

# NIH Update

**Michelle G. Bulls, Director**  
**Office of Policy for Extramural Research Administration,**  
**OER, NIH**

Federal Demonstration Partnership, May 2016



National Institutes of Health

# NIH FY 2016 Budget News

NIH is currently funded under the Consolidated Appropriations Act, 2016 (Public Law 114-113) signed by President Obama on December 18, 2015.

NIHs FY 2016 budget amount is \$32.3 billion which represents a \$2 billion increase over FY 2015.

NIH awarding ICs have developed and posted their fiscal policies on their respective websites. These policies are consistent with NIHs overall spending goals for FY2016.

See [NOT-OD-16-046](#) for details.



# Precision Medicine Initiative (PMI)

The PMI will enable a new era of medicine through research, technology and policies that empower patients, researchers, and providers to work together to develop individualized care.

\$200 million was allocated to NIH for the PMI in FY16

- \$130 million to build a national, large-scale cohort (research participant group) of one million or more U.S. participants
- \$70 million to NCI to lead efforts in cancer genomics



# National Cancer Moonshot Initiative

The National Cancer Moonshot Initiative was established to accelerate cancer research, to make more therapies available to more patients, and to improve our ability to prevent cancer and detect it an early stage.

The FY2017 President's budget request includes \$680 million of additional funding for NCI to support the this national cancer research initiative and a \$260.5 million increase in NCI funding in its FY2016 appropriation.

Community input is critical to the success of the National Cancer Moonshot Initiative, and NIH is asking the community to submit their scientific ideas or suggestion for addressing cancer research challenges to [cancerresearch@nih.gov](mailto:cancerresearch@nih.gov) (closes July 1).



# Grants Oversight and New Efficiency (GONE) Act

Enacted January 28, 2016

## Key Provisions:

- HHS Secretary designated as lead because about 80% of all federal grants are provided through HHS and Treasury payment systems.
- Report due to HHS Secretary and Congress NLT 12/31/17 that:
  - Lists each Federal grant award held by such agency;
  - Provides the total number of Federal grant awards, including the number of grants—
    - by time period of expiration;
    - with zero dollar balances; and
    - with undisbursed balances;
  - For an agency with Federal grant awards, describes the challenges leading to delays in grant closeout; and
  - For the 30 oldest Federal grant awards of an agency, explains why each Federal grant award has not been closed out

***Key Point of Analysis – Grants 2+ years past project end date, including all extensions, not yet closed***

**NIH awaiting specific guidance and requirements for implementation from HHS.**



# Draft NIH Policy on the Use of a Single Institutional Review Board (sIRB) for Multi-Site Research

The purpose of this Policy is to increase the use of single Institutional Review Boards (sIRB) for multi-site studies funded by NIH while reducing the administrative burden on recipients without compromising the Protection of Human Subjects.

- Once effective, this Policy will apply to all domestic Extramural grant applications (Type 1 and 2) participating in NIH conducted or supported multi-site studies, whether supported through grants, or contracts.
- Although not required for Foreign sites participating in multi-site studies, they may opt to use the sIRB as well.
- Compliance with this Policy will be a term and condition in the Notice of Award and a contract requirement in the Contract Award.

See [NOT-OD-15-026](#) for details.



# Restructured and Streamlined Application Guides and Supplemental Instructions

NIH has updated the application guide and supplemental instructions for use with grant application due dates on or after May 25, 2016. In addition to incorporating policy changes, the updated (FORMS-D) application guide has been restructured and streamlined based on helpful feedback received from the NIH Request for Information issued last summer.

## Key changes:

- Created a new [How to Apply - Application Guide](#) webpage that will serve as your new central resource for competing application submission information.
- Took a new approach to the format of the general application instructions
- Provided new, filtered views of the application instructions specific to research, career development, training, fellowship, multi-project, and small business applications.
- Provided in PDF format only
- Posted a [chart](#) that shows which application instructions to follow for each activity code.
- Edited and formatted content to eliminate duplicative information, and to improve clarity and scanability.
- Provided automatic redirects from old to new URLs to minimize impact of change in approach.
- Provided access to format pages, including biosketch and data table documents, under the form at attachment link on the [How to Apply - Application Guide](#) webpage as well as on the [NIH forms page](#).

\*\*Updates to form instructions are listed at: <http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general/g.120-significant-changes.htm>. \*\*



# Updated Forms (Forms-D) for Administrative Supplement, Successor-in-Interest and Change of Institution Opportunities

## **FORMS-D Transition Plan for Administrative Supplement, Successor-in-Interest (Type 6) and Change of Institution (Type 7) Announcements without Specific Due Dates**

- On May 25, 2016 NIH will reissue Administrative Supplement, Successor-in-Interest (Type 6) and Change of Institution (Type 7) Announcements that do not have specific due dates with new funding opportunity announcement (FOA) numbers and FORMS-D application packages. Applications started on or after May 25, 2016 must use the new FOAs and FORMS-D.

## **FORMS-D Transition Plan for Administrative Supplement FOAs with Specific Due Dates**

- On May 25, 2016 NIH will close FORMS-C and add FORMS-D application packages to administrative supplement FOAs with specific due dates.

Note: The current FORMS-C FOA's and application packages will close on May 25, 2016. Although recipients **will not** have the ability to start new applications, you will have 30 days after the close date to submit any in-progress applications and complete the submission process. FORM-C submissions will not be accepted after June 24, 2016.

See [NOT-OD-16-068](#) for details.





# Research Terms and Conditions

On April 14, 2016, the RTC working group completed its review of the public comments received in response to the Draft RTC Overlay document published in the Federal Register on October 14, 2015.

**The Federal Register comments can be grouped into 3 overarching themes:**

- Request
- Concerns
- Positive Feedback

**High Level Next Steps:**

- Initiate formal OSTP Clearance Process
- Clear through OMB
- Participating Agency Implementation

To view the draft Research Terms and Conditions, see: <http://www.nsf.gov/awards/managing/rtc.jsp>.



# Reminder: Grant Closeout

**Unilateral Closeout is the closeout of an award without the receipt of acceptable reports from the recipient.**

- Unilateral closeout is an important action of last resort after discussions between the grantee and NIH staff are unable to remedy the situation.
- NIH staff will continue to partner with our grantees to obtain acceptable reports from our grantees.
- NIH asks that grantees identify and resolve financial discrepancies between the final FFR expenditure data (in eRA Commons) and the FCTR in the PMS prior to submitting final reports.

Thanks for your support!



# Reminder: Timely Reporting

## **Annual progress reports must be submitted in the RPPR format.**

- Non-SNAP annual progress reports are due the 1<sup>st</sup> of the month preceding the month in which the budget period ends.
- SNAP progress reports are due the 15<sup>th</sup> of the month preceding the month in which the budget ends.
- Multi-year funded progress reports due on the anniversary of the budget/project period start date of the award (electronic submission RPPR only).

## **Federal Financial Report (FFR)(SF-425) Expenditure Data**

- Annual (Non-SNAP Awards)
  - FFR submitted for each budget period no later than 90 days after the end of the calendar quarter (CQ) in which the budget period ended.
  - Budget period ends 1/31/2016 – FFR due 6/30/16  
(90 days after the end of the CQ of 3/31/16)
- Final – (SNAP and Non-SNAP Awards)
  - FFR submitted within 120 days following the end of the **project** period.



# Reminder: 2016 NIH Regional Seminars

## **Spring Session:**

May 11<sup>th</sup>-13<sup>th</sup>

Baltimore, MD

## **Fall Session:**

October 26<sup>th</sup>-28<sup>th</sup>

Chicago, IL

See [NOT-OD-16-083](#) for details.



THANK YOU!

