



NIH Scientific Management Review Board



Deliberating Organizational Change and Effectiveness Working Group Update

March 10, 2010

William Brody, MD, PhD
President
Salk Institute for Biological Studies
La Jolla, California

Membership

Non-Federal

William Brody, MD, PhD
(Chair)

Gail Cassell, PhD

Hon. Daniel Goldin

Thomas Kelly, MD, PhD

Eugene Washington, MD

Norman Augustine
(ad hoc)

Federal

Jeremy Berg, PhD

Stephen Katz, MD, PhD

John Niederhuber, MD

Francis Collins, MD, PhD
(ex officio)

Charge

- **To Articulate:**
 - **The factors and circumstances that might prompt the agency to contemplate organizational change**
 - **A set of principles to guide the consideration of organizational change and its implementation**
- **Always a work-in-progress**
 - **The work of this group will inform, and be informed by, the real-life organizational issues contemplated by the SMRB and the experience of the NIH**
 - **DOCE report will be a living document**

Briefings to Date

- **NIH Director's Vision for NIH and the SMRB, including an overview of his 5 opportunities for biomedical research at NIH and reflections upon the group's charge**
- **Perspectives from distinguished scientific and public health leaders on criteria for initiating and implementing organizational change to advancing science and meeting public health needs. Participants included...**

Briefings to Date *(cont...)*

- **National Academy of Sciences Committee: *Enhancing the Vitality of the NIH: Organizational Change to Meet New Challenges***
 - **Kenneth I. Shine, M.D.**, *Executive Vice Chancellor for Health Affairs at University of Texas System*
 - **Myrl Weinberg, C.A.E.**, *President of the National Health Council*
 - **Mary Woolley**, *President of Research!America*
 - **Lydia Villa-Komaroff, Ph.D.**, *Chief Scientific Officer at Cytonome/ST*
 - **Gilbert S. Omenn, M.D., Ph.D.**, *Professor of Internal Medicine, Human Genetics, and Public Health and Director of the Center for Computational Medicine and Biology at the University of Michigan*

Briefings to Date *(cont...)*

- **Perspectives from organizational change experts or those with experience leading organizational change in a research organization:**
 - **Hal Rainey, Ph.D.**, *Alumni Foundation Distinguished Professor at the School of Public and International Affairs at the University of Georgia*
 - **Judith Swain, M.D.**, *Executive Director at the Singapore Institute for Clinical Studies within the Agency for Science, Technology, and Research*
 - **Charles Sanders, M.D.**, *Former Chairman and CEO of Glaxo Inc.*
 - **Carla Schatz, Ph.D.**, *Director of Stanford University's Bio-X Program and Professor of Biology and Neurobiology*

Perspectives from Panelists

- ***Echoed familiar but nonetheless important themes:***
 - **Increasingly interdisciplinary nature of science**
 - Need to engage fields beyond the life sciences, including engineering and the physical, informational, and computational sciences and engineering
 - Need for new approaches for training next-generation scientists
 - **Need for increased collaborations**
 - Within NIH, across agencies, between intra-/extramural, and internationally
 - **Need for balance between fundamental basic science and translational research**
 - Importance of basic science as fueling the pipeline of discovery
 - Importance of translational research in increasing the impact of NIH on health
 - Need for more effective communication with public
 - Viewed through the lens of the NIH Director's opportunities in biomedical research

REPORT FRAMEWORK

Context for Discussions

NIH Organization: Formative Forces



Current NIH Organization

Functional

ASTHMA PHENOTYPES TASK FORCE • BARRIERS TO CLINICAL RESEARCH • THE BIOENGINEERING CONSORTIUM • DOWN SYNDROME WORKING GROUP • FOUR INSTITUTE GENE THERAPY CONSORTIUM • THE GENES, ENVIRONMENT AND HEALTH INITIATIVE • THE INTER-INSTITUTE IMAGING GROUP • LUPUS FEDERAL WORKING GROUP • MUSCULAR DYSTROPHY COORDINATING COMMITTEE • NEURODEGENERATION WORKGROUP • NIH AUTISM COORDINATING COMMITTEE • NIH BIOMEDICAL INFORMATION SCIENCE AND TECHNOLOGY INITIATIVE CONSORTIUM • NIH BLUEPRINT FOR NEUROSCIENCE RESEARCH • NIH END OF LIFE SPECIAL INTEREST GROUP • NIH INTERNATIONAL TUBERCULOSIS NETWORK • NIH NIA AGING RESEARCH AND POLICY CONSORTIUM • NIH PUBLIC TRUST INITIATIVE • NIH RESVERATROL CLINICAL RESEARCH • NIH SCIENTIFIC INTEREST GROUPS • NIH STEM CELL TASK FORCE • PARKINSON'S DISEASE COORDINATING COMMITTEE • PHARMACOGENETICS RESEARCH NETWORK • SYNCHROTRON PROGRAM OFFICERS GROUP • SYSTEMS BIOLOGY SCIENTIFIC INTEREST GROUP • TRANSLATIONAL RESEARCH INTEREST GROUP • TRANS-NIH AMERICAN INDIAN AND ALASKA NATIVE HEALTH COMMUNICATIONS AND INFORMATION WORK GROUP • TRANS-NIH BIOETHICS COMMITTEE • TRANS NIH BRAIN TUMOR COMMITTEE • TRANS-NIH COMMUNICATIONS GROUP ON GENETICS AND COMMON DISEASE • TRANS-NIH COORDINATING COMMITTEE FOR LYMPHATIC RESEARCH • TRANS-NIH DIABETES COMPLICATIONS WORKING GROUP • TRANS-NIH NANOTECHNOLOGY TASK FORCE • TRANS-NIH SARCOIDOSIS COMMITTEE • TRANS-NIH SICKLE CELL GROUP • TRANS-NIH SLEEP RESEARCH COORDINATING COMMITTEE • TRANS-NIH WORKING GROUP ON GLOBAL HEALTH AND CLIMATE CHANGE • TRANS-NIH ZENOPUS COORDINATING COMMITTEE • TRANS-NIH ZEBRAFISH COORDINATING COMMITTEE

39 Committees, Working Groups, Task Forces

Structural



NCI	NEI	NHLBI	NHGRI	NIA	NIAID	NIAMSD	NIBIB	NICHD
NIDCD	NIDCR	NIDDK	NIDA	NIHES	NIGMS	NIMH	NINDS	NINR
NIAAA	NLM	CIT	CSR	FIC	NCCAM	NCMHD	NCRR	CC

27 Institutes and Centers

Current NIH Organization *(cont.)*

NIH's existing structure is the result of a set of complex evolving social and political negotiations among a variety of constituencies including the Congress, the administration, the scientific community, the health advocacy community, and others interested in research, research training, and public policy related to health.

From any particular point of view or for any particular set of interests, the current situation is not only imperfect, but is certainly not one that either the Congress or the scientific community would designate *ab initio*. Rather it has evolved as a very useful and largely productive outcome of a series of political and social negotiations that took place over time. The outcome is typical of the design of important social organizations in a pluralistic democracy.

Any major modifications at this point in time should focus directly on enhancing NIH's capacity to pursue major time-limited strategic objectives that cut across all the institutes and to acquire a special ability to pursue more high-risk, high-return projects. ... [A]t this moment the widespread consolidation of institutes and centers is not the next best organizational step for NIH to undertake, as any benefits to be gained would be offset by the costs involved.

Current NIH Organization: Strategies for Functional Integration



- Increasingly, the interdisciplinary nature of science has prompted NIH to develop strategies for the functional integration of its expertise and resources in ways that cut across relevant ICs
- NIH has created a variety of “platforms” for integrating staff and resources to tackle emerging scientific issues; These can be rapidly assembled and either sustained or disassembled as needed
 - May be focused on certain diseases, organ systems, emerging technologies, and/or data needs
 - Often initiated by several ICs working collectively or by the OD

Current NIH Organization: Examples of Integration Efforts at NIH

1. Institutes focusing on analytic approaches, resources, technologies, or techniques that span across diseases and/or organ systems. Examples include:
 - *National Center for Research Resources*
Provides clinical and translational researchers with the training and tools they need to transform basic discoveries into improved human health—a mission of uniquely trans-NIH interest and value
 - *National Institute for Biomedical Imaging and Bioengineering*
Leading the development and accelerating the application of biomedical technologies - a mission of uniquely trans-NIH interest and value

Current NIH Organization: Examples of Integration Efforts at NIH *(cont.)*

2. **Critical initiatives that transcend the mission of any given IC may be promoted and funded by the NIH Office of the Director. Examples include:**
 - ***NIH Common Fund***
\$568 million initiative, coordinated by OD with input from all ICs, supporting a series of cross-cutting, trans-NIH research programs

Current NIH Organization: Examples of Integration Efforts at NIH *(cont.)*

3. Initiatives (e.g., committees, working groups, task forces) promoted and funded by the NIH Institutes and Centers. Examples include:
 - *NIH Blue Print for Neurosciences Research*
Cooperative effort among 16 NIH ICs and Offices; supports development of new tools, training opportunities, and other resources to assist neuroscientists in both basic and clinical research
 - *Obesity Research Task Force*
Cooperative effort among 26 NIH ICs and Offices;
Established to accelerate progress in obesity research across the NIH

REPORT FRAMEWORK

Aspects of Organizational Change

Defining Organizational Change

- **Any significant modification of an organization's status quo—that is, its ways of arranging and coordinating its component parts in order to achieve its mission**
 - **May be driven by internal and/or external forces**
 - **May be *structural* (existing components merged or eliminated; new components created)**
 - **May be *functional* (new efforts to coordinate existing components)**

Organizational Change: Considerations

Threshold

- **Change is undertaken to achieve hoped-for benefits; however, change is also associated with costs (i.e., risks, disadvantages, disruption, and resource costs)**
 - **In particular, structural changes in any organization often carry such costs**
 - **Therefore, the rationale for undertaking significant structural change should be include a high likelihood of significant benefit**

Organizational Change: Considerations *(cont.)*

Resources

- It is critical to identify resources that will either be needed or freed up to invest in the reorganized entity or new initiative

REPORT FRAMEWORK

Process for Deliberating
Organizational Change and
Effectiveness

Fundamental Premise

- **The only defensible rationale for organizational change at NIH is to improve the agency's ability to fulfill its mission**

The NIH Mission

“SCIENCE IN THE PURSUIT OF FUNDAMENTAL KNOWLEDGE ABOUT THE NATURE AND BEHAVIOR OF LIVING SYSTEMS AND THE APPLICATION OF THAT KNOWLEDGE TO EXTEND HEALTHY LIFE AND REDUCE THE BURDENS OF ILLNESS AND DISABILITY”

- **“Foster fundamental discoveries, innovative research strategies, and their applications to advance the nation’s capacity to protect and improve health**
- **Develop, maintain, and renew scientific human and physical resources to assure Nation’s capability to prevent disease**
- **Expand the knowledge base in medical and associated sciences to enhance the Nation’s economic well being and ensure high return on the public investment in research**
- **Exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science”**

Process for Deliberating Organizational Change and Effectiveness

Guiding Principles

Steps and Considerations

Underpinning Attributes

Guiding Principles

Contemplated change should (and/or):

- 1. Strengthen the ability of the NIH to effectively carry out its mission in advancing science and improving public health;**
- 2. Provide an environment that will enable more effective collaboration, coordination, and interaction across all disciplines to advance the pace of scientific discovery and improve health;**
- 3. Bring together units in which there are synergies of the scientific and/or clinical foundations for discovery and translation;**
- 4. Enhance public understanding of, confidence in, and support for science;**
- 5. Increase operational efficiency and ensure a high return on public investment in biomedical research.**

Steps and Considerations

- **STEP 1:**
Assess the need for change
- **STEP 2:**
Evaluate options for change
- **STEP 3:**
Implement and navigate the change

Steps and Considerations: STEP 1

- **Assess the need for change:**
 - Immediate crisis
 - Unaddressed scientific opportunities
 - Changes in the scientific landscape
 - Evolving emergent public health needs
 - Economic and financial trends
 - Organizational impediments to effective response to external forces
 - Need for improvements in quality and/or efficiency of research

Steps and Considerations: STEP 2

- **Evaluate the options for change:**
 - **Identify viable options for change**
 - **Conduct a risk-benefit analysis of each viable option**
 - **Solicit and analyze key stakeholder perspectives on each option**
 - **Identify and analyze the broader implications of each option**

Steps and Considerations: STEP 2 *(cont.)*

SPECTRUM OF OPTIONS

- **Important to consider a spectrum of options for organizational change ranging from:**
 - **Merger of selected scientific programs**
 - **Visionary scientific plans or blueprints that cut across multiple ICs to encompass relevant areas of science**
 - **Merger of existing ICs to encompass current missions of the individual ICs**
 - **Merger of existing ICs to create a new IC with a new mission that transcends the missions of the individual IC**

Steps and Considerations: STEP 2 *(cont.)*

SPECTRUM OF OPTIONS



Degree of organizational change

Functional ⇨ ⇨ ⇨ ⇨ ⇨ ⇨ ⇨ ⇨ Structural

Steps and Considerations: STEP 3

- **Implement, navigate, and evaluate the change. Develop and implement plans for:**
 - **Operationalizing change including timeframes, clearly delineated tasks, and the key responsibilities and accountabilities**
 - **Addressing unforeseen consequences (short and long term)**
 - **Evaluating change at specified intervals, including identifying/analyzing relevant data and information, communication with key stakeholders, etc.**

Underpinning Attributes

- **The ultimate success of the deliberative process dictates that the process be distinguished by the following attributes:**
 - **Transparency**
 - **Communication**
 - **Accountability**

Process for Deliberating Organizational Change and Effectiveness

GUIDING PRINCIPLES

- Strengthen ability of NIH to carry out mission
- Provide environment for collaboration, coordination, and interaction
- Bring together synergies
- Enhance public understanding, confidence, and support
- Increase operational efficiency

STEPS AND CONSIDERATIONS



UNDERPINNING ATTRIBUTES

Transparency

Communication

Accountability

Next Steps

- **Circulate draft report to the full SMRB for review and feedback**
- **Discuss report at next SMRB meeting**



DISCUSSION

Patterns of Successful Organizational Change

Hal G. Rainey
Department of Public Administration and Policy
School of Public and International Affairs
The University of Georgia

Sergio Fernandez
School of Public and International Affairs
Indiana University

March 7, 2010

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Patterns of Successful Organizational Change

- **Based on Sergio Fernandez and Hal G. Rainey, "Managing Successful Organizational Change in the Public Sector: An Agenda for Research and Practice." *Public Administration Review*, Vol. 66, no. 2 (March/April, 2006): 168-176. 2006.**
- **A review of research on successful large-scale organizational change, seeking points of consensus among researchers and expert observers.**
- **The research consists mainly of case studies and expert observations, and produces very general generalizations.**
- **The generalizations have value because they are easier said than done, and because change leaders often omit them or do not succeed at fulfilling them.**

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Table 1 Determinants of Successful Organizational Change in the Public Sector	
Proposition	Sub-propositions
Ensure the need. Leaders must verify and persuasively communicate the need for change.	<ul style="list-style-type: none"> • Convince organizational members of the need and desirability for change. • Craft a compelling vision of change. • Employ written and oral communication and forms of active participation to communicate and disseminate the need for change.
Provide a plan. Leaders must develop a course of action or strategy for implementing change.	<ul style="list-style-type: none"> • Devise a strategy for reaching the desired end state, with milestones and a plan for achieving each one of them. • The strategy should rest on sound causal theory for achieving the desired end state.
Build internal support and overcome resistance. Leaders must build internal support and reduce resistance to change through widespread participation in the change process and other means.	<ul style="list-style-type: none"> • Encourage participation and open discussion to reduce resistance to change. • Avoid criticism, threats, and coercion aimed at reducing resistance to change. • Commit sufficient time, effort, and resources to manage participation effectively.

Table 1 (Continued) Determinants of Successful Implementation of Organizational Change in the Public Sector	
Ensure top management support and commitment. An individual or group within the organization should champion the cause for change.	<ul style="list-style-type: none"> • An “idea champion” or guiding coalition should advocate for and lead the transformation process. • Individuals championing the change should have the skill to marshal resources and support for change, to maintain momentum, and to overcome obstacles to change. • Political appointees and top-level civil servants should support the change.
Build external support. Leaders must develop and ensure support from political overseers and key external stakeholders.	<ul style="list-style-type: none"> • Build support for change among political overseers. • Build support for to change among interest groups with a stake in the organization.
Provide resources. Successful change requires adequate resources to support the change process.	<ul style="list-style-type: none"> • Provide adequate financial, human, and technological resources to implement change. • Avoid overtaxing organizational members. • Capitalize on synergies in resources.

Table 1 (Continued)
Determinants of Successful Implementation of Organizational Change in the Public Sector

<p>Institutionalize change. Managers and employees must effectively institutionalize changes.</p>	<ul style="list-style-type: none"> • Employ a variety of measures to displace old patterns of behavior and institutionalize new ones. • Monitor the implementation of change. • Institutionalize change before shifts in political leadership cause commitment to and support for change to diminish.
<p>Pursue comprehensive change. Leaders must develop an integrative, comprehensive approach to change that achieves subsystem congruence.</p>	<ul style="list-style-type: none"> • Adopt and implement a comprehensive, consistent set of changes to the various subsystems of the organization. • Analyze and understand the interconnections between organizational subsystems before pursuing subsystem congruence.

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- Widespread belief in the need for change
- Clear, sustained leadership, including support from top executives
- Broad participation in diagnosing problems and planning the change
- Flexible, incremental implementation, involving experimentation, feedback, and adaptation
- Institutionalization: building on prior success to institutionalize change

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CONDITIONS FOR A SUCCESSFUL CHANGE IN A FEDERAL AGENCY

1. *A durable power center, committed to successful change*
 - Strong, stable leadership by career civil servants
 - An internal change agent (career agency executive) with sufficient authority and resources
 - Active, creative bureau staff

2. *Appropriate timing for collective support*
 - A political “window of opportunity”
 - Political overseers (congressional committee heads) who are supportive but not interventionist
 - Political sophistication of agency leaders and staff—effective management of relations with Congress and oversight agencies (OPM, GSA)
 - Strategies that blend sincere employee involvement with decisive exercise of authority

3. *A comprehensive, clear, realistic alternative process*
 - A long-term change strategy, using group processes to develop new structures
 - A major structural reform, focused on measurable outputs, that decentralizes operational responsibility
 - Reasonable clarity about the nature and objectives of the new structure and process

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Determinants of Lasting Change in Public Organizations

- | |
|------------------------------------------------------------------------------------------------|
| • Crafting a compelling vision for change and persuasively communicating the need for change. |
| • Transforming the vision for change into a course of action. |
| • Reducing resistance to change through widespread participation and other means. |
| • Top management support and leadership. |
| • Resource munificence. |
| • Support from political overseers and key external stakeholders. |
| • Adopting and institutionalizing change. |
| • Developing an integrative, comprehensive approach to change—achieving sub-system congruence. |

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Patterns of Successful Organizational Change: Additional Sources

- **Glenn W. Rainey and Hal G. Rainey, "Structural Overhaul in a Government Agency: Implications of Social Security Claims Modularization for O.D. Principles and Techniques." Public Administration Quarterly, Vol. 10, No. 2 (Summer, 1986): 206-223.**
- **Glenn W. Rainey and Hal G. Rainey, "Breaching the Hierarchical Imperative: The Modularization of the Social Security Claims Process," in Donald J. Calista (Ed.), Bureaucratic and Governmental Reform. JAI Research Annual in Public Policy Analysis and Management. Greenwich, Connecticut: JAI Press, 1986: 171-196.**
- **Hal G. Rainey, A Weapon in the War for Talent: Using Special Hiring Authorities to Recruit Crucial Personnel. Washington, D.C.: PricewaterhouseCoopers Endowment for the Business of Government, 2001.**
- **Hal G. Rainey, Understanding and Managing Public Organizations, 4th edition. Sa Francisco: Jossey-Bass, 2010.**
- **Hal G. Rainey and James Thompson, "Leadership and Transformation of a Major Institution: Charles Rossotti at the U.S. Internal Revenue Service." Public Administration Review, Vol. 66, no. 4 (July/August, 2006): 596-604.**
- **James Thompson and Hal G. Rainey, Modernizing Human Resource Management in the Federal Government: The IRS Model. Washington, D.C.: IBM Endowment for the Business of Government, 2003.**



NIH Scientific Management Review Board



Substance Use, Abuse, and Addiction Working Group Update

March 10, 2010

William Roper, MD, MPH
Dean of the School of Medicine and
Vice Chancellor for Medical Affairs,
University of North Carolina;
CEO of the UNC Health Care System

Overview

- **SUAA Membership**
- **Context for Deliberations**
- **SUAA Working Group Charge**
- **Summary of Briefings to Date**
- **Deliberative Process**
- **Review of Data**
- **Next Steps**

SUAA Working Group Membership

- **Non-Federal Members**

- **William Roper, MD, MPH (Chair)**

- Dean of the School of Medicine, Vice Chancellor for Medical Affairs, and CEO of the UNC Health Care System, University of North Carolina*

- **Deborah Powell, MD**

- Associate Vice President for New Models of Medical Education and Dean Emeritus, University of Minnesota Medical School*

- **Eugene Washington, MD, MSc**

- Dean of the David Geffen School of Medicine and Vice Chancellor of Health Sciences, University of California, Los Angeles*

- **Huda Zoghbi, MD**

- Professor and Howard Hughes Medical Institute Investigator, Baylor College of Medicine*

- **Norman Augustine (ad hoc)**

- Retired Chairman and CEO, Lockheed Martin Corporation*

SUAA Working Group Membership *(cont.)*

- **Federal Members**

- **Josephine Briggs, MD**

Director, National Center for Complementary and Alternative Medicine, NIH

- **Richard Hodes, MD**

Director, National Institute on Aging, NIH

- **Griffin Rodgers, MD, MACP**

Director, National Institute of Diabetes and Digestive and Kidney Diseases, NIH

- **Lawrence Tabak, DDS, PhD**

Director, National Institute of Dental and Craniofacial Research, NIH

- **Francis Collins, MD, PhD *(nonvoting, ex officio)***

Director, NIH

Context for Deliberations

- **Neuroscience research has revealed that addictive substances, including drugs and alcohol:**
 - **Differentially affect brain receptors and can result in unique neuropathologies**
 - **Similarly activate certain physiological pathways including the brain's reward circuit, which can result in compulsive substance use**
- **Considering both biological differences and similarities, does the current organization separating research institutes on drug and alcohol use, abuse, and addiction provide optimal infrastructure for supporting these areas of scientific research?**

Context for Deliberations *(cont...)*

- **Social-Political:**
 - The NIH Reform Act established the SMRB to advise NIH on the use of organizational authorities
 - In 2003, the National Academies recommended considering merging NIAAA and NIDA (option of a combined institute of addiction also identified by the Lewin Group in 1988)
 - The Drug Abuse Education, Prevention, and Treatment Act of 2001 (S.304) required the DHHS Secretary to request an IOM study to determine whether combining NIDA and NIAAA would strengthen scientific research efforts and increase economic efficiency (*study has yet to be conducted*)

SUAA Working Group Charge

—..to recommend whether organizational change within NIH could further optimize research into substance use, abuse, and addiction and maximize human health and/or patient well being.”

Briefings to Date

Briefings to Date

- Introduction to SUAA research at the NIH from current Institute Directors



Dr. Kenneth Warren
Acting Director, NIAAA



Dr. Nora Volkow
Director, NIDA

Briefings to Date *(cont.)*

- **Perspectives from prevention specialists, treatment providers, patient advocates, and policy specialists**
 - **Ms. Nancy Freudenthal**, *First Lady of Wyoming*
 - **Dr. Sheppard Kellam**, *Johns Hopkins Bloomberg School of Public Health*
 - **Dr. Herbert Kleber**, *Columbia University College of Physicians and Surgeons and NY State Psychiatric Institute*
 - **Dr. Marc Schuckit**, *University of California and the VA San Diego Healthcare System*
 - **Mr. Tom Donaldson**, *National Organization on Fetal Alcohol Syndrome*
 - **Ms. Sue Rusche**, *National Families in Action and Parent Corps*
 - **Dr. John Carnevale**, *Carnevale Associates, LLC*

Briefings to Date *(cont.)*

- **Perspectives on the science of SUAA research**
 - **Dr. Huda Akil**, *University of Michigan*
 - **Dr. Adron Harris**, *University of Texas at Austin*
 - **Dr. Michael Charness**, *Harvard Medical School and Boston University School of Medicine*
 - **Dr. Mary Jeanne Kreek**, *Rockefeller University Hospital*
 - **Dr. Mark Goldman**, *University of South Florida*
 - **Dr. Linda Porrino**, *Wake Forest University School of Medicine and College on Problems of Drug Dependence*

Briefings to Date *(cont.)*

- **Perspectives on the science of SUAA research** *(cont.)*
 - **Dr. Thomas Kosten**, *Baylor College of Medicine*
 - **Dr. Stephanie O'Malley**, *Yale University School of Medicine and Connecticut Mental Health Center*
 - **Dr. Scott Friedman**, *Mount Sinai School of Medicine*
 - **Dr. David Vlahov**, *New York Academy of Medicine, Columbia University, and Johns Hopkins Bloomberg School of Public Health*
 - **Dr. Thomas Greenfield**, *Public Health Institute and University of California*
 - **Dr. David Rosenbloom**, *Columbia University*

Briefings to Date *(cont.)*

- **Alternative models for organizing SUAA research: Perspectives from the judicial system, academia, and industry**
 - **Ms. Linda Chezem, *Purdue University***
 - **Ms. Pamel Rodriguez, *Treatment Alternatives for Safe Communities***
 - **Dr. Steven Hyman, *Harvard Medical School***
 - **Dr. John Krystal, *Yale University, U.S. Department of Veterans Affairs***
 - **Dr. Bankole Johnson, *University of Virginia***
 - **Dr. Steven Paul, *Eli Lilly and Company***

Briefings to Date *(cont.)*

- **Perspectives from former NIAAA and NIDA Directors:**
 - Dr. Enoch Gordis, *Former Director of NIAAA (1986 – 2001)*
 - Dr. Alan Leshner, *Former Director of NIDA (1994 – 2001)*
 - Dr. Ting-Kai Li, *Former Director of NIAAA (2002 – 2008)*
- **Perspectives from the NIAAA and NIDA Advisory Councils**

Briefings to Date *(cont.)*

- **Briefed the NIH Director, SMRB Chair, and Chair of SMRB Working Group on the NIH Intramural Research Program on SUAA Working Group status**
 - **Francis Collins, M.D., Ph.D.,** *Director of NIH*
 - **Norman Augustine,** *Retired Chairman and CEO of Lockheed Martin Corporation, Chair of SMRB*
 - **Arthur Rubenstein, M.B.B.Ch.,** *Executive Vice President of the University of Pennsylvania for Health System and Dean of the University of Pennsylvania School of Medicine, Chair of SMRB IRP Working Group*

Summary of Findings from Briefings to Date

Advocates FOR Reorganization

- **Science would benefit from synergy of commonalities:**
 - **Emerging scientific research indicates similar reward pathways underlie compulsive behavior**
 - **Alcohol and drug abuse often begins in adolescence with similar early risk factors**
- **High prevalence of drug users also use alcohol, suggesting both scientific and policy justification**
- **Segregation of disciplines creates public health gaps**

Advocates FOR Reorganization *(cont...)*

- **Reorganization, particularly merging, would:**
 - **Create synergy for advancing the science of substance use, abuse and addiction**
 - **Increase flexibility in cross-training**

Advocates **AGAINST** Reorganization

- **Reorganization would create research gaps in understanding:**
 - **Ubiquitous effects of alcohol**
 - **Unique factors underlying abuse and addiction**
- **Contextual and socio-cultural differences warrant separate, focused research efforts**
- **Lack of compelling evidence to suggest reorganization would improve treatment, prevention, research, and/or training**
- **Current organization mirrors the separation of professional and scientific associations**

Advocates **AGAINST** Reorganization *(cont...)*

- **Reorganization, particularly merging, would:**
 - **Decrease emphasis on effects of alcohol on multiple organ targets**
 - **Jeopardize priority/budget of alcohol-related research**
 - **Create organizational/administrative obstacles and reversals**

Questions Raised

- **Are other areas of research being examined for potential inclusion in a merged Institute?**
- **Has the SMRB considered broadening the mission/scope of a merged Institute?**
- **Has the SMRB investigated intra-governmental relationships (e.g., ONDCP oversight of NIDA budget)?**
- **Has industry participated in the discussion and/or voiced an opinion?**
- **Patients have no difficulty combining substances, why does the government?**
- **Will the SMRB recommend a single solution or multiple solutions?**

Issues the Board should Consider

- **Both Institutes are already underfunded despite the burden of illness; Potential funding loss due to stigma associated with combining these areas of research**
- **The public health message for alcohol is different: moderate alcohol usage may be healthy; immoderate usage is not**
- **Focusing on reward pathways creates a dogma about abuse and addiction; constrains science to only one potential mechanism**
- **NIDDK or NIA are more logical partners for NIAAA than NIDA**
- **If a merger is recommended, there needs to be a —genuine” merge of the Institutes and not the creation of two departments within one IC**

NIAAA Advisory Council Position

- **Resolution of Council passed on February 3, 2010: 14 in favor; 0 opposed; 1 abstention**
- **—The NIAAA Council strongly advises against an NIH reorganization that eliminates NIAAA as an independent Institute. We encourage increased collaboration across NIH Institutes and Centers to strengthen research on the use, abuse, and addiction to alcohol, tobacco, drugs of abuse, and high-fat and high-sugar foods. We also advocate increased collaboration to improve the diagnosis and treatment of the co-morbid mental health disorders associated with addiction.”**

NIDA Advisory Council Position

- Resolution of Council passed on March 1, 2010: 15 in favor; 0 opposed
- **—We resolve that the benefits derived through combining the research efforts for all drug use and addiction into a single entity outweigh the benefits in continuing the status quo. Therefore, the National Advisory Council of the National Institute on Drug Abuse advises that the Secretary of Health and Human Services and Director of NIDA vigorously should support efforts to combine and focus within a single NIH Institute research on the causes, mechanisms, prevention, and treatment of the non-medical use of, and addiction to, all addictive drugs.”**

Deliberative Process Step 1: Assessing the Need for Change

Step 1.
Assess the Need for Change

Is SUAA research at NIH capitalizing on scientific opportunities and/or meeting public health needs?

Could reorganization better optimize SUAA research at NIH?

Steps and Considerations: STEP 1

- ***Immediate Crisis***
 - Are there significant organizational impediments preventing effective responses to external forces?
- ***Unaddressed Scientific Opportunities***
 - Is there a health problem or an important area of scientific inquiry not addressed because of the limitations imposed by the current organization?
- ***Changes in Scientific Landscape***
 - Have there been scientific discoveries that create new opportunities for innovation and advance that would benefit from reorganizing components of the NIH?
- ***Evolving Emergent Public Health Needs***
 - Are there evolving public health needs on the horizon that will create new challenges and opportunities that would be best faced by reorganizing components within NIH?
- ***Need for Improvements in Quality and/or Efficiency of Research***
 - Is there a problem (or could things be more effective) in the supply and demand of human and/or physical resources (e.g., training, dissemination of research/public health messages)?

Steps and Considerations: STEP 1 *(cont.)*

- In assessing the need for organizational change to optimize SUAA research at NIH, the working group has requested the following data:
 - Major challenges facing the advancement of SUAA research
 - Funding history and Institute success rates
 - Institute support for early career investigators
 - Extent of SUAA research in the entire NIH research portfolio
 - SUAA demographics

Data Requested

Research/Public Health Needs Not Currently Addressed – NIAAA Perspectives

- **A compendium of the pharmacokinetic and pharmacodynamic interactions between alcohol and the therapeutics used to treat general medical and psychiatric conditions (e.g., hypertension, diabetes, epilepsy, depression, etc.)**
- **Research on the generation of novel metabolites resulting from the in situ interaction of alcohol with opiates, stimulants, hallucinogens, or inhalants (e.g., the production of coco-ethylene) and their pharmacokinetic and pharmacodynamic properties and toxicity**
- **Mechanisms by which alcohol increases risk for certain cancers**
- **Encouraging the hesitant patient to seek treatment**

Research/Public Health Needs Not Currently Addressed – NIDA Perspectives

- **Lack of pharmaceutical industry interest in developing medications to treat addiction/alcoholism**
- **Insufficient involvement of the medical community in preventing and treating drug addiction and alcoholism**
- **Although treatments for substance abuse are available, they are not being widely used by those who need them**
- **There is a bottleneck in translating treatments for substance abuse from bench to bedside to the community**

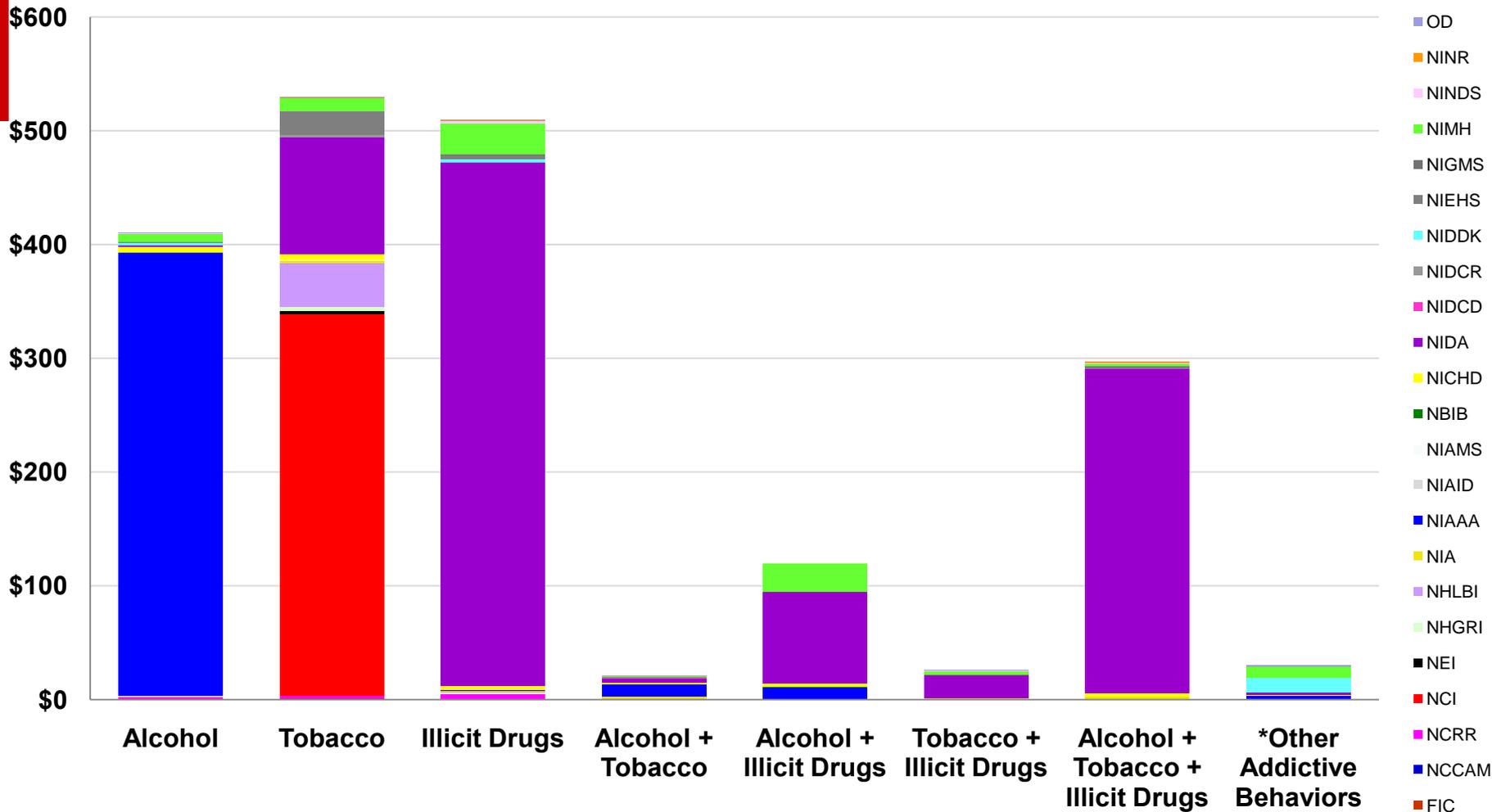
Funding History and Success Rates - Findings

- **Similar rates of budget growth**
 - NIAAA = 69% increase from 1999 appropriation
 - NIDA = 67% increase from 1999 appropriation
- **Currently similar grant success rates, although different trends since 1999**
- **Different rates of growth in number of research project grants reviewed**
 - NIAAA = 23% increase since 1999
 - NIDA = 81% increase since 1999

Support for Early Stage Investigators - Findings

- **Training support (FY09)**
 - Pre-doctoral awards: NIAAA = 164; NIDA = 289
 - Post-doctoral awards: NIAAA = 131; NIDA = 244
- **K Awards (FY09)**
 - NIAAA = 97 (21% increase from 2003)
 - NIDA = 251 (9% increase from 2003)

Funding for SUAA Research Across NIH



* Data estimates were provided by individual ICs and do not reflect official NIH budget numbers.

Demographics of SUAA - Findings

- **Age groups with highest percent use within the last month:**
 - Alcohol: 21 and older
 - Illicit drugs: 16-29
 - Cigarettes: 18 and older
- **Number of 12 yr olds and older reporting substance abuse or dependence in the last year (rates of abuse have not changed 2002 - 2008)**
 - Alcohol: ~15 million
 - Illicit Drugs: ~4 million
 - Both Alcohol and illicit drugs: ~3 million

Demographics of SUAA - Findings *(cont.)*

- **Percent of individuals aged 12-17 reporting substance abuse or dependence in the last year**
 - ONLY Alcohol: 5.9% in 2002; 4.9% in 2008
 - ONLY illicit drugs: 5.6% in 2002; 4.6% in 2008
 - EITHER alcohol or illicit drugs: 8.9% in 2002; 7.6% in 2008
- **Substance Abuse and Mental Health**
 - 2.5 million adults have both a substance use disorder and a serious mental illness

Demographics of SUAA - Findings *(cont.)*

- **Substance Abuse and Mental Health *(cont.)***
 - **Percent of adults reporting a major depressive episode in the past year who were dependent upon:**
 - Either drugs or alcohol: 20%
 - Drugs only: 8%
 - Alcohol only: 16%
 - **Percent of 12-17 year olds reporting a major depressive episode in the past year who used:**
 - Illicit drugs: 37%
 - Cigarettes: 4%
 - Alcohol: 3%

Preliminary Findings

- **Working Group has thoroughly discussed and debated the issue, based on perspectives heard and data collected**
 - **Agreement that the status quo is not ideal for fulfilling NIH mission and optimizing research into substance use, abuse and addiction**
 - **Eager to improve how NIH manages research into substance use, abuse and addiction**

Deliberative Process Step 2: Considering the Spectrum of Options

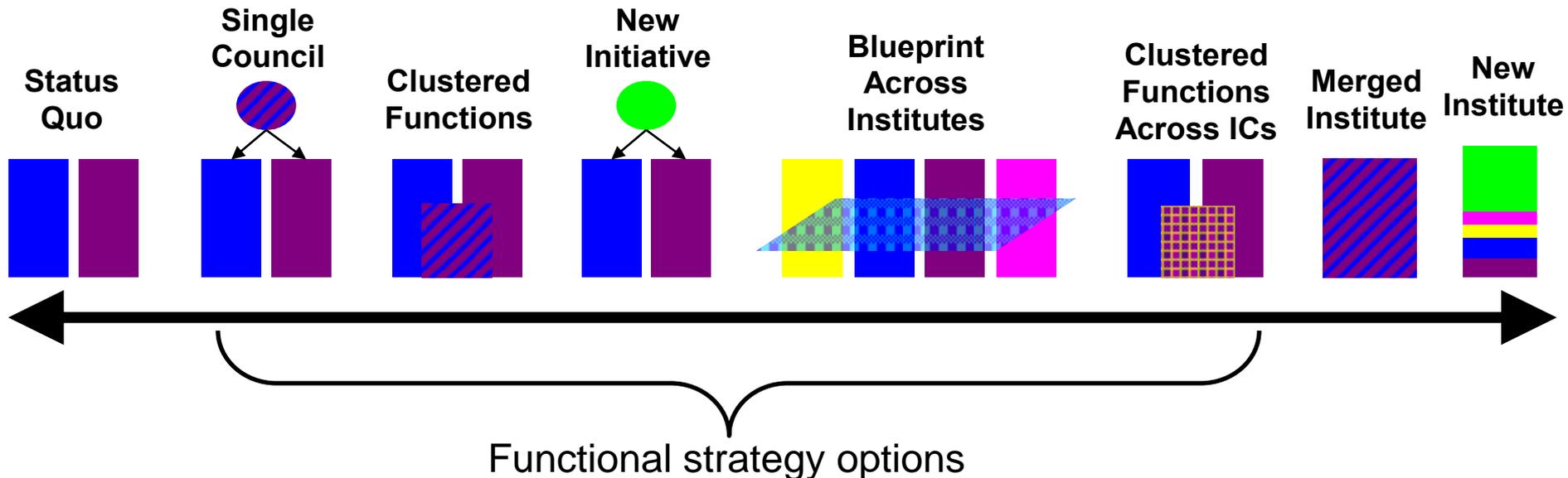
Step 2.
Evaluate Options for Change

**What are the options
for organizational
change?**

**Which one is best for
addressing the need
for change?**

Full Spectrum of Options

- Each option needs to be carefully considered to maximize integration
- Each option is a possible element of final recommendation—various strategies are not mutually exclusive and a combination can be identified to best address the need



Preliminary Findings

- To date, the working Group disagrees as to best way to proceed: structural vs. functional integration

Preliminary Findings *(cont.)*

- **Minority View:**
 - **A structural reorganization is needed, involving a merger of NIDA and NIAAA into a single institute focused on alcohol and drug abuse and addiction**
 - **The change in scientific landscape, research opportunities, public health needs, and the potential for more efficient research provide the rationale for considering structural change**
 - **Substantial vision of a new way of approaching the science and addressing public health needs ought to compel us to take the difficult step towards merging the two**

Preliminary Findings *(cont.)*

- **Majority View:**
 - **Best way to proceed is a functional reorganization of all research programs with a relevant scientific focus**
 - **The change in scientific landscape, research opportunities, public health needs, and the potential for more efficient research provide the rationale for considering change, but the majority are not yet convinced structural changes would benefit the science in a way that functional integration could not**
 - **See substantial room to improve the science through functional integration across the entire NIH**
 - **Evidence that functional strategies have worked in the past, in other scientific areas, with varying degrees of success**

Next Steps

- **Having agreed that there is a need for organizational change, Working Group will:**
 - **Fully analyze potential structural and functional options, including historic success of different models**
 - **Fully analyze pros and cons of each option**
- **Present working group recommendation at next SMRB meeting**

Anticipated Timetable

- **April: Draft recommendations proposed to full Board via public teleconference**
- **May 17-19: Stakeholder meetings held during full Board meeting in Bethesda**
- **May-June: Integrate feedback from stakeholder meetings into recommendations**
- **June-July: Full Board teleconference vote via public teleconference**



NIH Scientific Management Review Board



NIH Intramural Research Program Working Group Update

March 10, 2010

Arthur Rubenstein, M.B.B.Ch.
Executive Vice President of the University of
Pennsylvania for Health System and Dean of the
University of Pennsylvania School of Medicine

IRP Working Group Charge

- **Recommend whether organizational change could further optimize the Agency's intramural research program and thereby maximize human health and patient well-being.**
- **Given the urgency of addressing the fiscal vitality of the NIH Clinical Center, recommend steps to enhance the fiscal sustainability and utilization of the NIH Clinical Center.**

IRP Working Group Membership

Non-Federal

Arthur Rubenstein, MBBCh
(Chair)

Gail Cassell, PhD

Solomon Snyder, MD

Norman Augustine
(ad hoc)

Federal

Anthony Fauci, MD

Stephen Katz, MD, PhD

Susan B. Shurin, MD

Francis Collins, MD, PhD
(ex officio)

Context for Deliberations

- **Historically, the NIH Clinical Center (CC) has provided a versatile clinical research environment enabling the NIH mission to improve human health.**
- **However, unresolved problems in governance and budget are impediments to realizing the Center's full potential.**



Briefings to Date

- **Concerns and current status of the NIH Clinical Center: An overview of current fiscal challenges from Institute Directors and key NIH staff:**
 - **Dr. Stephen Katz**, *Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases*
 - **Dr. Elizabeth Nabel**, *Former Director of the National Heart, Lung, and Blood Institute*
 - **Dr. John Gallin**, *Director of the NIH Clinical Center*
 - **Dr. Michael Gottesman**, *Deputy Director of the Office of Intramural Research*

Briefings to Date *(cont.)*

- **The NIH Clinical Center: Perspectives from distinguished NIH investigators and advisers regarding its mission, function, capabilities, and vision for the future:**
 - **Dr. Anthony Fauci**, *Director of the National Institute of Allergy and Infectious Diseases*
 - **Dr. Daniel Kastner**, *Clinical Director of the National Institute of Arthritis and Musculoskeletal Diseases*
 - **Dr. Clifford Lane**, *Clinical Director of the National Institute of Allergy and Infectious Diseases*
 - **Dr. Steven Rosenberg**, *Chief of Surgery at the National Cancer Institute*

Briefings to Date *(cont.)*

- **Business models for hospital management : Perspectives from research hospital administrators**
 - **Dr. Ronald Evens**, *Chair of the NIH Advisory Board for Clinical Research and Senior Executive Officer of BJC HealthCare*
 - **Dr. Edward Benz**, *President and CEO of the Dana Farber Cancer Institute*
 - **Mr. John Finan**, *President and CEO of the Franciscan Missionaries of Our Lady*
 - **Mr. Edward Howell**, *Vice President and CEO of the University of Virginia Medical Center*

Briefings to Date *(cont.)*

- **Collaborations between extramural and intramural communities regarding current and potential uses:**
 - **Ms. Barbara McGarey**, *Office of the General Counsel at the U.S. Department of Health and Human Services*
 - **Mr. John Bartrum**, *Former Associate Director of the NIH Office of Budget*
 - **Ms. Colleen Barros**, *Deputy Director for Management and Chief Financial Officer at NIH*

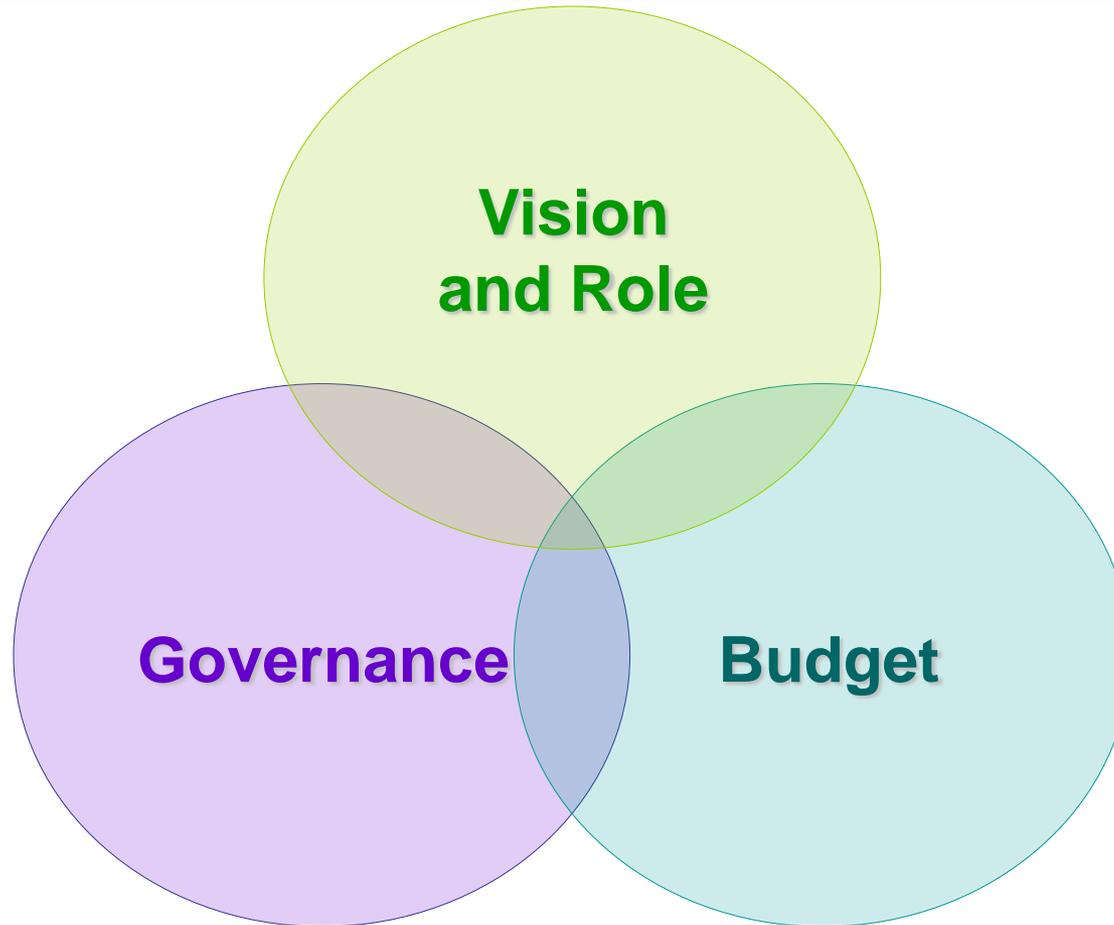
Briefings to Date *(cont.)*

- **Perspectives from the NIH Advisory Board for Clinical Research (ABCR)**
 - **The ABCR provides advice and guidance to integrate the vision, planning, and operations of the intramural clinical research programs of the NIH, including clinical research conducted at the CC and CC operations, budget, and strategic operating plans**
 - **Chaired by Dr. Ronald Evens, *Senior Executive Officer, BJC HealthCare***
 - **Per the statute, the Board must consult with the advisory councils of the relevant national research institutes and centers**

Briefings to Date *(cont.)*

- **Briefed the NIH Director, SMRB Chair, and Chair of SMRB Working Group on Substance Use, Abuse, and Addiction on IRP Working Group status and preliminary findings**
 - **Francis Collins, M.D., Ph.D.,** *Director of NIH*
 - **Norman Augustine,** *Retired Chairman and CEO of Lockheed Martin Corporation, Chair of SMRB*
 - **William Roper, M.D.,** *Dean of the School of Medicine and CEO of Health Care System of University of North Carolina, Chair of SUAA Working Group*

Summary of Findings: CC Challenges



CC Challenges: Vision and Role



Vision and Role

Challenges

- **Perceived lack of prioritization of and commitment to funding clinical research at the CC**
- **Barriers to partnerships and leveraging resources (e.g., barriers to intra-/extramural collaborations, intellectual property)**
- **Barriers to recruitment, mentorship, and retention of investigators**

CC Challenges: Governance



Governance

Challenges

- **Lack of trans-NIH vision for priority setting in clinical research**
- **Complexity in administrative approval processes**

CC Challenges: Budget



Challenges

- **Increasing costs of CC associated with healthcare inflation - current “School tax” method does not keep up with inflation**
- **Instability of CC funding**
- **Cost shifts have had unintended and undesirable consequences (e.g., significantly reduce use of CC use by ICs)**
- **Budget mechanism does not support outside investigators’ use of CC**

CC Challenges: Budget *(cont.)*

- **CC is within range of costs, on per inpatient day basis, with comparison hospitals**
- **CC is a research-focused hospital and has significantly fewer beds - which precludes the same economies of scale that can be achieved by the others**
- **All CC patients are on a research protocol which often drives up costs**

Meeting CC Challenges



**Vision
and Role**

CLINICAL CENTER AS A NATIONAL RESOURCE

The role of the CC should be to serve as a state-of-the-art national resource, with resources optimally managed to enable both internal and external investigator use

Current CC Use by External Investigators

NIH Clinical Directors were recently queried on current use of CC by outside investigators.

Many institutes have training programs involving collaborations with outside institutions; many use outside consultants via established federal mechanisms.

Current CC Use by External Investigators

Examples include:

- **Studies of cohorts of patients with rare diseases using either an intra-agency personnel agreement (IPA) [NIAMS] or utilizing funding from the NIH Office of Rare Diseases [NCI]**
- **Early phase clinical protocols - genesis by extramural investigators but conducted at the CC in partnership with intramural [NINDS]**
- **Extramural investigators working in partnership with CC intramural investigators while utilizing the special volunteer mechanism [NINDS]**

Current CC Use by External Investigators

Examples include: *(cont.)*

- **Collaborative research partnership with a PhD receiving an NIH R-01 grant to conduct clinical studies on obesity research. The research is conducted at both the outside facility and the CC with no co-mingling of funds [NICHD]**
- **The CC administered bench-to-bedside program - In 2006 the scope broadened to include partnerships between intramural and extramural investigators in an effort to reduce barriers between the two communities. Sixty-one intramural-extramural partnerships have been supported by this mechanism.**
- **Many institutes reported relationships with industry partners using the CRADA mechanism.**

Expanding the Vision: CC as a National Resource

- **Growth in four programmatic areas would be key to realizing the vision of the NIH CC as a national resource**
 - Collaborative research studies (e.g., development of new therapies or phenotyping expertise)
 - Access to NIH clinical services (e.g., utilize special resources such as PET ligands or candidate drugs made in the Pharmacy Development Section's GMP facility)
 - Clinical research training (e.g., access to core curriculum in clinical research offered by CC)
 - Bench to Bedside programs - Stable funding could increase size and duration of awards (requires new legislation)

Expanding the Vision: CC as a National Resource *(cont.)*

- **Broadening the scope of CC use for the extramural community requires additional considerations regarding:**
 - **Feasibility**
 - Availability of resources
 - Identification of “Specialized Health Resources”
 - Capacity analysis
 - Public posting of availability resources
 - **Administration**
 - Patient care
 - Conflicts of interest
 - Intellectual property
 - Peer review process
 - Personnel designation of outside investigators
 - Protocol approval/IRB
 - HIPAA
 - **Reimbursement**
 - Recovery of costs
 - Allocation of funding from appropriate sources for extramural usage of CC

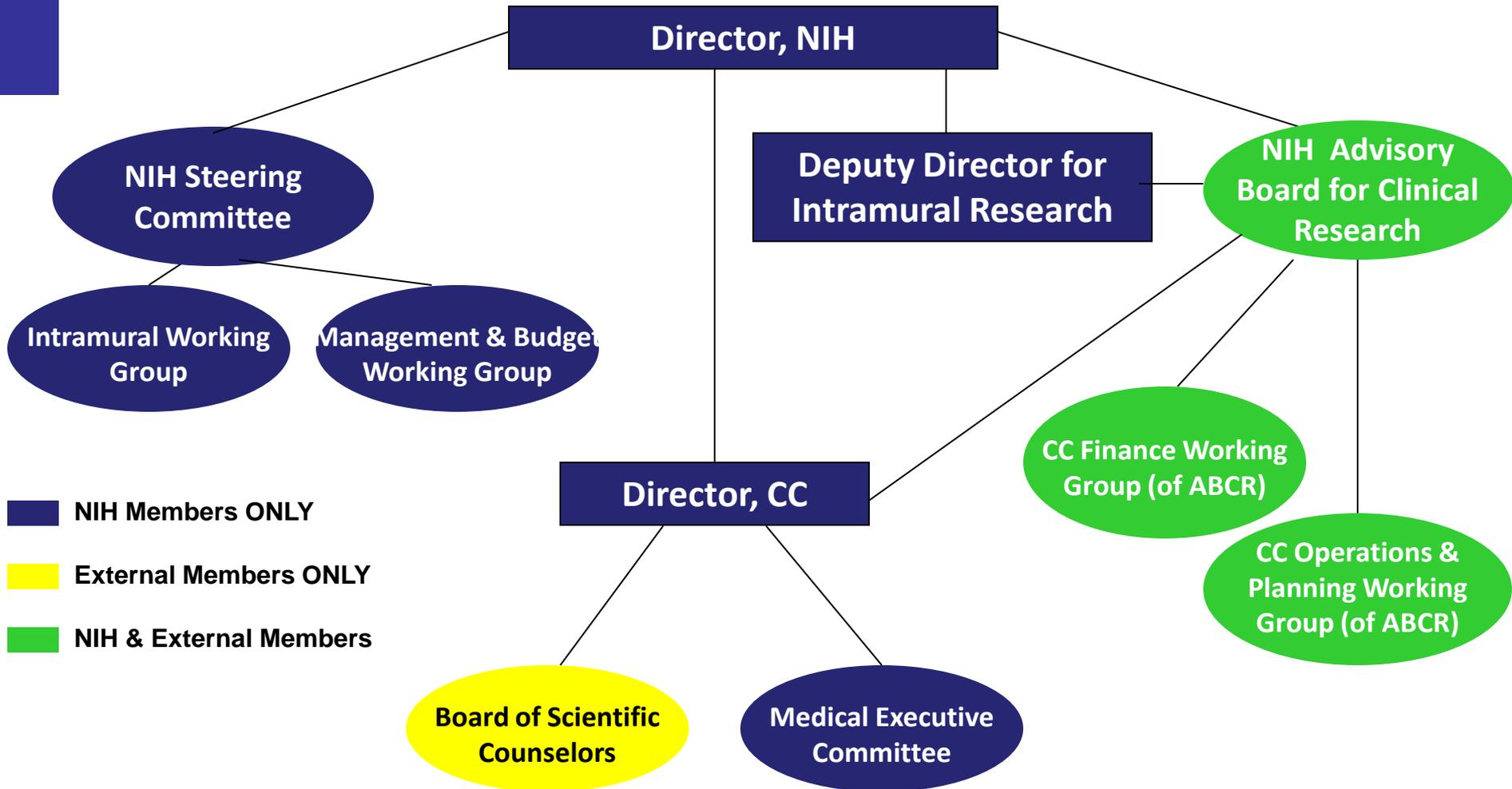
Meeting CC Challenges



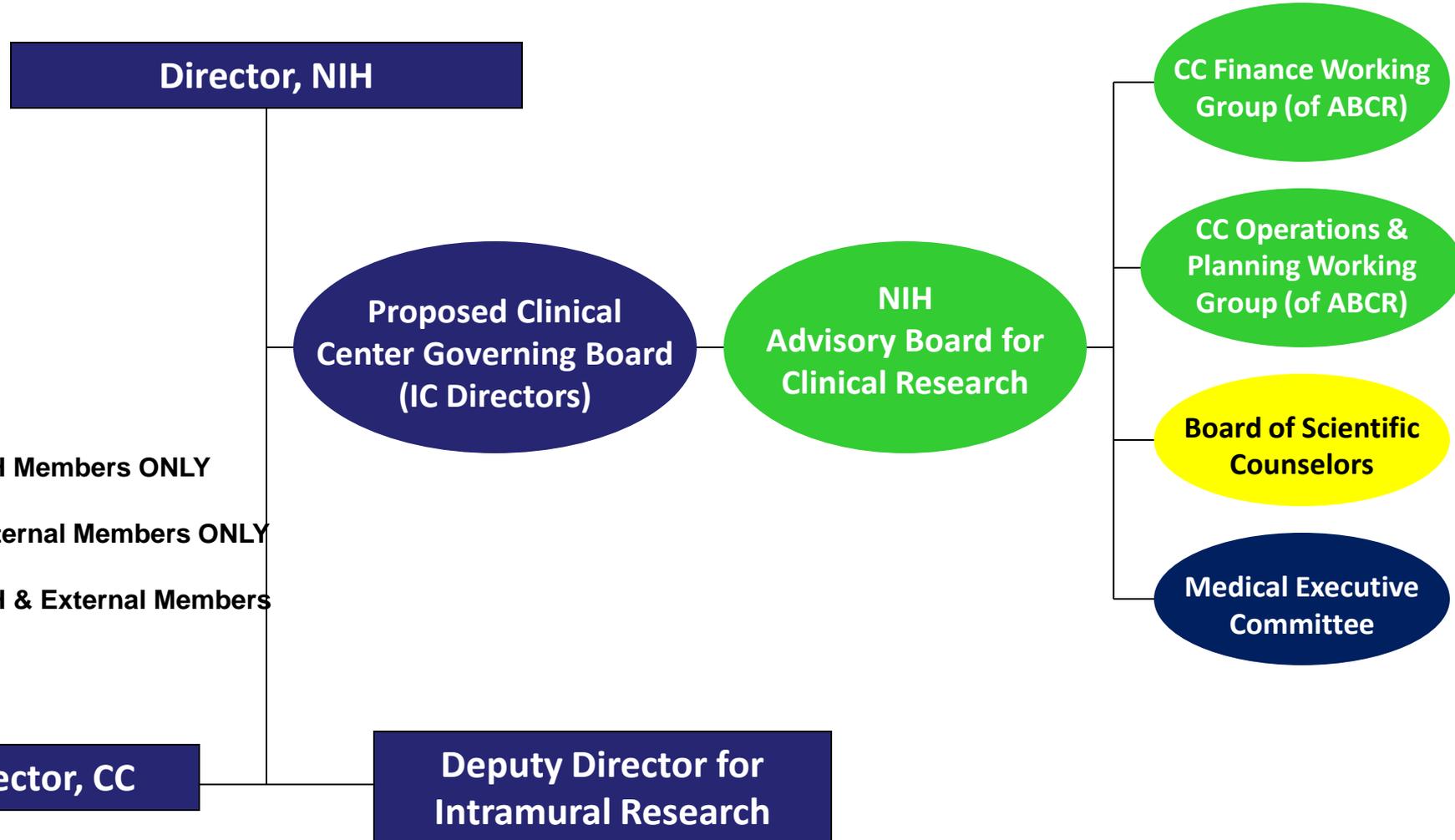
STREAMLINED GOVERNANCE STRUCTURE

Governance should have a simplified structure, capable of developing and overseeing a clear, coherent plan for clinical research

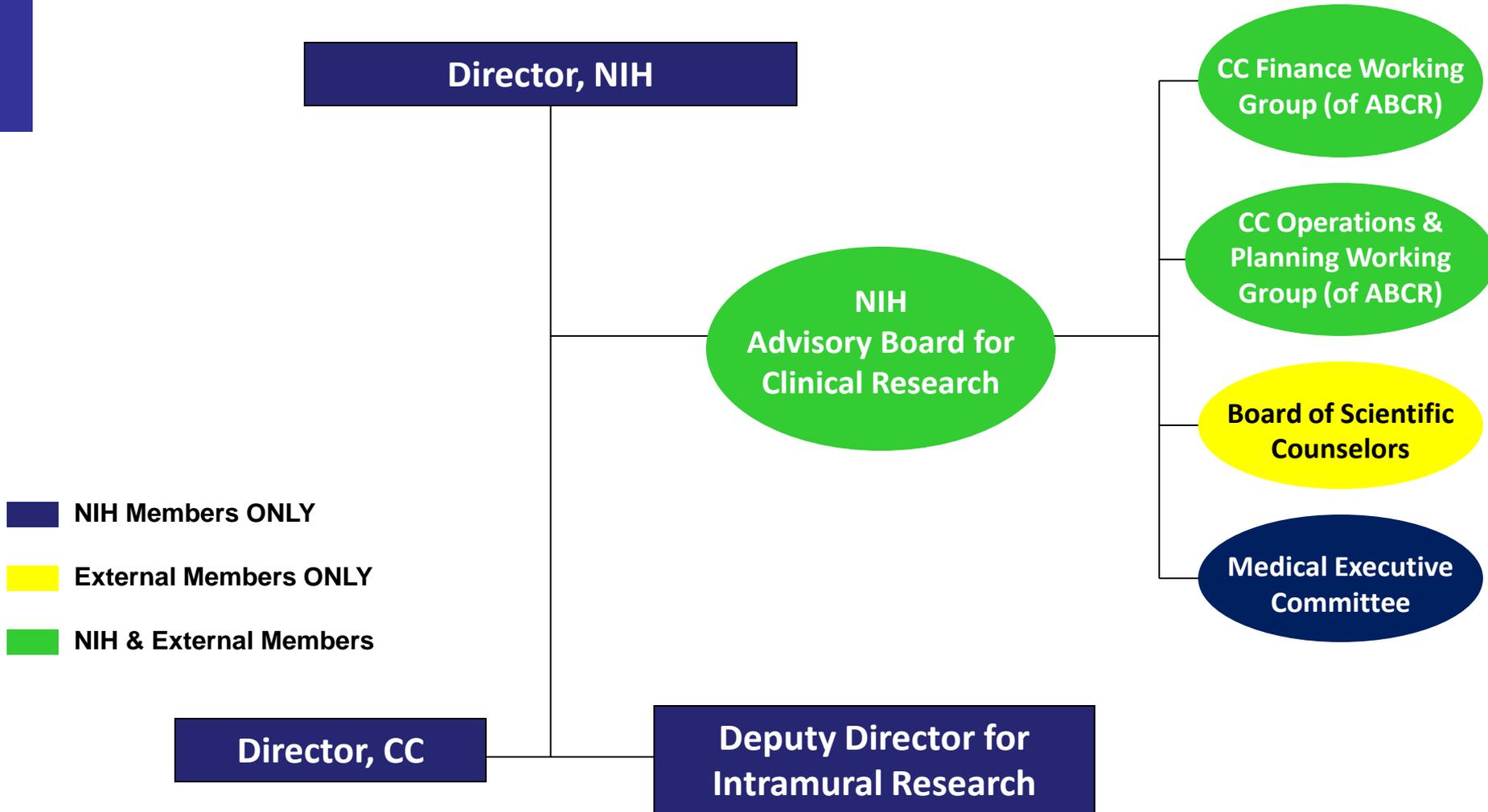
Current CC Governance Structure



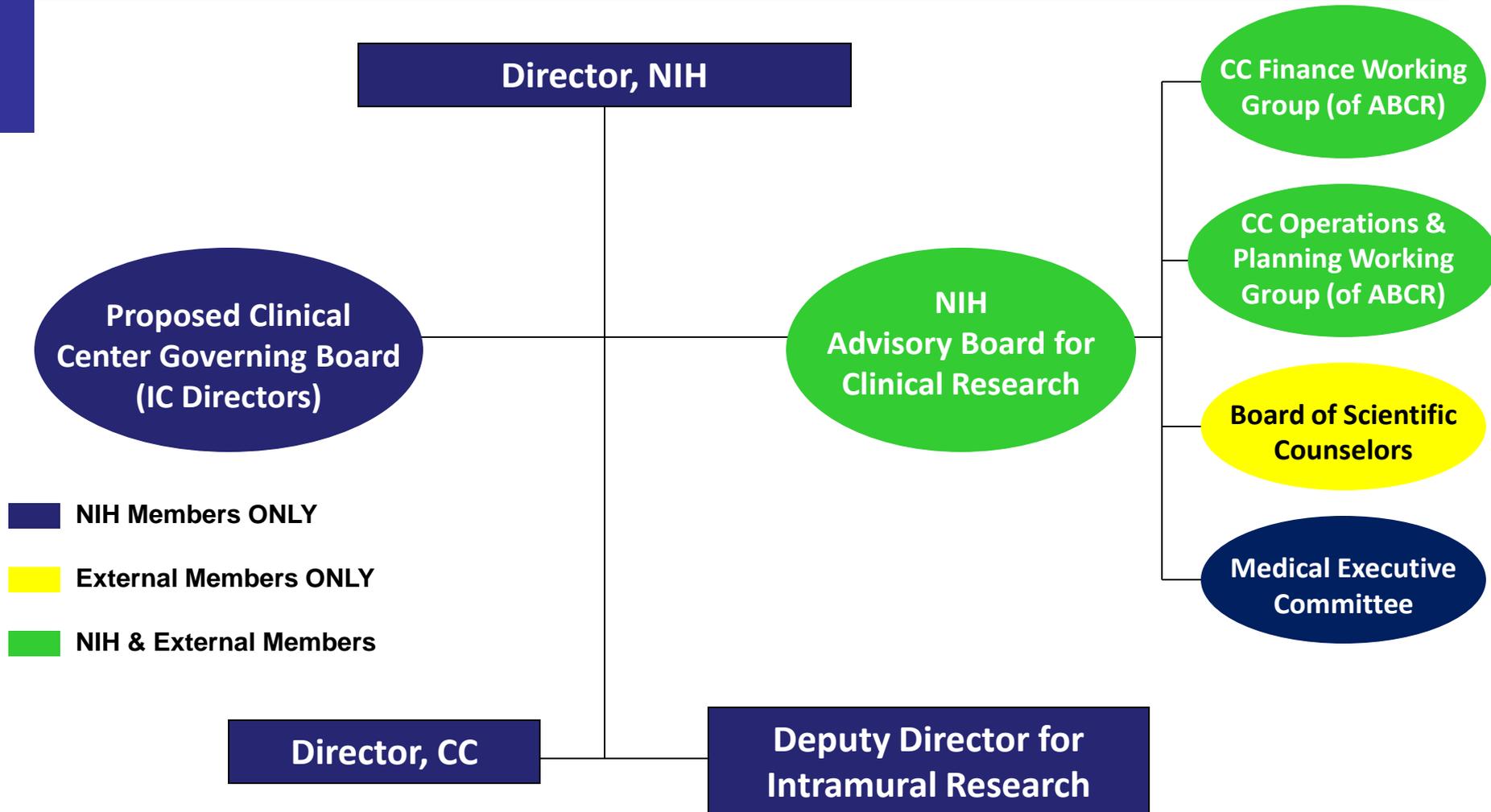
Potential New Governance Structure: Option 1



Potential New Governance Structure: Option 2



Potential New Governance Structure: Option 3



Meeting CC Challenges



Budget

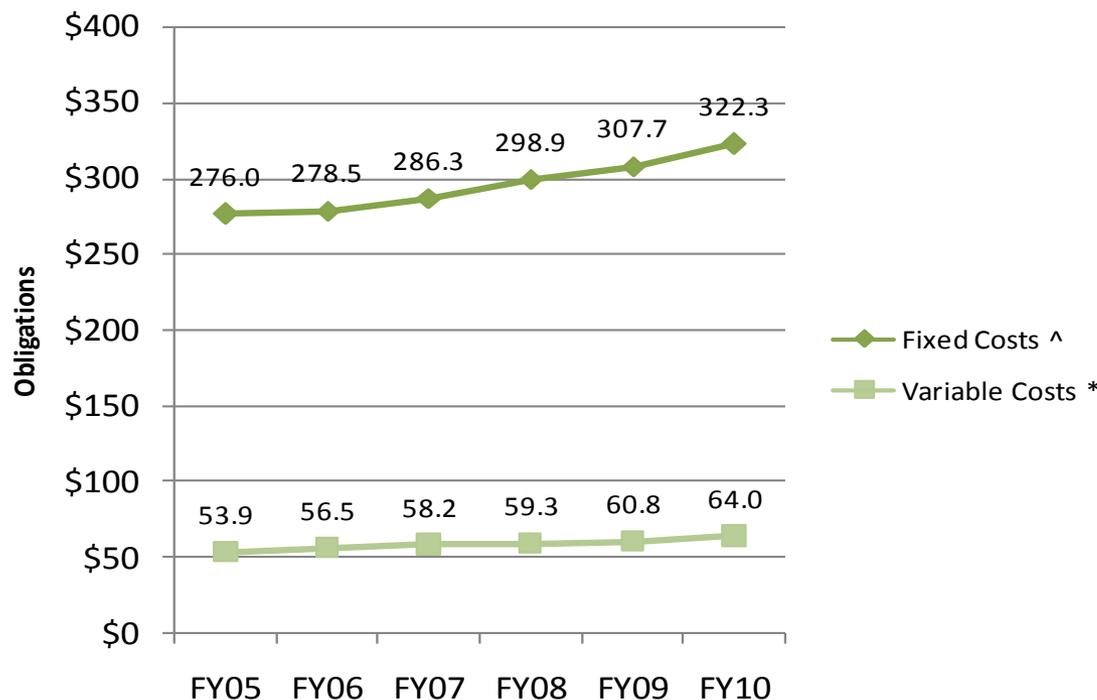
STABLE RESPONSIVE BUDGET

UNDERPINNED BY PRIORITY SETTING

Budget should be linked to a strong planning process, remain stable (in source) and equitable (in distribution), be effective in attracting and supporting a high quality workforce, and assure efficient use

CC Budget: Critical Analyses

CC Fixed & Variable Obligations
 FY05 - FY10 Budget
 (Dollars in Millions)



Fixed vs. Variable Costs

Changes in patient census = primary source of impact on fixed & variable costs

Fixed costs - incurred regardless of volume or services (e.g., personnel, equipment, administrative costs)

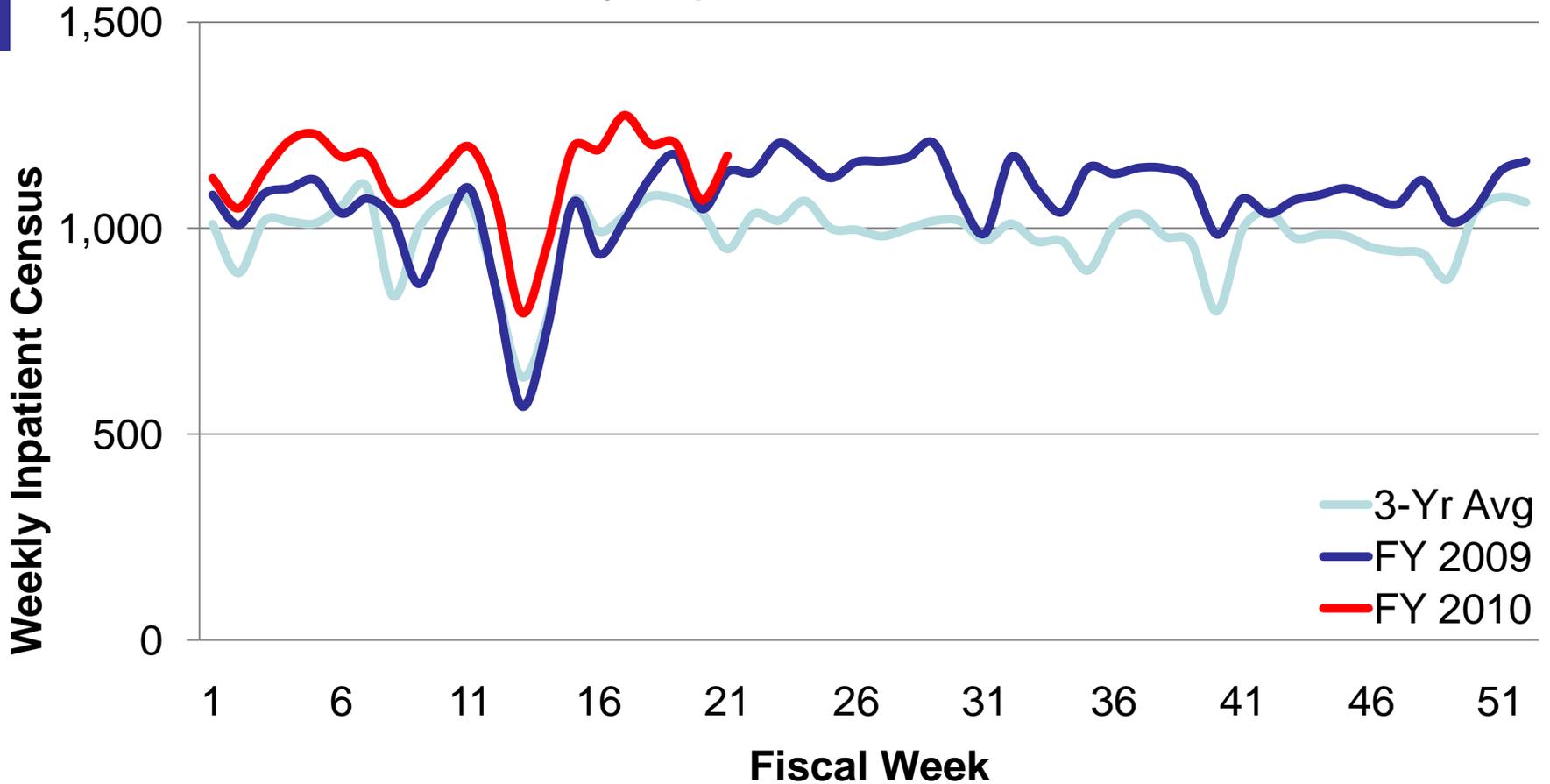
Variable costs - change with output and saved if service not provided (e.g., supplies, temporary labor, pharmaceuticals)

Comparable level of increase in fixed and variable costs over past years

- Fixed = 16.7% increase
- Variable = 18.7% increase

CC Budget: Critical Analyses *(cont.)*

Weekly Inpatient Census*



3-Yr Avg
FY 2009
FY 2010

*FY 2010 includes census through February 28, 2010
Total 234 beds

CC Budget: Critical Analyses *(cont.)*

Historical Bed Occupancy

Fiscal Year	% Occupancy	Average Daily Census
2000	54.6%	148.0
2001	58.3%	158.1
2002	55.3%	147.6
2003	60.1%	158.0
2004	62.6%	168.3
2005	67.1%	168.8
2006	64.4%	150.7
2007	63.5%	148.6
2008	63.5%	148.6
2009	69.1%	161.6
2010*	72.3%	169.2

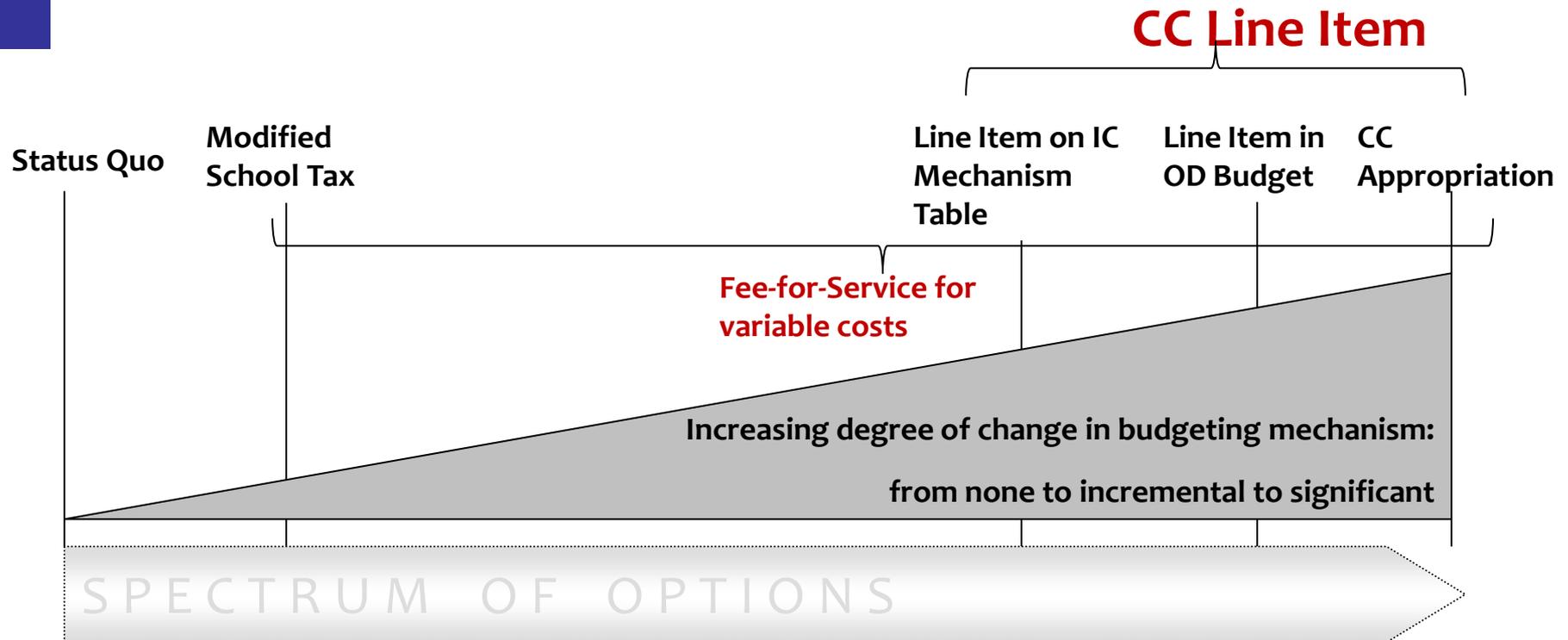
YTD FY 2010* Occupancy by Inpatient Unit

Location	Beds	% Occupancy
1NW Pediatrics	22	69.9%
1SE Alcohol/Behav. Health	14	77.5%
1SW Ped. Behav. Health	6	68.7%
3NE Hematology-Oncology Transplant	26	98.2%
3NW Adult Oncology	32	85.3%
3SEN Adult Oncology	12	81.4%
3SWN IMC / Procedures	6	30.8%
3SWS ICU	12	69.5%
5NW General Medicine	32	56.1%
5SEN Medicine - Telemetry	14	76.0%
5SES Medicine - Telemetry	13	76.4%
5SWN Metabolic	10	42.3%
7SE Adult Behav. Health	23	73.3%
7SWN Neurology/Sleep Lab	12	54.1%
TOTAL	234	72.3%

Indicates sustained occupancy of greater than 80%

* FY 2010 includes census thru March 8, 2010

Potential Funding Models: A Spectrum of Options





Potential Funding Models: A Spectrum of Options – Overall Impact

Current School Tax	Modified School Tax	CC Line Item in		
		Mechanism Table	OD Appropriation	Cong. Appropriation
<p>CC Budget Decision-making Passes from NIH to DHHS/OMB/Congress</p>				
<p>CC Competes for Funding from within Larger Pool of Resources</p>				

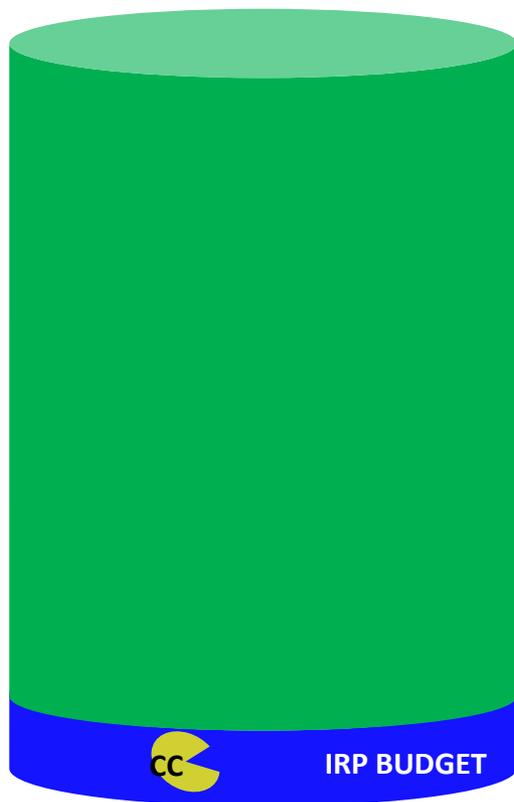


Potential Funding Models: A Spectrum of Options – Specific Impact

	Current School Tax	Modified School Tax	CC Line Item in IC Mechanism	Line Item in OD Approp.	CC Appropriation
Governance	Conflates NIH-driven program oversight and internal NIH budget review. However, no oversight/governance from DHHS/OMB/Congress.	Conflates NIH-driven program oversight and internal NIH budget review. However, no oversight/ governance from DHHS/OMB/Congress.	Budget formulation shifts to NIH-wide budget process as opposed to the central services process for “core” costs; discretionary cost covered from IRP. Introduces potential oversight/governance from DHHS/OMB/Congress independent of NIH governance.	Simplifies NIH governance by eliminating NIH budget review as budget formulation shifts to NIH-wide budget process. However, introduces potential oversight/governance from DHHS/OMB/Congress independent of NIH governance.	Simplifies NIH governance by eliminating NIH budget review as budget formulation shifts to NIH-wide budget process. However, introduces potential oversight/governance from DHHS/OMB/Congress independent of NIH governance.
Program Planning	Strong IC planning but no NIH-wide strategic focus.	Strong IC planning but no NIH-wide strategic focus.	CC funding may continue to be seen as IC funds, thus impacting development of an NIH-wide strategic focus.	CC funding provided from single source outside of IC budgets may facilitate development of NIH-wide strategic focus.	CC funding provided from single appropriation may facilitate development of NIH-wide strategic focus.
Budget Stability (Providing a base level of resources including inflation)	CC funding unilaterally determined by NIH from funds appropriated to NIH-wide IRP;CC competes for funds with campus infrastructure.	CC funding unilaterally determined by NIH from funds appropriated to NIH-wide IRP (and possibly ER depending on mission). CC competes for funds with campus infrastructure.	Allows NIH to propose total CC budget from total NIH allocation and CC competes for funds on basis of science rather than with campus infrastructure. However, Congress makes final decisions and they (and DHHS/OMB) will likely scrutinize requests higher than the overall NIH rate of growth.	Allows NIH to propose total CC budget from total NIH allocation and CC competes for funds on basis of science rather than with campus infrastructure. However, Congress makes final decisions and they (and DHHS/OMB) will likely scrutinize requests higher than the overall NIH rate of growth.	Allows NIH to propose total CC budget from total NIH allocation and CC competes for funds on basis of science rather than with campus infrastructure. However, Congress makes final decisions and they (and DHHS/OMB) will likely scrutinize requests higher than the overall NIH rate of growth.
Budget Flexibility (Ability to expand the number of protocols)	Current formula provides incentive to increase number of protocols; however, all CC funding is at the discretion of the Director, NIH but is collectively assessed from IRP.	Impact dependent on formula chosen; however, expanding formula to include ER likely improves flexibility and final funding is at the discretion of the Director, NIH.	Budget increases can be proposed by the Director NIH from within total NIH allocation but program increases likely to receive DHHS, OMB, Congressional scrutiny; increases after appropriation may require reprogramming within IC mechanisms.	Budget increases can be proposed by the Director NIH from within total NIH allocation but program increases likely to receive DHHS, OMB, Congressional scrutiny; reprogramming within the OD.	Budget increases can be proposed by the Director NIH from within total NIH allocation but program increases likely to receive DHHS, OMB, Congressional scrutiny; expansion by one IC after appropriation must be offset by another IC.
Clinical Center Capacity	Likely to allow expansion to extramural partners.	Likely to allow expansion to extramural partners.	Likely to allow expansion to extramural partners and appropriation process may provide vehicle for Congressional endorsement.	Likely to allow expansion to extramural partners and appropriation process may provide vehicle for Congressional endorsement.	Likely to allow expansion to extramural partners and appropriation process may provide vehicle for Congressional endorsement.

Potential Funding Models: A Spectrum of Options *(cont.)*

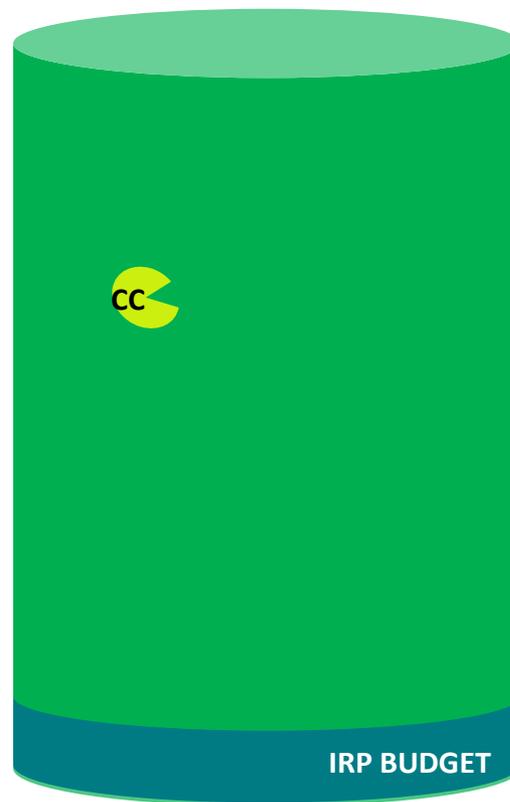
TOTAL NIH BUDGET
(~\$31 billion)



Options 1 and 2

FY09 = CC is ~11% of IRP Budget

TOTAL NIH BUDGET
(~\$31 billion)



Options 3, 4, and 5

FY09 = CC is ~1% of Total NIH Budget

CC Budget: Potential Funding Models

- **School Tax (status quo)**
 - Funding for CC supported by Institutes' and Centers' IRP budgets (a % of the IC IRP allocation)
 - NIH internally reallocates funds appropriated to Institutes' IRP
 - Funding actions and decision-making by NIH and no CC-specific action by others (Exec./Leg. Branches) required

CC Budget: Potential Funding Models

- **Modified School Tax**
 - Funding for CC supported by Institutes' and Centers' IRP budgets (a % of the IC IRP allocation)
 - NIH internally reallocates funds appropriated to Institutes' IRP
 - Funding actions and decision-making by NIH and no CC-specific action by others (Exec./Leg. Branches) required
 - Fixed and variable costs are dissociated:
 - Fixed costs assessed via school tax model
 - Variable costs assessed based upon IC usage (similar to a fee-for-service system)

CC Budget: Potential Funding Models



- **CC Line Item in IC Mechanism Table**
 - **Fixed Costs coverage**
 - **NIH proposes to Congress its intent to provide a specified amount to CC from total funds appropriated to the Institutes**
 - **Funding for fixed costs allocated to CC drawn from entire Institute budget and not as a portion of the IRP budget**
 - **Each Institute carries its portion of the fixed cost payment in this new line item in its mechanism table**
 - **Amount will be requested as part of the appropriations process and is visible in the DHHS/OMB/Congressional submissions**
 - **The amount will initially be subtracted from other appropriate mechanisms where these costs are currently budgeted, presumably IRP (through a one time adjustment)**

CC Budget: Potential Funding Models



- **CC Line Item in IC Mechanism Table** *(cont.)*
 - **Fixed Costs (cont)**
 - **Once funds are appropriated, they are transferred from ICs to CC via Central Services**
 - **Amounts listed establish a funding limitation and Congress must be notified of reprogramming (which must come from each individual IC's appropriation)**
 - **Should additional funds be required for fixed costs during budget year that exceed an IC's reprogramming threshold, a reprogramming request to Congress may be submitted; source of reprogramming must be directly related to purpose for which funds are being used**

CC Budget: Potential Funding Models



- **CC Line Item in IC Mechanism Table** *(cont.)*
 - **Variable costs continue to be budgeted in each Institute's IRP line in its mechanism table**
 - Amount not visible in DHHS/OMB/Congressional submissions
 - Amounts determined by NIH Director with input from the governing board and should be developed initially when fixed costs are calculated; can be refined prior to beginning of fiscal year
 - Variable cost assessments to each IC can be introduced based upon total usage (similar to a fee-for-service mechanism) and would be budgeted in each Institute's IRP line
 - Once budget levels are approved, funds transferred from ICs to CC via Central Services
 - Additional funds can be provided during the fiscal year from Institute IRP appropriations without a reprogramming request to Congress

CC Budget: Potential Funding Models



- **Line Item in an OD Appropriation**
 - **NIH proposes to Congress its intent to provide a specified amount of funding to the CC as a line item (PPA) within OD Appropriation**
 - **Amount will be requested as part of the appropriations process and visible in DHHS/OMB/Congressional submissions**
 - **Amount budgeted developed by the NIH Director with input from the governing board**
 - **Amount will initially be subtracted from other appropriate mechanisms where these costs are currently budgeted, presumably IRP (through a one time adjustment)**
 - **Congress, in taking action on the budget proposal, ultimately sets funding level**
 - **Once funds are appropriated, they are allocated directly to CC (no transfer through Central Services)**

CC Budget: Potential Funding Models



- **Line Item in an OD Appropriation** *(cont.)*
 - Should additional funds be required during budget year that exceed amount appropriated, a reprogramming request may be submitted; however, source of funds must be from OD (not Institute funds) - Congress must be notified of reprogramming
 - Funding allocated to CC is drawn from entire NIH budget and not as a portion of IRP budget
 - Variable cost assessments to each IC can be introduced based upon total usage (similar to a fee-for-service mechanism) and would be budgeted in each Institute's IRP line, with Congressional approval

CC Budget: Potential Funding Models

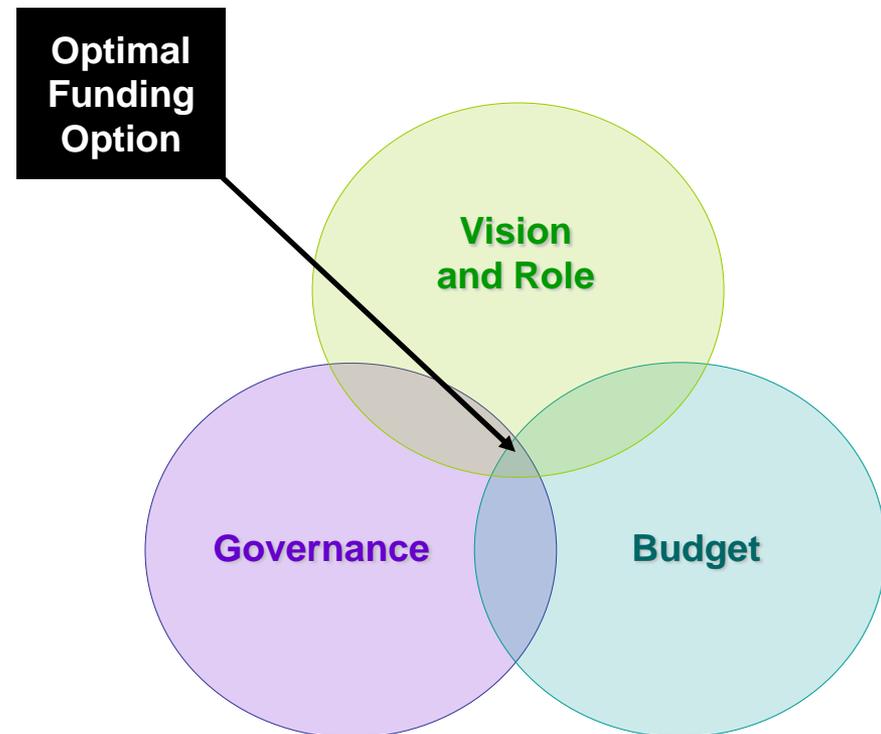
- **Congressional Appropriation**
 - NIH proposes funding levels to Congress which are directly appropriated to CC (similar to IC appropriation process), enacting funding level into law
 - Amount will be requested as part of the appropriations process and visible in DHHS/OMB/Congressional submissions
 - Amount budgeted developed by the NIH Director with input from the governing board
 - Amount will initially be subtracted from other appropriate mechanisms where these costs are currently budgeted, presumably IRP (through a one time adjustment)
 - Congress, in taking action on the budget proposal, ultimately sets funding level
 - Once funds are appropriated, they are allocated directly to CC (no transfer through Central Services)

CC Budget: Potential Funding Models

- **Congressional Appropriation** *(cont.)*
 - Funding for fixed costs allocated to CC is drawn from entire NIH budget and not as a portion of IRP budget
 - Should additional funds be required during budget year that exceed amount appropriated, a budget transfer request may be submitted – requires statutory budget transfer authority
 - Variable cost assessments to each IC can be introduced based upon total usage (similar to a fee-for-service mechanism) and would be budgeted in each Institute's IRP line, with Congressional approval (because depending on the language that Congress uses for the appropriation, adding more funds for variable cost assessments might be an improper augmentation/supplementation)

Overcoming CC Challenges: Attributes of Optimal Funding Option

- **Positions CC as a national resource**
- **Prioritizes clinical research at NIH**
- **Streamlines governance**
- **Ensures fiscal sustainability - stable, responsive budget**
- **Enhances programmatic planning**



Preliminary Preferences

- **A majority of the working group prefer a line item in either an IC Mechanism Table or in the Office of the Director Appropriation**
 - **Facilitates use of CC by external community**
 - **Higher visibility of CC signals availability of resources to external community and indicates clinical research as a high NIH priority**
 - **CC funds come from overall NIH budget (larger pool of resources), which will enhance stability**
 - **May facilitate NIH-wide strategic focus on clinical research**

Next Steps

- **Continue analysis of each option in terms of how they compare to the optimal option**
- **Vision and Role – Further explore potential uses of CC by external community, including consultation with potential collaborators**
- **Governance – Continue development and refinement of optimal governance models and consult with NIH Director and leadership**
- **Budget – Continue ongoing internal, in-depth analysis of each funding option and consult with NIH Director and leadership**
- **Consult with the public and stakeholders**
- **Re-examine the IOM recommendations concerning clinical research across the NIH**

Anticipated Timetable

- **April: Draft recommendations proposed to full Board via public teleconference**
- **May 17-19: Stakeholder meetings held during full Board meeting in Bethesda**
- **May-June: Integrate feedback from stakeholder meetings into recommendations**
- **June-July: Full Board teleconference vote via public teleconference**