

Ethical, Political and Social Issues in Joint Ethics Review: Lessons from the Indiana University/Moi University Academic Research Ethics Partnership

Eric M. Meslin, Ph.D.

Director, Indiana University Center for Bioethics

Associate Dean for Bioethics, IU School of Medicine

Professor of Bioethics

Director, IU-Moi Academic Research Ethics Partnership



INDIANA UNIVERSITY
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GLOBAL FORUM
On Bioethics in Research
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Disclosures

- No commercial relationships/interests
- Prior consulting arrangement (within last three years, with Eli Lilly & Co.)
- Member of Science and Industry Advisory Board, Genome Canada (honorarium)
- Contractual relationship with Ethical, Social, Cultural Program in Global Health, University of Toronto
- Grant Support: NIH: UL1TR001108; 2 R25 TW006070-05

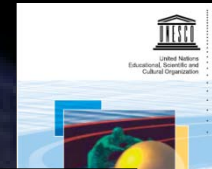


Ways of Achieving Efficient, Multi-Center Review

Top Down



Bottom Up



Top-Down Strategies

- *Agree to comply* with common regulations, rules (conditions of funding, e.g., OHRP Assurance)
- *Accept universal principles* adopted by recognized organizations (e.g., Helsinki, CIOMS)
- *Interpret and apply locally* by ensuring that each ERC independently works towards efficiencies, avoiding duplication, improving training quality

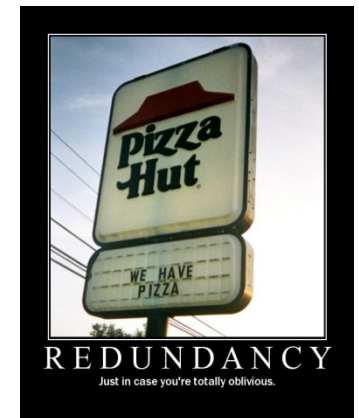


James V. Lavery
Christine Grady
Elizabeth R. Wahl
Ezekiel J. Emanuel



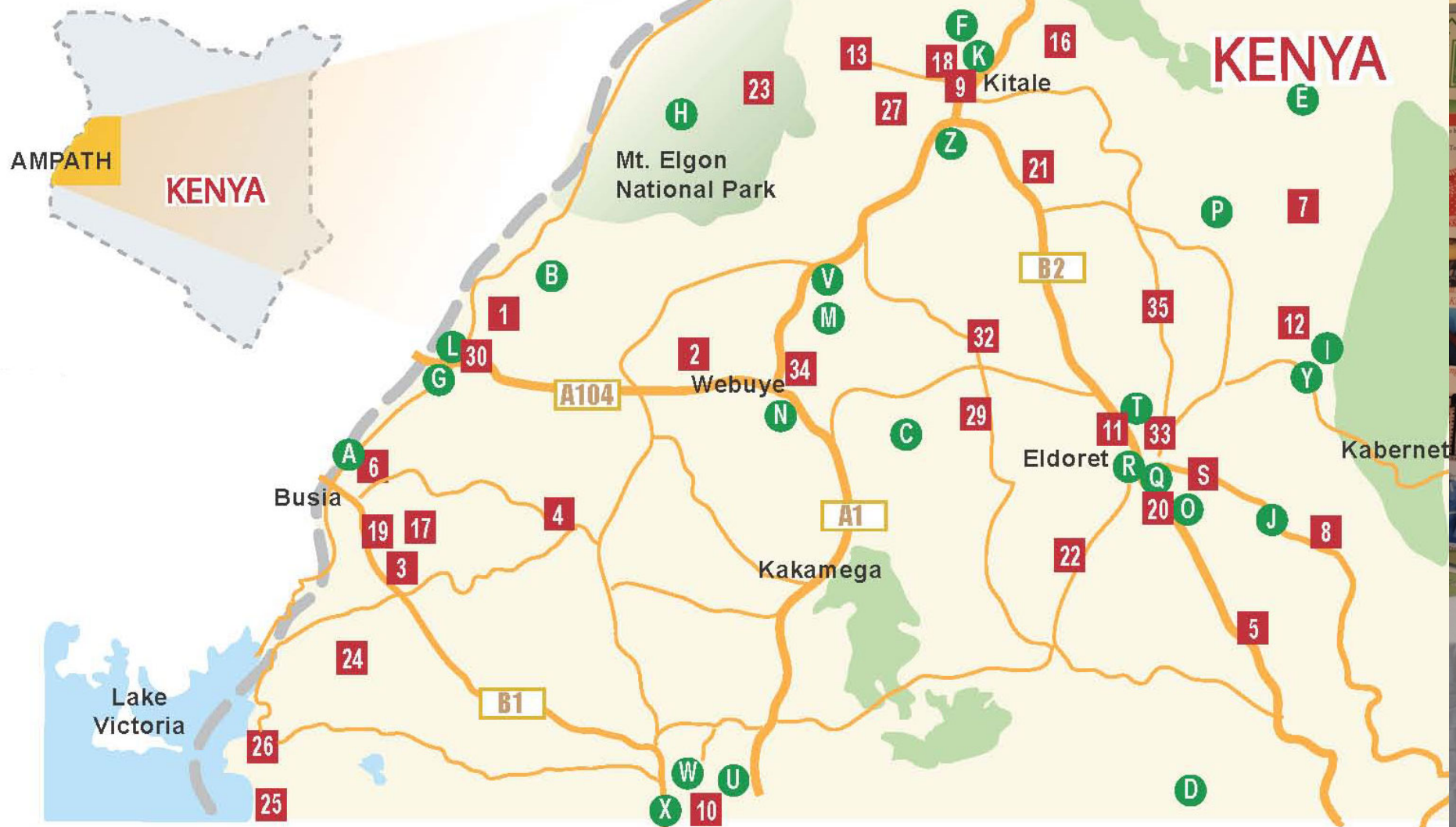
What Problems Does Collaborative Review Claim to Solve?

- **Time:** Reviews take longer to complete with multiple committees (inefficiency and asynchrony)
- **Redundancy:** Multiple reviews may add little 'value' (no additional protections)
- **Expertise:** Some ERCs are less skilled than others (quality)



Our Experience with Ethics Review: Moi University and Indiana University





Growth in grant numbers managed by RSPO

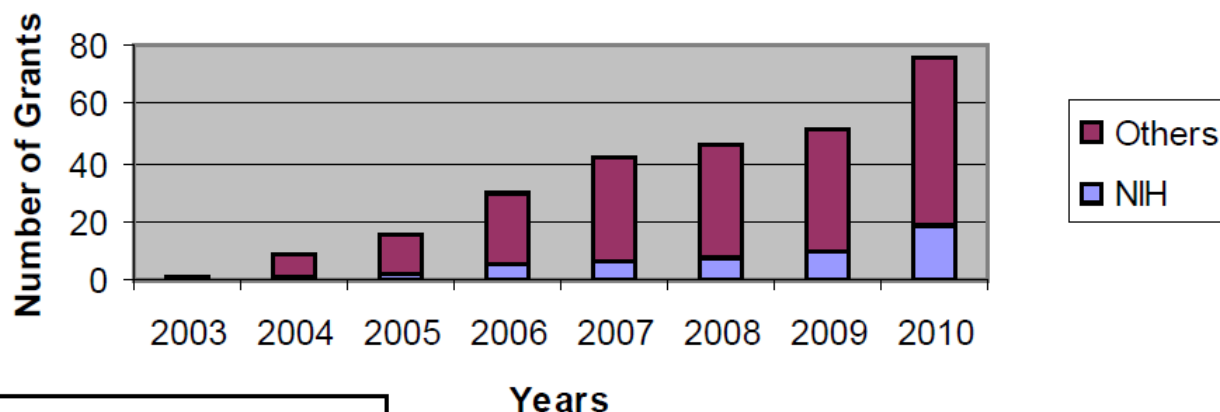


Table 2

Research and Training Awards

**IU Kenya/AMPATH Research Program
1998-2009**

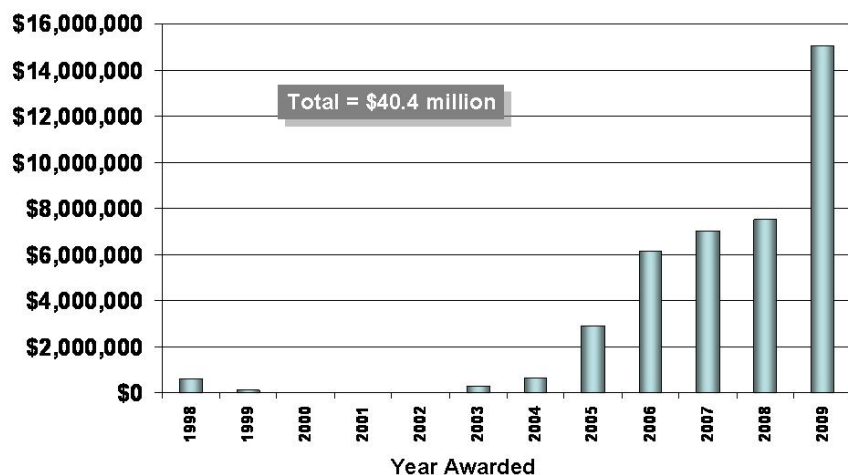
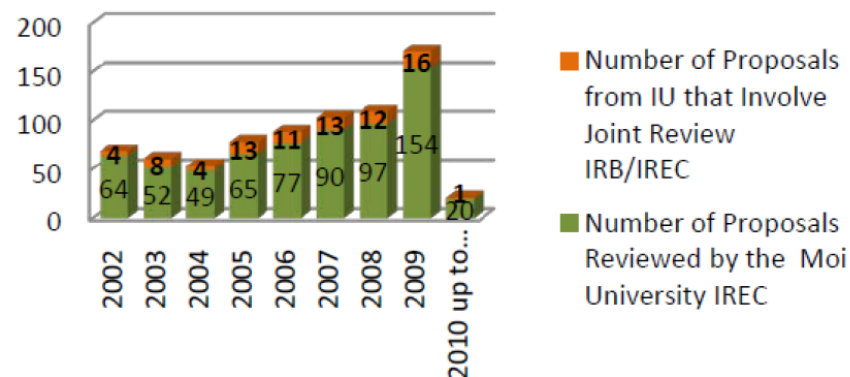


Table 3

IU-Moi IRB/IREC Reviews



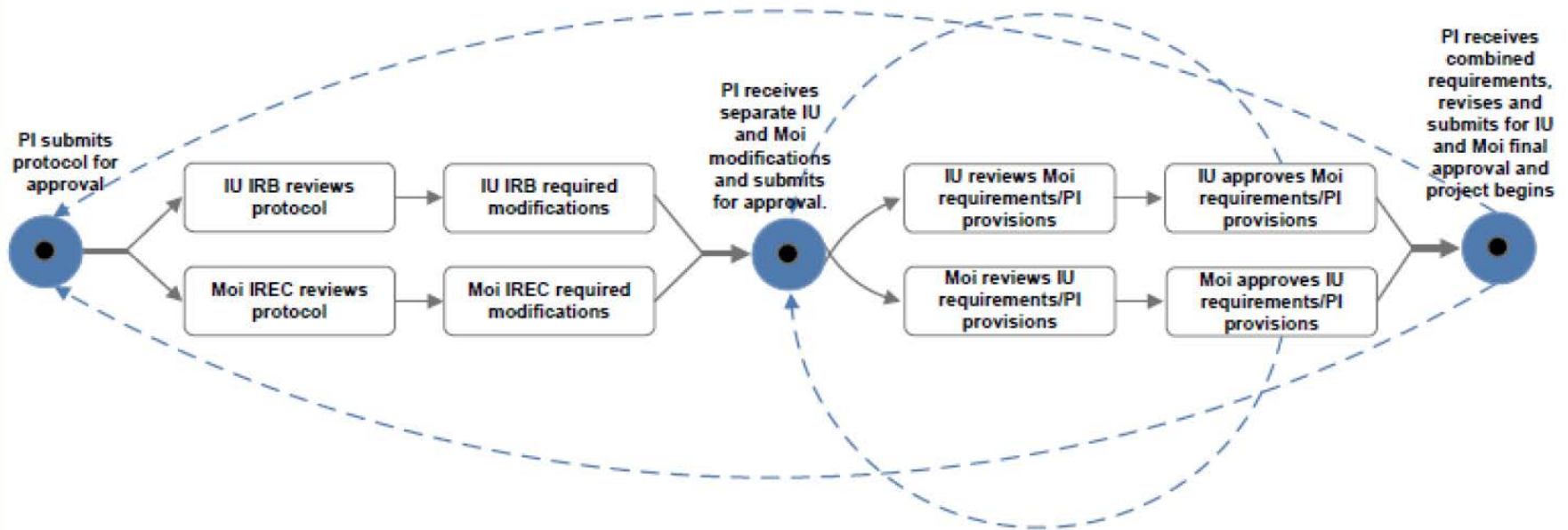
A Typical Protocol: IU and Moi PIs; NIH/KEMRI Funding

- 45 CFR 46, Subt. A (The Common Rule)
- 21 CFR 50/56 (FDA)
- The Privacy Rule (HIPAA)
- Indiana University policies (which includes *Belmont* through FWA and Helsinki indirectly)
- Moi Teaching and Referral Hospital policies (which includes *Belmont* through FWA and Helsinki indirectly)
- AMPATH SOPS
- Kenyan National Science and Technology Council
- Kenya Ministry of Health



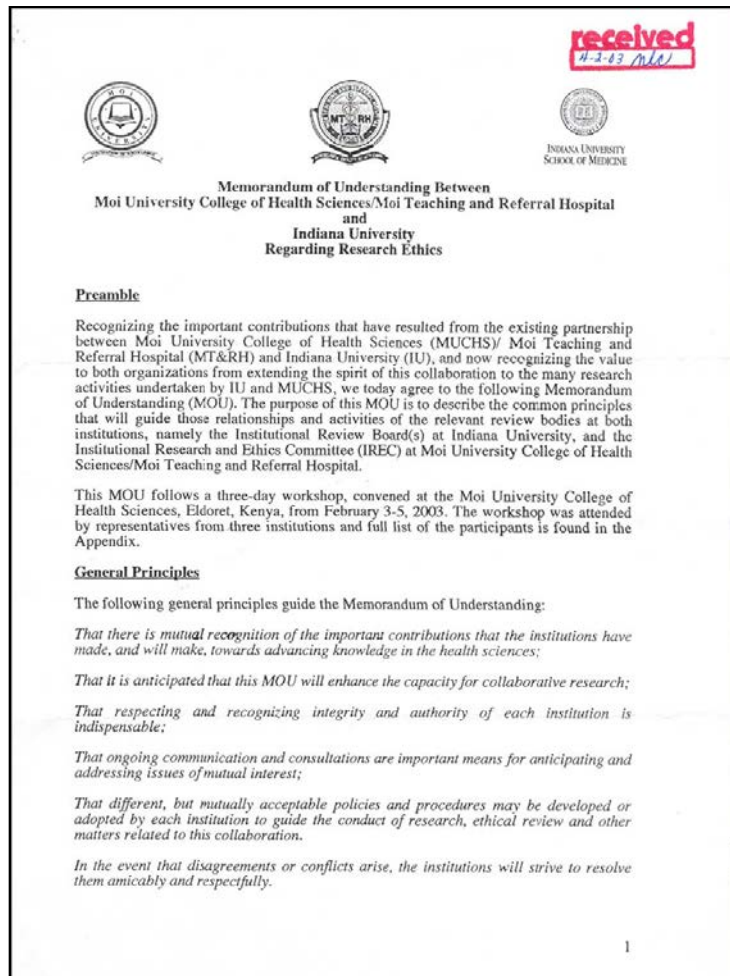
The Ethics Review System Between Indiana University and Moi University

Figure 2



Our “Bottom-Up” Approach:

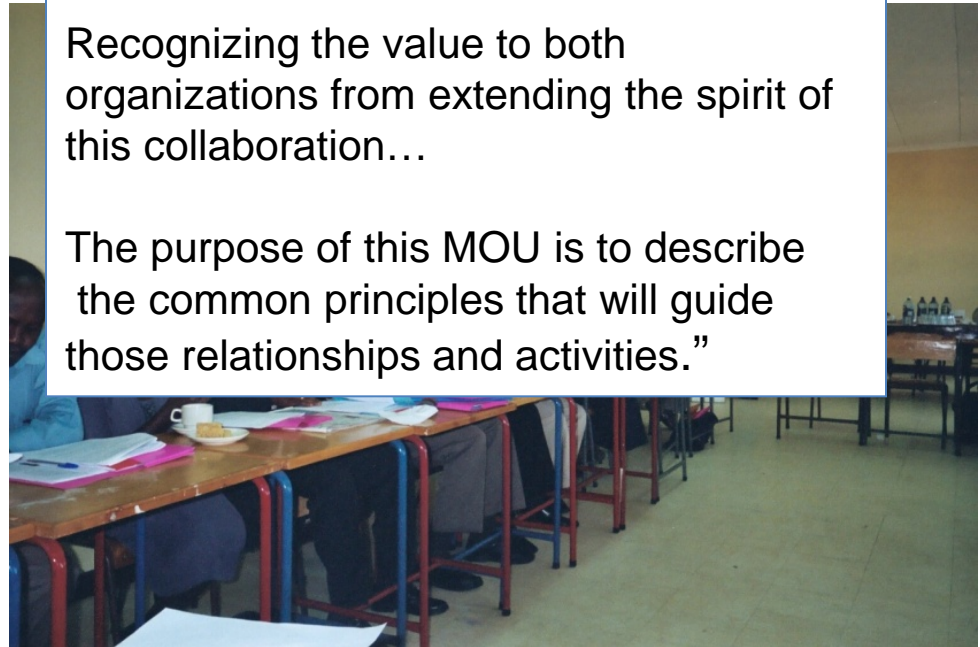
(1) Identify Common Values in Research Ethics



“Recognizing the important contributions that have resulted from the exiting partnership...

Recognizing the value to both organizations from extending the spirit of this collaboration...

The purpose of this MOU is to describe the common principles that will guide those relationships and activities.”



(2) Moving from MOU to Needs Assessment

International Research Ethics Partnership 23

A NEEDS ASSESSMENT TO BUILD INTERNATIONAL RESEARCH ETHICS CAPACITY

JOHN E. SIDLE
*Indiana University School of Medicine
Moi University Faculty of Health Sciences*

EDWIN WERE
Moi University Faculty of Health Sciences

KARA WOOLS-KALOUSTIAN
*Indiana University School of Medicine
Moi University Faculty of Health Sciences*

CHRISTINE CHUANI
Moi University Faculty of Health Sciences

KAREN SALMON
New England School of Law

WILLIAM M. TIERNEY
Indiana University School of Medicine

ERIC M. MESLIN
Indiana University Center for Bioethics

evaluation of the responses revealed important differences. Methods to address these misunderstandings are outlined in the recommended Best Practices.

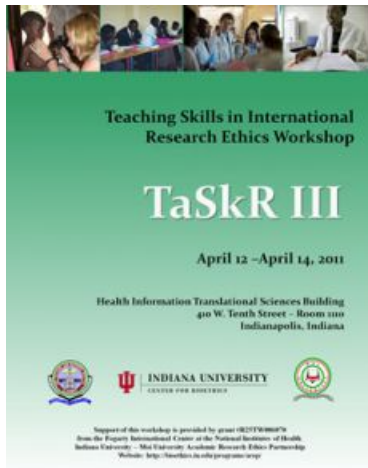
KEY WORDS: international collaboration, needs assessment, cross-cultural, ethics review committee, ethics capacity, informed consent, justice, guidelines

Received January 25, 2006, revised April 20, 2006

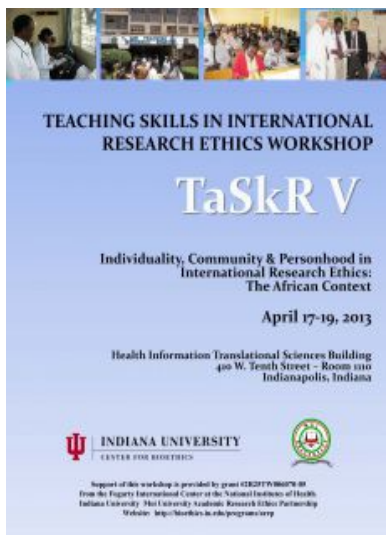
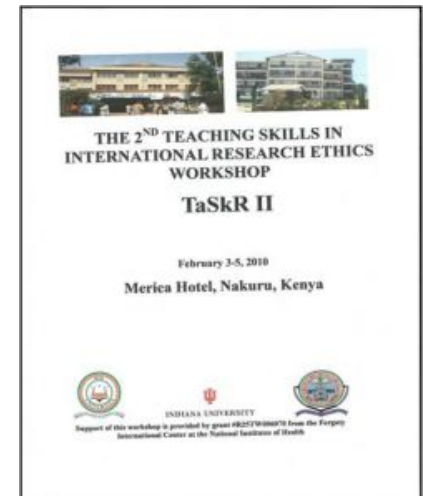
MANY GROUPS HAVE RECOMMENDED THAT research sponsors develop and implement strategies that assist developing countries in building local capacity for designing, reviewing and conducting clinical trials, and assist in building capacity for ethics review committees including: the U.S. National Bioethics Advisory Commission (NBAC) (2001), the World Health Organization (2001), UNAIDS (2000), the Council for International Organizations of Medical Sciences (CIOMS) (1993), and the Nuffield Council on Bioethics (2005). Common

- Little knowledge of the prior MOU
- Little awareness of how the other ERC operates
- Recognition that growth of research will require new approaches to review
- ERC members consider cultural values as part of their “local” review and approval of protocols
- More education and training in ethical issues in international health research are needed

(3) Build Capacity: IU-Moi Academic Research Ethics Partnership



- Parallel Master's degrees in international research ethics at Indiana and at Moi
- Annual workshops on "Teaching Skills in International Research Ethics" (TaSkR)



AMPATH Research Network

Director for Kenya: W. Nyandiko
Co-Director for North America: T. Inui

Field Co-Director

P. Braitstein

Field Co-Director

V. Naanyu

Field Co-Director

W. O'Meara

Field Co-Director

J. Sidle

Field Co-Director

R. Vreeman

Field Co-Director

K. Wools-Kaloustian

RESEARCH WORKING GROUPS

Adult Medicine

Kenya: L. Diero
N. America: T. Inui

Paediatrics

Kenya: S. Ayaya
N. America: R. Vreeman

Basic Science

Kenya: S. Mining
N. America: R. Kantor

Public Health/Primary Care

Kenya: D. Menya
N. America: D. Cole & G. Wilson

Oncology

Kenya: N. Busakhala
N. America: A. Moormann & J. Skiles

Tuberculosis

Kenya: L. Diero & W. Nyandiko
N. America: J. Carter

Reproductive Health

Kenya: H. Mabeya
N. America: A. Bocking

Behavioral & Social Science

Kenya: E. Kamaara & V. Naanyu
N. America: J. Dickerson-Putman

Cardiovascular

Kenya: J. Kamano
N. America: G. Bloomfield

CORES

Operations

Kenya: J. Kiplagat-Kirui
N. America: D. Plater

Data Management

Kenya: W. Nyandiko
N. America: J. Sidle & P. Braitstein

Biostatistics

Kenya: A. Mwangi
N. America: J. Hogan

Clinical Informatics

Kenya: TBN
N. America: P. Biondich

Pharmacy

Kenya: B. Jakait
N. America: S. Pastakia

Laboratory

Kenya: N. Buziba & W. Emonyi
N. America: B. Van Der Pol

Bioethics

Kenya: D. Ayuku & E. Were
N. America: E. Meslin

The Proposed IU-Moi Joint IRB*

Strategy

- Goal: increase efficiency of reviews, ensure protection of human subjects in protocols conducted by IU and Moi
- How:
 - Develop Administrative Structure
 - Build Research Ethics Training And Competency Standards
 - Design Evaluation Metrics
 - Obtain Approval and Authorization

*supported by a Supplement from the Fogarty International Center

Outcomes

- Develop Administrative Structure
 - ✓ Appointed co-chairs from each university
 - ✓ Identified equal membership/representation from each university
 - ✓ Developed procedural rules to ensure fairness in voting
 - ✓ Utilized teleconference and online presence
- Build research ethics training and competency standards
 - Build joint research ethics training programs (TaSkR)
 - Pilot-tested review with a protocol
- Design evaluation metrics
 - Started
- Obtain Approval and authorization
 - Agreement by Moi and IU; OHRP; FDA
 - Disapproval by Kenya National Bioethics Committee

Another Approach: Use Existing Rules/Regs

§46.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative

With the approval of the agency head, an institution...may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort

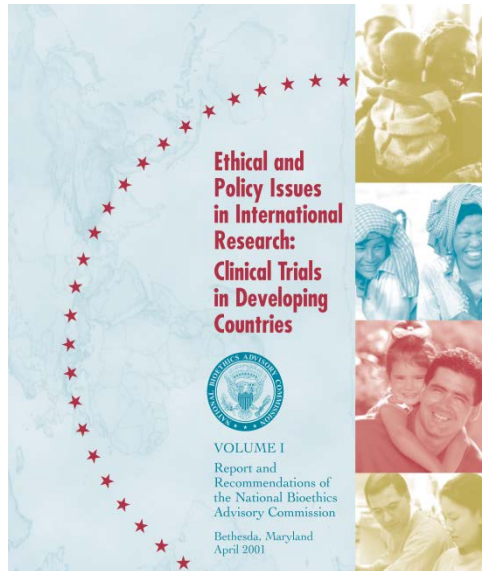
§46.101 To what does this policy apply?

- h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from

In these circumstances, if ...an agency head determines that the protections by the institution afford protections that are at least equivalent to those provided in this policy....the agency head may approve the substitution of the foreign procedures in lieu of the requirement provided in this policy

- procedures that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy.

The EP Experiment



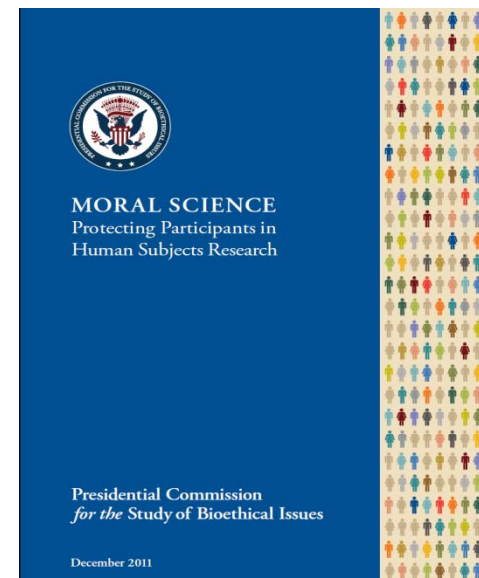
THE HASTINGS CENTER
REPORT

**Should the Gold Rule? Assessing
“Equivalent Protections” for Research
Participants across International
Borders**

Jeremy Sugarman

Research Ethics Across the 49th Parallel: The Potential Value of Pilot Testing “equivalent protections” in Canadian Research Institutions

James V. Lavery, Michael McDonald & Eric M. Meslin



A Proposal for Obtaining EP status

1. Identify specific protections in the US Common Rule;
2. Assess institution's procedures, and fairly assess what protections follow from them;
3. Undertake a comparison between institution's procedures and those of the CR;
4. Determination of equivalence made by US agency

[Federal Register Volume 70, Number 57 (Friday, March 25, 2005)]
[Notices]
[Pages 15322-15327]
From the Federal Register Online via the Government Printing Office
[\[www.gpo.gov\]](http://www.gpo.gov)
[FR Doc No: 05-5947]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Protection of Human Subjects, Proposed Criteria for
Determinations of Equivalent Protection**

AGENCY: Department of Health and Human Services, Office of the
Secretary.

ACTION: Notice.

“Because It Was Hard . . .”: Some Lessons Developing a Joint IRB Between Moi University (Kenya) and Indiana University (USA)

Eric M. Meslin, Indiana University Center for Bioethics
David Ayuku, Moi University, Eldoret, Kenya
Edwin Were, Moi University, Eldoret, Kenya

A proposed committee involving Moi University in Eldoret, Kenya, and Indiana University (IU) School of Medicine was cited by Barachi and colleagues as an example of “joint review/combined review” without comment. While some of this is described elsewhere (Meslin, Were, and Ayuku 2013), we suspect it may not have been not available to those authors; therefore, in this commentary we offer further

explanation of our experience, which may be instructive for those contemplating collaborative ethics review and offer some further lessons we have learned.

The idea for a joint institutional review board (IRB) arose as a logical evolution of the two-decade-long IU–Kenya Partnership between Indiana and Moi universities (Tierney et al. 2013). The partnership’s mission expanded in 2001 to

Address correspondence to Eric M. Meslin, Indiana University, Center for Bioethics, 410 West 10th Street, Indianapolis, IN 46202, USA. E-mail: emeslin@iu.edu

May, Volume 14, Number 5, 2014

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Lessons We’re Learning

Taking Stock of the Ethical Foundations of International Health Research: Pragmatic Lessons from the IU–Moi Academic Research Ethics Partnership

Eric M. Meslin, Ph.D.^{1,3}, Edwin Were, MBChB, MMed, MPH^{2,3}, and David Ayuku, Ph.D.^{2,3}

¹Indiana University Center for Bioethics, School of Medicine, Indianapolis, IN, USA; ²Moi University, Eldoret, Kenya; ³Indiana University–Moi University Academic Research Ethics Partnership, Indianapolis, IN, USA.

1. Collaborative review is a journey, not a destination
2. Building capacity only works with institutional support, clear goals, and leadership
3. Even with shared ethical foundations, ethics review invokes other deeply held moral and political values
4. Understanding regulations is necessary but not sufficient
5. There are always more people to talk to, but when?
6. Proposed North/South IRBs must acknowledge power differences
7. The symbolic and instrumental value of the ‘nation’ state

Discussion Questions

- What are the impediments (social, political, ethics, regulatory) to developing *institution-to-institution* arrangements to undertake joint ethics review? Are the potential benefits worth the costs?
- Are ‘bottom-up’ institutional arrangements like the one between IU and Moi preferable to the many ‘top down’ approaches attempted over the years to harmonize guidelines, adoption of Declaration of Helsinki,
- Is “local review” still superior to centralized review?

