

**After the Award is Made...  
Then What?**

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## The Grants Management Perspective

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Cheryl Chick

### Important Award & NIH Grants Management Guidance

- Notice of Grant Award
- Fiscal Monitoring  
<http://grants.nih.gov/grants/funding/2590/2590.htm>
- NIH Grants Policy Statement  
<http://grants.nih.gov/grants/policy/policy.htm#gps>  
-Post-Award Issues

### Notice of Grant Award (NGA)

**Indicates:**

- Who has Received the Award?
- What For?
- How Much?
- Start and End Dates
- NIH Contact Information
  - Program Director (Officer)
  - Grants Management Specialist
- Terms and Conditions

### Notice of Grant Award (NGA):

**TERMS AND CONDITIONS**

- Grant program legislation and regulations
- Restrictions on the expenditure of funds in appropriation acts
- 45 CFR 74 or 92, as applicable
- NIH Grants Policy Statement

### Notice of Grant Award (NGA): STANDARD Terms and Conditions

- Included or excluded from carryover, as appropriate
- Streamlined Noncompeting Award Procedures (SNAP)
- Program Income

## Notice of Grant Award (NGA): SPECIAL Terms and Conditions

- Revised Award
- Supplemental Award
- Cooperative Agreement
- Restrictive Terms
  - Failure to follow the restriction = Disallowance of costs
- Requirement Terms
- Information Terms

## Grantee Acceptance

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

## NIH: SNAP Administrative and Fiscal Monitoring (PHS 2590)

- **SNAP: Streamlined Non-Competing Award Process**
  - The NGA will specify whether an award is subject to SNAP.
  - Annual detailed budgets and justification not required.
  - Modified financial reporting – FSR only due at the end of the competitive segment
  - SNAP awards have automatic carryover (However, reference NGA for special restrictions.)
  - Three questions in non-competing progress report

## NIH: SNAP Administrative and Fiscal Monitoring

Answer the three questions as honestly as possible.

- Provide **complete other support** for any change in active support of the PI and those considered key to the project.
- Will there be a significant change in the level of effort for the PI or other personnel designated on the NGA from what was approved for the project? (Significant indicates a 25% or greater reduction in time devoted to the project.)
- Explain why there is a balance (including prior year carryovers) >25% of the current year's total budget and how you plan to use the funds

## NIH: Traditional/Non-SNAP Administrative and Fiscal Monitoring

- Submit complete non-competing progress report (PHS 2590)
  - Detailed categorical budget, justification, and updated other support (where applicable)
  - Address unobligated balance greater than 25%
- Annual Financial Status Reports
  - For those awards without automatic carryover, the "remarks" section of the FSR must specify the amount to be carried over

## What Can Delay the Award Process?

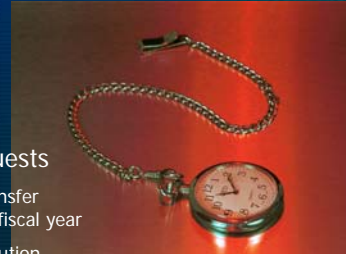
- Lack of or Slow Response to Inquiries
  - Late non-competing applications
- Delays Sending Just-In-Time (JIT) Info
  - IRB Approvals
  - IACUC Approvals
  - Certification of Education
  - Other Support

## What Can Delay the Award Process? (Continued)

- Missing Information
  - Signature of the Business Official
  - Adequate Budget Justifications
  - Biosketches of Key Personnel
  - Population data for clinical trials
  - In-depth justifications for carryover

## What Can Delay the Award Process? (Continued)

- Overlap
  - Scientific
  - Budgetary
  - Commitment
- Timing of Requests
  - Requesting a transfer at the end of the fiscal year
  - Continuing Resolution



## Top 4 Items Missing From An Application?

## NCI Analysis of Type 5 Applications

Major Deficiencies – Causes of Delays  
(information missing or not acceptable)

- Human IRB
- SNAP Questions
- Animal IACUC
- Cost Analysis Info

Results in an average of 30% of progress reports incomplete!

## NIH Grants Policy Statement

A Necessary Resource for Grants Management (NIH and the Grantee). . .

- Provides Guidance on almost every policy issue
- Exception to the Policy Statement are rare and may only be done with the approval of the Grants Management Officer

## Most Frequent Post Award Issues

- Transfers between grantee organizations
- Change in scope
- Prior approvals
- Over or under expenditure of funds
- Carryover of Unobligated Funds
- Extensions with or without funds
- Supplements

## Transfers

- Must submit
  - Relinquishing Statement
  - Transfer Application – PHS 398 with a progress report
- 2 months in advance of start date
- Supplements for additional expenses rare

## Change of Scope

- Primarily a programmatic consideration
- For managers...look for indicators...ask questions
  - For example:
    - Purchase of equipment >\$25,000
    - New consortium
    - IRB approvals on new protocols
    - Shifting funds into or out of patient care costs

## Actions Requiring NIH Prior Approval

- Change in scope
- Change in status of key personnel
- Change of grantee organization
- Pre-award costs >90 days
- Transfer of funds awarded for trainee costs (stipends, tuition, and fees) except travel.

## Actions Requiring NIH Approval

- Foreign component added to a grant
- Deviation from NGA terms and conditions
- Second no-cost extension or one >12 months
- Construction ↔ non construction work funds

## Over/Under Expenditure

- Over expenditures
  - Discuss possibility of supplemental funds with Program Director/Officer
  - Supplements are rare, but possible
- Under expenditures
  - Large balances often indicate two things
    - Progress issues
    - Over funding

## Carryover of Funds

- Consult your NGA for authority to carryover unobligated balance from one budget period to another.
  - Is the mechanism excluded from automatic carryover?
  - Although mechanism has automatic carryover, are there restricted funds?
- Requesting a carryover?
  - Explain reason for unobligated balance
  - Submit a categorical breakdown of carryover request and justification on how funds will be used if carryover is authorized.

## Supplements - Administrative

- Cannot support a change in scope
- Must provide at a minimum:
  - Detailed categorical budget
  - Description of what is proposed
  - Discussion on currently available funds
- Administrative supplements are not routine!
- Variable among different Institutes

## Supplements - Competitive

- Are only to support a change in scope of the research.
- Are received 3 times a year and are reviewed by both a study section and council
- Funding may or may not be the same as regular grants

## Extensions With or Without Funds

- With Funds
  - Rare, but possible!
  - Discuss possibilities with your Program Director/Officer
- Without Funds
  - First request for up to 12 months done without a need for NIH approval.
  - All other requests need NIH approval.
  - Extensions completed through the Commons will not receive a revised NGA.

\*Only at the end of the project period

## Prior Approval Issues

- All requests for prior approval must be:
  - Submitted in writing
  - Submitted to the awarding IC's Grants Management Specialist no later than 30 days before the proposed change
  - Signed by the PI and administrative official
  - Only responses to prior approval requests signed by the GMO are valid.

See NIH Grants Policy Statement:

[http://grants2.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part1.html](http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part1.html)  
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Reminder

## CLOSEOUT: Final Reports

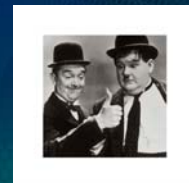
Failure to submit timely and accurate closeout reports may affect future funding!

- Final Financial Status Report (FSR)
- Final Invention Statement and Certification
- Final Progress Report

90-day requirement is a term and condition of all NIH grant awards!

## Rule of Thumb

Whenever PI's are contemplating post-award changes and are uncertain about the need for prior approval, consult in advance with:



### •Office for Sponsored Research

•Written policies and regulations  
(e.g.: NIH Grants Policy Statement)

•NIH awarding component's Grants Management Specialist and/or Program Director named on your NGA

## Program Management - After the Award Is Made

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Roger G. Sorensen

## Program Issues

- Delays in First Year Award
- Annual Progress Report
- Delays in "Out-Year" Awards
- Actions Requiring Prior Approval
- Administrative Supplements
- Grant Termination

## Delays in First Year Award

- **IRG Comments and Recommendations**
  - IRG reduces scientific scope, budget or time
  - Summary statement recommends design changes
  - NIH requests response to reviewer concerns
  - Requires NIH prior approval
- **Data Safety Monitoring Plan**
  - NIH must approve specific plan
- **Funding institute makes administrative cuts**
- **NIH Appropriation Status**

## Annual Progress Report: General Issues

- **Due**
  - 60 days prior to budget period start date
  - 45 days prior for eSNAP
- **Submit**
  - to NIH's Centralized Receipt Point
  - NIH Guide Notice [NOT-OD-04-063]:**  
<http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-04-063.html>
  - Better Yet: thru NIH eRA Commons
- **Don't wait for us to remind you!**

## Annual Progress Report: Science

- **Summary of accomplishments**
  - Specific aims – *as funded*
  - Results
  - Significance
  - Plans in next budget period
  - Keep it brief - 2 pages
- **What isn't working**  
*...and what will you do about it?*

## Annual Progress Report: Science

- Explain any changes in Human Subjects or vertebrate animal research
- Report on gender and minority inclusion
  - Inclusion Enrollment Report
- Discuss supplements in separate section
- List of publications generated by this study
  - Copy must be attached

## Potential Delays in "Out-Year" Awards

- Inclusion Enrollment Report is missing
- Apparent Changes in Scope not approved in advance
- Late submission of application
- Little or no progress with no discussion of problems and potential solutions
  - Contact program officer early!

## Actions Requiring Prior Approval

### *Changes in Scope -- Definition*

- Significant change in aims, methodology, approach, or other aspects of project objectives
- Reflects significant change from the peer-reviewed and Council-approved project
- Grants Management Specialist must approve
  - Program Officer will review scientific issues

## Actions Requiring Prior Approval

### *Changes in Scope -- Examples*

- Changes in specific aims
- Changing to a different animal model
- Any change from the approved use of animals or human subjects
- Shifting research emphasis to a different disease area
- Significant rebudgeting (>25% total award)

## Actions Requiring Prior Approval

### *Change of Grantee Institution*

- NIH Program Officer assesses
  - Adequacy of resources and environment
  - Availability of expertise (key personnel)
  - Potential problems (e.g., equipment)
- Contact NIH early!
  - Grants Management and Program Officer

## Actions Requiring Prior Approval

- Change of PI
- Significant change in PI effort
  - 25% change or greater
  - Impact on commitment to project completion
- PI absence of 90 days or more

## Administrative Supplements

- Increase diversity in researcher community
- Cover unanticipated expenses of work within scope of grant
- Maintain lab or team during funding hiatus in competitive renewal phase
- Closeout of grant

## Supplements to Increase Diversity in Researcher Community

- Research Supplements to Promote Diversity in Health-Related Research (PA-05-015)
  - Individuals from underrepresented racial and ethnic groups
  - Individuals with disabilities
  - Individuals with disadvantaged backgrounds
- Supplements to Promote Reentry into Biomedical or Behavioral Research Careers (PA-04-126)
  - Individuals with high potential to reenter research after taking time off to care for children or attend to other family responsibilities

## Supplements to Cover Unanticipated Expenses of Work Within Scope of Grant

- Not intended to cover inflationary increases in supplies, animal care, etc.
- Critical equipment breakdowns
- Catastrophes or natural disasters
- Loss of source for critical reagents
- Generally one-time supplements, not to cover changes in scope

## Supplements to Maintain Lab During Funding Hiatus in Competitive Renewal Phase

- Referred to as Bridge or Hardship Awards
- Applications with high likelihood that revision will improve score enough to fund
- Avoids disruption caused by loss of personnel or scientific momentum
- Maintains a unique or critical resource

## Supplements to Close Out Grants

- Finish work that would be of clear benefit to NIH and research community
- R01 Clinical Trials where termination without completion of studies is particularly undesirable
- *VERY RARE!*

## Grant Termination

- Early Termination
  - PI leaves research project without qualified and willing replacement
  - PI changes research direction or takes on new projects
- Grant not renewed
  - Maintain active status of grant during competitive renewal process with No-Cost Extension

## Grant Termination

- Grantee legally bound to submit
  - Financial Status Report
  - Final Invention Statement and Certification
  - Final Progress Report
- Failure to submit timely final reports may affect future funding
- Tracking these down can take significant NIH staff time

Before "Closing Out"  
this presentation,  
we want to test your  
knowledge...



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# Face-to-Face with the NIH

On the Field Today...  
Your NIH Panel:  
**Cheryl Chick & Roger Sorensen**  
March 31, 2006



## Administrative Requirements



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### Who Makes the Call?



## Who Makes the Call?

Grantee or the NIH

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Your quarterback (PI) needs more time to complete the final year of his U01 grant (at least 9 months).

### Who Makes the Call?

**The Grantee**



## Grantee's Expanded Authorities

- No Cost Extensions:
  - At the end of the project period, the grantee may extend the project up to 12 months without prior approval.
  - Notify NIH awarding office 10 days prior to the expiration date of the project period or up to the last day of the budget period if submitting through the Commons.

See NIH GPS Summary of Expanded Authorities  
[http://grants2.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part7.htm](http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm)

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Your quarterback (PI) requests additional players to complete the play - or to clarify, the PI determines that the addition of a local physicians group would be helpful in completing one of the aims approved by the SRG.

Who Makes the Call?  
The Grantee



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## Grantee's Expanded Authorities

- Third Party:
  - The grantee may transfer the performance of programmatic work to a 3<sup>rd</sup> party without prior approval, unless it involves a foreign site or there is a change in scope.



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You're in the 3<sup>rd</sup> year of a U01 and discover that there is an unobligated balance of 20% from last year and the PI wants to use the balance in this year's budget.

Who Makes the Call?  
The NIH



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## Carryover Authority

- Expanded Authorities (EA):
  - Although all awards are under EA, (in general) the following mechanisms still require carryover approval:
    - Center Grants (P50, P60, P30, etc)
    - Cooperative Agreements (U's)
    - T's and F's (Kirschstein-NRSA)\*
    - Individuals
  - Unobligated balances over 25% of total amount awarded should be submitted to the GMO for review.

\*Check your NGA for confirmation of automatic carryover authority.



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On last year's NGA, the awarding IC restricted funds for travel on a P01. The PI wants to carryover the unobligated funds to the current year for possible travel use in this year's budget.

Who Makes the Call?  
The Grantee



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## Carryover Authority

- Expanded Authorities (EA):
  - On mechanisms with automatic carryover, restricted funds may be carried over, but may not be used without prior approval.
  - On mechanisms without automatic carryover, who have restricted funds, must make 2 requests:
    1. Carryover the unobligated balance
    2. Use the restricted funds in the new budget period



When the PI submits the noncompetitive renewal for her R01, she has included a budget and justification for the use of mice. In reviewing the application, you discover that mice studies were not approved during the Scientific Review Group's review.

**Who Makes the Call?**

**The NIH**



**Prior Approval Issues**

- Change in Scope:
    - Grantee makes the initial determination of significance of a change and should consult with their grants management specialist as needed.
    - The following items may indicate a change in scope:
      - Change in aims
      - Significant rebudgeting (deviation between categories of more than 25% of total awarded costs)
      - Change in use of animals or humans
      - Significant change in key personnel
      - Shift in research emphasis
      - Application of new technology
- Refer to NIH Grants Policy Statement for further information!



The PI has notified the Sponsored Project's Officer that he needs to reduce his effort from 60% to 30%.

**Who Makes the Call?**

**The NIH**



**Prior Approval Issues**

- Change in Status (including absence of PI & other Key personnel):
  - Grantee must notify NIH if the PI will:
    - Reduce his/her time by more than 25% of approved effort at time of award
    - Withdraw from the project
    - Be absent for more than 3 months



Your quarterback (PI) decides to leave the team (transfer without the grant) in the middle of the game and wants to recommend one of his co-investigators as the new PI.

**Who Makes the Call?**

**The NIH**



**Prior Approval Issues**

- Change in Status (including absence of PI & other Key personnel):
  - Prior approval must be from NIH for the replacement of the PI or Key Personnel
  - Request should include:
    - Justification for the change
    - Biographical sketch of the individual proposed
    - Other sources of support
    - Budget Changes resulting from the change
    - Human Subject Certification (if applicable)



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### What would a football game be without equipment?

The PI has provided you with 3 quotes for a special microscope that is necessary for the project, but not previously approved by NIH. All of the quotes are between \$25,000 and \$30,000. (Significant rebudgeting is not required for the purchase.)

Who Makes the Call?

The Grantee



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### Prior Approval Issues

Under Expanded Authorities, prior approval from NIH is not required for equipment costs exceeding \$25,000 (as long as it does not qualify as a change in scope).



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### Grants Management Issues

TRUE or FALSE

It is acceptable for the PI to sign the application or progress report after the business official.

FALSE



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### Grants Management Issues

The business official signs the progress report/application on behalf of the grantee organization confirming to the NIH that the grantee is in compliance.



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### Grants Management Issues

TRUE or FALSE

At the NCI, the most frequent item missing from the progress report is the Human Subjects IRB approval date.

TRUE



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### Grants Management Issues

TRUE or FALSE

The final closeout reports are required from the grantee within 60 days following the end of the project period.

FALSE

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## Grants Management Issues

All Final Closeout Reports are due within 90 days following the end of the project period.

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## Grants Management Issues

**TRUE or FALSE**

You may contact NIH for PHS 398 and/or PHS 2590 application kits.

**FALSE**

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## Grants Management Issues

Application kits for the PHS 398 and PHS 2590 are no longer available.

Application forms and instructions are available on-line.

The newest version of these forms required for applications submitted after May 2005.

Also...

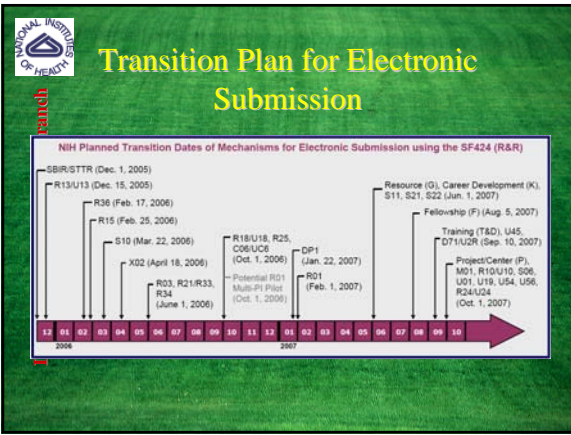
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## Are you ready for the "new kid" in town? - SF 424 (R&R)

- Electronic submission via Grants.gov
- Go to <http://era.nih.gov/ElectronicReceipt> !
- Guide Notice provided detailed instructions
- Grants.gov & NIH eRA Commons registration needed

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-067.html>



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## You Make the Call!

On average, what is the percentage of progress reports are submitted late or incomplete?

- 10
- 20
- 30

**←**



**You Make The Call!**

**Name the Top 4 Missing Items from Progress Reports!**

- #1. Human Subjects (IRB)
- #2. SNAP Questions
- #3. Animal Approval Dates (IACUC)
- #4. Cost Analysis Information

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**Who Makes the Call?**

Program Director (PD)  
or  
Grants Management Specialist (GMS)

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**Program Director or Grants Management Specialist?**

- Who reviews and approves program announcements to ensure compliance with laws, regulations, and sound business practices?
- GMS

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**Program Director or Grants Management Specialist?**

- Who evaluates grant applications for their scientific merit and determines which applications best meet program goals?
- PD


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**Program Director or Grants Management Specialist?**

- Who performs post-award monitoring activities, including site visits?
- Both

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It's Monday Night Football and the teams are on the field.

New England Patriots vs. Washington Redskins.

Who will win the game?

**You Make the Call!**

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**Questions?**

**Bring 'em on!!!**

