

# **NIH Clinical Center: Where Have We Been & Where Are We Headed**

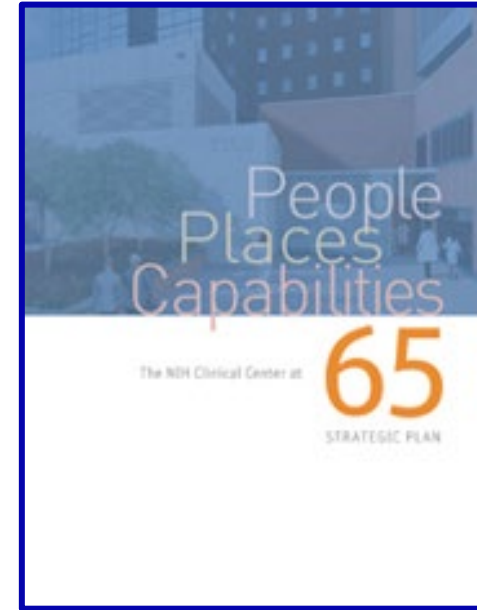
Dr. Gilman, CC CEO

7 October 2024

IRBO Retreat

# Timeline

- **2015** – FDA inspects the CC Pharmacy
- **2016** – Red Team Report
- **January, 2017** – CEO arrives
- **2017-2018** – efforts focused on response to Red Team Report
- **2019** – Strategic Plan – “People, Places, & Capabilities” published
- **2019** – present – execution of Strategic Plan



# Corporate Rhetoric

- **Mission** – “We provide **hope** through **pioneering clinical research** to improve human health.”
- **Guiding Principles**
  1. Passion for high reliability in the clinical research environment
  2. Diversity and inclusion of people and ideas
  3. Compassion – patients, families, staff
  4. Innovation in solving **AND** preventing problems
  5. Accountability for resources
  6. Excellence in scientific discovery and application
  7. Commitment to professional growth and development

# Four Strategic Aims

- Continuing to lead the world in conducting safe first-in-human clinical research in rare and refractory diseases.
- Increasing the use of the CC by the NIH intramural research program.
- Demonstrating profound respect for our patients, our full partners in the clinical research enterprise.
- Partnering with IC's to recruit, develop, and retain the next generation of NIH clinical researchers and the CC staff that will support their efforts.

# People, Places, & Capabilities

- Personalized, inclusive healthcare leadership

1. Taking care of those on the front lines
2. Accurate position descriptions
3. Accurate time cards the first time
4. It's the *staff member's* annual leave (not the supervisor's)
5. Individual development plans
6. Support for more leadership training
7. Banished the terms “ancillary and support staff”

# People, Places, & Capabilities

## • Recognition

- Length of Service Recognition?
- Annual CEO Awards Program (~700 honorees in 2021)
- Staff Clinician, APP (NPs & PAs), Administrator of the Year Program – began in 2018, with 16 awardees to-date
- CCND Awards
- Quarterly patient safety “Superstars”
- Staff Clinicians as *Voting Members* on Search Committees
- Staff Clinicians selected to be Chief of Radiology, Lab Medicine, and Chief Medical Officer

## • Communication

- Quarterly townhall meetings – 3 shifts until pandemic hit
- “3 Main Things” emails – weekly pre-pandemic, as needed (more frequently) during the pandemic
- CEO daily hospital walk-arounds

# People, **Places**, & Capabilities

- **Job #1 – get the Surgery, Radiology, & Laboratory Medicine Wing project moving**

Partnered with ORF, Chiefs of DLM, DPM, and RADIS

Met with the study group from the National Academies

Number of meetings with HHS and Congressional staff

CCRHB letter

**Anyone else who would listen!**

**Groundbreaking later this summer – finish in 2028!**

Strategic Communication – Same Message, Many Voices, Sustained over time

# People, **Places**, & Capabilities

- **Pharmacy**

**\$50 M / 6 years.**

**Required construction of interim and swing spaces**

**Swing space move – fall of 2019 – with interim leadership**

**Out-patient pharmacy and unit dose pharmacy both back in position**

**Permanent IVAU (intravenous admixture unit) – winter of FY 24-25**

**Recently also revamped the P & T Committee with new leadership**

# People, **Places**, & Capabilities

- **Radiopharmacy**

p15. “The history of the radiopharmacy has been fraught with complexity and setbacks.”

Approved plan

Latest setback – project set back a year to make certain there were enough funds for the SRLM

Should get back to the plan in FY 25

# People, **Places**, and Capabilities

- **Center for Cellular Engineering**

- 3T – best **20<sup>th</sup>** century facility money could buy

- 2J – 21<sup>st</sup> century facility embedded in a poorly constructed 20<sup>th</sup> century building

- Terrace modular – finally a 21<sup>st</sup> century facility

- 12<sup>th</sup> floor E wing – coming in FY 25

p. 16 “ In a 2016 plan developed by IC Directors focused on the future of the CC, the growing demand for cellular engineering became apparent.”

# People, **Places**, & Capabilities

- **Enhanced Simulation Center**
  - No plans yet, may not be necessary
  - Will discuss more in Capabilities



# **People, Places, & Capabilities (Patient Safety)**

- **Safety Tracking & Reporting System (STARS)**
- **Frequent use of Failure Mode and Effects Analysis – focus on problem prevention and not just problem solving**
- **Low threshold for communication with The Joint Commission, and using Root Cause Analysis methodology**
- **Institute for Safe Medication Practice visit with 90 recommendations – prioritized and addressed in a disciplined fashion since their visit**
- **Daily patient safety huddle**
- **Less insularity – more use of outside experts**

# Capital Investment Fund

- First made available in FY 18
- Up to \$50 M per year (usually spend \$20-30M)
- Facilities – re-sized the main supply line to reduce sludge & biofilm; re-piped patient rooms used by immunocompromised patients
- Facilities – renovated patient rooms, out-patient clinics, almost all DLM, now starting on in-patient nurses stations
- Equipment – CT in ICU, new PET-MR, added 3<sup>rd</sup> CT in RADIS
- IT – extensive investment in security, network re-design to eliminate single points of failure, now moving to 100 G from 10 G

# **People, Places, & Capabilities (Patient & Staff Safety)**

- **Code BRT (Behavioral Response Team)**
- **AHaRT (Anti-harassment Response Team)**
- **Spiritual Care Division presence for the CC staff**
- **Screening, testing, PPE, CC policies focused on staff safety throughout the pandemic**

# **People, Places, & Capabilities** **Clinical Care**

- **Transplantation and Cellular Therapy (TCT) initiative – NIAID, NCI, NHLBI, NHGRI, CC – one medical director, one operations program manager, and one program manager for donor services and quality assurance.**
- **Difficult Airway Response Team (DART) – 6/2022**
- **Pediatric hospitalists / Pediatric intensivists – 7/2022**
- **Reorganization of the resources for pediatric care to form an organization that looks more like a Department of Pediatrics in an academic medical center**

# People, Places, & Capabilities Telehealth

1. No capability before COVID-19
2. Policy & standard operating procedures developed and put in place in a very short period of time
3. Replacing Microsoft Teams with a platform that interfaces more seamlessly with our electronic health record
4. Investigators and coordinators requesting still more capability (needs to be considered in the context of the CC's historical mission)

p.19 “If the CC is to be a national resource, it must be a more robust virtual resource”

# People, Places, & Capabilities (Simulation)

1. Not a new capability – CCMD & CCND both used simulation
2. Accessed Dr Mabel Gomez-Mejia who completed medical simulation training in Boston
3. Dr. Gomez-Mejia developed strategy focused on “in situ” simulation training – reduced need for a more robust center
4. Invested in better equipment, especially for simulation involving children and infants. Hired full-time, experienced simulation tech.
5. Train the trainer program
6. Provided executive sponsorship – Dr. Tom Burklow
7. Have executed a number of tailored programs in areas where simulation had not been deployed before
8. Just getting started!

p. 16 “As an institution focused on rare....issues committed to preventing lapses and errors...., improving our simulation capabilities is of high importance

# People, Places, & Capabilities (Hospice Suites)

- None prior to 2017 – NIH Clinical Center not a place where people come to die
- Championed by Pain & Palliative Care Service
- Supported by Spiritual Care Division, CCND, and many others
- Ribbon cutting by Dr Collins (July 10, 2018)
- Supports clinical research – protocols requiring rapid autopsy



# **People, Places, & Capabilities (Research in Pediatric Patients)**

- **Historically limited**
- **For the past several years – only children older than 3 and larger than 15 kg**
- **GM 1 experience suggests we can do more with a good partner**
- **Only can be done if it is done safely**
- **Has been studied by one intramural working group assessing the near-term requirements**
- **Further evaluation by separate intramural work group**
- **Dr. Devaskar has agreed to lead group of extramural thought leaders to evaluate the work of the intramural groups**

# 2020 Culture of Patient Safety Survey

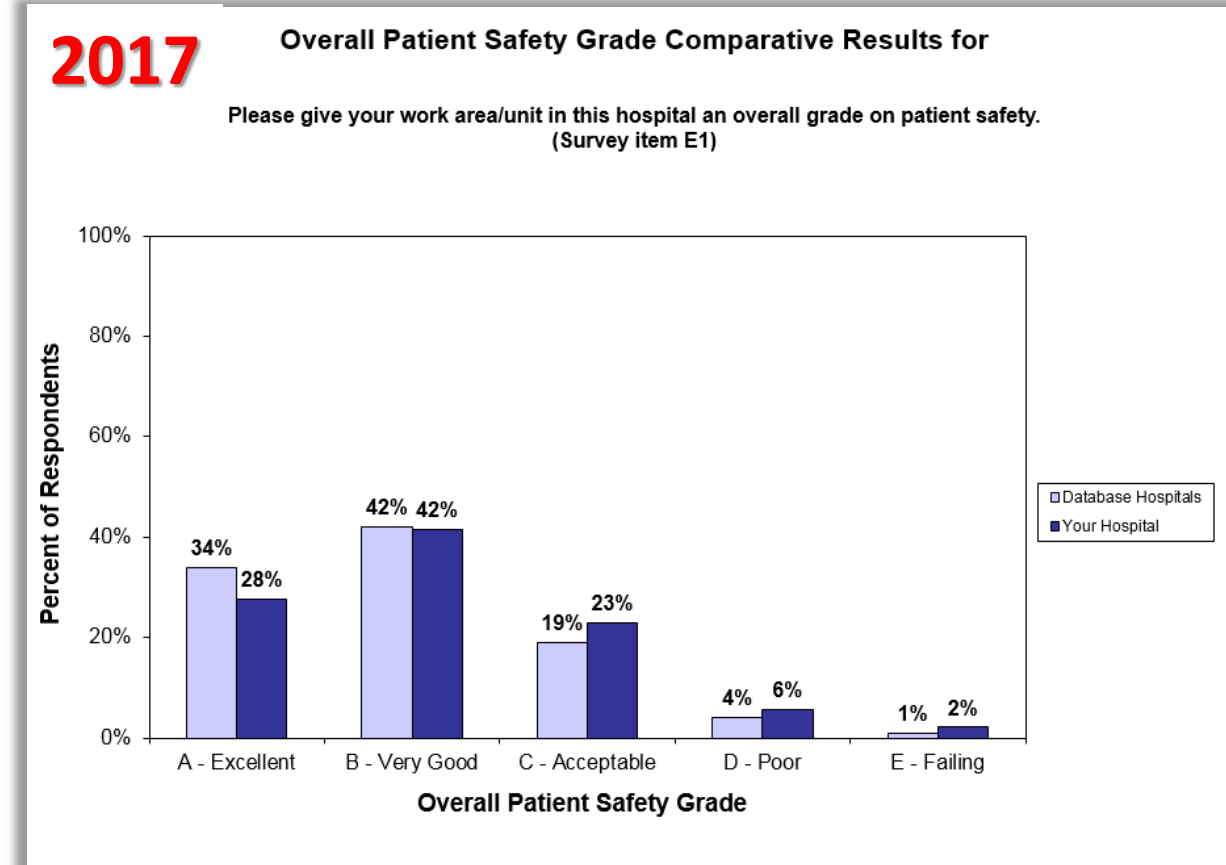
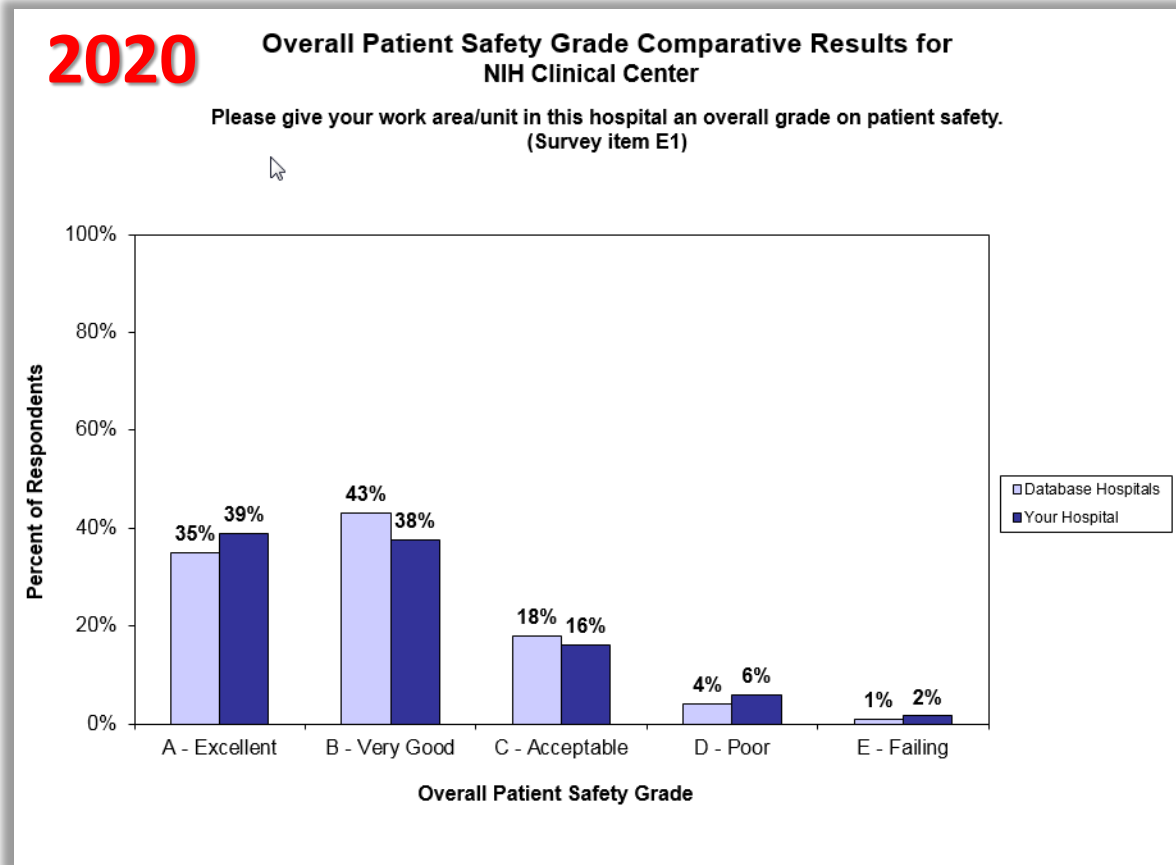


**CC improved in each of the  
12 domains compared to  
2017 scores!**

Overall Patient Safety Grade Comparative Results for  
NIH Clinical Center

<b>Excellent + Very Good</b>	<b>NIH</b>	<b>AHRQ</b>
2020	77	78
2017	70	76

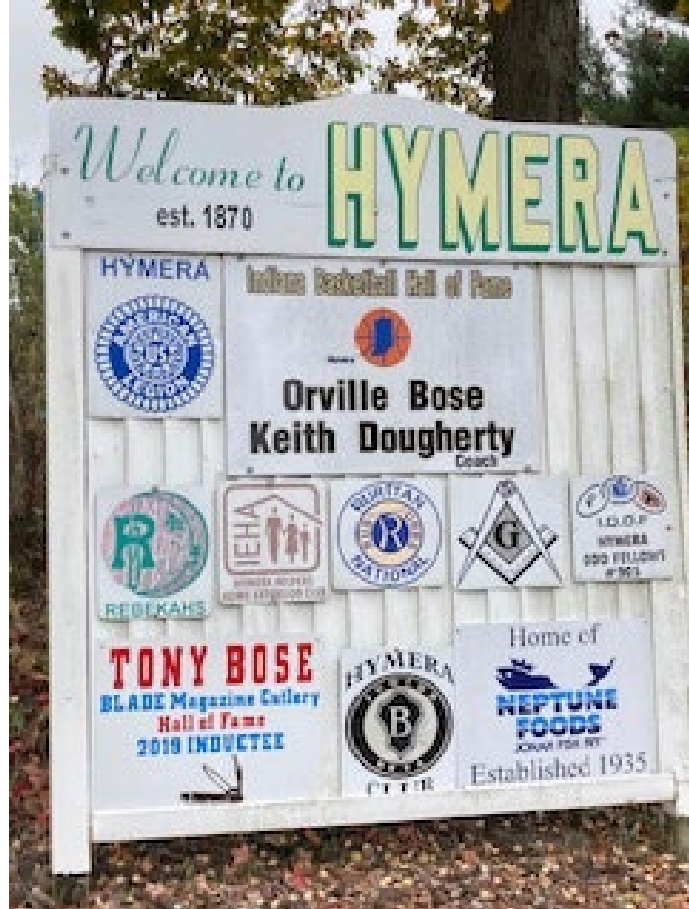
# Overall Patient Safety Scores 2020 and 2017



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It's Only a Plan

**Unless You Try to Follow It**



**\* Compassion for Our Patients, Their Families, & One Another**

- Did not include compassion for self



**\*\* Diversity and Inclusion of People and Ideas**

- Did not include accessibility
- Much heavier emphasis now than in 2019



**\*\*\* Commitment to Professional Growth and Development**

- Programs discussed in this meeting



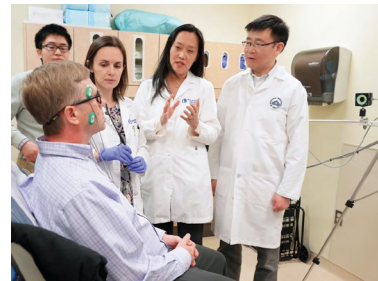
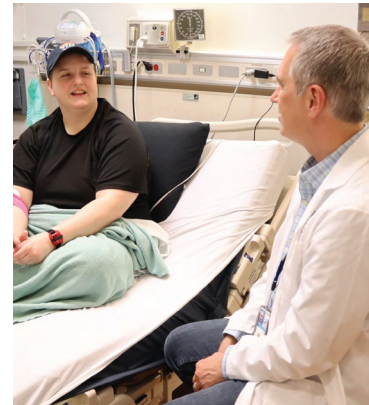
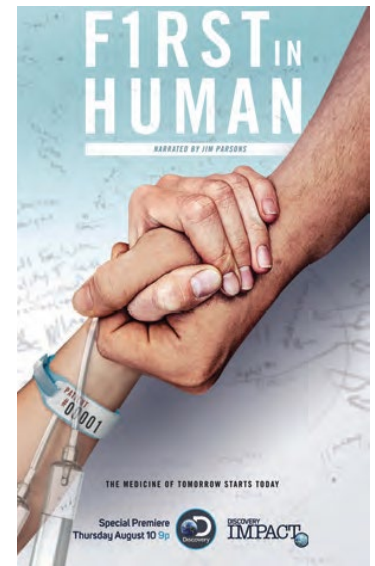
# Four Broad Aims

**(1) Continuing to lead the world in conducting first-in-human clinical research while maintaining our focus on rare and refractory disease.**

**(2) Increasing the use of the CC by the NIH intramural research program while simultaneously accelerating the CC's status as a national resource for the extramural community.**

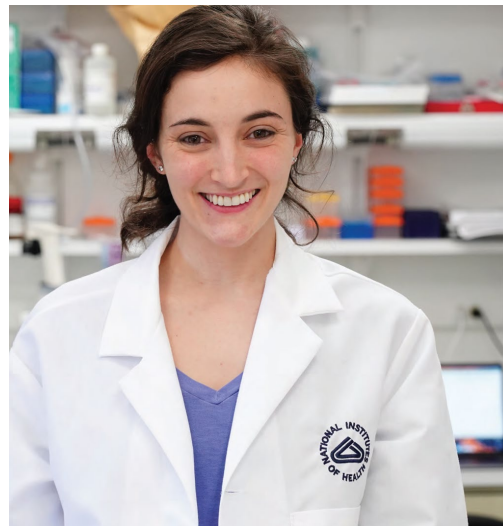
**(3) Demonstrating profound respect for our patients, whom we recognize as our full partners in the clinical research enterprise.**

**(4) Partnering with the IC's to recruit, develop, and retain the next generation of great NIH clinical researchers and the CC staff that will support their efforts.\***



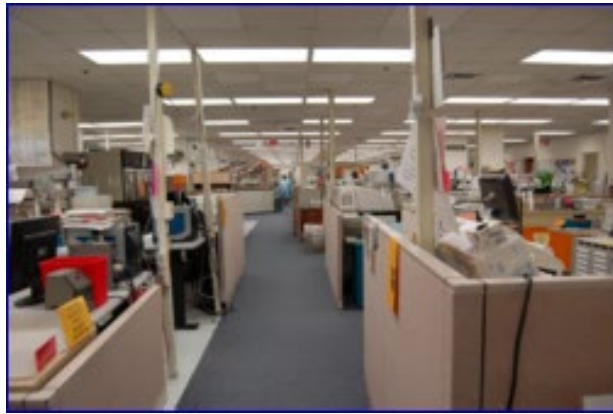
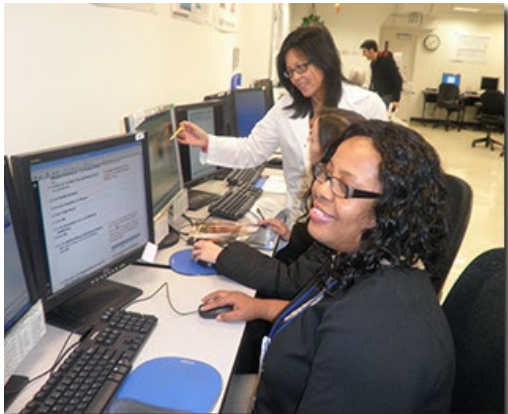
# \* Recruit, Develop, and Retain the Next Generation of Great NIH Clinical Researchers

- Even more important today than in 2019
- Even harder today than in 2019
- DEIA makes task even more complex
- Does DEIA focus become part of this strategic aim or does it need to stand alone?



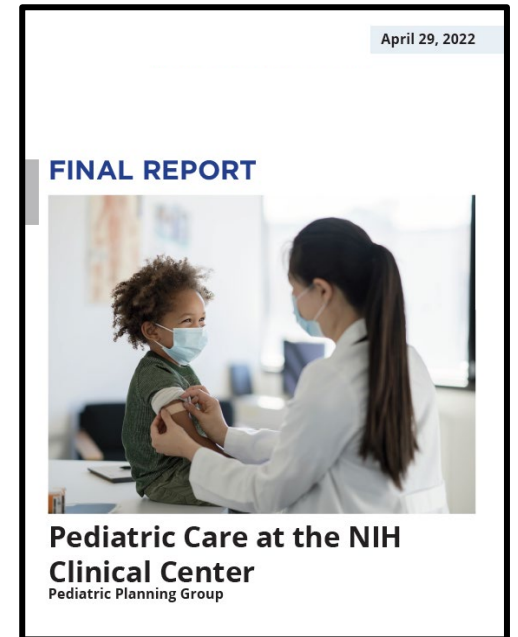
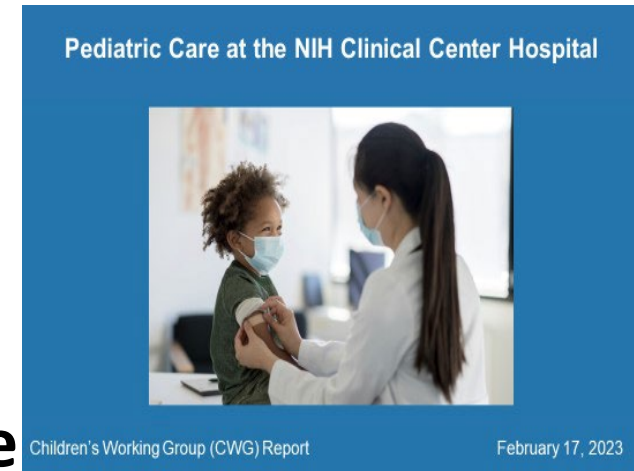
# New Strategic Aim – Improved Ability to Access and Use Information of All Types

- **Admin** - Too much for anyone to remember – is it all necessary?
- **Admin** - Not always easy for anyone to find – is it organized as well as it could be?
- **Admin** - Poor search function
- **Admin** - Probable new CC website
- **Clinical** – procure new Electronic Health Record (EHR) or try to make the current EHR better



# What about Pediatrics?

- Report of extramural working group led by Dr. Devaskar heard and accepted
  - Dr. Devaskar: plan proposed by intramural Pediatric Planning Group (PPG) using extramural partner is feasible but there are significant barriers to overcome
  - Dr. Bogue: Alternative approach – do early-in-human work at extramural academic medical centers
- PPG (intramural) reviewed report – not in favor of alternative approach



# **Pediatrics – Next Steps**

- **Further steps to organize as a Pediatrics Department**
- **Advance the model of care so that all pediatric patients are cared for by doctors and nurses with age specific competencies**
- **Carefully assessing decreasing the lower limit of age for admission to 2 years**
- **No request for 2024 for resources to develop PICU (driven primarily by 2024 budget concerns)**
- **Add Child Life Specialists**

# **Clinical Research Throughout the Spectrum of Life**

**“.....the new Institute for Child Health and Human Development, which was originally thought of as an institute for extramural grants to support activities in the universities. ....they are looking for some beds, and they are looking for some laboratories, and all of the original settlers, the early squatters, will have no part of this.”**

Oral History of Dr. Jack  
Masur, July 11, 1963.

# Transition Issues

- Is the CC an IC?
- NFBY
- What kind of research should be done in the CC?
  - What are the IRP's strengths?
  - Historically – CC reserved for research that cannot be done elsewhere
  - Historical definition is narrow
  - Historical definition may not attract the best and brightest
- CC's involvement in research sites outside of Bldg 10
- SRLM – initial outfitting, modification of plans developed long ago
- Electronic health record
- Funding model – no one likes the one we have
- Working in a more heavily unionized environment

# Questions