National Institutes of Health Who, What and How

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PRESENTER: DAVID NGO

JULY 2014

National Institutes of Health Who, What and How



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Who is NIH:

• They are an agency within the Public Health Service (PHS), under the umbrella of the Department of Health & Human Services (DHHS)

What is their purpose:

 To improve human health by increasing scientific knowledge related to disease & health.

How are they set-up?

• NIH is made up of 27 Institutes and Centers, each with its own mission and functions, separate appropriations and statutory authorities.

http://www.nih.gov/icd/

NIH Research: Intramural vs. Extramural







- The NIH conducts its own Intramural Research Program utilizing staff scientists on its Bethesda campus.
- The NIH Extramural Research Grants Program funds research nationally at universities and research centers through grants, cooperative agreements and contracts. <u>UTSW and other Universities utilize the Extramural Research</u> <u>Grants Program.</u>

The 27 (yes, I counted!) Institutes and Centers of NIH



(4)

NIH INSTITUTES

- 1. National Cancer Institute (NCI)
- 2. National Eye Institute (NEI)
- 3. National Heart, Lung, and Blood Institute (NHLBI)
- 4. National Human Genome Research Institute (NHGRI)
- 5. National Institute on Aging (NIA)
- **6.**National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- 7. National Institute of Allergy and Infectious Diseases (NIAID)
- **8.**National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
- **9.**National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- **10.** Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
- 11. National Institute on Deafness and Other Communication Disorders (NIDCD)
- 12. National Institute of Dental and Craniofacial Research (NIDCR)
- 13. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- 14. National Institute on Drug Abuse (NIDA)
- **15.** National Institute of Environmental Health Sciences (NIEHS)
- 16. National Institute of General Medical Sciences (NIGMS)
- 17. National Institute of Mental Health (NIMH)
- **18.** National Institute on Minority Health and Health Disparities (NIMHD)
- 19. National Institute of Neurological Disorders and Stroke (NINDS)
- 20. National Institute of Nursing Research (NINR)
- 21. National Library of Medicine (NLM)

NIH CENTERS

- 1. Center for Information Technology (CIT)
- 2.Center for Scientific Review (CSR)**
- 3. John E. Fogarty International Center (FIC)
- **4.**National Center for Complementary and Alternative Medicine (NCCAM)
- **5.**National Center for Advancing Translational Sciences (NCATS)
- **6.NIH Clinical Center (CC)**
- ** The Center for Scientific Review (CSR) is the portal for NIH grant applications and their review for scientific merit. CSR organizes the peer review groups or study sections that evaluate the majority of the research grant applications sent to NIH. The CSR mission has remained clear and timely: to see that NIH grant applications receive fair, independent, expert, and timely reviews free from inappropriate influences so NIH can fund the most promising research.

NIH Office of Extramural Research

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Because UTSW does <u>Extramural Research</u>, the OER website is the best place to start when looking for information about NIH grants:

http://grants.nih.gov/grants/oer.htm



Important Links on NIH Site

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The "Grants Policy" link includes the roles, responsibilities, processes, what's allowed and not allowed. Of special interest is Item 7 which discusses Cost Considerations, and includes an excellent chart for an explanation of Allowable Costs .

7.9.1 Selected Items of Cost

Exhibit 5: Selected Items of Cost
The table presents specific items that may or may not be included in the
cost portion of grants.

Items	Explanation of Allowable Costs
Advertising	Allowable only for recruitment of staff, trainees, or study participants; procurement of goods and services; disposal of scrap or surplus materials; and, other specific purposes necessary to meet the requirements of the grant-supported project or activity.
Alcoholic Beverages	Unallowable as an entertainment expense, but allowable if within the scope of an approved research project.
Alteration and Renovation	Individual A&R projects that are treated as direct costs and that will not exceed \$500,000 will be subject to the A&R policies specified in this exhibit and in the <u>Construction Grants</u> chapter, as applicable. Individual A&R projects exceeding \$500,000 in direct costs will be subject to the requirements specified in the <u>Construction Grants</u> chapter.

Important Links on NIH Site



The "Forms" link includes the Application Guides (i.e. SF424) and links to all the Available Forms.

Note this is a sampling of the guides and forms.

Research Grants and Fellowships				
Forms / Applications / Instructions	Revision Dates	Description / Comments		
<u>SF424 (R&R)</u>	03/2011	Standard Form 424 (Research & Related) Grant Application Forms Includes application guides and forms to be used with all competing applications for Research, Career Development, Institutional Training awards, and SBIR/STTR Awards. See Applying Electronically Page and Related NIH Guide Notices.		
PHS 398	06/2009	Competing - Public Health Service Grant Application Includes application guides and forms to be used with all competing applications for Cooperative Agreements and Complex Mechanisms that do not use the SF424 (R&R) application package. See 11/23/2009 NIH Guide Notice.		

Additional Format Pages

NIH requires all text attachments in an SF424 (R&R) application to be PDF. However, to avoid system errors, applicants should create text attachments using word processing software and then convert to PDF using PDF-generating software. While Word samples are provided below, applicants will need to convert the finished product to PDF before attaching within an SF424 (R&R) application. Do not use the PDF samples from the PHS398 application page. Those are fillable-PDF forms which will cause an error in the electronic submission of an SF424 (R&R) applications.

Additional Format Pages	Date Posted	File Link/Format/Size
Biographical Sketch Format Page – Adobe Forms Version B (use also for Fellowship Sponsor/Co-Sponsors)	11/13/2009	MS Word (36 KB)
Biographical Sketch Sample – Adobe Forms Version B	03/25/2011	MS Word (44 KB)
Fellowship Applicant Biographical Sketch Format Page	02/05/2010	MS Word (52 KB)
Fellowship Application Biographical Sketch Sample	04/19/2011	MS Word (79 KB)
Referee Instructions for Mentored Career Development Awards	08/11/2011	MS Word (38 KB)
References for Fellowship Awards	02/05/2010	MS Word (49 KB)
Targeted/Planned Enrollment Table Format Page	10/12/2005	MS Word (48 KB)
Inclusion Enrollment Report Format Page (New Format)	10/12/2005	MS Word (71 KB)
Modular Budget Sample: Same Modules	11/08/2005	<u>PDF</u> (27 KB)
Modular Budget Sample: Variable Modules	07/23/2008	<u>PDF</u> (26 KB)



NIH Staff Contacts



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- **Program Official:** The PO is responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants. This is the PI's main contact.
- **Scientific Review Officer**: SROs are health science administrators who manage the activities of SRGs, including CSR study sections. The SRO reviews applications for completeness and conformity to requirements, and serves as the overall point of contact with applicants during the initial phase of the peer review process.
- **Grants Management Officer/Specialist:** The GMO whose name appears in the Notice of Award (NOA) is the NIH official responsible for the business management and other non-programmatic aspects of the award. This is the department/grant manager main contact, in coordination with SPA.



Types of Funding Opportunities

Request for Application

NIH requested research in a well defined area. Very specific program objectives. Single submission date designated.

Program Announcement

Often broadly defined or a reminder of a scientific need. Investigator Initiated "unsolicited research". Standard submission dates apply.

Parent Announcement

Not specific. Investigator initiated unsolicited research. Maybe submitted on any topic in the breadth of the NIH's mission. Standard submission dates.



How to Apply for Funding

• **eRA Commons** -Registration required. Each PI and Post Doc must individually be registered here. The department administrator must also be registered.

• **Grants .gov** - This is a government portal where almost all NIH applications are submitted electronically. Very few paper submissions are still being done.



What is ERA Commons?



Overview of the eRA Commons

- eRA Commons is an online interface where grant applicants, grantees and federal staff at NIH can access and share administrative information relating to research grants.
- The functions available to a user in Commons are based on the "role" associated with their eRA Commons account (see RA Commons Roles).
- eRA Commons users, based on their role, can conduct a variety of business in Commons, including: Track the status of their grant applications.

View summary statements and score letters

View notice of award and other key documents.

Submit <u>Just-in-Time</u> information (SO only) requested by the grantor agency prior to a final award decision.

Submit the required documentation, including the Financial Status Report and Progress Reports (via esnap).

Submit a No-Cost Extension notification (SO only).

Submit a streamlined annual progress report electronically, provided the grantee institution is eligible to submit one under the Electronic Streamlined Non-competing Award (eSNAP) process.

https://commons.era.nih.gov/commons/

ERA Commons Roles



Signing Official (SO)



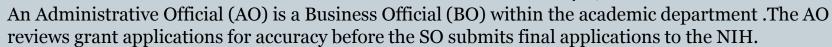
A Signing Official (SO) is a Business Official (BO) within an extramural organization. The SO has institutional authority to legally bind the institution in grant-administration. The SPA rep "Signs" or "Submits" on behalf of UTSW.

Principal Investigator (PI)



A Principal Investigator (PI) directs a research project or program supported by the NIH. The PI will also receive a <u>eRA commons ID that is needed for the grant application</u> that will be submitted in grants.gov.

Administrative Official (AO) -Department/Grant Manager



Grants.gov



What is Grants.gov?

Grants.gov is the web site that the government is using to inform citizens of grant opportunities and provide a portal for submitting applications to government agencies.

http://www.grants.gov/



Types of Funding Instruments



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Grant

<u>Financial assistance</u> mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. <u>There is no substantial programmatic involvement between the sponsor and the recipient during performance of the financially assisted activities. <u>There are no guaranteed deliverables.</u></u>

Cooperative Agreement

A support mechanism used when <u>there will be substantial Federal scientific or programmatic involvement</u>.

Contract

A contract is an award instrument <u>establishing a mutually binding legal relationship</u> <u>between the Government (buyer) and a Contractor (seller). There is a guarantee on deliverables.</u>

Grants Process At-A-Glance



Planning, Writing, Submitting

<u>Planning</u>: Applicant should start early, collect preliminary data, and determine internal deadlines.

Writing: Applicant often begins writing application several months prior to application due date.

<u>Submitting</u>: Applicant organization submits most applications to NIH through Federal portal, Grants.gov.

Receipt and Referral

Applications compliant with NIH policies are assigned for review by the Division of Receipt and Referral in the Center of Scientific Review (CSR).

Months 1-3

CSR assigns application to an NIH Institute/Center (IC) and a Scientific Review Group (SRG). Scientific Review Officer (SRO) assigns applications to reviewers and readers.

Peer Review

Months 4-8

<u>Initial Level of Review</u>:

SRG members review and evaluate applications for scientific merit.



Priority Scores:

Available to Principal Investigator on eRA Commons.



Summary Statement:

Available to Principal Investigator on eRA Commons.



Second Level of Review: Advisory council/board reviews applications.

Award

Months 9-10

<u>Pre-Award Process:</u> IC grants management staff conducts final administrative review and negotiates award.*



Notification of Award: NIH Institute/Center (IC) issues and sends Notice of Award (NoA) to applicant institution/organization.



Congratulations!

Project period officially begins!

*NIH Requests additional information needed just-in-time for award.

Most Common Type of Research Grant



R01 NIH Research Project Grant Program (R01)

- o Used to support a discrete, specified, circumscribed research project
- o NIH's most commonly used grant program
- o No specific dollar limit unless specified in FOA
- o Advance permission required for \$500K or more (direct costs) in any year
- o Generally awarded for 3 -5 years
- o All ICs utilize
- o See parent FOA: PA-11-260

We found a funding opportunity, now what?

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The PI decides he is going to submit an R01. This PI decides on a investigator-initiated R01 application, which means: a good idea for an application, no specific program requirements (better know as "Unsolicited").

However, the R01 research plan must be related to the program interests of one or more of the NIH Institutes and Centers (e.g. National Institute of General Medical Sciences "NIGMS") based on descriptions of their programs.

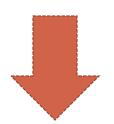
Funding Opportunity Announcement (FOA) Number	PA-11-260
Companion FOA	None
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.113, 93.121, 93.143, 93.172, 93.173, 93.213, 93.233, 93.242, 93.279, 93.286, 93.361, 93.389, 93.389, 93.394, 93.395, 93.396, 93.399, 93.837, 93.838, 93.839, 93.846, 93.847, 93.853, 93.855, 93.856, 93.859, 93.866, 93.867, 93.879
FOA Purpose	The Research Project Grant (R01) is an award made to an institution/organization to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in areas representing the specific interests and competencies of the investigator(s). The R01 research plan proposed by the applicant institution/organization must be related to the stated program interests of one or more of the NIH Institutes and Centers (ICs) based on descriptions of their programs.
Key Dates	
Posted Date	July 22, 2011
Open Date (Earliest Submission Date)	August 12, 2011 (Previously September 5, 2011)
Letter of Intent Due Date	Not Applicable
Application Due Date(s)	Standard dates apply, by 5:00 PM local time of applicant organization.
AIDS Application Due Date(s)	Standard dates apply, by 5:00 PM local time of applicant organization.
Scientific Merit Review	Standard dates apply

Sample Program Announcement

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Funding Opportunity Announcement (FOA) Number PA-11-260

Apply for Grant Electronically



CFDA	Opportunity Number	Competition ID	Competition Title		Instructions and Application
	PA-11-260	ADOBE-FORMS-B2	ADOBE-FORMS-B2	National Institutes of Health	<u>download</u>

Know Your Due Dates (Timeline for Applications)

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February 5	June 5	.
	Julie 3	October 5
March 5	July 5	November 5

Review and Award Cycles

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

The timeline is very important for budget reasons. It can take up to 10 months from application to funding (i.e., Feb to Dec), so plan accordingly. On renewals, consider the timeline because you do not want a gap in funding between the original award and the renewal.

Note that SPA requires a completed application 3 business days before the due date

http://grants.nih.gov/grants/funding/submissionschedule.htm#elec

Parts of the Application





You must follow page limits and font requirements.

- Font: Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.)
- Attachments must be in PDF file format



The SF424 Application Guide

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This is the all inclusive manual on the grant application process-Bookmark this site. The pdf version contains a multitude of links to all parts of the application(s). The next slide is just a portion of the table of contents

SF424 (R&R) Application Guide for NIH and Other PHS Agencies

A guide developed and maintained by NIH for preparing and submitting applications via Grants.gov to NIH and other PHS agencies using the SF424 (R&R)

Sample Page-SF424 Guide

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PHS SF424 (R&R) Adobe Forms Version B Application Guide

Biosketch instructions are here. This is discussed on the next slide

		2.16.1	Finding Help for Grants.gov Registration or Submissions	I-34
		2.16.2	Finding Help for the eRA Commons Registration or eRA Commons	
			Validation Processes	
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4.	Com	pleting	the SF424 Research and Related (R&R) Forms	I-38
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	4.3	Project	Performance Site Locations Component	I-53
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		4.7.4	Cumulative Budget	I-88
	4.8	Special	Instructions for Preparing Applications with a Subaward/Consortium	I - 89

Parts of Application (continued)



Research & Related Key Personnel:

- PI and Key personnel
 - Include NIH Bio Sketch in proper format. This includes:
 - ➤ Personal Statement- why your experience and qualifications make you particularly well-suited for your role. Within this section you may, if you choose, briefly describe factors such as family care responsibilities, illness, disability, and active duty military service that may have affected your scientific advancement or productivity.
 - Positions and Honors-listed in chronological order, concluding with present position
 - Peer Review Publications limited to 15 with PMCID #
 - Research Support-List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). *Begin with the projects that are most relevant to the research proposed in the application*
 - Include eRA Commons ID for PI and all Post Doc's

Parts of Application (continued)



Budget and Justification:



Know How Much Money to Request:

- Ask for only enough money to do the work.
- Reviewers look for reasonable costs

Types of Budgets:

- If your budget is less than \$250K in Direct Costs per year and you are from a domestic institution, you usually prepare a modular budget that requests funding in \$25K increments.
- If your budget is more than \$250K in Direct Costs per year or you are from a foreign institution (or both) you are required to do a detailed line item budget.
- NOTE: Direct cost requests equal to or greater than \$500K per year require prior approval from the NIH Institute/Center before application submission. This limit is exclusive of any consortium F&A costs.

Budget Justification "Cap" Disclosures



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- NIH Salary Cap: When preparing a budget the current NIH Salary Cap is \$181,500 (Awards issued Jan 12, 2014 September 30, 2014) which is the Executive Level II pay scale. This is for AY and Summer salary. When calculating summer salary, if the PI's total salary (AY and Summer) is over the Cap, the base used in the calculation is the NIH CAP. Any amount over this must be charged to separate account.
- <u>Graduate Student Compensation Cap</u>: The maximum amount that can be budgeted for Grad. Student compensation (stipend and tuition) is the zero level post doc salary rate posted by NIH. This amount is currently \$38,496. (Predoctoral level is: \$21,600)

In the budget justification (modular and detailed), there must be a statement on these two line items stating the amounts requested in the budget are in accordance with the NIH policy.

Both of these topics are covered in detail in later SPA training sessions.

http://grants.nih.gov/grants/policy/salcap_summary.htm NIH Salary Cap
http://grants.nih.gov/grants/policy/fy2012_salary_cap_faqs.htm NIH Salary Cap frequently asked questions
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-067.htm Grad Student Compensation

Budget Justification

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Modular Budget Justifications

Personnel Justification(Required): all Personnel by position, role, and level of effort. This includes consultants, personnel on any Consortium/Contractual arrangement and any "to be appointed" positions. Do not provide salary information. Note that UTSW does not commit to Academic Year Effort for any faculty and that compensation budgeted is in accordance with the NIH policy regarding the NIH Salary Cap and Graduate Student Compensation.

Narrative Justification: will be required in the application only if there is a variation in the number of modules requested. This usually occurs when equipment is requested in any of the budget periods.

Budget Justification-Continued

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Detailed Budget Justification

Use the budget justification to provide the additional information requested in each budget category identified and any other information the applicant wishes to submit to support the budget request. The level of effort (in person months) is listed on the budget page. Note that UTSW does not commit to Academic Year Effort for any faculty. Also note that compensation budgeted is in accordance with the NIH policy regarding the NIH Salary Cap and Graduate Student Compensation.

The following budget categories must be justified, where applicable: personnel costs, equipment, travel, participant/trainee support and other direct cost categories.

Submit, Track and Review

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- UTSW requirement is to get a full and final Grant Application 3 business days prior to submission deadline. (Notification of intent to submit proposal due 14 days prior to submission deadline).
- SPA administrator will submit via grants .gov and get a tracking number
- Status of application is tracked in eRA commons
- The PI and department can review and correct the application and resubmit only *prior to the submission deadline*.

Just In Time Request (JIT)

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The eRA Commons users will find a feature to submit Just-In-Time information when requested by the NIH. NIH policy allows the submission of certain elements of a competing application to be deferred.

- Other Support: Send up-to-date information on active and pending support for key.
- Vertebrate Animals: updated protocol and approvals are included
- **Human Subjects Research:** updated protocol and approvals are included
- **Human Subjects Education:** if required, provide certification that each person identified under Key Personnel has completed an educational program on the protection of human subjects.
- **Response to Summary Statement:** Only the PI will see this. They may be asked to respond to scientific or administrative concerns.

Grant Numbers: What do they mean? 1 Ro1 CA 123456-04S1A1



Application Type

1=New

2=Renewal

3=Revision

4=Extension

5=Non-competing

7=Transfer

Activity Code

Ro1= Research Project

R21=Exploratory/Developmental

Ro3=Small Research Grant

Institute Code

CA=Nat'l Cancer Institute

AG= Nat'l Institute on Aging

MH=Nat'l Institute of Mental

Health

Serial number

123456 (always 6 numbers)

Grant Year

Actual segment or budget period

Other

S=Supplement

A=Amendment

NOA-Notice of Award



- Legally binding document
- Identifies grantee and PI
- Provides terms and conditions
- Establishes funding and support period
- Provides contact information:
 Grant Management Officer
 Grants Management
 Specialist
- E-mailed to the business official:grants.mgt@utsouthwestern.edu
- Also available in Commons "Status" tab



What is in the Notice of Award?



The first few paragraphs of the award document contain the following information:

- Budget Period: 07/01/10-06/30/11
 Project Period: 07/01/10-06/30/14
- Why the NOA is being issued:
 - New funding for a specific year
 - No-cost extension
- Statement accepting NIH Terms and Conditions when funds are drawn
- NIH acknowledgement & disclaimer language for each publication
- Requirement of Public Access Policy-PubMed
- Conflict of Interest statement establishing NIH requirements
- Name of Grants Management Officer who is authorizing the award

Sample of Actual Notice of Award



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 Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release or other document that cites results from NIH grant-supported research must include an acknowledgment of NIH grant support and disclaimer such as "The project described was supported by Award Number Ro1GMo59383 from the National Institute Of General Medical Sciences. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute Of General Medical Sciences or the National Institutes of Health."

Award recipients are required to comply with the NIH Public Access Policy. This includes submission to PubMed Central (PMC), upon acceptance for publication, an electronic version of a final peer-reviewed, manuscript resulting from research supported in whole or in part, with direct costs from National Institutes of Health. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. For additional information, please visit http://publicaccess.nih.gov/.

What is in the Notice of Award?



Section I:

Award Data

Section II:

Payment Information

Section III:

Terms & Conditions (standard)

Section IV:

Special Terms and Conditions

Actual Section I-Award Data



Detailed Budget

Modular Budget

Salaries and Wages \$87,326
Fringe Benefits \$29,429
Personnel Costs (Subtotal) \$116,755
Equipment \$13,260
Supplies \$1,545
TOTAL FEDERAL DC \$131,560
TOTAL FEDERAL F&A \$72,163
TOTAL COST

\$203,723

Award Calculation (U.S. Dollars)

Federal Direct Costs \$241,441 Federal F&A Costs \$129,613 Approved Budget \$371,054 Federal Share \$371,054 TOTAL FEDERAL AWARD AMOUNT \$371,054

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$371,054

Actual Section I-Award Data



 SUMMARY TOTALS FOR ALL YEARS YR THIS AWARD CUMULATIVE TOTALS

```
3
$282,667
$282,667
4
$283,381
$283,381
```

5 \$284,095 \$284,095

These usually change in competitive periods as the NIH FY Policy changes and are pending satisfactory progress reports.



Section II-Payment Info

No action is needed by PI or SPA.

Sponsored Research Accounting draws down the money monthly as it is spent on the award.



Section III-Standard Terms & Conditions



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- How to handle unobligated balance
 - Carry over to next budget period without GMO approval
 - Requires GMO prior approval
- Reference to SNAP- Streamlined Noncompeting Award Procedures
 - Applicable
 - Not Applicable
- Treatment of Program Income
- References the Grants Policy Statement in effect at the beginning date of the budget periods.

Actual Section III-Standard Terms & Conditions



SECTION III - TERMS AND CONDITIONS - 5Ro1MHo83686-03

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a.The grant program legislation and program regulation cited in this Notice of Award. b.Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.

c.45 CFR Part 74 or 45 CFR Part 92 as applicable. d.The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.

e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at 'http://grants.nih.gov/grants/policy/awardconditions.htm' for certain references cited above.)

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Section IV-Special Terms & Conditions



- Special Terms & Conditions-specific to the particular grant
 - Less funding than original NOA estimate
 - Recycled start date-to even out NIH award budget periods
 - Specific Consortiums may be mentioned
 - Key personnel may be spelled out
 - Other special restrictions/requirements that apply to this award.



Actual Section IV-Special Terms & Conditions



SECTION IV - MH Special Terms and Conditions - 5Ro1MH123456-03

KEY PERSONNEL:

In addition to the PI, any absence, replacement, or substantial reduction in effort of the following individual(s) below, requires the written prior approval of the National Institute of Mental Health.

Dr. XXXXXXX

Dr. XXXXXXX

Grantee Acceptance

(42)

The grantee indicates acceptance of the NIH award and its associated terms and conditions by **drawing down funds** from the Payment Management System.

This is done by SRA as previously mentioned.



Stewardship

NIH may disallow costs if it determines through audit or otherwise, that the costs do not meet the tests of:

- Allowability
- Allocability
- Reasonableness
- Necessity
- Consistency

Progress Reports are required annually as part of the noncompeting continuation award process



PHS 2590-Paper

- Forms & instructions can be found here <u>http://grants.nih.gov/grants/funding/</u>
 2590/2590.htm
- P50, U, R35 and others
- Generally these awards also do NOT have automatic carryforward
- Lots of info required including a detailed budget
- Must be submitted (mailed) and approved by NIH before each additional budget period.

SNAP-Electronic

- NOA will specify if you can use SNAP
- Guide is located here:
 http://era.nih.gov/services for applic ants/reports and closeout/esnap.cfm
- K awards and R awards-except R35
- Generally these awards also have automatic carryforward
- Simplified info for next budget period
- State no or yes (yes requires a justification) to 3 questions.
- Submit electronically in eRACommons.

Some Details for a SNAP report



- #1-Any change in "other support" (active only) of senior/key personnel?
- #2-Any reduction > 25% in level of effort PI or anyone named in NOA?
- #3-Unobligated balance >25% of current year total funding including prior year carryforward?
- For any of these-if yes provide detailed justification, why it happened, include the plan for this year.

Things to Remember for **both** SNAP and Non-SNAP Reports

If a balance of unobligated funds > 25% of total amount awarded for the budget period-the GMO will review to see if these funds are necessary to complete the project. If it is determined NOT to be necessary:

- Automatic carryforward may be restricted in future year
- Balance may be used to reduce NIH funding in the next budget period
- Any combo of these actions

The decision will be detailed by the GMO in the Terms & Conditions of the next Notice of Award.

Things to Remember for **both** SNAP and Non-SNAP Reports-Cont'd



Unliquidated

These funds are committed but not yet used and should not be reported as unobligated.

Unobligated

These funds are not used and the disposition of these balances are in the Terms & Conditions of the award.

Auto carryforward <u>or</u> Prior approval required

Grantees can make some changes



No cost extension-1 time for up to 12 months

Pre-award costs-If allowed in NOA

Rebudgeting-if Scope of Work is not changing

Add a subcontract-if it is not foreign and SOW doesn't change

Automatic carryforward of unobligated balance-except P50, P60, P30, U, T and others



Grantees can make some changes



No Cost Extensions can be made without NIH approval **one time** for up to 12 months if:

No additional funds are needed

Scope of work will not change

One of the following applies:

Needed to ensure adequate completion of approved project Continuity while a competing continuation is under review To permit an orderly phase out

Having unspent funds is NOT an acceptable reason to request an extension.

Some changes require Prior Approval*



- Change of Grantee organization
- Change of PI or Key Personnel named in NOA
 - Withdraw
 - Absence > 3 months
 - Reduce proposed effort $\geq 25\%$
- New subcontract if foreign or results in change in SOW
- Change in Scope
 - Research aims or emphasis
 - New use of humans or animals
 - New technology use
- 2nd no cost extension
- Pre-award costs > 90 days

^{*} There are many more that require approval.

Some changes require Prior Approval Cont'd



Any of these requests must be:

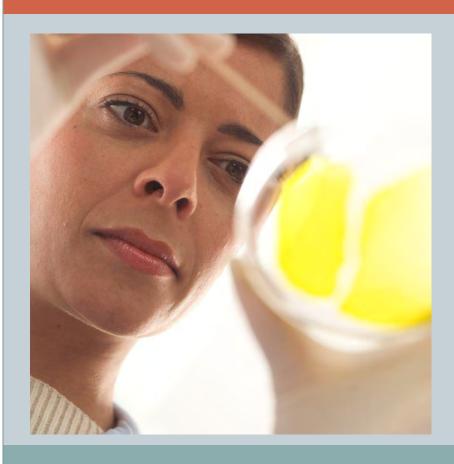
- Made in writing
- Signed by PI and SPA (Sent to GMO by SPA representative)
- No later than 30 days before requested change

If approved-change will be documented by GMO through a revised NOA or letter.

Some changes require Prior Approval Cont'd



Example



Change of PI

- Justification for change
- Bio of proposed new PI
- Current & Pending for new PI
- Any budget changes

All must be in written request to GMO

Closeouts



53)

A timely closeout (within 90 calendar days of the end of grant support) is required by NIH.

Failure to submit timely and accurate documents may affect future funding to UTSW.

Requirements are:

- 1. Final Federal Financial Report (FFR)
- 2. Final Progress Report
- 3. Final Invention Statement

Closeout Details



Final Federal Financial Report (FFR)

Final Progress Report

SPA-Reporting does this through eRACommons.

Unobligated funds are returned to NIH-or reflected in an appropriate accounting adjustment

Submitted by the PI-through eRACommons.

Should include:

Progress made toward aims
Positive/negative results
List of publications
Any other specific requirements

Link:

http://grants.nih.gov/grants/policy/ni hgps_2010/nihgps_ch8.htm#_Final_ Progress_Report

Closeout Details



Final Invention Statement:

After confirming with TechDev, the PI submits this through eRA Commons and Cheryl Anderson signs, as UTSW Signing Official.

Currently not required for:

Training (T)

Fellowship (F)

R13, R25, S15

Questions [56]



