

The NIH Hatfield Clinical Research Center: Current and Future Challenges

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Mission of the NIH Clinical Research Center

As the nation's clinical research center, the NIH Clinical Center is dedicated to improving human health by providing an outstanding environment that facilitates:



- Development of diagnostic and therapeutic interventions
- Training of clinical researchers
- Development of processes that ensure conduct of clinical research that is safe, efficient, and ethical

Key Dates in the Hatfield Clinical Research Center History

- **November 4, 1997:** Groundbreaking for the Hatfield Clinical Research Center (\$504.5M cost)
- **September 22, 2004:** Dedication ceremony
The “house of hope.”
Former patient Susan Butler
- **April 3, 2005:** First new patient admitted; building fully operational

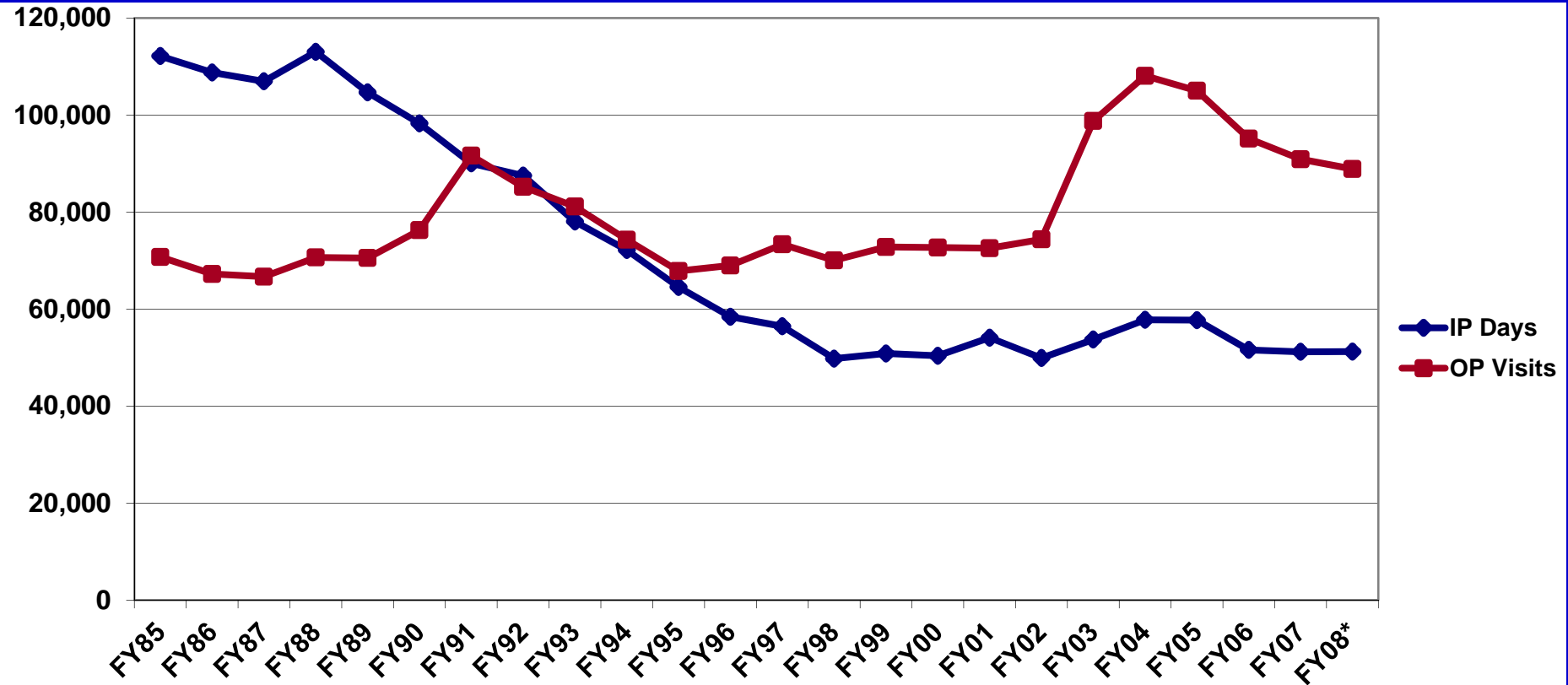


Recurring Theme

Our issues are not new

Patient census levels and equity in funding among ICs are recurring issues facing the NIH Director, with no single solution acceptable to all ICs.

CC Inpatient and Outpatient Utilization



- Following school-tax implementation, utilization generally increased through FY2004
- Since that time, utilization has held steady or declined
 - Overall IC census down 14% in past 3 years
 - Bed utilization at ~2/3 of capacity

Reviews

“At least 3 previous advisory committees have made recommendations for improving the IRP/CRC — some of which have been implemented but many of which have been ignored.”

Excerpt from Nov. 17, 1994 report

Reviews

- **Nov. 17, 1994:** “Report of the External Advisory Committee of the Director’s Advisory Committee”
 - Gail H. Cassell and Paul A. Marks, co-chair
 - Renewal of the Clinical Center by additional funds allocated by Congress

- **March 31, 1997:** “Report of the NIH Committee on the Recruitment and Career Development of Clinical Investigators”submitted by Stephen E. Straus

Issues:

- Recruiting and retaining clinical investigators
- Progressive fall in bed occupancy at the CC
- Recommendation to provide a fixed allocation to the CC or taxing all Institutes in proportion to the size of the IRP
- Alter tenure process for clinical investigators
- Establish staff physician status

Reviews (cont'd)

- **January 2004: “NIH Director’s Blue Ribbon Panel on the Future of Intramural Clinical Research”**
 - Edward J. Benz, chair and Joseph L. Goldstein, co-chair
 - CRC represents a major national investment in clinical research
 - NIH must define a specific vision for the CRC
 - Develop a distinctive research portfolio that complements that of the extramural community
 - Develop novel programs to attract clinical investigators to Bethesda
 - Need for streamlined and comprehensive governance of the ICRP
 - Strengthen the role of the Office of the Director and IC leadership in clinical research

IC Directors' Mini Retreat

July 12, 2007; Drs. Katz and Niederhuber, Co-Chairs

Programmatic Review-How can we enhance the research programs at the NIH CRC and increase usage?

- **Trans-NIH initiative: Inflammation, Immunology and Autoimmunity**
 - Completed commitment for space and \$2.8M per year to launch center-NCI, NIAID, NHLBI, NIAMS, NINDS, NIDDK, NICHD
 - Planning retreat June 23, 2008
- **Facilitate interesting cases or patients with rare/difficult problems to be seen at the CRC**
 - Dr. Bill Gahl leads this trans-NIH program, many clinician-scientists committed

IC Directors' Mini Retreat

July 12, 2007 (cont'd)

Programmatic Review

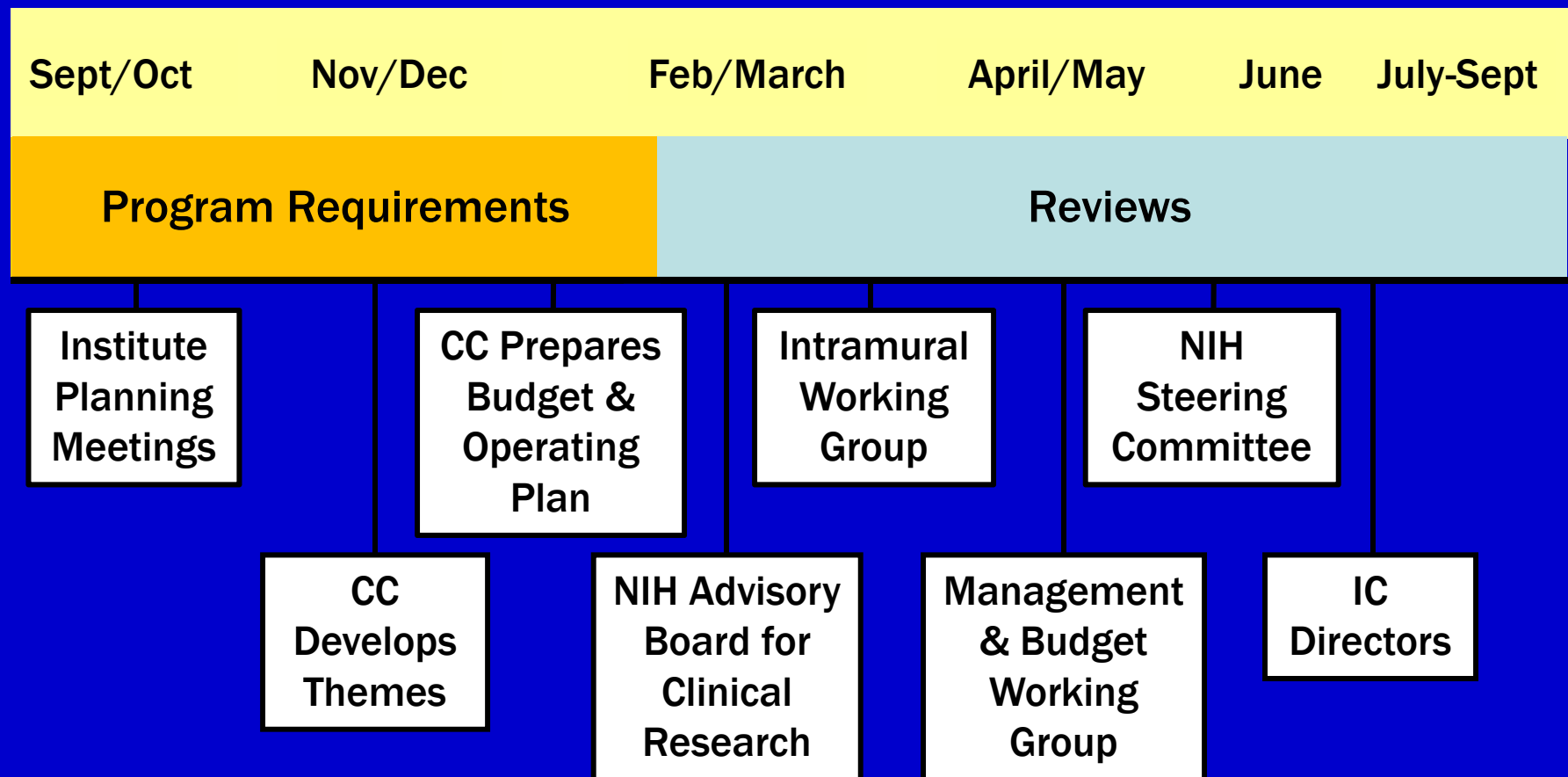
- Identify “Manhattan-like” projects
 - Identifying ICs to commit funds to a Bone Marrow Stromal Cell Transplantation Center – NCI, NINDS, NIDCR, NIAMS—need others
 - Dr. Cliff Lane is working on identifying the barriers to accelerating clinical protocol activation (report due June 2009)
- Emphasize recruitment and retention of Clinical Investigators
 - New intramural professional designation for Assistant Clinical Investigators

Clinical Center Financing

Historical Finance Models

Year Implemented	Assessment Method	Concerns Over Time
1953	Bed allocation	<ul style="list-style-type: none">• Inequities in charge vs. use<ul style="list-style-type: none">–ACRF opens in 1981
1986	Quarterly usage	<ul style="list-style-type: none">• Wide fluctuations in usage• Mid-year taps• Inability to plan
1991	Annual usage (4 prior quarters)	<ul style="list-style-type: none">• Predictability• Stability• Fairness
1993	Annual usage (fixed and variable costs)	<ul style="list-style-type: none">• Declining utilization• Unwieldy formula• No cost accounting
2000	School tax	<ul style="list-style-type: none">• De-link cost from usage• Encourage utilization• More predictable cost• Based on IRP budget

Clinical Center Planning & Budget Review Process



**Dec. 2007, Dr. Zerhouni charged
the MBWG to address how best to
finance the CRC**

- Recommend how best to allocate the costs of the Clinical Center, given its current role.
- More fundamental review is necessary to review the role of the Clinical Center and how best to increase its vitality.

Committee Membership

- Dr. Stephen I. Katz, Chair, Director, NIAMS
- Ms. Colleen Barros, Deputy Director for Management, NIH (MBWG co-chair)
- Mr. John Bartrum, Associate Director for Budget, NIH
- Dr. James Battey, Director, NIDCD
- Dr. Michael Gottesman, Deputy Director for Intramural Research, NIH (IWG co-chair)
- Dr. Lee Helman, Scientific Director for Clinical Research, NCI
- Dr. Story Landis, Director, NINDS
- Dr. John J. McGowan, Director, Office of Management and Operations, NIAID
- Dr. Elizabeth Nabel, Director, NHLBI (MBWG co-chair)
- Dr. Paul Sieving, Director, NEI (IWG co-chair)
- Ex-Officio
- Dr. John I. Gallin, Director, Clinical Center
- Staff Support
- Ms. Anita Linde, Director, Office of Science Policy and Planning, NIAMS
- Mr. Jack Mahoney, Contractor

Clinical Center Costs – CC Assessed Costs vs. IRP Budget

	NIH IRP		Clinical Center		CC as % of IRP
	Amount	% Increase	Amount	% Increase	
FY 2001	1,915,249	N/A	268,299	N/A	14.0%
FY 2002	2,116,228	10.5%	296,163	10.4%	14.0%
FY 2003	2,368,090	11.9%	324,364	9.5%	13.7%
FY 2004	2,580,101	9.0%	331,406	2.2%	12.8%
FY 2005	2,722,735	5.5%	330,865	-0.2%	12.2%
FY 2006	2,744,279	0.8%	335,908	1.5%	12.2%
FY 2007	2,699,867	-1.6%	344,832	2.7%	12.8%
FY 2008	2,719,674	0.7%	351,932	2.1%	12.9%

- Amount assessed as percentage of IRP budget declined from FY 2001-2005.
- Percentage has increased since that time as IRP budget became more constrained.

Clinical Center Costs – CC Assessed Costs Plus Cost-Shifts vs. IRP Budget

	NIH IRP		Clinical Center		CC as % of IRP
	Amount	% Increase	Amount	% Increase	
FY 2001	1,915,249	N/A	268,299	N/A	14.0%
FY 2002	2,116,228	10.5%	296,163	10.4%	14.0%
FY 2003	2,368,090	11.9%	324,364	9.5%	13.7%
FY 2004	2,580,101	9.0%	331,406	2.2%	12.8%
FY 2005	2,722,735	5.5%	330,865	-0.2%	12.2%
FY 2006	2,744,279	0.8%	338,308	2.2%	12.3%
FY 2007	2,699,867	-1.6%	350,132	3.5%	13.0%
FY 2008	2,719,674	0.7%	*366,532	*4.7%	* 13.5%

- Since FY 2006, costs identified where it is more appropriate to charge IC's directly (non-clinical blood products, research nurses, etc.).
- When these costs are included, trend is same but higher proportion of IRP budget.

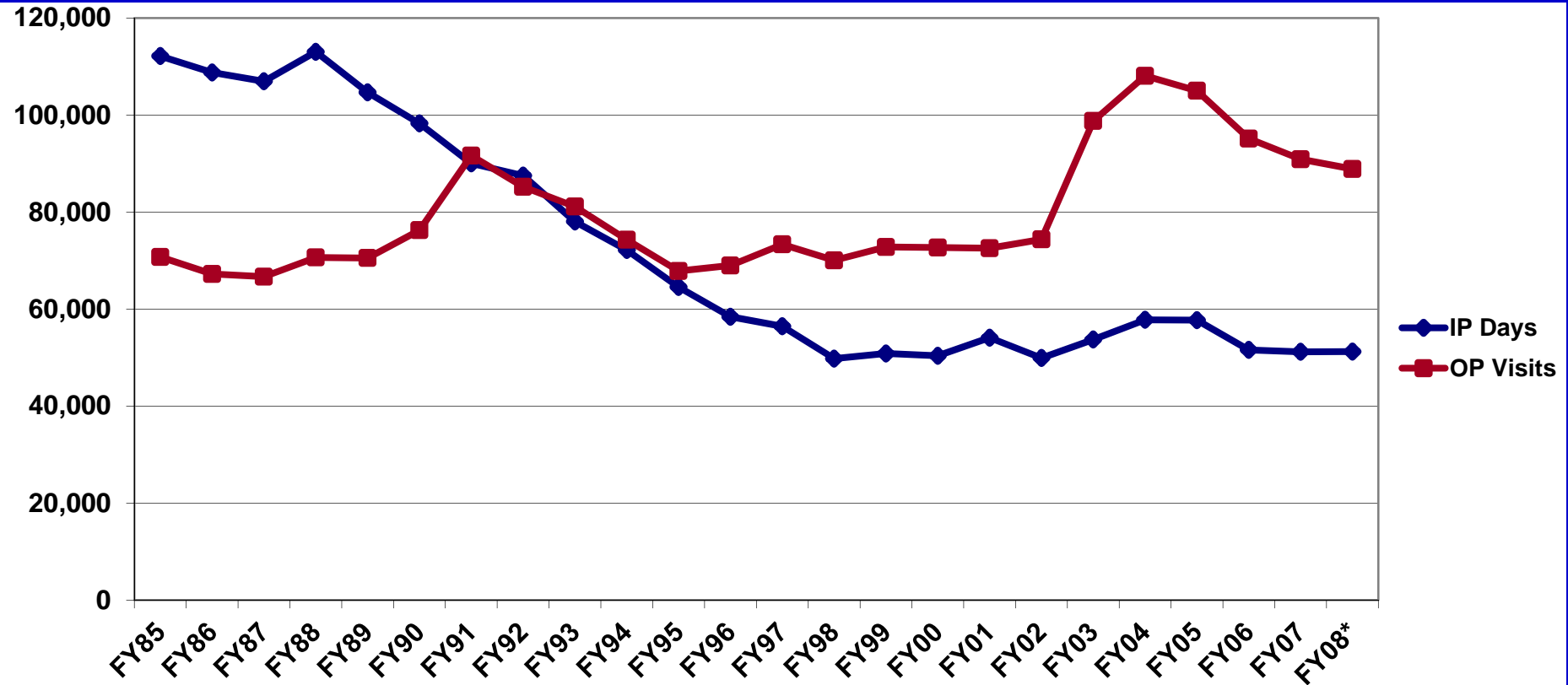
* In reality, these costs will not be realized

Clinical Center Costs – Long Range Implications

	IRP @ 0%/yr.	CC @ 3.5%/yr.	CC as % of IRP		CC @ 6.0%/yr.	CC as % of IRP
FY 2009	2,719,674	379,361	13.9%		388,524	14.3%
FY 2010	2,719,674	392,638	14.4%		411,835	15.1%
FY 2011	2,719,674	406,381	14.9%		436,545	16.1%
FY 2012	2,719,674	420,604	15.5%		462,738	17.0%
FY 2013	2,719,674	435,325	16.0%		490,502	18.0%

- Assumptions
 - No increase to IRP budget (same as FY 2006-2008).
 - Increase CC at 3.5%/year (same as FY 2006-2008); or 6% (closer to hospital rate of inflation).
- By FY 2013, costs as percentage of IRP increase to 16% and 18% respectively.
- In the absence of fundamental change, costs will quickly outpace resources available to finance it – costs will continue to increase even if utilization is stable or declines.

CC Inpatient and Outpatient Utilization



- Following school-tax implementation, utilization generally increased through FY2004
- Since that time, utilization has held steady or declined
 - Overall IC census down 14% in past 3 years
 - Bed utilization at ~2/3 of capacity

Financing Options

- Option 1 – Continue School Tax
- Option 2
 - CC Appropriation
 - Appropriation language authorizing CC funding from the total amounts appropriated for NIH
- Option 3 – Hybrid Model in which some costs are assessed by utilization and others assessed by formula such as school tax.
- In identifying options, the Committee:
 - Did not consider third party payments since approach was rejected by previous studies.
 - Encouraged pursuit of supplemental funding through philanthropy, royalties, etc., but potential amounts are small.

March 2008 Financing Committee Recommendations

- **Committee recommends:**
 - Continuation of school tax for short-term
 - For the longer term, **undertake fundamental review** of the mission of, and opportunities for, the NIH Clinical Center
 - **Should be undertaken by an outside panel with expertise both in clinical research and hospital administration, or by the soon-to-be-formed Strategic Management Review Board**
 - **Should be undertaken as quickly as possible**

Committee Recommendation (adopted by the IC Directors)

- No option was unanimous.
 - Most thought disadvantages of appropriation outweighed advantages.
 - Some favored hybrid model – however, implementation depends on cost accounting that will not be available soon.
- As a result, Committee recommends:
 - Continuation of school tax for short-term.
 - For the longer term, undertake fundamental review of the mission of, and opportunities for, the NIH Clinical Center
 - Should be undertaken by an outside panel with expertise both in clinical research and hospital administration, or by the soon-to-be-formed Strategic Management Review Board.
 - Should be undertaken as quickly as possible.

IC Directors' Budget Retreat

May, 2008

- CRC funding issue readdressed
- John N led discussion
- Other issues addressed and options proposed

CRC Funding Option: Continue School Tax

- Acceptable approach, but not working well with less-than-inflation budgets
- ICs benefit from corporate NIH image
- Not tied to IC usage
- Predictive model of assessment for ICs
- Recent history has proven the tax does not incentivize usage

Under Current Model

- **Steady movement over the past several years to “cost shift” expenses to the ICs**
 - **In theory, would maintain same level of effort, only source of funds differs**
 - **ICs have limited opportunity to budget for such unforeseen direct costs**
 - **Result is a decrease in Clinical Center utilization**

Principal Questions

- Is the CRC to remain as the singular unique asset that sets NIH apart as an exceptional Federal research enterprise?
- What is the NIH and IC commitment for a CRC within tight budget constraints?
- Is there — or should there be — a direct tie to the overall NIH budget level?

Principal Questions (cont'd)

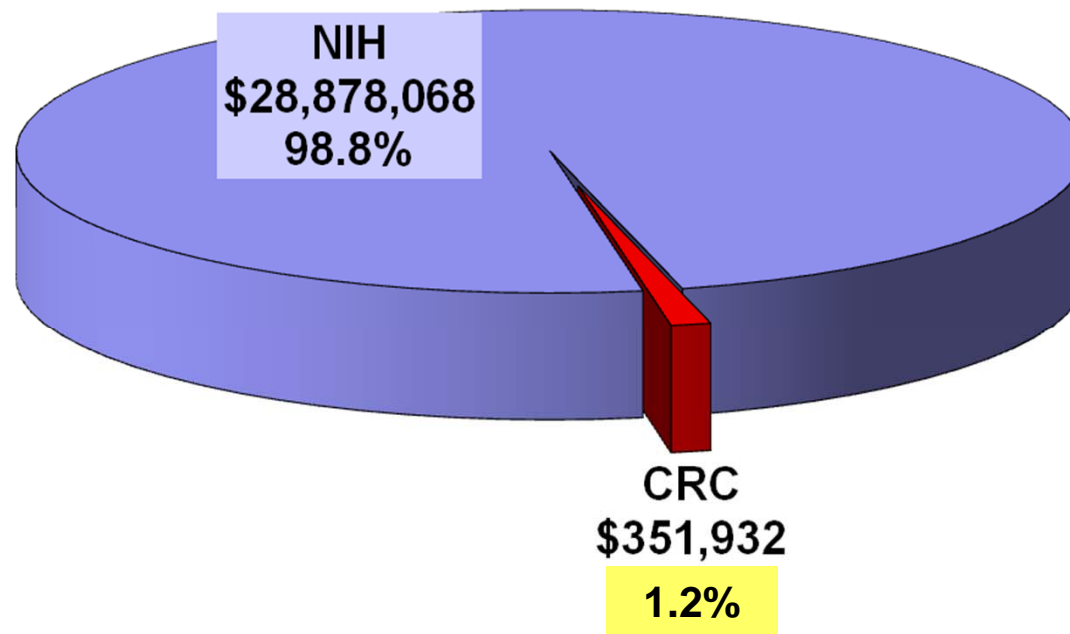
- Is it necessary to tie CRC budget growth to either IR or RMS budget lines?
- Is another Blue Ribbon Panel review useful?
 - Have the prior reviews resulted in any lasting constructive change?

If the CRC Did Not Exist...

- NIH would lack the ability to attract outstanding clinical scientists
- Study of rare diseases would be compromised at NIH (bench to bedside to bench)
- Translational research would not be done here
- The NIH would lack a unique Federal resource: the nation's largest hospital devoted entirely to clinical research
 - Most of the 1,500 trials are Phase I and Phase II

NIH FY2008 Budget

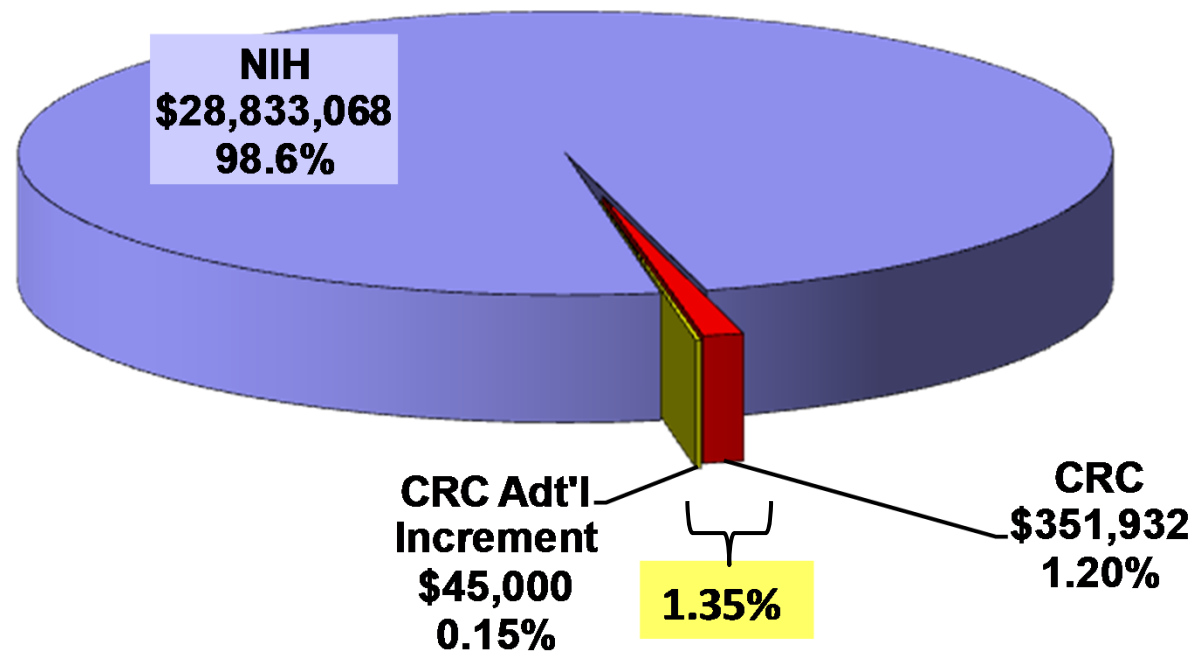
A critical need



Dollars in thousands

NIH FY2008 Budget

A critical need



Dollars in thousands

Total = \$396,932

A Consideration

- Engage a professional consultant to advise on the most appropriate:
 - Management structure
 - Tracking system to collect real-time, actual operational cost data



CRC Funding Options

- School Tax
- Congressional Appropriation
- IC Consortium of Primary Users

CRC School Tax

	Amount (in thousands)	% of total
NCI	\$ 93,422	26.6%
NHLBI	22,596	6.4%
NIDCR	7,630	2.2%
NIDDK	21,870	6.2%
NINDS	18,938	5.4%
NIAID	72,505	20.6%
NIGMS	153	0.0%
NICHD	21,242	6.0%
NEI	8,954	2.6%
NIEHS	17,705	5.0%
NIA	6,613	1.9%
NIAMS	6,763	1.9%
NIDCD	4,713	1.3%
NIMH	21,596	6.2%
NIDA	5,396	1.5%
NIAAA	6,061	1.7%
NINR	446	0.1%
NHGRI	13,008	3.7%
NIBIB	1,026	0.3%
NCRR	0	0.0%
NCCAM	988	0.3%
NCMHD	307	0.1%

Total:
\$351,932

CRC Funding Option: IC Consortium

- 6-7 ICs account for ~80% of census
 - These ICs would be financially and programmatically responsible
- Same operating base would be created by a one-time transfer of funds from other ICs using existing school tax contribution
- Add one-time infusion of funds to establish a realistic base
 - Current base is too low
 - Could come from central NIH pool

CRC Funding Option: IC Consortium (cont'd)

- NIH leadership would need to commit to adequate growth
- Contributions to the CRC budget by the 6-7 sponsoring ICs would be negotiated separately within the IC budgets
- Other IC needs could be on a fee-for-service basis thereafter
- Management/operational issues adapted based upon study group's look at mission and opportunities

Where are we now?

- Continue the school tax
- Establish the Scientific Management Review Board (SMRB), as authorized by Congress in 2007 (IC Directors and reps from outside NIH)
- First order of business of the SMRB is to undertake a fundamental review of the mission of, and opportunities for, the NIH Clinical Research Center



Patients & Families





Option 1 – Continue School Tax

- Pros:
 - Should maximize utilization since there is no relationship between cost and utilization.
 - Emphasizes that Clinical Center is an NIH-wide resource and facilitates decision making for the “good of the whole” as resource decisions are not associated with the impact on any individual IC.
 - Simple formula assures that amounts assessed are transparent.
- Cons:
 - Though difficult to establish a precise relationship, the school tax may be perceived as unfair by some ICs because there is no relationship between the amount paid and the benefits received.
 - Provides no incentive for efficiency on the part of the ICs in their use of the Clinical Center.
 - Has the potential to increase the inherent tension that exists when funding for IRP is not growing as fast as Clinical Center costs.

Option 2a – CC Appropriation

- Pros:
 - Provides increased visibility to the Clinical Center’s needs during the Appropriations process, including the need for inflationary increases at a higher level to maintain the same level of services. Also acknowledges that the nature of services provided by the CC is distinct enough that they should not compete with other central service budgets.
 - Places direct control of the Clinical Center budget with the Director, Clinical Center.
 - Provides defined budget level to which Clinical Center operations must be managed.
 - Should reduce the inherent tension that exists when Clinical Center costs rise faster than the overall funding for IRP.
 - May produce the opportunity to integrate extramural collaborations within the Clinical Center.
- Cons:
 - Reduces flexibility to increase the budget with internal resources during difficult fiscal years.
 - Offers the potential for Executive and Legislative Branch “interference” with respect to specific clinical research imperatives.
 - CC funding may not compete well against extramural research priorities within appropriations process.
 - If CC funding does compete well, it may not necessarily result in an increase to the overall sum of NIH resources.
 - Eliminates IC investment in Clinical Center and therefore could result in disengagement from the Clinical Center.

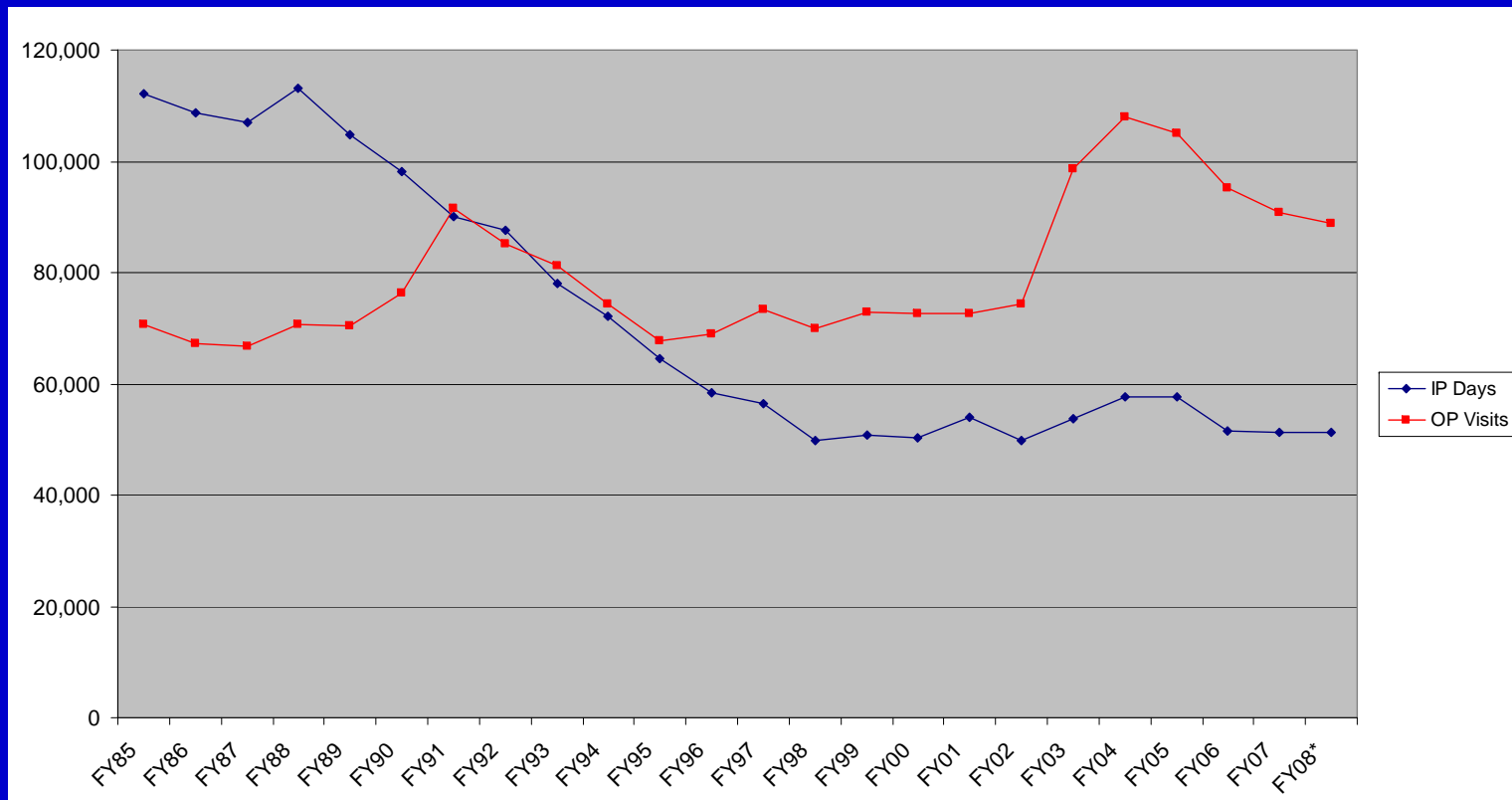
Option 2b – Authority to Fund CC from Total NIH Appropriations

- Pros:
 - Same potential pros as Options 1 and 3 but provides larger funding base for financing the Clinical Center.
- Cons:
 - Same potential Cons as Options 1 and 3 but may generate concern in extramural community that potential grant funds are used for intramural research activities.

Option 3 – Hybrid Model

- Pros:
 - Provides a better relationship between the amounts paid and the benefits received.
 - Provides some incentive for efficiency on the part of the ICs regarding use of services.
- Cons:
 - Variations of this option implemented in the past have resulted in reduced utilization.
 - Lessens, but does not totally reduce, the tension that inherently exists when funding for IRP is not growing as fast as Clinical Center costs.
 - Will require a sophisticated accounting system to precisely identify those costs assessed by utilization.

CC Inpatient and Outpatient Utilization



- Following school-tax implementation, utilization generally increased through FY 2004.
- Since that time, utilization has either held steady or declined.

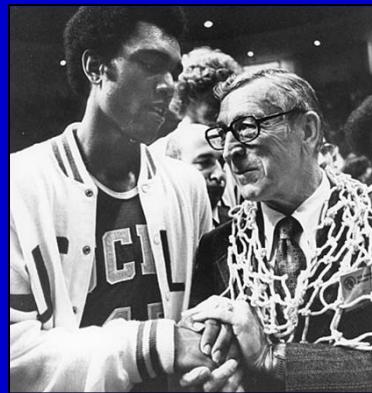
Historical Financing Methodologies

<i>Assessment Method</i>	<i>Concerns Over Time</i>	<i>Catalyst for Change</i>
1953 <i>Bed Allocation</i>	<ul style="list-style-type: none"> • <i>Inequities in charges versus use</i> -ACRF opens (1981) -Variable patient acuity 	<ul style="list-style-type: none"> • <i>NIH-wide examination of Central Services accounts (1984)</i>
1986 <i>Quarterly Usage</i>	<ul style="list-style-type: none"> • <i>Wide fluctuations in usage</i> • <i>Mid-year Institute taps</i> • <i>Inability to plan</i> 	<ul style="list-style-type: none"> • <i>NIH committee to evaluate management fund assessments (1989)</i> • <i>Easton II Retreat (1990)</i>
1991 <i>Annual Usage (four prior quarters)</i>	<ul style="list-style-type: none"> • <i>Predictability</i> • <i>Stability</i> • <i>Fairness</i> 	<ul style="list-style-type: none"> • <i>NIH committee to evaluate MF assessments (1992)</i> • <i>CC Advisory Board (1993)</i>
1993 <i>Annual Usage (fixed and variable)</i>	<ul style="list-style-type: none"> • <i>Declining utilization</i> • <i>Unwieldy formula</i> • <i>No cost accounting</i> 	<ul style="list-style-type: none"> • <i>Scientific Director discussions(1994)</i> • <i>Options Team (1995)</i> • <i>CC Board of Governors</i>

- In FY 2000, “school tax” assessment instituted – initially suggested by CC Board of Governors.
- ICs funding assessment based on their proportional share of NIH intramural budget.
- De-linking assessment from utilization intended to provide more predictable assessment and promote increased utilization.

“If you don’t have time
to do it right, when
will you have time to
do it over?”

Legendary UCLA basketball
coach John Wooden



CRC Funding Option: Congressional Appropriation

- Funds managed by CRC Director
 - Flexibility could be limited
- NIH sets level of funding at all relevant opportunities in budget process
 - Public statement of resources
 - Control of COLA and growth
- Unlikely to be new money
- Could result in favorable treatment
- Increased visibility