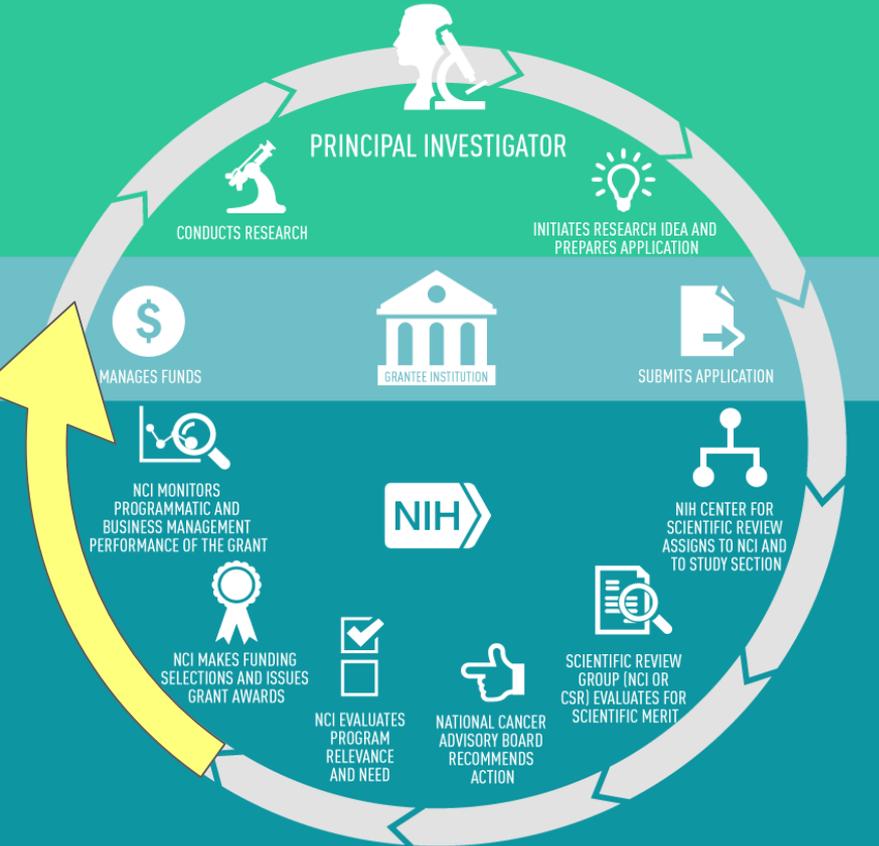


OVERVIEW OF THE NATIONAL INSTITUTES OF HEALTH AND NATIONAL CANCER INSTITUTE GRANTS PROCESS



The Office of Grants
Administration
Shane Woodward

Grants Management Branch B, Branch Chief
Office of Grants Administration

History of NCI's Research Grant Program

- In 1937, the [National Cancer Institute \(NCI\)](#) was created by the National Cancer Act with sponsorship from every Senator in Congress.
 - It was the first time Congress had appropriated funds toward a non-communicable disease.
 - The Act established the National Cancer Institute (NCI) as the federal government's primary agency to address research and training needs for the cause, diagnosis, and treatment of cancer.
 - The NCI was authorized to award grants to non federal scientists for research on cancer and to fund fellowships at NCI for young researchers.
- The first NCI grant was awarded on November 27, 1937, for \$27,550.

National Cancer Act of 1971



- National Cancer Advisory Board (NCAB), a presidentially appointed committee of 18 members
- A three-member panel, the President's Cancer Panel (PCP), review the program by holding periodic public hearings and submitting an annual progress report directly to the President.
- The annual budget of NCI, called the bypass budget, be submitted directly to the President, bypassing traditional approval by the NIH or the Department of Health and Human Services required of other NIH institutes.

National Cancer Act of 1971 continued



- The director of NCI was given additional authorities, in consultation with NCAB, under the act that include:
 - Create new cancer centers and manpower training programs
 - Appoint advisory committees, allowing the director to explore new issues/opportunities
 - Expand the physical location at NIH and other research facilities across the country
 - Award contracts for research
 - Collaborate with other federal, state, or local public agencies and private industry
 - Conduct cancer control activities
 - Establish an international cancer research data bank that collects, catalogues, stores, and disseminates results of cancer research
 - Award research grants



What is the Office of Grants Administration (OGA)?

- Manages all NCI business-related activities associated with NCI grants and cooperative agreements
 - Pre-Award - negotiation of budgets, period of performance, etc.
 - Award – determining terms & conditions of award, issuing Notices of Award
 - Post-Award - changes in the project (PI, effort, budget, scope, etc.), answering questions related to the Notice of Award (NoA), the reporting requirements, etc.
- Ensures that all legal, regulatory, and policy requirements are met by NCI and the recipients during all stages of the award process

Office of Grants Administration (OGA) Overview

- [NCI OGA Grants Management Staff](#)
- Offices located in Shady Grove and Frederick
 - Currently Full Time Telework
- Organizational Structure:
 - Director/Chief Grants Management Officer
 - Deputy Director
 - 4 Branches – 3 Grants Branches, 1 Business Operations Branch
 - 2-3 Teams per Branch for a total of 10 teams - 8 Grant Teams, 2 Business Operations Teams
 - Each Team has up to 5 individuals
 - Currently ~35 Grants Management Specialists (GMS)
 - ~65 total staff



Funding after CRCHD

- Types of Mechanisms to apply for:
 - R01 – Basic Research Project Grant (RPG)
 - R03 – Small grants, \$50K Direct Cost for 2 years
 - R21 – Generally \$275K Direct Cost over 2 years
 - R37 – A highly scored R01 that is converted to allow for the possibility of 2 more years.
 - R41 and R43 – Small Business Grants
 - U01 – R01 with substantial programmatic involvement
 - Developmental and Career Enhancement Funding
 - Offered through Cancer Centers and other Large networks



What are the Legal, Regulatory, & Policy Requirements?

- OGA – Standard Operating Procedures (SOPs)
- NCI – SOPs, Funding Policy, etc.
- NIH – NIH Grants Policy Statement (NIHGPS), NIH Guide Notices, Funding Opportunity Announcements (FOAs), etc.
- Others – a sampling:
 - Code of Federal Regulations – 45 CFR Part 75, 2 CFR Part 200
 - Public Laws – 109-282 (FFATA),
 - Office of Management & Budget – OMB Circulars
 - US Code – 44 USC Chapter 35 (Paperwork Reduction Act)



OGA Office of the Director

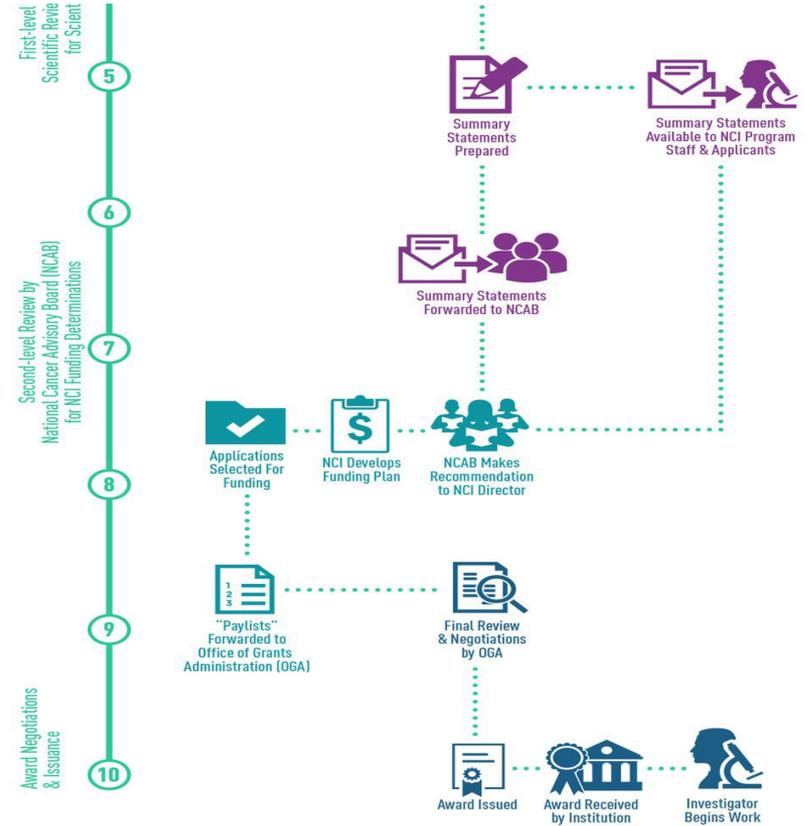
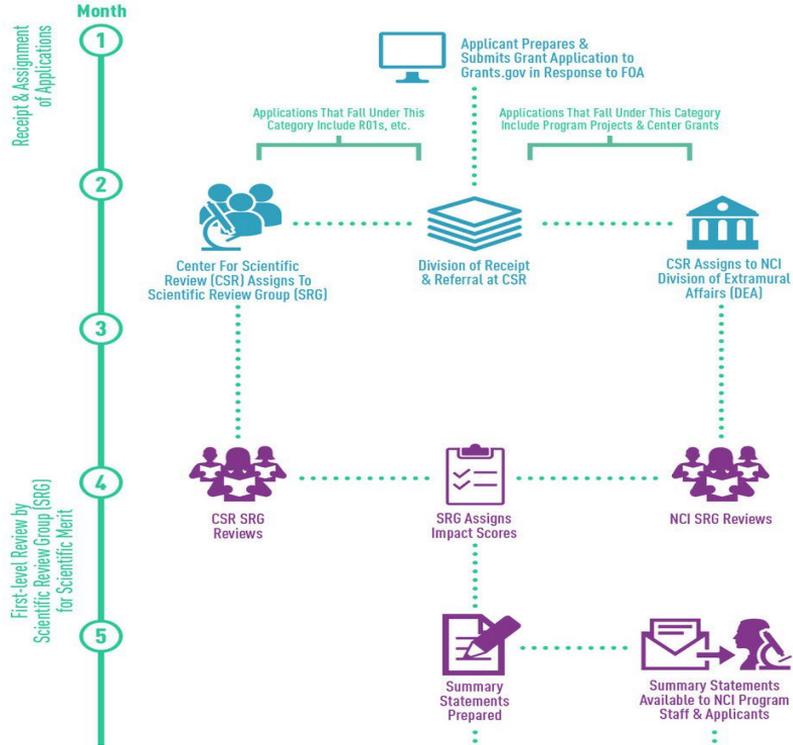
- Provides leadership, direction, and operational oversight
- Director is also NCI-designated Chief Grants Management Officer (CGMO)
 - 1 CGMO per NIH Institute/Center (IC)
 - Crystal Wolfrey
 - Provides leadership for the office which is responsible for the business and fiscal management of NCI's grant portfolio (over 8,000 grants, over 12,000 award actions)



OGA Office of the Director - Responsibilities

- Monitoring the financial assistance process
- Evaluating and monitoring the business management capability and performance of applicant organizations and recipients
- Evaluating and monitoring the internal operating procedures of the grant award process
- Interpreting and developing financial assistance policy
- Appointing and overseeing other Grants Management Officers (i.e. Specialists and other staff who can sign Notices of Award and obligate funds)

NATIONAL CANCER INSTITUTE GRANT APPLICATION DEVELOPMENT, SUBMISSION, REVIEW, & AWARD





Where Does OGA Fit In?

- Funding Opportunity Announcement (FOA) Review –
 - Grant Team Leaders review draft FOA prior to publication for any grants management related concerns
 - Grants Management contact will be listed in the FOA to address any questions

- After Review (IRG & NCAB) & Funding Selection
 - GMS will contact the applicant to request additional information
 - Just in Time Information (JIT) – Cannot be more than 120 days old at the time of award
 - Any other information needed to adequately determine the capability of the applicant organization to manage Federal Funds appropriately



Where Does OGA Fit In? cont'd

- After Award Issued -
 - Questions regarding the Notice of Award
 - Terms & conditions
 - Budget
 - Period of support
- Research Performance Progress Report (RPPR) Submission -
 - Questions about:
 - due dates
 - what to include
 - how to interpret instructions
 - GMS, in cooperation with Program, will follow up with recipient to address any missing items, to clarify any inconsistencies, etc.



Where Does OGA Fit In? cont'd

- Prior Approval requests – must go through Authorized Organization Representative (AOR) for submission to NCI
- Examples of common Prior Approval requests:
 - Significant reduction in effort for PI and/or Senior/Key Personnel
 - Changes in scientific Scope – Change in Human or Animal subjects use, modified aims, etc.
 - Carryover of unobligated balances – for awards that do not have automatic carryover authority

So, when do you hear from your GMS?

- Just in Time (JIT)
 - You will have likely already been contacted by NIH. However, funding is most likely when you hear from the GMS.
 - The GMS may also request additional budget information.
 - They will also be negotiating the dates and notifying of the award amount.
 - Funding cuts are universally applied.

I received my Notice of Award, now what....

- Read your entire NOA
 - Understand how much you have available spend on your research.
 - Approved budget is the amount you can spend.
 - NOA includes anticipated amounts of funding for future years (subject to policy of that Fiscal Year).
 - Work with your business official to receive regular reports of expended and remaining funds.

SECTION I – AWARD DATA – 1R01GM317713-01A1		
<u>Award Calculation (U.S. Dollars)</u>		
Salaries and Wages		\$87,146
Fringe Benefits		\$7,160
Personnel Costs (Subtotal)		\$94,306
Materials & Supplies		\$35,274
Subawards/Consortium/Contractual Costs		\$58,748
Tuition Remission		\$40,805
Federal Direct Costs		\$229,133
Federal F&A Costs		\$84,890
Approved Budget		\$314,023
Total Amount of Federal Funds Obligated (Federal Share)		\$314,023
TOTAL FEDERAL AWARD AMOUNT		\$314,023
AMOUNT OF THIS ACTION (FEDERAL SHARE)		\$314,023
SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
1	\$314,023	\$314,023
2	\$298,650	\$298,650
3	\$297,160	\$297,160
4	\$294,765	\$294,765
5	\$294,763	\$294,763
Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project		

I received my Notice of Award, now what....

- Understand all the terms on your NoA
 - Restriction – Most important, can identify costs or effort that is not changeable. Can also pertain to missing information that may not allow for specific work to be conducted until submitted.
 - Requirement – Something that must be adhered to. An example is reporting on a certain aspect of research in the RPPR.
 - Information – a term that highlights a particular policy that applies to the award.
- **Contact the GMS or PD when you have questions**

New Grant Policies

Please review prior to submitting documents

- Minimum Level of Effort
 - <https://grants.nih.gov/grants/guide/notice-files/NOT-CA-20-047.html>
 - This will also be included in the Funding Announcement, if applicable.
- Biosketches and Other Support
 - <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-110.html>
 - Detailed Explanation of Requirements
 - <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-073.html>
- Fiscal Policies in Effect for FY 2022
 - <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-105.html>



Recent Grant Policy Updates

- Genomic Data Sharing (GDS)
 - <https://datascience.cancer.gov/data-sharing/genomic-data-sharing>
- Clinical Trials Access Policy
 - Requires results to be reported within 12 months of completion date
 - <https://grants.nih.gov/grants/guide/notice-files/NOT-CA-15-011.html>
- Clinical Trial Requirements for Grants & Contracts
 - Grants with clinical trials must apply to specific announcements
 - <https://grants.nih.gov/policy/clinical-trials.htm>

Recent Grant Policy Updates

- Human Subjects System (HSS)
 - Replaced previous Inclusion Management System (IMS)
 - Consolidates human subjects and clinical trial information
 - <https://era.nih.gov/help-tutorials/hss>
 - [Inclusion Reporting Requirements](#)
- Common Rule (see [NOT-OD-22-001](#))
 - Removal of requirement for IRB approval of application
 - New categories of research exemption



Helpful Hints from OGA

- Talk to your Grants Management Specialist
 - [Specialist Assignments](#)
- Know who you need to contact in your organization.
 - Authorized Organizational Representative (AOR)
- Send in prior approval requests early. Use Commons when possible.
 - [Prior Approval Module](#)
- If you plan on changing institutions (transferring your grant), notify NCI early so we can guide you through the process. This will significantly reduce delays to your award.

Helpful Tools and Links

- [NCI Grants Process Book](#)
- [Grant Funding](#)
- [Prior Approval Items](#)

Thank you...



**U.S. Department of Health and Human Services
National Institutes of Health | National Cancer Institute**

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