

Presidential Commission for the Study of Bioethical Issues

August 30, 2011



Roger I. Glass, M.D., Ph.D.

NIH Associate Director, International Research
Director, Fogarty International Center



The Fogarty Mission



FOGARTY

- One of 27 Institutes & Centers of NIH
- Focus on training & research for global health
- Strategic Plan:
 - Global health includes both infectious diseases & non-communicable diseases
 - Emphasis on implementation
 - Training for research is key
 - Build partnerships to link US & foreign researchers & their academic centers
- 2010:
 - ~\$70m in grants & contracts
 - 400 separate grants
 - Focus on low- & middle-income countries



Rhode Island Congressman John E. Fogarty

Ethical and Scientific Implications of the Globalization of Clinical Research

Seth W. Glickman, M.D., M.B.A., John G. McHutchison, M.D., Eric D. Peterson, M.D., M.P.H.,
Charles B. Cairns, M.D., Robert A. Harrington, M.D., Robert M. Califf, M.D.,
and Kevin A. Schulman, M.D.

Globalization of international clinical trials

- Large increase in clinical research being conducted abroad
 - e.g. In 2007, US pharma phase 3 trials: 1/3 of trials & over 1/2 sites outside US

Reasons for shift

- Harsh bureaucratic & regulatory environment in US
- Cost per case overseas is often a fraction of cost in US

Problem

- Major concern is ethical oversight & training

“We must ensure the ethical & scientific integrity of clinical research globally, promote harmonization of international research, & provide information about the benefits & risks of new drugs and devices in the populations & environments in which patients live, wherever they may be.”

What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research

Ezekiel J. Emanuel, David Wendler, Jack Killen, and Christine Grady

Department of Clinical Bioethics, Warren G. Magnuson Clinical Center, National Institutes of Health, Bethesda, Maryland

Ethical principles and benchmarks for multinational clinical research

- ➔ • **Collaborative partnership**
- Social value
- Scientific validity
- Fair selection of study population
- Favorable risk-benefit ratio
- Independent review
- Informed consent
- Respect for recruited participants & study communities

The Fogarty Mission: A Decade of Bioethics



FOGARTY

- Build research ethics capacity in low- & middle-income countries
- Strengthen local input on ethical issues
- Address ethical controversies & dilemmas about research in low- & middle-income countries
 - E.g. Standards of care in HIV/AIDS research

To promote clinical global health research at NIH, it is imperative that we have a framework in place for the protection of human subjects



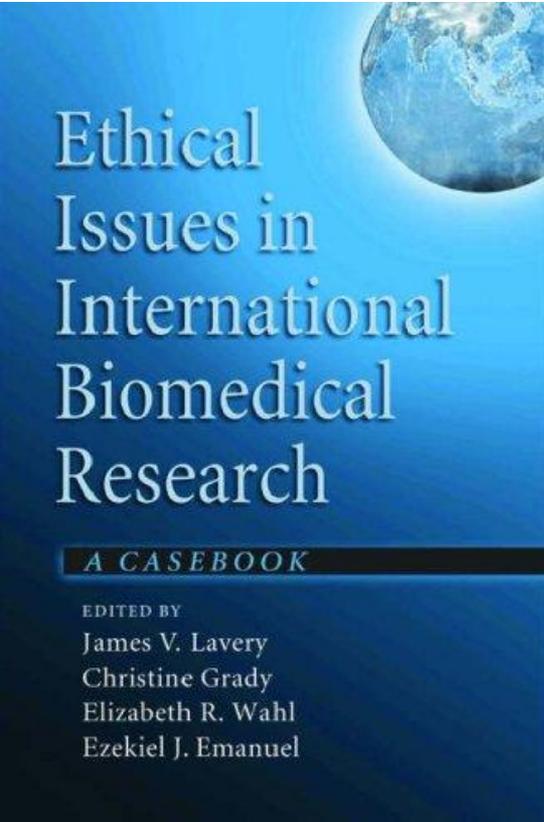
Global Forum on *Bioethics* in Research

Bethesda, Maryland
November 7-9, 1999

Recommendation: to train experts in bioethics

International Research Ethics Training Program (R25)

- Develop culturally relevant curriculum
 - Focus on clinical research in global health
 - Direct impact on distance learning
- Train professionals for leadership in bioethics



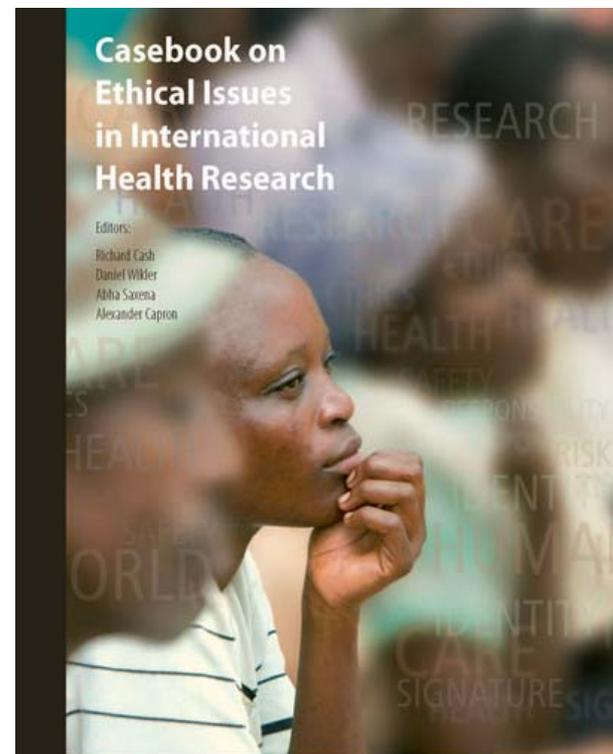
Ethical Issues in International Biomedical Research

A CASEBOOK

EDITED BY

James V. Lavery
Christine Grady
Elizabeth R. Wahl
Ezekiel J. Emanuel

- Masters level programs
- Courses to develop skills
 - Teach bioethics
 - Run IRBs & research review
 - Conduct ethics research
 - Write guidelines, papers & case studies



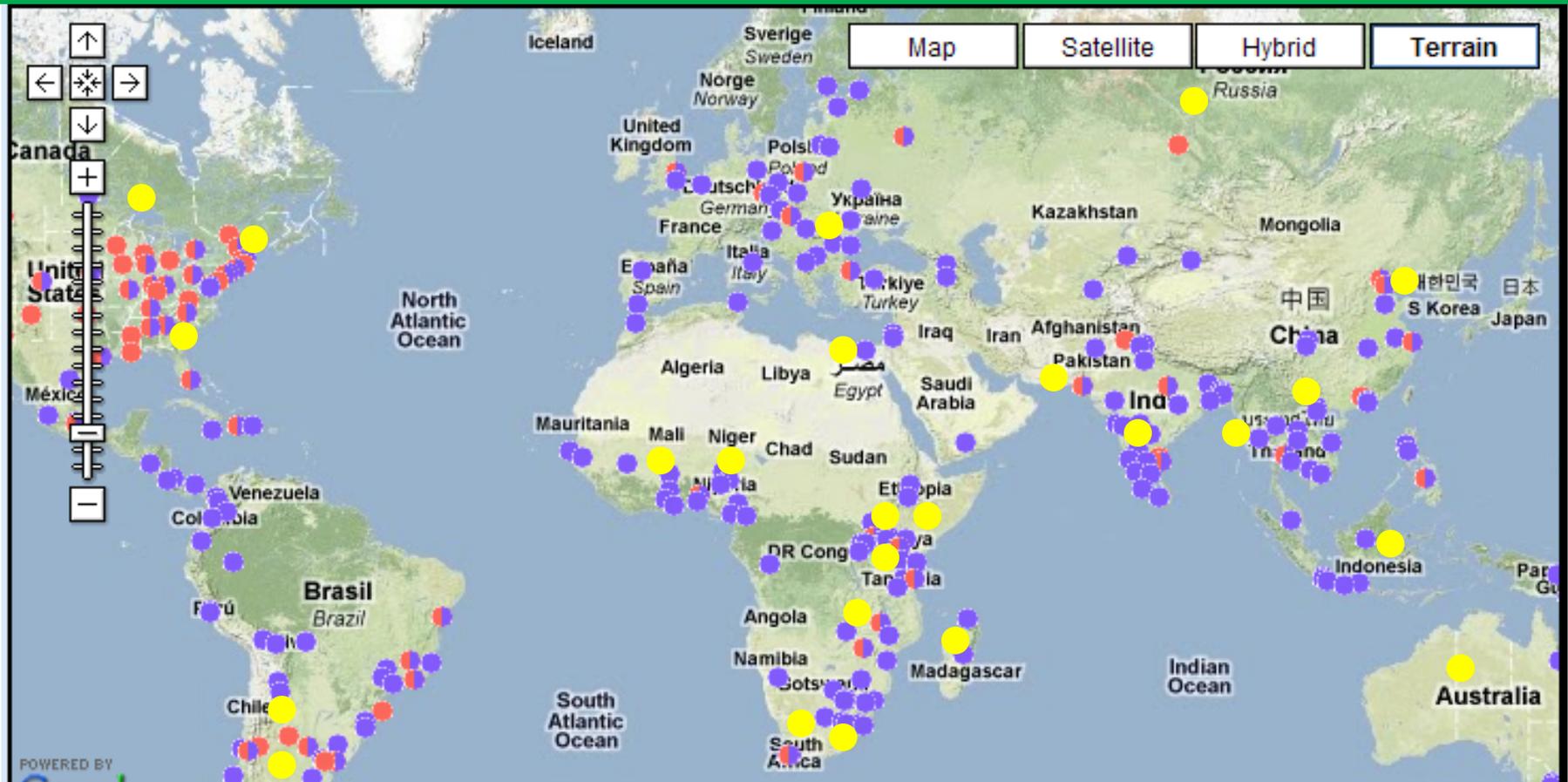
Casebook on Ethical Issues in International Health Research

Editors:
Richard Cash
Daniel Wikler
Abha Saxena
Alexander Capron

Fogarty Bioethics Sites (●), Awardees (●), Collaborators (●)



FOGARTY



Over 560 masters level bioethics trainees

Employment of Recent Bioethics Trainees: a snapshot



FOGARTY

First Name	PI	Training Start Date	Training End Date	Job Title	Major Emphasis	Employment Sector	Training Status	Research Area
MAYRA	MACKLIN, RUTH MEHENDALE,	01-01-2003, 01-01-2005, 01-01-2008, 02-01-2009	12-01-2004, 12-01-2007, 01-01-2009,	Member of the Provisional Commission, Master in Bioethics, Director of the School of Anthropology and Sociology, Director of the School of Sociology, Coordinator of the Program of Spreading of Chinese Culture	Administration, Administration, Administration, Administration	{Other}, {Other}, {Other}, {Other}	Post-Training, Post-Training, Post-Training, Post-Training	BEHAVIORAL AND SOCIAL SCIENCES
KAVITA	SANJAY	03-01-1989		Senior Executive Officer (Projects)	Teaching	{Other}	Post-Training	
GUSTAVO	MACKLIN, RUTH	03-01-2010, 03-01-2010		Member of Bioethics Committee, Professor	Policy, Teaching	{Other}, {Other}	Post-Training, Post-Training	
ADEMOLA	KASS, NANCY	01-01-2004		Associate Professor, Department of Health Promotion and Education, College of Medicine	Teaching	{Other}	Post-Training	
RUBÉN JORGE ALBERTO	MACKLIN, RUTH LOLAS FERNANDO	01-01-2010, 01-01-2010, 01-01-2010		Senior Member of the VIH/AIDS Interdisciplinary Commission at the SIBASI Center 2010, Specialist Advisor in Risk Assessment at the SIBASI Center 2010, Advisor Member of the Inter-sector Health Board at the Ayutuxtepeque's Local Council	Policy, Policy, Policy	{Other}, {Other}, {Other}	Post-Training, Post-Training, Post-Training	
ANGELICA	MACKLIN, RUTH	01-01-2004, 08-01-2004, 03-01-2008	12-01-2009, 08-01-2004, 08-01-2008	Technical Secretary of the Epidemiology Professors College, Guest professor at the Actualization in Public Health and Epidemiology Program, Professor in Research Ethics	Research, Teaching, Teaching	{Other}, {Other}, {Other}	Post-Training	
(REVEREND) JOHN	KASS, NANCY	10-01-2006	01-01-2008	Associate Professor of Bioethics, Dean of Faculty of Allied Health Sciences, Associate Professor and Head of Department	Teaching, Teaching, Teaching	{Other}, {Other}, {Other}	Post-Training	
MELBA-DE-LA-CRUZ	LOLAS FERNANDO	01-01-2008		Responsible rational use of drugs	Administration	{Other}	Post-Training	
NICOLA	KASS, NANCY	09-01-2009	09-01-2011	NIH Dept of Bioethics Fellow	Research	{Other}	Post-Training	
MARIA	MACKLIN, RUTH			Legal Assessor in Bioethics (Health and Integration Area)	Policy	{Other}	Post-Training	
CATALINA	LOLAS FERNANDO	01-01-2009, 01-01-2010	01-01-2012	Director Medical administration and genetic counseling, Medical advisor vaccine development MSD Pharmaceutic	Administration, Research	{Other}, {Other}	Post-Training	
ELIZABETH	MACKLIN, RUTH	04-01-2010, 01-01-2006, 03-01-2008	07-01-2009	Director of the Master in clinical research and epidemiology, University teacher, External Examiner of Reserch Programs	Teaching, Teaching, Teaching	{Other}, {Other}, {Other}	Post-Training	
BLANCA	LOLAS FERNANDO	01-01-2007, 03-01-2008, 01-01-2007		Researcher Dept of Studies and Publications National Library of Congress Chile, Faculty, Coordinator Teaching and Research EJESALUD Ltda	Research, Teaching, Teaching	{Other}, {Other}, {Other}	Post-Training	
ALEXANDRE	LOLAS FERNANDO	06-01-2004		Researcher	Research	{Other}	Post-Training	
JOSELINE	KASS, NANCY			Health Champion		{Other}	Post-Training	
ANA LAURA	LOLAS FERNANDO	01-01-2008		Assistant Professor	Teaching	{Other}	Post-Training	

Member of the Provisional Commission, Master in Bioethics, Director of the School of Anthropology and Sociology, Director of the School of Sociology, Coordinator of the Program of Spreading of Chinese Culture

Senior Executive Officer (Projects)

Member of Bioethics Committee, Professor

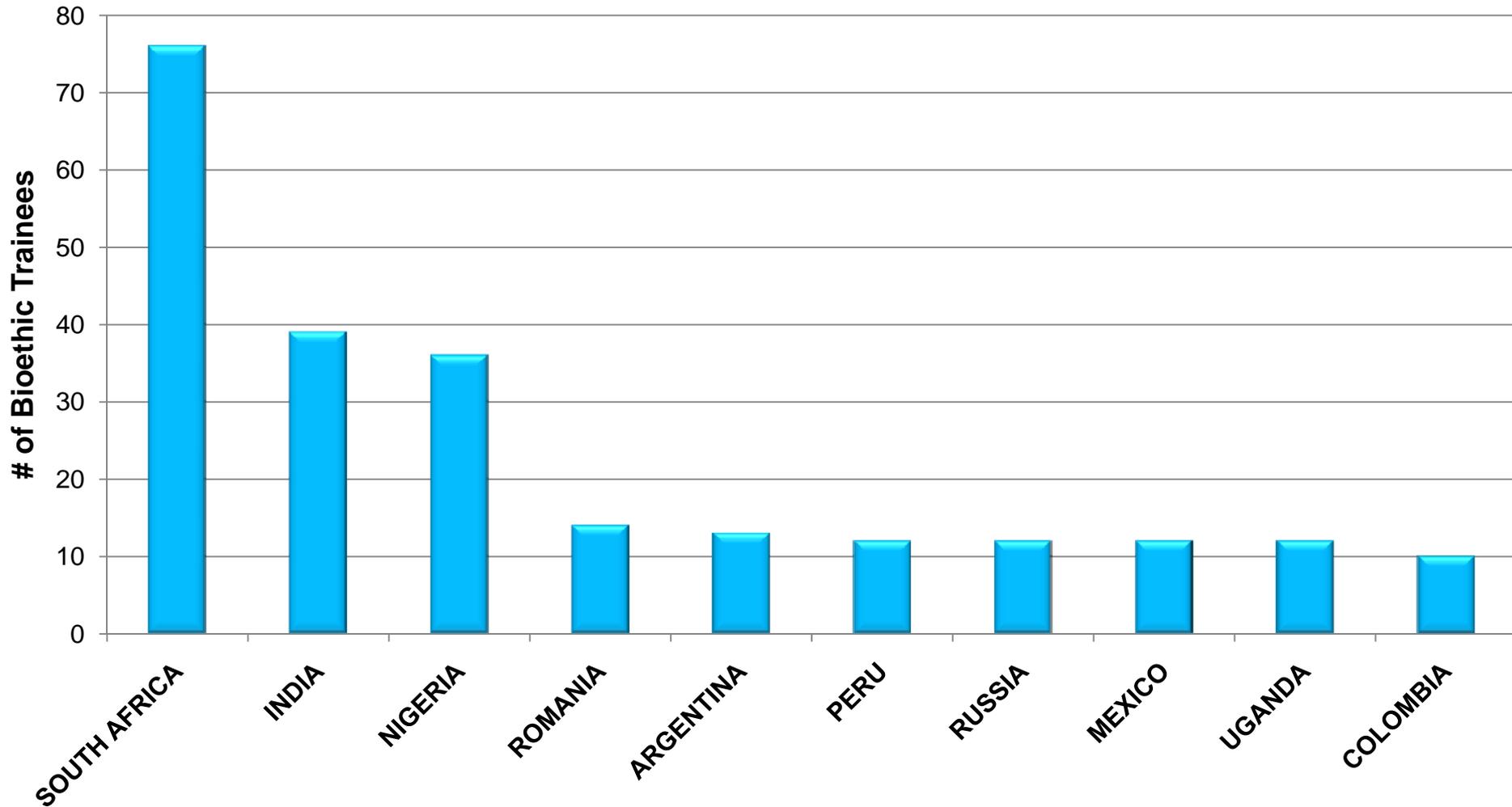
Associate Professor, Department of Health Promotion and Education, College of Medicine

Senior Member of the VIH/AIDS Interdisciplinary Commission at the SIBASI Center 2010, Specialist Advisor in Risk Assessment at the SIBASI Center 2010, Advisor Member of the Inter-sector Health Board at the Ayutuxtepeque's Local Council

Countries with the most Long-Term Bioethics Trainees



FOGARTY

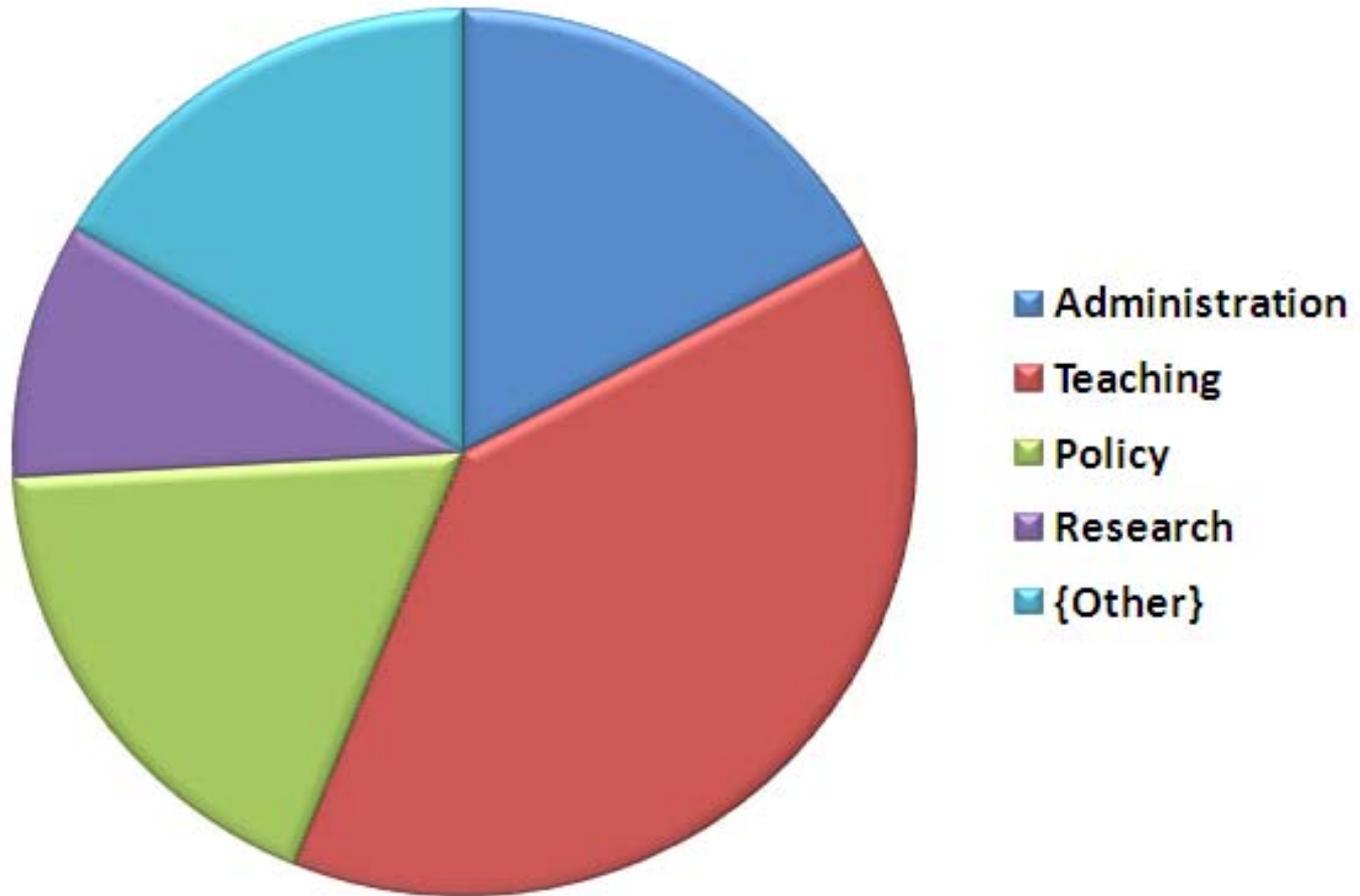


Data: CareerTrac

Major Emphasis of Employment



FOGARTY



N= 78 with a Post-Training Employment Reported in CareerTrac

Data: CareerTrac

Nigeria: Grantee Transforming the Bioethics System



- **Results (2005-2010)**

- 8 Faculty - Masters degrees at JHU, Case Western, U. Toronto
- 21 Masters U. Ibadan students
- Over 1000 West African researchers-
- ethics short courses

- **Transformed Nigerian National Ethics System**

- Re-established, chaired & provided member training- National Health Research Ethics Committee, MOH

-  **Drafted Nigerian National Code for Research Ethics**

- Created web-based research protocol tracking system
- Initiated or strengthened 25 IRBs

- **Leadership in Ethics & Genetics in Africa**

- Member, HAPMAP Consortium
- Co-chair, Ethics Subcommittee H3 Africa
 - Host “Ethics & Genomics Research in Africa” Conference Nov 2011



Clement Adebamowo



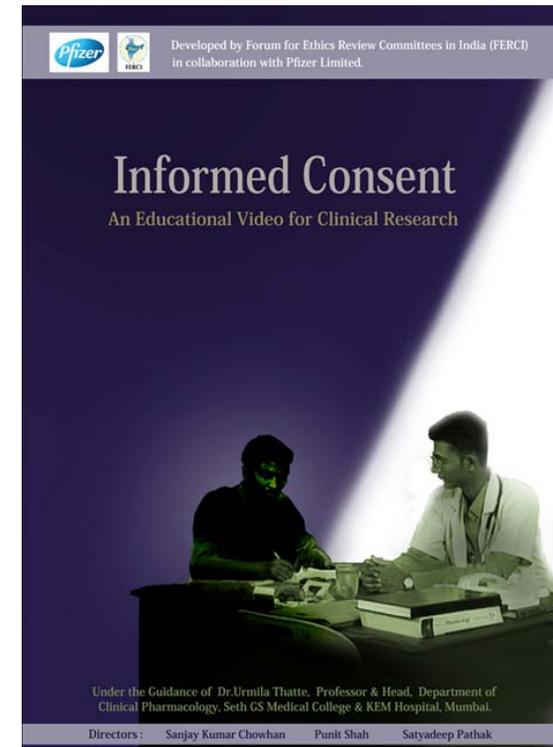
University of Ibadan

India: From Trainee to National Leader



Nandini Kumar

- **Masters in Bioethics – U. Toronto 2002**
- **Bioethics Training Program Results (2004-2011)**
 - 5 Western IRB ethics committee management trainees
 - 51 long term trainees
 - 18 intensive workshops/courses in 11 cities
 - Initiated distance learning Diploma & Masters through Indira Gandhi National Open University- mandatory for all REC members in India
- **ICMR Deputy Director General-Bioethics, Clinical Pharmacology & Traditional Medicine Research**
- **Bioethics Activities**
 - **India**
 - Member, ICMR Secretariat - Ethical Guidelines
 - Member, ICMR Central Ethics Committee for Human Research
 - Steering Committee, created Forum for Review of Ethics Committees in India (FERCI)
 - **International**
 - Member, SciDev.Net Advisory Panel- Ethics of Research in Developing Countries
 - ICMR Representative to IAVI Consultation on HIV Vaccine Trials
 - Member, International Research Panel of the U.S. President's Bioethics Commission



South Africa: From Trainee to Academic Bioethicist



FOGARTY

- **Masters in Bioethics – U. Toronto 2003**
- **HIV/AIDS-related Bioethics Activities**
 - Head: Bioethics & Health Law Program, Center for AIDS Program of Research in South Africa (CAPRISA), NIH AIDS Prevention Clinical Trials Network
 - Columbia University-Southern Africa Fogarty AITRP Scientific Advisory Committee
 - Member: NIH International Therapeutic DSMB (Africa)
 - Member: WHO Task Force on Addressing Ethical Issues in TB Control Program Epidemiology & Clinical Research (NCHECR), U. New South Wales, Australia
- **Extensive HIV/AIDS-related Bioethics Publications**
 - Key issues: HIV drug rollout, microbicide trials
 - High impact factor journals: BMJ, Lancet, Nature, PLoS Med



Jerome Singh



Building Ethics Research Capacity - The Way Forward -1



State of play

- We project huge increases in clinical research in low- and middle-income countries in the next decade
- We cannot adequately protect human subjects without a substantial increase in infrastructure and training in bioethics
- Fogarty has played a unique role in addressing this need thus far

Building Ethics Research Capacity - The Way Forward -2



Future Challenges

1. **Ethics starts at home:**

Everyone engaged in research on human subjects needs grounding in first principles of bioethics & understanding of their own accountability

- Challenge 1: How do we adequately train the next generation of researchers to learn & embrace these principles?

2. Global health research has evolved **from parachutes to partnerships:** Ethics practice must follow

- Challenge 2: How do we build independent local bioethics capacity & programs?

3. **Sustainability** of all bioethics programs for training, service & research is critical

- Challenge 3: How can bioethics programs for global health be made sustainable?

Masters in Bioethics, Class of 2010, Aga Khan University, Karachi, Pakistan



FOGARTY

