

Downstate Medical Center

Fundamentals of Research Administration

Office of Research Administration

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Agenda

- Internal Requirements for Submission
- The Submission
- What happens afterwards?
- Scientific Review what does it entail?
- Just-In-Time (J-I-T) submission
- Notice of Award (NOA)
- Setting up the Account

Proposal Tracking / Signature Worksheet

- Why is it necessary?
 - Tracking Data & Metrics
 - Institutional Review and Approvals
- Who Reviews and Signs?
 - What do the signatures mean?
- Why is it Required Prior to Submission?

Signature on PHS 398 facepage

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

Overlap confirmation: Scientific, Budgetary or Effort

- The PI certifies on the Proposal Tracking/ Signature Worksheet the following:
 - To the best of my/our knowledge, any scientific, budgetary or overlap between this proposal and any other proposal or award <u>has been appropriately disclosed in this proposal</u>. If this project is awarded, any such overlap that exists will be identified, reported and approved by the requisite sponsors prior to acceptance of such award.

Cost Share Template

- Why is it necessary?
 - Federal Requirement, UG Section 200.306
 - Effort Reporting
- Who Reviews and Signs?
 - What do the signatures mean?

Why is it Required Prior to Submission?

Routing Process

Grant Review

- Application complete
- Budget finalized
- All required forms in place
- PI and Department Chair signature on Proposal Tracking/Signature Worksheet

Additional signatories

- Dean's office
- CFO (cost share template)
- Operations Manager
- Hospital CFO (for 3-accounts)

The Final Steps...

- Application is <u>almost</u> complete
 - PI is still tweaking Research Plan
- Internal Documents are signed
- Final Review is taking place

The Submission

- Package is Complete
- Prior to Deadline (5 p.m. on due date)
- Pre-Award submits application to sponsor
 - We "press the button" and submit
 - We wait for confirmation of submission

The Submission – Lift Off !



Electronic Submission Process

- Grants.gov receipt
 - Confirmation screen
 - Tracking number
- Grants.gov submission status
 - Email notifications
- Track the application

Electronic Submission Process

eRA Commons (electronic Research Administration)

- Retrieval from Grants.gov
- Validation
- Submission Errors/Warnings
- 2-day correction window

David Letterman's Top 10 :

- #10 Does the DUNS number on the application match our registration with SAM?
- #9 Did you select the Correct Type of submission?
 Provide the Federal Identifier? Check the Application Type on the Cover Form?
- #8 Did you include the eRA Commons username for all Key Personnel? The same is required for Project Leads and the Sponsor on Fellowship Applications

• David Letterman's Top 10 :

- # 7 If submitting a Multiple PD/PI application, did you give all the MPI's the PD/PI role on the Senior R&R Key Personnel page?
- #6 Did you include the organization names for all key personnel listed on the Senior R&R Key Personnel page?
- #5 Did you include all required attachments?

David Letterman's Top 10 :

- #4 Are all your attachments in PDF format?
- #3 Did you follow all the page limits as identified in the FOA and the application guide?
- #2 Did you include effort >0 in the budget for all key personnel listed in Section A of the budget pages

David Letterman's Top 10 :

- The #1 top error is:
 - Did you follow all special instructions noted in Section IV of the FOA, "Application and Submission Information?"



Avoiding Common Warnings

- Role of Co-PD/PI is not used by NIH
- No degrees submitted on Senior Key Personnel page
- Wrong application package was used

Submit Early

- Remains the best way to ensure successful submission
 - Review system identified errors/warnings
 - Review application in its entirety for any possible changes

Roles and Responsibilities

- Signing Official (SO) role in eRA Commons
 - The Signing Official (SO) has institutional authority to legally bind the institution in grants administration matters. The SO can register the institution, submit applications, and create and modify the institutional profile and user accounts. The SO also can view all grants within the institution, including status and award information. An SO can create additional SO accounts as well as accounts with any other role or combination of roles.

Roles and Responsibilities

PI role in eRA Commons

• A Principal Investigator (PI) is designated by the grantee organization to direct the project or activity being supported by the grant. The PI is responsible and accountable to the grantee for the proper conduct of the project or activity. The role of the PI within the eRA Commons is to complete the grant process, either by completing the required forms via the eRA Commons or by delegating this responsibility to another individual. A PI can access information for any grant for which they are designated the PI.

Roles and Responsibilities

- Assistant (ASST) role in eRA Commons
 - The ASST is a designated role assigned by the PI. This role provides access to his/her account to assist with:
 - Completion of the progress report (RPPR)
 - Edit PIs Personal Profile (except Publications)
 - View Grant Status
 - Perform xTrain functions (except submit to agency)

Validation Complete - Now What?

- Receipt and Referral, DRR
 - Checks for completeness
 - Determines area of research
 - Assigns application to specific NIH Institute or Center for possible funding
 - Assigns an identification number
 - Assigns application to a Review Group

Initial Review

- Receipt and Referral, CSR
 - Reviews most R01s, fellowships and small business applications (SBIR & STTR)
 - Institute review groups handle applications that have Institute-specific features such as program projects, training grants, career development awards, and responses to RFAs

Post Submission Materials

- Allowable Materials:
 - <u>Revised budget pages</u> due to institutional acquisition of equipment and/or new funding
 - <u>Biographical sketches</u> or <u>Letters of Support</u> due to change in Senior Key Personnel (hiring, replacement or loss of investigator)
 - Adjustments resulting from natural disasters OR a change in institution
 - News of a professional promotion OR positive tenure in Senior Key Personnel
 - Approval by the NIH Stem Cell Registry about the creation of a new human embryonic cell line
 - <u>Videos</u>, within defined limits, that demonstrate devices and exploratory data (with a temporal element)
 - Other materials specific in the FOA

Peer Review Process

- To maintain our edge . . . we've got to protect our rigorous peer review system and ensure that we only fund proposals that promise the biggest bang for taxpayer dollars . . . that's what's going to maintain our standards of scientific excellence for years to come."
 - President Barack Obama, April 29, 2013

Core Values of Peer Review

- Expert Assessment
- Transparency
- Impartiality
- Fairness
- Confidentiality
- Integrity
- Efficiency

Peer Review Roles

- Scientific Review Officer (SRO)
 - Analyze the content of each application, and check for completeness
 - Document and manage conflicts of interest
 - Recruit qualified reviewers based on scientific and technical qualifications
 - Assign applications to reviewers for critique preparation and assignment of individual criterion scores
 - Attend and oversee administrative and regulatory aspects of peer review meetings
 - Prepare summary statements for all applications reviewed.

SRG members

- Chair
 - Moderator of the discussion and a peer reviewer
- Reviewers
- Other NIH Staff

Levels of Review

- First Level of Review
 - Carried out by SRG composed primarily of <u>non-</u> <u>federal</u> scientists who have the expertise in relevant scientific disciplines

- Second Level of Review
 - Performed by Institute & Center National Advisory Council or Boards

eRA Commons - Status Information

Status Information 🛿

General Grant Information Status: Institution Name: School Category: Division Name: Department Name: Pepartment Name: Application ID: Proposal Title: Proposal Title: Proposal Title: Current Award Notice Date: Current Award Notice Date: Application Source: Project Period Engin Date: Project Period End Date: eApplication Status: FOA:	04/26/2005 09/19/2005 01/23/2006 Paper 09/26/2005 08/31/2010 [MH05-010] - HIV ANI	NE		<u>e-Applicat</u> Latest NG Abstract (A		
NIH Appl. ID:	7060228					
Status History					Institute or Center Assignment	
Effective Date Status Message					Institute or Center	Assignment Date
09/19/2005 Award prepared: refer questions to Grants Management Specialist.					NATIONAL INSTITUTE OF MENTAL	04/26/2005
06/30/2005 Scientific Review Grants Managem	d: Council review pending. Refer an	y questions to the Pro	gram Official or	HEALTH (Primary) NATIONAL INSTITUTE OF MENTAL	04/26/2005	
04/27/2005 Scientific Review	Group review pending.				HEALTH (Primary)	
04/26/2005 Application enter	ed into system				NATIONAL INSTITUTE ON DRUG ABUSE	04/26/2005
Application Information		Study Section		Advisory Cou	incil(AC) Information	
Award Document Number:	RMH076537A	Scientific Review Group:	ZMH1 ERB-S (11)	Meeting Date:		
FSR Accepted Code:	N	Council Meeting Date(YYYY/MM	,	Meeting Time:	10:30	
Snap Indicator Code:	Y	Meeting Date:	06/29/2005			
Review Outcome Available:	Yes	Meeting Time:	10:00			
Summary Statement Available Early Stage Investigator Eligit		Study Roster:	View Meeting Roster	L		
New Investigator Eligible:						
Eligible for FFATA Reporting:	No					
Reference Letter(s)						
	ers associated with this	particular Grant Application. Princip	al Investigator can see	a list of all Refe	erence Letters within Personal Profile - Refe	rence Letters
Contacts						
Administration		Name	Phone	Ema	il	
Scientific Review Administrator(SRO)		Sheridan, Peter J.	301-443-1513		rida@mail.nih.gov	
Grants Management Speciali	· · ·	Oken, Lisa A.	301-594-5250		n@mail.nih.gov	
Program Official(PO)		Kopnisky, Kathy Lynn	301-443-7726		nisk@mail.nih.gov	

Review Criteria

- Standard Review Criteria all applications
 - Significance
 - Investigators
 - Innovation
 - Approach
 - Environment

Additional Review Criteria

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards

What does the review entail?

- Prepare a written critique
- Assign a numerical score
- Make recommendations concerning protections for human subjects
- Make recommendations concerning protections for vertebrate animals
- Make recommendations concerning appropriateness of budget requests

WHAT's that about the budget?

- Make recommendations concerning <u>appropriateness</u> of budget requests
 - Budget is insufficiently justified by the project as described in the application
 - Insufficient information provided in the application in out years
 - Can the project be carried out in fewer years?

Scoring an application

- Scores are applied to overall impact <u>and</u> individual review criteria
- Scoring system was updated for applications received on or after January 25, 2009
- Scoring system utilizes a 9-point rating scale
 - 1 = exceptional; 9 = poor
 - Results shared with PI unless "not discussed"

The Appeal Process

- The four acceptable bases for an appeal of initial peer review are
 - Evidence of bias on the part of one or more peer reviewers
 - Conflict of Interest on the part of one or more peer reviewers
 - Lack of appropriate expertise within the SRG
 - Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Just-In-Time (JIT) process

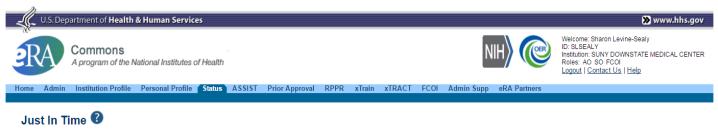
Formal request to submit J-I-T paperwork

Review for other considerations

- Alignment with funding principles
- Review of project budget
- Assessment of applicants systems
- Determination of applicant eligibility
- Compliance with public policy requirements

Not a guarantee of funding

Just-in-Time submission screen



Just in Time (JIT) allows the Principal Investigator (PI) or Signing Official (SO) to provide Other Support, Budget Upload, Other Upload, IACUC, IRB, and Human Subject Assurances Just In Time information directly to the NIH when that information is requested. Guidance follows:

- Although a PI may save this information through Commons, only an SO may submit it to NIH
- Any element of the JIT form may be submitted at different times while the JIT link is available.
- Once the information has been submitted to the NIH, it will be available for viewing in Status in the Other Relevant Documents section.
- 'Number of Submission' provides the user with the number of times the JIT form was submitted to Agency.
- · All elements on the JIT form can be submitted multiple times and will be appended to the JIT report, with the latest version at the top of the report.
- If the application involves care and use of vertebrate animals or involves Human Subjects, verification of the date of the respective IACUC or IRB approval is required on this 'Just in Time' page.

Application Information					
Grant Number:	2R25NS079211-06				
PI Name:					
Proposal Title:	SUNY DOWNSTATE "R TRAIN": NEUROLOGY RESEARCH EDUCATION PROGRAM				

Please provide active and pending support for all key personnel. Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included.

To provide the NIH Other Support, follow the suggested format available at http://grants1.nih.gov/grants/funding/phs398/othersupport.doc and upload the document using the Import button provided below.

Files	File Name	Date Created	Status		Number of Submissions
Other Support File:			NOT UPLOADED	Import	
Budget Upload:			NOT UPLOADED	Import	
Other Upload:			NOT UPLOADED	Import	

Genome Data Sharing Certification. An Institutional Certification is expected prior to funding award for all research generating large-scale human genomic data under the NIH Genomic Data Sharing Policy (http://gds.nih.gov/Dgolicy2.htm)). The Institutional Certification is a document from the authorized Institutional Signing Official of the institution submitting the data, and assures that the data submission and sharing is appropriate (see http://gds.nih.gov/Dgolicy2.htm). The Institutional Certification is a document from the authorized Institutional Signing Official of the institution submitting the data, and assures that the data submission and sharing is appropriate (see http://gds.nih.gov/Dgolicy2.htm). The Institutional Certifications is not available at Just-In-Time, you may submit a provisional Institutional Certification along with other Just-In-Time documents. A final version of the Institutional Certification may be uploaded in the "Additional Information" section of your grant folder at a later date. You should keep Program Staff of the funding IC informed of the expected date of submission of the final Institutional Certification.

Files	File Name	Date Created	Status		Number of Submissions
Genome Data Sharing Certification:			NOT UPLOADED	Import	

Submit Save View Just In Time Report

Federal Requirements... J-I-T

Applicants must:

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- Continue to verify the accuracy and validity of all administrative, fiscal, and programmatic information identified in the application
- Promptly notify NIH of any substantive changes to previously submitted Just-in-Time information up to the time of award
 - Other Support changes identifying overlap or effort commitment
 - Changes in the use or approval of vertebrate animals or human subjects
- Establish and maintain the necessary processes to monitor its compliance and inform NIH of any problems or concerns

Just-In-Time; what's required?

- Each FOA will include specific guidance
- Standard application elements:
 - Other Support pages for all Senior/Key Personnel
 - <u>Certification of IRB approval</u>
 - Evidence of compliance with the education in the <u>Protection of Human Subjects requirement</u>

Verification of IACUC approval

J-I-T requirements

Other Support pages

- Information on <u>other</u> Active and Pending support
- Includes <u>all</u> financial resources available in direct support of one's research endeavors
 - Federal
 - Non–federal
 - Commercial
 - Institutional
- Does NOT include prizes or gifts

Other Support pages

- Review by the Institute/Center's scientific program staff and Grants Management staff to ensure:
 - Sufficient levels of effort are committed to the project
 - No scientific, budgetary, or commitment overlap
 - Only funds necessary to the approved project are included in the award.

Other Support – Overlap

- The 3 types of overlap:
 - Scientific
 - Budgetary
 - Commitment

Other Support - Scientific Overlap

Scientific Overlap occurs:

When substantially the same research is proposed in more than one application

<u>OR</u>

Is submitted to two or more funding sources for review and funding consideration

Other Support - Budgetary and Commitment Overlap

- Budgetary Overlap occurs:
 - When duplicate or equivalent budgetary items are requested in an application but already are provided by another source.
- Commitment Overlap occurs:
 - When an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested in the application.

Additional J-I-T requirements

- Certification of IRB Approval
 The certification date of IRB review ar
 - The certification date of IRB review and approval
- Verification of IACUC Approval
 - Verification of the IACUC approval date must be submitted
- Human Subjects Education Requirement
 - Certification that Senior/Key personnel have completed training in the Protection of Human Subjects
 - CITI training done through the IRB

Additional J-I-T requirements

> Other Requirements may include:

- <u>Human Embryonic Stem Cells</u> if it wasn't identified in the application, it should be uploaded here
- <u>Genomic Data Sharing Institutional Certification</u> certification form and instructions on the Data Sharing website
- <u>Other Information</u> Requested by the Awarding IC
 - Revised budgets
 - Detailed budgets for a submitted modular application
 - Changes to Human Subjects section
 - Changes to Vertebrate Animals section

Just-In-Time submission

- All Overlap must be resolved or addressed prior to award
- Grants Management Official (GMO) may request additional information
- All documentation should be sent by the Authorized Official (AOR)

Pre-Award Office - contact your Project Associate

Other Applicable Changes

- When requested by NIH, as part of the pre-award process, PD/PIs and the AOR should discuss potential changes in scope with program
 - May be able to revise certain sections of the application, i.e. Project Summary/Abstract, Specific Aims, and/or Public Health Relevance sections
- All revised application information submitted to the NIH must be approved by an AOR – your
 Project Associate in ORA

Other Required J-I-T requirements

- FCOI documentation for outside collaborators
 - Consultants
 - Consortium / Subcontractors
- Same requirements hold true for all PD/PI's and research team who are "investigators" based on the FCOI definition

The Administrative Burden and the Federal Demonstration Partnership

- The Federal Demonstration Project (FDP) is a cooperative initiative among 10 federal agencies and 155 institutional recipients of federal funds
- The FDP is a program convened by the Government-University-Industry Research Roundtable of the National Academies
- Its purpose is to reduce the administrative burdens associated with research grants and contracts.

Subrecipient FCOI documentation

- Is the entity an FDP participating member?
 - If Yes no further action
 - If No other documentation must be reviewed
- Other Required Documentation
 - FCOI certification
 - FCOI follow-up
 - FCOI exception request

Subrecipient Questionnaire

- Sent to all subrecipients prior to award
- Information obtained is a requirement of the Uniform Guidance
- Information is used to do a Risk Assessment
- Outcome of risk assessment will identify any additional terms and conditions for the subrecipient
- FDP pilot program

Subrecipient FCOI documentation

Home / Resources / Forms

Pre-Award Forms

Required for every grant and contract submission:

- Proposal Tracking Data Sheet and Signature Worksheet
- Cost Share Template (if applicable)
- Submission Budget
- · Capitation Budget (clinical research/industry awards, Excel)

If there will be subrecipients:

- Subcontract Proposal Face Page
- · Subrecipient vs. Contractor Decision Tree
- Subrecipient FCOI Certification
- Subrecipient FCOI Follow-Up (if applicable)
- Subrecipient FCOI Exception Request (if applicable)

At the time of J-I-T or award:

Subrecipient Risk Assessment Questionnaire

If subrecipients cost are greater than 49% of total budget:

· Pre-Award Assessment of Proposed Subawards

If there will be external consultants:

Consultant FCOI Request

Post-Award Forms

Notice of Award (NOA)

The Notice of Award (NOA) is the legal document issued to notify the grantee that an award has been made and that funds may be requested from the designated HHS payment system or office. The NOA is issued for the initial budget period and each subsequent budget period in the approved project period

Notice of Award (NOA)

- Funding is different than what was applied for
 - Is it part of the continuing resolution?
 - Can I do the research as outlined in my proposal with less funds?
 - Yes terrific!
 - No contact your Sponsored Project Associate (sPA)

Setting up the Award

- Sponsored Project Associate (sPA) will review the file and confirm all required documents are in place
 - Application with internal paperwork from submission
 - FCOI confirmation for DMC research team, the "investigators"
 - J-I-T application with any additional correspondence
 - Consultant FCOI (if applicable)
 - Subcontract FCOI paperwork (for non-FDP members)

Setting up the Award

- An award is set up to allow the spending of dollars that are <u>allowable</u> and <u>allocable</u>.
- If required documents are not in place, award will be set up "on hold."
- What is "at risk" and what does it mean?
- Pre-Award Costs

Compliance

- Know the rules!
 - What's your responsibility when submitting and accepting an award?
- What are the pitfalls?
 - Start-up costs weren't requested
 - Milestones weren't realistic, can't recruit
 - Understanding the out-years
- Institutional Compliance
 - Routing/Approval paperwork
 - FCOI

Resources

- Office of Research Administration
 - <u>http://research.downstate.edu/</u>
- Pre-Award division
 - <u>http://research.downstate.edu/administration/pre-award.html</u>
- Post-Award division
 - <u>http://research.downstate.edu/administration/post-award.html</u>
- Forms
 - <u>http://research.downstate.edu/resources/forms.html</u>
- Policies
 - <u>http://research.downstate.edu/policies-downstate.html</u>
- Funding Opportunities
 - <u>http://research.downstate.edu/funding/funding-</u> opportunities.html
- Institutional Information
 - <u>http://research.downstate.edu/resources/information.html</u>

Contact Us

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