# NIH CC CEO Update for the ACD

James K. Gilman, MD MG, USA (ret) FACC/FACP 8 June 2017 Mission: We provide hope through pioneering clinical research to improve human health.

Guiding principle #1: Individual and collective passion for high reliability in the safe delivery of patient-centric care.

# **Fill Key Positions**

- CNO /CNE well into search process
- Radiology and Imaging Science Chief just appointed Search Committee\*
- COO still awaiting green light from HHS

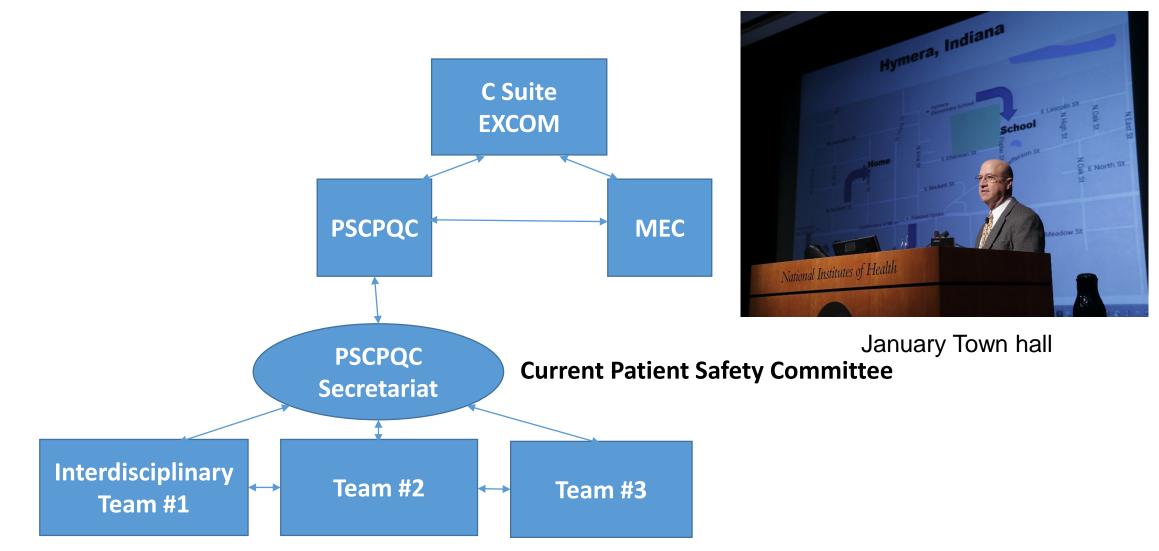
# Priority Area #1 – Patient Safety & **Clinical Quality**



January Town hall

- 1. Red Team Practice Committee
- 2. January Medical Executive Committee **Clinical Care Committee**
- 3. Involve the MEC
- 4. Get patient safety out of the Office of Patient Safety & Quality, move toward **High Reliability**
- 5. No filter safety and clinical quality info goes directly to the CEO
- 6. Avoid marginalizing those staff members who had carried the effort before the reorganization

#### **Concept Approved by Medical Executive Committee**



#### Patient Safety, Clinical Practice & Quality Committee

#### **Chair:** Janice Lee, DDS, MD, MS Clinical Director, NIDCR

#### Members:

- Lauren Bowen, MD, NINDS
- Jeremy Davis, MD , NCI
- Colleen Hadigan, MD, MPH, NIAID
- Lisa Horowitz, PhD, MPH, NIMH
- Deldelker James, MSN, RN, CC
- Dachelle Johnson, PharmD, BCPS, CC
- CAPT Toni Jones, MSOD, RN, CC
- Jen Kanakry, MD, NCI

- Carrie Kennedy, JD, OGC
- Chris Koh, MD, MHSc, NIDDK
- David Lang, MD, CC
- Laura Lee, RN, MSc, CC
- Tara Palmore, MD, CC
- Nitin Seam, MD, CC
- Janet Valdez, PA, NHLBI
- Ford, Gina, RN, MSN, staff



Dr. Janice Lee

**Clinical Center Quarterly Medical M&M Conference** 

#### "Systems Failures in a Complex Patient: A Case Based Report for Lessons Learned"

- When: Thursday March 16th, 2017 at 12:00pm
- **Location:** Lipsett Auditorium

Kinder, gentler M & M Overflow crowd Est 250 hrs prep!

- **Case Presentation:** Phuong Vo, MD, Clinical Fellow, NHLBI
- **System Failures:**
- Lin Tang, MD, Anesthesiology; Jennifer Jo Kyte, DNP, CNS, Critical Care Medicine;
- Nadia Biassou, MD, Neuroradiology; Naomi O'Grady, MD, Critical Care Medicine
- Discussion: Laura Lee, RN, M.Sc., Office of Patient Safety and Clinical Quality

# CC Grand Rounds – 22 March



Dr. Gilman: Macro Medical Errors & The Just Culture Dr. Pronovost: Working Toward High Reliability



Masur Auditorium filled to capacity!

## 11 April 2017 – Interim IVAU Opened



#### NEW! Patient Safety Event Reporting System

- Retiring the 30 year old "Occurrence Reporting System";
- Improved user interface (event entry and tracking);
- Enhanced data management capacity
- Robust data analytics
- Roll out in mid-April
- Test drive the system this week....



# Continued

- Daily patient safety huddles
- Follow patient safety rounds each week in one or two patient care areas
- Focus on communication, transitions, and hand-offs (IPASS)

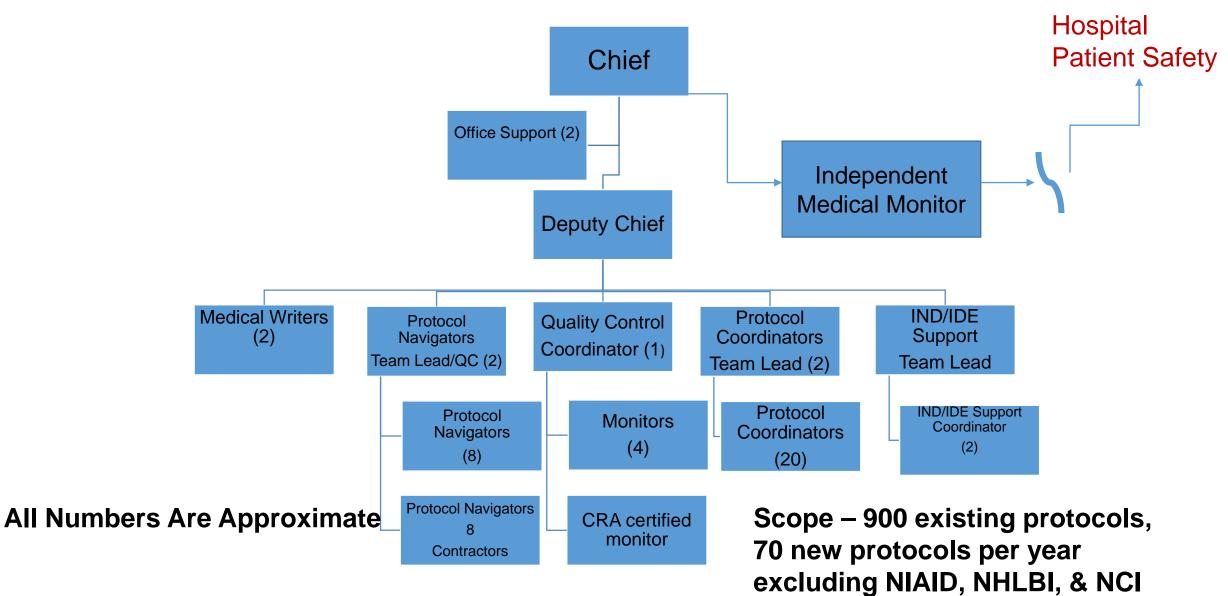
#### Priority Area #2 – Improve Support for Clinical Research in the CC

- Issue brought to the forefront CNS lymphoma study serious adverse events not reported to FDA by PI or sponsor
- Self-reporting by institutes indicated late reporting of adverse events and unanticipated problems is a systemic issue
- Retraining initiated aggressively
- Began development of proposal to reorganize support for clinical research centered on the CC

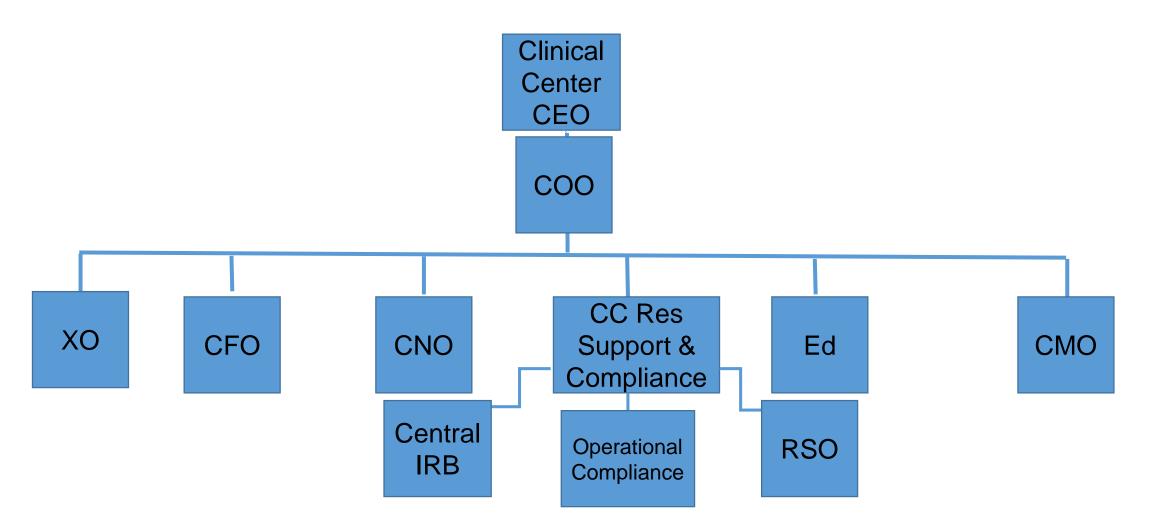
# What Are We Trying to Accomplish?

- Build a culture of quality & compliance while facilitating compliance compliance with FDA regulations compliance with AAHRP, ORP, & OHSRP regulations and policies compliance with HHS & NIH policies and regulations
- Reduce gaps in clinical research support between larger institutes and smaller institutes
- Facilitate clinical research especially for early investigators
- Separate policy and operations
- Improve patient safety and clinical quality at the same time that clinical research support is enhanced

#### **CC Research Support Office**



#### **Organizational Chart**



# **Priority Area #3 – Understand Our Business**

- Billing is a forcing function for cost consciousness
- We do not bill
- As we approached mid-year, one off emails asking for support for unanticipated and, therefore, unfinanced requirements
- During budget build for FY 18, occasional requests for large increases with little supporting justification
- NIH CC is more than a business but it is a business!

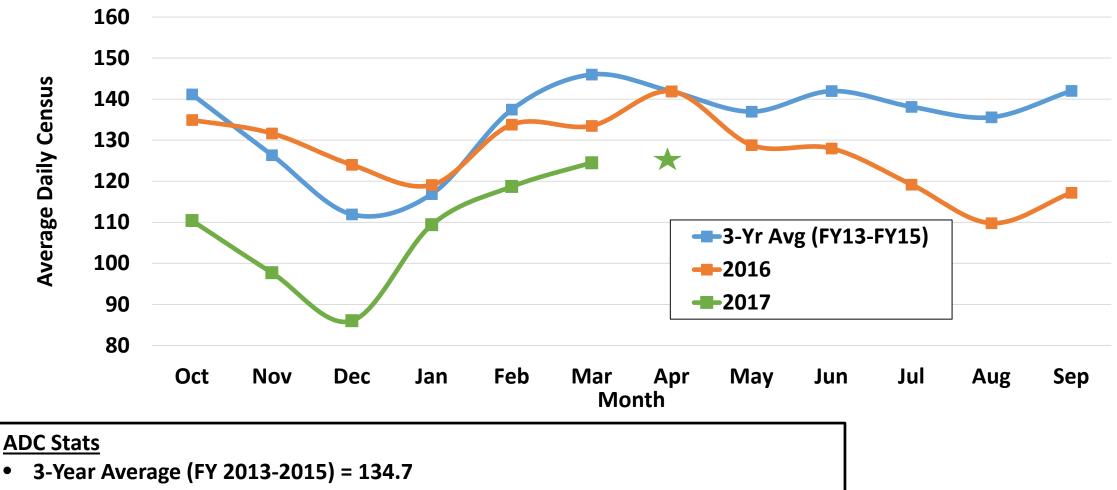
# **Understand Our Business**

- Use mid-year sweep to begin the process of understanding our business
- Unfinanced requirements evaluated transparently from across the entire CC rather than considered individually
- Institute quarterly business meetings 1<sup>st</sup> is in July evaluate workload metrics and budget execution data in open forum. Less capable fiscal planners and managers will learn from those more accomplished.
- Build the airplane while in flight work for 2018 budget continues

## Priority Area #4 – Develop Concept for the Center for Cellular Engineering

- Re: Working Group led by Dr. Steve Katz focusing on low census
- Short-term recommendation to increase OR availability we are in the process of doing (hiring additional staff)
- More mid-term recommendation increase capacity to produce engineered cellular products
- Demand is already high and continues to increase
- Protocols will be prioritized by processes overseen by Dr. Gallin
- Department of Transfusion Medicine (Drs. Klein and Stroncek) will oversee operations.

#### **Average Daily Census (ADC)\***



Year End FY 2016: 126.8 •

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Year-to-Date FY 2017 (through April 10): 108.2 ٠

\*ADC = average number of inpatient days on a daily basis.

#### **Year-to-Date Activity\***

	Year-to-Date FY16	Year-to-Date FY17	% Change FY16-17
Inpatient Admissions	2,842	2,360	-17%
Average Length of Stay	8.4	8.7	3%
Inpatient Days	25,015	20,770	-17%
Average Daily Census (7-Day)	129.6	108.2	-17%
Outpatient Total Visits	51,145	46,916	-8%
Clinic Visits	41,474	38,337	-8%
Day Hospital Visits	9,671	8,579	-11%
New Patients	5,191	5,053	-3%

\*Through April 10th

#### **Cell Processing**



- The aseptic, state-of-the-art module is a mini version of a large, sterile product manufacturing facility
- Located at CRC ambulance entry on the west side of the hospital
- Trailer 1, the viral vector unit, will be devoted to NCI's immunotherapy research
- Three other trailers are on order
- Modular facilities are in addition to work on 2J, 3T, future renovation of 12-E, and the interim IVAU when it is no longer needed by the pharmacy

#### **CC Focus Groups** Action Items/Recommendations

**April Town hall** 

Risk management for high risk patients/protocols	<ul> <li>Patient Safety, Clinical Practice &amp; Quality Committee (details to follow)</li> <li>Pediatric program expansion</li> <li>'Ward doctor' concept endorsed by MEC</li> </ul>
IRB uniformity/unification	<ul> <li>Single IRB</li> <li>Goal of Clinical Research Centralization Group with oversight by DDIR</li> </ul>
Consistent documents and documentation requirements for patient care	• Implementation of standard progress notes in February 2017 ( <i>details to follow</i> )
Swift transfer of patients to other facilities in emergency situations	<ul> <li>Response needs identified for ambulance transfers identified and associated administrative tasks assigned (details to follow)</li> </ul>
Align CC and IC orientation programs and require all NIH staff who work in CC to attend CC orientation	<ul> <li>CC orientation program streamlined</li> <li>Online option being pursued for non-CC employees/contractors who work in clinical care positions</li> <li>Involvement of NIH HR orientation staff</li> </ul>
Increase frequency of M&M Conferences	Quarterly M&M Conferences
Increase frequency of town hall meetings and consider more focus groups	• Quarterly Town Halls 23

# What's Next

- Continue work on FY 18 budget
- Continue to develop the plan for the Center for Cellular Engineering
- Await final decision on the CC Research Support Office
- Continue to fill key positions
- 3-5 year plan ideas that have come up during meetings with IC directors

NIDA – phase 1 trials of medications to combat opiate addiction

NIA – dementia

NHGRI – whole genome sequencing for all CC patients

# Looking Ahead!!



#### 'First In Human: The Trials of Building 10' 3-part documentary series



Series narrated by Jim Parsons



## Questions

# Miscellaneous

- Visited 1 on 1 with every Institute Director who subscribes to the CC
- Two trips to Capitol Hill one social and one to talk about the CC
- Group meeting with Secretary of HHS, Dr. Price
- Met by teleconference with staffers for the Senate's HELP Committee
- Met with both the Clerk of the Senate Committee on Appropriations and the Staff Director of the Subcommittee on Labor, HHS, Education, and Related Agencies