

The NIH Clinical Center



**NIH Scientific Management Review Board
April 28, 2009**

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Director, NIH Clinical Center**



Outline

- **Overview**
- **Key Challenges**

CC Vision

**As America's research hospital,
we will lead the global effort
in training today's investigators
and discovering tomorrow's cures.**

The NIH Clinical Center Profile



- **More than 350,000 patients since opening in 1953; currently follow ~86,000 patients**
- **A national hospital**
- **234 beds**
- **1,850 CC employees and ~4,000 IC employees**
 - **1,222 credentialed MDs**
- **1,449 active protocols**

“There’s No Other Hospital Like It” So What Makes Us Different?

- **Every patient is enrolled on a protocol**
- **Care is free**
- **Highly educated nurses familiar with clinical research**
- **A hospital surrounded by research labs with gifted investigators**
- **1st in human clinical trials**
- **Unique cohorts of patients with rare diseases**
- **Long term and high intellectual/economic risk studies**
- **Rapid response to public health emergencies and scientific opportunities**

Selected Accomplishments

- **Chemotherapy and immune therapy for cancer**
- **1st platelet transfusions; 1st continuous flow blood cell separator**
- **Lithium for bipolar disorders**
- **Blood tests for AIDS, hepatitis**
- **1st gene therapy (ADA Deficiency)**
- **Pathogenesis and treatment of AIDS**
- **1st fluoride gels to treat dental caries as an infectious disease**
- **Cardiac MRI for chest pain to identify high vs low-risk pts.**
- **Technology for human papilloma virus vaccine**
- **PET scans to clarify some abnormalities in schizophrenia**

Specialized Services and Facilities

- **GMP facility for producing candidate drugs**
- **Imaging equipment**
 - 3 cyclotrons
 - MRI center
- **Biomechanics laboratory**
- **Blood products; stem cell**
- **IT Tools for clinical resea**
 - ProtoType
 - BTRIS
- **Phenotyping**



Multi-modality minimally-invasive procedural suite



Alex Witchel: Rupert Everett, Out and About Jon Mocallem: The Great Whooping-Crane Con

The New York Times Magazine

FEBRUARY 22, 2009



The Medical Detectives

Some patients have spent their lives suffering from mysterious diseases that no one can conclusively diagnose. A team of N.I.H. researchers is working against time to find answers where other doctors are not equipped to go. BY ROBIN MARANTZ HENIG

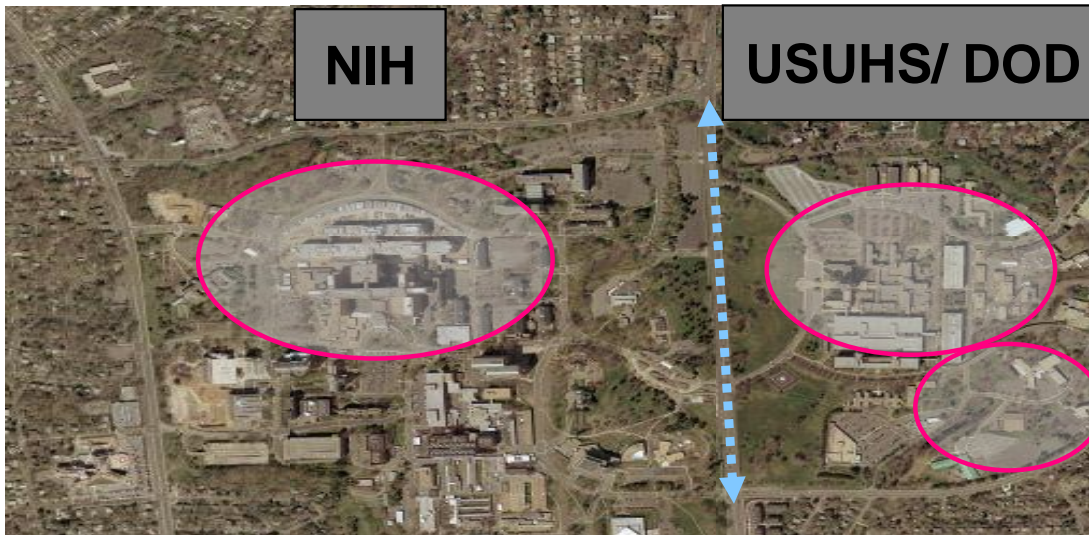
TBI/PTSD Initiative-2009

Partnership with USUHS & DOD

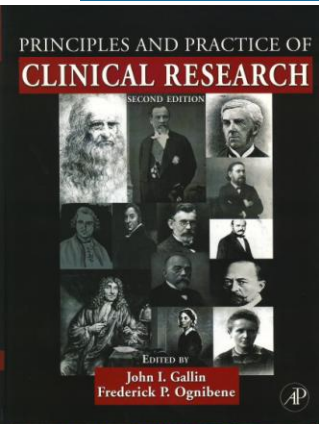
- \$70M
 - ~\$8.8M expected to CC
 - ~\$800K Rehab Med
 - ~\$8M Radiology
- Soldier and civilian participants



Laura Rauch / AP

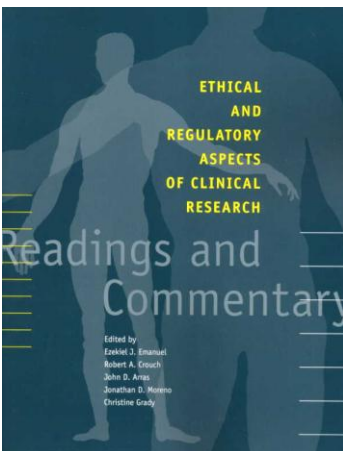
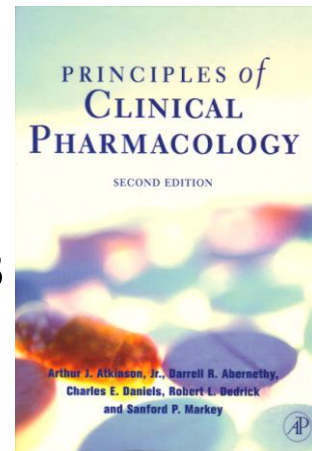


NIH Training Curriculum In Clinical Research

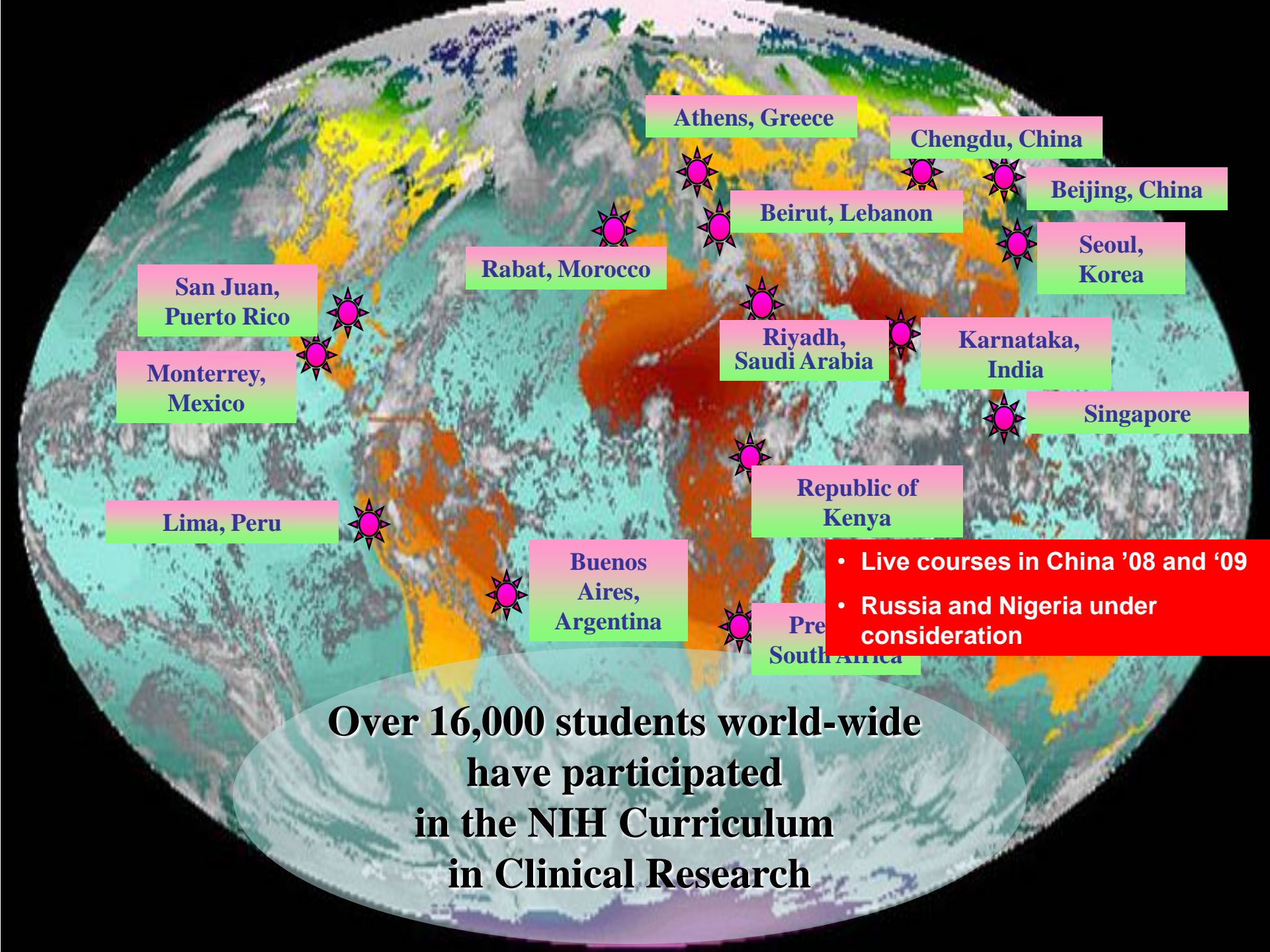


Introduction to the Principles & Practice of Clinical Research
>7,600 participants since course introduced in 1995

Principles of Clinical Pharmacology
>4,500 registrants since course began in 1998



Ethical and Regulatory Aspects of Human Subjects Research
>3,400 participants since course began in 1999



Athens, Greece

Chengdu, China

Beijing, China

Seoul, Korea

Beirut, Lebanon

Rabat, Morocco

San Juan, Puerto Rico

Monterrey, Mexico

Riyadh, Saudi Arabia

Karnataka, India

Singapore

Lima, Peru

Republic of Kenya

Buenos Aires, Argentina

• Live courses in China '08 and '09

• Russia and Nigeria under consideration

Pre South Africa

Over 16,000 students world-wide have participated in the NIH Curriculum in Clinical Research

2009 Training Initiatives to Support Extramural AHCs

- **Sabbatical in clinical research management**
- **Inventory and build virtual clinical research “university” within CTSA network**

Barrier: Prohibition of co-mingling intramural and extramural \$

Bench-to-Bedside Awards Promote Intramural/Extramural Partnerships

\$4.5 M/year from:

- **NIH offices/centers**
- **FDA**
- **intramural programs**

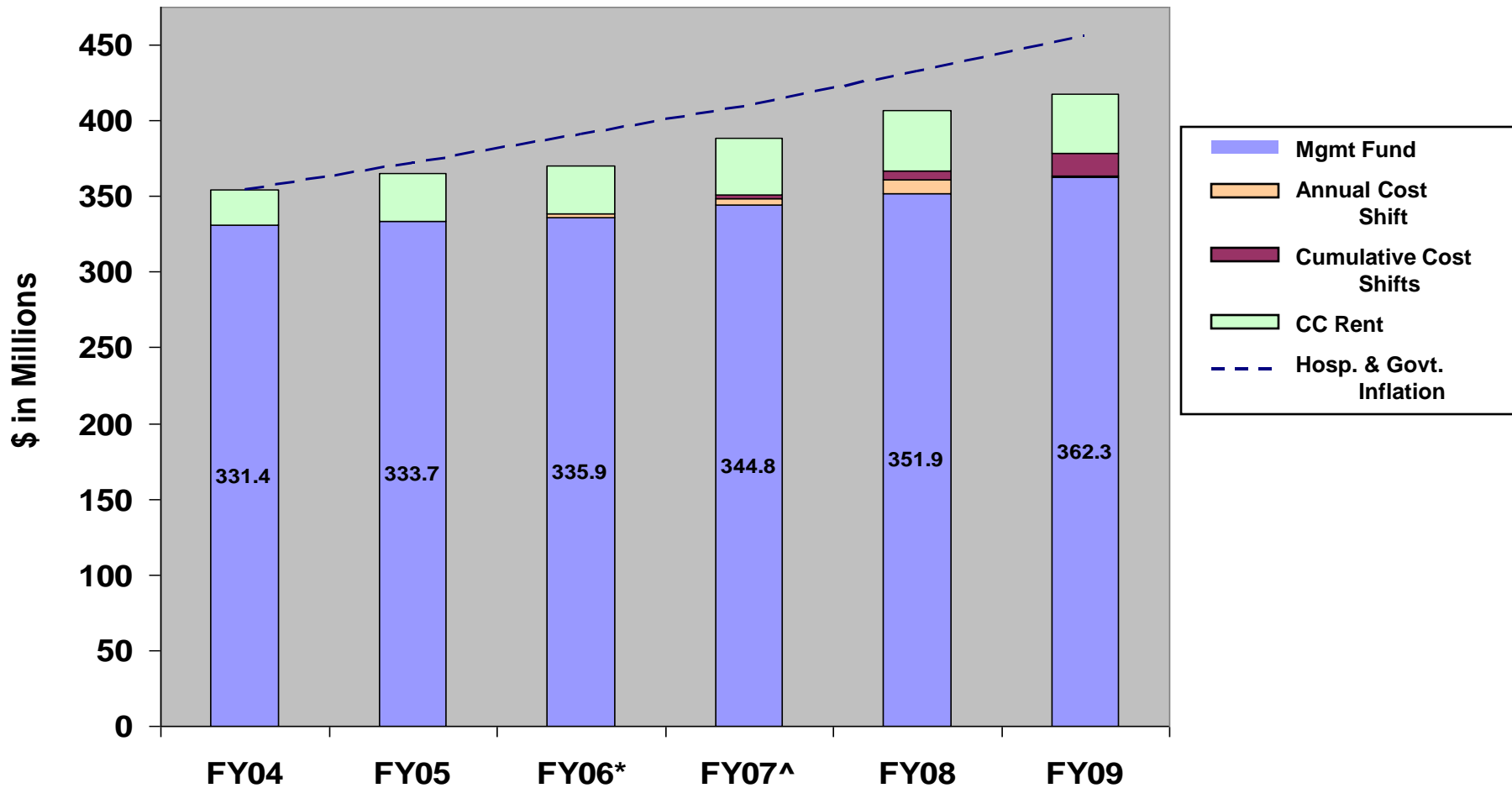
• Supports ~17 awards/year; 47 AHC partnerships

Next Steps: Secure stable long-term funding

The Key Challenges

- **Budget**
- **Patient Activity**
- **Protocol Activity**
- **PIs**

CC Budget FY 2004-FY 2010



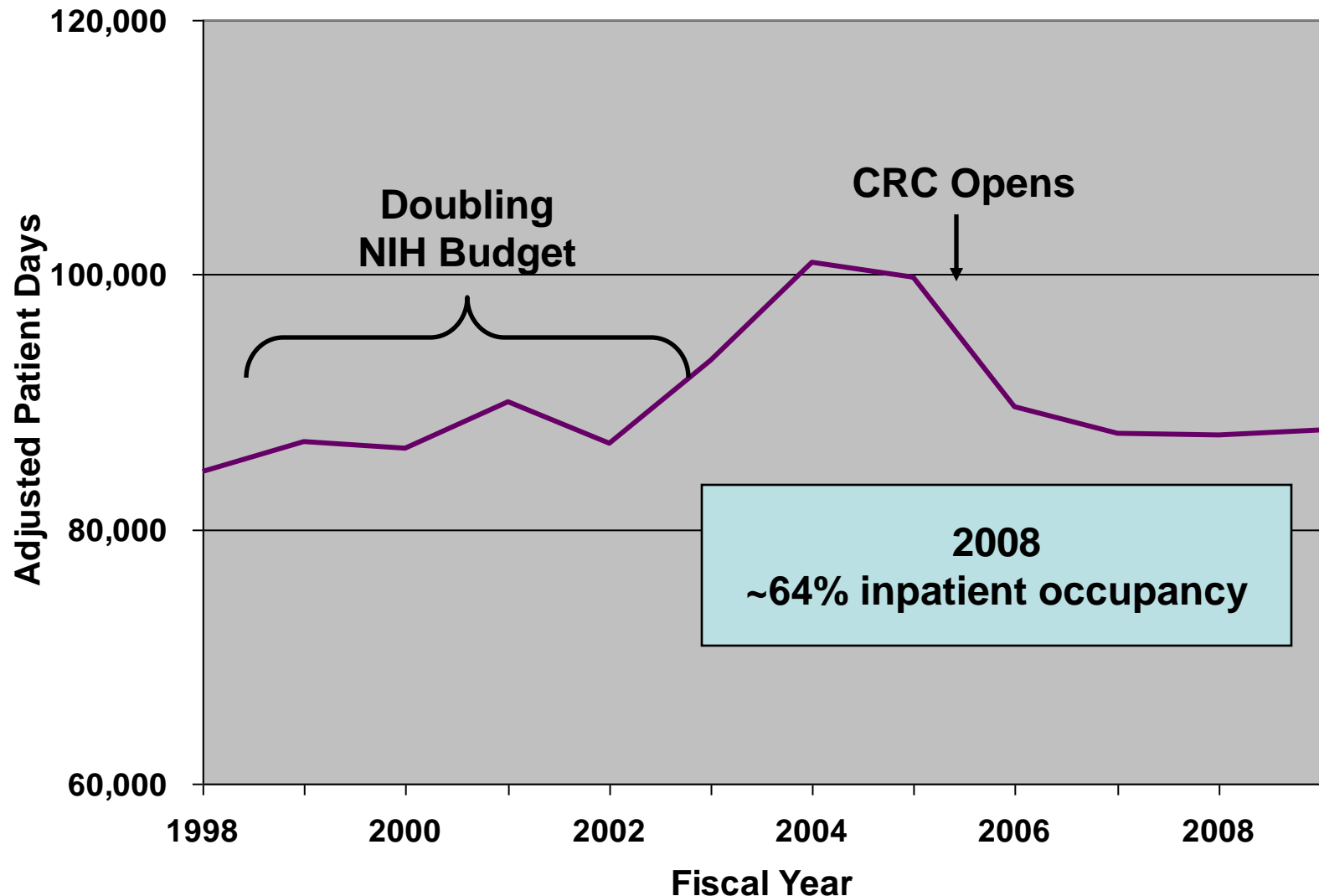
*FY06 includes budget neutral adjustments for security (\$2.2M) and NIBIB transfer (-\$1.5M).

^FY07 includes budget neutral adjustment for CRIS (\$6.5M)

Hospital inflation rate source: R-C Healthcare Management (Feb 12, 2008)/HFMA

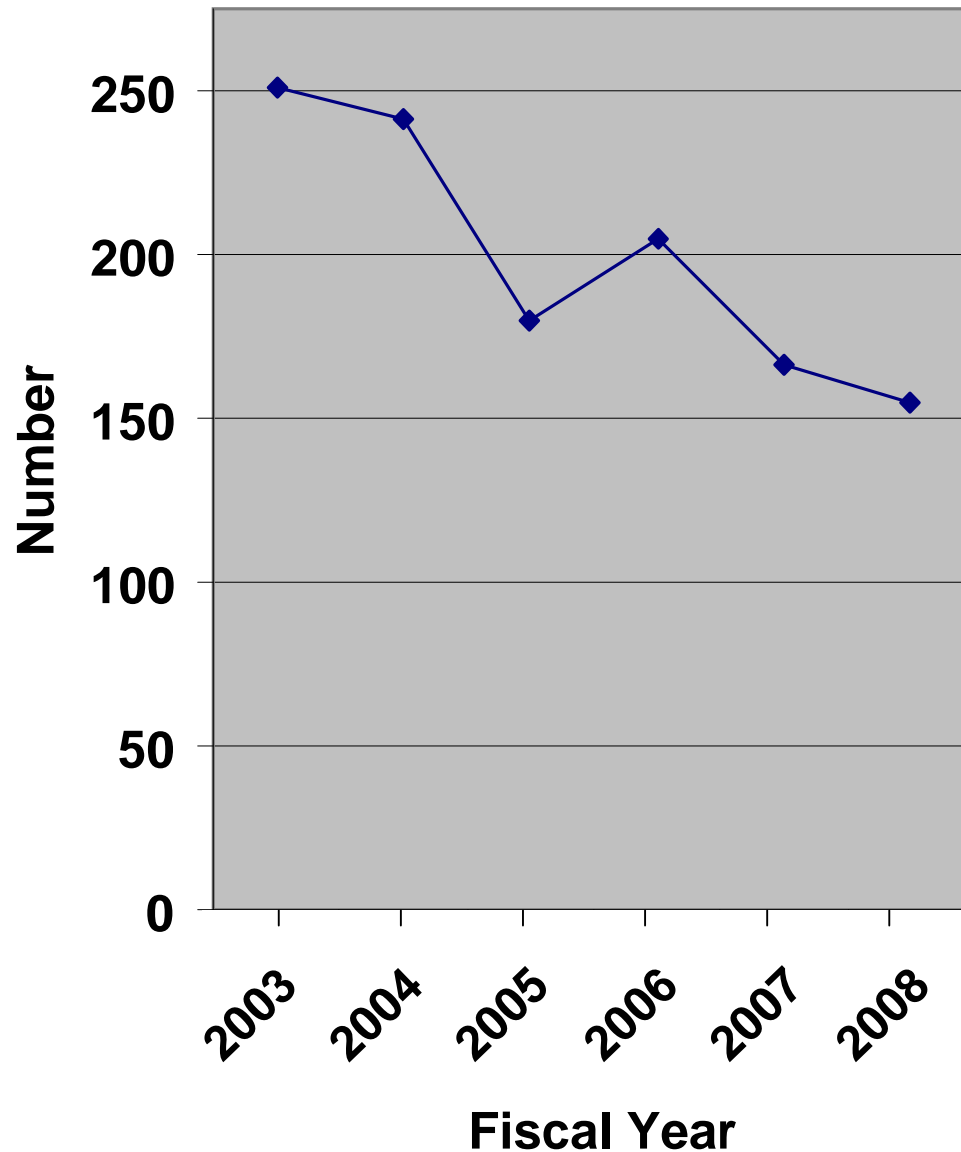
Adjusted Patient Days*

(FY 1998 – 2009)

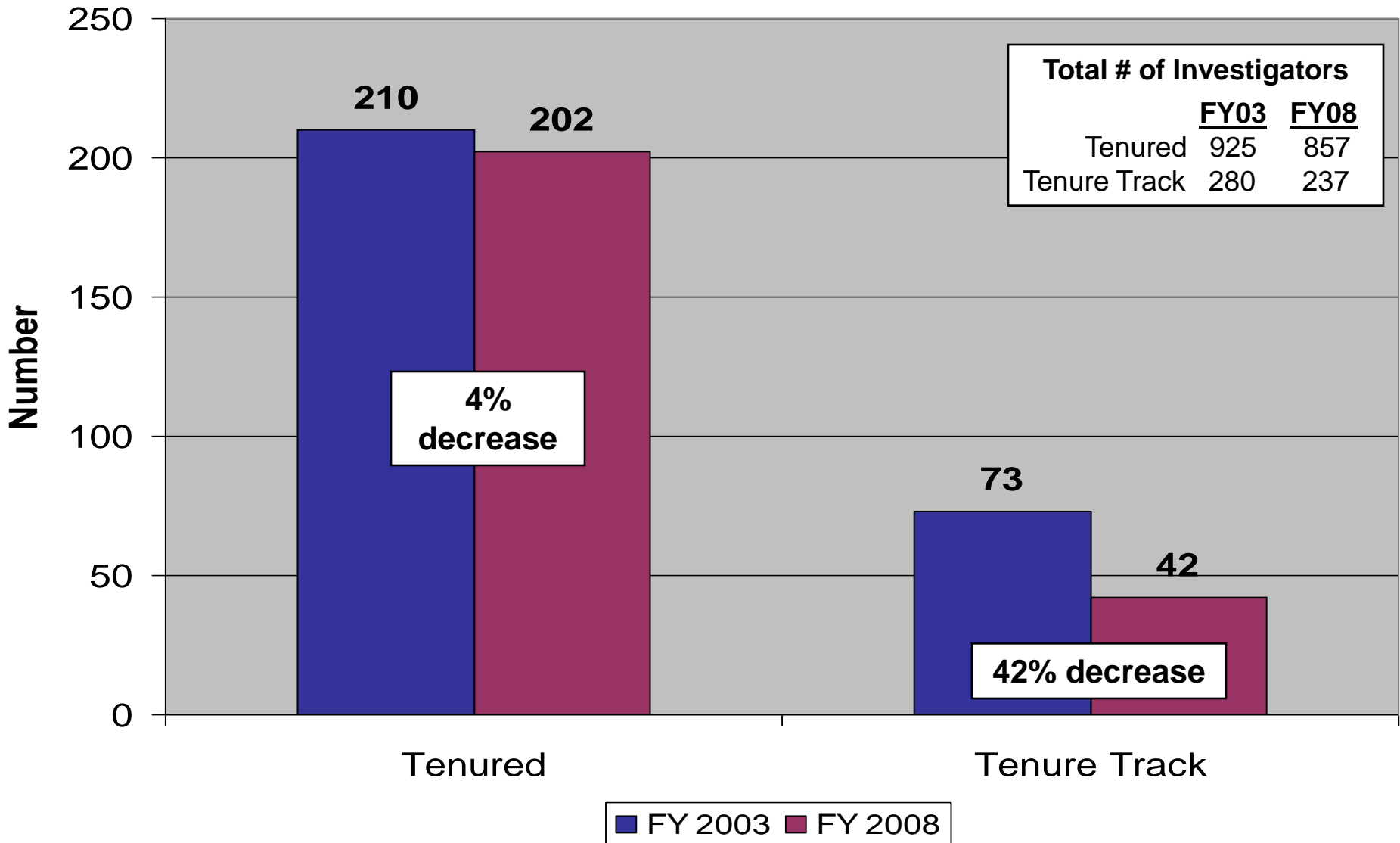


* Adjusted Patient Days = Inpatient Days + (Outpatient Visits x 0.4)

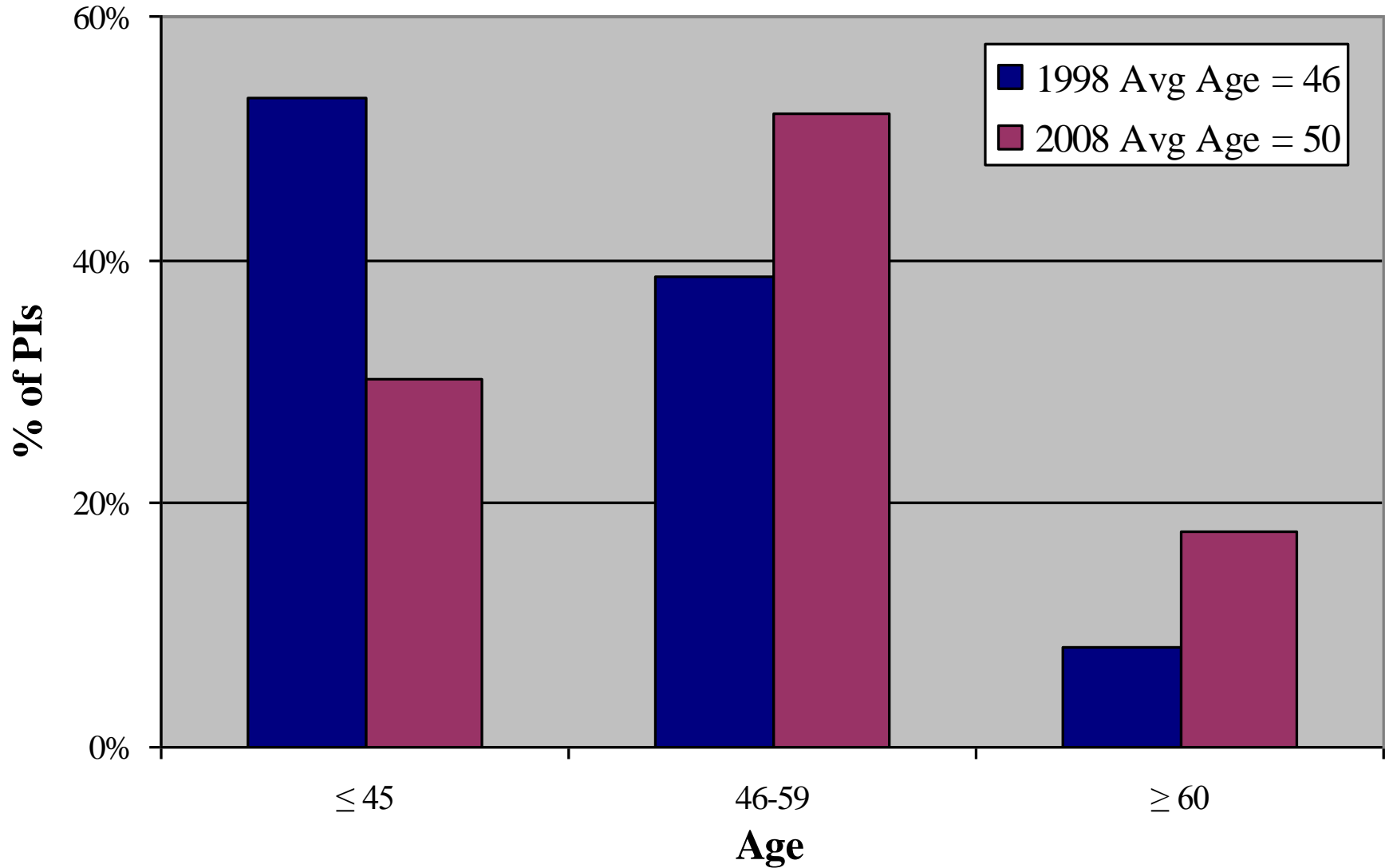
New Research Protocols



PIs on Clinical Protocols



Aging of Clinical PIs



Recruitment Challenges

- **Conflict of interest**
- **Expensive housing/childcare**
- **Salaries**

Summary

Key Challenges

- **Budget – 5 yr. relatively flat; prohibition of co-mingling intramural and extramural \$**
- **Patient Activity – untapped capacity**
- **Protocol Activity – # new protocols ↓**
- **Principal Investigators – ↓ tenure track; aging; recruitment challenges**

Opportunity

- **Strong infrastructure for clinical research, model for the nation, opportunity for future accomplishments**

Questions for the SMRB about the Clinical Center

- **Can we create a business model that makes the CC viable for the foreseeable future?**
- **How can we align the research requirements of the intramural research program with the new business model for the CC, and encourage intramural-extramural interactions?**