

Evolution of the Division of Program Coordination Planning and Strategic Initiatives

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National Institutes of Health Reform Act of 2006



One Hundred Ninth Congress
of the
United States of America

AT THE SECOND SESSION

*Began 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

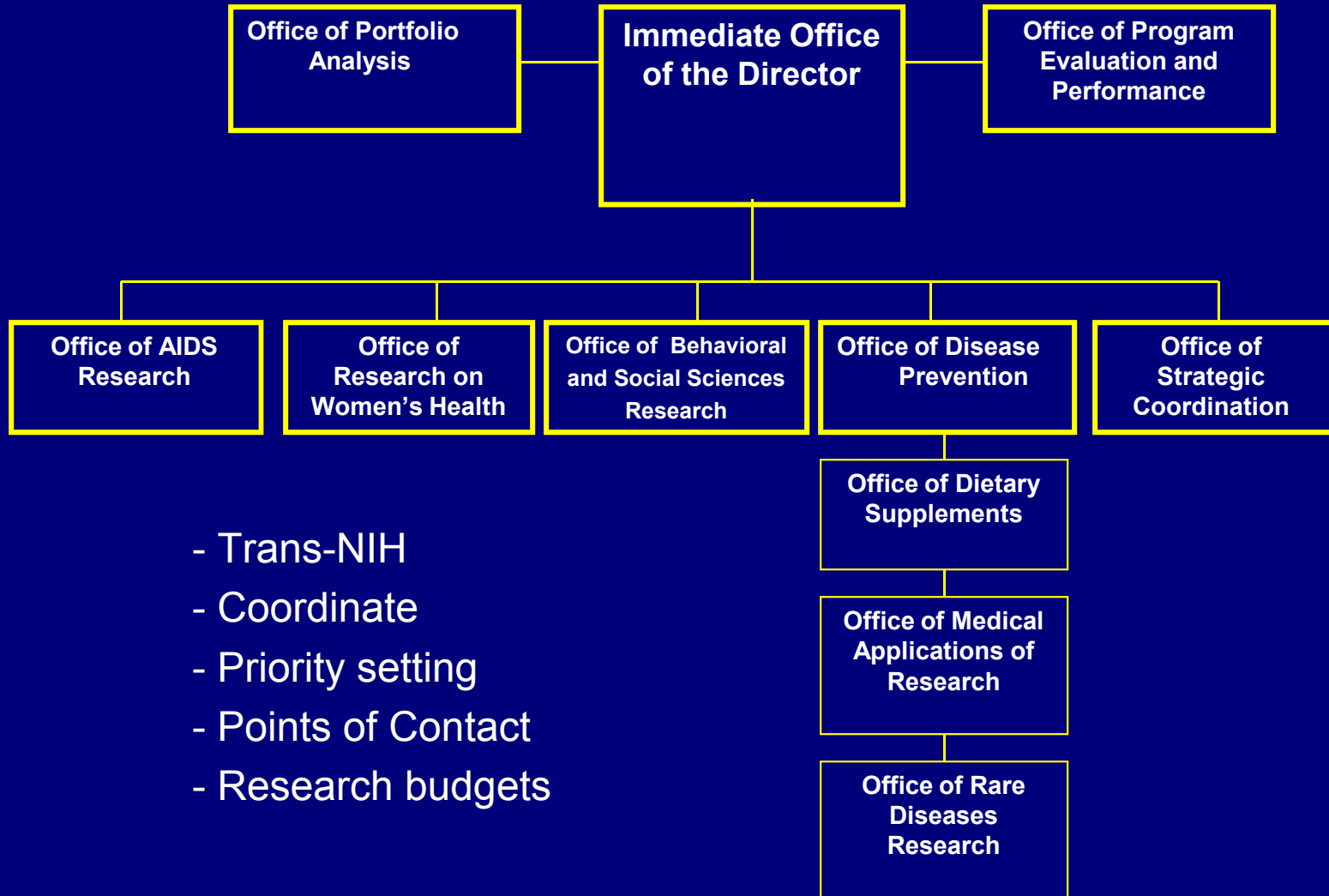
December 9, 2006: Congress unanimously passes a reauthorization bill affirming importance of NIH and its vital role in advancing biomedical research to improve the health of the Nation



Establishes:

- **Division of Program Coordination, Planning, and Strategic Initiatives** (replacing OPASI)
- **NIH Common Fund** to facilitate *trans*-NIH research (replacing Roadmap)
- **Council of Councils**

Division of Program Coordination, Planning, and Strategic Initiatives





Criteria for Common Fund Programs

Transformative:

Synergistic: Involves participation by multiple NIH ICs

Cross-Cutting: Program areas must cut across missions of multiple NIH ICs and be relevant to multiple diseases or conditions

Broad Benefit: Must be something no other entity is likely or able to do, and research results must benefit public health

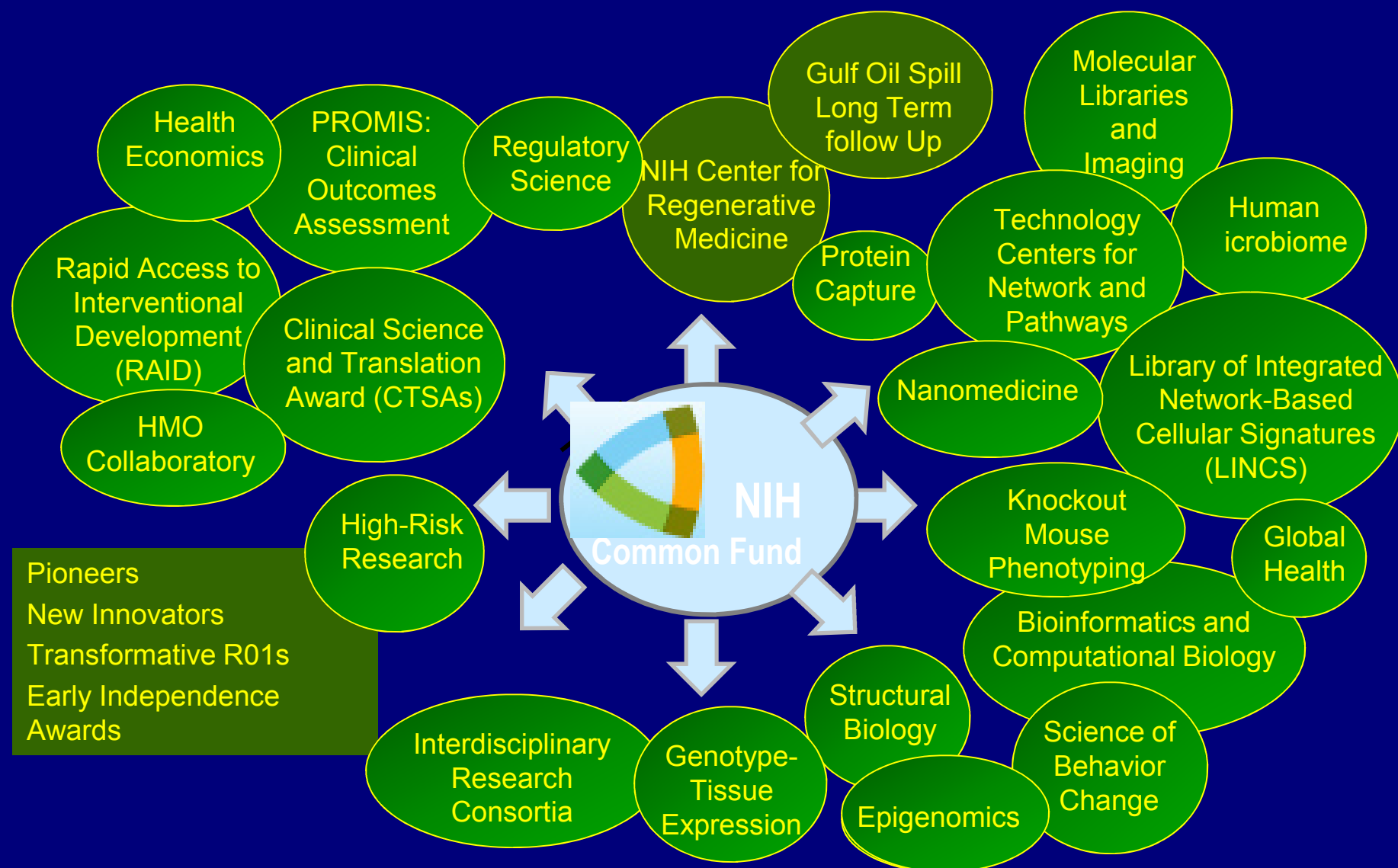
Implementation: Goals, milestones and deliverables transition to the community within the timeframe. Flexible Research Authority

Currently 24 Programs
FY2011 budget: \$543M

Common Fund Programs Are Catalytic

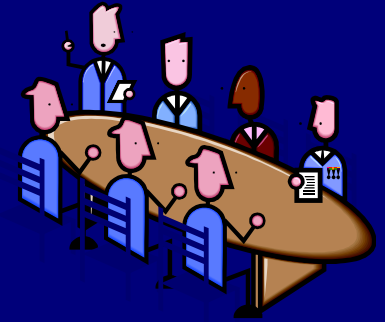
- **New Tools, Infrastructure, and Data to support or establish new fields of study**
 - Molecular Libraries and Imaging
 - Human Microbiome Project
 - Genotype-Tissue Expression Resources (GTEx)
 - Protein Capture Reagents
- **New Technologies and Approaches to overcome barriers to progress in a field**
 - Structural Biology
 - HMO Collaboratory
 - Technology Centers for Networks and Pathways
- **New Approaches to foster innovation and creativity**
 - Interdisciplinary Research
 - High-Risk High-Reward (HRHR)
 - Pioneer Awards
 - New Innovator Awards
 - Transformative R01 (TR01) awards
 - Early Independence Awards

Common Fund Programs 2004-2011



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

Council of Councils



- **Focus:**
 - Policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives
- **Specific Activities:**
 - Advise on research responsive to emerging scientific opportunities, public health challenges, and knowledge gaps and would benefit from conducting or supporting additional research that involves collaboration between two or more ICs, or would otherwise benefit from strategic coordination and planning
 - Major foci:
 - Several subcommittee reports
 - Advise the IC Directors during the “concept approval” stage for Common Fund Projects
 - 2nd level review of TRO1 & EIA Awards

Comparison Among Director's Advisory Committees

- **Council of Councils (2008)**
- **The Scientific Management Review Board (2009)** advises the Director on organizational issues, helping to ensure that NIH's structure is optimal for supporting the advancement of science.
- **The Advisory Committee to the Director (1996)** advises on NIH mission responsibilities in the conduct and support of biomedical research, medical science, and biomedical communications.

Scientific Management Review Board (SMRB) Recommendations to NIH



- May 2010
 - NIH Director Francis Collins asks SMRB to determine how NIH could better support translational and therapeutic sciences.
- December 2010
 - SMRB recommends (12 to 1) that a new translational medicine and therapeutics center be created.
 - SMRB also recommends NIH undertake a more extensive and **detailed analysis through a transparent process to evaluate the new center's impact.**

Proposed National Center for Advancing Translational Sciences (NCATS)

To advance the discipline of translational science and catalyze the development and testing of novel diagnostics and therapeutics across a wide range of human diseases and conditions



NCATS: Planning Process

- NIH Director established three panels to guide planning:
 - Institute and Center Directors' NCATS Working Group
 - Presented recommendations on NCATS mission, functions, and organization to NIH Director on Feb. 17, 2011
 - Advisory Committee to the Director (ACD) NCATS Working Group
 - Asked to provide high-level advice on how NCATS can best engage the private sector in translational science
 - Will report findings to full ACD later this year
 - NIH Clinical and Translational Science Awards (CTSA) Integration Working Group
 - Formed in March 2011 to facilitate transition of CTSAs into NCATS

NCATS WG recommended inclusion of:

- **Components of Molecular Libraries Program**
- **Therapeutics for Rare and Neglected Diseases**
- **Office of Rare Diseases Research**
- **Rapid Access to Interventional Development**
- **Clinical and Translational Science Awards**
- **FDA-NIH Regulatory Science**
- **Cures Acceleration Network**



NCRR Task Force

- Following the SMRB's December 2010 recommendations that NIH undertake a more extensive and **detailed analysis through a transparent process to evaluate the new center's impact**, the NIH Director established the NCRR Task Force to perform an analysis of all NCRR activities for possible inclusion in the proposed NCATS, the potential impact of moving those activities on NCRR, and whether NCRR programs should be moved elsewhere at the NIH.

NCRR Task Force Members

Name	Title
Lawrence Tabak (Co-chair)	Principal Deputy Director, NIH
Alan Guttmacher (Co-chair)	Director, NICHD
Hugh Auchincloss	Deputy Director, NIAID
James Battey	Director, NIDCD
Isabel Garcia	Acting Director, NIDCR
Richard Hodes	Director, NIA
Kathy Hudson	Deputy Director for Science, Outreach, and Policy, NIH
Gail Pearson	Medical Officer, NHLBI
Sally Rockey	Deputy Director for Extramural Research, NIH

NCRR Subject Matter Experts

Name	Title
Anthony Hayward	Director, Division of Clinical Research Resources
Iris Obrams	Deputy Director, Division of Clinical Research Resources
Amy Swain	Acting Director, Division of Biomedical Technology
Douglas Sheeley	Senior Scientific Officer, Division of Biomedical Technology
Franziska Grieder	Director, Division of Comparative Medicine
Harold Watson	Deputy Director, Division of Comparative Medicine
Michael Sayre	Health Scientist Administrator, Division of Research Infrastructure
Shelia McClure	Deputy Director, Division of Research Infrastructure
Sidney McNairy	Director, Division of Research Infrastructure
Gregory Farber	Acting Director, Office of Extramural Construction

Initial Task Force Analysis

- The Task Force concurred with the SMRB recommendation to transfer the CTSA program from NCRR to the proposed new Center, NCATS.
- The Task Force concluded that many of the programs that would remain in NCRR after the proposed CTSA transfer would benefit from the enhanced scientific adjacency that would be achieved by transfer of these programs to other Institutes or Centers.
- A “straw model” was drafted to facilitate planning of potential transfers by providing a framework for comment by stakeholders across NIH and from the extramural community .
 - The Straw Model was informed by input from NCRR leadership and Subject Matter Experts selected by NCRR leadership.
 - The Task Force also received input from the leadership of potential recipient Institutes and Centers.

Feedback Informed the Recommendations of the Task Force to the Director, NIH

- The Straw Model was posted to <http://feedback.nih.gov/> on January 18, 2011.
 - Over 1,400 comments have been received.
- Seven conference calls were convened with NCRR stakeholders (January 19-24).
- Dr. Tabak has also spoken with individual stakeholders by telephone or in person including a group representing the National Primate Research Centers.
- The NCRR Task Force considered comments on placement of NCRR programs from NCRR staff, from conference calls, the NCRR Advisory Council, and from the feedback website on placement of NCRR programs.

NCRR Task Force Recommendations

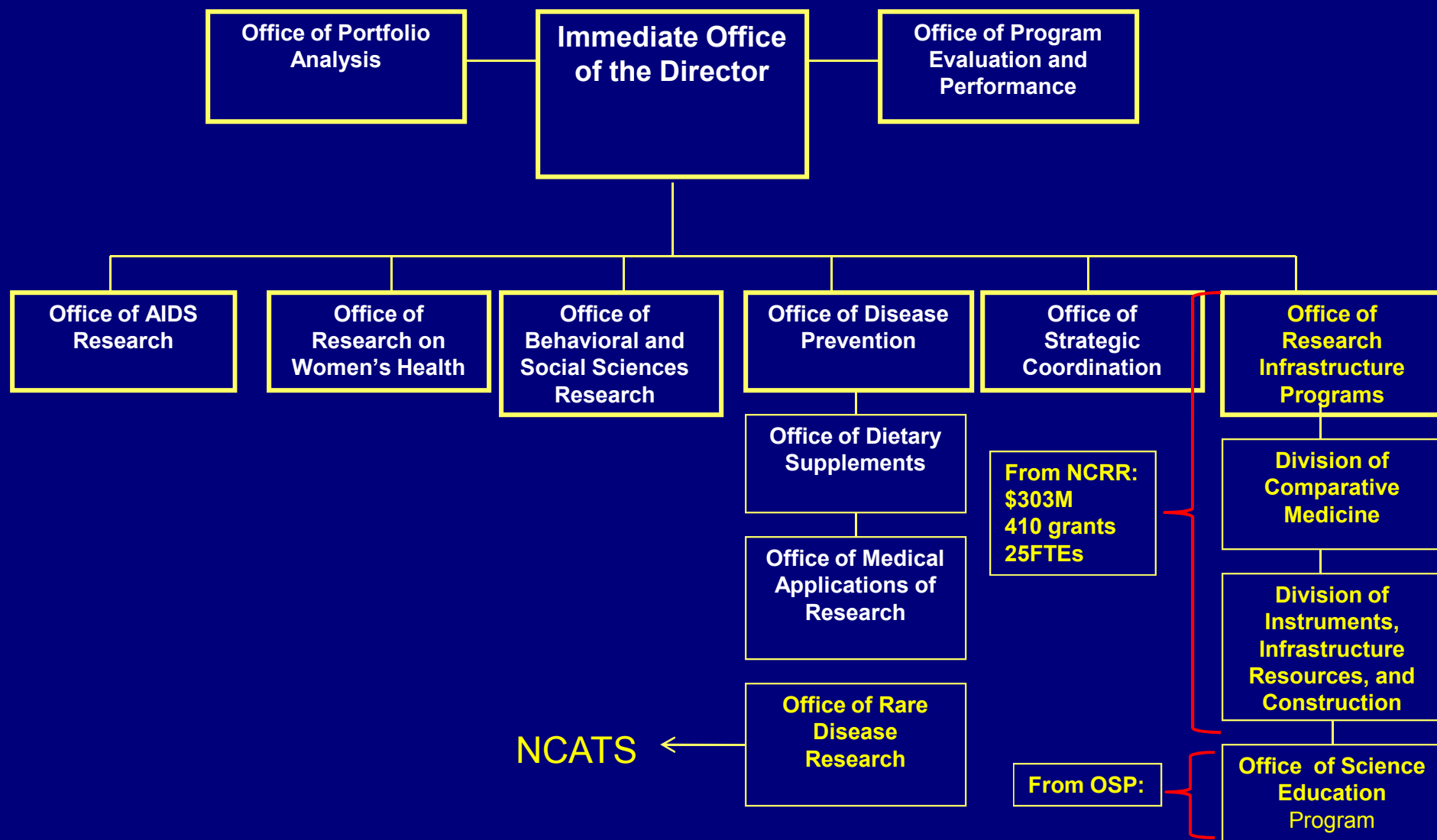
The Task Force used the following considerations and guiding principles in developing these recommendations:

- The scientific synergies that could be achieved by placing the NCRR program in adjacency to the existing (or in the case of NCATS, proposed) portfolio/mission of the recipient IC versus the existing synergies among the NCRR programs.**
- The “goodness of fit” for the NCRR program within the recipient IC versus the negative effects of adding a program that is disproportionately large and/or not well aligned to the recipient IC’s current (or in the case of NCATS, proposed) mission.**
- The level of disruption to long-standing NCRR programs led by dedicated NCRR staff versus the disruptive innovation from reassigning NCRR staff to enable interactions with new colleagues and/or new programs.**

NCRR Task Force Recommendations

Placement	Program
NCATS	<ul style="list-style-type: none"> Clinical and Translational Science Awards (CTSA)
NHLBI	<ul style="list-style-type: none"> Gene Vector Repository
NIBIB	<ul style="list-style-type: none"> Imaging and Point-of-Care Biomedical Technology Research Centers (BTRC) grants Biomedical Imaging and Point-of-Care research grants for Technology Research and Development and SBIR/STTR grants
NIGMS	<ul style="list-style-type: none"> Institutional Development Awards (IDeA) All other BTRC grants All other research grants for Technology Research and Development, and the SBIR/STTR and BIRN network grants
NIMHD	<ul style="list-style-type: none"> Research Centers in Minority Institutions program (RCMI)
OD - Office of Research Infrastructure Programs	<ul style="list-style-type: none"> Comparative Medicine Program Extramural Construction and Animal Facilities Improvement Shared and High-End Instrumentation Science Education Partnership Awards (SEPA)

Proposed - Division of Program Coordination, Planning, and Strategic Initiatives

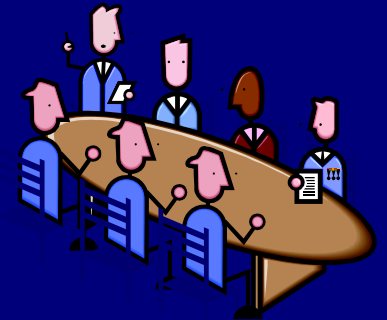


Office of Science Education

- **Started and matured in the Office of Science Policy (OD)**
- **Mission: *coordinates science education activities at the NIH for K-12 and college students and teachers and the public.***
- **Activities:**
 - Develop curriculum supplements
 - Website as a central source of information about NIH science education resources
 - Establish national model programs in public science education
 - Promote science education reform
- **Requesting statutory authority for educational activities (vs. training)**

Expanded Role of the Council of Councils

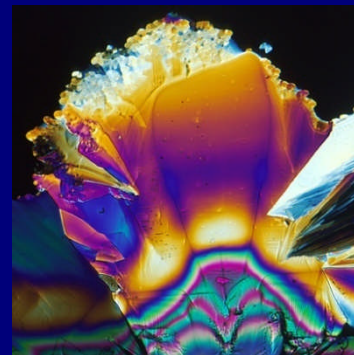
- 2nd level review for all grants moving to DPCPSI
- Concept clearance for new programs
- Requires 3 meetings each year
- Targeted subcommittees



DPCPSI Planning Efforts are Underway

for example

- **Expand Council expertise**
- **DPCPSI & OER staff working on grants and contract transitions**
- **Grants management through NCATS service center (previous NCRR grants staff)**
- **IRGs**
 - **Scientific and Technical Review Board on Biomedical and Behavioral Research Faculties**
 - **Comparative Medicine Review Committee**
 - **SEPs**
- **Personnel, budget and management plans are being prepared**
- **Implementation can begin after HHS-Congressional appropriations committees face-to-face review of reorg plan and budget**



NIH

*Turning discovery
into health*

