

Fogarty International Center

The Evolving Biomedical Research Ethics Environment in Africa





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

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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



Global Forum on *Bioethics* in Research

- Bethesda, Maryland
- November 7-9, 1999

Recommendation:
Train experts in bioethics

Ethics committees recorded for 20 African countries

Rwabihama, Girre, Duguet (2010) J. Med. Ethics 36:243-249 Table 1



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Committee (Country)	Year of creation	Year of continuous establishment	National board (name, year)	Total committees
IRB, Witwatersrand (South Africa)	1967	1990	NHREC, 2003	34
IRB, Ibadan (Nigeria)	1980	2002	NERB, 2003	30
IRB (Tanzania)	1980	2003	NHRERC, 2002	6
IRB (Ghana)	1985	2003	NBC, 2007	6
IRB (Gambia)	1980	2002	Gov/MRC	1
EC (Cameroon)	1995	2002	CNE, 1987	2
EC (Mali)	1994	2001	CNESS, 2002	3
EC (Benin)	1999	2002	CNERS, 2004	2
EC (Burkina Faso)	2001	2002	CERS, 2002	4
EC (Gabon)	1998	2002	CNE, 2009	2
EC (Guinea)	1999	2004	CNB, 2009	2
EC (RD Congo)	2003	2005	CNB, 2009	3
EC (Senegal)	2002	2003	CNERS, 2004	1
EC (Togo)	2003	2005	CCNB, 2007	1
EC (Rwanda)	1986	2003	CNER, 2003	1
EC (Sudan)	1979	2001	NEC, 2003	3
IRB (Egypt)	1996	2002	EGY/NCB	2
IRB (Libya)	2000	2004	LPNCBB	4
IRB (Zimbabwe)	1974	2000	MRCZ	3
IRB (Kenya)	1982	1999	NCST	4

Constraints hindering operations of ethics review committees (ERCs)

Nyika, et al. (2009) J. Med. Ethics 35:189-193



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Constraints	Number of ERCs*
Insufficiency of resources	25/30
Lack of/insufficient expertise on ethical review	13/30
Pressure from researchers	11/30
Lack of active/consistent participation of members	11/30
Lack of recognition of the importance of ERC functions	11/30
None or poorly supported by the institute	10/30
Not completely independent	4/30
Pressure from sponsors	3/30
Unequal treatment of applicants in review	1/27
Biased committee members	0/27

The Structure & Function of RECs in Africa

Kass, et al. (2007) PLoS Medicine 4(1):e3



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REC Funding	Number of RECs (n=12)
No operating budget	6
Government support	2
Foreign agency	1
Review fees	6
Paid staff	5
Paid members	4

The Structure & Function of RECs in Africa

Kass, et al. (2007) PLoS Medicine 4(1):e3



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# Protocols reviewed (n=12)	8-12	3
	30-50	3
	100-250	5
	~600	1
	Review all protocols	7
	Review only if funder required	5
Committee Focus (n=12)	Science, Ethics, Budget	4
	Science & Ethics	4
	Science only	2
	Ethics only	1

Duration of training of committee members

Nyika, et al. (2009) J. Med. Ethics 35:189-193



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Duration of training	Number of committee members
None	132
1 day	13
2–3 days	42
4–7 days	92
>7 days	48
Online training	14
Not known	4
Total	345

Training needs of ERCs in Africa, ranked by respondents

Nyika, et al. (2009) J. Med. Ethics 35:189-193



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Training needs	Very important	Quite important	Important	Not important	Total institutions
Scientific design issues in intervention trials	27		2		29
Determination of potential risks of vaccine research	25	3		1	29
Determinations to run phases (I,II,III) in a country or community	25	2	1		28
Monitoring and oversight	23	5	1		29
Post-trial access to benefits (e.g, successful intervention)	20	6	1	1	28
The interpretation of preclinical studies	19	7	3		29
The use of placebo in controlled trials	16	9	3	1	29
Assessment of understanding for informed consent	16	10	1	1	28
Assessment of anticipated benefits	15	8	5	1	29
Assessment of cultural sensitivity for informed consent	15	9	3	1	28
Community participation	14	11	3	1	29
Determination of appropriate subject selection in vulnerable population	14	8	5	1	28
Determination of appropriate subject selection with regard to women	13	6	8	1	28
Incentives for participation	12	10	5	1	28
Social and behavioral studies	12	10	6	1	29
Privacy and confidentiality	11	13	4	1	29
Determination of appropriate subject selection with regard to minors	11	9	6	1	27

Goals of the FIC International Research Ethics Training Program



- Develop socio-culturally relevant, masters level international research ethics curricula including:
 - Foundational ethics theory
 - International guidance
 - LMIC research case studies
 - Practicum opportunities
- Develop LMIC researchers, health professionals & academics in positions to have immediate impact at their institutions with in depth bioethics expertise in order to:
 - Train others in research ethics
 - Lead ethical review of research
 - Contribute to discussion of ethics issues in LMIC research
 - Develop institutional, national and international ethics guidance

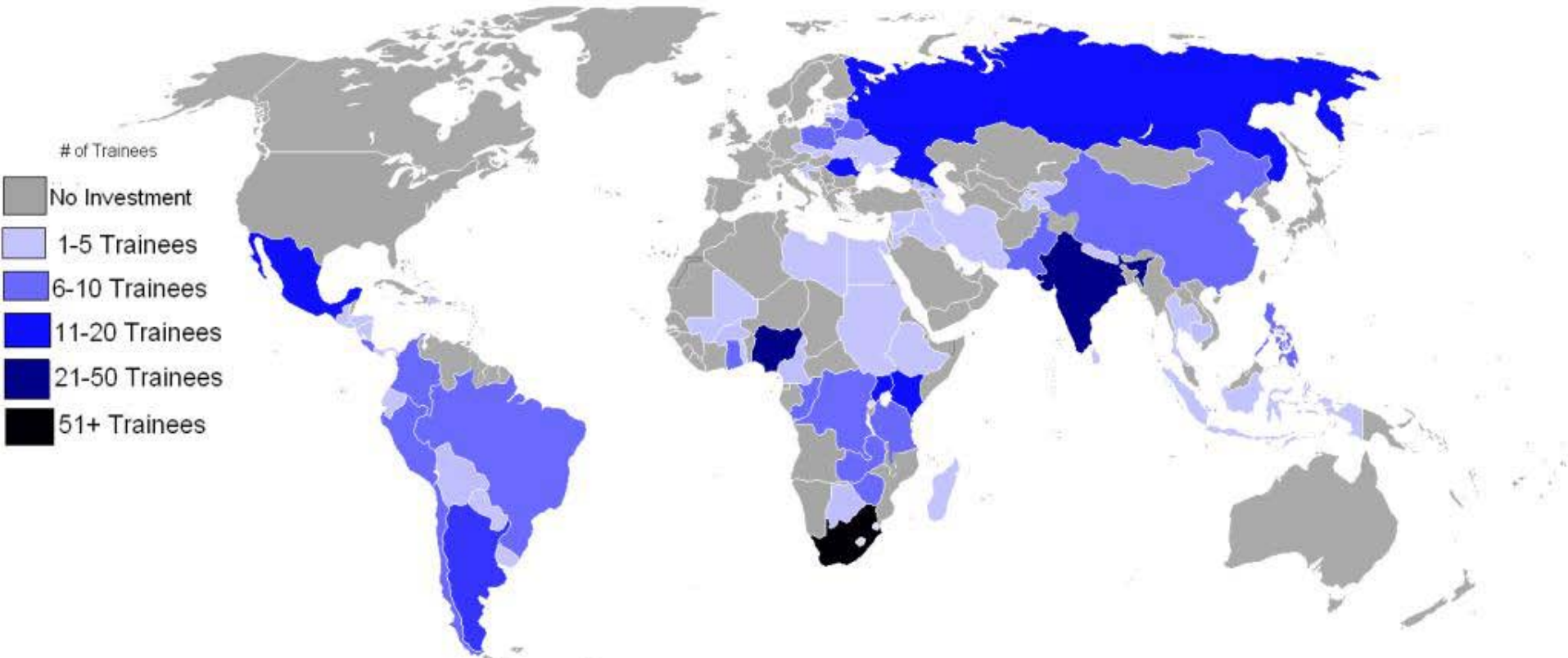
International Research Ethics Training Programs- Masters Level



Africa	Asia	L. America	E. Europe	Middle East
Johns Hopkins U.	Yale- Central South Univ. Xiangya SoM China	FLACSO- Argentina- Einstein U.	Union U./U. Vilnius, Lithuania	U. Maryland-Egypt
UMD-U. Ibadan Nigeria	India Centers Med.Research	Vanderbilt/U. Costa Rica	CWRU-Russia, Romania	
U. KwaZulu-Natal	U. Toronto- India, Pakistan	U. Miami-6 LAC Inst.		
U. Indiana- Moi U. Kenya	U.Washington- U. Indonesia	U. Chile		
UNC-Belgium-U. Kinshasa	Aga Khan U, Pakistan			
U. Toronto- Nigeria, Ghana				
Stellenbosch U- South Africa				
Dartmouth/Penn- Muhumbili U-TZ				



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FIC Research Ethics Trainees

- ~560 Trainees 2001-2011
- ~50% African Trainees

The Structure & Function of RECs in Africa

Kass, et al. (2007) PLoS Medicine 4(1):e3



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Characteristic	# RECs (n=12)	Trainee Initiated
FWA	6	3
Members Trained	10	6
SOPs	9	5
Annual reviews	2	2
Amendment reviews	12	4

Nigeria: Grantee Transforming the Bioethics System



- **Results (2005-2010)**

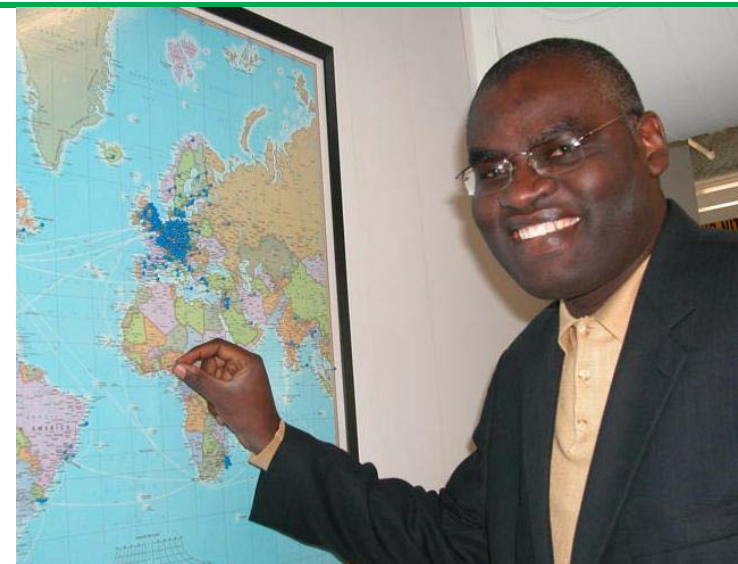
- 8 Faculty - Masters degrees at JHU, Case Western, U. Toronto
- 21 Masters U. Ibadan students
- Over 1000 West African researchers-ethics short courses

- **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, NHGRI Ethics Subcommittee H3 Africa-hosted “Ethics & Genomics Research in Africa” Conference Nov 2011



• **Clement Adebamowo**



• **University of Ibadan**

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



Research Ethics Updates: RCR Training



FOGARTY

- **New RCR Training Guidelines**
 - Required section in FIC research training grant applications
 - Required annual progress reporting
- **Supplements for RCR courses in Africa**
 - Essex, Myron/Harvard School of Public Health-Supplement for Responsible Conduct of Research Training at BHP (**Botswana** Harvard Program)
 - Kanya, Moses R./Makerere University College of Health Sciences-Supplement for Training in RCR in **Uganda**
 - Mugenyi, Peter N./Joint Clinical Research Centre, Uganda-Responsible conduct of research Training at the JCRC (Joint Clinical Research Centre, **Uganda**)
 - Murphy, Robert Leo/Northwestern University- Supplement for RCR Training at University of Ibadan (**Nigeria**)
- **RCR training & IRB development at MEPI sites**

Medical Education Partnership Initiative (MEPI)



U.S. Department of Health and Human Services
HRSA
Health Resources and Services Administration



USAID
FROM THE AMERICAN PEOPLE

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- Kenya

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- Mozambique

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- Nigeria

[University of Ibadan](#)

- South Africa

[University of KwaZulu-Natal](#)

[Stellenbosch University](#)

- Tanzania

[Kilimanjaro Christian](#)
[Medical Centre](#)

- Uganda

[Makerere University](#)

- Zambia

[University of Zambia,](#)

- Zimbabwe

[University of Zimbabwe](#)



Just the Beginning.....



FOGARTY

- New African voices in international research ethics-refocusing the discussion
- Building workable systems in African settings
- Ethics career development
- Sustainability
- Reaching non-Anglophone Africa
- Ethics related to upcoming research in Africa more complex (especially HIV/AIDS)



JOHN E.

U.S. National Institutes of Health

FOGARTY INTERNATIONAL CENTER

FOR ADVANCED STUDY IN THE HEALTH SCIENCES

News & Alerts

➔ Global Health Matters newsletter, July-Aug. 2008 [PDF 3.8M]

➔ Fogarty Releases New Strategic Plan

➔ New NIH Public Access Policy

➔ How to Apply for or Manage a Grant

➔ New FIRCA program announcements. Receipt date is Sept. 29, 2008.

➔ Fogarty intends to reissue: Informatics Training for Global Health (D43) in November.

➔ Current funding opportunity listed for the International Cooperative Biodiversity Groups (ICBG). Receipt date is October 21, 2008.

PROGRAMS

FUNDING

NEWS

ABOUT



Funding

- Research Grants
- Research Training Grants
- Dates & Deadlines
- How to Apply for or Manage a Grant
- Directory of Grants and Fellowships
- Funding Strategy

News & Outreach

- Announcements & News Releases
- Global Health Matters newsletter
- Calendar of Events
- Fogarty Grantee Publications
- Fogarty Publications
- Staff Publications
- International Polar Year

International Services

- Passports and Visas

Programs & Divisions

- International Epidemiology and Population Studies
- International Relations
- International Science Policy, Planning and Evaluation
- International Training and Research

About Fogarty International Center

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Spotlight



Top AIDS trainees salute Fogarty