A Needs Assessment to Build International Research Ethics Capacity at Moi University and Indiana University

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Abstract: (164 words)

International collaborators in biomedical sciences face ethical challenges in the design, review, and conduct of research. Challenges include differences in research ethics capacity, cultural differences in interpretation and application of ethical principles, and cooperation between ethics review boards at collaborating institutions. Indiana University School of Medicine (Indianapolis, USA) and Moi University Faculty of Health Sciences (Eldoret, Kenya) developed a Memorandum of Understanding (MOU) to establish greater cooperation between their ethics review boards, followed by a joint needs assessment to assess barriers to implementing the MOU. Focus groups and interviews at each institution revealed that while each side verbalized understanding and respect for the other's culture, there were misunderstandings deeply rooted in each culture that could potentially derail the collaboration. Although the participants at each university agreed on the major principles and issues in research ethics and on the importance attributed to them, a more in-depth evaluation of the responses revealed important differences. Methods to address these misunderstandings are outlined in the recommended Best Practices.

Introduction

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 to these proposals has been recognition that capacity building in research ethics can take two complementary routes:

(1) enhance the capacity of researchers and sponsors in developing countries to conduct research through training and education of potential researchers, and providing infrastructure to permit research to continue after a particular study is completed, and (2) build local capacity to conduct scientific and ethics review of research protocols.[1] As NBAC observed: "Building capacity to conduct scientific and ethics review... is primarily a matter of providing training and helping to establish systems designed to review proposed protocols and sustain mutually beneficial partnerships with other, more experienced review bodies, including U.S. IRBs." (NBAC, 2001, pg. 78).

At the heart of many ethical issues in international collaborative research lies an accepted truth that cultural, linguistic and social differences between collaborators pose certain challenges to the success of research partnerships between institutions (Serrano & Linares, 1990). Likewise, differences in history, politics, wealth, and power between cultures can lead to unintentional conflicts between collaborators (Page, 2004). These challenges for research ethics capacity building have been particularly acute in sub-Saharan Africa and other low-income countries, where a growing number of international research collaborations have been initiated to carry out clinical trials of new treatment regimens.[2] As more research occurs in these countries with collaborators from economically developing countries, it is likely that

certain weaknesses in the respective research ethics review infrastructure will be exposed. Without adequate attention to these weaknesses any knowledge gained from research cannot be translated into practice.

Capacity Building in Research Ethics Between Moi University and Indiana University

Moi University Faculty of Health Sciences (MUFHS) was established in Eldoret, Kenya, in November 1987, and started training medical students in October 1990. It is one of two medical schools in the country, and currently has approximately 100 active faculty members. The Moi Teaching and Referral Hospital (MTRH) in Eldoret became Kenya's second referral hospital in 1997. Located on the campus of MUFHS, the hospital is the major urban teaching facility for the medical school. An Institutional Research and Ethics Committee (IREC) has operated as an ethics review board (ERB) within the Faculty of Health Sciences since shortly after the Faculty's establishment. The institution has a Federalwide Assurance from the U.S. Office for Human Research Protections. Committee members are jointly appointed by both the Dean of MUFHS and the Director of MTRH, and the ERB reviews all protocols conducted within both the hospital and the health sciences campus. Standard Operating Procedures (SOPs) for IREC have been in place since 2002. In July 2005, the Moi University Faculty of Health Sciences (MUFHS) became the Moi University School of Medicine (MUSOM). Since our study occurred before this transition, we refer to the MUFHS throughout this paper.

The Indiana University School of Medicine (IUSM), located on the Indianapolis campus of Indiana University is the second largest medical school in the U.S., and it has over 1,100 faculty members. The campus has five Institutional Review Boards (IRBs), including four biomedical IRBs and one Behavioral/Social Sciences IRB. Twenty-five SOPs have been developed to govern the review process, though it should be noted that at present, an SOP focusing on international research is not among them.

MUFHS and IUSM have enjoyed a partnership in health education, medical care, and research since the beginning of the Kenyan medical school in 1989. As part of its collaboration with MUFHS, IUSM has maintained a continuous faculty presence at MUFHS since 1990. Termed the IU-Kenya Partnership, this collaboration has provided bilateral educational exchange for hundreds of students, residents, faculty and researchers over the past 15 years (IU-Kenya Partnership, 2005). Under the umbrella of this partnership, more than twenty research projects are ongoing or have been completed. These studies have included research involving: clinical trials, informatics, clinical epidemiology, microeconomics, bioethics, and health services research.

Senior administrators at MUFHS and IUSM developed an innovative strategy to meet the challenges of research ethics capacity building through academic partnership between the institutional ethics review boards (ERBs) and relevant faculty of the two institutions. The two components of this strategy were: (1) developing a joint Memorandum of Understanding (MOU) in Research Ethics that arose from a Workshop held in Eldoret in 2003, and (2) conducting a comprehensive needs assessment at both medical schools in 2004 to determine how best to implement the MOU. Below we report on these two components to illustrate both the methodology we used to develop research ethics capacity and the outcomes of our work.

The Moi University Workshop and the Memorandum of Understanding

From the outset, leaders at both institutions recognized that an authentic partnership in research required a deliberate effort to overcome potential cultural barriers and identify opportunities for collaboration, including specific efforts to build research ethics capacity. They recognized that each institution had unique expertise, and they believed that joint efforts to enhance research capacity and research collaboration would benefit both institutions. To move this idea forward, we convened a workshop in Eldoret to develop an approach between MUFHS and IUSM for conducting research that is sensitive to local values and consistent with

accepted principles of research ethics. In February 2003, 39 individuals met in Kenya, including 25 faculty members from Moi University, 12 from Indiana University, and one each from Brown University and (a long-time participant in the IUSM-MUFHS collaboration) and the Fogarty International Center at NIH. All participants were directly involved with research at their institution: investigators, ERB members, senior research administrators, and senior university leadership with oversight responsibility.

The two-day agenda included Kenyan and U.S. perspectives on substantive and procedural issues in research ethics; the respective institutional perspectives on these issues; transnational and global guidelines and standards; a taxonomy of research; informed consent; confidentiality and privacy; and issues involving justice and equity—topics seen as important to both universities. Investigators from both universities used ongoing research protocols to provide concrete examples for the discussion. At the end of the Workshop, participants drafted and approved a Memorandum of Understanding (MOU) outlining the desire of each institution to cooperate in the ethical oversight of research involving human subjects, with an initial emphasis on areas of equity, informed consent, and the development of standard operating procedures (SOP) for international collaborative research.

The MOU was not intended to be a statement of SOPs or rules for compliance between the universities. Among the general "principles" guiding the MOU is the following: "That different but mutually acceptable policies and procedures may be developed or adapted at each institution to guide the conduct of research, ethical review, and other matters related to this collaboration." These and other statements in the document reflect the shared commitment to a collaborative approach to research ethics. The Vice Chancellor of Moi University, the Director of MTRH, and the Vice Chancellor for Research at IUPUI signed the MOU in February/March 2004. The MOU was distributed to the senior research administration, and at each university and medical school and placed on the website of the IU Center for Bioethics (it can be viewed at http://www.bioethics.iu.edu/mou.html).

Workshop participants recognized that the MOU was only the first of many steps toward building research ethics capacity at both universities. Therefore, we conducted a joint needs assessment to identify barriers to and opportunities for implementing the MOU.

The Needs Assessment: Methods

The needs assessment used a qualitative rather than a quantitative approach because it provided a better opportunity to understand the subtle and potentially important differences that may exist in the knowledge, attitudes and opinions of MUFHS and IUSM participants. Focus group discussions and key informant interviews were used to compare the attitudes, opinions, policies, and practices at both IUSM and those at MUFHS that affect implementation of the MOU. The cross-sectional sampling plan outlined below was designed to explore key issues with individuals who engage in research or who direct and implement policies related to the conduct of ethical research within each institution. This design provided direct comparison of attitudes, opinions, and general level of knowledge of research ethics infrastructure at the two institutions. It also permitted identification of any gaps or other institutional barriers that might prevent implementation of the MOU. The protocol for conducting the focus groups and key informant interviews was separately approved by the ERBs at both IUSM and MUFHS. Table 1 provides a summary of the number and types of participants.

Table 1: Number and Type of Participants (per site)

Composition	Participants	IU	MUFHS
Decision-Makers	Administrative leadership at each institution	2	**5**
Researchers	Researchers involved in or planning to participate in international research	3	**4**
Researchers/ERB members	Participants who were both researchers (defined above) and ERB members	1	**2**
ERB members	ERB members	6	**2**
Other individuals	Other participants who participated in the development of the MOU	1	**2**
Total Participants:		**13**	**15**

Key informant interviews were conducted with Deans, Chief Administrators and other individuals who set policy within the institutions as their participation in a focus group setting would have inhibited other discussants from expressing any conflicting ideas.

Data collection

All investigators collaborated on the development of identical interview guides for use with both focus groups and key informant interviews at each institution. Investigators at both institutions contacted focus group participants and key informants with either mail or email invitations, followed by verbal invitations explaining the purpose of the study and the procedures involved. Participants were informed that a decision not to participate would not be shared with their employers or colleagues. However, the investigators asked them to share their reasons for refusal. Copies of the MOU were dispersed to participants prior to discussion so they could familiarize themselves with the materials.

At IUSM, 27 of 38 individuals responded to the letter of interest regarding participation. Eleven did not respond, even after reminders were sent. Of the 27 who agreed, four subsequently declined to participate, citing lack of time as their reason for refusal. Of the remaining 23 potential participants, 13 were scheduled for interviews or focus group discussions based on availability. Ten individuals were not able to arrange a time to participate. Key informant interviews were conducted with two decision makers, two ERB leaders, and one researcher. The remaining four researchers and four ERB members participated in two focus group discussions. While larger numbers of participants were sought for the focus group discussions, scheduling conflicts prevented participation by more potential respondents.

At MUFHS in Kenya, 15 of the 23 invited individuals participated. One focus group discussion involved six participants consisting of three researchers, one ERB member, and two individuals who were both researchers and ERB members. Nine individuals completed

key informant interviews: five administrators or ERB leaders, two individuals involved in development of the MOU, one Kenyan researcher who had been studying in the U.S. , and one ERB member who was the only person to attend the second scheduled focus group. Those who could not attend cited scheduling conflicts as their reason for not participating. Composition of the interviews and focus group discussions at each institution are presented in Table 2.

Table 2: Composition of Key Informant Interviews and Focus Group Discussions

	IUSM		**MUFHS**	
Data Collection	**Participants**	**n=13**	**Participants**	**n=15**
Key Informant Interviews	Decision-makers ERB Leaders Researchers	2 2 1	Decision-makers ERB Leaders Researchers ERB Member MOU Workshop Members	3 2 1 1 2
Focus Group Discussions	FGD1: Researchers FGD2: ERB Members	 4 4	FGD1: Researchers ERB Member Researcher/ERB Member	 3 1 2

The interview teams consisted of a facilitator (one of the project investigators EMM, JES, KWK) and an observer (responsible for written impressions and audio-taping). The facilitators of the focus groups in both the U.S. and Kenya have had previous training and experience in focus group facilitation, and all had in-depth knowledge of the ERBs, review policies, and research practice at each institution. The interviews and focus groups at IUSM were co-facilitated by two project investigators (EMM, KWK). The interviews and focus group at MUFHS were all conducted by one investigator (JES) with a research assistant present for tape recording and notation at the focus group and two of the interviews. A detailed interview guide informed the discussion for all interviews and focus group discussions, although interviewers and group facilitators were allowed to deviate from the prepared guide as new

themes emerged from the conversations. Open-ended questions elicited opinions about any differences in policy and practice that existed between the two institutions, and interviewers were allowed to probe more deeply to clarify responses that were unclear or required additional explanation. The same interview guide was used at both institutions; see http://www.bioethics.iu.edu/moi_vol2.pdf. All interviews and focus group discussions took place in a private meeting room in order to maintain privacy and confidentiality. Interviews and focus group discussions were tape recorded and transcribed. The format for both Focus Group Discussions and Key Informant Interviews are outlined in Table 3.

Table 3. Format for Focus Group Discussions and Key Informant Interviews.

Focus Group Discussions	Key Informant Interviews
• The purpose of the focus group interview was explained. • An additional verbal explanation of the study was provided to the participants to supplement the previous mail communication. This included a discussion of procedures, risks and potential benefits as well as information on confidentiality. • Many or most participants in the focus groups knew each other; therefore the use of names was permitted during the discussion. However, all participants were assured that names would not be attached to final transcripts of the discussions. Participants were asked to respect the confidentiality of opinions expressed during the discussions and to avoid discussing the specific opinions of any individual with others outside the interview. • The participants were seated with audio taping equipment placed in a manner conducive to data collection. The facilitator/investigator(s) faced the group for easy moderation of the discussion. An observer (research assistant) was present to ensure equal participation while jotting notes to supplement the taped data and to record nonverbal cues. • The facilitator(s) had an allotted time of two hours for focus group interviews. The interview guide was used to initiate the discussion but also allowed for natural discussion among participants. The facilitator was obliged to cover all the broad topics of interest. • At the end of the interview, participants were allowed to ask questions pertaining to the topics under discussion.	• The purpose of the key informant interview was explained. • An additional verbal explanation of the study was provided to the participant to supplement what had been previously communicated. This included a discussion of procedures, risks and potential benefits as well as information on confidentiality. • The participant was seated with audio taping equipment placed in a manner conducive to data collection. The facilitator/investigator(s) faced the individual for easy moderation of the discussion. In most instances, an observer (research assistant) was present to take handwritten notes to supplement the taped data. • The facilitator(s) had an allotted time of one hour for key informant interviews. The interview guide was used to gather information on the participants' knowledge and opinions regarding the MOU, informed consent procedures, policies for equity in research, and existing SOPs at their respective institutions. • At the end of the interview, participants were allowed to ask questions pertaining to the topics under discussion.

Data Management.

Audiotapes were transcribed in English into WORD 2000. In the case of MUFHS participants, any interviews that included Kiswahili were translated into English. To protect participant confidentiality, full names were not transcribed. Tapes will be destroyed after final data analyses, and transcripts will be kept at Indiana University for seven years after publication.

Data Analysis.

The data collection teams in Indianapolis and Eldoret met immediately respectively, following each focus group discussion or key informant interview to debrief and discuss the day's findings with the aim of identifying points and areas that were missed during discussion. In the case of the single interviewer at MUFHS, field notes from the interview guides were used to identify these areas when a research assistant was not present. These debriefing sessions prepared the team for the next group discussion or interview. As the transcripts became available, the research team matched each transcript to the taped interview in order to determine the quality and consistency of the transcripts. Once the majority of the transcripts were available, investigators became the analysts.

Investigators viewed all transcripts from the interviews and focus groups. Coding software was not used for this project; investigators individually coded manuscripts for themes, specific language and emerging issues. At IUSM, two investigators coded all IUSM transcripts individually and then met to compare findings and identify common themes. Inter-coder reliability was not formally measured. At MUFHS, one investigator coded all MUFHS transcripts and provided findings in a written report to all investigators. Other investigators at MUFHS lacked sufficient experience to complete the initial coding. Summary themes from both institutions were consolidated into summary documents, and a consensus opinion was reached by all investigators regarding the most important themes and issues emerging from the data. All investigators participated in identification of quotes illustrating specific themes

and issues. Themes were selected that best represented the commonly held views among participants at each institution. The investigator group collaboratively generated consensus recommendations for each institution following data analysis, and the summary findings were distributed to participants at each institution for comment.

Results

A complete content summary of the needs assessment findings is available at http://www.bioethics.iu.edu/pub_center.html.

During the analysis questions were divided into three categories: (1) Prior Knowledge, to assess prior knowledge about the ERB activities at each institution, informed consent and equity; (2) Specific Issues, to address the subcategories of ERB activities, informed consent, and equity; and (3) Identified Needs, to address the issues identified by respondents for improvements to standard operating procedures, education and training, communication, and remuneration.

Prior Knowledge

We sought to understand participants' level of prior knowledge about four issues relating to policies and procedures at MUFHS and IUSM respectively: knowledge of the MOU; knowledge about international protocol reviews at each institution; knowledge about procedures for review at each institution; and knowledge about the institutional officials responsible for implementing policies at each institution. Understanding this prior knowledge would serve as a baseline from which any education and training program might be developed. For each of the areas we provide representative statements from MUFHS participants and IUSM participants.

Knowledge of the MOU. Most of the individuals interviewed at IUSM had no prior knowledge of the MOU. For those who were aware of the MOU, attitudes were predominately positive, and the general consensus was that the purpose of the MOU was to develop a common understanding of the perspectives of the ethics review committees at each institution. Respondents also expressed the hope that reviews would be streamlined by improvement of each review body's perspective. A representative statement from a focus group participant from IUSM is found below:

> *"I saw the MOU as an opportunity and still see the MOU as an opportunity for those who are responsible for regulating research on this end to link with their counterparts in Kenya in order to achieve mutual understanding of each other's sandbox and in fact to play in each other's sandbox a little bit—' Share in each other's sandbox' perhaps would be a more appropriate descriptor." [Key informant interview, IUSM administrator and researcher]*

All participants interviewed at **MUFHS** had prior knowledge of the MOU. The general consensus of the purpose of the MOU was to find a mutual agreement between the two collaborating universities regarding research through creation of a better understanding between the ERBs.

> *"I think the purpose was to institute a formal arrangement between IRB (IUSM ERB) and IREC (MUFHS ERB), so that we begin to understand our cooperation, and more so on the policy guidelines so that the two institutions would function in a collaborative manner with respect to each other, and appreciating the conditions prevailing in each institution and how together we can resolve those." [Key informant interview, MUFHS ERB member]*

Knowledge of international protocol reviews at each institution. The majority of the **IUSM participants** believed that international research protocols are reviewed in a manner similar to U.S. protocols. Some acknowledge that international protocols need to be reviewed by both the host country's ERB and the IUSM ERB and that there were issues related to reconciliation of differing reviews.

> "I *think that the general elements [of research ethics review] are certainly the same. Subject protection, informed consent and no coercion at all. I think that there has been an obvious sensitivity to cultural issues. I think there has been some recognition that the informed consent process might be somewhat different in a developing country and that ...the written informed consent may not be the appropriate vehicle to obtain [In Kenya]." [Key informant interview, IUSM ERB administrator]*

A few participants at **MUFHS** believed that the procedures for reviewing an international protocol were the same between the two institutions. Other participants believed that the IUSM procedures for reviewing international protocols were unclear or simply non-existent, claiming that an international protocol should not be reviewed any differently.

> *"I think my understanding is that all protocols are treated the same regardless of whether it is international. It's only that, of course, the expectation is that that protocol will be reviewed in the other institution where it is going to be conducted." [Key informant interview, MUFHS ERB leader]*

Knowledge of protocol review procedures at MUFHS. When asked about the procedures at MUFHS the majority of the participants at **IUSM** were unaware of how the MUFHS or other foreign ERBs functioned. One participant noted:

> "I *think conflict of interest- you have to be very careful that you don't have the investigator and investigators you know best friends, sitting on the board and pushing things through or something that's obvious to us here. I'm not sure if different cultures have that addressed. The issues of informed consent and risk benefit and privacy have to be threaded through reviews with I think continuing education, and I'm not sure what process is used with other IRBs in other countries." [Key informant interview, IUSM ERB member]*

For those aware of the ERB procedures, they indicated that these were quite similar to the IUSM ERB but that it sometimes takes longer to obtain approval for a proposal being reviewed by the MUFSH ERB compared to the IUSM process. One participant was able to explain the MUFHS ERB procedures as follows:

> *"The process doesn't appear fundamentally that different in that each project has a primary and a secondary reviewer, they seem to pay attention to exactly the same issues...I think the IREC (MUFHS ERB) looks more at the scientific methods than our IRB does. Mostly it's (IUSM ERB) concerned with human rights, understandability of informed consent statement, dotting I's and crossing T's." [Focus Group Discussion, IUSM researcher]*

When the participants at **MUFHS** were asked about the MUFHS ERB procedures, all of the participants were aware that the ERB had specific procedures for reviewing a protocol. A participant noted that international protocols are currently reviewed like all other protocols:

> "I *don't think there are any (policies and procedures) as of now for international protocols, but we just take them through the review procedures that are there for even just like any other protocol that would be submitted whether it's done internally or externally. There are standards that are required-- that you have to meet the required IREC (MUFHS ERB) format, fill in the review guideline form, and submit the required number of copies. Then it's up to the Secretariat to determine if it's going to go for full review, expedited review, or if its going to be given exempt status as of yet." [Key informant interview, MUFHS ERB member]*

Knowledge of the responsible authorities at each institution. The majority of those interviewed at **IUSM** indicated that the Vice Chancellor for Research for the medical school is responsible for decisions surrounding cooperation between the two review bodies, with or without input from the executive committee.

The majority of participants at **MUFHS** believed that the Director of the Moi Teaching and Referral Hospital and the Dean of the Faculty of Health Sciences have the primary authority over decisions about cooperation between the IU ERB and the MUFHS ERB. Other potential decision makers included the ERB chairman, the ERB committee, the Human Subjects Office, the Vice-Chancellor of Research and the Director of Research for AMPATH, a large HIV care program at MUFHS.

Issues Relating to Collaboration

We sought to understand participants' views about three specific issues relating to collaboration: Interaction between the ERBs from each institution, informed consent, and remuneration of ERB members.

Interactions between the ERBs. When asked about the interactions that had occurred between IUSM and MUFHS, the majority of **participants at IUSM** were unaware of any formal interactions between the two review bodies. However there was support for future interaction. A representative comment was as follows:

> *"You know, one would think that there would be formalized interactions but there aren't a lot of formalized interactions. At least nothing particularly codified." [Key informant interview, IUSM administrator]*

The majority of the **participants at MUFHS** believed that interaction had taken place between their ERB and the IU ERB. Some participants were able to identify specific interactions that had taken place. One participant noted their interpretation of communication between the two institutions:

> *"...First, when it comes to the training component, I believe that the IREC (MUFHS ERB) and the IRB at Indiana University have assisted us so much especially in getting us people up to speed with international standards..." [Key informant interview, MUFHS ERB member]*

Apparent institutional differences regarding informed consent. In response questions about using different informed consent processes at the two institutions, **participants at IUSM** expressed no concern. One participant noted:

> "I *mean I think we have to follow that custom of the country and trust that the investigator will document the manner in which the informed consent was administered and I mean I think that we can require you know somebody to witness a verbal consent but I don't think we're in a position to try to tell them what is the best way to do it..." [Key informant interview, IUSM researcher and ERB member]*

However, when asked if there were any differences apparent between the two institutions regarding the informed consent process, the majority acknowledged that they would prefer to defer to written consent. They emphasized that a way must be found to document an individual's understanding of the research and their willingness to participate. One participant explained:

> ".. *my main consideration for having a written document is really more or less to have proof or documentation that some certain standard or some information, some basic information was--there was an attempt to communicate that specific information. So would I consider possibly using alternative forms? I would have to be convinced of the use of those forms or at least the ability to record information acknowledging acceptance of that. So I think my default would be, in general, some form of written documentation." [Focus Group Discussion, IUSM researcher]*

Most of the **discussion by MUFHS participants** centered on the difference between using verbal and written consent. Some participants believed that the process of informed consent could be similar at both locations, but most stressed that differences in the African environment and culture should be considered. Others believed that consent has to be different in Kenya due to varying degrees of illiteracy, poor understanding of research, and unwillingness of subjects to sign consent forms. A majority of participants believed that it was

necessary to include verbal consent as an option in the informed consent process to accommodate the African culture. Two participants explained:

> *"In the IRB [IUSM ERB] system they require written—the individual must give written consent by signing. However, in the African set up, we have socio-cultural factors that must be considered so that the consent is culturally appropriate. So there you may require the consent of the family or the larger community which may not be written-could be verbal." [Key informant interview, MUFHS researcher and ERB member]*

> *"In principle it (informed consent) should (be the same). The only thing is that the level of understanding and appreciating research in this country is not as high as in the U.S., and therefore we have to customize the informed consent in various settings.. For example, most people would not like to sign out their names or signature on the informed consent statements. They would rather say no and just give verbal statements because of some of their reservations regarding signatures. So I think in principle 'yes', but I think we have to make sure that it is customized to the area you are working in." [Key informant interview, MUFHS administrator and researcher]*

Remuneration. When asked about remuneration of ERB members there was general consensus **at IUSM** that some compensation should be offered for participation on a review committee. However, most individuals appeared more comfortable with non-monetary compensation such as release time or recognition of service when being considered for promotion. Respondents expressed concern over conflict of interest if ERB members were to receive financial remuneration. One representative response was expressed as:

> ".. *you are asking people to spend time reviewing protocol and if they are, I mean that's time taking them away from their research, from their clinical responsibility and if we want people to do right ...it doesn't have to be money. I mean if percent effort whatever the department feels is appropriate then they need to be compensated for that." [Key informant interview, IUSM researcher and ERB member]*

There was general consensus at MUFHS that a form of remuneration could be offered for participation on the ERB. However, most participants preferred not to call it a "payment" but rather an "honoraria" or "allowance." Respondents discussed appropriate methods for paying members without compromising their objectivity in reviewing protocols. A representative comment was as follows:

> *"I think what you should be going for is the recognition and appreciation of their time. .. this may not be in monetary terms.. However in our environment; most of the staff are poorly remunerated, and sometimes the government or the university does pay for services by giving a token allowance... I think that most of the people that are nominated or appointed into IREC (MUFHS ERB) are people with credibility in the institution, and I don't think a small allowance could compromise their judgment." [Key informant interview, MUFHS ERB member]*

Identified Needs

The focus group discussions and key informant interviews provided a wealth of information about the current knowledge, policies, procedures, and the structure of institutional systems for human subjects research review. When asked to focus on specific needs and how they should be addressed, there were a number of needs in common to

between the two universities. The following four areas were identified as key points for further study and/or intervention.

Recognition of Culture. The most commonly expressed need, described by participants at both institutions, stemmed from the recognition that cultural differences between the U.S. and Kenya have an impact on the conduct of research at IUSM and MUFHS. Some of these needs were expressed in general terms as follows:

- Investigators at IUSM and MUFHS should consider cultural values when designing, conducting research, or.
- ERB members should consider such values as part of their "local" review and approval of protocols.

Informed Consent. The second identified need focused on the most appropriate method for obtaining informed consent in specific settings. This included the expectation that collaborative research between the two institutions could accommodate different cultural and social values on matters such as seeking permission from women, and on more legalistic matters such as the acceptability of oral rather than written consent.

Institutional Policy. The third area arose from the recognition that different institutional policies, procedures and practices have an impact on the conduct of research at IUSM and MUFHS. This led to an obvious need—to increase investigator and ERB member awareness and acceptance of the general review policies, procedures and practices at each institution. Some participants noted the need to harmonize practice between the ERBs at each institution to better facilitate research. Finally, participants at **IUSM** agreed that the Vice Chancellor for Research should continue to have primary authority over cooperation between the ERBs at the two institutions, although they felt that the executive committee of ERB chairs and University Council members should have input. At **MUFHS,** the majority of participants felt that the primary responsibility should reside with the ERB or the ERB chair. As one administrator explained:

"It is basically IREC [MUFHS ERB], the chairman and the secretary.. because once we established the committee with the Dean we would like as much as possible to allow it to operate independently, so that they're not seen as if they are being controlled by two offices. I would like to think that the IREC can operate independently and liaise with Indiana directly." [Key informant interview, MUFHS Administrator]

Capacity Building. The fourth area of common need was to develop procedures and mechanisms at both universities for helping ERB members carry out their responsibilities more effectively. Several items were identified, including the need for more training and education of ERB members on international research ethics issues, and the development of compensation policies for ERB members.

Discussion

From the outset, we must acknowledge the limitations of this study. To identify needs for improved collaboration in research ethics capacity at our institutions, the questions, out of necessity, were broad in scope, and the data generated by the interviews and discussions can only be viewed as a starting point for more focused research into specific topics and themes that emerged. Each topic requires further focused evaluation to provide more specific approaches in the future. As a result, our discussion can only focus on general concepts and themes.

Also, it is likely that the outcomes reflect some bias both in the selection of participants and in the analysis of the data. There are significant differences in the research infrastructure between MUFHS and IUSM. With over 1,100 faculty and 5 ERBs, participants at IUSM would be less likely to have intimate knowledge of the research, policy, and practice at MUFHS, even though the participants were invited based on their involvement with the

design, conduct, or review of international research. Conversely, MUFHS has only 100 faculty members, and the bulk of funded research in the past five years has occurred in collaboration with IUSM or other U.S. institutions. Most of the MUFHS participants would be expected to have first-hand experience with the MUFHS ERB and/or the IUSM ERB, and the ongoing presence of IUSM faculty in the MUFHS ERB and research projects has added to the knowledge of IUSM among MUFHS faculty. Likewise, the ERB administrator received training at IUSM, thereby increasing knowledge of IUSM procedures for the Kenyan ERB members.

Investigators who performed the majority of the analysis for this project were all well acquainted with the development of the SOPs and procedures for the MUFHS ERB, and all but one have actively participated on the MUFHS ERB. While this was a significant advantage in interpretation of responses by the Kenyan participants, it is also likely that some bias existed despite all efforts to evaluate data objectively.

In discussing our findings, we want to emphasize how crucial it was to be attentive to the participants themselves, both during the interviews and the subsequent analysis. We realized, for example, that there were times when individuals may have been using the same words, but were saying different things. Even the best qualitative methods can not guarantee that what was heard was identical to what was meant. However, the probes that interviewers used during discussions to explore ideas that emerged were helpful in understanding the intended meaning of many of the responses.

It would be easy upon initial review of the interviews and focus group data to conclude that that there were few substantive differences between the two institutions. Although the participants at each university agreed on the major principles and issues in research ethics and on the importance attributed to them, a more in-depth evaluation of the responses revealed important differences. For example, all participants agreed that informed consent not only was a *recognized* principle of research ethics, and that it was an *important* principle, but that greater emphasis should be placed on the *process* rather than the content of a form..

And yet, a more detailed review of the responses reveals subtle but important differences in the way that the principle is implemented and applied in practice, including important differences in the way that verbal rather than written consent should be used to authorize permission to participate in studies.

Interactions Between the ERBs

Most IUSM participants were unaware of any interaction between the IU ERBs and the MUFHS ERB, whereas the majority of respondents at MUFHS were able to identify specific interactions between the two review bodies. Many reasons may account for this uneven knowledge, but one is certainly obvious: IUSM's ERBs have relatively little experience with the MUFHS ERB and (with clinical research at Moi University being a relatively recent phenomenon) with MUFHS protocols in particular. Only 1 of the 5 ERBs on the IUSM campus reviews MUFHS protocols, so it stands to reason that IUSM participants in the needs assessment who did not sit on the IUSM ERB with this responsibility and who have not been directly involved in collaborative research with MUFHS would have less reason to know about MUFHS and its protocols and procedures. In contrast, all MUFHS protocols are currently conducted in collaboration with IUSM and therefore all MUFHS ERB members would be aware of the IUSM ERB and its procedures. But whether awareness is completely or only partially present, the differences in knowledge of policy, procedures, and ongoing interaction highlight an important challenge for collaborative research and the interactions between ERBs: current regulations require institutions to work out review mechanisms for collaborative studies, and it is generally accepted that studies be reviewed by both the sponsoring institution (usually in a developed country) and the host institution (usually in the less developed country).

It is often tempting for collaborators from economically developed countries to assume that they must take the lead in a partnership and that they bring more to the table than those

from a lower-income country. In our case, it appeared that our colleagues at MUFHS were better informed about the IU ERB system than IUSM faculty were about MUFHS's ERB system. The same IUSM faculty admitted that they were not knowledgeable about the guidelines, policies and procedures that the MUFHS ERB uses to assess research (whether research undertaken alone or in collaboration with other universities). Thus, the needs assessment revealed something important about how to understand the nature of partnerships—economic superiority does not mean superiority in other facets of the relationship. But note that MUFHS faculty members' superior knowledge of IUSM's ERB system does not mean that the MUFHS ERB is any better prepared to review collaborative, multi-center protocols than IUSM's ERBs. All we know is that a knowledge gap exists. Filling it (by providing educational materials and orientation to IUSM's ERBs) may be a necessary first step, but it is not sufficient to ensure that collaborative research ethics review occurs. Unless research ethics review infrastructure gains adequate capacity to review international protocols at both institutions, knowledge cannot be translated into practice.

On the other hand, while MUFHS participants were also more aware of existing interactions between the ERBs, participants at IU had a better grasp of who was responsible to authorize interaction between the ERBs for their institution. There was some disagreement between MUFHS participants on who held the authority for such interactions at MUFHS. Nevertheless, both groups consistently agreed on who *should* hold primary authority over communication and interaction between ERBs at the two institutions. Clearly, the process of collaboration can only proceed smoothly once clear avenues of communication are established, and the creation of these avenues would constitute an important first step in the development of a more productive collaborative relationship.

Both institutions and their respective investigators, ERB members, and administrators are well versed in the literature on informed consent, and on the regulatory requirements of the U.S. Common Rule (45 C.F.R. 46, Subpart A, 2005) as well as on

international documents such as the Declaration of Helsinki (though the Kenyan participants were more familiar with Helsinki than the IUSM participants). Surprisingly, agreement about finding an appropriate method for obtaining informed consent was not difficult; many IUSM participants indicated that they would be comfortable with a decision by the MUFHS ERB to permit verbal rather than require written informed consent. This apparent deference to local customs and values is laudable, and yet by probing deeper we learned that the basis for this claim was a feeling on the part of the IUSM participants that they lacked sufficient knowledge of local customs to feel comfortable "overriding" them and imposing U.S. standards.

Kenya is one of a small number of African countries with national guidelines for research involving human subjects (Oduwo, Wassunna & Rashid, 2004). Institutions in Kenya (including MUFHS) are also familiar with and make use of additional transnational guidance documents, such the CIOMS guidelines (CIOMS, 1993), UNAIDS (2000), and the World Health Organization's Operational Guidelines (2001). MUFHS has a set of standard operating procedures for the ERB based on the WHO guidance document. In contrast, IUSM's ERBs rely almost exclusively on the Common Rule, the relevant FDA regulations (21 C.F.R. 50/51, 2005) and, since April 2003, the relevant procedures arising from the Health Insurance Portability and Accountability Act (HIPAA) (1996). Increasing awareness of relevant institutional policies is a laudable goal, but without a mechanism for adjudicating conflicts between policies, awareness alone may not be enough.

Informed Consent

This issue best illustrated the different cultural, political, social and ethical perspectives of the two institutions. Kenyan participants noted that while the principle of informed consent should be the same between institutions, the actual consent process may need to be altered to meet the cultural needs and limitations of Kenyan research subjects. This includes recognition that in some instances, subjects are illiterate, are unwilling to sign a document, or

have a poor understanding of research. While IUSM participants acknowledged that they had no objections or concerns regarding the use of verbal informed consent, the majority continued to maintain that written informed consent was preferable or that some method of documenting informed consent with a witness would be necessary. In addition, some IUSM participants did not understand the concept of community consent (Andanda, 2005) or the need for it. This apparent acceptance of a cultural norm, while still demanding acquiescence to a different standard, highlights the difficulties inherent in cross-cultural work (Macklin, 2004). When sitting around a conference table, everyone wishes to be cooperative, and it often appears that everyone is in agreement. However, in practice it is difficult to adopt new policies that are contrary to ethnocentric beliefs, especially those based on years of experience in one's own culture.

Likewise, the Kenyans' apparent acceptance that the process of informed consent should be the same between the institutions despite immediately noting problems with the American procedure is striking. Imposition of the policies of one institution upon another may not always meet with resistance. Collaborators in less-developed settings may be willing to embrace different ways of doing things, even when those policies do not work well within their own culture. This situation could easily create barriers to successful conduct of research within the local culture. Such misunderstandings on both sides can only be resolved with open dialogue and a willingness to mutually seek the most culturally appropriate methods that maintain ethical integrity of a project.

Lessons Learned and Next Steps

We learned several important lessons. The most important lesson we learned from the MOU is that an agreement on paper, regardless of how collaborative its language is not the same thing as a partnership. A true partnership is a fluid process that requires ongoing discussion of cultural similarities and differences, institutional commitment to mutual problem-

solving, and a concerted effort by collaborators to understand each other as the partnership matures. Cultural differences cannot be overcome in a three-day workshop, or by the creation of policies, or institutional procedures arrived at by a few decision-makers. In a similar vein, the main lesson we learned from the needs assessment is that there is much to learn from what people say, but words alone in an interview or a focus group discussion environment may not capture the full story of their needs. We recognize that no one wants to appear uninformed or present themselves in a group as insensitive to issues that their collaborators face. This may explain why there was considerable satisfaction on all sides when participants in the Eldoret Workshop agreed on the language in the MOU, or in their responses to prompts and probes in the focus group.

In both situations, there was movement towards consensus that provided comfort and avoided overt disagreement, even though, as has been noted elsewhere, consensus is the weakest form of agreement that can be used to settle disputes (Beauchamp, 1987). Agreement about the content of a document does not ensure that agreement exists or how the document is understood by all parties, nor does it ensure that there is agreement on how the document will be implemented. For example, what precisely does it mean to say that one "should consider" another's values when designing or conducting research? "Should consider" might mean any of the following: "be mindful of", "be aware of", or even "be sensitive to", any of which are desirable practices that may contribute to productive collaboration. But what if "should consider" means: "should adopt where possible", "should make reference to", or "should rely on"? We did not probe deeply into the responses of participants at either institution to investigate these different conceptual possibilities. However, it is clear that very different outcomes might occur (e.g., in protocol review) depending on which interpretation is operative. Imagine the IUSM ERB proudly announcing that, consistent with the MOU signed by both universities and supplemented by the data from this needs assessment, that it had *considered the cultural values* of the rural Kenyan population where a proposed study would

be conducted and found these values to be unacceptable. Or that the MUFHS ERB, in reviewing a proposed IUSM study to be conducted in Eldoret, *considered the cultural values* of U.S. patients or citizens and found them to be contrary to commonly held cultural beliefs in a particular tribe.

Policy pronouncements alone will not prophylactically prevent the many dimensions of misunderstanding that may continue to exist. Kenyan collaborators want to learn to correctly follow U.S. procedures (even if they think that those procedures are based on legalistic paper trails) and American collaborators want to learn about and become more sensitive to the diverse cultural values, as well as economic, historical and political factors of their Kenyan collaborators to better appreciate issues arising the design and conduct of international research. A successful collaboration requires an ongoing partnership that has the ability to learn from experience, revise procedures when issues arise, and continue to hone policy and practice while respecting the needs of participants at both institutions.

Best Practices

Research collaboration is a continuous process, and development of relationships between institutions and investigators evolves over time. Both partners must strive to develop an approach to collaborative research that is of the highest scientific and ethical standards, and at the same time is mutually respectful of the culture, values, and environments in which research will occur. Many of the best practices recommended below, while arising from the needs assessment carried out at IUSM and MUFHS, may apply equally well to other parties who seek to establish research partnerships with international universities or organizations.

Administrative

1. Administrators and researchers involved in collaborative international research must have clear insights into the requirements for ethical review at participating institutions. This

requires that collaborating institutions provide each other with complete information about the procedures, guidelines, and policies that are used to review research.

2. Administrators and research leaders at collaborating institutions should develop a procedure for ongoing bilateral exchange between review bodies/researchers in order to facilitate communication. While such measures may require outside funding, an appreciation of the cultural barriers to collaboration cannot be adequately appreciated without careful observation of the practice and infrastructure at each site.
3. Collaborating institutions must agree to a process for establishing regular communication between leaders of the ERB at each institution. While researchers involved in collaborative research are expected to maintain continuous communication with their collaborators, a similar system for communication of research priorities may be needed for decision-makers within each institution. For instance, investigators at IUSM and MUFHS now hold weekly conference calls to allow researchers at each institution to air their ideas and mutually determine the direction of both current and planned projects.
4. Stakeholders at all levels of administration within each institution should be informed regularly of developments in the ongoing collaboration and progress in each project.

Education/Training

1. Specific information about issues in international research ethics and the SOPs of the ethics review committee should be included in an orientation package provided to all individuals considering research with/at the partner institution.
2. Institutions should require all individuals involved in international research to demonstrate a proficiency in international research ethics. At U.S. institutions this may include addition of specific questions related to international research with which NIH-funded

investigators must comply. At other institutions a similar proficiency must be demonstrated.

3. Institutions should continue to seek out external funding opportunities to support research and development of research ethics capacity building.

Policy/Procedures

1. Institutions should jointly develop a Standard Operating Procedure that specifically addresses issues in international collaborative research. This SOP should, at a minimum address the following issues:
   - Format a flow chart for submission of proposals to the each of the ethical review bodies (dual submission)
   - methods for obtaining and documenting informed consent that are acceptable to both institution's review committees
   - mechanisms for anticipating and addressing areas of conflict or disagreement between the review committees should they arise
   - Interactions between US federal research regulations and international guidelines
2. Investigators from the institution where research is being conducted should guide decisions on culturally appropriate procedures for that locale.
3. Policy and procedures for research collaboration need to be viewed as fluid processes that are able to change and improve as collaborators grow to appreciate and respect their cultural differences.
4. Regular communication between the ERBs must be facilitated and supported by each institution. Differences must be revisited at regular intervals to allow understanding and policy to evolve with the needs of each institution and each individual project.

Research Agenda

Our experience highlights the need for ongoing, collaborative research in the area of international partnerships in research ethics capacity building. In the short term, the following areas are likely to be fertile ground for both policy development and research evaluation:

1. Further development of harmonized policies and procedures for oversight of international collaborative research.
2. Additional projects to evaluate the appropriateness of verbal informed consent in Kenyan culture and the harmonization of informed consent policies between institutions.
3. Further evaluation of methods to resolve equity issues at both the researcher and institutional level.
4. Establishment of an "international" collaborating ERB with members from both MUFHS and IUSM to review ethics of international proposals.

Educational Implications

Our needs assessment had educational implications that extend to all levels of the university. First, training on international research ethics and policy is required for ERB members at each institution. This in turn will give rise to improved ethical review and improved access to ethics materials by researchers and faculty. The ultimate goal of this process should be the development of a shared international research ethics curriculum that can be taught with health sciences students, post-doctoral trainees, graduate students, and faculty members at each institution.

Endnotes:

[1] Many international proposals have included measures designed to build research capacity in the host country. These measures include: training local personnel in research

methods and clinical procedures; providing training in grant writing, analysis of data, and manuscript preparation; and leaving behind equipment (NBAC, 2001). Likewise, UNAIDS recognized that capacity building is essential to developing a vaccine against HIV, and that it can be accomplished in several additional ways: scientific exchanges; developing exchange programs in the science and ethics of vaccine development; developing national and international research ethics capacity; providing information exchange programs for use with affected communities; and involving potential communities early in the design and conduct of research protocols (UNAIDS, 2000). These methods are being employed by other organizations, including the International AIDS Vaccine Initiative (IAVI) (2000) and the International Clinical Epidemiology Network (INCLEN) (Singer & Benatar, 2000). Indeed, Singer and Benatar (2000) proposed that INCLEN would serve as a useful model for creating a global network of physicians and researchers with expertise in research and research ethics.

[2]The situation in Africa warrants particular attention with respect to capacity building in research ethics. For example, there has been considerable growth in the amount of FDA funded research outside the U.S.; one influential report showed a 16-fold increase in the number of foreign clinical investigators conducting FDA research between 1990-1999 and a commensurate increase in the number of number of countries involved in such studies (Office of the Inspector General, DHHS, 2001). This same study concluded that many foreign ERBs are not well trained to deal with these issues.

Some African countries, such as Uganda (National Consensus Conference on Bioethics and Health Research, 1997) and South Africa (Medical Research Council of South Africa, 1993), have established national guidelines for collaborative international research, while others including Congo, Ivory Coast, Kenya, Malawi, Tanzania, The Sudan, and Zambia have well established research ethics systems. But according to data from a major workshop on African research ethics, of the eight countries that have national guidelines, only three

have national ethics committees for the review of research protocols (Rugemalila & Kilama, 2001). The same survey also found that there is variability in the practices, ethics awareness, frequency of meetings, and membership of these committees.

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