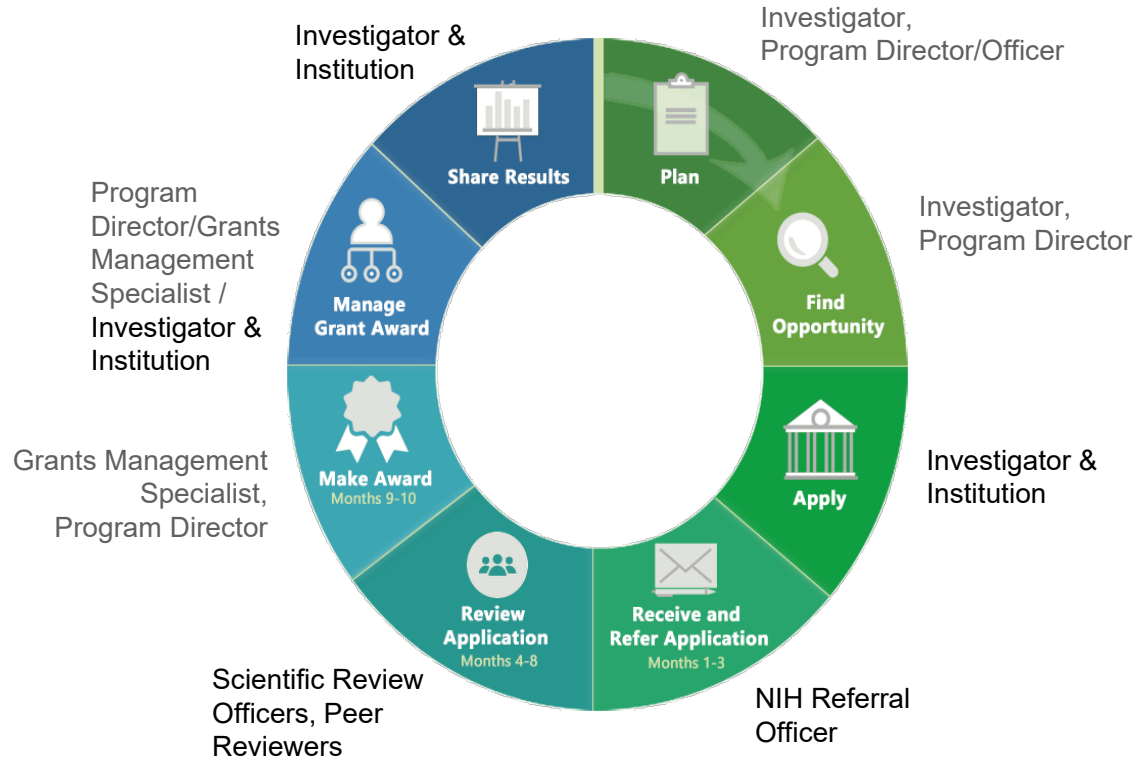


Session I

Enhancing Your Interactions with NCI Staff

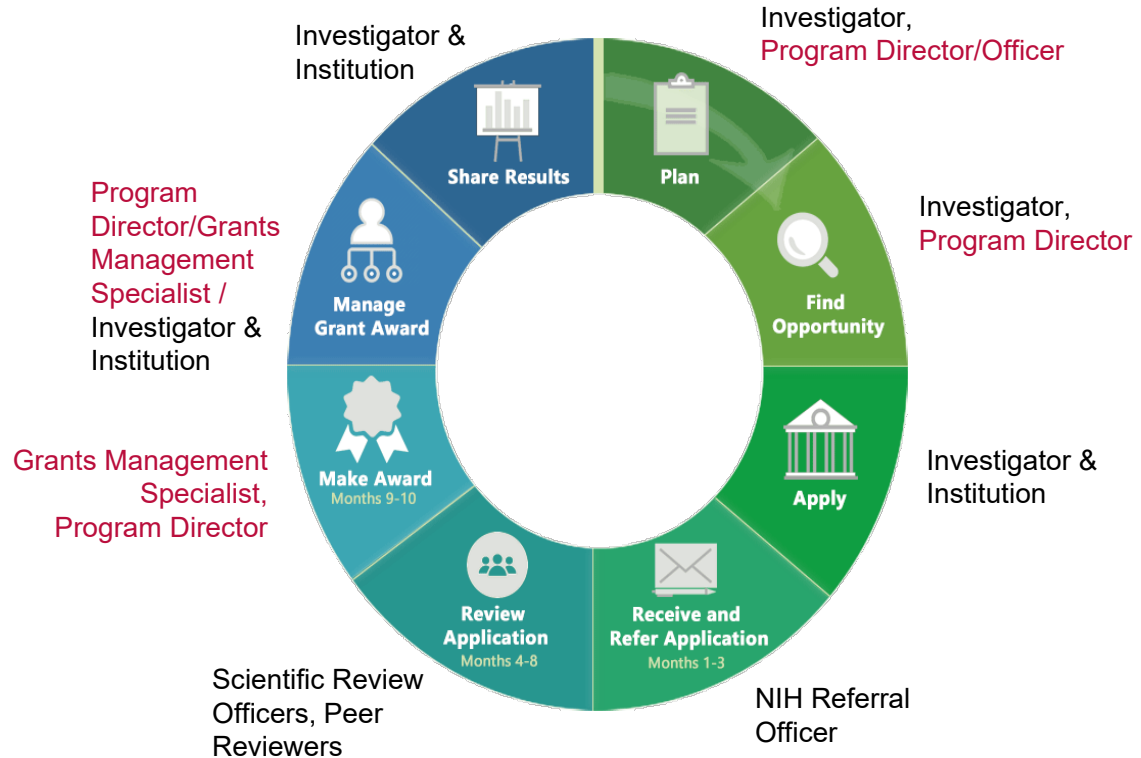
Danielle Carrick, MHS, PhD
Epidemiology & Genomics Research Program
Division of Cancer Control and Population Sciences
October 30, 2023

Grants Process at the NIH - Key Players



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

Grants Process at the NIH – Key Players



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Session I: Enhancing Your Interactions with NCI Staff

| | |
|-----------|---|
| 9:20-9:35 | Role of the Program Director Frank Perna, Ed.D., Ph.D., Program Director, BRP, DCCPS |
| 9:35-9:50 | Role of the Grants Management Specialist Dawn Mitchum, M.P.H., CRA, Branch Chief, NCI Office of Grants Administration (OGA) |

A New Investigators' Guide: Tools and Tips for NIH Funding and Advancing Your Science

*Prepared and written
by Norbert Tavares (a
fellow at NCI in 2019)*



<https://www.grantshub.iastate.edu/wp-content/uploads/2019/04/New-Investigators-Guide-v2.pdf>

Role of Program Director

An Overview for New Investigators

Frank Perna, EdD, PhD

Program Director, Behavioral Research Program

Division of Cancer Control and Population Sciences

October 30, 2023

Role of Program Director

Promotion of Science within NCI and Across NIH

- Identify gaps in the research portfolio and future directions
- Scientific liaison with other institutes, agencies, professional societies
- Develop NCI/Trans-NIH FOAs and other scientific opportunities

Scientific Oversight

- Manage portfolio of grants within scientific area of expertise
- Oversee programmatic, scientific and technical aspects of grant
- Work with prospective and current grantees on grant idea development/submission and scientific management, respectively

Work with Prospective and Current Grantees

- Review and discuss specific aims prior to submission
- Help connect PI with other relevant work and possible collaborators
- Identify possible NOFAs (e.g., grants) and study sections
- Review summary statement and discuss next steps
- Post Award: Review grant progress, answer questions, and generally discuss issues that arise e.g.,
 - Changes to aims, protocol adaptations, measurement update
 - Participant recruitment
 - Relocation
- Discuss next grant(s) and possible supplements
- Data Sharing Requirements- Session dedicated to topic Day-2

Thank You

Frank Perna, Ed.D., Ph.D.
Program Director
Health Behaviors Research Branch
BRP/DCCPS
pernafm@mail.nih.gov



Role of Grants Management & Post-Award Administration

An Overview for New Investigators

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

Investigator
Initiates
Research Idea



Inst. Submits
Application
to NIH

Center for Scientific Review

Assign to SS

Assign to Institute

Study Section: Scientific Review Officer

Review for Scientific Merit

Institute: Program Director

Programmatic Evaluation

Advisory Councils and Boards

2nd Level Review Recommendations

Institute Director

Approves Funding

Conducts
Research

Allocates Funds
(NoA)

Grants Management
Specialist

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:

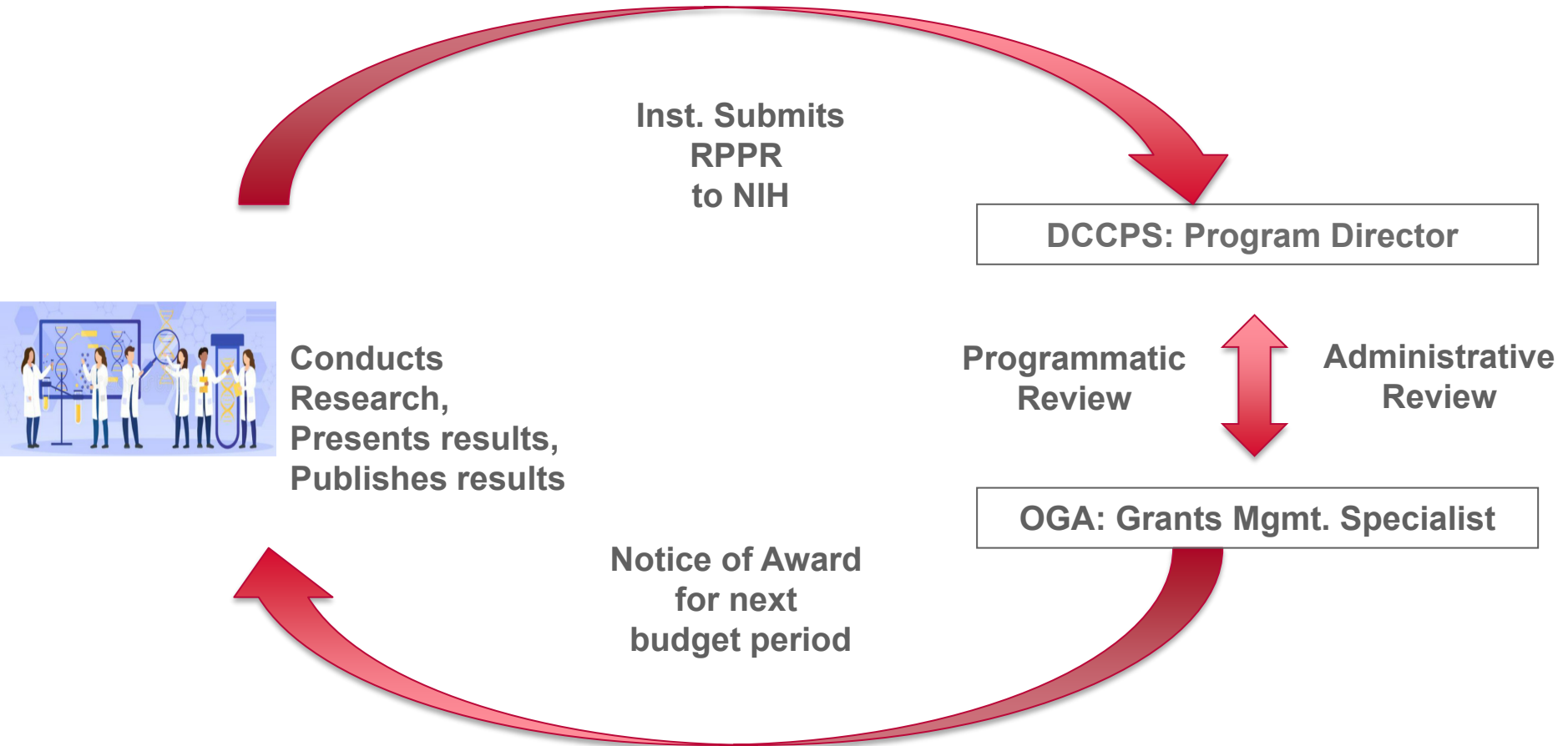
- Establishes funding levels
 - Initial year is obligated via the Notice of Award
 - Future year amounts are commitments & subject to change, pending FY funding policy
- Funds are made available via the Payment Management System
- All restricted funds must be tracked separately
- Recipients are responsible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



Annual Reporting:

- 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%?
 - 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 in working with NIH on situations regarding the balance:
 - Balances typical 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, OIA
 - 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:

- The following items do require prior approval, provided by OGA:
 - Additional 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 NCIGrantsPostAward@nih.gov 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
 - 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://grants.nih.gov/grants/olaw/olaw.htm>
 - 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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