Post-Award Administration

An Overview for New Investigators

NIH NATIONAL CANCER INSTITUTE

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Topics to Discuss:

- NCI Budget Process – a quick overview
- The Notice of Award (NoA) – What is it?
- Annual Reporting – What's Due & when?
- Post Award Issues – Hit a bump in the road?
- Prior Approvals – Is approval needed to make this change?
- Resources – I have more questions!
- Final Reminders & Things to Consider

NCI Budget Process

A Quick Overview

NCI Budget Process – A very quick overview

- NCI receives funding when the President signs the appropriations bill into law making funds available to executive agencies, including NCI.

- NCI Budget offices allocate the budget to various areas:
  - Intramural - ~18%
  - Research Management & Support - ~7%
  - Building and Facilities - ~0.4%
  - R&D Contracts - ~13%
  - Grants - ~62%

- How is the 62% divided up among the different grants?

NCI Budget Process – A very quick overview (cont'd)

- Commitments:
  - Mandated Small Business Set Aside each year – approximately 6% of the allocated grant budget
  - Non-competing awards – usually totals about 71% of the allocated grant budget

- Leaves only 23% of the grant allocation to be spent on competing awards
  - Any funding opportunity set asides must be considered – approximately 2% of the budget
  - Remaining 21% of budget can be utilized for RPGs.

- Applications are funded in score order until the funds are expended.

The Notice of Award (NoA)

What is it?

The Notice of Award (NoA) – In Detail!

- Available in the eRA Commons & Provides:
  - Grant number, recipient organization, and Principal Investigator(s)
  - Period of support
  - Amount of funds provided
    - Funds for the current year are available.
    - Future years are commitments & subject to change, depending on Fiscal Year funding policies.
  - Terms and Conditions
    - legally binding, so be familiar with what they are!
    - Drawing funds from the award constitutes agreement with the terms.

- Your institution's sponsored projects staff will help you navigate this – reach out to them for assistance!

Annual Reporting

What's Due When?

Annual Reporting – What's Due & When:

- Annual reports are required to be submitted using the [Research Performance Progress Report (RPPR)](#) 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%?
  - Public Access (publications) and Invention Reporting, if applicable
  - Ensure all programmatic requirements are accounted for (as appropriate)

Annual Reporting – What's Due & When, continued:

- Due Dates
  - Streamlined Non-Competing Award Process (SNAP) RPPRs (e.g. Most R series grants) – 45 days prior to start date
  - Non-SNAP RPPRs (e.g. U01, P01, etc.) – 60 days prior to start date
  - Multi-Year Funded (MYF) RPPRs (e.g. DP2s) – by the anniversary date
- Other Reports
  - Federal Financial Reports for awards not subject to SNAP
    - 90 days after the calendar quarter of the budget end date (3/31, 6/30, 9/30 or 12/31)
  - Financial Conflict of Interest Reports
    - any investigator on the award with a significant financial interest that could directly & significantly affect the award

Post-Award Issues

Hit a Bump in the Road – Now what?

Unobligated Balances:

- Funds remaining at the end of the budget period are an "unobligated balance"
- Does the award have "carryover authority"? (listed on NoA)
  - Generally, R series – Yes; U series – No
  - Carryover authority is not applicable to Multi-Year Funded awards
- Bona Fide Need Rule
  - Can NCI expect all currently available funds plus the 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:

- Balances greater than 25% of the current year's award must be reported on the RPPR
  - If award does not have carryover authority, prior approval request to carryover funds to next budget period is required.
- 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
  - The earlier we know, the more options for resolution you will have!

Prior Approval: Needed or Not?

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Recipient Authorities – What you can do:

- 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)
  - 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 Notice of Funding Opportunity (NOFO)

The Rules – What you need prior approval to do:

- 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 – Asking for approval:

- Requests should be submitted via the [eRA Prior Approval module](#)

  - If it must be emailed, the AOR must send the request to NCIGrantsPostAward@mail.nih.gov with a cc: to the assigned Program Official

- Submit the request at least 30 days prior to the proposed change

- Provide a scientific and/or budgetary justification for the change

- Approval for any prior approval request *must* come from the Office of Grants Administration

Prior Approval:
Some Common 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 – report changes for those individuals on the annual RPPR
  - Be sure to detail any scientific and budgetary impact in the request
  - Include biosketch and current Other Support
  - If multi-PI, address the leadership plan

Change of Recipient Organization:

- Award belongs to the recipient organization and must be relinquished
- New institution needs 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 &/or the proposed new recipient 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

Available Resources

I have A LOT more questions…

Resources:

- NIH Grants & Funding Page - https://grants.nih.gov/grants/oer.htm
  - NIH Grants Policy Statement – update published annually
  - NIH Guide for Grants & Contracts (NOFOs, Policy Notices, etc.)
- NCI Grants and Training Page - https://www.cancer.gov/grants-training
  - Policies and Processes
  - Grant Funding Information (NOFOs, Funding Strategy, etc.)
- Office of Laboratory Animal Welfare - https://olaw.nih.gov/
  - Policy Changes & Guide Notices
  - Reporting Noncompliance
- Invention Reporting - https://seed.nih.gov/small-business-funding/small-business-program-basics/grant-policy/ip

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/
  - Managing Papers & Reporting to NIH
- Financial Conflict of Interest Policy - https://grants.nih.gov/grants/policy/coi/index.htm

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 (e.g. 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

Thank You!

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