdf](http://www.cdc.gov/od/sap/docs/salist.pdf)

- NIH instructions for Appendices
  - [http://www.cdc.gov/od/sap/docs/salist.pdf](http://www.cdc.gov/od/sap/docs/salist.pdf)
Contact Us

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  - Elliot.feder@downstate.edu