Role of Program Director and Grant Specialist

Damali Martin, PhD, MPH
Division of Cancer Control and Population Sciences
Sharon Ross, PhD, MPH
Division of Cancer Prevention
Amy Bartosch
NCI Office of Grants Administration

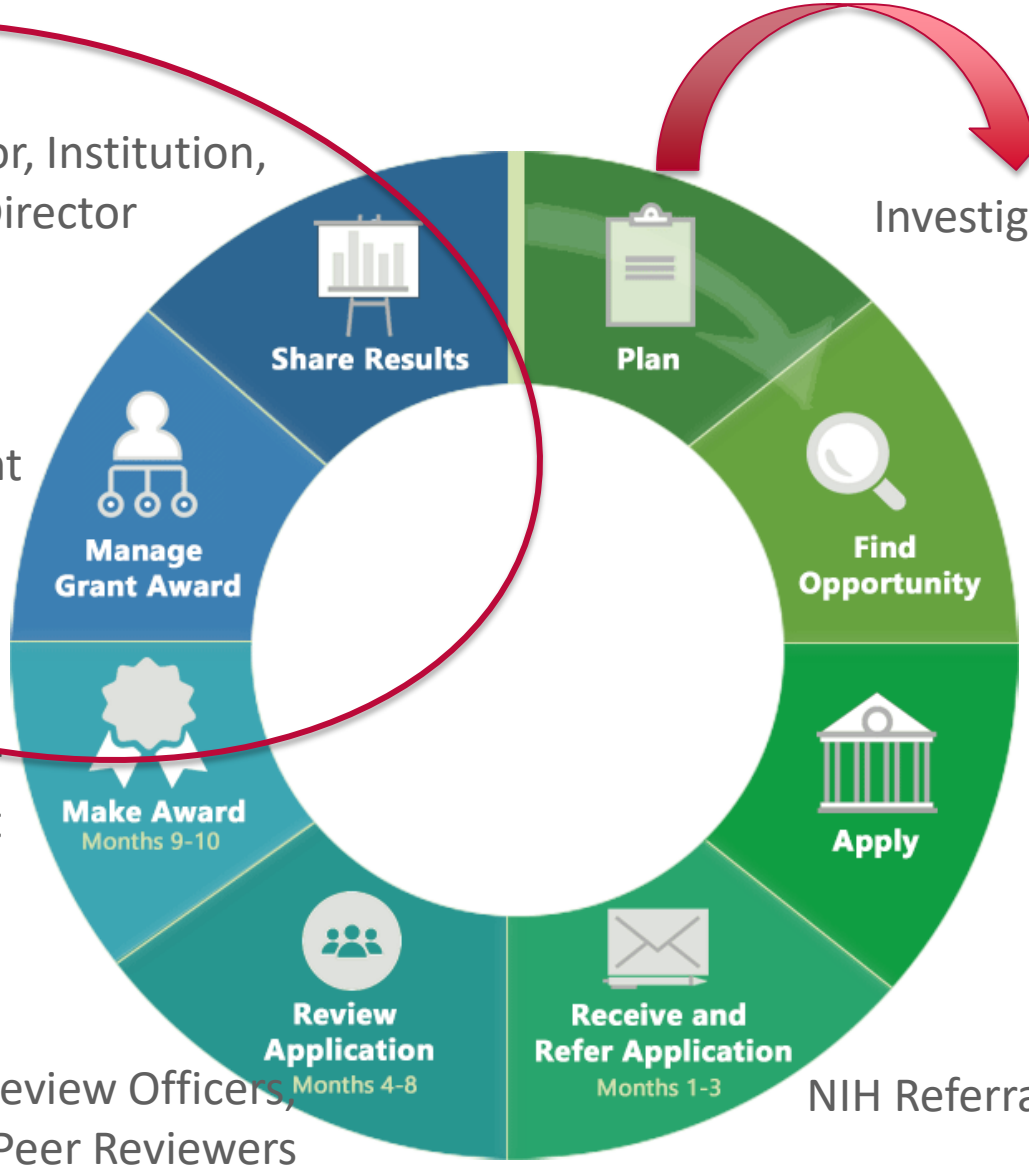
NIH NATIONAL CANCER INSTITUTE

2019 New Grantee Workshop
Division of Cancer Control and Population Sciences
Division of Cancer Prevention
November 21 - 22, 2019

Overview of Presentation

- Overview of roles of program directors and grant specialists
- Managing your R01
  - Notice of grant award (yearly)
  - Annual Research Performance Progress Report (RPPR)
  - Requests that requires prior approval e.g. carry-overs, re-budgeting
  - Transfers e.g. Change in institution, PI or Key personnel
  - Other requests e.g. second no – cost extensions, administrative supplements
  - Data sharing
  - Closing out
- Considerations for renewals

Grants Process at the National Institutes of Health (NIH)



Investigator, Institution, Program Director

Program Director, Grants Management Specialists

Grants Management Officer / Specialist

Scientific Review Officers, Peer Reviewers

NIH Referral Officer

Investigator, Institution

Investigator, Program Director

Investigator, Program Director

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

Role of Program Directors

- Oversee programmatic, scientific, and technical aspects of grants
- Manage portfolio grants within scientific area of interest/expertise
- Identify scientific opportunities, gaps in portfolio, future directions or trends in science
- Scientific liaison with institutes, agencies, professional societies
- Foster excellent science and promote effective communication and collaboration
- Stewards of taxpayers' funds ensuring that scientific investments are maximized and used to fullest potential

Role of Grants Management Specialists

- Oversee legal, administrative and financial aspects of award
- Negotiated the Notice of Award (NoA – formerly NGA) – legal terms of award
- Post Award
  - Assess progress reports (business side)
  - Prior Approval requests
- Stewards of taxpayers' funds ensuring that scientific investments are maximized and used to fullest potential

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!

The NIH Research Performance Progress Report (RPPR) Cycle

Conducts Research, Presents results, Publishes results

Inst. Submits RPPR to NIH

DCCPS/DCP: Program Director

Programmatic Review

Administrative Review

OGA: Grants Mgmt. Specialist

Notice of Award for next budget period

Annual RPPR:

- Submit using the Research Performance Progress Report (RPPR) module in eRA Commons
  - Required for all awards
  - No updated IRB or IACUC approvals needed
  - RPPR Questions: Change in Other Support? Change in effort for key personnel? Unobligated balance greater than 25%?
  - Ensure all programmatic requirements are addressed
  - Public Access, Financial Conflict of Interest, & Invention reporting requirements
    - Non-compliance can hold up issuance of the next segment of the award

Annual RPPR, continued:

- Streamlined Non-Competing Award Process (SNAP – ex. R01s)
  - 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
  - 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

Annual RPPRs:

- *What we do:*
  - Assess annual scientific progress
  - Ensure compliance with NIH policies

- *What we are mindful of:*
  - Life happens
  - Science doesn't always go as planned
  - Drifting scope
  - Change in human subjects research or in vertebrate animals use
  - No/few publications in latter years of award
  - Excessive or consistently limited progress
  - Excessive personnel changes
  - Reporting unrelated work
  - Repetitively not spending all money in a given year (carryover balance)

Prior Approvals – 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)
  - 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 before a competing award
  - Change in scope – some potential indicators could be:
    - Change study sites, Using new or different technology, Reducing study subjects numbers
    - Changes in Human and/or Animal Subjects
    - Significant re-budgeting of more than 25% of total award
  - 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 of more than 12 months
  - Need for additional funding

The Requirements:

- All requests for prior approval must be:
  - Submitted in writing/e-mail letter – included complete grant number, PD/PI name and recipient name
    - Some can be submitted electronically via Prior Approval Module
  - Must be submitted by the Authorized Organization Representative for the recipient
  - Submit the request approximately 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)

Requests that require prior approval

- *What we do:*
  - Assess need
  - Assess whether prior approval is required
  - Assess whether all required documentation is provided and signed by an Authorized Organizational Representative (AOR)
  - Work with OGA staff to complete appropriate internal approval processes
- *What we are mindful of:*
  - Whether the request needs an official response
  - Whether the request involves money
  - Repetitive requests from same individual

Unobligated Balances & Carry-Over

- 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 & Carry-Over, continued

- Tips in working with NCI 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 assess and are aware of the following:*
  - Why carry-over exists
  - How will the investigator propose to spend down carry-over in the upcoming year
  - How was scientific progress affected
  - Squirreling or repetitive carry-over balances (yearly)

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

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 & 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 Investigator, Key personnel or Institution

- *What we do:*
  - Discuss requirements with PIs in advance
  - Assess appropriateness of new investigator, key or institution and facilities
  - Assess progress
  - Assess remaining work to be accomplished

- *What we are mindful of:*
  - Time of transfer
  - Single PI or MPI, who's moving?
  - Including new collaborators
  - New subcontracts
  - Foreign sites – PI will need to indicate amount of funds to foreign site

Second No-Cost Extensions (NCEs)

- Justification to Program Director and OGA should describe what has been accomplished since first NCE:
  - Describe what was not completed and why
  - Describe how much funds are unobligated
  - Provide updated IRB and IACUC approvals, if applicable
  - What will be done during NCE period – timeline for completion, how will budget be used and any relevant information specific to the award

Administrative Supplements

- *What we do:*
  - Assess type of request
    - Diversity, equipment, or other topic specific supplements
  - Assess whether all required documentation is provided
  - Assess eligibility
    - Sufficient time remaining
    - Scope, relevance to active parent award
    - Request from PIs with previous carryover balance
  - Provide written justification/rationale to support (or not) the request
  - Submit a program funding request (PFR)

Data Sharing

2003 Data Sharing policy

- Applications seeking $500K or more in direct costs in any single year
- Policy expects final research data, especially unique data, from NIH-supported research efforts to be made available to other investigators
- Program directors ensure DS plan ins appropriate and adequate
- DS should be timely and no later than the acceptance for publication of main findings from the final dataset

2015 Genomic Data Sharing policy

- All NIH-funded research that generates large scale human or non-human GD, regardless of funding level.
- Smaller scale genomic data for a high priority area or special requirement of FOA
- Data should be submitted once it has been cleaned. Data will be released and available via controlled access for research that is consistent with dataset's data use limitations, either six months after submission process is initiated or at the time of first publication (whichever comes first)
- All PIs are expected to comply with Data sharing policies

Grant Close-Out – Final/Interim RPPR

What we do:

- Read all final progress reports to assess the following:
  - Overall progress for the grant e.g. publications, training, inventions, etc.
  - Scientific output/impact of the grant and determine whether aims were addressed
  - Ensure timely sharing of data e.g. dbGAP (also during annual progress reviews too!)
- Follow up with investigators on any outstanding issues
- Submit an approval of final/interim progress report

What we are mindful of:

- Issues throughout the life of the grant
- Publication policy compliant
- Reporting of unrelated work
- Reporting of unrelated publications
- Data that is not shared by end of the grant award

Renewals

- *What we do:*
  - Discuss renewal content, timing and budget with PIs in advance
  - Discuss options with PIs (renewal vs new)
  - Assess progress

- *What we are mindful of:*
  - Budgetary cap limits
  - Change in scientific direction
    - Appropriate program locus
  - Competing award policies
    - Number of active awards
    - Direct costs >$1M
    - Overlap issues
    - Bars to award
  - Current award end date

Competing Renewal vs. a New application

- Please consider the following for making the decision to submit a competing renewal:
  - Completion of previous study aims
  - New discoveries or new infrastructure created
  - Impact on the field – what do we know now from your research (in the previous grant) that we did not know before
  - Other metrics for progress – publications, training, career track for early stage investigators (esp. minority investigators)

Reminders & Things to Remember:

- Submit timely reports and applications – be sure to follow the instructions!
- Stay on top of the associated requirements (ex. Public Access, Financial Conflict of Interest, & Inventions)
- 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

Resources:

- NCI Cancer Currents - http://www.cancer.gov/news-events/cancer-currents-blog
- All About Grants Podcast - https://grants.nih.gov/podcasts/All_About_Grants/index.htm
- NIH Extramural Nexus - https://grants.nih.gov/grants/nexus.htm
  - Monthly newsletter for the extramural community
- RePORTER - http://projectreporter.nih.gov/reporter.cfm
  - NIH project databases and funding records
  - PubMed abstracts and full-text articles
  - U.S. Patent and Trademark Office Project descriptions, funding details, and research results

Resources, continued:

- 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

www.cancer.gov www.cancer.gov/espanol