Accelerating Diversity in Clinical Research

Ninth Annual National Summit on Health Disparities

John I. Gallin, MD
Director NIH Clinical Center

April 23, 2012
Science in pursuit of **fundamental knowledge** about the nature and behavior of living systems... and the **application of that knowledge** to extend healthy life and reduce the burdens of illness and disability.

Francis S. Collins, M.D., Ph.D
Director, NIH
Challenges to Diversity in Clinical Research

- Insufficient Community-Based Research
- Insufficient Patient Awareness
- Minority Access to Clinical Trials
- Minorities in Medical Schools/Allied Health
- Minority MD’s ‘Pre-Screen’ and ‘Pre-Select’ Patients
- Lack of Pharma Outreach to Minority MD’s in Community
- Cost/Lack of Insurance
- Language/Linguistics/Literacy Challenges
- Inclusion Criteria
- Diversity Among Clinical Investigators
- Lack of Trust by Minority Providers and Patients
- Inclusion Criteria
- Minority Access to Clinical Trials
Accelerating Diversity in Clinical Research

Policy

Science

Practice
**NEW NIH POLICY - Patients**

**NIH Task Force for Inclusion of Women and Minorities in Clinical Research (2011)**

- Ensures inclusion of women, minorities and children
- Numbers must be adequate to allow valid analyses
- Cost issues should not exclude inclusion
- NIH initiates outreach efforts to recruit and retain women, minorities and children in clinical studies:
  - Populations considered during initial protocol review
  - Development of electronic tracking mechanisms to support the monitoring and tracking of these populations

*NIH Revitalization Act of 1993 (PL 103-43) includes a section entitled Women and Minorities as Subjects in Clinical Research to reinforce existing NIH inclusion policy*
The Patient Protection and Affordability Act eliminates challenge of eligibility restrictions for research participation due to insurance availability.
The NIH Clinical Center can serve as a test site to model solutions for accelerating diversity in clinical research.
Clinical Center Profile

- More than 450,000 patients since opening in 1953
- 240 beds
- 2012 budget $395.2M
- Hospital surrounded by research labs
- Every patient is on a research protocol
- Care is free
- Patient travel/housing provided as needed
- 2,250 CC employees + ~4,000 employees from 17 ICs that use hospital
- 1,255 credentialed physicians
- 1,513 active protocols
Clinical Center Mission

Science

Patient Care

Training
Major Emphasis

- First in human with new therapeutics
- Study of patients with rare diseases

18 – 25 million people in the United States have a rare disease!
Specialized Services and Facilities

• Phenotyping
  o Biomechanics laboratory
  o Metabolic chambers

• Cell Processing/GMP Facility
## CC Under-represented Minority Patients

<table>
<thead>
<tr>
<th></th>
<th>Clinical Center</th>
<th>U.S. Population</th>
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<tbody>
<tr>
<td>African American</td>
<td>16%</td>
<td>13%</td>
</tr>
<tr>
<td>Hispanics</td>
<td>7%</td>
<td>16%</td>
</tr>
<tr>
<td>Asian</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>American Indian/Alaskan Native</td>
<td>1%</td>
<td>3%</td>
</tr>
<tr>
<td>Pacific Islander</td>
<td>&lt;1%</td>
<td>1%</td>
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### ResearchMatch:
- National online clinical research recruitment registry
- Developed through CTSAs
- CC joined ResearchMatch in February 2012
  - 234 registrants
Accelerating Diversity in Clinical Research

Science

- A balanced research portfolio
- A balanced workforce
- Adequate resources
CC Balanced Research Portfolio

- Sickle cell anemia
- Rheumatic Diseases
- Renal Disease
- AIDS
- Prostate Cancer
- Stroke
- Obesity
- Diabetes
Established in 1999 to promote new partnerships between basic science and clinical investigators

**Goals:**

- Develop new clinical protocols to discover new therapeutics and devices
- Foster long standing collaborations
- Since 2006 Intramural and Extramural Investigator partnerships at the Clinical Center; 2 recent at Howard University
National Institute on Minority Health & Health Disparities (NIMHD)

• Bedside-to-Bench Program donor since 2006

• 19 projects funded to-date on these topics:
  • Sickle Cell Disease
  • Vascular Disease
  • Breast Cancer
  • Prostate Cancer
  • Obesity
  • Diabetes
  • Drug Addiction

John Ruffin, PhD, Director
Encouraging a More Balanced Workforce

- African Americans, Hispanics, and Native Americans:
  - Represent **31%** of U.S. college age population
  - Account for only **14%** of undergraduates in life sciences
- Racial barriers persist at later stages of career development
- Efforts to increase research workforce diversity:
  - Systematic effort to remove bias from peer review process
NIH Loan Repayment Programs
Facilitating the Path to a Biomedical Research Career

• 1998 U.S. Congress created eight loan repayment programs administered by NIH

• Repays up to $35,000 of eligible educational debt/year

• Applicants must commit to performing qualified research for at least two years

• Overall success rate is 51%

• Average debt is $96,484
Funding by LRP (New & Renewal)

- Clinical Research
- Pediatric Research
- Health Disparities Research
- Clinical Research LRP for individuals from Disadvantaged Backgrounds
- Contraception and infertility Research

Fiscal Year: 2003 - 2010

Funding (millions)
Accelerating Diversity in Clinical Research by Training Clinical Investigators

The Clinical Center has trained many of the leaders of academic medicine throughout the United States and abroad.
NIH Curriculum in Clinical Research

Introduction to the Principles & Practice of Clinical Research
>11,900 participants since course introduced in 1995

Principles of Clinical Pharmacology
>7,500 registrants since course began in 1998

Ethical and Regulatory Aspects of Human Subjects Research
>4,600 participants since course began in 1999
Since 1995, Over 30,000 students world-wide have participated in the NIH Curriculum in Clinical Research.

- Live course in China: 2008-2009
- Live course in Nigeria: May 2010
- Live course in Russia: November 2011
- Live course in India: October 2012
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Recruiting Investigators

• Need to engage medical and dental students early to “hook” them into a clinical research career.
Portfolio of Clinical Research Training Opportunities at the NIH CC

Combines HHMI & CRTP
Clinical Research Training Program (CRTP) Composite Demographic Data

1997 - 2012:

- 340 students (335 medical, 5 dental)
- 55 under-represented minority participants (16%)
- 53% alumni who have completed fellowships engaged in clinical research; 11% minorities
- 19 CRTP alumni have returned to the NIH for post-doctoral fellowships (3 are under-represented minorities)
- 2 CRTP alumni currently hold junior faculty/staff positions at the NIH (1 under-represented minority)
Student National Medical Association (SNMA) Leaders and the CRTP


Lisa Green, M.D. OB/GYN Resident, Howard University SNMA National President 2008-2009 CRTP Fellow 2008-2009

Michael G. Knight 4th year Cleveland Clinic Lerner College of Medicine Case Western Reserve University SNMA National President 2011-2012 CRTP Fellow 2010-2011
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Community Practice

- More minority patients
- More community-based research relevant to minorities
“...very small differences in the willingness of minorities to participate in health research compared to non-Hispanic whites.”

“...efforts to increase minority participation in health research should focus on ensuring access to health research for groups, rather than changing minority attitudes.”
THE DISTRICT is getting substantial help for the first time from the National Institutes of Health (NIH) in its urgent battle against the HIV/AIDS epidemic. A two-year, $26.4 million partnership aims to improve the city's ability to get people tested and into treatment.
Outreach for Sickle Cell Studies

• Collaborative research with Howard University Hospital & Children's National Medical Center

• Positive engagement with community based organizations

• 150-200 mostly African American patients enrolled in 5 NIH research protocols

• Physician exchanges between Howard and NIH:
  • On going emphasis on collaborative research with Howard University physician faculty

Gregory J. Kato, M.D.
Director, Sickle Cell Vascular Disease Section, NHLBI
Nursing Outreach: Health Disparities

Protocols targeted for Native Americans, African Americans & Hispanics:

1. 03-CC-0301 Health Beliefs and Health Behavior Practices, Including Complementary and Alternative Medicine Use, Among Minorities with Rheumatic Disease (collaboration with NIAMS)

2. 04-CC-0070 Exploring Patient-Provider Trust Among Individuals with End-Stage Renal Disease (collaboration with NIDDK and Walter Reed Army Medical Center)

Collaborations:
Nursing Research Focus: Creating a Clinical Research Infrastructure to Address Health Disparities in American Indians / Alaska Natives
“The role of the NIH Clinical Center should be to serve as a state-of-the-art national resource, …to enable both internal and external investigator use.”

http://smrb.od.nih.gov/
Goal of Opening Doors of Clinical Center

Access to:

• Special services

• New “Bedside to Bench and Back” partnerships with outside investigators
  • Awards
Conclusion

To Accelerate Diversity in Clinical Research we need to:

• Increase minority clinical investigators
• Increase clinical research protocols addressing minority issues
• Increase minority patient participation