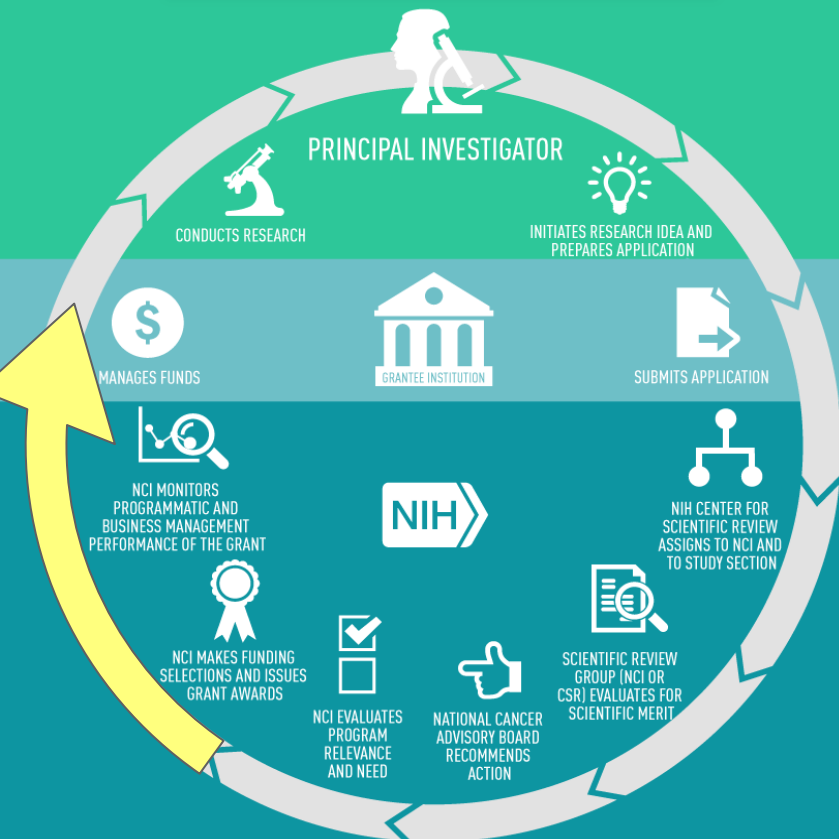


# OVERVIEW OF THE NATIONAL INSTITUTES OF HEALTH AND NATIONAL CANCER INSTITUTE GRANTS PROCESS



## The Scoop on the Office of Grants Administration

*Shane Woodward*

*Grants Management Branch B, Branch Chief*

*Office of Grants Administration*

- <https://grants.nih.gov/policy/early-investigators/list-smaller-grants.htm>
- <https://grants.nih.gov/faqs#/early-investigators.htm?anchor=question55719>
- **New investigator.** NIH considers you new if you have not yet competed successfully as a PI to receive substantial independent NIH funding.
- <https://grants.nih.gov/policy/early-stage/index.htm>
- <https://era.nih.gov/grantees/submit-no-cost-ext.htm>

# 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 NCI director and members of the NCAB and PCP be presidential appointees.
- 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

# NCI Grants By the Numbers

Fiscal Year 2019

- Total NCI Budget = \$5,992 Billion
- Extramural Grants and Contracts = \$4,577 Billion
- Overall, extramural obligations were 76.3% of the NCI Budget

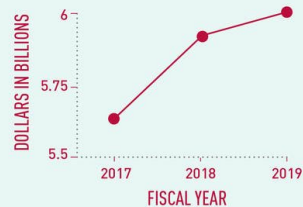
1991 → 2015

**THE OVERALL  
CANCER DEATH RATE  
IN THE UNITED STATES  
FELL**

↓ 26%

SEER Cancer Statistics Review, 1975-2015  
cancer.gov

## Budget At A Glance: Fiscal Year 2019



NCI BUDGET  
INCREASED BY  
**\$67.3 MILLION**  
(1.1%) FROM FISCAL  
YEAR 2018

**42.4%**

OF THE TOTAL  
NCI BUDGET  
ALLOCATED FOR  
RESEARCH  
PROJECT GRANTS

THE NATIONAL CANCER INSTITUTE (NCI)  
PROVIDES FUNDING AND SUPPORT FOR  
HEALTH-RELATED RESEARCH AND  
DEVELOPMENT THROUGH THE RPG (R01)  
GRANT MECHANISM.



R01 EARLY STAGE  
INVESTIGATORS BETWEEN  
THE 1<sup>ST</sup> AND 9<sup>TH</sup>  
PERCENTILES WERE  
CONVERTED TO R37  
AWARDS GIVING THEM  
THE OPPORTUNITY TO  
EXTEND THEIR RESEARCH  
AN ADDITIONAL 2 YEARS.



OF RPG  
AWARDS WERE  
NEW (TYPE 1)  
OR COMPETING  
RENEWAL (TYPE  
2) AWARDS



OF THE TOTAL  
NCI BUDGET  
SUPPORTED  
ONGOING,  
NON-COMPETING  
(TYPE 5) RPGs

**1,178**

NCI-FUNDED  
COMPETING RPGs



TOTALING OVER \$136.7 MILLION  
FUNDED AS SMALL BUSINESS  
INNOVATION RESEARCH (SBIR) AND  
SMALL BUSINESS TECHNOLOGY  
TRANSFER (STTR) AWARDS.

**4,984**

TOTAL NCI-FUNDED  
RPGs (INCLUDING  
SBIR & STTR)

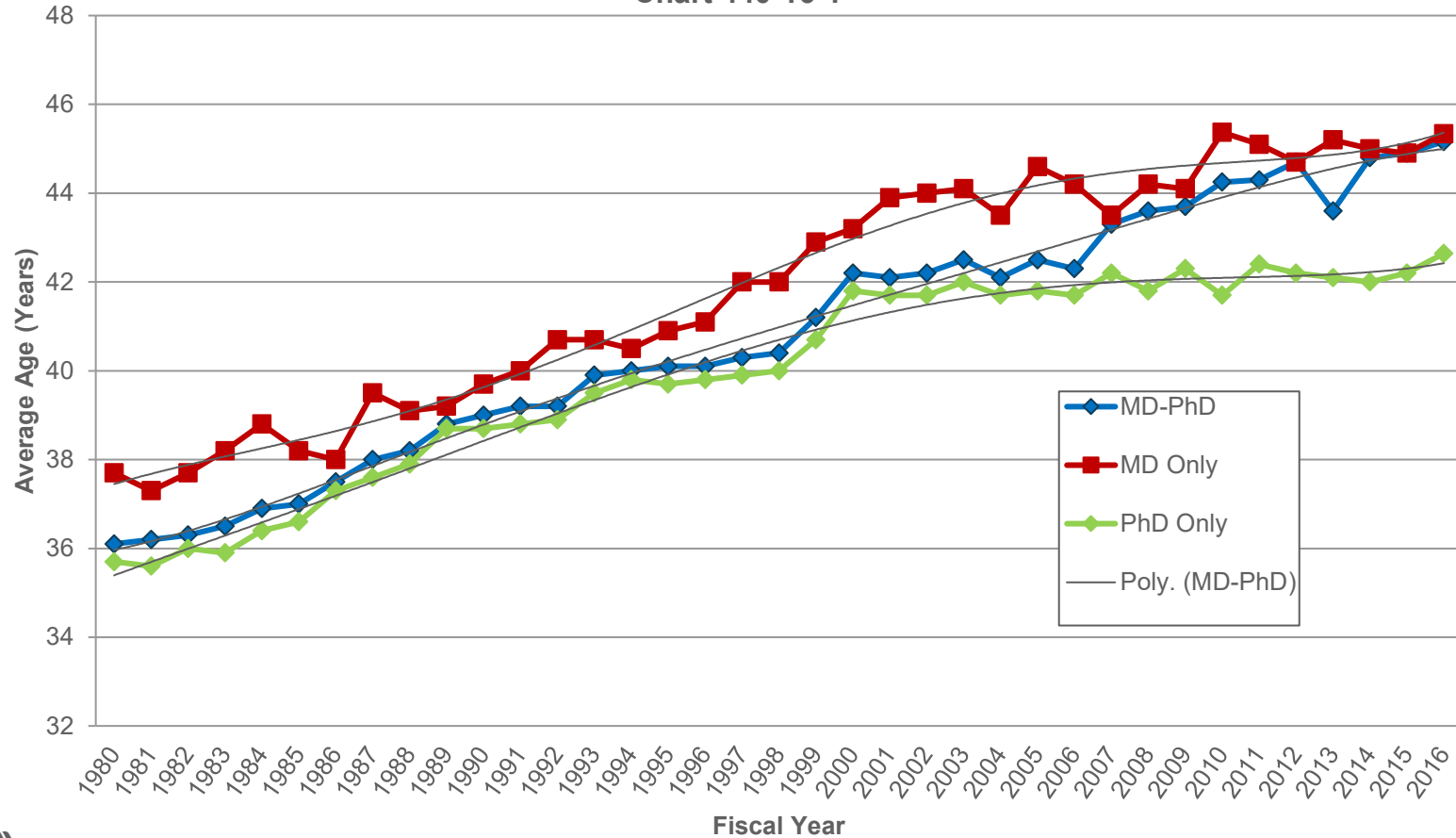
# Funding after CRCHD

- 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



# Average Age and Degree of NIH R01-Equivalent First-Time Awardees\* Fiscal Years 1980-2016\*\*

Chart 440-16-1



# What is the Office of Grants Administration (OGA)?

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- 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

# What are the Legal, Regulatory, & Policy Requirements?

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- 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)

# Office of Grants Administration (OGA) Overview

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- [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 Teams per Branch for a total of 8 teams - 6 Grant Teams, 2 Business Operations Teams
  - Each Team has between 5 & 8 individuals
    - Currently ~35 Grants Management Specialists (GMS)
  - ~60 total staff



# OGA Office of the Director

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- 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 7,000 grants, over 10,000 award actions)

# OGA Office of the Director - Responsibilities

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- 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)

# OGA Grants Management Branches

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- Branch Chiefs and Team Leaders serve as liaisons within NCI for specific cancer research areas:
- CGMO -
  - Crystal Wolfrey – OCC, DDES, DEA, OD, CSSI, CCG
- Branch Chiefs
  - Shane Woodward – DCTD, CRCHD, SBIR
  - Dawn Mitchum – DCCPS, CGH
  - Amy Bartosch– DCP, DCB, CCT
- Team Leaders -
  - Mutema Nyankale – Food and Drug Administration
  - Jason Gill – NIH Common Fund
  - Shellie Wilburn – NRSA (Fs and Ts)
- Help facilitate special grant program needs – FOAs, Funding Plans, special terms of award, etc.

## OGA Grants Management Branches, cont'd

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- Grants Management Specialist (GMS) assignments are organized by extramural institution - <https://www.cancer.gov/grants-training/manage-award/contacts>
- Why?
  - Facilitates an in-depth understanding of the recipient's business administration practices
  - Helps to identify any concerns with a recipient's business practices quicker
  - Develops strong collaboration between the GMS and the recipient organization
  - Minimizes the requests for duplicative institutional information and oversight at each institution



# Where Does OGA Fit In?

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- 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

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- 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

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- 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

# New Grant Policies

- Minimum Level of Effort

- <https://grants.nih.gov/grants/guide/notice-files/NOT-CA-20-047.html>

- Biosketches and Other Support

- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-110.html>

- Fiscal Policies in Effect for FY 2021

- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-058.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

- Single IRB
  - All multi-site clinical trials must use one IRB of record
- Human Subjects System (HSS)
  - Replaced previous Inclusion Management System (IMS)
  - Consolidates human subjects and clinical trial information
  - <https://era.nih.gov/help-tutorials/hss>
- Common Rule (see NOT-OD-19-050)
  - Removal of requirement for IRB approval of application
  - New categories of research exemption

# Helpful Hints from OGA

- Ensure publications are compliant prior to RPPR submission
- Send in prior approval requests early. Use Commons when possible.
- If you plan on moving (transferring your grant), notify NCI early so we can guide you through the process
- Read through all the terms on your NoA
- **Contact the GMS or PD when you have questions**

# Helpful Tools and Links

- [NCI Grants Process Book](#)
- [Grants Funding](#)



# Thank you...



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

**1-800-4-CANCER**

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