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

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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
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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
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>
<thead>
<tr>
<th>Year</th>
<th>Others</th>
<th>NIH</th>
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<tbody>
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<td>2009</td>
<td>9</td>
<td>3</td>
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<td>2010</td>
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Table 2

Research and Training Awards
IU Kenya/AMPATH Research Program
1998-2009

Year Awarded

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<th>Year</th>
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<td>2009</td>
<td>65</td>
</tr>
<tr>
<td>2010</td>
<td>85</td>
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</table>

Total = $40.4 million

Table 3

IU-Moi IRB/IREC Reviews

- Number of Proposals from IU that Involve Joint Review
- IRB/IREC
- Number of Proposals Reviewed by the Moi University IREC

<table>
<thead>
<tr>
<th>Year</th>
<th>IU Proposals</th>
<th>Moi Proposals</th>
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<td>1</td>
<td>20</td>
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<tr>
<td>2010 up to...</td>
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<td>7</td>
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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
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

- 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

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

Visit our website at: www.medicine.iu.edu/ampathresearch

Revised 1 May 2014
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 those 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.

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 procedural requirements provided in this policy.
The EP Experiment

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
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?