



NIH Scientific Management Review Board



NIH Intramural Research Program Working Group

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Overview

- **Membership**
- **Historical Context**
- **Working Group Charge**
- **Briefings (Past and Future)**
- **Summary of Findings to Date**
- **Future Activities**

Membership

Non-Federal

Arthur Rubenstein, MBBCh
(Chair)

Gail Cassell, PhD

Solomon Snyder, PhD

Norman Augustine
(ad hoc)

Federal

Anthony Fauci, MD

Stephen Katz, MD, PhD

Elizabeth Nabel, MD

Francis Collins, MD, PhD
(ex officio)



NIH Intramural Research Program: A Strong Foundation

- **Since its inception, the NIH has supported an intramural research program (IRP) with a unique set of characteristics**
 - **Size**
 - **Retrospective model of scientific review**
 - **A relatively stable budget (until recently)**
- **To date, the IRP at NIH has demonstrated numerous accomplishments, including:**
 - **Transformative advances in biomedical research**
 - **Training the leaders of our nation's academic health centers**
 - **Serving as a trusted source of medical information**
 - **Facilitating numerous collaborative interactions**

Charge

The NIH Intramural Research Working Group of the SMRB is convened to recommend whether any change in the organization and/or management of NIH intramural research could further optimize the opportunities available in a central research program at NIH and maximize human health and/or patient well being.

Charge *(cont...)*

Given that recent internal assessments have pointed towards the urgency of addressing the fiscal vitality of the NIH Clinical Center, the Working Group will carry out the following tasks in order:

- **Analysis of and recommendations regarding the fiscal sustainability and utilization of the NIH Clinical Center**
- **Analysis of and recommendations regarding the optimal organization of the overall NIH intramural research program**

Re-examining the NIH Clinical Center

- **Historically, the NIH Clinical Center (CC) has provided a versatile clinical research environment enabling the NIH mission to improve human health**



Briefings to Date

- **Concerns and Current Status of the NIH Clinical Center** - overview on current fiscal challenges and options for future sustainability
- **The NIH Clinical Center: Mission, Function, Capabilities, and Vision for the Future** - perspectives from distinguished NIH investigators and advisers
- **Business Models for Hospital Management** - perspectives from research hospital administrators
- **Collaborations between Extramural and Intramural Communities**
 - limitations and possibilities
 - existing collaborations

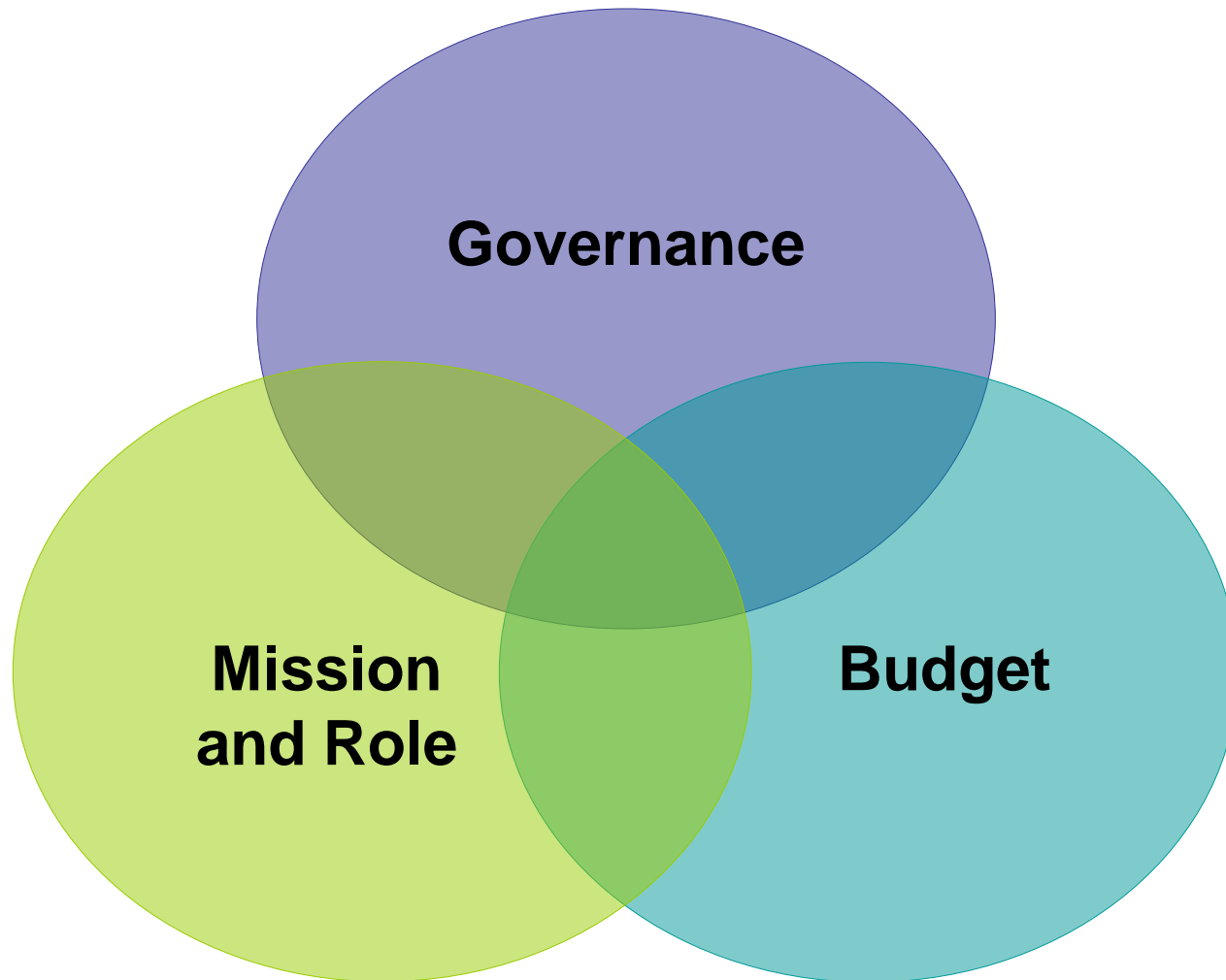
Summary to Date: Benefits

- **Research Flexibility**
 - **Investigators free to devote full attention on research**
 - **Permits nimble responses to emergent scientific opportunities and public health needs**
 - **Patient care is fully funded**
 - **Staff has immediate access to cutting-edge technologies**
 - **Provides opportunities to conduct high-risk trials for life threatening diseases**
 - **Permits failure**

Summary to Date: Benefits *(cont...)*

- **Houses a critical mass of highly skilled individuals**
- **Plays a critical role in first-in-human studies and rare disease research**
- **Supports longitudinal studies**
- **Serves as a laboratory to study human biology and pathology**
- **Fosters distinctive training opportunities**
- **Provides a visible window to NIH for the public and policy makers**

Summary to Date: Challenges

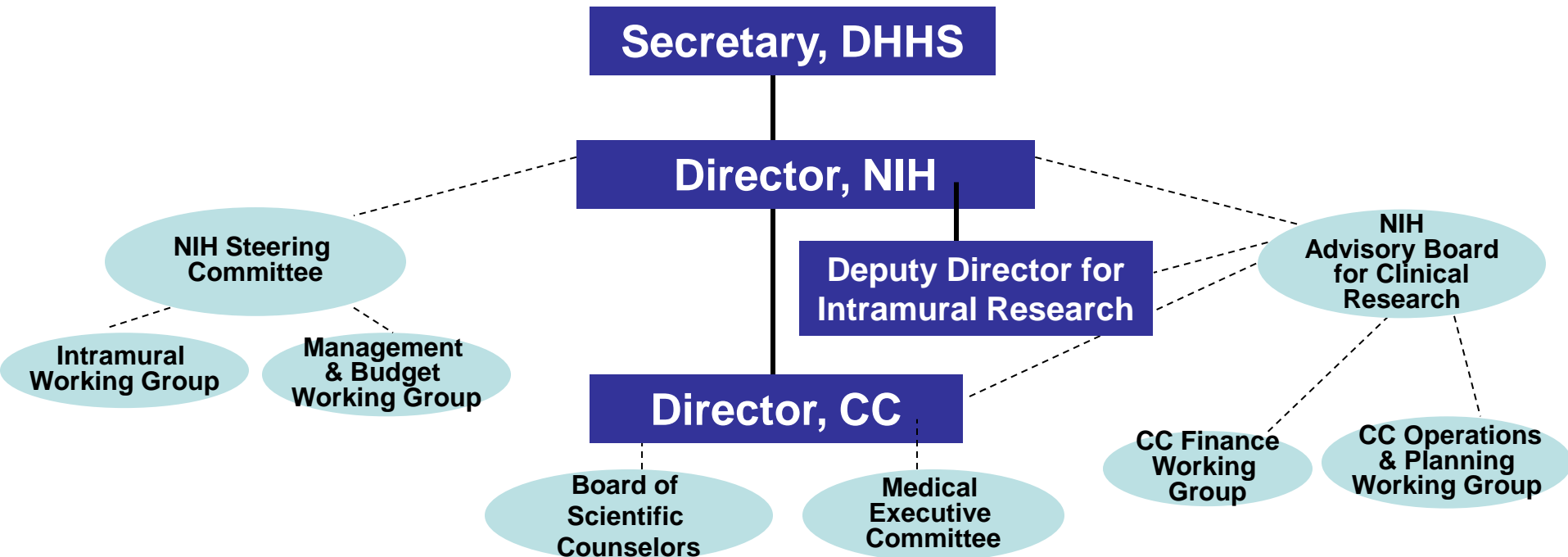


Challenges: MISSION

- **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**

Challenges: GOVERNANCE

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



Challenges: BUDGET

- **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**

Emerging Findings

- ***Clinical Center as a National Resource.*** CC should be a state-of-the-art national resource; resources should be optimally managed to enable both internal and external investigators to use the CC
- ***Streamlined Governance Structure.*** A clear, coherent plan for clinical research at the Clinical Center and a simplified governance structure are needed to oversee appropriate use and adequate funding
- ***Stable, Responsive Budget Underpinned by Priority Setting Process.*** Budget should be linked to a strong planning process and be stable, equitable (in source and distribution), effective in attracting and supporting a high quality workforce, and should assure efficient use of the CC

Current Activities: Examining Potential Funding Models



- **Identifying attributes of potential models:**
 - Source of funds and locus of control
 - Legal and regulatory considerations
- **Evaluating potential for models to provide:**
 - Stability and continuity of funding
 - Responsiveness to trends in science and health
 - Incentives for IC collaboration
 - Ability to position the CC as a national resource, both internally and externally
 - Resiliency in the face of economic constraints

Future Activities

- **Additional briefings**
- **Evaluate potential strategies for enhancing the role of the Clinical Center as a national resource, including various models for governance and funding**
- **Brief the Advisory Board for Clinical Research**
- **Host public forum with relevant stakeholders**

DISCUSSION
