The Common Fund at 10 Years:
How are we doing?

September, 2013
Council of Councils

Betsy Wilder
Director, Office of Strategic Coordination, DPCPSI
The CF represents a significant investment and a new way of managing science:

• Over $4 Billion expended since inception
  ❖ FY 2013 budget of $513,475,595
  ❖ Similar to mid-sized IC budgets

• Over 70 staff across the NIH contribute at least 50% effort to manage ~30 programs
  ❖ Many more contribute between 10-50%
Many ICs lead Common Fund Programs

- NCI
- NEI
- NHLBI
- NHGRI
- NIA
- NIAAA
- NIAID
- NIAMS
- NIBIB
- NICHHD
- NICHD
- NIDCR
- NIDDK
- NIDA
- NIH Library
- NICHD
- NIMHD
- NINDS
- NIMH
- NLM
- CT
- CSR
- FIC
- NCATS
- NCCAM
- CC

Number of CF programs
# Lead ICs in Common Fund Programs

|                | NCI | NEI | NHLBI | NHGRI | NIA | NIAAA | NIAID | NIAMS | NIBIB | NICHD | NIDCD | NIDCR | NIDDK | NIDA | NIEHS | NIGMS | NIMH | NIMHD | NINDS | NINR | NLM | CIT | CSR | FIC | NCATS | NCCAM | CC  |
|----------------|-----|-----|-------|-------|-----|-------|-------|-------|-------|-------|-------|-------|-------|------|-------|-------|------|-------|-------|-----|-----|-----|-----|------|-------|-----|
| BD2K           |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| NCBC           | X   |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| BrIDGs         |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| TCNP           |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| EG xRNA        |     | X   |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| GTeX           |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| GH            |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| GuLF        |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| HC            |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| HE         |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| HMP         |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| DV            |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| MP            |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| LINCS         |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| ME            |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| ML            |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| NM            |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| NIH CRM       |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| CR6           |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| PROMIS        |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| PC            |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| RS            |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| SO            |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| SC            |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| BW            |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| SB            |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
| UDN           |     |     |       |       |     |       |       |       |       |       |       |       |       |      |       |       |     |       |       |     |     |     |     |      |       |     |
Outline of today’s presentation

• Review of the Common Fund’s origins
  ❖ Rationale
  ❖ Original processes for planning and management
  ❖ Changes brought by the 2006 Reform Act

• Review of Unusual Features of Common Fund Programs
  ❖ Planning: Two phases
  ❖ Ten Year Lifetime
  ❖ Distributed Management: the OD and ICs as Partners

• Overview of Planning and Management for 3 Example CF Programs

• Discussion of the need for evaluation
  ❖ What do we want to know?
Scientific Challenges:
What are the most significant bottlenecks in biomedical research, and what needs to be done to address them?

Organizational Challenges:
In 2002, there was no mechanism for the NIH as a whole to consider and address challenges and opportunities.

“Twenty-seven fingers without a palm is not a hand.”
Elias Zerhouni, 2003
Recommendations included:

- Enhance and increase trans-NIH strategic planning and funding

  “The committee recommends that the Director be given the responsibility and authority to develop and implement, with and through the ICs, a series of time limited trans-NIH initiatives that are identified through a broad-based strategic planning process open to participation by all internal and external stakeholders and transparent to the public.”
Original processes for planning and management

The original Roadmap planning process led to the development of 9 major programs, involving 28 initiatives.

How did we get there?
<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>August 2002</td>
<td>Consultation with over 100 thought leaders</td>
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<td>September 2002</td>
<td>IC Directors Leadership Forum</td>
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<tr>
<td>March 2003</td>
<td>Formation of 15 Roadmap Working Groups, involving over 300 experts</td>
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<td>April 2003</td>
<td>Presentation to Council of Public Representatives (COPR)</td>
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<td>May 2003</td>
<td>Working Groups Develop Proposed Roadmap Initiatives and Plans</td>
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<td>June 20, 2003</td>
<td>IC Directors’ Retreat</td>
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<td>June 30, 2003</td>
<td>Presentation to the Advisory Committee to the Director (ACD)</td>
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<td>2003 and beyond</td>
<td>Adaptive Implementation</td>
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Roadmap Participants were asked:

- What are today’s scientific challenges?
- What are the roadblocks to progress?
- What do we need to do to overcome roadblocks?
- What can’t be accomplished by any single Institute – but is the responsibility of NIH as a whole?
<table>
<thead>
<tr>
<th>Increasing Level of Difficulty</th>
<th>1-3 years</th>
<th>4-7 years</th>
<th>8-10 years</th>
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<tr>
<td>Ultimate Goal</td>
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Sample Matrix -

Time

National Institutes of Health
Office of Strategic Coordination - The Common Fund
<table>
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<tr>
<th>Increasing Level of Difficulty</th>
<th>Based on experimental and computational studies, link selected sequences and structures with biological function and disease etiology.</th>
<th>Study protein dynamics and flexibility through time resolved structural determinations</th>
<th>Routinely determine the structures of most proteins at high resolution from their DNA sequences</th>
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<td>Determine the structure of post-translationally modified proteins at high resolution.</td>
<td>Determine the structure of stable, mid-sized macromolecular assemblies for functional and disease-related studies.</td>
<td>Routinely determine large macromolecular assemblies</td>
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<tr>
<td></td>
<td>Develop infrastructure, methods/instruments, and bioinformatics/ computational tools for structural biology Enhance the automated structural genomics pipeline leading from DNA sequence to protein structure</td>
<td>Complete the structural determination of representatives of 75% of all protein families, permitting structural coverage of most proteins in nature Engineer proteins for selected biological function</td>
<td>Apply protein structural information to basic biological problems and medical applications.</td>
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<table>
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<tr>
<th>Time</th>
<th>1-3 years</th>
<th>4-7 years</th>
<th>8-10 years</th>
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Roadmap Considerations

- Is the initiative truly transforming -- will it dramatically change how or what biomedical research is conducted in the next decade?

- Would the outcomes from the initiative be used by and synergize the work of many ICs?

- Can the NIH afford NOT to do it?

- Will the initiative be compelling to our stakeholders, especially the public?

- Does the initiative position the NIH as unique -- doing something that no other entity can or will do?
Common Fund Criteria

**Transformative:** Programs are expected to have exceptionally high and broadly applicable impact. They should be relevant to many diseases and many ICs. They should set new standards for research or clinical practice, create entirely new approaches to research or clinical care, or establish new biological paradigms.

**Catalytic, Short Term and Goal-driven:** Programs must achieve - not just work toward - a goal. They have deliverables - data sets, tools, technologies, approaches, or fundamental principles of biology, etc – that can be achieved within 5-10 years. If the deliverable is expected to have ongoing maintenance costs, a vision for transition and sustainment must be articulated.

**Synergistic /Enabling:** Programs should be valued-added to the ICs, with the output enabling the mission of multiple ICs.

**Requires a high level of Trans-NIH Coordination:** CF programs should address complex issues that require trans-NIH teams, insights and perspectives to design and manage. There must be a reason why strategic coordination is required.

**Novel:** Programs should provide new solutions to specific challenges. If similar efforts exist, the CF program should be tightly coordinated to prevent duplication of effort.
NIH ROADMAP—THEMES, IMPLEMENTATION GROUPS, AND INITIATIVES*

New Pathways to Discovery
Building Blocks, Pathways, and Networks Implementation Group
  National Technology Centers for Networks and Pathways
  Metabolomics Technology Development
  Standards for Proteomics and Metabolomics/Assessment of Critical Reagents for Proteomics
Molecular Libraries and Imaging Implementation Group
  Creation of NIH Bioactive Small-Molecule Library and Screening Centers
  Cheminformatics
  Technology Development
  Development of High-Specificity/High-Sensitivity Probes to Improve Detection
  Comprehensive Trans-NIH Imaging Probe Database
  Core Synthesis Facility to Produce Imaging Probes
Structural Biology Implementation Group
  Membrane Protein Production Facilities
Bioinformatics and Computational Biology Implementation Group
  National Centers for Biomedical Computing
Nanomedicine Implementation Group
  Planning for Nanomedicine Centers

Research Teams of the Future
High-Risk Research Implementation Group
  NIH Director’s Innovator Awards
Interdisciplinary Research Implementation Group
  Interdisciplinary Research (IR) Centers
  Interdisciplinary Research Training Initiative
  Innovations in Interdisciplinary Technology and Methods (Meetings)
  Removing Structural Barriers to Interdisciplinary Research.
  NIH Intramural Program as a Model for Interdisciplinary Research
  Interagency Conference on the Interface of Life Sciences and Physical Sciences
Public-Private Partnerships Implementation Group
  Designation of a Public-Private Sector Liaison
  High-Level Science-Driven Partnership Meetings

Reengineering the Clinical Research Enterprise
Clinical Research Implementation Group
  Harmonization of Clinical Research Regulatory Requirements
  Integration of Clinical Research Networks
  Enhance Clinical Research Workforce Training
  Clinical Research Informatics: National Electronic Clinical Trials and Research (NECTAR) Network
  Translational Research Core Services
  Regional Translational Research Centers
  Enabling Technologies for Improved Assessment of Clinical Outcomes

*This document is a summary of the NIH Roadmap—Themes, Implementation Groups, and Initiatives.
Roadmap coordination/implementation structure (2004):

- **Director, NIH** (Elias Zerhouni)
- **Deputy Director, NIH** (Raynard Kington)
- **Assistant Director for NIH Roadmap Coordination** (Dushanka Kleinman)

**NIH Roadmap Implementation Coordination Committee**
- OSP, OER, OIR, OB, OM, OCPL rep
- 9 Implementation Group Chairs

**Institute and Center Directors**

**IC-designated Roadmap Liaisons**
Roadmap Implementation Coordination Committee (RICC)

• Provided governance for overall Roadmap
  – Set policy and oversight
  – Reviewed fiscal and human resources

• Facilitated coordination and communication among working groups

• Provided guidance for evaluation of overall Roadmap

• Worked within funding levels projected for FY04-FY09
Roadmap Working Groups

- 2-3 IC Director Co-Chairs
- 1-3 Program Coordinators
- Multiple Project Team Leaders – Program Officials responsible for individual initiatives
- Many Working Group Members – Program Officials representing their IC’s interests
- 1 Budget Point of Contact

- Each group worked independently to:
  - Articulate goals
  - Establish consortium partnership practices
  - Develop processes to assess progress
  - Communicate about the programs to stakeholders
  - Manage the budget
Management Challenges

• Static, silo’ed budgets limited flexibility
  ➢ Programs proposed budget envelopes that were approved and became fixed
  ➢ No clear route to plan for future opportunities and challenges

• Information flow between OD and ICs was limited and inconsistent across groups

• The OD required evaluative information about the programs, but there was no structure to do this.
  ➢ Each group conducted self-evaluations.
  ➢ All evaluations were positive.
Challenges aside, many felt the RM was off to a good start...

“This has been a great experience – I would not have ordinarily had a chance to interact with many of the committee members and it was really eye-opening. The depth and breadth of the talent around NIH is really impressive........

I suspect you are hearing similar things from other groups – this has been NIH at its finest!

Thanks for the opportunity to be involved in this.”
The Committee provides $45,000,000 within the Office of the Director for the Director’s Discretionary Fund (DDF), which is the same as the Administration request and $25,130,000 above the fiscal year 2003 comparable level. The Director is encouraged to maximize the use of the fund to implement the “roadmap” being developed by NIH to structure its future research portfolio. Within the “roadmap” research supported by the DDF, the Committee urges the Director to emphasize translational and clinical research designed to expedite delivery of new treatments with therapeutic promise and cures to patients with serious and degenerative illnesses. The Committee also encourages the Director to use the one percent transfer authority that is provided in the bill to allocate additional resources to clinical and translational research identified in the roadmap.
Changes Brought by the Reform Act

2004: NIH Roadmap is launched

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 the Office of the Director and the NIH Common Fund to provide a dedicated source of funding to enable *trans*-NIH research.
Impact of the Reform Act on the Roadmap

• The Common Fund
  ➢ Appropriation of funds to the NIH Director strengthened the role of the Director in overseeing the funds.
  ➢ The description of the CF perpetuated the goals of the RM to address strategic, trans-NIH needs.

• DPCPSI
  ➢ The creation of DPCPSI provided the OD with the administrative structure to manage the CF.

The net effect is that management of the CF became a partnership between the ICs and the OD.
Impact of the Reform Act on the Roadmap

• Stronger ties between the OD and the ICs at all phases of CF programs
  ➢ OD Leadership not only selects broad program topics, but also participates in articulation of specific goals and provides guidance at critical points.
  ➢ DPCPSI/OSC works in partnership with IC teams to:
    ▪ Develop management plans
    ▪ Implement initiatives and track budgets
    ▪ Oversee and assess progress
    ▪ Make adjustments to address changes in field
    ▪ Communicate about the programs
    ▪ Plan for transition at end of CF support
Review of Unusual Features of Common Fund Programs
Two Phase Strategic Planning

**Phase 1:** Identification of strategic needs and opportunities, with a “rough draft” proposal of initiatives that would be required

**Phase 2:** Refinement of broad program and development of a strategy

- **PHASE 1**
  - **External Input**
    - Meetings with stakeholders
    - Requests for Information
    - Council of Councils
  - **Internal Input**
    - IC Directors
    - IC Senior Staff
    - OSC/DPCPSI Directors
    - NIH Director input

- **PHASE 2**
  - **Refinement**
    - Portfolio Analysis
    - Focused meetings
    - Trans-NIH Working Group proposals
  - **Decision Making**
    - IC Director discussions and priority setting
    - NIH Director decisions

- A new round of Common Fund strategic planning is initiated annually
- The entire process (Phase 1 through Phase 2) lasts 18 months
Specific Goals -> Defined Lifetime -> Sustained Impact

- **Strategic Planning for the Common Fund** involves definition of specific deliverables – goals for the program to achieve within a defined, 5-10 year period of time.

- **IC Strategic Plans** have a broader focus. The focus tends to be at the level of entire fields, with the IC in a position to lead: “where should this field go and how do we lead it there?”

- **CF Programs** ask “What specific deliverables can we provide that will transform the field and thereby have a sustained impact?”

Articulating clear goals for a defined timeframe is the hardest part of CF Program Planning.
OD-IC-IC Partnership

- All CF programs are managed by multi-IC teams.
  - Brings the most relevant NIH expertise to bear on the program and keeps the IC Directors engaged
  - Helps to ensure that the ICs benefit from the program – that the output of the program is maximally useful and widely disseminated

- OSC staff are part of each team and provide a bidirectional link between each team and OD Leadership.
  - Guidance from OD Leadership to groups
  - Information and recommendations about program to Leadership
What types of programs are “Common Fundable”?

How do our planning and management practices influence them?

• Human Microbiome Project
• Patient Reported Outcomes Measurement Information System
• Metabolomics
NIH Common Fund Human Microbiome Project
(http://commonfund.nih.gov/hmp)

Community resources

Repositories:
- sequence data
  - microbiome
  - human
- strains
- clinical/phenotype data
- nucleic acid extracts
- cell lines

Healthy cohort study

**Clinically healthy**

- 300 male/female
- 18-40 y.o.
- 18 body sites
- Up to 3 visits in 2 yrs
- 16S rDNA, WGS metagenomes

**Skin**: eczema, psoriasis

**GI**: Crohn’s disease, esophageal adenocarcinoma, necrotizing enterocolitis, pediatric IBS, ulcerative colitis

**Urogenital**: bacterial vaginosis, circumcision, sexual histories

9 Initiatives in HMP

Interact through DACC and 400+ member consortium

IHMC founding member

www.hmpdacc.org

Healthy cohort study

Demonstration Projects

**Technology Development**

**Sample Collection**

**Demonstration Projects**

**Data Generation**

**Sequencing Centers**

**Computational Tools**

**Data Analysis**

**Data Analysis and Coordination Center**

Healthy cohort study

Clinical healthy

300 male/female

18-40 y.o.

18 body sites

Up to 3 visits in 2 yrs

16S rDNA, WGS metagenomes

Skin: eczema, psoriasis

GI: Crohn’s disease, esophageal adenocarcinoma, necrotizing enterocolitis, pediatric IBS, ulcerative colitis

Urogenital: bacterial vaginosis, circumcision, sexual histories
 NIH Human Microbiome* Project 
(HMP I: 2008-2012) 

* Human microbiome: full complement of microbes living in/on the human body and their collective genes & genomes.
The Patient-Reported Outcomes Measurement Information System (PROMIS) aims to provide clinicians and researchers access to efficient, precise, valid, and responsive adult- and child-reported measures of health.

PROMIS uses measurement science to create an efficient state-of-the-art assessment system for self-reported health.
Sample Questions
See samples of actual questions taken from selected physical health, mental health, and social health short forms.

More...
PROMIS OUTCOMES

Informatics: Assessment Center Supports >100 Studies

Tools: 40 Adult Measures, 20 Pediatric Measures

Translations: 11 Fatigue items in Spanish and 8 short forms into Chinese

Advancing Knowledge: >100 Peer-Reviewed Publications

Cooperative Group: 12 Research Sites, 3 Centers, 150+ Scientists

Outreach: ~140 users downloaded short-forms in the three week period following the availability to the public in September 2012 (http://www.nihpromis.org/default.aspx)

Integration into Healthcare: Selected short-forms Version 1.0 have been added to the Epic “Miscellaneous Assessment Tools Collection. Epic MyChart is the most widely used patient portal.
Epigenomics

The concept was proposed as “Epigenetics” with enthusiasm for exploration of epigenetic mechanisms underlying many diseases.

What was being done, and what were the challenges and opportunities?
NIH Common Fund Epigenomics Program

- Mapping Centers
- Data Coord. Center
- NCBI
- Health and Disease
- Technology Development
- In vivo Epigenetic Imaging
- Novel Marks

The diagram illustrates the relationships between various components of the NIH Common Fund Epigenomics Program, emphasizing the integration of mapping centers, data coordination, technology development, in vivo epigenetic imaging, novel marks, and health and disease.
# NIH Epigenomics Working Group

Co-Chairs: Nora Volkow (NIDA), Linda Birnbaum (NIEHS), James Battey (NIDCD)

Co-Coordinators: John Satterlee (NIDA), Pat Mastin (NIEHS)

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<tr>
<th>Name</th>
<th>Institute</th>
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<tr>
<td>Christine Colvis</td>
<td>NCATS</td>
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Astrid Haugen         | NIEHS         |
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Kimberly McAllister   | NIEHS         |
Srikanth Nadadur      | NIEHS         |
Kristi Pettibone      | NIEHS         |
Fred Tyson            | NIEHS         |
Leroy Worth           | NIEHS         |
Anthony Carter        | NIGMS         |
Andrea Beckel-Mitchener| NIMH        |
Michelle Freund       | NIMH          |
Thomas Lehner         | NIMH          |
Roger Little          | NIMH          |
Aleksandra Vicentic   | NIMH          |
Robert Riddle         | NINDS         |
Randall Stewart       | NINDS         |
Stephanie Courchesne  | OSC           |
Patricia Labosky      | OSC           |
Johanna Dwyer         | ODS           |
Deborah Olster        | OBSSR         |
The Need for Evaluation: What do we want to know?
Are Common Fund processes working optimally to:

- Identify programmatic areas where transformation is needed and possible?
- Articulate specific goals and manage programs to ensure the goals are met?
- Adapt to evolving scientific needs?
- Assess program outcomes?

Are OD-IC partnerships adequate to support program management?

- Do Working Groups receive appropriate guidance from OD Leadership?
- Do ICs have the resources they need to manage CF programs?
- Is IC-DPCPSI/OSC communication fluid and effective?
- Do Working Groups see OSC as part of the team, or as “them” versus “us”?
Consistent with the role of the Council of Councils to “advise the Director on matters related to the policies and activities of DPCPSI, including making recommendations with respect to the conduct and support of research [supported by the Common Fund].”
Proposed Charge to the Council of Councils

CF Planning and Management Working Group (CPMWG)

Assess and advise on the processes used to manage the CF, including those used to plan and implement/oversee programs.

1. Are planning processes optimal for identifying program areas that meet the CF criteria?
2. Are management/oversight processes optimal for achieving program goals?
Proposed Charge to the Council of Councils
CF Planning and Management Working Group (CPMWG)

Assess and advise on the processes used to manage the CF, including those used to plan and implement/oversee programs.

1. Are planning processes optimal for identifying program areas that meet the CF criteria?
2. Are management/oversight processes optimal for achieving program goals?

Request a motion to approve creation of the Council of Councils Common Fund Planning and Management Working Group.
Proposed Process for the CPMWG

**Work Plan:** review of materials prepared by OSC, interviews and surveys of stakeholders

**Timeline:**
- Oct. 22, 2013 – Kick-off meeting to charge WG and review background materials and draft work plan
- Jan. 31, 2014 – Present findings and recommendations for planning process (Question 1) to Council of Councils
- Jun. 20, 2014 – Working group presents to Council of Councils findings and recommendations for CF oversight, and governance processes (Question 2)
Comments?