

# NIH Reform Act of 2006

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# Evolution of NIH Reauthorization

- **1944 - 1985 – Individual bills amending missions of existing ICs or creating new ICs.**
- **1985 – First omnibus reauthorization of NIH.**
- **1993 – Second omnibus reauthorization of NIH.**
- **1993 – 2004 – Authorization process subsumed by appropriations laws. Some individual bills created new ICs or amended authorities. Failed attempt for omnibus reauthorization in 1996.**
- **2004 –2006– Post doubling era, focus on accountability and oversight, new successful attempt for omnibus reauthorization.**



# Proposals for NIH Reauthorization

- Consolidate ICs to as few as 14.
- Divide ICs into 6 budget clusters, with a lead IC responsible for coordination.
- Divide ICs into mission-specific and science-enabling categories, with two appropriations funds.
- Require independent review and reorganization of NIH (base-closing model).



# National Institutes of Health Reform Act of 2006

- Passed Congress with virtually unanimous support (Dec 2006)
- Signed into law by the President (Jan 2007)
- Act authorizes appropriations of:
  - \$30,331,309,000 for FY07
  - \$32,831,309,000 for FY08
  - such sums as may be necessary for FY 2009
- New structure to facilitate *trans-NIH* research

One Hundred Ninth Congress  
of the  
United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Tuesday,  
the third day of January, two thousand and six*

An Act

To amend title IV of the Public Health Service Act to revise and extend the authorities of the National Institutes of Health, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Institutes of Health Reform Act of 2006".

TITLE I—NIH REFORM



# NIH Director

## New authorities to improve coordination

- Responsible for program coordination across the ICs.
- Required to assemble accurate data to be used to assess research priorities.
- Required to ensure that scientifically based strategic planning is implemented in support of research priorities determined by the ICs.
- Ensure that the resources of NIH are sufficiently allocated for research projects identified in strategic plans.
- In coordination with the Directors of the ICs, the Director of NIH will be required to ensure that investigator-initiated research is maximized, when appropriate.

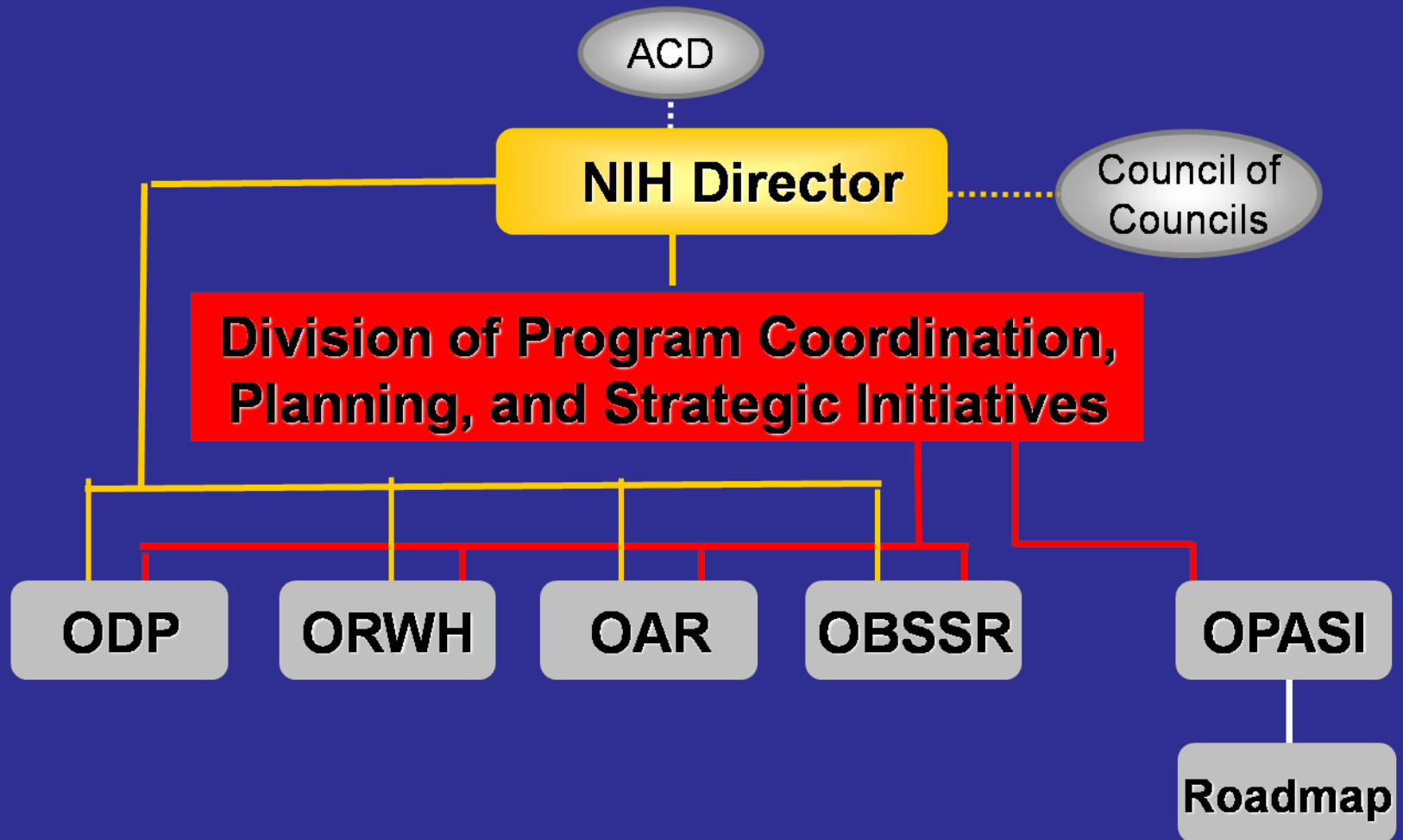


# NIH Reform Act Establishes: Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)

- **Authorized to identify *Trans*-NIH research (e.g., through Roadmap process) for support by Common Fund**
  - *Trans*-NIH Research proposals must include milestones and goals for the research activities
  - Appropriate consideration must be given to proposals from first time NIH investigator applicants
- **Must include information on *Trans*-NIH research in the new Biennial Report**
- **Moves ODP, ORWH, OAR, and OBSSR within DPCPSI**
  - Legislation explicitly states that these offices are to retain authorities in effect prior to enactment



# Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) Transition Structure



# NIH Reform Act Establishes: Council of Councils

- Advises the Director on matters related to the policies and activities of DPCPSI
- Makes recommendations on the conduct and support of *trans*-NIH research proposals supported by the Common Fund





# Council of Councils: Membership

- Composed of 27 members selected by NIH Director
- Terms are currently six year staggered terms
- Members must represent broad range of disciplines and perspectives
- Members must have ongoing inclusion of at least one representative from each Institute whose budget is substantial relative to a majority of the other Institutes
- Each IC nominates three individuals
  - Two must be scientists
  - One must be from general public or leader in field of public policy, law, health policy, economics, or management
- DPCPSI to nominate one individual from each program office
- Members of COPR



# NIH Reform Act Establishes: A Common Fund

- Source of funds for innovative and cross-cutting initiatives that will improve and accelerate biomedical research and its impact on the health of the Nation
- Managed by DPCPSI
- How does the Common Fund work?
  - It is the Roadmap for Medical Research Fund – currently 1.7% NIH Budget
  - Act does not establish formula for growth, but the Fund cannot ever drop as a percentage of the NIH budget
  - Review required when Common Fund reaches 5% of the NIH Budget



# NIH Reform Act Establishes: Scientific Management Review Board

## Mission:

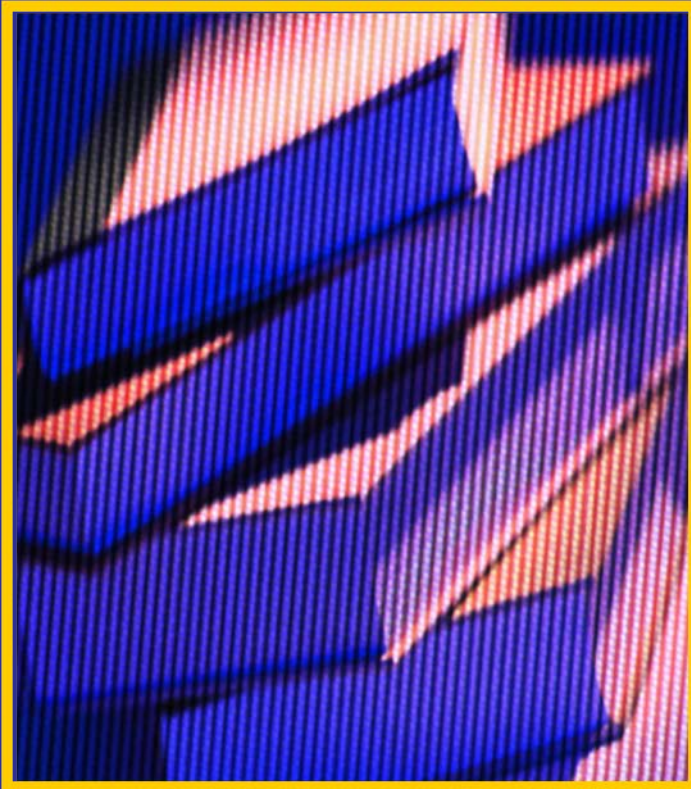
- Advise the NIH Director
- Conduct organizational reviews of NIH every seven years

## Composition:

- Board will include no more than 21 members
  - Directors of at least 9 ICs (big and small, old and young)
  - Director of NIH as non-voting *ex officio* member
  - Additional non-federal individuals from academia and private industry that received NIH funding



# NIH Reform Act Establishes: *Biennial Report*



- Biennial report will be:
  - An assessment of the state of biomedical and behavioral research
  - A detailed description of the research, priorities, and plans of the Institutes and Centers
- ~30 reports are eliminated or subsumed in new biennial report
- First report due January 15, 2008
- 11 additional reports also added by Reform Act

# Modified Reporting Requirements

## New Reports

ICs must report annually on:

- Trans-NIH collaboration
- Intra-HHS collaboration
- Experts and Consultants
- Human Tissue Samples

Extramural institutions must report to applicants to their doctoral programs:

- Length of time to degree completion
- Percentage of students that successfully attain doctoral degree



# Modified Reporting Requirements

## New Reports (cont'd)

NIH must report on:

- Whistleblower Complaints
- Clinical Trials to FDA
- Organizational Changes recommended by SMRB
- Evaluation of the Common Fund (when reaches 5%)



# NIH Reform Act: Additional Provisions

- Establishment of an electronic coding system to uniformly code research grants and activities.
- Advisory council review of grants under \$50K
- Public process involved for reorganizing NIH programs
- Demonstration Programs
  - Bridging the Sciences
  - High-Risk, High-Reward Research



# NIH Reform Act of 2006

“This affirmation from Congress has come at a critical time, and we want to ensure that we take the best possible advantage of its promise. We will be communicating with the community regularly as we make progress in this process.”

—Elias A. Zerhouni, M.D.

