How to Identify and Apply for the Right R01

NCI Center to Reduce Cancer Health Disparities

NATIONAL CANCER INSTITUTE

June 28, 2023

ANNOUNCEMENTS

The Nuts and Bolts of Peer Review at the NIH

July 26, 2023, 3-4 pm EST Register Here

Thomas Cho, Ph.D.
Scientific Review Officer at NIH Center for Scientific Review, Division of Basic and Integrative Biological Sciences, Cell and Developmental Biology Review Branch

Objectives
1) Learn about the review process and priorities
2) Identify review criteria/questions reviewers are instructed to focus on
3) Identify what reviewers are instructed to evaluate in a resubmission

Professional Advancement Virtual Engagement Series

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For questions, please contact the team at Paves@nih.gov

Upcoming Paves				
Date	Title	Time	Speakers	Registration Link
August 30, 2023	Alternative Pathways	3:00-4:00 pm EST	Dr. James Lillard	Register Here
October 25, 2023	Physician Scientist Forum - Managing the Dynamics of Multiple Responsibilities of a Research Career	3:00-4:00 pm EST	Dr. Narjust Florez, Dr. Idalid Franco	Register Here
November 29, 2023	You've Reached Research Independence, Now What?	3:00-4:00 pm EST	Dr. Saavedra Harold	Register Here
December 13, 2023	Thriving as a Cancer and Cancer Health Disparity Researcher and Clinician Scientist	3:00-4:00 pm EST	Jennifer Wiggins	Register Here

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View previous sessions on our Paves website.

QUICK POLL

Learning Objectives

1. *Familiarize Yourself with the NIH/NCI research funding mechanisms and announcement types*

2. *Identify ways in which to select the right funding mechanism to support your scientific research*

3. *Learn how to connect with NIH, apply and track your application, the research and review process, and resources available through NCI*
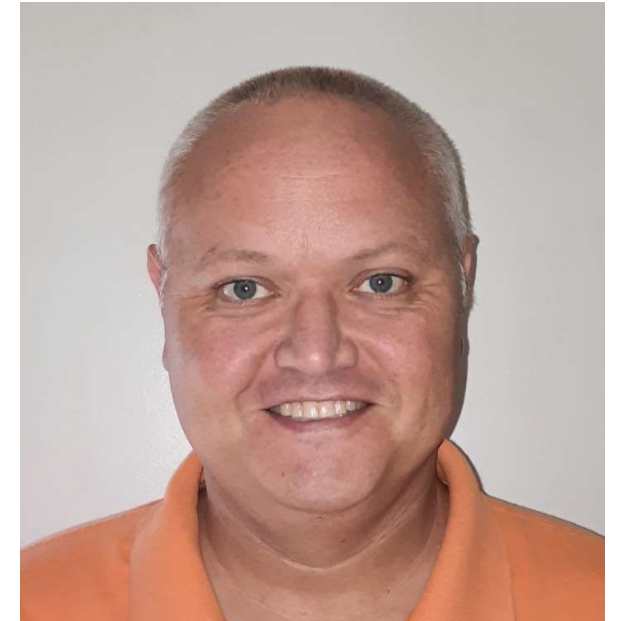
Today's Presenters

Kamal Datta, M.D.

Program Coordination & Scientific Review Officer
Division of Extramural Activities, NCI

Shane Woodward, MBA

Supervisory Grants Management Specialist
Office of Grants Administration, NCI

Navigating NIH/NCI Research Funding Opportunities: A Journey of Exploration & Understanding

Kamal Datta, M.D.
Program Coordination & Scientific Review Officer

Program Coordination & Referral Branch (PCRB)
Division of Extramural Activities (DEA)
National Cancer Institute (NCI)

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Presentation Outline

- Development of a Notice of Funding Opportunity (NOFO)

- Spectrum of Funding Mechanisms at NIH/NCI

- NOFO Types

- Components of an NOFO

- Notices related to NOFOs

- Finding NOFOs

- Applying for a NOFO

- Review of Grant Applications

National Institutes of Health's Mission and Its Components

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.
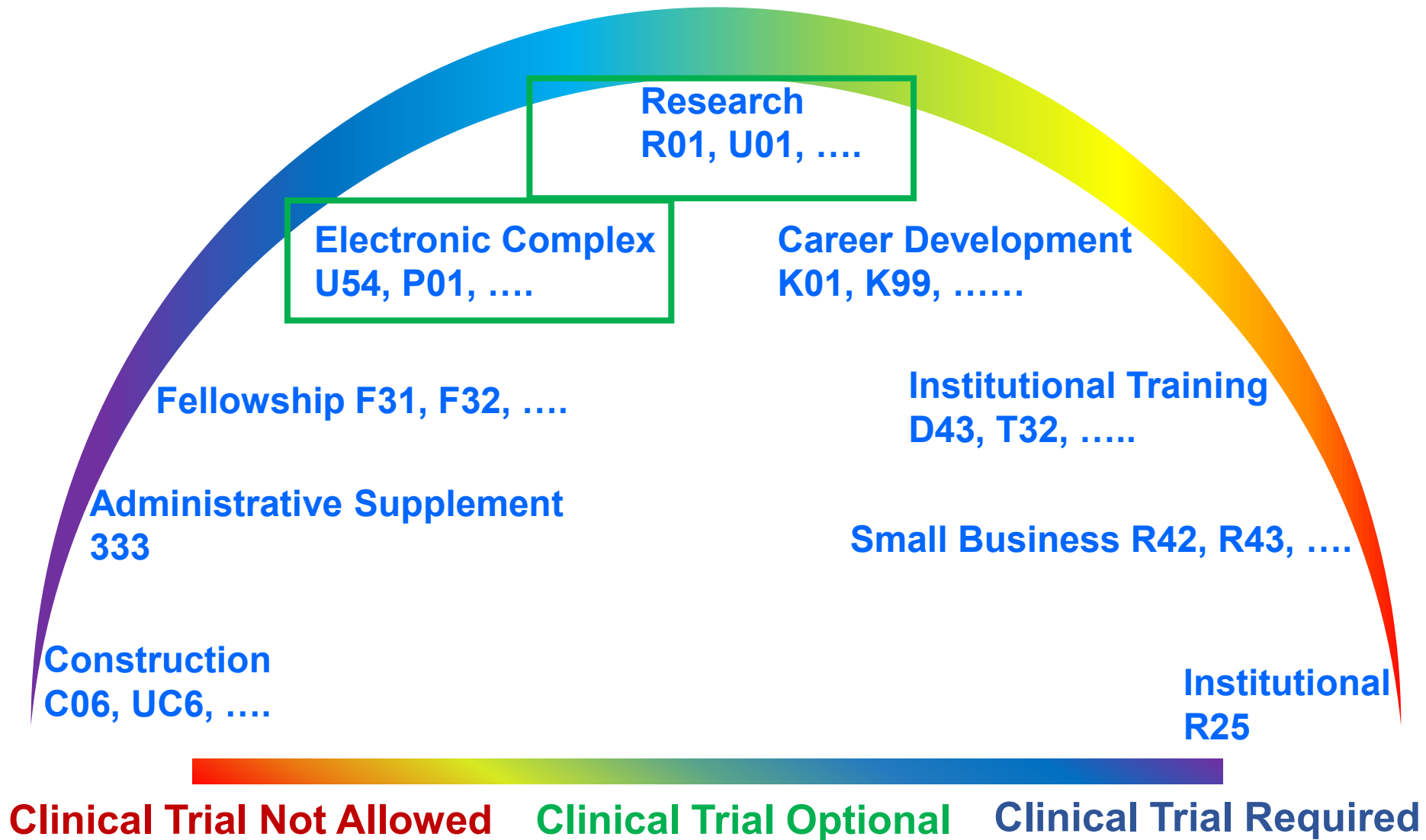
- **Intramural Research**

- **Extramural Research**
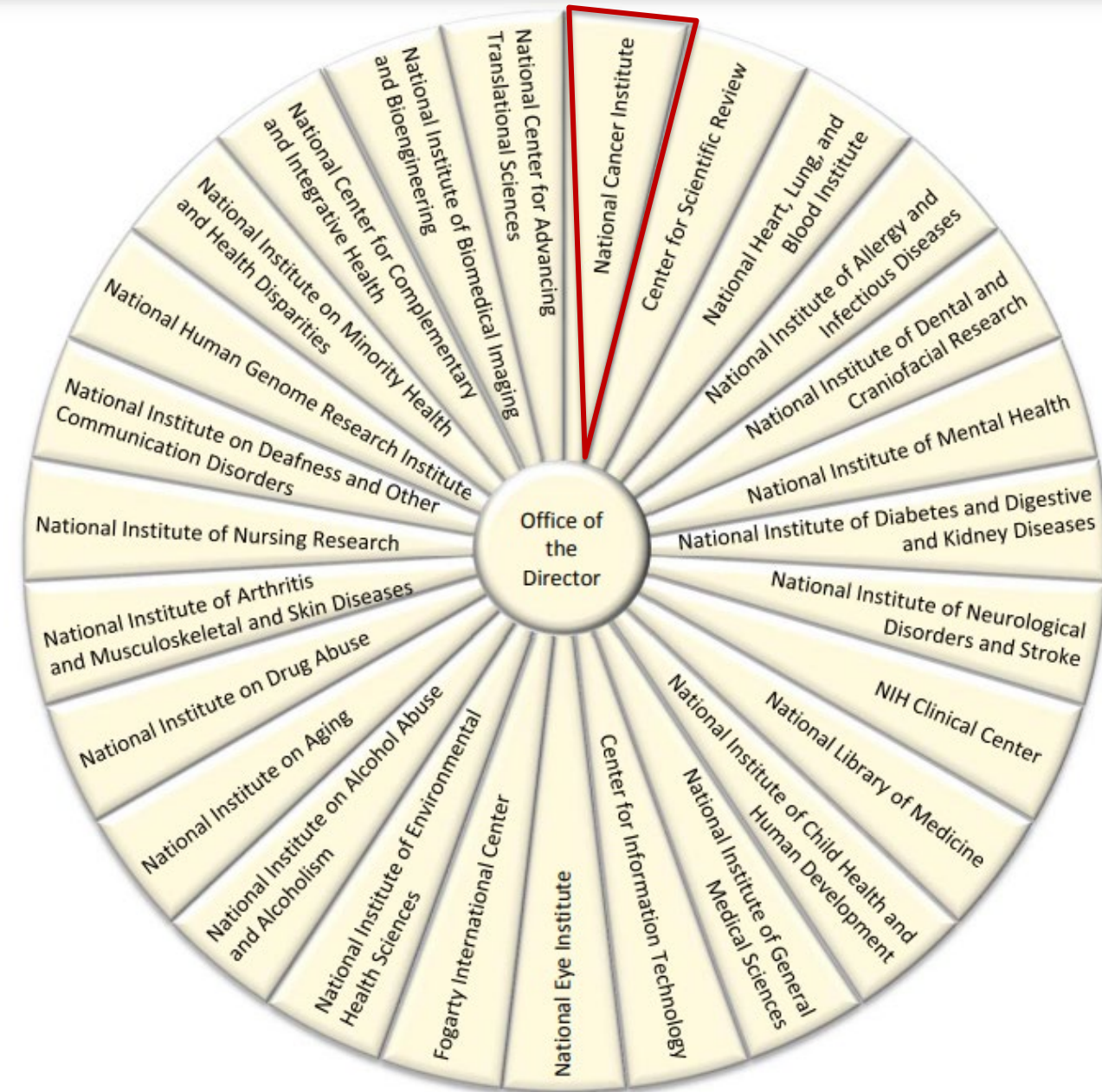
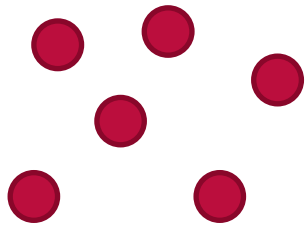# NOFO Development at NCI: Overview of the Process

➢ **Concept:** Scientific Research Area to Focus

➢ **Approval:** First tier of review (DOC Director, SPL, & BSA)

➢ **Writing:** Using the right template

➢ **Review:** Second tier of review (NCI DEA)

➢ **Review:** Third tier of review (NCI OGA & NIH Guide)

➢ **Address Review Comments:** Final tier of review (NIH Guide Quality Control)

➢ **Publication:** The Funding Opportunity is Announced to the Public

NOFO: Choosing the Right Mechanism from a Spectrum of Mechanisms

Research
R01, U01, ….

Electronic Complex
U54, P01, ….

Career Development
K01, K99, ……

Fellowship F31, F32, ….

Institutional Training
D43, T32, …..

Administrative Supplement
333

Small Business R42, R43, ….

Construction
C06, UC6, ….

Institutional
R25

Clinical Trial Not Allowed   **Clinical Trial Optional**   **Clinical Trial Required**

https://grants.nih.gov/grants/funding/funding_program.htm

NOFO: Choosing the Right Mechanism from a Spectrum of Mechanisms

Single Component
Rs, Fs, Ks, etc.

Cooperative Agreement
Substantial Programmatic Involvement
U mechanisms

Multi-Component
With OR Without
Cooperative Agreement

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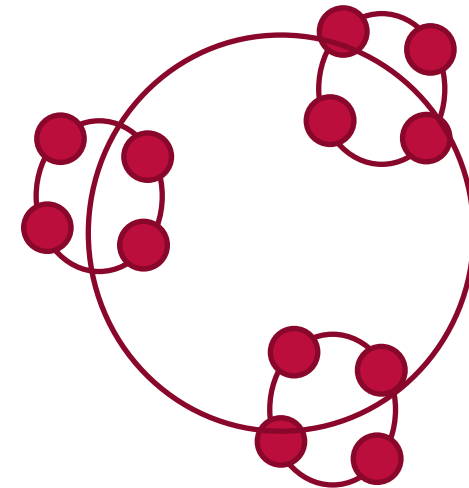
NOFO: Choosing the Announcement Type

➢ **Request For Application (RFA)**
- **Science:** Well-defined scientific area to accomplish specific program objectives
- **Fund:** Set-aside fund (all participating ICs must commit funds) **required**.
- **Receipt Date(s): Special**; Single or Multiple
- **Review**: NCI
- **Review Criteria:** Standard NIH review criteria + NOFO Specific

Special

➢ **Program Announcement (PA)**
- **Parent PA:**
  - Broad scientific areas issued by NIH OD/OER requesting "investigator-initiated" or "unsolicited" applications
  - **Receipt Date(s):** Standard
  - **Review:** CSR
  - **Review Criteria:** Standard NIH review criteria
  - **Note:** Not all ICs participate in the Parent PAs

NOFO: Choosing the Announcement Type

➢ **Program Announcement (PA)**

- ○ **PA** with **S**et-aside funds (**PAS**)
  - • **Science: H**ighlight areas of specific scientific interest
  - • **Fund:** Set-aside fund is **required**
  - • **Receipt Date(s):** Standard
  - • **Review**: CSR/NCI
  - • **Review Criteria:** Special review criteria not allowed

- ○ **PA** with special **R**eceipt, **R**eferral and/or **R**eview (**PAR**)
  - • **Science:** A new or ongoing interest in a research area
  - • **Fund:** Set-aside fund is allowed but not required
  - • **Receipt Date(s):** Standard or Special
  - • **Review**: CSR/NCI
  - • **Review Criteria:** Standard NIH review criteria + NOFO Specific

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Different Components of a NOFO

Part 1. Overview Information - Participating ICs; Key Dates

Part 2. Full Text of the Announcement

   Section I. Funding Opportunity Description – Science; Non-Responsive Applications

   Section II. Award Information – Application Type; Fund Available; Award Budget & Period

   Section III. Eligibility Information – Required Registration

   Section IV. Application and Submission Information – LOI; Budget; Research Plan

   Section V. Application Review Information – NOFO Specific Review Criteria

   Section VI. Award Administration Information – Cooperative Agreement - U mechanisms

   Section VII. Agency Contacts – For additional questions specific to this NOFO

   Section VIII. Other Information

Special NOFO: Notice Of Special Interest (NOSI)

Notice **O**f **S**pecial **I**nterest **(NOSI)**

- **Two Types:** Regular & Administrative Supplement
  - *Regular NOSI*:
    - Scientific topics of interest that **point to published NOFO(s)** to which applicants can apply using that NOFO's rules.
    - NOSIs don't change the NOFO rules.
    - Only science is different than target NOFO(s)
  - Administrative Supplement:
    - Used for supplemental fund (travel, program specific research, diversity) to active grants through NIH Parent Administrative Supplement PA
    - Can modify Project period; Budget limits and allowable costs; Due dates; Eligibility; Page limits; Review process
- **Fund:** Set aside fund not required
- **Receipt Date(s):** Special or follow the target NOFO(s)
- **Review:** NCI Program (Admin Suppl) or Follow Target NOFOs (Regular)

Notices Related to Notice of Funding Opportunities (NOFOs)

- **Notice of Information:** *Such as pre-application webinar*

- **Notice of Change:** *Such as change in 'Key Date(s)'*

- **Notice of Intent to Publish:** *NOFO will be published soon*

- **Notice of Policy:** *Any policy change related to NOFOs*

- **Request for information:** *on an area of science from the research community*

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Connecting with NIH: Getting Notified About New NOFOs

Subscribe to get notified: https://grants.nih.gov/funding/about-nih-guide-to-grants-and-contracts.htm

Search for NIH NOFOs Starts Here

https://grants.nih.gov/funding/searchguide/index.html

Know Before You Apply

Matchmaker

https://reporter.nih.gov/matchmaker

Enter abstracts/scientific text

15,000 characters are permitted

Terms weighted by the frequency of appearance

Automated & Confidential

Does not track and store text

Returns lists of similar projects/ program officials from RePORTER

Summarizes the projects by the program official, institute or center, review panel, and activity code.

Important Questions to Ask Before Applying

NIH funding is very competitive: https://report.nih.gov/funding/nih-budget-and-spending-data-past-fiscal-years/success-rates

Which IC might be interested in your area of science?

↓

Does your area of science fits into that IC's mission and priorities?

↓

Has your area of science (planned project) already been funded?

↓

Is your project/science novel?

↓

Have you decided on the right mechanism (fellowship/career development/research…) & activity code (F, K, R…)?

↓

Have you read carefully different sections ('Participating ICs', 'Key Dates', 'Funding Opportunity Description', Award Information, Eligibility, Submission Requirements, Review Criteria, Award Administration, Agency Contacts) of the NOFO.

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Early Stage Investigator (ESI)

Early Stage Investigator (ESI) Status

What is ESI?

NIH defines an *Early Stage Investigator (ESI)* as a Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award.

What is the benefit of having an ESI status?

ESI applications with meritorious scores will be prioritized for funding by the institute or center receiving the application.

How can I check if I have an ESI status?

Check the Education section of your eRA Commons profile. ESI status is determined automatically by functionality built into eRA Commons. The status is based on the investigator's record of receiving NIH grants and the completion date of his/her terminal research degree or the completion of post-graduate clinical training entered into the eRA Commons personal profile.

Where can I find out more?

You can find more information here:
https://grants.nih.gov/policy/early-investigators/index.htm

Related NEXUS posts: https://nexus.od.nih.gov/all/tag/esi/

FAQS: https://grants.nih.gov/policy/early-investigators/faqs.htm

NIH National Institutes of Health
Office of Extramural Research

Created 4/9/2020

Will I lose ESI status if…

YES

- It has been more than 10 years since my terminal research degree or end of post-graduate clinical training and I have not experienced situations that qualify for an ESI extension request. (See these FAQs about ESI Extensions.)

MAYBE

- I am the PD/PI (or multi-PD/PI) on an NIH award.
  - Yes, if you successfully competed as a PD/PI for a substantial independent research award.
  - No, if you are the PD/PI of an award on our list of smaller grants & awards that maintain ESI status.

- I am the PD/PI (or multi-PD/PI) on a multi-project award.
  - Yes, if you successfully competed as a PD/PI for the overall multi-project application.
  - No, if you led a component but were not the PD/PI of the overall application.

NO

- I'm a Co-Investigator on the grant. (NIH only recognizes senior/key with the role PD/PI as principal investigators.)

- I'm the PD/PI on a subaward or subcontract.

- I became the PD/PI due to a change of investigator action. (If you did not compete successfully as the PD/PI for a substantial NIH independent research award you won't lose status.)

R01-equivalent ESI applications with meritorious scores will be prioritized for funding.

New Investigator

An investigator who **has not** previously competed successfully for substantial, independent funding from NIH.

NIH Institutes and Centers (ICs) fund New Investigators according to the ICs' programmatic and strategic interests.

If your status is incorrect, please contact the NIH eRA Service Desk.

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https://grants.nih.gov/policy/early-stage/index.htm

How to Apply

Prepare to Apply

- Systems and Roles
- Register
- Find Grant Funding
- Understand Funding Opportunities
- Types of Applications
- Submission Options
- Obtain Software

Write Application

- Write Your Application
- How to Find Forms
- Develop Your Budget
- Format Attachments
- Rules for Text Fields
- Page Limits
- Data Tables
- Reference Letter
- Biosketches

Submit

- How to Submit

Planning & Writing

Planning

Submission Pitfalls

Target Your Application

Understand Your Reviewers

Early Stage Investigator Advantages

Get Application Help

Duplicate and Overlapping Applications

Continuous Submission

Writing

Sample grant applications

Writing Your Application – Advice from NIH

Writing Your Application – Advice from CSR

Writing Your Cover Letter

Grant Writing Tips

Additional Resources

Research Involving Human Subjects

Clinical Trials

Inclusion of Women and Minorities

Inclusion of Children

NIH Policy on Data Monitoring

NIH Data Sharing Policy

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Preparing to Apply

✓ Start early & understand timeline including institutional timeline

✓ Teamwork: Institutional administrator & scientific colleagues

✓ Understanding NOFO: Types, Participating ICs, Due date, applications types allowed, Requirements, Agency contact

✓ Register in various systems: Institutional & Individual

✓ Know which application submission option to use

✓ Request documents from colleagues

✓ Follow instructions: Form (correct version) instructions (https://grants.nih.gov/grants/how-to-apply-application-guide.html) + **NOFO guidance**

✓ Special attention: Budget & Research Plan in Part 2 Section IV

Finding the Correct Set of Forms

1. Find an Opportunity ➡️ 2. Choose submission 0ption ➡️ 3. Initiate an application & Correct forms will be presented

- **Each funding opportunity has its own unique set of application forms.**

- Once you have identified a funding opportunity of interest, you must use one of these submission options to access, prepare and submit the forms needed to apply.
  - ○ ASSIST
  - ○ Institutional Solutions (System-to-System, S2S)
  - ○ Grants.gov Workspace (not available for complex, multi-project applications)

- **Check with your administrative officials before choosing how you will submit.**

https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/find-forms.htm

Required Application Instructions

It is critical that applicants follow the Fellowship (F) instructions in the SF424 (R&R) Application Guide except where instruc in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide a strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any progran ection IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific **not comply with these instructions may be delayed or not accepted for review.**

There are several options available to submit your application through Grants.gov to NIH and Department of Health and **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   [Apply Online Using ASSIST]

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eR application. Check with your institutional officials regarding availability.

3. Use Grants.gov Workspace to prepare and submit your application and eRA Commons to track your application.

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Submitting an Application

- ✓ Submitting
- ✓ Tracking
- ✓ Viewing Application
- ↻ Errors = Repeat
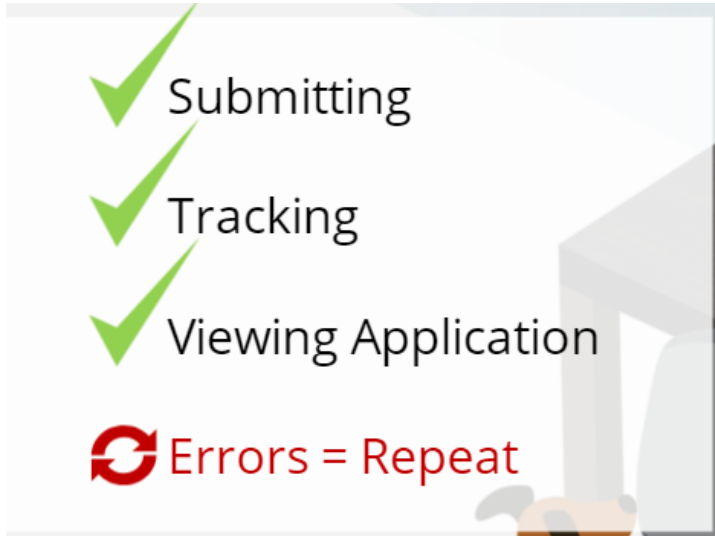
✓ Submit days in advance of the due date to allow time for required correction

✓ Authorized Organization Representative (AOR) is responsible for submission

1 GRANTS.GOV℠   **2** eRA   **3** NIH

Application check for completeness →

eRA Service Desk:
https://www.era.nih.gov/need-help
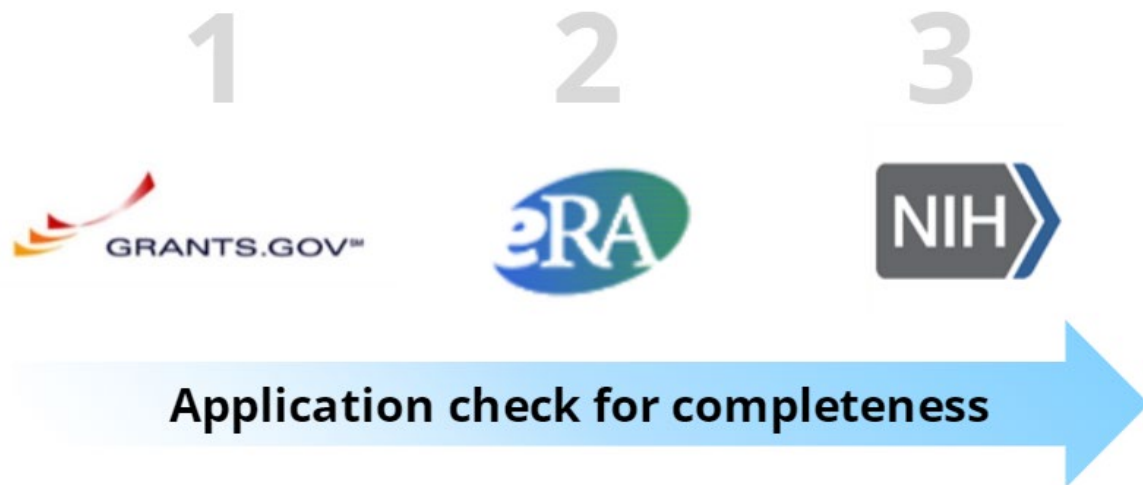
Identify a Study Section

Assisted Referral Tool (ART)   Help | Disclaimer | User Guide

NIH Center for Scientific Review

ART Home >> SRG   ☐ Animal Usage?

Enter application text and hit the Submit button to get a list of relevant study sections in two groups, "Strong" and "Possible". Within a group, study sections are listed alphabetically by the SRG acronym

Title [Optional but strongly recommended, as title concepts receive full weight in the model]   [Sample] [Clear]

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Request a Study Section for Your Application

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.600-phs-assignment-request-form.htm

PHS Assignment Request Form

OMB Number: 0925-0001
Expiration Date: 2/28/2023

Funding Opportunity Number:

Funding Opportunity Title:

Awarding Component Assignment Suggestions *(optional)*

If you have a suggestion for an awarding component (e.g., NIH Institute/Center) assignment, use the link below to identify the appropriate short abbreviation (e.g., "NCI" for National Cancer Institute) and enter it below in the boxes for "Suggested Awarding Components". All suggestions will be considered; however, not all assignment suggestions can be honored.

Information about Awarding Component can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents

Suggested Awarding Components:

Study Section Assignment Suggestions *(optional)*

If you have a suggestion for a study section assignment, use the link below to identify a study section(s). Enter the short abbreviation for that study section in the boxes for "Suggested Study Sections." Remove all hyphens, parentheses, and spaces. All suggestions will be considered; however, not all assignment suggestions can be honored.

For example, enter "CAMP" if you wish to suggest assignment to the NIH Cancer Molecular Pathology study section, or "ZRG1HDMR" if you wish to suggest assignment to the NIH Healthcare Delivery and Methodologies SBIR/STTR panel for informatics.

Information about Study Sections can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection

Suggested Study Sections:
Each entry is limited to 20 characters

Rationale for assignment suggestions *(optional)*   *Entry is limited to 1000 characters*

Track Your Application

- You are responsible for tracking your application through Grants.gov to a visible application image in eRA Commons.
- You will receive a series of Grants.gov and eRA Commons email notifications throughout the submission process. Email can be unreliable, so it is good practice to proactively track your application status in Grants.gov and eRA Commons.
  - Track submission status in Grants.gov ⧉
  - Steps for PI to track submission status in eRA Commons
  - Steps for Signing Officials (SOs) to track submission status in eRA Commons
- You must address any errors identified in Grants.gov and eRA Commons before the submission deadline. Warnings do not stop application processing. Read all warnings carefully and use your discretion to determine which, if any, you will address.
  - Learn How We Check Your Application for Completeness
  - Submit a Changed/Corrected Application

Note that PIs can check status information in eRA Commons on the go, using Commons Mobile (see info).

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Application Review & Funding Process at NIH/NCI

➢ **Submitted Applications**

↓

➢ **Division of Receipt and Referral (DRR)**
Center for Scientific Review (CSR)

↓

➢ **Assigned to Institute/Center**

1. Level I Review: Peer-review

Scientific Review Officer (SRO): CSR or NCI

- Reviewer Recruitment
- Applications Assigned to Reviewers
- Reviewers Meet, Discuss, & Score
- Score Released
- Summary Statement Released

2. Level II Review: Council/Board Review

Program Officials: NCI

- Overall Impact Scores, Percentile Rankings
- Summary Statements
- NCI Priorities

↓

Grant-Funding Plan

↓

National Cancer Advisory Board (NCAB)

access to
- Applications
- Summary Statements

↓

➢ **Final funding decisions: NCI Director – with staff and Advisory Council/Board advice**

Thank You!

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
- 3 Teams per Branch for a total of 10 teams - 9 Grant Teams, 2 Business Operations Teams and 2 Office of the Director 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

Percent Share of Total RPG Funds, FY 21

- R01/R37
- P01 Program Projects
- R03 Small Grants
- R21 Exploratory Phase I
- R33 Exploratory Phase II
- R35
- SBIR/STTR
- Other

13.8%

5.8%

5….

0…

3….

0….

7.2%

63….
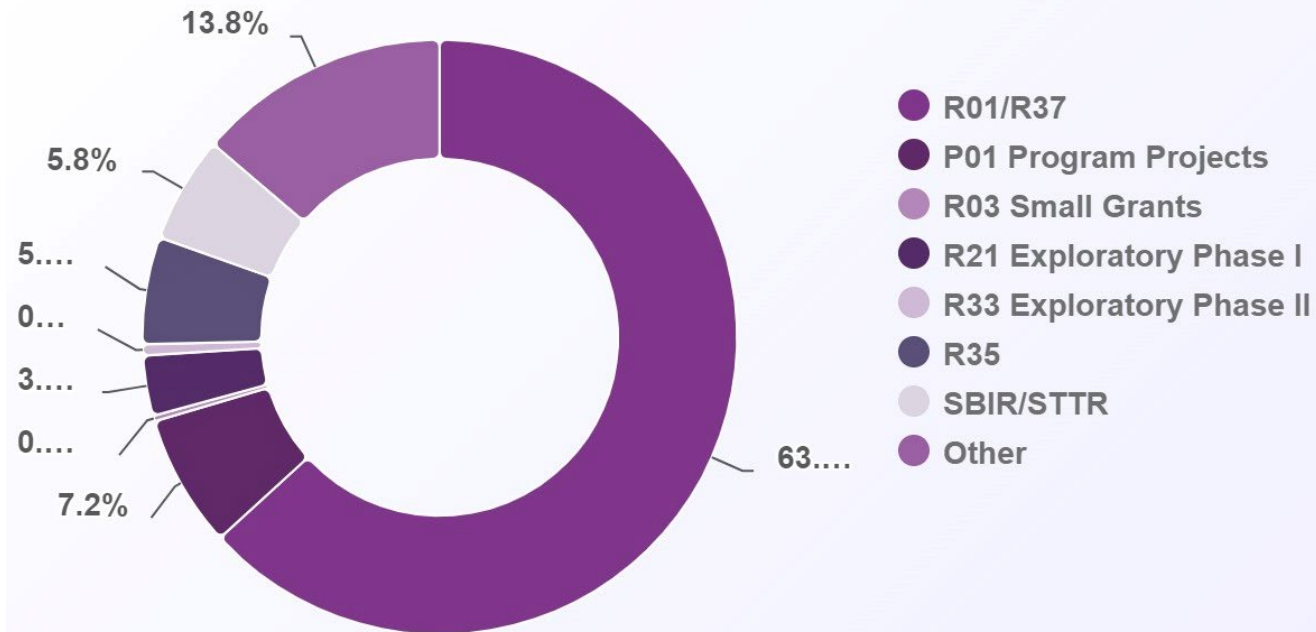
cancer.gov

The "Other" category includes DP1, DP2, DP5, R00, R37, U01, U19, UH2, UH3, UG3, UA5, R50, UM1, R15, R55 and R56 grant activities.

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

Month

Receipt & Assignment of Applications

1

Applicant Prepares & Submits Grant Application to Grants.gov in Response to FOA

Applications That Fall Under This Category Include R01s, etc.

Applications That Fall Under This Category Include Program Projects & Center Grants

2

Center For Scientific Review (CSR) Assigns To Scientific Review Group (SRG)

Division of Receipt & Referral at CSR

CSR Assigns to NCI Division of Extramural Affairs (DEA)

3

First-level Review by Scientific Review Group (SRG) for Scientific Merit

4

CSR SRG Reviews

SRG Assigns Impact Scores

NCI SRG Reviews

5

Summary Statements Prepared

Summary Statements Available to NCI Program Staff & Applicants

First-level Scientific Revie for Scient

5

Summary Statements Prepared

Summary Statements Available to NCI Program Staff & Applicants

6

Summary Statements Forwarded to NCAB

Second-level Review by National Cancer Advisory Board (NCAB) for NCI Funding Determinations

7

Applications Selected For Funding

NCI Develops Funding Plan

NCAB Makes Recommendation to NCI Director

8

"Paylists" Forwarded to Office of Grants Administration (OGA)

Final Review & Negotiations by OGA

9

Award Negotiations & Issuance

10

Award Issued

Award Received by Institution

Investigator Begins Work

www.cancer.gov

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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

Award Calculation (U.S. Dollars)

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

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](#)

Budget At A Glance: Fiscal Year 2021

DOLLARS IN BILLIONS

6.35

6

5.75

2019 2020 2021
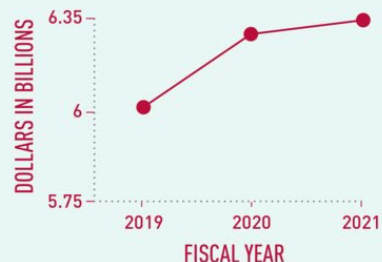
FISCAL YEAR

NCI BUDGET INCREASED BY $99.3 MILLION (1.6%) FROM FISCAL YEAR 2020

42.3%

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 1ST AND 10TH **PERCENTILES** WERE CONVERTED TO R37 **AWARDS** GIVING THEM THE OPPORTUNITY TO EXTEND THEIR RESEARCH **AN ADDITIONAL 2 YEARS.**

OVER 1/4 OF RPG AWARDS WERE NEW (TYPE 1) OR COMPETING RENEWAL (TYPE 2) AWARDS

1/3 OF THE TOTAL NCI BUDGET SUPPORTED ONGOING, NON-COMPETING (TYPE 5) RPGs

1,331

NCI-FUNDED COMPETING RPGs

238 GRANTS

TOTALING OVER $158.3 MILLION FUNDED AS SMALL BUSINESS INNOVATION RESEARCH (SBIR) AND SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) AWARDS.

5,210

TOTAL NCI-FUNDED RPGs (INCLUDING SBIR & STTR)

Thank you…

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

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A great question
doesn't simply inform...

it enlightens.

LF LEADERSHIP FREAK

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