

21st Century Cures Act Implementation

Update for
Advisory Committee to the Director
June 8, 2017



Adrienne Hallett, MTS
Associate Director for Legislative Policy & Analysis



Enacted December 13, 2016



One Hundred Fourteenth Congress
of the
United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Monday,
the fourth day of January, two thousand and sixteen*

An Act

To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,



Implementation Overview

- Over 50 provisions have a direct impact on NIH or touch on the agency's activities
- Unlike most legislation, 21st Century Cures is predominantly concerned with trans-NIH policy
- Two OD offices are responsible for implementing 72% of the provisions:
 - Office of Extramural Research 38%
 - Office of Science Policy: 17%
 - OER & OSP Collaborating: 17%

Legislative Implementation Work Group

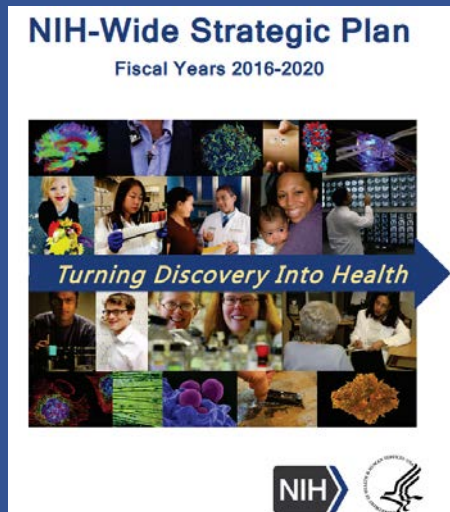
IC Director Representatives:

- Dr. Gary Gibbons, Director, NHLBI
- Dr. Jon Lorsch, Director, NIGMS
- Dr. Josie Briggs, Director, NCCIH

OD Representatives:

- Adrienne Hallett, Associate Director for Legislative Policy and Analysis
- Dr. Mike Lauer, Deputy Director for Extramural Research
- Barbara McGarey, Deputy Associate General Council for Public Health
- Mike Shannon, Director, Office of Management Assessment
- Neil Shapiro, Associate Director for Budget
- Dr. Carrie Wolinetz, Associate Director for Science Policy

Completed Actions



NIH-Wide Strategic Plan

Released December 2015

Rehabilitation Research Plan

Published September 2016

National Institutes of Health (NIH)
**Research Plan on
Rehabilitation**



MOVING THE FIELD *FORWARD*

Completed Actions

Establishment of *All of Us* Research Program (Precision Medicine Initiative)

- May 22, 2017: IRB approval of master protocol
- May 31, 2017: Launch of Beta Phase, 1st participants enrolled at University of Pittsburgh
- Summer/Fall 2017: Beta Phase continues; new sites come onboard every 2 weeks
- All leading to national launch in late 2017



Completed Actions

Exemption of NIH Research From Paperwork Reduction Act Requirements

- OER published guidance on April 5, 2017

Innovation Fund Projects

- Work Plans: ACD approved 03/28/17
- Funding Opportunity Announcements published
 - Moonshot: 12 FOAs issued in 2017
 - BRAIN Initiative: 28 FOAs issued in 2017
 - Precision Medicine Initiative: Ongoing
 - Regenerative Medicine: 12 FOAs issued 04/28/17
 - ❖ Note: ACD will act as advisory council for these awards

Completed Actions

Workshop on Inclusion Across the Lifespan

- When: Took place June 1st and 2nd
- Goal: Have right people represented in studies
- Preliminary conclusions:
 - New Criteria: Assume inclusion / justify exclusion of subgroups
 - Involve stakeholders in study design / targeted recruitment strategies to ensure representation
 - Require participant reporting by age
 - Should be no across-the-board arbitrary age limit for trials
- Deadlines:
 - 06/30/17: RFI to solicit input from scientific community and public concerning inclusion in research
 - 11/19/17: NIH Director must determine whether NIH polices need to be updated

In Progress

Task Force on Research Specific to Pregnant Women and Lactating Women

(<http://www.nichd.nih.gov/about/advisory/PRGLAC>)

- Led By NICHD
- Charter filed March 13, 2017
- Report to the Secretary and Congress due Sept 13, 2018
- Meetings scheduled:
 - August 21-22, 2017;
 - November 6-7, 2017;
 - February 26-27, 2018; and
 - May 14-15, 2018

In Progress

Next Generation Researcher Initiative

“(b) ACTIVITIES.—The Director of the National Institutes of Health, through the Initiative shall—

“(1) promote policies and programs within the National Institutes of Health that are focused on improving opportunities for new researchers and promoting earlier research independence, including existing policies and programs, as appropriate;

“(2) develop, modify, or prioritize policies, as needed, within the National Institutes of Health to promote opportunities for new researchers and earlier research independence, such as policies to increase opportunities for new researchers to receive funding, enhance training and mentorship programs for researchers, and enhance workforce diversity;

- NASEM Study in progress: Chaired by Johns Hopkins President Ronald J. Daniels
- ❖ Enhanced support for early stage and mid-career researchers
- ❖ Pilot programs for physician scientists being developed based on a series of workshops in 2016

In Progress

Improving Clinical.Trials.gov

- Partnership between NLM and the GSA technology innovation office
- Official Project launched in February
- First round of stakeholder input completed in April
- First in a series of changes expected June 19
- Next Steps
 - Ongoing stakeholder input to validate improvements
 - Improved interface expected in FY 17

In Progress

Rigor and Reproducibility

SEC. 2039. ENHANCING THE RIGOR AND REPRODUCIBILITY OF SCIENTIFIC RESEARCH.

(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall convene a working group under the Advisory Committee to the Director of the National Institutes of Health (referred to in this section as the “Advisory Committee”), appointed under section 222 of the Public Health Service Act ([42 U.S.C. 217a](#)), to develop and issue recommendations through the Advisory Committee for a formal policy, which may incorporate or be informed by relevant existing and ongoing activities, to enhance rigor and reproducibility of scientific research funded by the National Institutes of Health.

- May 25, 2017: First ACD working group meeting
- ❖ June 8, 2017: Interim report to the ACD
- June 13, 2018: Deadline for ACD Consideration of Working Group Recommendations
- December 13, 2018: Deadline for Report to Congress

Upcoming Deadlines

- **June 12, 2017**
 - Innovation Work Plans due to Congress
- **October 1, 2017**
 - 1st Annual Innovation Fund Report due to Congress
- **November 29, 2017**
 - Policy updates re: appropriate age groups in clinical research must be revised
- **December 13, 2017**
 - Update of Inclusion Guidelines
 - Valid analysis of variables affecting women or minority groups