NASEM Consensus Study Committee

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NIH is the largest public funder of biomedical research in the world, investing more than $40 billion in taxpayer dollars to achieve its mission to enhance health, lengthen life, and reduce illness and disability. In pursuing this mission, NIH **improves health** by promoting treatment and prevention, **contributes to society** by driving economic growth and productivity, and **expands the biomedical knowledge base by funding cutting-edge research and cultivating the biomedical workforce of today and tomorrow.** NIH is made up of 27 Institutes and Centers, each with a specific research agenda, often focusing on particular diseases or body systems.

More than 80 percent of NIH's funding is awarded for extramural research, largely through almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state. About 10% of the NIH's budget supports projects conducted by nearly 6,000 scientists in its own laboratories, most of which are on the NIH campus in Bethesda, Maryland.

NCI (team of approximately 3,500) is part of the National Institutes of Health (NIH), one of 11 agencies that make up the Department of Health and Human Services (HHS). NCI is deeply committed to the core values of equity, diversity, and inclusion that allow all staff to reach their potential and fully contribute to the Institute's cancer mission.

The National Cancer Institute (NCI) was established in its current form by the National Cancer Act of 1971, signed into law by President Richard Nixon. **Mission**-NCI leads, conducts, and supports cancer research across the nation to advance scientific knowledge and help all people live longer, healthier lives.

As a federal agency, NCI receives its funds from Congress. The bulk of NCI's budget supports extramural grants and cooperative agreements to facilitate research conducted at universities, medical schools, hospitals, cancer centers, research laboratories, and private firms in the United States and abroad. These funds also support intramural research at NCI's laboratories and offices in Bethesda, Rockville, and Frederick, MD.

Public Health Service Act

Funding mandates a two-tiered peer review system for NIH grant applications:

- Must review a written description of the work proposed
- Must provide a written outcome of review to the funding Institute or Center

NIH cannot award a grant unless the application has been recommended by both levels of peer review.

Legal and Policy Framework: Grants and Cooperative Agreements

Statute: PHS Act (42 U.S.C. 289a)

Regulation: Peer Review (42 C.F.R. 52h)

NIH Policy: Manual Chapter 4204-204B*

NIH Guide to Grants and Contracts

NIH Grants Policy Statement

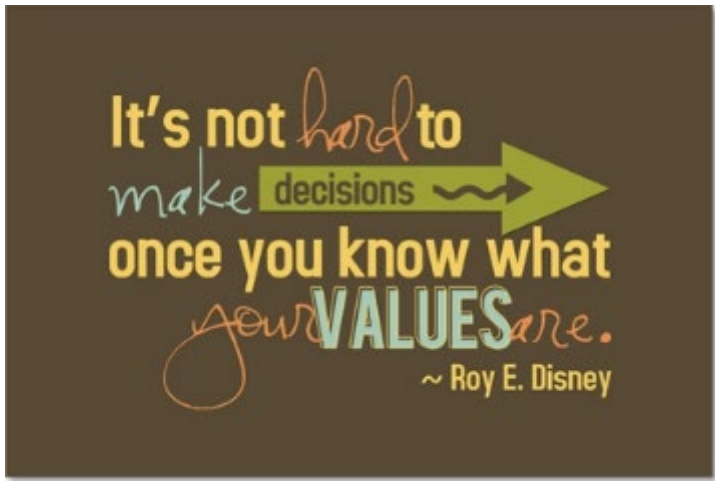
OER Policy Announcements*

Receipt and Review Cycles

	Cycle I	Cycle II	Cycle III
Application Due Dates	Jan 25-May 7	May 25-Sept 7	Sept 25-Jan 7
Scientific Merit Review	June-July	Oct-Nov	Feb-March
Council (NCAB)	Aug/Oct (Sept)	Jan (Feb)	May (June)

Core Values of NIH Peer Review

- Expert assessment
- Fairness
- Impartiality
- Transparency
- Integrity
- Confidentiality
- Efficiency



Expert Assessment

"Experts qualified by training or experience in particular scientific or technical fields, or as authorities knowledgeable in the various disciplines and fields related to the scientific areas under review" (42 C.F.R. 52h)

Fairness

All applications are evaluated using equivalent review processes

- Standard review criteria
- Same scoring system
- Written outcome of review

Review Criteria

“Scored” Review Criteria

- Significance
- Investigator
- Innovation
- Approach
- Environment

Additional Review Criteria

Study Timeline (clinical trials)
Protection of Human Subjects/Inclusion
Vertebrate Animals
Biohazards
Resubmission
Renewal
Revision

Additional Review Considerations

Budget/Overlap
Resource Sharing Plan
Authentication of Key Biological and/or Chemical Resources
Select Agents

Review Panels

- **Standing Study Sections**
  - Members
  - Typically have expertise in a defined scientific area(s)
    - Ad hoc reviewers can be added to round out expertise
- **Special Emphasis Panels (SEPs)**
  - Can be one-time only for specific FOA or cluster of applications
  - Can be recurring

There must be diversity with respect to the geographic distribution, gender, race, and ethnicity of the panel membership

NCI-Program Project (P01)

The NCI provides support for **investigator-initiated** Program Projects in the belief that a collaborative research effort can accelerate the acquisition of knowledge more effectively than a simple aggregate of research projects that have no interaction or thematic integration. Therefore, every P01 Program Project proposed should have a well-defined unifying research theme.

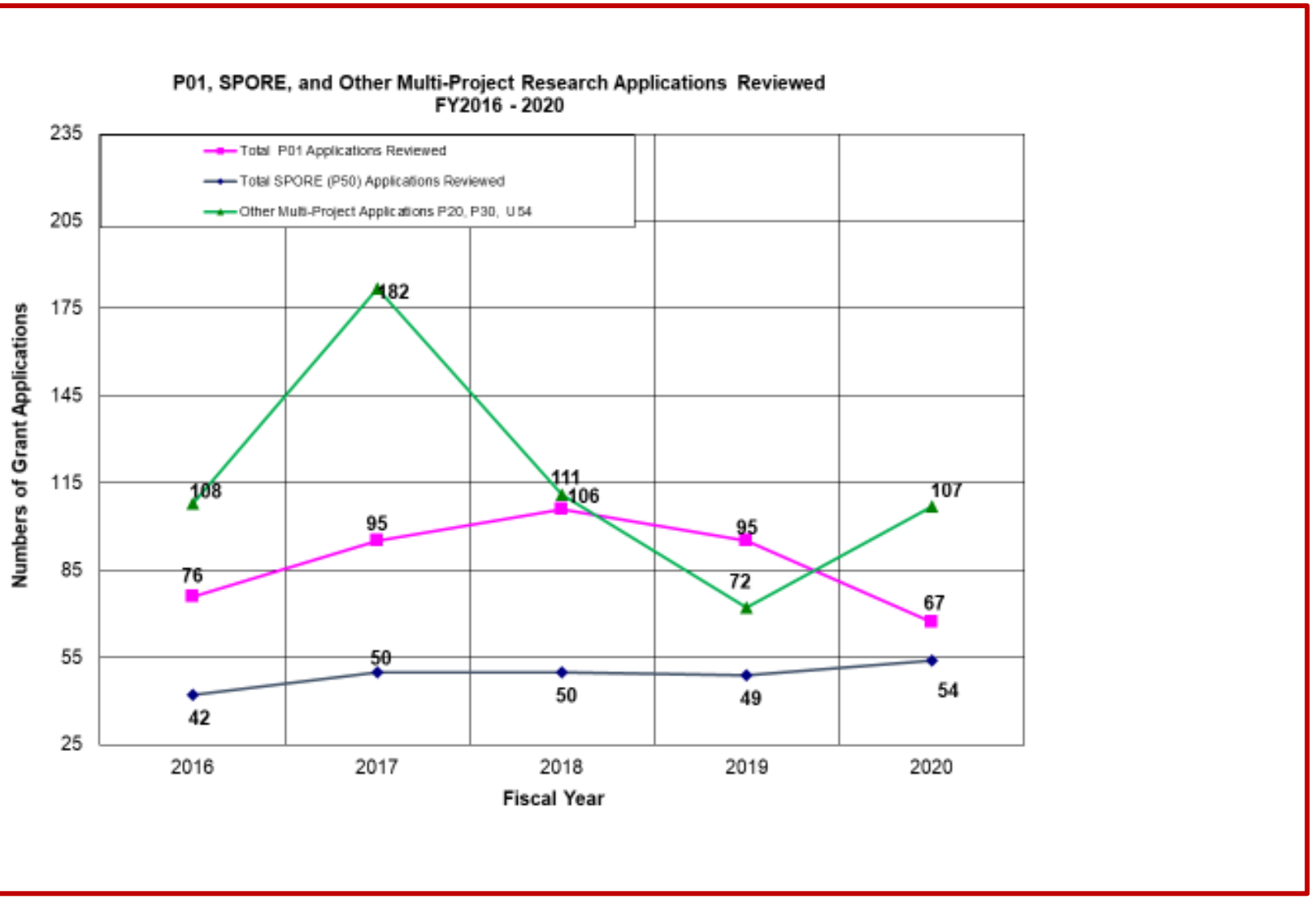
The NCI's P01 Funding Opportunity Announcement (PAR-20-077) invites multidisciplinary coordinated research programs in any of the broad areas of cancer research, including (but not limited to) studies of cancer biology, cancer prevention, cancer diagnosis, cancer treatment, and cancer control. Basic, translational, clinical, and/or population-based studies in all of these research areas are appropriate.

P01 requirement: Three projects (minimum) and an Administrative Core

Optional: Shared Resource Core (s) supporting at least two proposed projects.

P01 Review Process at NCI

- All applications are reviewed in Special Emphasis Panels (SEP)
- Applications are grouped together based on science proposed
- Multiple SEP meetings are held to review P01 applications
- Reviewers are recruited based on expertise needed for the applications submitted
- Reviewers are assigned across different applications in the meeting
- All Panel members (not in conflict) score all applications


P01, SPORE, and Other Multi-Project Research Applications Reviewed
FY2016 - 2020
Total P01 Applications Reviewed
Total SPORE (P50) Applications Reviewed
Other Multi-Project Applications P20, P30, U54
Numbers of Grant Applications
235
205
175
145
115
85
55
25
108
182
111
107
95
106
95
76
72
67
50
50
49
54
42
2016
2017
2018
2019
2020
Fiscal Year

Fund Type: Appropriated				% of NCI Total Grants			Fiscal Year: 2020	
Mechanisms	Awards #	Awards $	Average Cost	Number	Dollars	Competing Requested	Competing Awarded	Success Rate
Program Projects-P01	83	185,768,871	2,238,179	1.19%	4.59%	69	12	17.39%
Centers - P20	14	4,081,560	291,540	0.2%	0.1%	19	2	10.53%
Centers - P30	71	337,898,699	4,759,137	1.02%	8.35%	18	17	94.44%
SPORE Grants - P50	60	121,510,620	2,025,177	0.86%	3.0%	48	12	25.0%
Specialized Center (Cooperative Agreement)-U54/U41	58	85,538,089	1,474,795	0.83%	2.11%	81	5	6.17%
Specialized Center (Cooperative Agreement)-U54/U41 - MOONSHOT	9	11,915,474	1,323,942	0.13%	0.29%	0	0	0.0%
Other P50/P20 - Moonshot	7	8,019,211	1,145,602	0.1%	0.2%	1	1	100.0%

Feasibility Studies to Build Collaborative Partnerships in Cancer Research (P20 Clinical Trial Not Allowed) PAR-18-911	A major goal of the NCI P20 partnership programs is to provide support for investigators at institutions serving underserved health disparity populations and underrepresented students (ISUPS) and Cancer Centers to conduct cancer research pilot projects and cancer research education program. **The purpose of the pilot projects and education program is to allow awardees to obtain preliminary data that will lead to competitive grant applications for funding by the NIH/NCI and/or other Federal/Non-Federal agencies.**
Partnerships to Advance Cancer Health Equity (U54, PACHE) PAR-18-767	Program that provides institutional awards for the development of partnerships between institutions serving underserved health disparity populations and underrepresented students (ISUPS) and NCI-designated Cancer Centers (CCs). **Each partnership is expected to conduct cancer and cancer health disparities research, develop and implement cancer research experiences and research education for scientists and students, and to effectively outreach and disseminate cancer advances to underserved communities.**
NCI Transition Career Development Award to Promote Diversity (K22 No Independent Clinical Trials) PAR-18-366	The purpose of the NCI Transition Career Development Award to Promote Diversity is to assist postdoctoral fellows or individuals in equivalent positions to transition to positions of assistant professor or equivalent and initiate a successful biomedical career as an independent research scientist.
Exploratory Grant Award to Promote Workforce Diversity in Basic Cancer Research (R21 Clinical Trial Not Allowed) PAR-21-061	NCI program to enhance the diversity of the pool of the cancer research workforce by **recruiting and supporting eligible New Investigators and Early-Stage Investigators from diverse backgrounds, including from groups that have been shown to be nationally underrepresented in the biomedical, behavioral, clinical and social sciences**

Program Name	Program Info
Research Supplements to Promote Diversity in Health-Related Research (Admin Supp - Clinical Trial Not Allowed) PA-20-222	Funds are available for administrative supplements to enhance the diversity of the research workforce by recruiting and supporting students, postdoctorates, and eligible investigators from diverse backgrounds, including those from groups that have been shown to be underrepresented in health-related research. This supplement opportunity is also available to PD(s)/PI(s) of research grants who are or become disabled and need additional support to accommodate their disability in order to continue to work on the research project.
The Continuing Umbrella of Research Experiences (CURE) **Over two decades supported >3000 CURE students**	The Center to Reduce Cancer Health Disparities (CRCHD) CURE program offers unique training and career development **opportunities to enhance and increase diversity in the cancer and cancer health disparities research workforce. The CURE program supports promising candidates from middle school through junior investigator levels and provides them with a continuum of competitive funding opportunities.**
Intramural Continuing Umbrella of Research Experiences **iCURE Program**	iCURE supports mentored research experiences for qualified, underrepresented postbacs, graduate students, and postdoctoral fellows. iCURE scholars are U.S. citizens, permanent residents or noncitizen nationals. NCI is particularly interested in **encouraging applications of individuals from groups identified in NIH's Notice of Interest in Diversity (NOT-OD-20-031) as underrepresented in the biomedical, clinical, behavioral, and social sciences**
NIH Academy Enrichment Program (**NAEP**)	Offers competitive funding to **trainees at the postbaccalaureate level interested in learning about health disparities** while performing world-class research at the National Institutes of Health, Bethesda campus.

Thank you

Questions?