NIH CLINICAL CENTER HOSPITAL BOARD

NIAID Update
Clinical Center Operations
Extramural Use of the Clinical Center

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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
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
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
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
AIDS Clinic Staff Faces Heavy Workload

By Blair Garey

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)
“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.”
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
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 Division of Clinical Research

Office of the Director

- Intramural Clinical Management and Operations Branch
- Collaborative Clinical Research Branch
- Integrated Research Facility
- Office of Clinical Research Policy & Regulatory Operations
  - Biostatistics Research Branch
  - Program Planning & Analysis Branch
  - Office of Planning & Operations Support
  - Mathematical Biology Section
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
Bioterrorism: 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.
Nina Pham, Nurse Who Contracted Ebola, is Now Free of Virus and Leaves NIH
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

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

Shoshana Kahana
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.
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 U01

- 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.
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