



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*

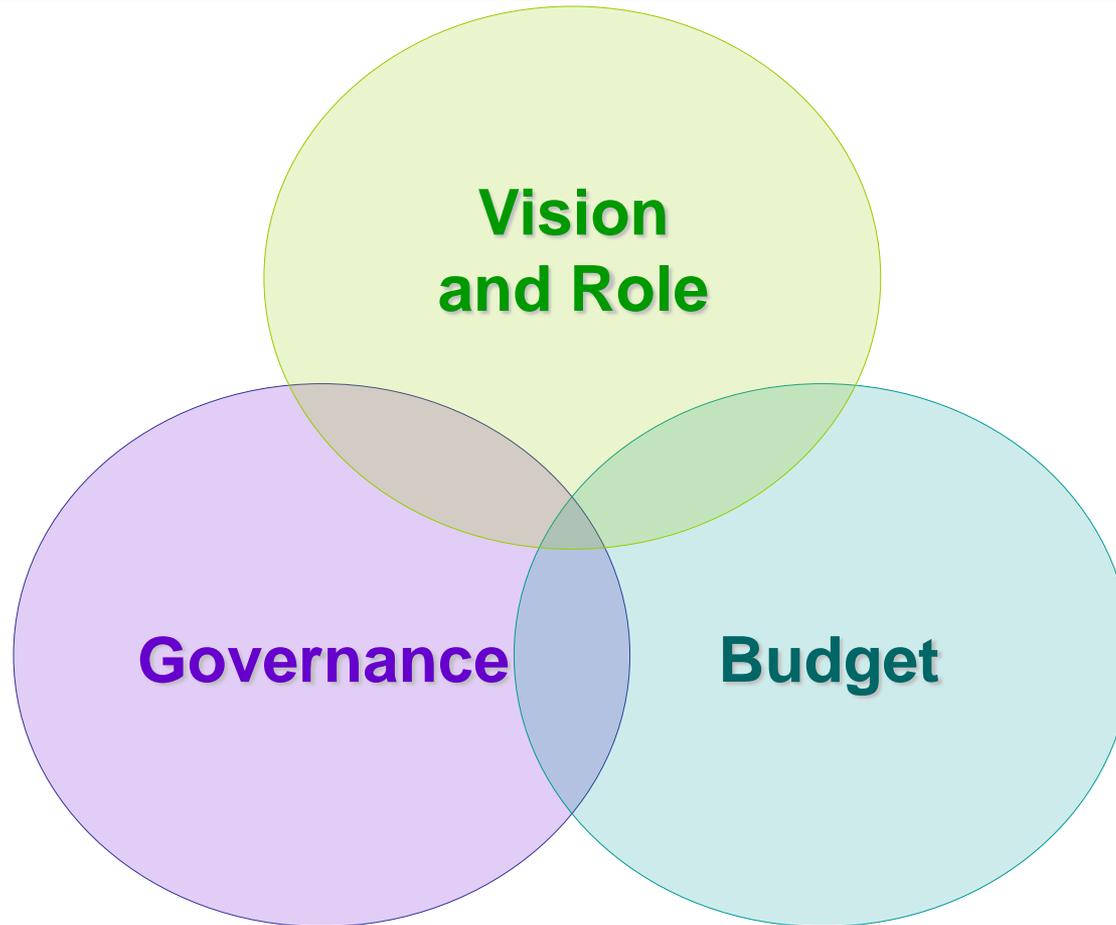
Briefings to Date *(cont.)*

- **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

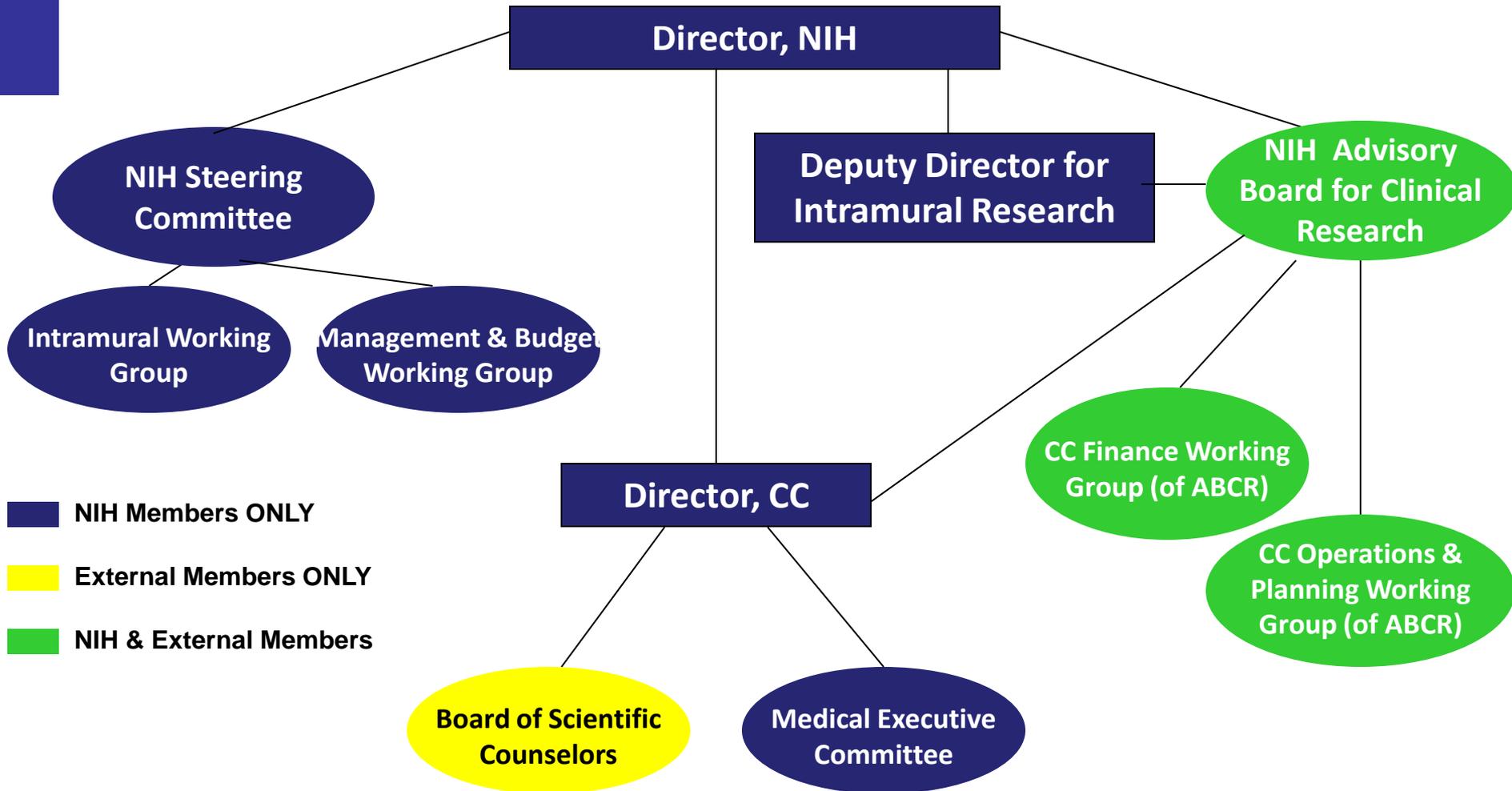
Meeting CC Challenges



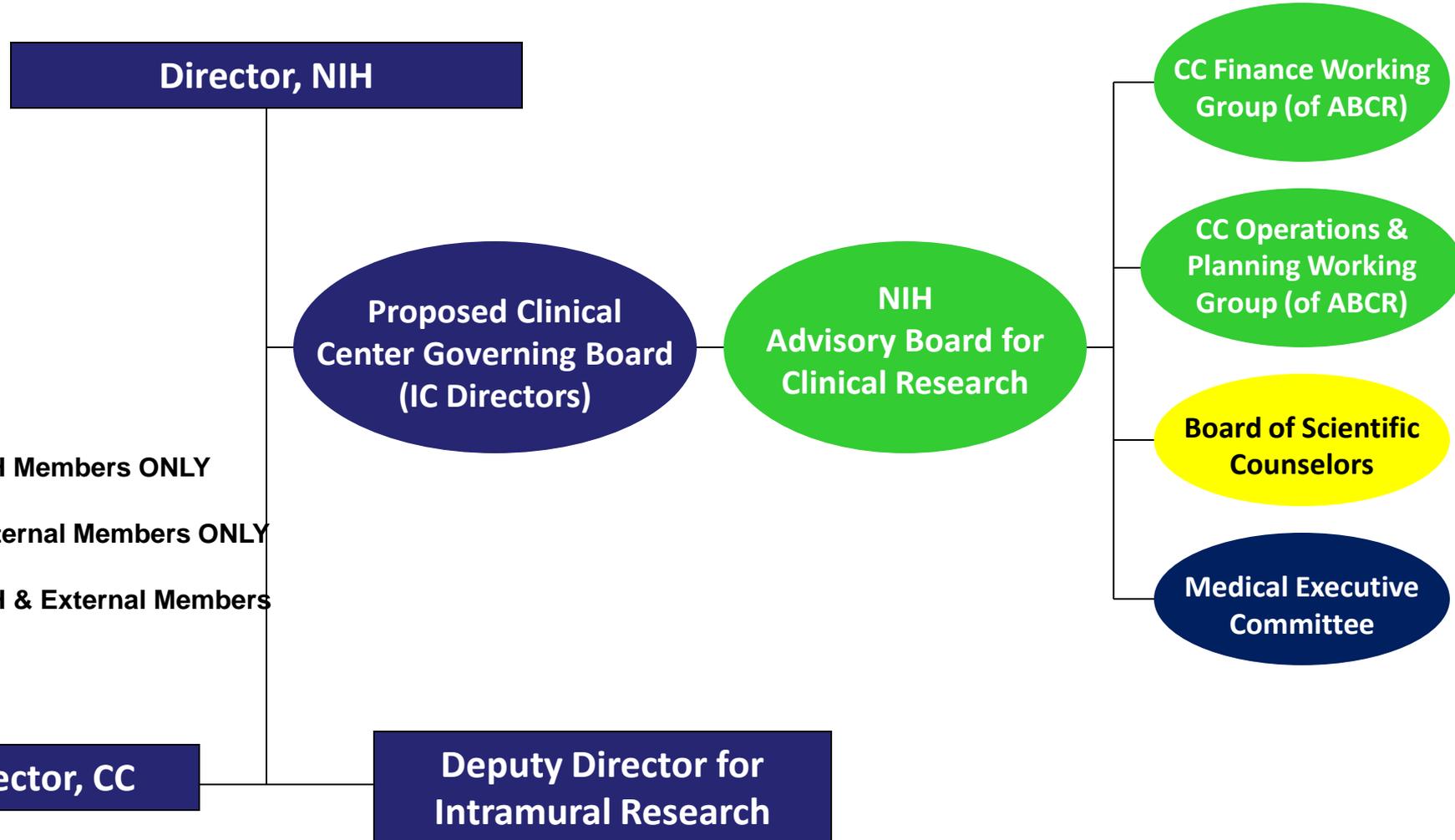
STREAMLINED GOVERNANCE STRUCTURE

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

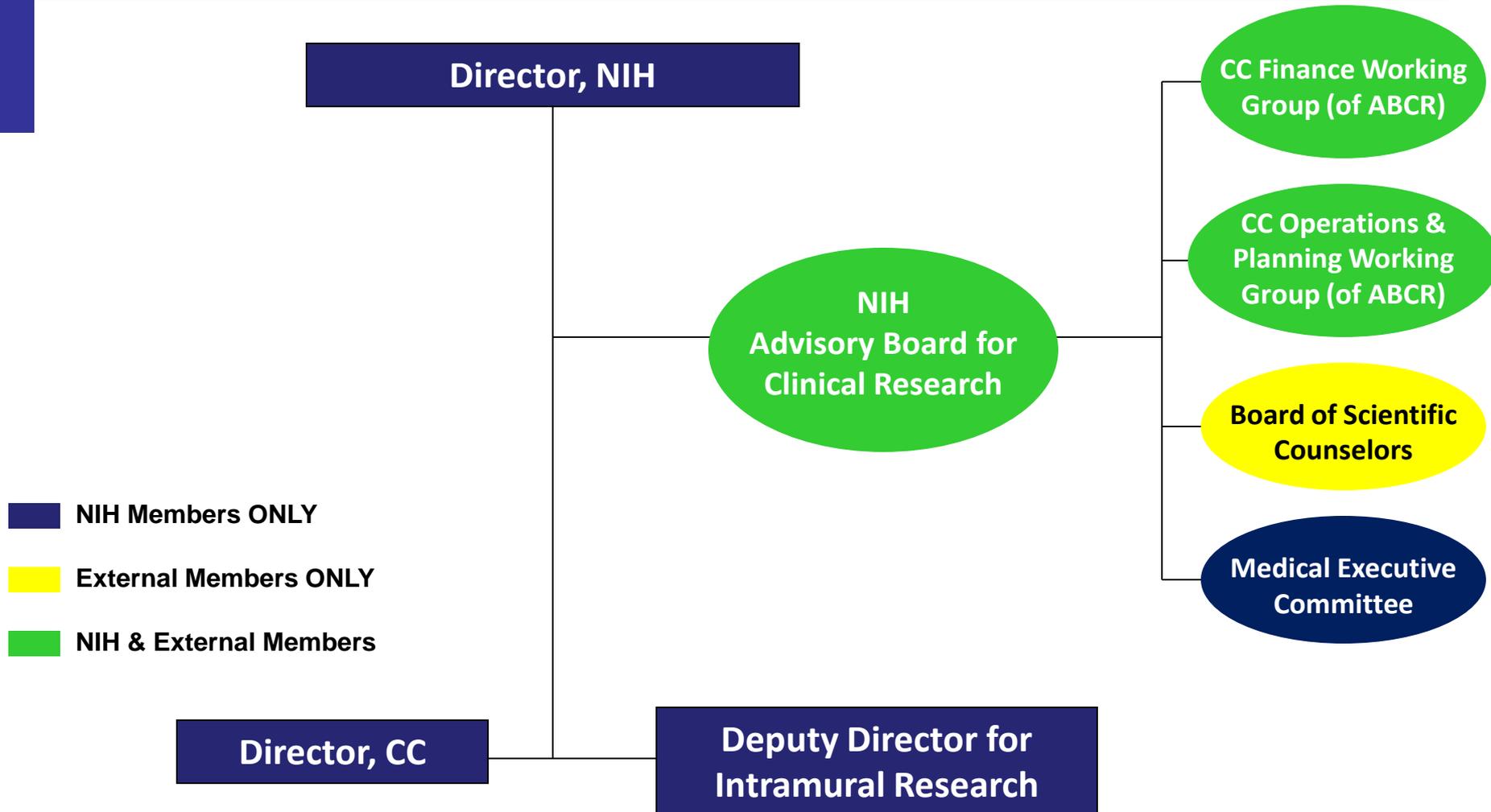
Current CC Governance Structure



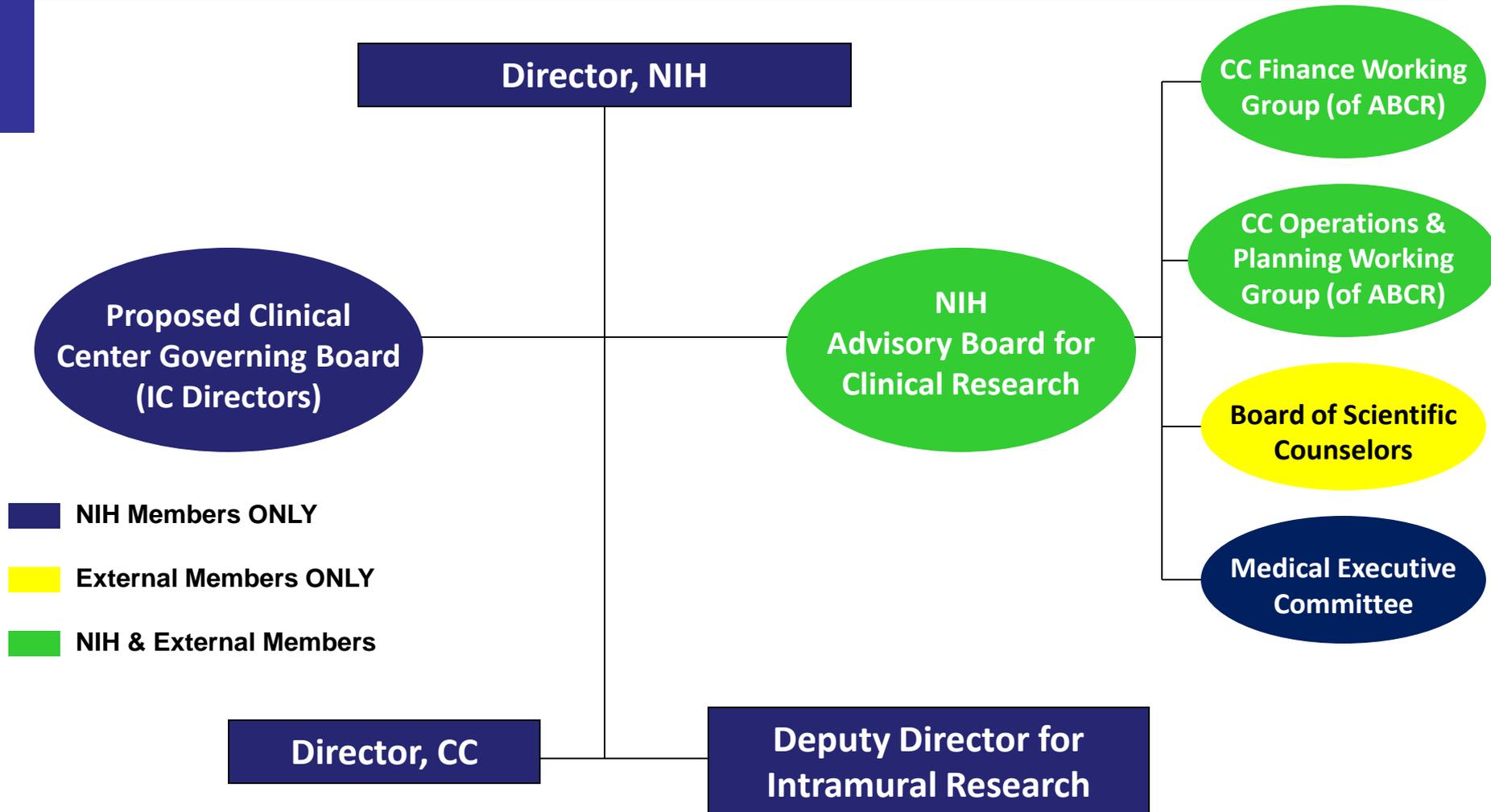
Potential New Governance Structure: Option 1



Potential New Governance Structure: Option 2



Potential New Governance Structure: Option 3



Meeting CC Challenges



Budget

STABLE RESPONSIVE BUDGET

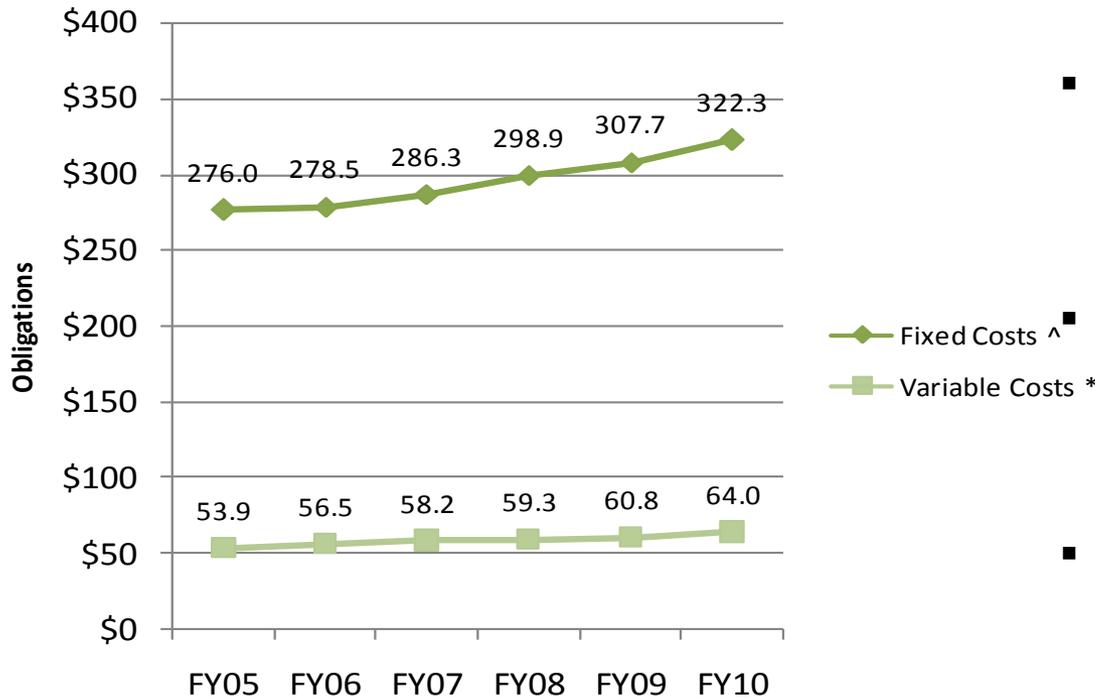
UNDERPINNED BY PRIORITY SETTING

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)

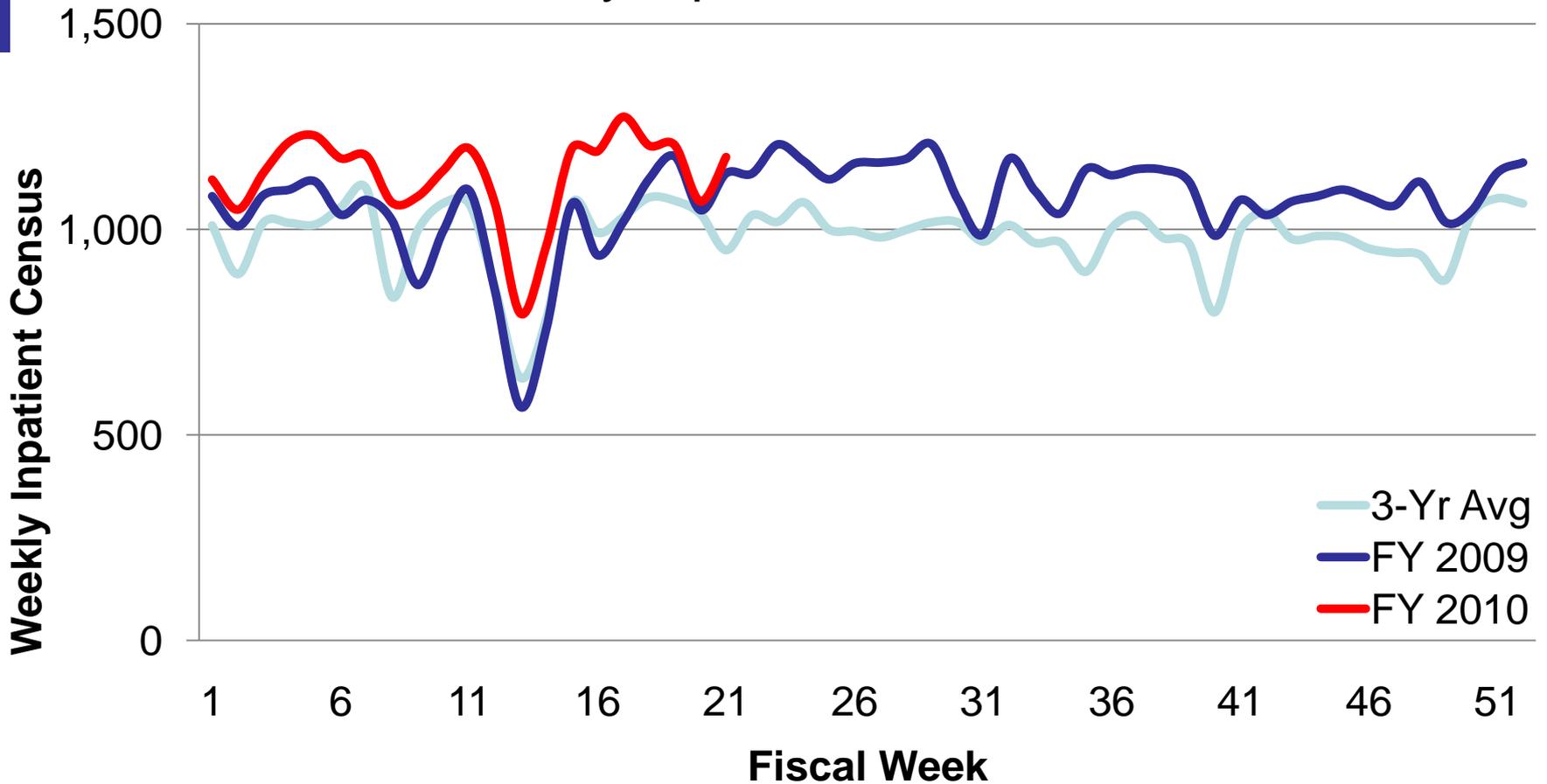


Fixed vs. Variable Costs

- 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 5 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

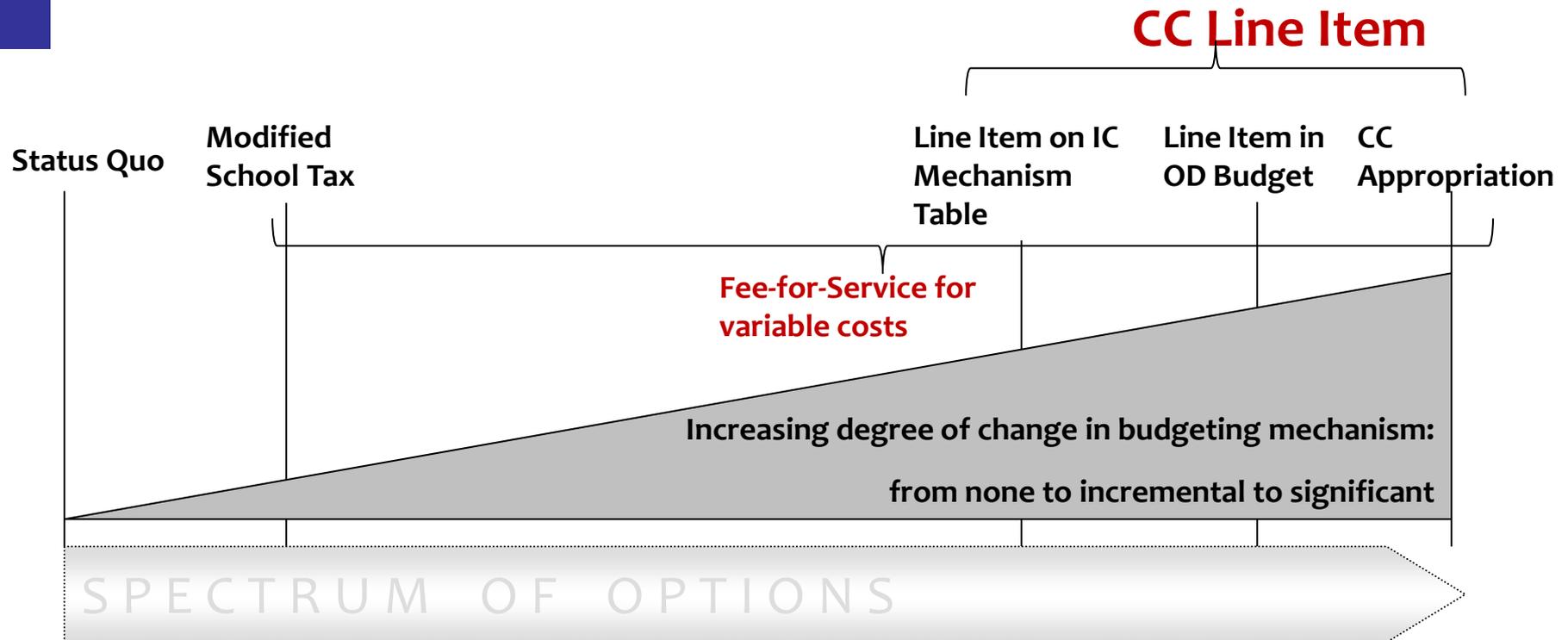
YTD FY 2010* Occupancy by Inpatient Unit

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
CC Budget Decision-making Passes from NIH to DHHS/OMB/Congress 				
CC Competes for Funding from within Larger Pool of Resources 				



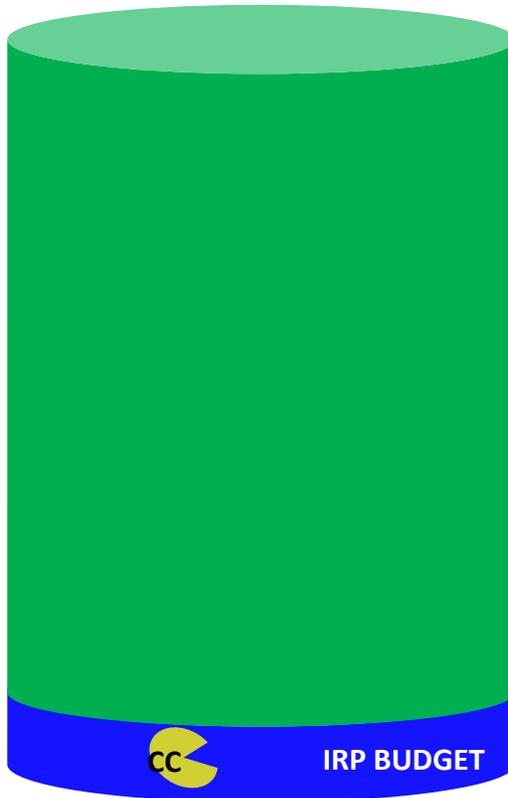
Potential Funding Models: A Spectrum of Options – Specific Impact

IRP

	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.)*

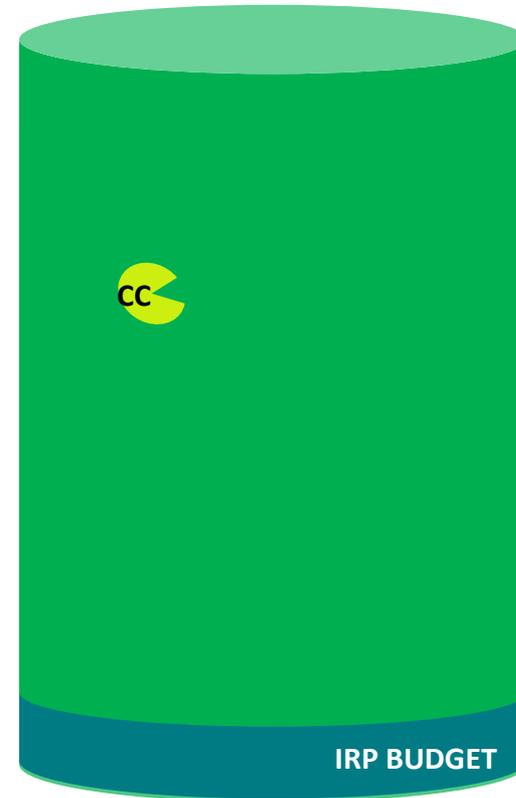
TOTAL NIH BUDGET
(~\$31 billion)



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)

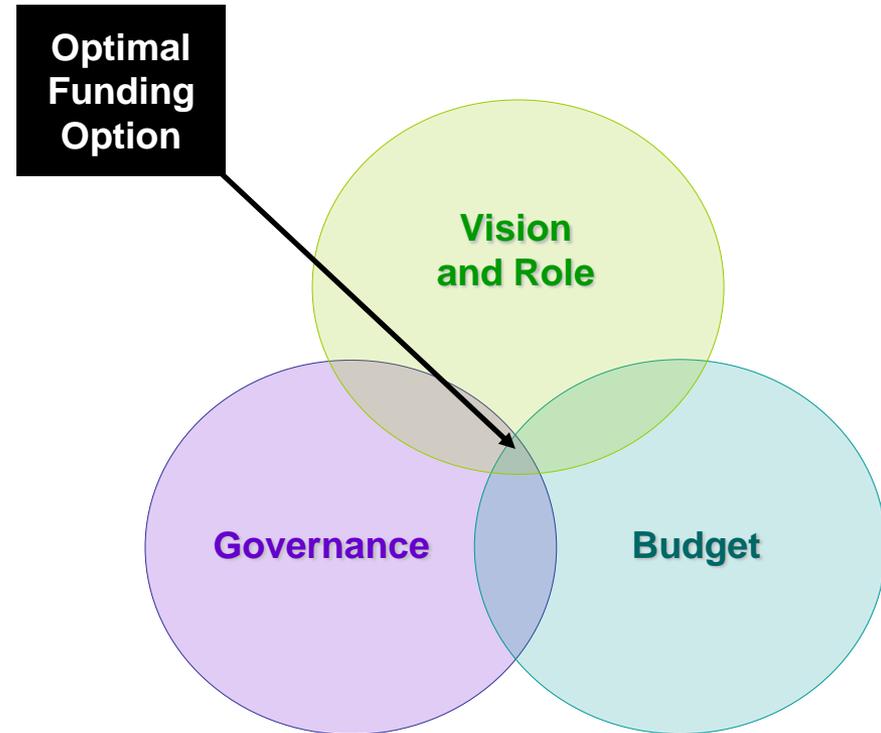
CC Budget: Potential Funding Models



- **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**