Council of Councils Meeting DPCPSI Update

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Director

Division of Program Coordination, Planning, and Strategic Initiatives

February 1, 2012

Updates

- Organizational changes in DPCPSI, one of which introduces a new Council responsibility
- Common Fund updates
- New Council Working Group to implement IOM recommendations on chimpanzees in NIH-supported research
- Second-level review and early concurrence of grants

National Institutes of Health Reform Act of 2006

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

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 the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within Office of the Director and the NIH Common Fund to facilitate *trans*-NIH research

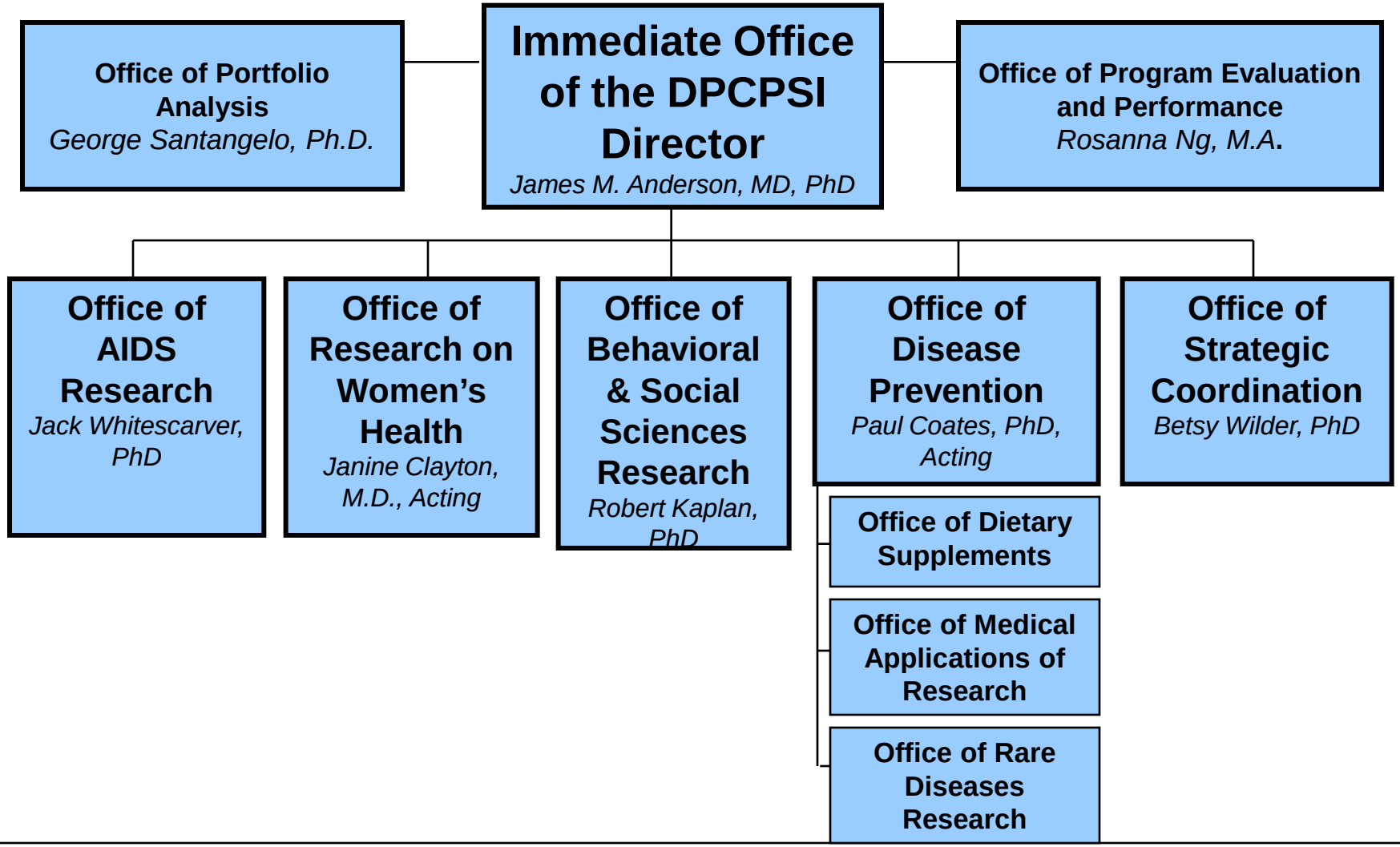
Organizational Changes to NIH

- ~ 5 years after DPCPSI was established
- The President signed the FY2012 Consolidated Appropriations Act on December 23, 2011:
  - Established the National Center for Advancing Translational Sciences (NCATS) as a new IC
  - Dissolved the National Center for Research Resources (NCRR)
- As a result, former NCRR grants, contracts, scientific, and administrative staff reassigned to NCATS, DPCPSI, or other ICs including NIBIB, NIGMS and NIMHD.
- Additional organizational realignments also occurred at or around the same time to functionally align offices or programs with common interests.

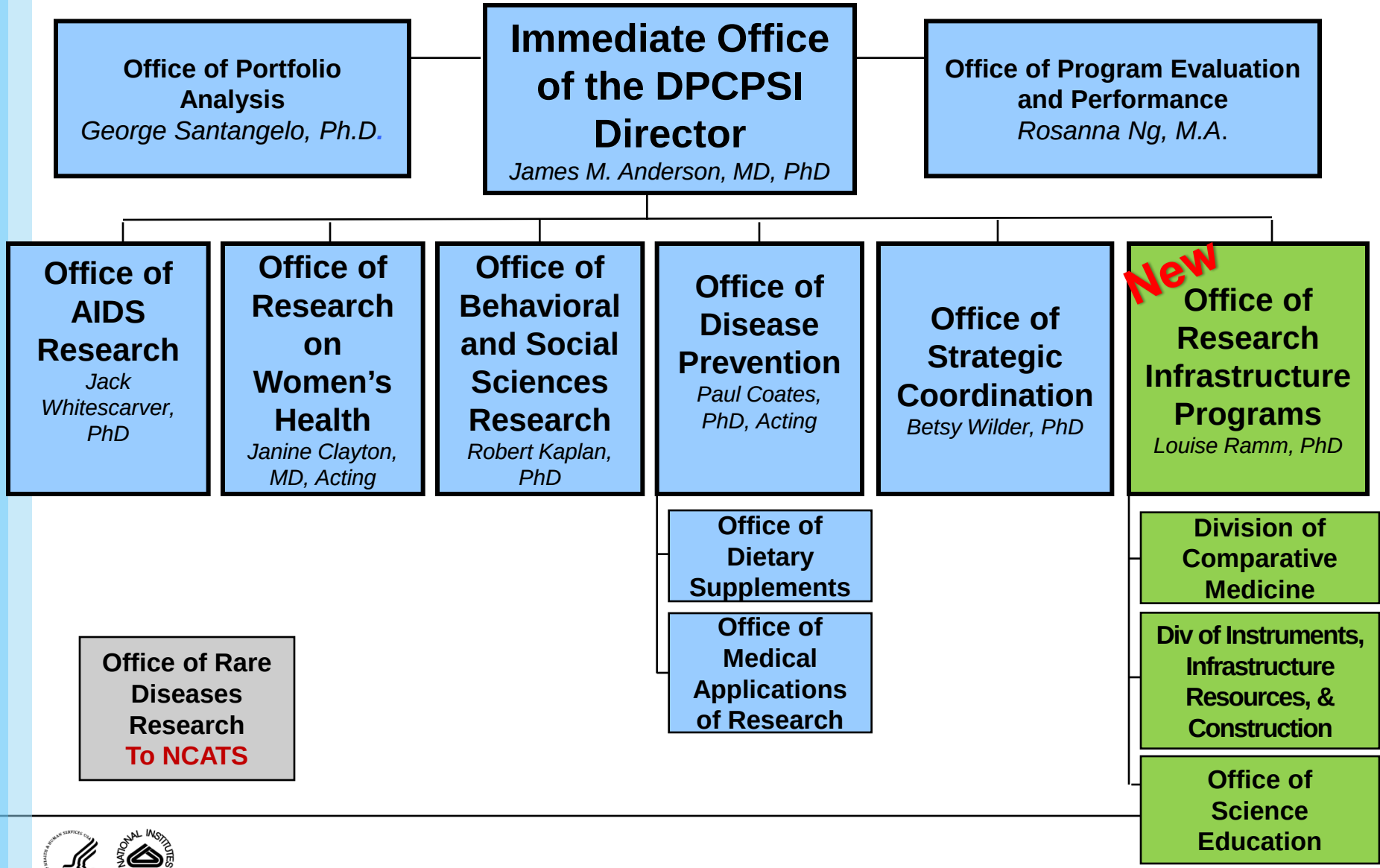
National Center for Advancing Translational Sciences (NCATS)

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

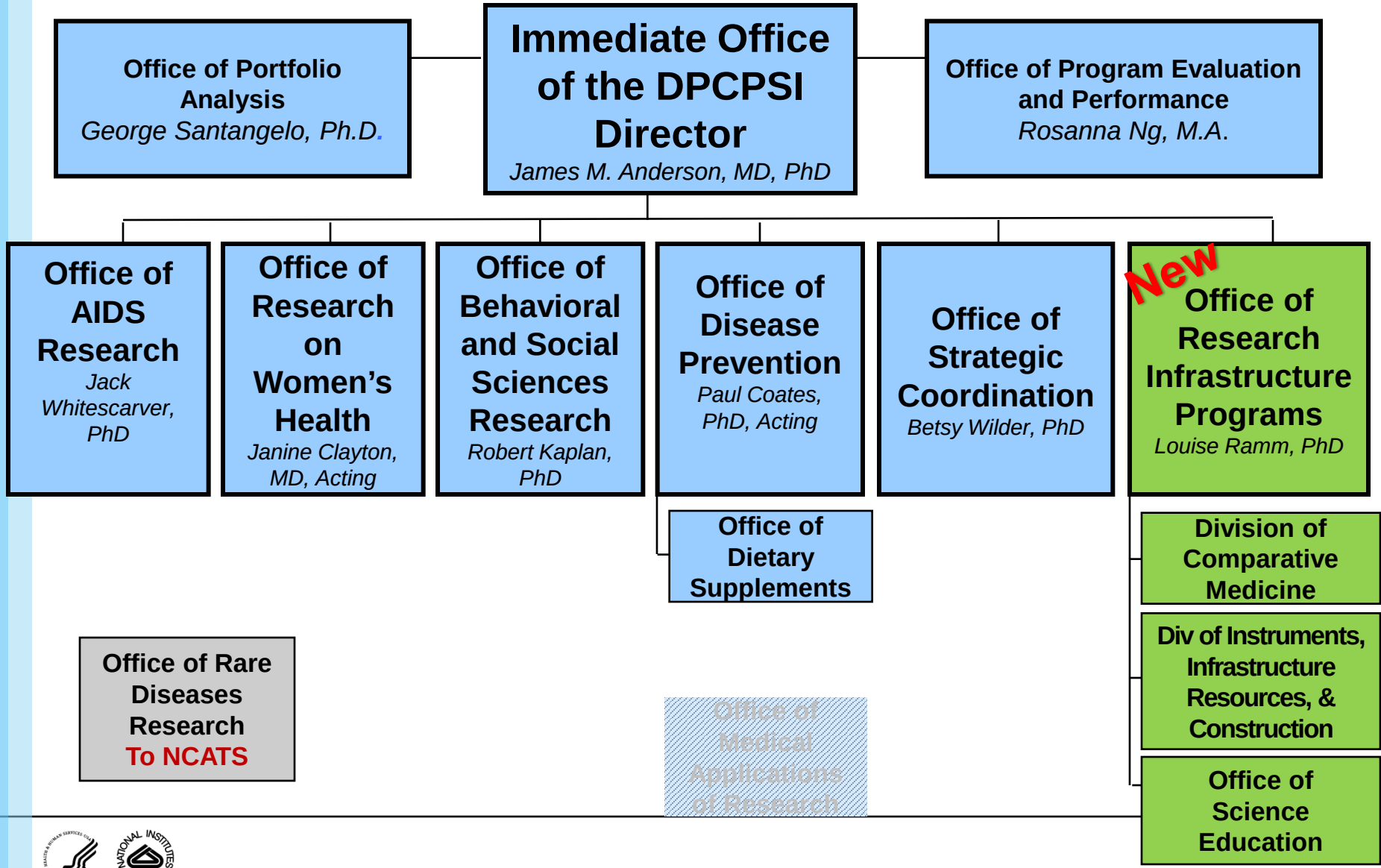
Division of Program Coordination, Planning, and Strategic Initiatives *Before December 23, 2011*



Division of Program Coordination, Planning, and Strategic Initiatives *After December 23, 2011*



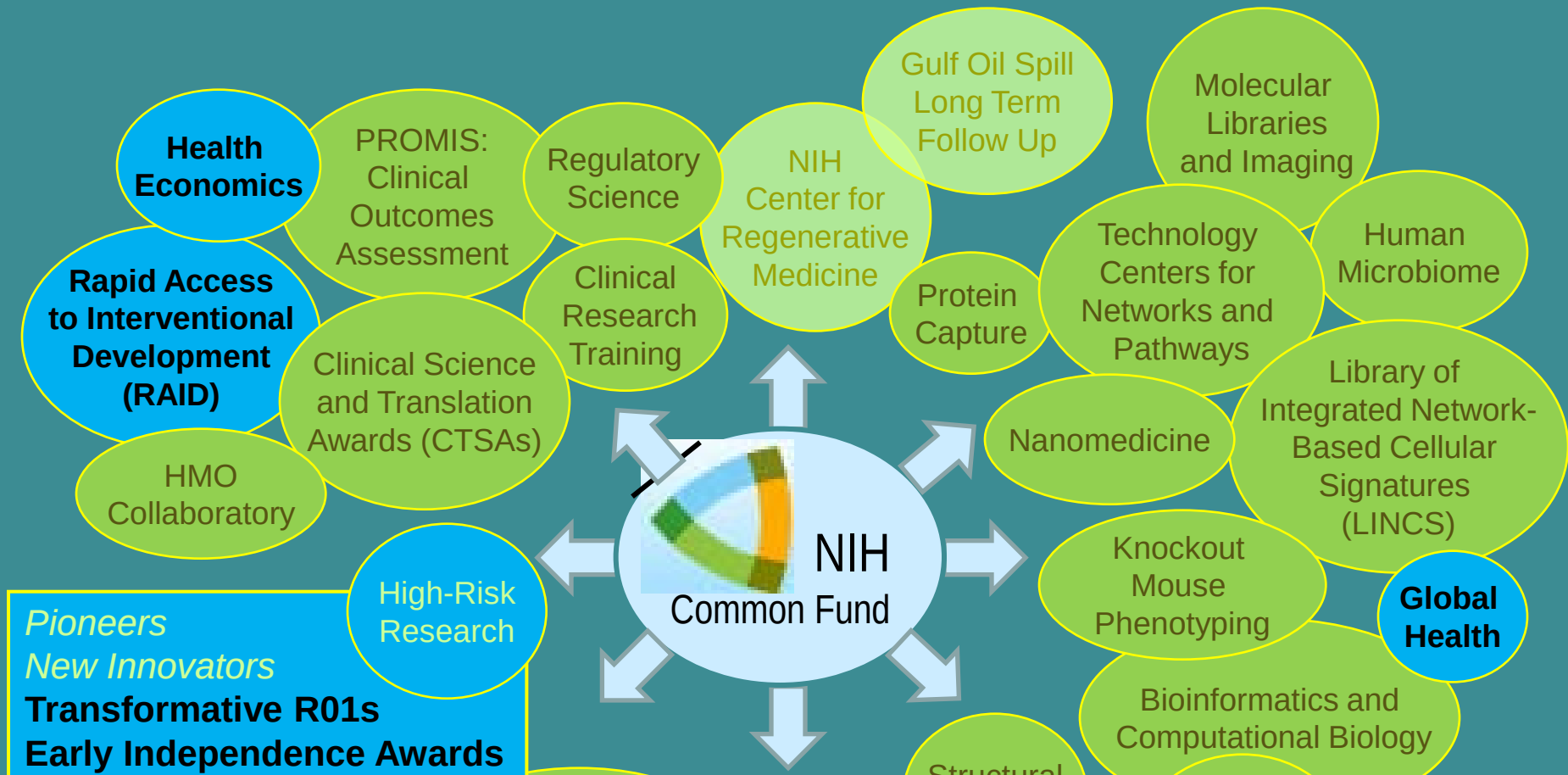
Division of Program Coordination, Planning, and Strategic Initiatives *After January 10, 2012*



DPCPSI Staff Updates

- Welcome to
  - Louise Ramm, Ph.D., Director, Office of Research Infrastructure Programs
  - New DPCPSI and ORIP staff from NCRR
  - ORIP staff from the Office of Science Education
  - Former NCRR Council members serving as *ad hoc* members of the Council of Councils
- Ongoing Leadership Searches
  - Director, Office of Disease Prevention
  - Director, Office of Research on Women's Health

Common Fund Programs 2004-2011



Pioneers
New Innovators
Transformative R01s
Early Independence Awards

$540M
Cross-cutting
transformative

http://commonfund.nih.gov/

IOM Report

- Assessing the Necessity of Chimpanzees in Biomedical and Behavioral Research
- Issued December 2011

Principles

- The IOM committee was guided by the following three principles:

1. The knowledge gained must be necessary to advance the public's health,
2. There must be no other research model by which the knowledge could be obtained, and the research cannot be ethically performed on human subjects,
3. The animals used in the proposed research must be maintained in either ethologically appropriate physical and social environments or in natural habitats.

IOM Conclusions

"While the chimpanzee has been a valuable animal model in past research, most current use of chimpanzees for biomedical research is unnecessary."

- Some areas may continue to require the use of chimpanzees:
  - Some ongoing research on monoclonal antibody therapies, research on comparative genomics, and non-invasive studies of social and behavioral factors that affect the development, prevention, or treatment of disease.
- Unable to reach consensus on the necessity of the chimpanzee for the development of prophylactic hepatitis C virus vaccine.
- New, emerging, or re-emerging diseases may present challenges that may require the use of chimpanzees.

Council Working Group

- Council of Councils Working Group on the Use of Chimpanzees in NIH-Supported Research
- Provide advice on the implementation of the recommendations, and to consider the size and placement of the active and inactive populations of NIH-owned or -supported chimpanzees
- Co-chaired by Council of Council members Drs. Kent Lloyd and Dan Geschwind
- First Working Group meeting tomorrow, February 2, 2012

Working Group Timeline

February 2012

- Working Group charged
- 60 days for public comment period on charge

June 2012

- Update to the Council of Councils

September 2012

- Update to the Council of Councils; Initial recommendations

January 2013

- Final report to the Council of Councils
- 60 days for public comment period

Expanded Role of the Council

- Establishment of ORIP in DPCPSI requires the Council of Councils' purview to expand:
  - Concept clearance for ORIP – you will be asked to provide feedback on two concepts today.
  - Second-level review of grant applications – you will be asked to follow the early concurrence process
- 2nd level review of applications assigned to ORIP is a **NEW ROLE** for the Council of Councils from this meeting forward
- Similar to the duties you perform as part of your IC's Advisory Council

Early Concurrence

- You may be familiar with early concurrence - a procedure to expedite funding for eligible applications.
- Like most ICs, NCRR used early concurrence to expedite funding.
- What is the status of those “early” applications?
  - If reviewed BEFORE Dec. 23, 2011 satisfied 2nd level review (HHS Secretary)
  - If reviewed AFTER Dec. 23, need the Council of Councils to determine that the NCRR council member review satisfied 2nd level review

Asking for Two Motions

1

That NCRR's Early Concurrence review post-Dec. 23 satisfies 2nd level review for eligible grants this round.

2

To adopt the Early Concurrence procedure for the rest of 2012.

(Discuss later today.)

1 NCRR's Post-December 23rd Early Concurrence

- The Executive Secretary identified applications eligible for Early Concurrence review process.
- Not used for any application with the following:
  - Human subject, animal, or biohazard concerns
  - Foreign institutions
  - Issues regarding recruitment of women and minorities or data monitoring
  - Identified by a Council member to be of special concern; posing any special policy issues
  - Previously deferred by Council for additional information or for re review
  - Identified by DPCPSI staff as requiring special consideration (e.g., high program priority, applications with high costs, restoration of time) for discussion by Council.
- Applications with any of these concerns will be discussed during today's closed session.

1 NCRR's Post-December 23rd Early Concurrence

- NCRR Council Early Concurrence review process was already underway for their February 1 meeting.
- NCRR Council members, including a Council of Councils member, agreed to complete Early Concurrence reviews.
- Ad hoc members from NCRR's council who participated in this review are here today.
- Applications reviewed by NCRR's Early Concurrence process after December 23 need a determination that 2nd level review was satisfied.
- These applications are not able to be funded until the Council of Council either 1) makes this determination or 2) itself performs 2nd level review.

1

Is there a motion to accept the NCRR 2nd level review performed by NCRR Council members after December 23, 2011?

2

Early Concurrence for 2012

- Most ICs use Early Concurrence to expedite funding of eligible applications. Many of you are familiar with this process.
- NIH Policy sets overarching guidelines for Early Concurrence.
- I would like the Council of Councils to consider using Early Concurrence procedures for eligible ORIP grant applications for all 2012.
- Longer term plans can be discussed at a future meeting.
- Here's how the process would work (follows NCRR's council operating procedures).

2

Early Concurrence for 2012

1. The Executive Secretary identifies applications eligible for Early Concurrence review on behalf of the Council. Early concurrence will not be used for any application with the concerns previously discussed.
2. For applications not excluded by this criteria, the Executive Secretary selects at least two Council members to conduct reviews for each application.
   - Selected members will be provided with a list of grant numbers for applications assigned to review
   - Summary statements available through electronic council book

2

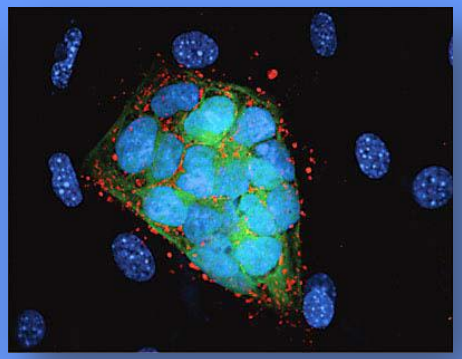
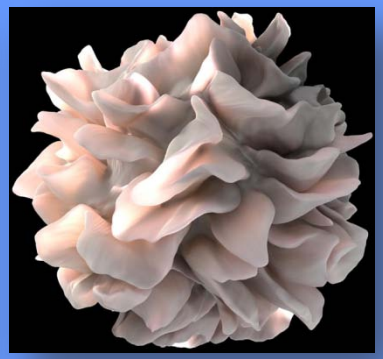
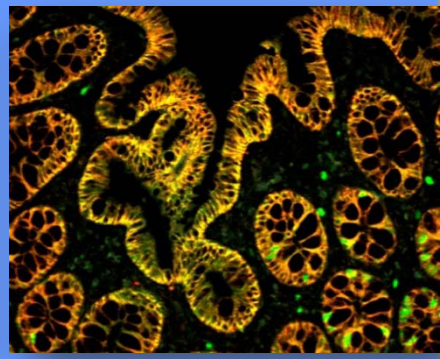
Early Concurrence for 2012

3. If a member determines an application should come to the full Council for discussion, notify the Executive Secretary and the application will be removed from the en bloc list
   - Council members will have access to the list of en bloc applications and summary statements through the Electronic Council Book.
4. Council members selected to review notify the Executive Secretary of the results within a defined period of time
   - Applications that receive positive Early Concurrence from the assigned reviewers are considered to be recommended for approval for funding and will not be voted on by full Council
5. A report of Early Concurrence recommendations will be presented at each Council meeting

2

Will revisit #2 after you have discussed applications during closed session.

QUESTIONS?

NIH...

Turning Discovery Into Health