Post-Award Administration An Overview for New Investigators

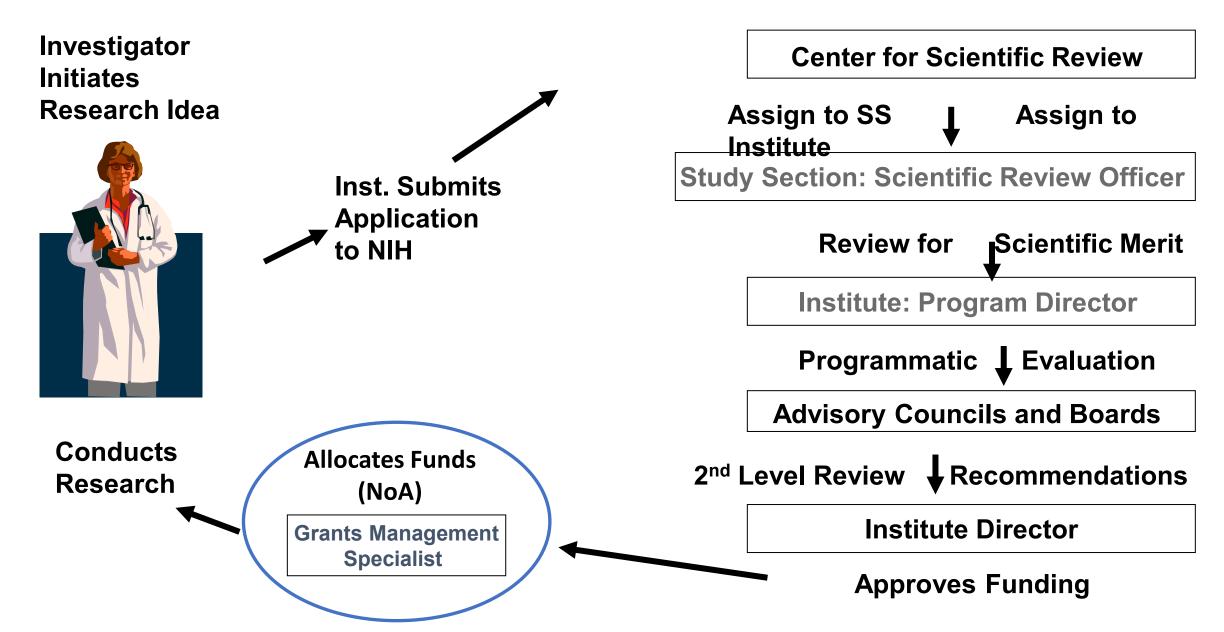


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Topics to Discuss:

- The Notice of Award (NoA)
- Annual Reporting
- Post Award Issues Unobligated Balances, Problems with the Research
- Prior Approvals Recipient Authorities, the Rules, the Requirements, Examples
- Closeout
- Resources
- Final Reminders & Things to Consider

The NIH Grant Application Cycle



The Notice of Award (NoA)

What is it?

The Notice of Award (NoA):

- Electronically available to recipient
- Legally binding document
- Identifies grant number, recipient organization, PD/PI
- Establishes period of approved support
- Sets forth terms and conditions
 - accept these by drawing down funds from the Payment Management System
- Includes awarding agency contact info Grants and Program

The NoA, continued:

- Establishes funding levels
 - Initial year is obligated via the Notice of Award
 - Future year amounts are commitments & subject to change, pending FY funding policy
- Funds are made available via the Payment Management System
- All restricted funds must be tracked separately
- Recipients are responsible for connecting all expenses to the award

Your institution's Sponsored Projects staff will help you with this!

Annual Reporting: Research Performance Progress Report (RPPR)

What's Due When?

The NIH Research Performance Progress Report (RPPR) Cycle

Inst. Submits RPPR to NIH

DCB: Program Director

OGA: Grants Mgmt. Specialist

Conducts
Research,
Presents results,
Publishes results

Programmatic Review Administrative Review

ward

Notice of Award for next budget period



Annual Reporting:

- Annual reports are required to be submitted using the <u>Research</u> <u>Performance Progress Report (RPPR)</u> module in eRA Commons
 - Required for all awards
 - No updated IRB or IACUC approvals needed during RPPR submission
 - RPPR Questions: Change in Other Support? Change in effort for key personnel? Unobligated balance greater than 25%?
 - Ensure all programmatic requirements are accounted for (as appropriate)

Annual Reporting, continued:

- Streamlined Non-Competing Award Progress (SNAP) RPPRs (ex. virtually all R-series grants)
 - Due no later than 45 days prior to the listed start date
- Non-SNAP RPPRs (ex. U01, P01, etc.)
 - Due no later than 60 days prior to listed start date
 - Requires detailed budget
 - Annual Federal Financial Report
- Multi-Year Funded (MYF) RPPRs (ex. DP2s)
 - Due on or before the anniversary of the budget/project start date
 - See terms and conditions of award for specific due date
 - Does not receive a Notice of Award each year

Post-Award Issues

What are they? What can be done?

Unobligated Balances:

- Does the award have "carryover authority"? (listed on NoA)
 - Generally, R series will have automatic carryover
 - Generally, U01s will not have automatic carryover
 - Carryover authority is not applicable to Multi-Year Funded awards
- Bona Fide Need Rule
 - Can the awarding agency expect all available and next year's funds to be spent in the listed time period?
- Provide an accurate estimate of the balance and assessment of the project
- Explain what may have occurred and what is planned

Unobligated Balances, continued:

- Tips on working with NIH on situations regarding the balance:
 - Balances typically equate to slow progress be forthcoming
 - Submit timely reports (FFRs) and information
 - Discuss options proactively there are a lot of different options!

WE ARE NOT LOOKING TO TAKE THE \$ - we are looking to do what is in the best interest for all parties!

Problems with the Research?

- Scientific and, therefore, budget delays do occur
 - Research is starting slower than expected
 - Issues with hiring personnel
 - Trouble with obtaining necessary approvals
 - Enrollment is lower than anticipated
- Engage with your Grants Management and Program staff sooner than later
 - Will greatly aid in future conversations and considerations

Prior Approval

Needed or Not?

Recipient Authorities:

- Standard terms and conditions of award give many authorities to the recipient (i.e. no need for prior approval). This includes (in general):
 - Carryover of unobligated balances unless stated otherwise on the award
 - Cost-related changes/rebudgeting unless change in scope
 - Extension of project period without additional funds (up to 12 months) except
 DP2
 - Transfer of work to a 3rd party unless change in scope or foreign entity
- Any authority listed in policy can be overridden by any special term on the award and/or specifics listed in the Funding Opportunity Announcement (FOA)

The Rules:

- The following items do require prior approval, provided by OGA:
 - Addition of a foreign component
 - Pre-award costs more than 90 days ahead of a competing award
 - Change in scope
 - Deviation from award terms and conditions
 - Change in the PI or other key personnel identified in the award
 - Change in recipient organization (i.e. transfer)
 - Extension for more than 12 months
 - Need of additional funding

The Requirements:

- All requests for prior approval must be:
 - Submitted via e-mail or eRA Prior Approval Module include complete grant number, PD/PI name and recipient name
 - Must be submitted by the Authorized Organization Representative for the recipient
 - Submit the request 30 days prior to change
 - Send the request to the award's Grants Management Specialist and Program Official
 - Detail the specific need with appropriate justification (scientific and budget, as appropriate)

Prior Approval

Some Examples

Key Personnel:

- Change in the PI or key person's status
 - NIH definition of key person PI or PIs (if multiple) and any person named on the award
 - Any change in effort greater 25% from approval level
 - Replacement or absence greater than three continuous months
 - All others do not need NIH's prior approval
 - Be sure to detail any scientific and budgetary impact in the request
 - Include biosketch and other support
 - If multi-PI, address the leadership plan

Change of Recipient Organization:

- Award belongs to the recipient organization and must be relinquished
- Need to submit a change of recipient organization application
- Address any impact to the award because of the change
- Issues that are typically encountered:
 - Late notice of a PI leaving (ex. find out in the RPPR)
 - Late submission of the relinquishing and/or transfer application
 - An associated change in scope of the project
 - Multi-PI situation where the contact PI is moving
 - The proposed new recipient organization will not be substantially involved in the project

Change in Scope:

- Recipient makes the initial determination on significance of change
- Consult with NIH as needed
- The following *may* indicate a change in scope:
 - Significant rebudgeting of more than 25% of total award
 - Change in use of animals or human subjects research
 - Significant change in key personnel
 - Shift in research emphasis
 - Application of new technology

Closeout

It's Serious Business!

Closeout:

- Process by which NIH determines that all applicable administrative actions and all required work of an award have been completed by the recipient and NIH.
- All applicable reports are due no later than 120 days after the project end date – See Project Period End Date on Notice of Award
 - Final Federal Financial Report
 - Final Research Performance Progress Report
 - Final Invention Statement and Certification
- Delinquent Reporting may result in Unilateral Closeout

Available Resources

A Very Small Sampling...

Resources:

- NIH Grants & Funding Page https://grants.nih.gov/grants/oer.htm
 - Instructions & Forms Library
 - NIH Grants Policy Statement update published annually
 - NIH Guide for Grants & Contracts (FOAs, Policy Notices, etc.)
- NCI Grants and Training Page https://www.cancer.gov/grants-training
 - Policies and Processes
 - Grant Funding Information (FOAs, Funding Strategy, etc.)
- Office of Laboratory Animal Welfare https://olaw.nih.gov/
 - Policy Changes & Guide Notices
 - Reporting Noncompliance

Resources, continued:

- Clinical Trial Requirements for Grants and Contracts https://grants.nih.gov/policy/clinical-trials.htm
 - Policies & Changes
 - Clinicaltrials.gov Registration & Reporting
- Research Involving Human Subjects https://humansubjects.nih.gov/
 - Regulations, Policies & Guidance
 - Human Subjects Protections Training
- Public Access Policy https://publicaccess.nih.gov/
 - When & How to Comply
 - Managing Papers & Reporting to NIH

Final Reminders & Things to Consider

Please, Don't Forget!

Reminders & Things to Remember:

- Submit timely reports and applications be sure to follow the instructions!
- Stay on top of the requirements (ex. Public Access and Financial Conflict of Interest)
- Make sure to know your organization's policies and procedures
- Have conversations at the appropriate time with Program about your continuation
- Prepare for closeout for any projects that are ending
 - Close-out is serious business see NIH guidance



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