

CCAF Grants Update

May 1, 2017

OGA Organization Chart

[Crystal Wolfrey](#)

Director, Chief Management Officer

Grants Portfolio Management
Branch A

[Sean Hine](#) - Branch Chief

Vacant - Lead Specialist

Team 1

[Amy Bartosch](#) - Team Lead
[Naliah Agyemann](#)
[Funmi Elesinmogun](#)
[Nicole Franklin](#)
[Rogers Gross](#)
[Tracie McGraw](#)
[Avery Tucker](#)

Team 2

[Mutema Nyankale](#) - Team Lead
[Marianne Galczynski](#)
[Kerry Gastley](#)
[Barbara Hodgkins](#)
[Viviana Knowles](#)
[Jake Pritchard](#)
[Long Nguyen](#)

Grants Portfolio Management
Branch B

[Shane Woodward](#) - Branch
Chief

[Jaime Montes](#) - Lead Specialist

Team 3

[Dawn Mitchum](#) - Team Lead
[Justin Birken](#)
[Sarah Lee](#)
[Stephanie Mitchell](#)
[Ashley Salo](#)
[Cornice Young](#)

Team 4

[Tawana McKeither](#) – Team Lead
[LeSchell Browne](#)
[Renee Carruthers](#)
[Alania Foster](#)
[Kimery Griffin](#)
[Leslie Hickman](#)
[Martinson Owusu](#)

Grants Portfolio Management
Branch C

[Carol Perry](#) - Branch Chief

[Alice Wong](#) - Lead Specialist

Team 5

[Erik Edgerton](#) - Team Leader
[Dianna Bailey](#)
[Becky Brightful](#)
[Mohammed Kurtom](#)
[Romy Reis](#)
[Jackie Saval](#)
[Ashley Utter](#)

Team 6

[Jason Gill](#) - Team Leader
[Candace Cofie](#)
[Joy Kearse](#)
[Jennifer Meininger](#)
[Debra Sowell](#)
[Angela Walters](#)

Business Operations Branch

[Crystal Wolfrey](#) - Acting
Branch Chief

[Hue Tran](#) - Program Specialist

Business Services Team 1

[Bryan Baker](#) - Team Leader
[Anna Shaner](#)
[Emily Driskell](#)
[Joe D'Avella](#)
[Nicole Jones](#)

Business Services Team 2

[Stacey Kocher](#) - Team Lead
[Eugenia Chester](#)
[Kevin Jackson](#)
[Robert Jones](#)
[Lisa Vytacil](#)
Imran Omair (contractor)
Hareesh Jayini (contractor)
Leon Chien (contractor)
Frances Gu (contractor)

FY16 Cancer Center GM Specialist Assignments

Institution	Specialist	Institution	Specialist
ALBERT EINSTEIN COL OF MED YESHIVA UNIV	Kimery Griffin	MASSACHUSETTS INSTITUTE OF TECHNOLOGY	Joy Kearsse
BAYLOR COLLEGE OF MEDICINE	Viviana Knowles	MAYO CLINIC	Debra Sowell
CASE WESTERN RESERVE UNIVERSITY	Jennifer Meininger	MEDICAL UNIVERSITY OF SOUTH CAROLINA	Tracie McGraw
CITY OF HOPE/BECKMAN RESEARCH INSTITUTE	Long Nguyen	NEW YORK UNIVERSITY SCHOOL OF MEDICINE	Dianna Bailey
COLD SPRING HARBOR LABORATORY	Martinson Owusu	NORTHWESTERN UNIVERSITY AT CHICAGO	Barbara Hodgkins
COLUMBIA UNIVERSITY HEALTH SCIENCES	Jackie Saval	OHIO STATE UNIVERSITY	Alice Wong
DANA-FARBER CANCER INSTITUTE	Justin Birken	OREGON HEALTH AND SCIENCE UNIVERSITY	Barbara Hodgkins
DARTMOUTH COLLEGE	Debra Sowell	PURDUE UNIVERSITY WEST LAFAYETTE	Renee Carruthers
DUKE UNIVERSITY	Jackie Saval	RBHS - CANCER INSTITUTE OF NEW JERSEY	Dianna Bailey
EMORY UNIVERSITY	Martinson Owusu	RESEARCH INST OF FOX CHASE CAN CTR	Candace Cofie
FRED HUTCHINSON CANCER RESEARCH CENTER	Sarah Lee	ROSWELL PARK CANCER INSTITUTE CORP	Viviana Knowles
GEORGETOWN UNIVERSITY	Barbara Hodgkins	SALK INSTITUTE FOR BIOLOGICAL STUDIES	Becky Brightful
H. LEE MOFFITT CANCER CTR & RES INST	Joy Kearsse	SANFORD-BURNHAM MEDICAL RESEARCH INSTIT	Sarah Lee
ICAHN SCHOOL OF MED AT MT SINAI	Romy Reis	SLOAN-KETTERING INSTITUTE FOR CANCER RES	Funmi Elesinmogun
INDIANA UNIV-PURDUE UNIV AT INDIANAPOLIS	Jennifer Meininger	ST. JUDE CHILDREN'S RESEARCH HOSPITAL	Kimery Griffin
JACKSON LABORATORY	Romy Reis	STANFORD UNIVERSITY	Leslie Hickman
JOHNS HOPKINS UNIVERSITY	Becky Brightful	THOMAS JEFFERSON UNIVERSITY	Stephanie Mitchell

FY16 Cancer Center GM Specialist Assignments

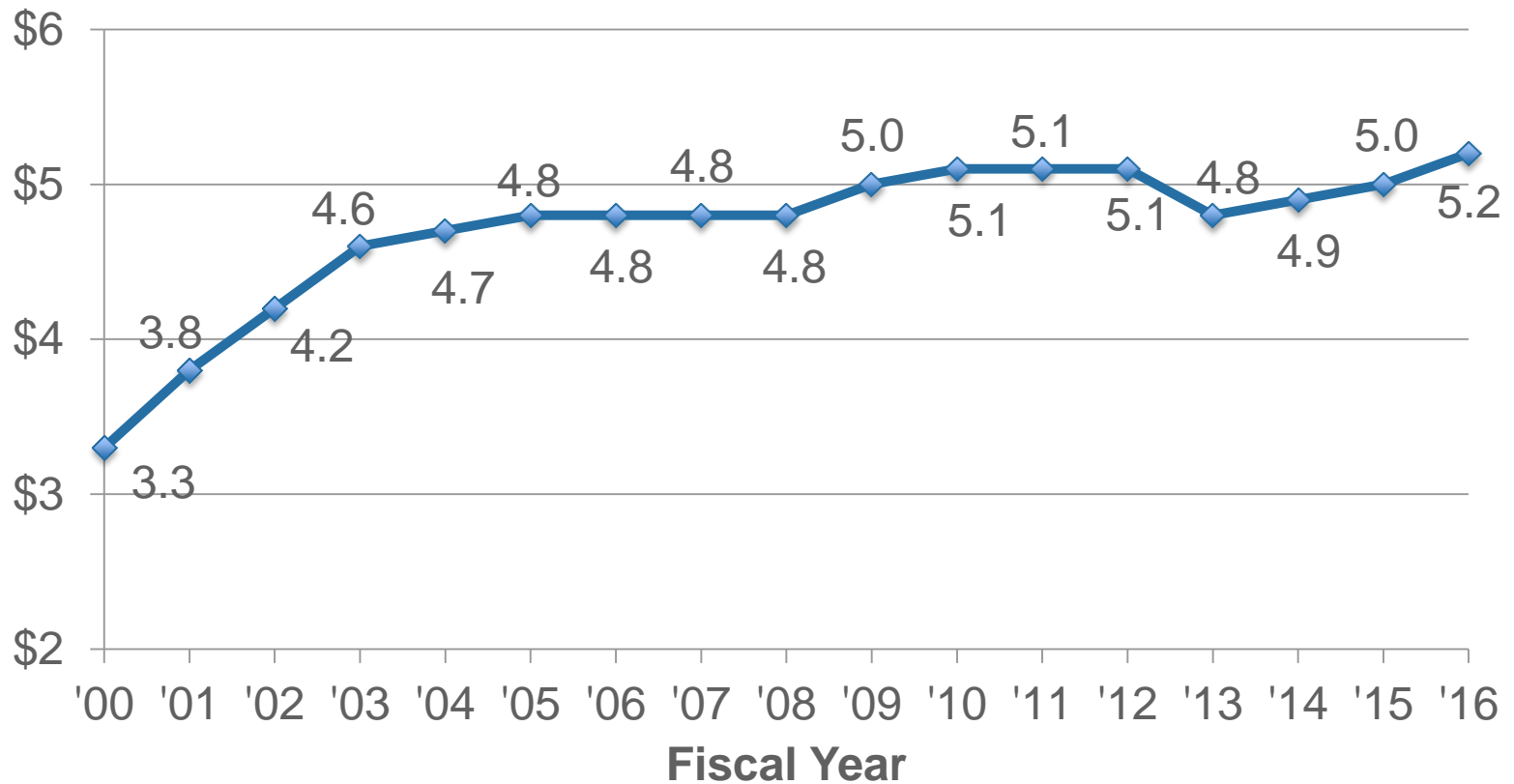
Institution	Specialist	Institution	Specialist
UNIV OF TX HSC, SA	Cornice Young	UNIVERSITY OF NEBRASKA MEDICAL CENTER	Leschell Browne
UNIVERSITY OF ALABAMA AT BIRMINGHAM	Marianne Galczynski	UNIVERSITY OF NEW MEXICO	Ashley Salo
UNIVERSITY OF ARIZONA	Marianne Galczynski	UNIVERSITY OF NORTH CAROLINA CHAPEL HILL	Cornice Young
UNIVERSITY OF CALIFORNIA	Candace Cofie	UNIVERSITY OF PENNSYLVANIA	Kimery Griffin
UNIVERSITY OF CALIFORNIA DAVIS	Long Nguyen	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	Renee Carruthers
UNIVERSITY OF CALIFORNIA IRVINE	Long Nguyen	UNIVERSITY OF SOUTHERN CALIFORNIA	Leschell Browne
UNIVERSITY OF CALIFORNIA LOS ANGELES	Jennifer Meininger	UNIVERSITY OF UTAH	Jackie Saval
UNIVERSITY OF CALIFORNIA SAN FRANCISCO	Tracie McGraw	UNIVERSITY OF VIRGINIA CHARLOTTESVILLE	Leslie Hickman
UNIVERSITY OF CHICAGO	Becky Brightful	UNIVERSITY OF WISCONSIN MADISON	Leslie Hickman
UNIVERSITY OF COLORADO DENVER	Debra Sowell	UT MD ANDERSON CANCER CTR	Martinson Owusu
UNIVERSITY OF HAWAII AT MANOA	Tracie McGraw	UT SOUTHWESTERN MED CTR	Rogers Gross
UNIVERSITY OF IOWA	Joy Kearse	VANDERBILT UNIVERSITY MEDICAL CENTER	Romy Reis
UNIVERSITY OF KANSAS MEDICAL CENTER	Rogers Gross	VIRGINIA COMMONWEALTH UNIVERSITY	Alice Wong
UNIVERSITY OF KENTUCKY	Funmi Elesinmogun	WAKE FOREST UNIVERSITY HEALTH SCIENCES	Alania Foster
UNIVERSITY OF MARYLAND BALTIMORE	Stephanie Mitchell	WASHINGTON UNIVERSITY	Alania Foster
UNIVERSITY OF MICHIGAN AT ANN ARBOR	Funmi Elesinmogun	WAYNE STATE UNIVERSITY	Dianna Bailey
UNIVERSITY OF MINNESOTA TWIN CITIES	Renee Carruthers	WISTAR INSTITUTE	Justin Birken
		YALE UNIVERSITY	Marianne Galczynski

An Overview of 2016

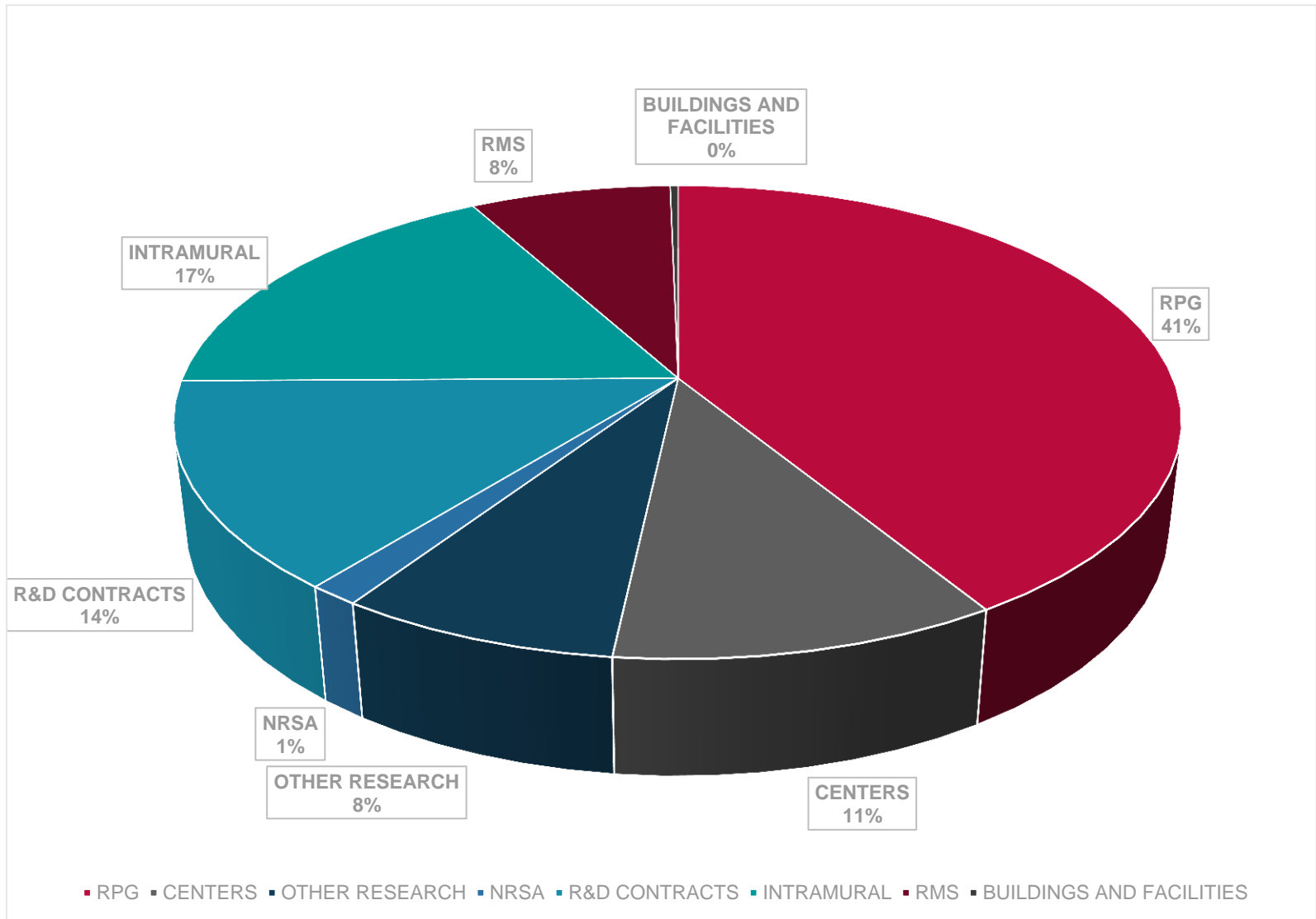


Budget Appropriation: History

NCI Historical Appropriations (in Billions)



FY16 Budget Allocation



Cancer Center Funding

Center Institution	Total Count by NCI (P30)	Total Awarded by NCI (P30)	Total Count by NCI (All Grants)	Total Awarded by NCI (All Grants)	Center Institution	Total Count by NCI (P30)	Total Awarded by NCI (P30)	Total Count by NCI (All Grants)	Total Awarded by NCI (All Grants)
SLOAN-KETTERING INST CAN RESEARCH	1	14,486,888	145	85,451,410	NORTHWESTERN UNIVERSITY AT CHICAGO	1	5,357,283	81	38,247,062
UNIVERSITY OF TX MD ANDERSON CAN CTR	1	13,449,135	165	88,831,330	WASHINGTON UNIVERSITY	1	5,077,655	77	41,961,142
DANA-FARBER CANCER INST	1	13,146,264	142	93,193,474	COLUMBIA UNIVERSITY HEALTH SCIENCES	1	4,945,000	89	40,021,498
FRED HUTCHINSON CANCER RESEARCH CENTER	1	11,534,215	106	90,913,482	UNIVERSITY OF CALIFORNIA SAN DIEGO	1	4,739,366	73	34,431,836
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	1	9,173,139	159	77,876,339	MASSACHUSETTS INSTITUTE OF TECHNOLOGY	1	4,714,477	38	20,600,603
UNIVERSITY OF PENNSYLVANIA	1	8,996,088	136	56,874,756	ALBERT EINSTEIN COLLEGE OF MEDICINE, INC	1	4,645,998	39	20,409,901
UNIV OF NORTH CAROLINA CHAPEL HILL	1	8,111,796	106	50,214,922	UNIVERSITY OF CALIFORNIA LOS ANGELES	1	4,613,042	64	57,382,377
JOHNS HOPKINS UNIVERSITY	1	7,685,078	148	72,472,736	H. LEE MOFFITT CANCER CTR & RES INST	1	4,482,554	55	29,111,025
VANDERBILT UNIVERSITY MEDICAL CENTER	1	7,431,836	57	46,338,161	UNIVERSITY OF WISCONSIN-MADISON	1	4,413,496	55	25,691,666
MAYO CLINIC ROCHESTER	1	7,216,386	94	68,892,246	COLD SPRING HARBOR LABORATORY	1	4,405,681	19	15,127,746
UNIVERSITY OF MICHIGAN	1	6,907,684	126	60,090,518	UNIVERSITY OF ARIZONA	1	4,403,098	19	11,866,865
UNIVERSITY OF SOUTHERN CALIFORNIA	1	6,452,396	51	34,797,834	BAYLOR COLLEGE OF MEDICINE	1	4,295,074	63	33,416,812
ST. JUDE CHILDREN'S RESEARCH HOSPITAL	1	6,301,234	29	27,453,567	UNIVERSITY OF COLORADO DENVER	1	4,143,350	74	24,832,401
OHIO STATE UNIVERSITY	1	6,262,257	101	54,025,362	YALE UNIVERSITY	1	4,094,557	82	38,823,133
UNIVERSITY OF PITTSBURGH AT PITTSBURGH	1	6,254,373	100	54,342,931	SANFORD BURNHAM PREBYS MEDICAL DISCOVERY INSTITUTE	1	4,033,698	33	18,898,478
DUKE UNIVERSITY	1	6,244,033	100	40,270,926	UNIVERSITY OF CALIFORNIA AT DAVIS	1	4,004,972	43	20,727,594
UNIVERSITY OF ALABAMA AT BIRMINGHAM	1	5,923,908	45	21,688,965	DARTMOUTH COLLEGE	1	3,675,405	30	13,918,952
ROSWELL PARK CANCER INSTITUTE CORP	1	5,800,493	52	23,763,151	UNIVERSITY OF MINNESOTA	1	3,672,748	71	31,125,863
CASE WESTERN RESERVE UNIVERSITY	1	5,524,545	63	26,125,870	RESEARCH INST OF FOX CHASE CAN CTR	1	3,494,444	26	12,000,699
UNIVERSITY OF CHICAGO	1	5,399,272	48	20,692,531	UNIVERSITY OF UTAH	1	3,414,052	57	22,524,548

Cancer Center Funding

Center Institution	Total Count by NCI (P30)	Total Awarded by NCI (P30)	Total Count by NCI (All Grants)	Total Awarded by NCI (All Grants)	Center Institution	Total Count by NCI (P30)	Total Awarded by NCI (P30)	Total Count by NCI (All Grants)	Total Awarded by NCI (All Grants)
STANFORD UNIVERSITY	1	3,345,301	127	57,078,391	OREGON HEALTH & SCIENCE UNIVERSITY	1	2,414,334	39	24,626,003
UNIVERSITY OF MARYLAND BALTIMORE	1	3,214,506	31	12,595,209	UNIVERSITY OF KANSAS MEDICAL CENTER	1	2,406,978	20	8,274,747
INDIANA UNIV-PURDUE UNIV AT INDIANAPOLIS	1	3,212,367	44	17,789,831	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	1	2,373,000	67	26,247,769
BECKMAN RESEARCH INSTITUTE/CITY OF HOPE	1	3,158,050	47	24,864,674	WAKE FOREST UNIVERSITY HEALTH SCIENCES	1	2,336,492	38	17,482,299
SALK INSTITUTE FOR BIOLOGICAL STUDIES	1	3,092,538	15	9,718,822	EMORY UNIVERSITY	1	2,334,778	63	22,548,465
UNIVERSITY OF IOWA	1	3,078,799	29	15,296,191	UNIVERSITY OF TEXAS HLTH SCIENCE CENTER	1	2,326,896	35	12,153,349
WAYNE STATE UNIVERSITY	1	3,013,085	23	10,546,282	UNIVERSITY OF CALIFORNIA-IRVINE	1	2,282,863	28	9,866,853
THOMAS JEFFERSON UNIVERSITY	1	2,924,751	40	14,107,670	UNIVERSITY OF HAWAII AT MANOA	1	2,229,295	12	13,972,208
UNIVERSITY OF NEW MEXICO HEALTH SCIS CTR	1	2,905,739	13	7,007,211	UNIVERSITY OF NEBRASKA MEDICAL CENTER	1	2,221,625	32	13,207,455
UNIVERSITY OF KENTUCKY	1	2,834,801	33	12,082,656	Total	69	326,832,251	4,146	2,135,160,118
WISTAR INSTITUTE	1	2,788,079	42	22,612,237	Center Institution Consortia				
NEW YORK UNIVERSITY SCHOOL OF MEDICINE	1	2,730,844	61	26,670,488	UNIVERSITY OF WASHINGTON	0	455,194	62	25,020,760
UT SOUTHWESTERN MEDICAL CENTER	1	2,679,396	52	24,448,885	HARVARD UNIVERSITY	0	383,271	5	2,815,261
MEDICAL UNIVERSITY OF SOUTH CAROLINA	1	2,676,354	41	19,479,695	MIRIAM HOSPITAL	0	219,841	0	219,841
RBHS -CANCER INSTITUTE OF NEW JERSEY	1	2,659,950	25	10,366,797	GEORGE WASHINGTON UNIVERSITY	0	210,140	11	3,890,921
GEORGETOWN UNIVERSITY	1	2,656,055	36	16,658,381	UNIVERSITY OF ROCHESTER	0	197,997	33	11,757,981
JACKSON LABORATORY	1	2,558,945	10	5,545,687	UNIVERSITY OF MIAMI SCHOOL OF MEDICINE	0	195,300	32	10,219,292
UNIVERSITY OF VIRGINIA	1	2,513,301	38	17,940,524	Total	6	1,661,743	143	53,924,056
PURDUE UNIVERSITY	1	2,475,310	15	6,396,022	Grand Total	75	328,493,994	4,289	2,189,084,174
VIRGINIA COMMONWEALTH UNIVERSITY	1	2,460,849	29	10,144,605					

NCI Awards in FY 2016

- NCI Awarded 1,230 competing Research Project Grants (RPGs) which was an overall success rate of 12%.
- 75% of the RPGs are R01s and R21s
- Funded nearly all R01 and R21 applications with scores up to and including the 10th percentile
- R03s and R15s with impact scores of 25 and better were funded.
- Additional applications with higher scores were funded after review and approval by the NCI's Divisions and Scientific Program Leaders

More information at [FY 2016 Funding Patterns](#)

R50 Research Specialist Award

- Designed to encourage the development of stable research career opportunities for exceptional scientists who want to pursue research within the context of an existing cancer research program, but not serve as independent investigators.
- [PAR-16-025](#) – 34 Awards issued in Summer 2016
 - Reminder – funds freed up on other NCI grants as a result of the R50 award are restricted and may not be used for any purpose without NCI prior approval
- 2017 – reissued as two separate FOAs – applications were due in February 2017 – for award this summer.
 - [PAR-17-049](#) – Exceptional researchers who want to pursue research activities in the context of a research program
 - [PAR-17-050](#) – Exceptional researchers who want to continue to support cancer research in the context of a core/shared resource

NCI Predoctoral to Postdoctoral Fellow Transition Award (F99/K00)

- Designed to facilitate the transition of talented grad students into successful cancer research postdoc appointments
- Provide opportunities for career development activities relevant to the long-term career goals of becoming independent cancer researchers
- [RFA-CA-16-005](#) – 36 awards issued in the summer of 2016.
- 2017 – RFA reissued as [RFA-CA-17-014](#) – closed in February 2017 with anticipated funding in September 2017.

Looking Into to 2017



NIH FY 2017 Continuing Resolution

- NIH is funded under the Continuing Appropriations Act, 2017 ([Public Law 114-254](#)) signed by former President Obama on December 10, 2016 which funds the government until April 28, 2017. (*anticipated extension for one week until May 5th*)
- NIH Funding under the current CR is continued at 99.8 percent of FY 2016 level (\$31.3 Billion)
- All FY 2016 legislative mandates remain in effect for the duration of the CR
- One change is in the Salary Cap level for awards issued under the CR
 - Still restricted at Executive Level II of the Federal Executive pay scale
 - Level II previously set at \$185,100 – increased to \$187,000 effective January 8, 2017.

see [NOT OD-17-048](#) and related notices

NRSA Postdoctoral FY 17 Stipends

- NIH announced stipend levels for postdoctoral trainees and fellows supported by Kirschstein NRSA awards in FY 2017.
 - **Tuition and Fees**
 - *Postdoctoral Trainees and Fellows:*
 - 60% of requested amount up to \$4,500 per year.
 - *If the trainee or fellow is enrolled in formal degree-granting training*
 - 60% of requested amount up to \$16,000 per year
 - **Training Related Expenses (Training Grant) and Institutional Allowance (Fellowship)**
 - *Postdoctoral Fellows and Trainees:* \$8,850
 - **Institutional Allowance for Federal and For-Profit Individual Fellows**
 - *Postdoctoral Fellows:* \$7,750
- See [NOT-OD-17-003](#) for additional information

NRSA Postdoctoral FY 17 Stipends

Career Level	Years of Experience	Stipend for FY 2017	Monthly Stipend
Postdoctoral	0	\$47,484	\$3,957
	1	\$47,844	\$3,987
	2	\$48,216	\$4,018
	3	\$50,316	\$4,193
	4	\$52,140	\$4,345
	5	\$54,228	\$4,519
	6	\$56,400	\$4,700
	7 or More	\$58,560	\$4,880

Adjustment to NRSA Postdoctoral Stipends

- Normally new stipend levels go into effect with the current Fiscal Year's Award
- However, effective December 1, 2016, NIH announced that we will provide one time supplements to currently active awards for trainees at levels 0, 1 and 2.
- Specifically, recipients of Kirschstein-NRSA institutional training grant and individual fellowship awards supporting appointments of currently active postdoctoral trainees and fellows at levels 0, 1, and 2, may apply for supplemental funding to support the stipend increase.
- Applications must be submitted by June 30, 2017.
- Guidance on adjusting appointment records to reflect the increases was published in [NOT-OD-17-057](#)

New Opportunities in FY 2017



21st Century Cures Act

Landmark piece of legislation - accelerating the discovery, development and delivery of 21st century cures and other purposes.

- Reducing Administration Burden for Researchers
 - Sub-recipient monitoring
 - The care and use of laboratory animals
- Privacy and Data Access Provisions
 - Authorizes NIH Director to require funding recipients to share data
 - Requires issuance of Certificates of Confidentiality and enhances their protections

21st Century Cures Act Cont...

- Inclusion and Workforce Provisions

- Ensure women, children and racial/ethnic minorities are appropriately represented in clinical research
- Assemble data on study populations in clinical research on women, minorities, and age categories

- Innovation Projects

- Brain Research through Advancing Innovative Neurotechnologies Initiative (BRAIN)
- Precision Medicine Initiative
- Regenerative Medicine
- Cancer Moonshot – authorized \$1.8 billion over 7 years.

Information on NCI's Cancer Moonshot activities – including milestones and funding opportunities to support the initiative can be found at [Cancer Moonshot](#) on Cancer.gov

NIH Policy Updates





Research Performance Progress Reports (FRPPR)

The Final Research Performance Progress Report (FRPPR) has replaced the Final Progress Report (FPR) for closeout effective January 1, 2017

- The general format is the same as the interim/annual RPPR
- Recipients are required to report on Project Outcomes
- Project Outcomes will be made publicly available
- Due dates have not changed – 120 days after the end of the final budget period

See [NOT-OD-17-022](#) for additional information

Renewal Application Progress Report Policy Change

In order to maximize public transparency, NIH will not maintain the current renewal application policy.

- **NIHGPS Chapter 8.6.2** states that “whether funded or not” the progress report contained within the renewal application may serve in lieu of a separate final progress report.

The change aligns NIH’s final performance reporting requirement with the requirements of other Federal research awarding agencies.



Interim-Research Performance Progress Reports (I-RPPR)

Effective February 9, 2017, NIH requires that organizations submit an “Interim-RPPR” while their renewal application (Type 2) is under consideration

- In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment
- If the Type 2 is not funded, NIH will treat the Interim-RPPR as the institution’s Final-RPPR

Like the Final-RPPR, recipients are required to report on Project outcomes in the Interim-RPPR.

- See [NOT-OD-17-037](#) for additional information

Workflow Process

Scenario	Status of Competing Renewal Application	Workflow Process
1	Competing Renewal not submitted	Submit a Final-RPPR <u>no later than 120 calendar days</u> from the period of performance end date.
2	Competing Renewal submitted	Submit an Interim-RPPR <u>no later than 120 calendar days</u> from the period of performance end date. If the competing renewal is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment.
3	Competing Renewal submitted but not funded	Submit an Interim-RPPR <u>no later than 120 calendar days</u> from the period of performance end date. If the competing renewal is not funded, NIH will treat the Interim-RPPR as the institution's Final-RPPR. To reduce burden NIH will not require recipients to submit an additional Final-RPPR if the renewal application is not funded.

NIH requires recipients to report on Project Outcomes in Section I of the Interim and Final-RPPR. Therefore, in each scenario listed above, Project Outcomes must be provided by the recipient in order for the recipient to submit their final report in eRA Commons. Otherwise, eRA Commons will not allow recipients to submit the required report and recipients will be considered non-compliant.

If a recipient fails to comply with this reporting requirement, NIH may take one or more enforcement actions, such as a decision to withhold a non-competing continuation award, consistent with **NIHGPS Chapter 8.5.2**.

NIH Implementation - RPPRs

- **Annual RPPR** – Use to describe a grant’s scientific progress, identify significant changes, report on personnel, and describe plans for the subsequent budget period or year.
- **Final RPPR** – Use as part of the grant closeout process to submit project outcomes in addition to the information submitted on the annual RPPR, except budget and plans for the upcoming year.
- **Interim RPPR** – Use when submitting a renewal (Type 2) application. If the Type 2 is not funded, the Interim RPPR will serve as the Final RPPR for the project. If the Type 2 is funded, the Interim RPPR will serve as the annual RPPR for the final year of the previous competitive segment. The data elements collected on the Interim RPPR are the same as for the Final RPPR, including project outcomes.

Final Rule -- Federal Policy for the Protections of Human Subjects

[The Final Rule](#) – effective January 19, 2018 – is intended to enhance protections for human research participants, facilitate valuable research, and reduce burdens for investigators, research institutions, and Institutional Review Boards (IRBs).

- Studies that have not undergone initial IRB review will be subject to the new Final Rule requirements.
- Research ongoing on that date will continue to be subject to the current Common Rule requirements.
- The single IRB requirement for cooperative research vs. multi-site studies takes effect three years later (January 20, 2020).

****The NIH policy on the use of single IRBs in multi-site studies takes effect in September 2017.****

See [NOT-OD-17-038](#) for additional information

NIH Policy - Use of a Single IRB for Multi-Site Research

Effective for competing grant applications with receipt dates on or after September 25, 2017.

- Domestic sites participating in multi-site studies involving non-exempt human subjects research funded by NIH are expected to use a sIRB to conduct the ethical review required by the DHHS regulations for the Protection of Human Subjects.
- Single Institutional Review Board (sIRB)
 - Costs – sIRB costs can be a direct or indirect charge to an NIH award as long as such costs are reasonable and consistent with the cost principles.
 - Exceptions to this policy will be made where review by the proposed sIRB would be prohibited by a federal, tribal or state law, regulation or policy. Requests for exceptions that are not based on a legal, regulatory or policy requirement will be considered if there is a compelling justification for the exception
 - FAQs for [sIRB Implementation](#) and [sIRB Costs](#) have been posted.

See [NOT-OD-16-094](#) and [NOT-OD-17-027](#) for additional information.

Enhancing Clinical Trial Stewardship & Transparency

NIH announced the following policy to improve its stewardship of clinical trials.

New NIH Policies:

- Expects all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials be trained in Good Clinical Practice (GCP). – Effective as of January 1, 2017
[NOT-OD-16-148](#)
- Expects all NIH-funded clinical trials are registered and that results are submitted to ClinicalTrials.gov whether or not subject to FDAAA – Applies to grants, contracts and NIH intramural clinical trials submitted on or after January 18, 2017 [NOT-OD-16-149](#)

Enhancing Clinical Trial Stewardship & Transparency

- Requires that all applications involving one or more clinical trials be submitted in response to a clinical trial-specific FOA – Effective for receipt dates on or after January 25, 2018 [NOT-OD-17-043](#)
- Applications requesting funding to support one or more clinical trials will be required to provide significantly more information on the trial – including things like a protocol synopsis, description of the study design, outcomes or measures, statistical design and power and a plan for complying with the NIH policy on dissemination. Application guides and instructions are being developed now.

Policy Reminders



Reminder Appendix Policy Change

NIH issued a new policy to eliminate most appendix materials submitted with applications. The new policy was effective for application due dates on or after January 25, 2017.

Allowable Appendix Materials:

- For all applications:
 - Blank informed consent/assent forms
 - Blank surveys, questionnaires, data collection instruments
 - FOA-specified items
- For Clinical Trials (all of the above plus the following):
 - Clinical trial protocols
 - Investigator's brochure from Investigational New Drug (IND)

Reminder: Applications will be withdrawn and not reviewed if they are submitted with appendix materials that are not allowed and/or required by the FOA.

Reminder Post-Submission Materials for Applications

NIH issued guidance which simplifies and consolidates the current NIH policy concerning post-submission materials effective for all applications submitted on or after January 25, 2017.

- The only post-submission materials that NIH will accept are those resulting from unforeseen events.

Reminder: The policy on post-submission application materials is not intended to correct oversights/errors discovered after submission of the application

See [NOT-OD-16-130](#) for additional information

Reporting Preprints and Other Interim Research Products

- The NIH encourages investigators to use interim research products, such as preprints, to speed the dissemination and enhance the rigor of their work.
- NIH published [NOT-OD-17-050](#) clarifying reporting instructions to allow investigators to cite their interim research products and claim them as products of NIH funding.
- Interim research products can be cited anywhere other research products are cited.
- For applications submitted for the May 25, 2017 due date and thereafter, awardees can claim these products on their progress report publication list. They can also report them on their RPPR as of May 25, 2017, and [link them to their award](#) in their My Bibliography account.

Update and Clarification on Continuous Submission

- NIH's continuous submission policy provides members of review and advisory groups and reviewers with recent substantial service the benefit of submitting R01, R21, and R34 applications at any time in response to active funding opportunity announcements (FOAs) that have standard due dates.
- [NOT-OD-17-042](#) – does not change any policy but simply consolidates seven (7) previous notices related to continuous submission to provide a single source for the policy.

Reminder Grant Closeout (Unilateral Closeout)

- Unilateral Closeout (action of last resort)-closeout of an award without the receipt of acceptable reports from the recipient.
- HHS policy requirement - Unilateral closeout of awards if the following final reports are not timely and acceptable.
 - Final Research Performance Progress Report (F-RPPR)
 - Final Invention Statement and Certification (FIS)
 - Final Federal Financial Report (FFR) - must ensure that there are no discrepancies between the final FFR expenditure data (in eRA Commons) and the FCTR in the PMS.

Electronic Submission & eRA Commons Updates



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Automated Post Award Changes

Recipients of NIH awards can submit certain prior approval requests electronically through eRA Commons.

Starting in March 2017

- **Prior Approval Request for Change of PD/PI**
- **Prior Approval Request for No Cost Extension (NCE)**

Plans for Summer 2017

- **Prior Approval Request for carryovers not included under automatic carryover authority.**

- For additional details please see [eRA Commons Online Help](#)

Working Together



Unobligated Balances and Carryovers

- NIH Grants Policy is that automatic carryover (authority to approve a carryover without NIH prior approval) is a standard term and condition of awards for all grants **except centers (including P30s)**, cooperative agreements, NRSA institutional training grants and clinical trials.
- NCI, recognizing the need for flexibility for the Cancer Center Director, has made an exception to that policy for the P30 CCSG – and allow automatic carryover on those awards
- Because we have made this exception to NIH policy, we take a very close look at the balances reported on the P30s.

OGA's Review of Large Balances

Specifically we are paying close attention to:

- Balances that maintain or grow year after year
- Balances that are a significant percentage of the pending award
- Developmental Fund balances and the plans for their use
- Balances that roll from one competitive segment to the next
- Status of funds in the HHS Payment Management System – including:
 - Subaccount Reports – reflect actual drawdown from PMS – this will tell us how much is still available in the current award
 - Estimated burn rate for remaining funds – based on historical draws how much can we expect will be expended in the current budget period
- Responses to requests for additional information from the grantee

Carryovers

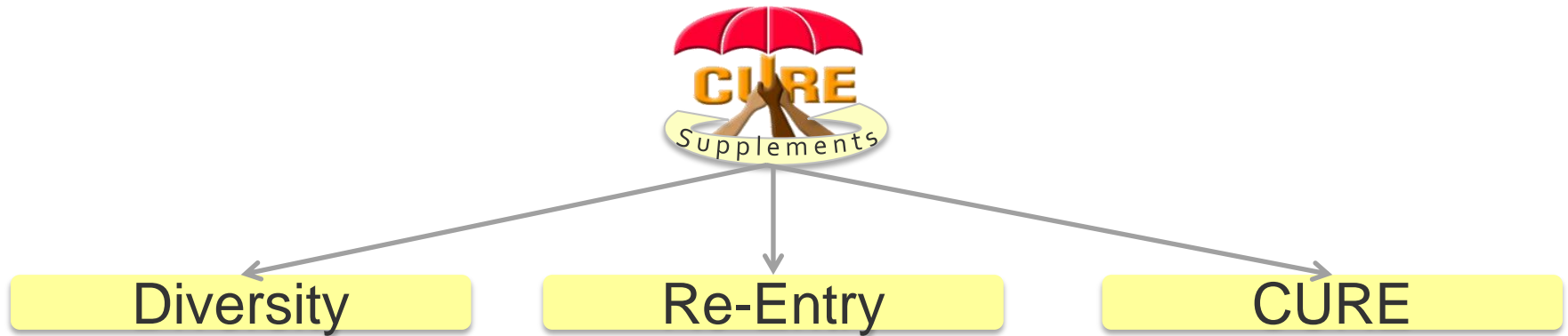
- NCI views a carryover to an award in the same way we would view a supplement to that award.
 - Things we look at and will ask for more information on:
 - How will the funds be used in addition to the new funds included in the award?
 - Is there a bona fide need for the additional funds? Do we have a reasonable belief that all of the funds will be needed and used in the next budget period?
 - Are funds already built into the award for this activity? Are there duplicative costs being requested in the parent award and the carryover?
 - Are there definitive plans for the use of the carryover funds? To be named individuals are a concern.
 - If the answers to these questions do not support the carryover, we may reduce the next Type 5 to allow the balance to clear.

Things that Contribute to the Balances

- Developmental Funds
 - Projects out of cycle with the parent award.
 - Timing of the solicitations for pilot projects.
 - Centers need to make every effort to get these projects to cycle as closely with the parent award as possible.
- Supplements
 - NCI causes the problem with the way we award supplemental funds
 - We are also trying to cycle supplements more closely with the parent award - short funding the first year and then fully funding outyears
 - However, because of the nature of the CCSG and because funding decisions on supplements are often made late in the year – we realize this isn't always possible. In these cases – we will be as flexible as possible.

CURE to R25 Mechanisms

Research Supplements within the CURE Program



- Parent grant of the Diversity supplement must have at least 2 years of active status at the time of supplement application (note – P30 not an eligible activity code)
- Candidates must be US citizens or Permanent Residents
- No concurrent PHS support for candidate
- Cannot be supported by parent grant
- For Re-Entry candidate must have been on hiatus from research for 1-8 years
 - Must be postdoctoral fellow or faculty before hiatus
- **Application receipt: Oct 1 – Dec 1 and Feb 1 – Mar 30**

[PA-16-288](#)

[PA-15-321](#)

Cancer Research Education Grants Program to Promote Diversity (R25)

Mechanism	Purpose
Research Experience (PAR-16-138)	<ul style="list-style-type: none"> • Support educational activities that enhance the diversity of cancer research workforce; • Participants may include biomedical researchers; health care providers; medical, dental, nursing, and other health professional students; and graduate and undergraduate students. <p>Standard Due Dates - January 25, May 25; September 25: DC ≤ \$300k per year for up to 5 years.</p>
Courses for Skills Development (PAR-16-139)	<p>Standard Due Dates - January 25, May 25; September 25: DC ≤ \$300k per year for up to 5 years.</p>
Youth Enjoy Science (YES) Program <u>PAR-17-059</u>	<ul style="list-style-type: none"> • Support program to engage grade 6-12 and undergraduate students from underrepresented populations; • Provide research experiences for K-12 teachers and undergraduate faculty members. <p>Standard Due Dates – January 25, May 25, September 25; DC ≤ \$500k per year for up to 5 years.</p>

R25 Research Experiences (PAR-16-138)

Purpose

- Provide innovative hands-on exposure and experience in cancer research in a laboratory and/or field setting
- Participants work closely with faculty and other researchers
- Enhance the diversity of the cancer research workforce
- Research Experiences may be related to a broad range of areas
 - i.e., cancer biophysics, therapeutics, biostatistics, translational, introduction to cancer, epigenetics, community outreach

R25 Research Experiences (PAR-16-138)

Key Points

- Provide innovative hands-on exposure to cancer research in a laboratory or field setting
- Full-time (40 hours per week) period of 10 to 15 weeks
- Participants must be at or above undergraduate career levels
- Research experiences and related training that are not available through formal NIH training mechanisms (i.e., T32)
- Maximum budget is \$300K DC/year; F&A is 8%; Maximum of 5 years
- Unless strongly justified, participants should be U.S. citizens or permanent resident status

R25 Courses for Skills Development

(PAR-16-139)

Purpose

- Provide innovative, state-of-the-art, evidence-based cancer education (biomedical, behavioral, clinical, or interdisciplinary)
- Enhance the diversity of the cancer research workforce
- Courses may be related to a broad range of areas:
i.e., cancer genomics, proteomics, nanotechnology, imaging, bioethics, policy, career development

R25 Courses for Skills Development (PAR-16-139)

Key Points

- Provide innovative cancer education course that is derived from biomedical, behavioral, and/or clinical cancer research
- Institutional grant
- Participants must be at or above undergraduate career levels
- Duration of course may not exceed 15 weeks per year
- Course may be in-person, online, or both
- Maximum budget is \$300K DC/year; F&A is 8%; Maximum of 5 years
- Unless strongly justified, participants should be U.S. citizens or permanent resident status

Eligibility Requirements for Both R25 FOAs

Eligible PDs/PIs:

- Any individual(s) with the necessary skills, knowledge, and resources
- Multiple PIs allowed, but not recommended due to level of effort and cost limits
- Foreign collaborators or sites require strong justification

Eligible Participants:

- Individuals at or above undergraduate career levels
- Individuals from racial and ethnic groups shown to be underrepresented in biomedical research, from disadvantaged backgrounds, and/or with disabilities
- Around 75% of participants should be from the above mentioned group (underrepresented, disadvantaged, and/or disabilities)

National Cancer Institute Youth Enjoy Science Research Education (PAR 17-059)

- The over-arching goal of this NCI R25 program is to support educational activities that enhance the diversity of the biomedical, behavioral and clinical research workforce.
- To accomplish the stated over-arching goal, the FOA supports creative educational activities with a primary focus on:
 - **Research Experiences:** With the aim of enhancing the pool of individuals from underrepresented backgrounds interested in pursuing a career in biomedical research via early intervention strategies, the NCI Youth Enjoy Science (YES) Program supports efforts to create and maintain a program to engage Grades 6-12 and/or undergraduate students from underrepresented populations in cancer research experiences.
 - **Curriculum or Methods Development:** Participants are expected to use their Research Experiences to develop and take back to their classrooms novel instructional approaches that improves science teaching. For programs that support students only, applicants are expected to develop educational tools for the students, in order to enhance their Research Experiences.
 - **Outreach:** Grade 6-8 students are expected to be exposed to various aspects of cancer research in an organized manner that will inspire continued interest and motivation to progress academically and scientifically. Programs that support Grades 6-12 students are expected to include activities that help educate their families and communities on the importance of science education, so that the students may carry out the Research Experiences in supportive environments.

Eligibility for YES Program

Program Faculty

- Researchers from diverse backgrounds, including racial and ethnic minorities, persons with disabilities, and women are encouraged to participate as preceptors/mentors. Mentors should have research expertise and experience relevant to the proposed program. Mentors must be committed to continue their involvement throughout the total period of the mentee's participation in this award.

Participants

- 6-12 grade and undergraduate students must be currently enrolled and in good standing at their respective middle or high school or undergraduate institutions. Teachers and faculty members must be currently employed at their respective schools or institutions and engaged in the teaching of the sciences.

Opportunity/Problem/Challenge

- **Diversification of the workforce on cancer research and biomedical research is a critical issue that needs to be addressed to reduce and eliminate cancer health disparities.**
- **Native Americans students and investigators are dramatically underrepresented in biomedical and cancer research.**
- **The NCI, through the CRCHD and in collaboration with NCI DOCs, has the opportunity to reach out to this population and develop an effective pipeline that would increase Native Americans representation in cancer research.**

What potential mechanisms could be used in implementing this initiative?

- Supplement funding to existing NCI grants to recruit Native American students and investigators.
- Administrative Supplements to Cancer Centers
- Technical assistance for preparing R25 applications (in FY 2017).
- Submission of R25s that target Native American and Alaska Native students training and skills development in close proximity to Native tribes and schools would be one of the goals (in FY 2018).

Administrative Supplements to Cancer Centers (PAR 17-241)

Supplement to CCSGs for developing collaborative partnerships between institutions serving underserved health disparity populations and underrepresented students (ISUPS), i.e., AI/ AN , and Cancer Centers with highly integrated cancer research programs.

Budget: Total Cost not to exceed \$75,000 total costs (\$50,000 Direct Costs)

Duration: 1 year (FY 2017)

Submission Date: 4/29/2017

Proposed Award Date: June 2017

At the end of the 1-year administrative supplement - it is expected that each participating Cancer Center will seek additional funding by developing and submitting an application to sustain the program. For example, through one of the R25 FOAs or any other suitable funding mechanism.

Questions?



NIH/NCI Resources



NCI Resources

- [Cancer.gov](https://www.cancer.gov) Website

- New design and layout for easier navigation
- ‘Audience-based’ to focus content where needed
- [OGA](#) has a grant specific page with a lot of useful information and more to come including FAQs for investigators and recipients

- NCI Grants Process Book

- [Online Edition](#)

- Formatted as web pages so it’s searchable
- Follows the lifecycle of a grant
- Easier to edit and keep current with new policies and changing guidelines

- New Print Edition

- PDF available to print online

Save the Date: 2017 NIH Regional Seminars

Fall Regional Seminar

Baltimore, MD

October 25th – 27th



See [NOT-OD-17-026](#) for details.

RPPR Resources

RPPR Webpage: <http://grants.nih.gov/grants/rppr/>

Includes links to:

- RPPR Application Guide
- RPPR Guide Notices
- Frequently Asked Questions
- Training
- Contacts

Frequently Asked Questions

FAQs –searchable websites for:

Application/progress report preparation, funding initiatives, policies, human subjects, animals, disaster response, PMS Subaccounts, Core Facilities, etc...

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

Summary of Helpful NIH Web Pages

Office of Extramural Research (OER) Web Page:

<http://grants.nih.gov/grants/oer.htm>

NIH Grants Policy Statement (Rev. 11/15):

<http://grants.nih.gov/grants/policy/nihgps/>

NIH Extramural Nexus – newsletter for the extramural community:

<http://nexus.od.nih.gov/all/nexus-by-date/>

Grant Application Basics:

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

eRA Training: Video Tutorials

http://era.nih.gov/era_training/era_videos.cfm

Summary of Helpful NIH Web Pages

Applying Electronically:

<http://grants.nih.gov/grants/ElectronicReceipt/index.htm>

Annotated SF424 (R&R) Application Forms (General and Small Business and Multi-project):

<http://grants.nih.gov/grants/ElectronicReceipt/communication.htm#forms>

Ten Checks to Help Avoid Common Application Errors:

http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm#10checks

Do I have the right electronic forms for my NIH application?:

http://grants.nih.gov/grants/ElectronicReceipt/files/right_forms.pdf

- Self Help Resources page:
- <http://grants.nih.gov/support/index.html>

Summary of Helpful NIH Web Pages

eRA Commons Web pages:

<http://era.nih.gov/>

eRA Commons User Guides:

http://era.nih.gov/commons/user_guide.cfm

Intellectual Property Policy:

<http://grants.nih.gov/grants/intell-property.htm>

■ Research Portfolio Online Reporting Tools (RePORT):

<http://report.nih.gov>

■ RePORT Expenditures & Results (RePORTER):

■ <http://projectreporter.nih.gov/reporter.cfm>

NIH OER Listservs

NIH Guide for Grants and Contracts:

Official publication for NIH Grant Policies, Guidelines & Funding Opportunities

<http://grants.nih.gov/grants/guide/listserv.htm>

Office for Human Research Protections (OHRP):

<http://www.hhs.gov/ohrp>

Office of Laboratory Animal Welfare (OLAW):

<http://grants.nih.gov/grants/olaw/references/list.htm>

eSubmission:

Separate listservs available for scientists and administrators

<http://grants.nih.gov/grants/ElectronicReceipt/listserv.htm>

OLAW Educational Outreach



OLAW free quarterly webinars series:

<http://grants.nih.gov/grants/olaw/e-seminars.htm>

- Recordings of past webinars

http://grants.nih.gov/grants/olaw/educational_resources.htm

Disaster planning resources:

http://grants.nih.gov/grants/olaw/disaster_planning.htm

- Disaster planning webinar & FAQ

OLAW-supported Workshops, Conferences and Educational Outreach



SCAW Workshops & Conferences

- May 5, 2017 – College Park, MD
- September 14, 2017 – New York
- September 15, 2017 – New York

IACUC 101 Series Workshops

- March 19, 2017 – New Orleans, LA
- April 19, 2017 Phoenix, AZ
- June 7, 2017 Missoula, MT

<http://grants.nih.gov/grants/olaw/workshop.htm>



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