

NIH CLINICAL CENTER HOSPITAL BOARD

NIAID Update

Clinical Center Operations Extramural Use of the Clinical Center

H. Clifford Lane, M.D.

National Institute of Allergy and Infectious Diseases

National Institutes of Health

April 20, 2018



Presentation Outline

- **NIAID Overview**
- **Evolution of the Clinical Program**
- **Current Operations**
- **Current Challenges**
- **RFI / FOA on Extramural Use of the Clinical Center**

Presentation Outline

➤ ***NIAID OVERVIEW***

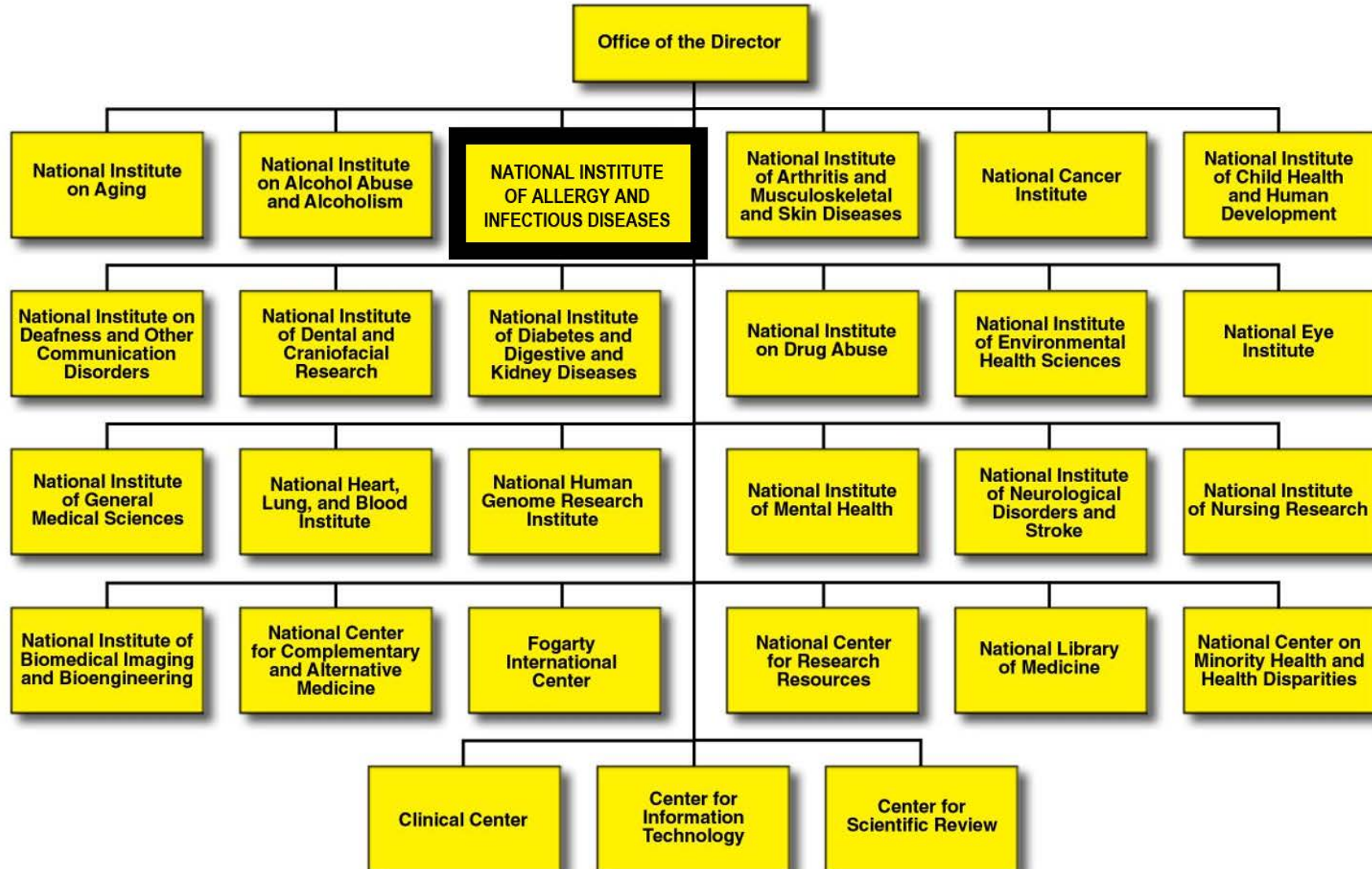
Evolution of the Clinical Program

Current Operations

Current Challenges

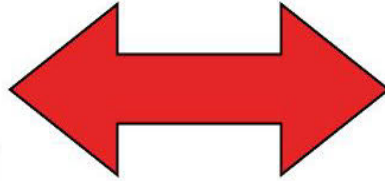
**RFI / FOA on Extramural Use of the
Clinical Center**

National Institutes of Health

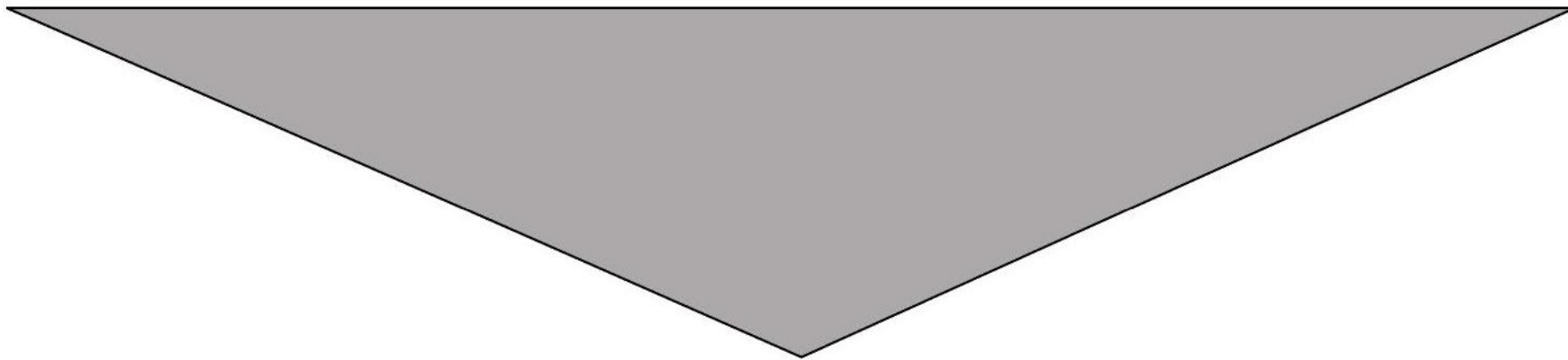


NIAID Infectious Disease Research: A Dual Mandate

**Maintain and “grow” a
robust basic and applied
research portfolio in
microbiology,
immunology and clinical
research**

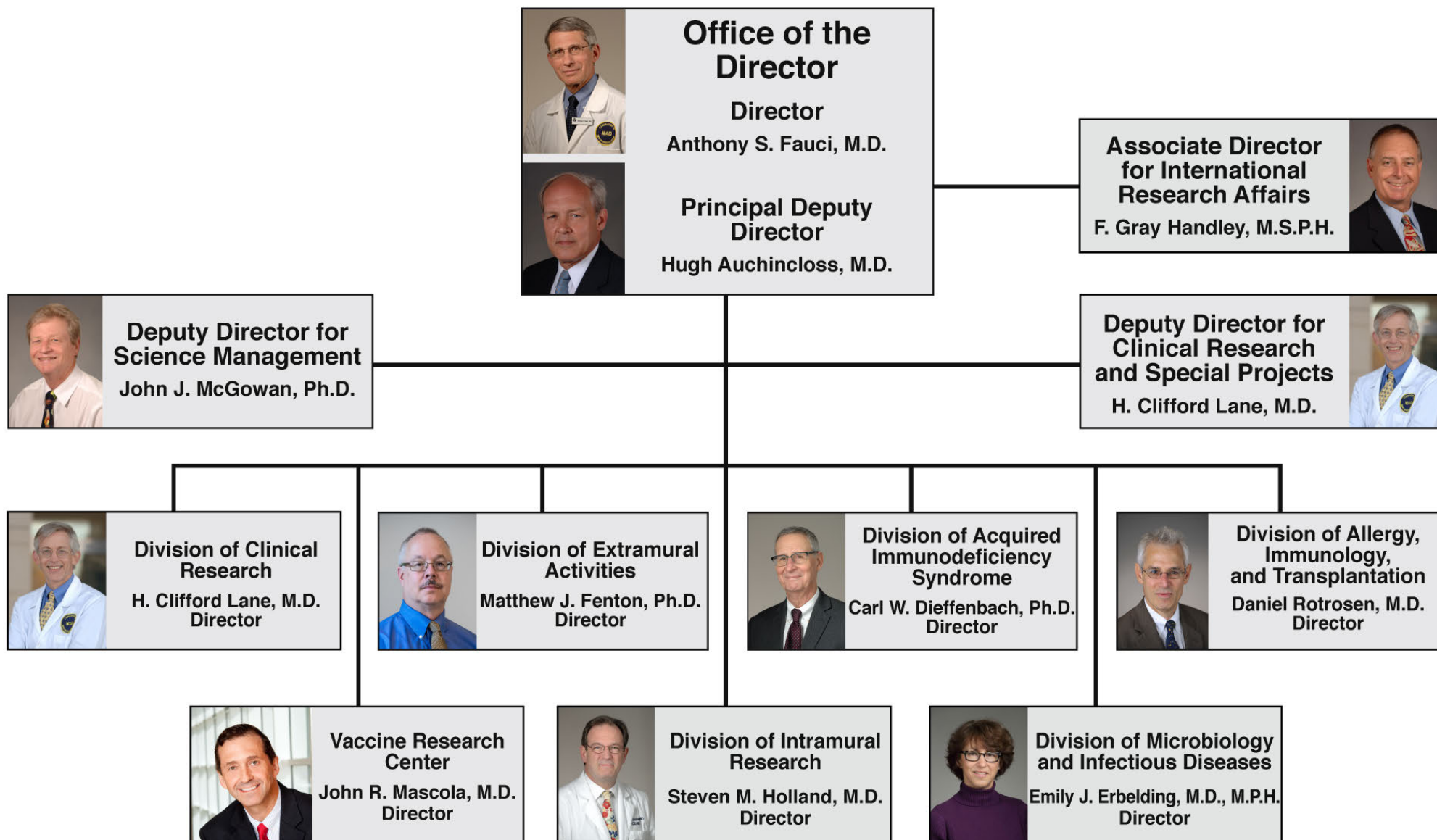


**Respond rapidly to
new infectious
disease threats**



New/Improved Countermeasures

NIAID Organizational Structure



Presentation Outline

NIAID Overview

➤ ***EVOLUTION OF THE
CLINICAL PROGRAM***

Current Operations

Current Challenges

**RFI / FOA on Extramural Use of the
Clinical Center**

Evolution of the NIAID Clinical Program

- **Prior to 1984 (AIDS; Anthony Fauci appointed NIAID Director)**
- **1984 – 2000 (Establishment of CC Standards for Clinical Research)**
- **2000 – 2009 (Establishment of NIAID Standards for Clinical Research)**
- **2009 - Present**

NIAID Clinical Program Prior to 1984

- **Only 3 laboratories conducted protocols**
 - **Laboratory of Clinical Investigation (LCI)**
 - **Laboratory of Parasitic Diseases (LPD)**
 - **Laboratory of Immunoregulation (LIR – 1980)**
- **Majority of protocols were “Natural History” protocols**
- **Clinical Director also functioned as Lab Chief of the LCI**
- **Fellows provided care; minimal outpatient activity**

CENTERS FOR DISEASE CONTROL

MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

June 5, 1981

***Pneumocystis Pneumonia –
Los Angeles***

July 3, 1981

***Kaposi's Sarcoma and
Pneumocystis Pneumonia
Among Homosexual Men –
New York City and
California***

NIAID Clinical Program 1984 - 2000

- **Expansion to 5 labs conducting clinical research (LCI, LPD, LIR, LAD, LHD); PAs added to ward**
- **Establishment of multiple interventional studies**
- **Development of multi-site and international studies in tropical diseases and HIV/AIDS**
- **Establishment of NIAID (LIR) / CC (CCMD) HIV/AIDS Program with dedicated clinical research staff**
- **Establishment of a dedicated pediatric unit**

Rounds at NIH Clinical Center, Early 1980s – AIDS Patient



■ Median survival of AIDS patients: ~8-15 months



The NIH Record

Nurses Play Key Role

January 26, 1988

AIDS Clinic Staff Faces Heavy Workload

By Blair Gately

The Clinical Center's 11th floor outpatient clinic is in the forefront of clinical AIDS research and, as its workload has increased with the scope of the epidemic, the teamwork of its staff has helped to ease the burden.

The clinic, which recently celebrated its second anniversary, is operating at full speed with both its support staff and an integrated computer system in place.

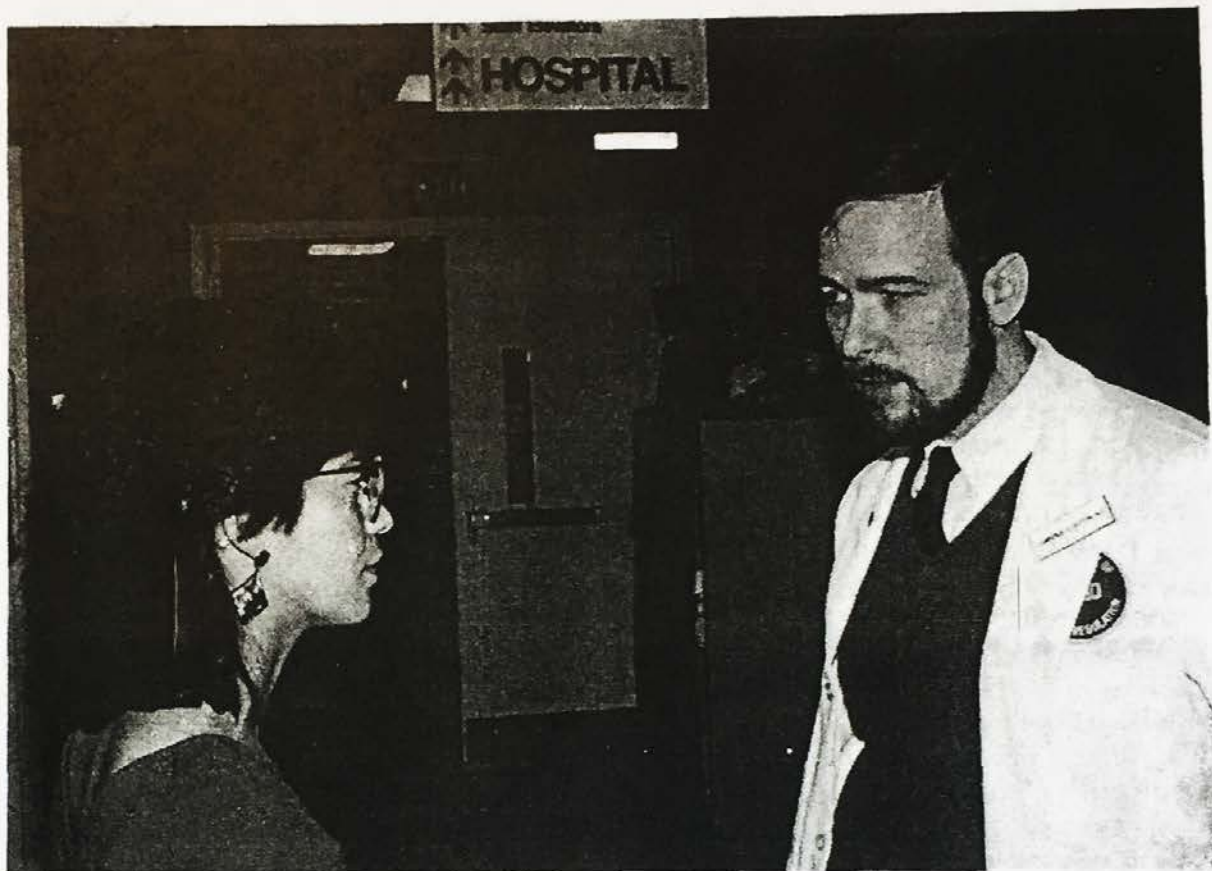
"The clinic is a truly collegial operation and there is a lot more autonomy than in other places," says Nancy Sears, a primary care nurse who has worked for the clinic since its inception in November 1985.

"We have established a state of the art system for drug trials, primary care nursing, evaluation of people with HIV and data collection," said Dr. H. Clifford Lane, senior investigator, Laboratory of Immunoregulation, NIAID, and deputy clinical director, NIAID.

Lane says one of the key features of the clinic is its computer system, which facilitates information sharing between the research lab, the clinical lab and the clinic.

During the last few years, the Laboratory of Immunoregulation has conducted clinical trials

(See CLINIC, Page 4)



Dr. Laurence Deyton (r) discusses one of his patients with nurse Laura Govoni. Deyton, a staff fellow assigned to NIAID's AIDS clinic for one year, serves as primary physician to patients participating in drug trials. The clinic recently celebrated its second anniversary.

“The nurses at the clinic have a very different role. They have more responsibility for supervising the day to day patient care and they have more direct involvement in the research activities. The clinic takes advantage of the multiple skills that a nurse has to offer.” □

NIH Record

January 26, 1988

NIAID Clinical Program 2000 – 2009 (1)

- **Development of the “Standards for Clinical Research Within The NIH Intramural Program”**
- **Development of the “NIAID Clinical Research Standards”**
- **Expansion of the Office of the Clinical Director to an NIAID Division of Clinical Research**

NIAID Clinical Program 2000 – 2009 (2)

- **Development of contracts to provide residents to the NIAID inpatient service**
- **Barriers to Clinical Research Report**
 - **Initiation of the Protocol Navigators Program**
- **Establishment of a Biodefense Program**

STANDARDS
FOR CLINICAL RESEARCH
WITHIN THE
NIH
INTRAMURAL RESEARCH
PROGRAM



STANDARDS
FOR CLINICAL RESEARCH
WITHIN THE
NIH
INTRAMURAL RESEARCH
PROGRAM

January 2000

I. Clinical Informatics,
Data Management and
Protocol Tracking

II. Biostatistics

III. Quality Assurance
and Quality control

IV. Protocol Review

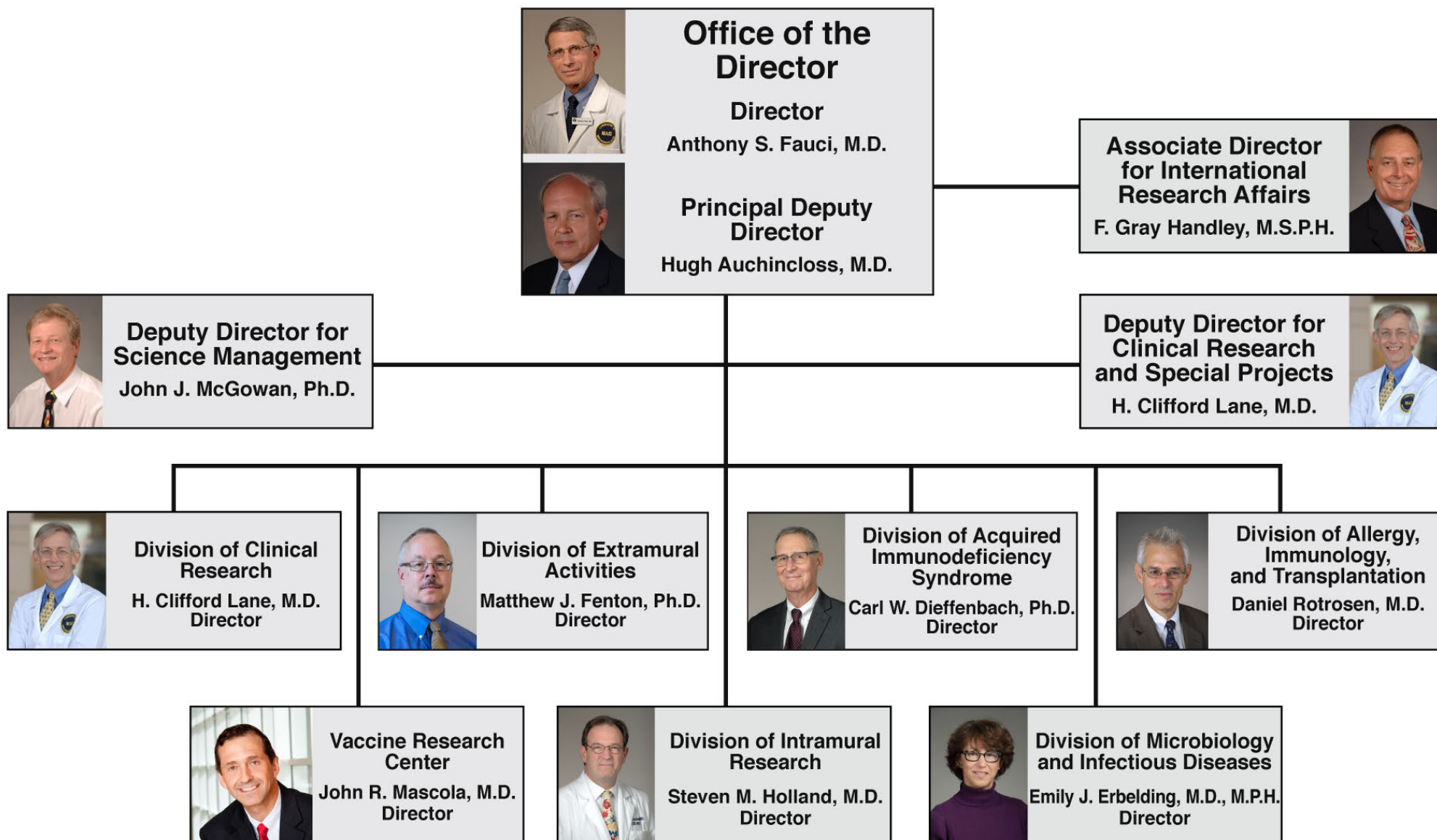
V. Human Resources
and Physical Plant

VI. Training and
Education

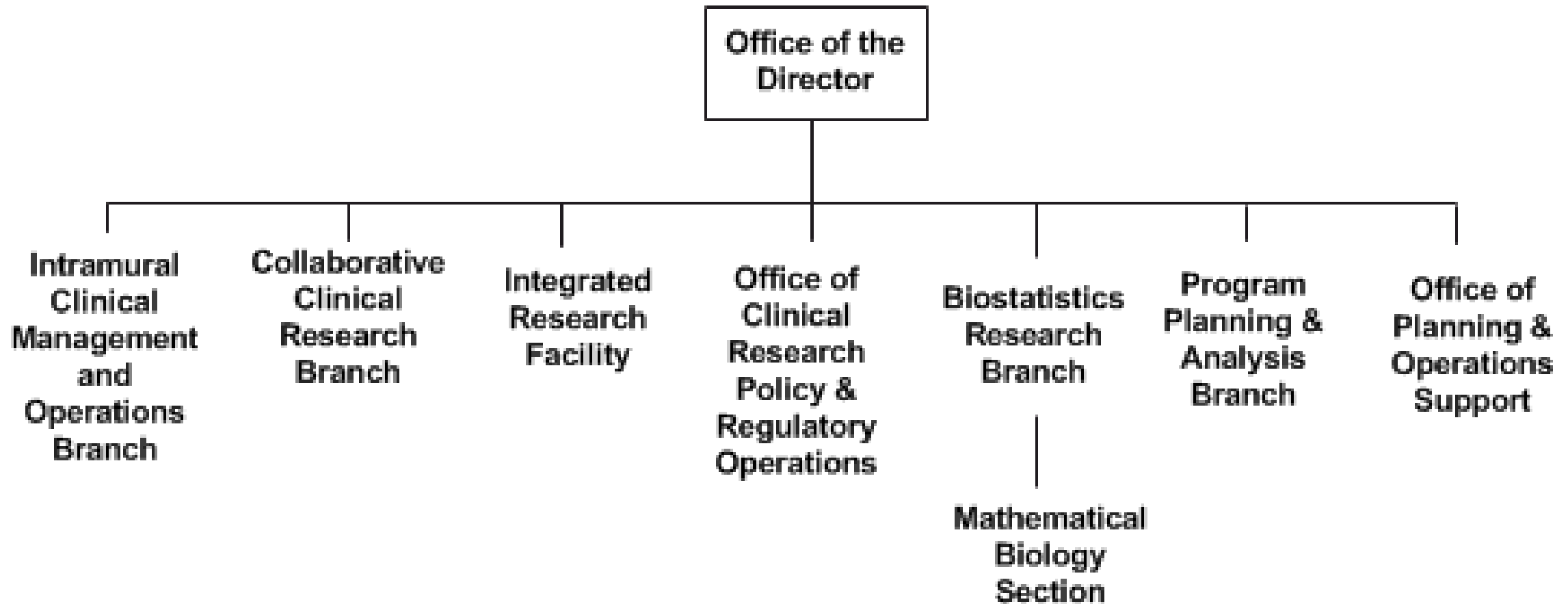
NIAID “Clinical Research Standards”

- **Modeled after the “Standards for Clinical Research Within The NIH Intramural Program”**
- **Covers 4 areas**
 - **Clinical Research Development, Review, Conduct and Oversight**
 - **Clinical Research Management**
 - **Training and Education**
 - **Quality Assurance and Quality Control**

NIAID Organizational Structure



NIAID Division of Clinical Research



Intramural Clinical Management and Operations Branch

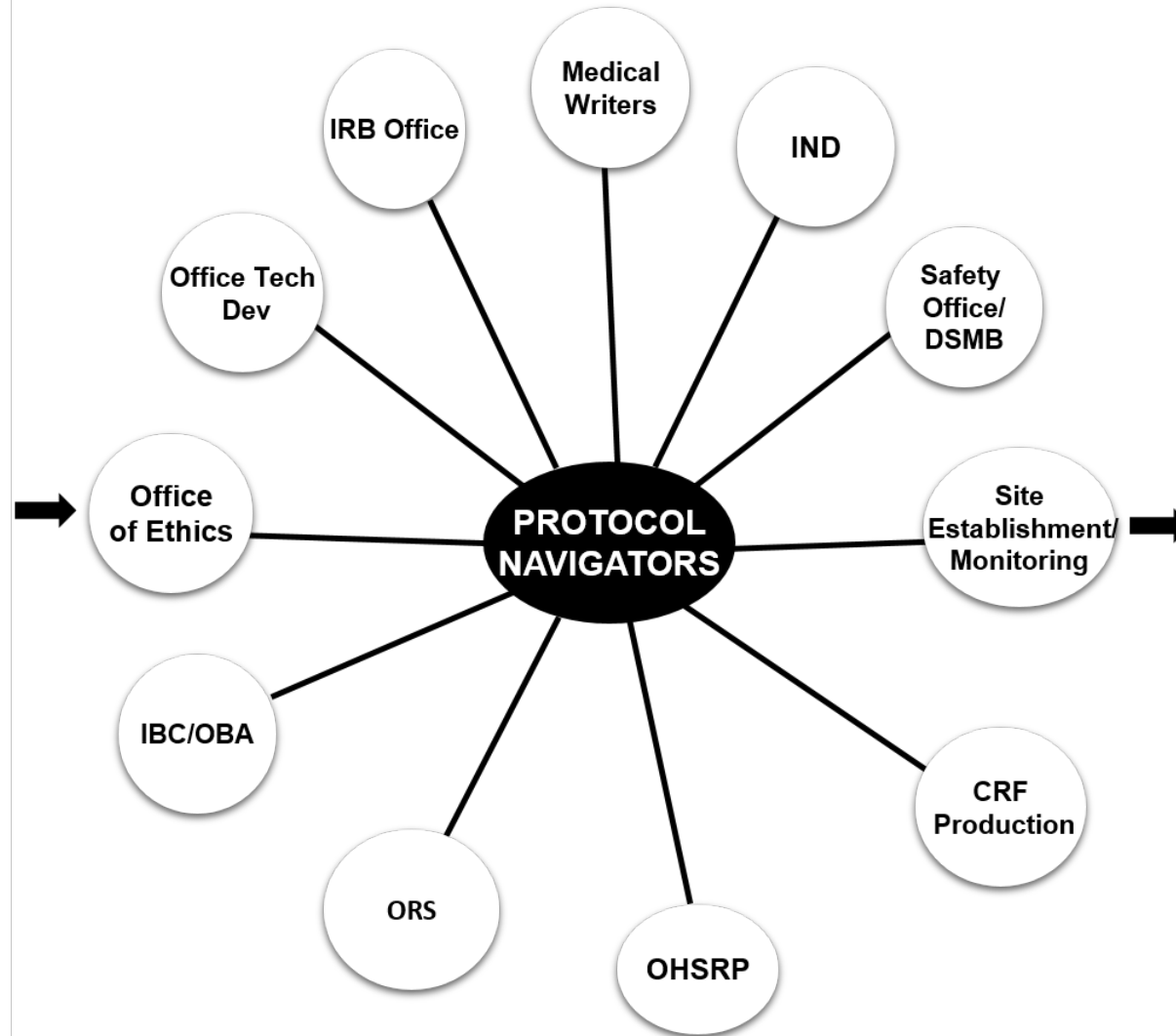
- **Responsible for inpatient and outpatient operations**
- **Provision of lab-based and clinic-based support staff in conjunction with the DIR, VRC and CC leadership**
- **Oversight of A/I and ID Consult Services**
- **Staff credentialing**
- **Grand Rounds / Continuing Medical Education**
- **Monthly Quality Assurance Meeting**

Office of Clinical Research Policy and Regulatory Operations

- **Clinical Safety Office**
- **Clinical Trials Management**
- **Protocol Navigation/Protocol Development Program**
- **IRB Support Office**
- **Regulatory Office (IND/IDE/MF)**
- **Research Pharmacy Oversight**
- **NIAID Clinical Research Subcommittee Support**

The Protocol Navigator Interface

**Scientifically
Reviewed and
Approved
Concept**



**Clinical
Protocol**

Juxtaposition of Events of September 11, 2001 and the Deliberate Release of Anthrax



SARS: A New Challenge to Global Health





Bi terrorism: A Clear and Present Danger

HC Lane, J La Montagne and AS Fauci



Establishment of a Special Clinical Studies Unit in Support of the Biodefense Program

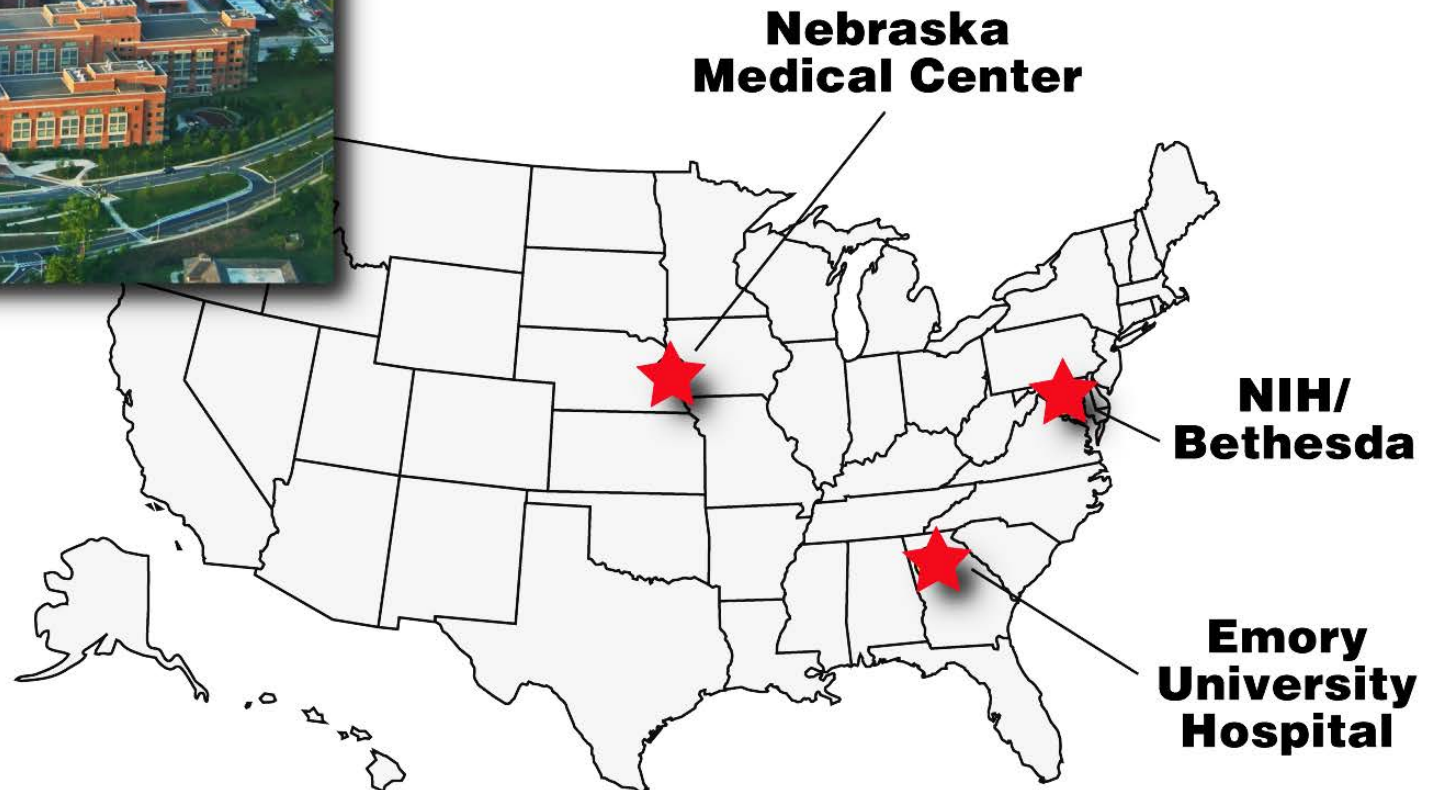
Ribbon-cutting ceremony April 14, 2010



April 6, 2018



NIH Special Clinical Studies Unit: Designated Ebola Treatment Facility



* As of Oct. 2014, three Designated Ebola Treatment Facilities existed in the U.S.



The Washington Post

October 25, 2014

Nina Pham, Nurse Who Contracted Ebola, is Now Free of Virus and Leaves NIH



Photo: The Washington Post

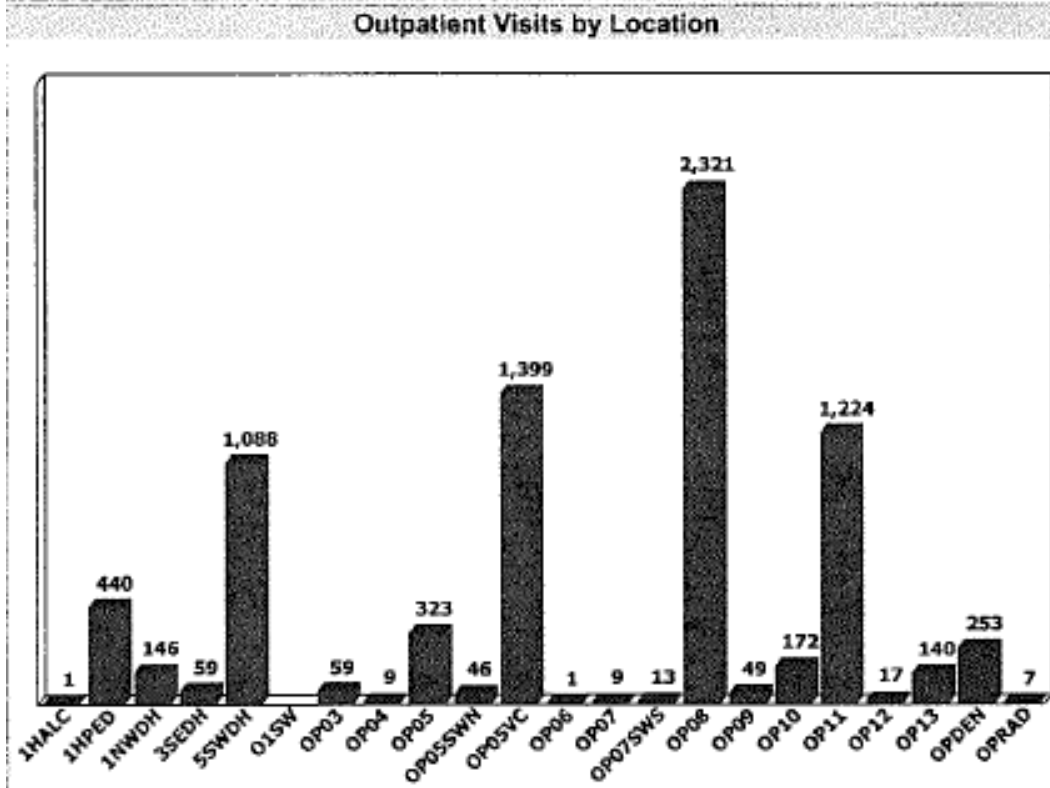
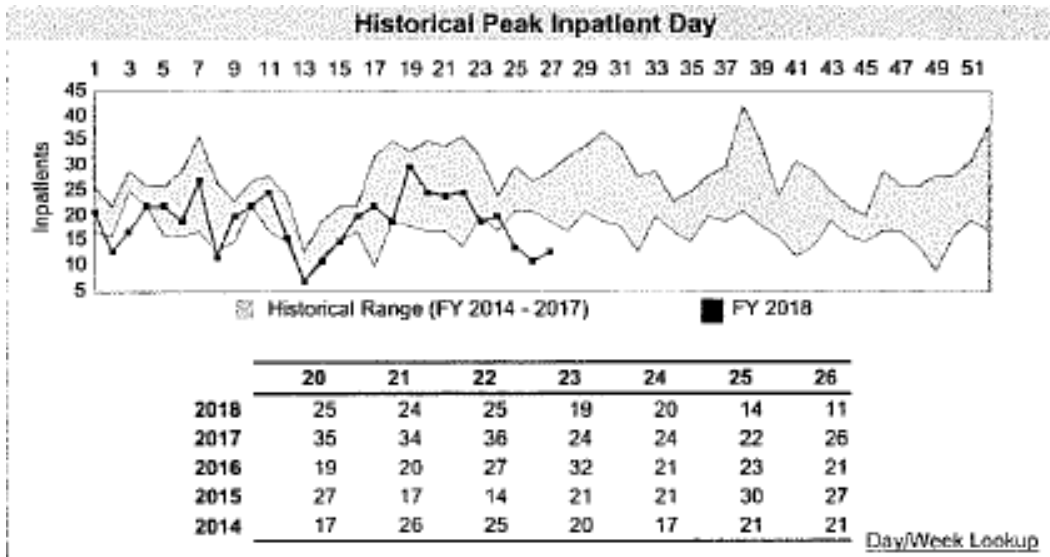


Photo: Nina Pham

NIAID Clinical Program 2009 - Present

- **Continued expansion of the number of labs doing clinical research (LCID/LHD/LCIM, LPD, LAD, LIR, LMI, LID, LMIV, LMVR, LI/LSB, VRC, LAD)**
- **127 Credentialed Physicians on Staff**
- **135 Protocols**
- **355 Principal and Associate Investigators**
- **Four outpatient clinics; two inpatient wards**
- **Initiation of Nurse Practitioners on the Pediatric ward**

FY 18 NIAID Projected Inpatient and Outpatient Activity



Inpatient Days: 5,709

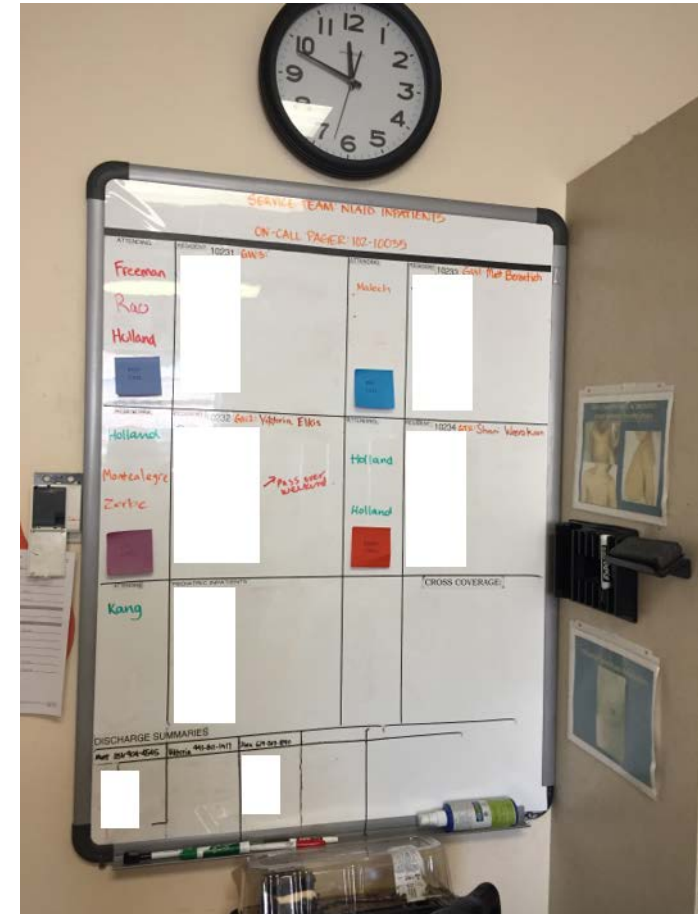
Outpatient Visits: 15,319

Admissions: 494

Avg. Length of Stay: 8

Ward Team Room

5SEN Clinical Research Center



NIAID Activities Geared Toward Enhancing Patient Care

- **Ward Rounds on Monday, Wednesday, Friday**
- **Mini-rounds on Tuesday, Thursday**
- **Weekly Medical Grand Rounds; 1 per month devoted to quality assurance**
- **Thursday am meetings with the ward team**
- **Monthly meetings with multi-disciplinary team (nursing, peds, regulatory)**

Selected Safety Tracking and Reporting System (STARS) Reports in March

- **1 Moderate Harm**
 - **Anaphylaxis during a food challenge**
- **4 Mild Harm**
 - **IV placed on the wrong patient**
- **5 Near Misses**
 - **Poor communication with Glucose Management Service**
 - **Laryngoscope handles not working x2**

Changes in the CC as a Whole with New Leadership of the Hospital

- **Daily Huddles**
 - **Hospital based**
 - **Patient Care Unit based**
- **Increased Communication Between Leadership and Staff**
 - **3 main things to know this week**
 - **Quarterly Town Hall meetings**
- **Enhanced Safety Reporting**
- **Consideration for consolidation of BMT Programs**

NIAID Clinical Program - Challenges

- **Expanding nurse case manager model to all protocols**
- **Maintaining a robust inpatient census**
 - **Additional Assistant / Tenure-Track investigators**
 - **FOA for extramural use of the CC**
- **Allocating space in the CC to clinically active staff**
 - **Upcoming inventory of space utilization**
- **Compliance with the changes to the Common Rule**
- **Partnership with Children's hospital**

Presentation Outline

NIAID Overview

Evolution of the Clinical Program

Current Operations

Current Challenges

➤ ***RFI / FOA ON EXTRAMURAL
USE OF THE CLINICAL CENTER***

Optimizing the Future of the Clinical Center

Working Group

Fall, 2017

**Jim Anderson
Chris Austin
Bill Dahut
Tony Fauci
John Gallin
Gary Gibbons**



Shoshana Kahana

**Jim Gilman
Michael Gottesman
Steve Katz
Walter Koroshetz
Cliff Lane
Mike Lauer**

Working Group Assessment (1)

- **The CC needs to have more studies utilizing the facility**
- **These studies should:**
 - **Involve intramural and extramural investigators**
 - **Require inpatient settings**
 - **Be difficult to do elsewhere because they are resource intensive and/or require special infrastructure**

Working Group Assessment (2)

- **The quality and breadth of the research at the CC would improve by “opening up” the CC to a broader swath of researchers.**
- **Redefine the role of the CC as a national resource**
 - **Allow extramural investigators to lead projects at the CC**
 - **No longer a hospital supporting just intramural research**

The Clinical Center as a National Resource

- **Long history of partnerships with extramural investigators and industry**
- **Bench-to-Bedside (BtB) Awards**
- **UO1 Grants: Opportunities for Collaboration at the NIH Clinical Center**

Challenges with the Current UO1

- **Requires an intramural co-PI**
- **Leads to extension of current programs as opposed to new programs**
- **May lead to funding of proposals below the payline in order to make sure some awards are made**
- **Does not address the need for adequate infrastructure to support the PI**

NIAID Pilot Funding Opportunity Announcement (FOA) (1)

- **NIAID plans to enhance clinical research opportunities for extramural investigators by providing access to both the Clinical Center and NIAID clinical research infrastructure resources**
- **Would still be a UO1 insofar as there would need to be significant involvement by NIH staff**
- **Would not require an intramural co-PI on the award**

NIAID Pilot Funding Opportunity Announcement (FOA) (2)

- **Would require approval by CC and NIAID leadership prior to submission**
- **Would provide infrastructure support from the CC and NIAID and funding to the investigator from NIAID**
- **A new paradigm for CC support**
- **Extramural investigators at the CC would receive the same infrastructure support as intramural investigators**

NIAID Pilot Funding Opportunity Announcement (FOA) (3)

- **Request For Information (RFI NOT-AI-18-028) released March 13, 2018**
- **Deadline for comments May 18, 2018**
- **Thus far no comments received**
- **Anticipate presentation to NIAID Council June 4, 2018**
- **If approved by Council, anticipate first awards June/July 2019**