International Research Ethics: 
A Needs Assessment of Research Ethics Capacity 
at Moi University and Indiana University 

Volume I: Final Report

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<tr>
<td>MOU</td>
<td>Memorandum of Understanding</td>
</tr>
<tr>
<td>MU</td>
<td>Moi University</td>
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<td>MUFHS</td>
<td>Moi University Faculty of Health Sciences</td>
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<tr>
<td>MTRH</td>
<td>Moi Teaching and Referral Hospital</td>
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<tr>
<td>IREC</td>
<td>Institutional Research and Ethics Committee</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>IUPUI</td>
<td>Indiana University Purdue University Indianapolis</td>
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<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
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<td>HSROTF</td>
<td>Human Subjects Research Oversight Task Force</td>
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<tr>
<td>IU</td>
<td>Indiana University</td>
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Executive Summary

International collaborative research often raises challenging ethical issues for researchers, review committees and institutions. To date, much of the commentary and discussion surrounding these issues have focused on difficulties in interpreting guidelines, regulations, and policies and on the lack of harmonization. Efforts at regulatory reform and guideline development is one method of contributing to research ethics capacity building, but these are “top-down” approaches involving governments, regulatory agencies, and the challenge of achieving consensus. A complementary strategy is to work from the “ground up”: fashioning collaborative agreements between institutions, ethics review committees, and researchers.

Working from the “ground up,” we conducted a needs assessment with participants from the Indiana University School of Medicine and the Moi University Faculty of Health Science in order to determine how best to implement a Memorandum of Understanding (MOU) developed between the two institutions. The MOU was designed to address the working relationship between the two universities with respect to their joint research activities and was the product of a Workshop convened in Eldoret, Kenya in February 2003. This work is a direct result of the MOU which explicitly states that “It is expected and intended that among the actions arising from this MOU will be the development of policies, Standard Operating Procedures and other resources that will address specific issues not mentioned here.”

A grant from the Indiana University Purdue University Indianapolis International Development Fund supported the conduct of this needs assessment at both institutions in 2004. Key informant interviews and focus groups were conducted with investigators, ethics committee members, and administrators. Areas explored during these interviews included issues related to: Standard Operating Procedures, education and training, consent, equity, and conflict resolution.

The interviews and focus groups provided a wealth of information about current knowledge, policies, procedures, and systems in place at MU and IU, respectively. They also provided a rich source of ideas for enhancing research ethics capacity. There were a number of findings common to both universities:

Common Findings

- Cultural differences between the U.S. and Kenya have an impact on the conduct of research at IU and MU. For example:
  - Investigators at IU and MU consider cultural and related values when designing, conducting research.
  - IRB and IREC members consider such values as part of their “local” review and approval of protocols.
  - There is a recognized need to identify the most appropriate method for obtaining informed consent in specific settings.
- Different institutional policies, procedures and practices have an impact on the conduct of research at IU and MU. For example, there is a need to:
- Increase investigator and IREC/IRB member awareness of the general review policies, procedures and practices at each institution.
- Develop procedures and mechanisms at both universities for enhancing training and education of IREC/IRB members.
- Discuss the development of compensation policies for members of both the IREC and the IRB.

These common findings, supplemented by findings specific to each institution gave rise to the following recommendations:

1. Communication/Dissemination

1.1 This report should be distributed for “comments” from participants involved in the needs assessment, all IRB/IREC chairs, the IREC administrator, the Dean and Director at Moi University, and the Vice Chancellor for Research at Indiana University. The comment period will be three months. Comments will be considered in preparing a final report.

1.2. The IU-Kenya Partnership should be encouraged to provide investigators at both MU and IU with sufficient information about the procedures, guidelines and policies that are used to review collaborative research protocols, whether they (a) originate at IU and are conducted at MU, (b) originate at IU and are conducted at MU and IU, (c) originate at MU and are conducted at IU, or (d) originate at MU and conducted at MU and IU. Such efforts might include: circulating this report, or creating an additional orientation package for IU and MU investigators relating to research ethics that outlines the procedures at both institutions.

1.3 The Office of the Vice Chancellor for Research at IUPUI, and the Office of the Dean at Moi University Faculty of Health Sciences should develop a process for establishing exchange programs between IREC and IRB members to facilitate and enhance communication. This may require identifying specific funding opportunities for this exchange. The Office of International Programs at IU/IUPUI may be useful in this regard.

1.4. The Office of the Vice Chancellor for Research at IUPUI should develop (or designate a delegate to develop) a process for establishing regular communication between the relevant IU IRB chairs and the IREC chair, and between relevant administrators and secretaries of the respective committees.

1.5. The two institutions should convene a workshop to follow-up on the February 2003 within one year of the dissemination of this report as a way to continue the momentum already underway.

1.6. The IUPUI/Clarian IRBs (including the Executive Committee) and MU IREC should be briefed on the content of this needs assessment.
2. Education/Training

2.1 Leaders of the IU/MU Partnership should include specific information about ethical issues in international research ethics, an overview of IREC, and related issues in the orientation package given to all IU students/trainees/investigators/visitors intending to visit Moi University.

2.2 The Office of the Dean at MUFHS (or its designee) should include specific information about ethical issues in international research, an overview of the IRB, and related issues in an orientation/education program or orientation package given to all MU students/trainees/investigators/visitors intending to visit IU.

2.3 Both institutions should require all IU trainees, investigators, and staff involved in international research activities to demonstrate a proficiency in international research ethics issues. This may include being required to complete specific questions on the Human Subjects Protection Test that is required for Protection of Human Subjects in Research Certification at IUPUI (See Rec 2.4).

2.4 Develop a distinct training module based on the international SOP (See Rec. 3.1).

2.5 IU and MU investigators should continue to seek out external funding opportunities to support research and development of research ethics capacity building. The IU-Kenya Partnership should make available information on funding opportunities (from local, state, federal, private and philanthropic sources).

3. Policy/Procedures

3.1 IU and MU should collaborate on development of a Standard Operating Procedure that specifically addresses issues in international collaborative research (with particular emphasis on collaborative research involving MU). This SOP should, at a minimum address the following issues:

- Format a flow chart for submission of proposals to the IRB and IREC
- Accepted methods of obtaining and documenting informed consent
- Mechanisms for anticipating and addressing areas of conflict or disagreement
- Remuneration/Incentives/Recognition of IREC/IRB members
- Interactions between US federal research regulations and international guidelines
It is our expectation that this report will provide a template for identifying and implementing the next steps in developing collaborative international research. We encourage the leadership at both institutions to review these recommendations with implementation in mind.

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Kara Wools-Kaloustian
Karen Salmon
Edwin Were
Christine Chuani
Background

The Moi University and Indiana University Partnership

Moi University

In 1984, Moi University became Kenya’s second university. In establishing MU, the Government of Kenya emphasized that the new University was expected “to introduce new areas of learning which would help meet the high level manpower requirements of a modern and increasingly technological society.” Moi University is a university committed to producing graduates who are equipped with the appropriate practical and intellectual skills necessary in order to be responsive to the present and future needs of Kenyan society. The University is committed to pursuing excellence in teaching, research, scholarship and community service.

The university is composed of seven faculties/schools: School of Social, Cultural and Development Studies; Faculty of Education; Faculty of Law; Institute of Public Health; Faculty of Information Science; Faculty of Science and Faculty of Health Sciences. MUFHS was established in November 1987 and started training medical students in October 1990. Located in the town of Eldoret, it is one of the two medical schools in the country. MUFHS has long standing collaborations with medical schools in Europe and the U.S. It is a World Health Organization Collaborating Center for Problem-Based/Problem-Solving Approaches to Education and Practice in Public Health. Its mission and philosophy is to train professionals who are well versed in health promotion and prevention as well as disease management. The curriculum emphasizes self-directed learning, problem solving, community based research and health communication. Because of this community-based focus, the faculty has always strongly emphasized the special needs of rural Kenyan populations.

The Moi Teaching and Referral Hospital (MTRH) in Eldoret became Kenya’s second referral hospital in 1997. Staffed by faculty from the MUFHS, the hospital provides tertiary referral services for the western part of the country.

An IREC has operated within the faculty of Health Sciences since shortly after the faculty’s establishment. Historically, IREC’s main responsibility was to promote the conduct of ethical research within the Faculty of Health Sciences, as such it was initially a standing committee appointed by the Dean of the Faculty. However with the establishment of the MTRH, committee members are jointly appointed by both the Dean of MUFHS and the Director of MTRH, and its role has expanded to the review of all protocols which are conducted within the hospital and in much of the Western Kenya region.

In April 2001, the Pan African Bioethics Network organized a workshop in Kisumu, Kenya on Ethics of Health Research. Following this workshop, the IREC identified the need to streamline its activities through formulation of the SOP. As a result a Task Force chaired by Dr. Edwin Were developed and disseminated the IREC SOPs. The development of these
SOPs was also aided by Dr. Douglas Shaffer. Both IU IRB procedures/polices and World Health Organization (WHO) “Operational Guidelines for Ethics Committees that Review Biomedical Research” provided templates for the SOP development (See Appendix C).

Indiana University School of Medicine

Indiana University Purdue University at Indianapolis (IUPUI) campus of Indiana University has a long tradition of excellence in health science, library science, law, liberal arts, and an emerging expertise in bioethics, the humanities, and informatics. The IU School of Medicine (IUSM), the second largest medical school in the country, has approximately 1100 medical students and over 1,000 postgraduate medical trainees.

The IUPUI campus has five Institutional Review Boards (IRBs): 3 IUPUI Biomedical IRBs (IRB-02, IRB-04, IRB-05), a Behavioral/Social Sciences IRB, and a Clarian and Methodist Biomedical IRB. There are 25 SOPs under which the IRBs conduct business (See Appendix B). A Human Subject Research Oversight Task Force (HSROTF) was established in 2001 by the Vice President for Research in order to facilitate further SOP development and revision.

The Partnership

Moi University Faculty of Health Sciences and Indiana University School of Medicine established a collaborative partnership in 1989 in order to assess issues related to medical education and health care. Since then the partnership has expanded to encompass collaborative educational, health care and research activities involving Brown University, University of Utah, University of Pennsylvania at Lehigh, and Portland Providence Medical Center. Under the umbrella of this partnership, over twenty research projects are ongoing or have been completed. These studies have included research involving clinical trials, informatics, microeconomics, bioethics and health services research. With the expansion of research programs, IU and MU also conduct collaborative research with academic institutions outside the consortium, including University of Washington and Columbia University. These expanding collaborations with multiple institutions make development of ethics infrastructure even more imperative.

The Workshop at Moi University, Eldoret, Kenya, February 3-5, 2003

While the IU-Kenya Partnership has much to be proud of in areas of teaching and clinical care, both institutions recognized that a legitimate partnership in research requires a deliberate effort to identify common barriers to and opportunities for collaborative research, including efforts to specifically build research ethics capacity. Neither university has superior knowledge or experience compared to the other—both have expertise that the other does not. They recognized, therefore, that an important opportunity existed to work in concrete ways to jointly enhance research ethics capacity in parallel with efforts to enhance collaborative research.

With funding from a grant to IU from the National Institutes of Health, Dr. Bill Tierney convened a workshop in Eldoret in February 2003 “International Collaborative Research,”
with the goal of developing an approach between MUFHS and IU for conducting research that is sensitive to local values and consistent with accepted principles of research ethics. Following three days of meetings involving researchers, IRB members, and senior administration from both universities, an MOU was developed (Appendix A). An MOU was chosen because of its aspirational quality and reflection of a shared commitment by IU and MU to a set of common interests and concerns on matters of research ethics. Participants recognized that it was only the first of many steps toward building research ethics capacity at both universities.

The MOU alone did not provide the necessary momentum to move the MU/IU Partnership forward with respect to research ethics. Further data was needed and a substantive plan for enhancing research ethics capacity at both institutions had to be developed. As such the needs assessment was undertaken in order to identify barriers, opportunities, and gaps which have to be addressed during the development of this collaborative research effort.

The Needs Assessment

Background

In 2004, the Indiana University Center for Bioethics received an International Development Fund grant from Indiana University Purdue University Indianapolis for $11,860, entitled “Needs Assessment for Implementing the IU/Moi Memorandum Of Understanding (MOU) in Research Ethics.” The project was the result of two complementary activities, the first of which was the MOU. The second activity was an International Research Ethics Independent Seminar that was led by Eric M. Meslin, Ph.D., and undertaken by Dr. J. Sidle and Dr. K. Wools-Kaloustian. As an activity of the seminar this project was jointly designed and implemented. Dr. Edwin Were served as the Moi University co-investigator for this project.

Overall coordination of the project occurred in four ways:

- Regular meetings between the Project Supervisor (Dr. E.M. Meslin) and the co-investigator in Indianapolis (Drs. Sidle and Wools-Kaloustian rotate their responsibilities between MU and IU with only one present in Indianapolis at any given time)
- Meetings, as needed by the co-investigator at MU and Dr. Were, supplemented by one visit to Kenya by the Project Supervisor
- Regular e-mail communication between co-investigators
- Occasional long distance phone calls

It was anticipated that the project would take approximately 8 months to complete, but given the issues associated with convening focus groups, conducting interviews, and carrying out data analysis in two different locations, the project took approximately 12 months.
Methods

Design
This was a qualitative research project which used focus groups and key informant interviews in order to address attitudes, opinions, polices and practices at IUSM and at MUFHS that affect potential implementation of the MOU at each institution. The sampling plan was designed to explore these issues with individuals who are engaged in research or direct and implement policies related to the conduct of ethical research within these institutions.

Study Population
Focus groups and key informant interviews were conducted with appropriate decision makers, researchers, members of the IRBs/IREC, and those who participated in the MOU. Table 1 provides a summary of the number of participants.

- Focus group discussions (FGD) with decision-makers such as administrators, researchers and members of the ethics review bodies at each institution were used to explore opinions regarding the MOU and its implementation as well as opinions on institutional differences in policy and practice that affect the conduct of international research.

- Key Informant Interviews (KII) with administrators, researchers and committee members gathered information similar to that obtained from focus groups. KIIs were needed because it was impossible to include all key participants in focus group discussions. In addition, documenting the opinions of individuals such as Deans, chief administrators and other policymakers within the institutions was imperative because their participation in a focus group might inhibit other members from expressing conflicting ideas.

Ethics Review
The protocol for conducting the focus groups and key informant interviews were approved by the IRB and IREC respectively.

Recruitment
Invitations to participate as either focus group participants or key informants were provided by mail and email. The invitations explained the purpose of the study and all procedures involved. Investigators followed the written invitation with a verbal invitation. Copies of the MOU were dispersed via email to individuals who consented to participate prior to key informant or focus group interviews. This enabled participants to review materials prior to discussion. Participants were informed that a refusal to participate would not be shared with their employers or colleagues. However, the investigators asked them to share their reason for refusal.
**Procedures**

A detailed interview guide was prepared (See Vol. II). All interviews took place in a private meeting room in order to maintain privacy and confidentiality. Interviews were tape recorded and transcribed. At each interview, participants underwent the following:

**FGD**
- The purpose of the FGD was explained.
- An additional verbal explanation of the study was provided to the participants to supplement what had been previously circulated. 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 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 (Appendix B) 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. With each consecutive FGD, topics that reached the saturation point were dropped.
- At the end of the interview, participants were allowed to ask questions pertaining to the topic under discussion.

**KII**
- The purpose of the KII was explained.
- An additional verbal explanation of the study was provided to the participant to supplement what had been previously circulated. 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. An observer 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 one hour for KIIs. The interview guide (Appendix B) was used to gather information on the interviewee’s knowledge and opinions regarding the MOU, informed consent procedures, policies for equity in research, and existing SOPs at their respective institution.
At the end of the interview, participants were allowed to ask questions pertaining to the topic under discussion.

Data Collection and Management
The interview teams consisted of a facilitator(s) (investigator) and an observer. The research observer, separate from the focus group facilitator(s), were responsible for detailed note taking and audio-taping of focus group sessions.

Audiotapes were transcribed in English into WORD 2000. To protect participant confidentiality, no names were transcribed from the audiotapes. All tapes and hard copies of the translations and transcriptions are stored in a locked cabinet that can only be accessed by the investigators. Tapes will be destroyed after final data analyses and transcripts will be kept for seven years after publication.

Data Analysis
The data collection team met immediately following each FGD/KII to debrief and discuss the day’s findings with the aim of identifying saturation points and areas that were missed during discussion. These debriefing sessions prepared the team for the next FGD/KII. 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, the investigators became the analysis looking for themes, specific language and emerging issues.

Table 1: Composition, Membership and Number of Participants (per site)

<table>
<thead>
<tr>
<th>Composition</th>
<th>Membership</th>
<th>IU</th>
<th>MUCHS</th>
</tr>
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<tbody>
<tr>
<td>Decision-Makers</td>
<td>Participants representative of administrative leadership at each institution</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Researchers</td>
<td>Participants consisting of researchers involved in or planning to participate in international research</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Researchers/IRB/IREC members</td>
<td>Participants who were both researchers (defined above) and IRB/IREC members</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>IRB/IREC members</td>
<td>Participants representative of the IRB or IREC membership</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Other individuals involved in the development of the MOU</td>
<td>Participants drawn from the list of those participating in the development of the MOU</td>
<td>1</td>
<td>2</td>
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Findings from Key Informants and Focus Groups
Respondents from both institutions were asked and prompted on the same nineteen questions from the Interview Guide containing three categories:
Prior Knowledge. This section addressed prior knowledge about the IRB/IREC functions and guidelines at IU and MU respectively.

Specific Issues. This section addressed three subcategories: IRB/IREC activities, informed consent and equity.

Identified Needs. This section addressed the needs or proposal by respondents regarding improvements to standard operating procedures, education and training, communication and remuneration (these are found below in B.4. Identified Needs).

A complete content analysis of all interviews is found in Volume II.

Prior Knowledge

We sought to assess participants’ prior knowledge about four issues relating to policies and procedures at MU and IU respectively: Knowledge of the MOU; international protocol reviews at each institution; knowledge about procedure for review at each institution; and knowledge about the responsible authorities at each institution.

Knowledge of the MOU.
A substantial number of the individuals interviewed at Indiana University had no prior knowledge of the MOU. For those that were aware of it, the 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 both IRBs. Some also expressed hope that reviews would be streamlined by improvement of each review body’s perspective.

“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.”

All participants interviewed at Moi University had prior knowledge of the MOU. The general consensus was that the purpose of the MOU was to find a mutual agreement between the two collaborating universities regarding research, more particularly an understanding between the IREC and the IU IRBs.

“I think the purpose was to institute a formal arrangement between IRB and IREC, 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.”

Knowledge of international protocol reviews at each institution
The majority of the IU participants believed that international research protocols are reviewed in a manner similar to U.S. protocols. Some acknowledged that protocols need to
be reviewed by both the local IRB and the IU IRB 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 there has been and obviously 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 you know the written informed consent may not be the appropriate vehicle to obtain that.”

A few participants at Moi University believed that the procedures for reviewing an international protocol were the same at each institution. Other participants believed that the IU procedures for reviewing international protocols were unclear or simply non-existent, claiming that an international protocol should not be reviewed any differently.

“…I don’t think that just because something is international—it’s an international proposal and it has minimal risks—it should be subjected to full review. I don’t think that is a fair thing; let’s use the standards that are already in place…”

“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.”

Knowledge of the procedures at MUFHS.
When asked about the procedures at MUFHS, the majority of the participants at IU were unaware of how the IREC functioned. For those aware of the procedures for IREC, they indicated that they were essentially similar to the U.S. IRB procedures but that it sometimes takes longer to obtain IREC approval for a proposal compared to the IU process. One participant was able to explain the IREC 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 looks more at the scientific methods than our IRB does. Mostly it’s (our IRB) concerned with human rights, understandability of informed consent statement, dotting Is and crossing Ts.”

Other participants at IU commented on what procedures they believed should be in place.

“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. You know with I think continuing education and I’m not sure what process is used, you know with other IRBs in other countries.”

When the participants at Moi University were asked about the IREC procedures, all of the participants were aware that the IREC 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 format, fill in the review guideline form, submit the required number of copies, them its up to the secretariat to determine if its going to go for full review, expedited review or if its going to be given exempt status as of yet.”

Knowledge of the responsible authorities at each institution.
The majority of those interviewed at IU indicated that the Vice Chancellor for Research for the medical school should be responsible for decisions about cooperation between the IRB and the IREC. Some individuals indicated that the IRBs held primary responsibility, and there was discussion of deferring to the local IRB when there were issues that were closer to the culture.

“… if our IRB board had approved something that was being conducted in Moi and if their IRB board had found issues I would think that given that they are closer to the culture and what’s necessary in their place, they would have to agree with that. I would not think that we could override what they would say.”

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 IREC and the IU IRBs. Other potential decision makers included the IREC chairman, the IREC committee, the Human Subjects Office, the Vice-Chancellor and the Director of Research for AMPATH. However, when asked who should have primary authority the majority of participants interviewed believed that it should be granted to the IREC and/or the chairman of the IREC.

“It is basically IREC, 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 the Indiana bodies directly.”

Specific Issues

We sought to understand participants’ views about three specific issues relating to collaboration, communication and prior review and approval of research:

- IRB Activities/Communication
- Informed consent
- Remuneration of IRB members

IRB Activities/Communication.
When asked about the interactions that had occurred between the IRB and IREC, the majority of participants at IU were unaware of any formal interactions between the two review bodies. However, there was support for future interaction. One 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.”

The majority of the participants at Moi University believed that interaction had taken place between their IREC and the IU IRB. 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 and the IRB at Indiana University have assisted us so much especially in getting us people up to speed with international standards…”

Potential differing arising from the consent process between two institutions.

The majority of participants at IU indicated that they found no difficulties arising from the consent process being different in Kenya than in the US. They emphasized that a way must be found to document an individual’s understanding of the research and their willingness to participate.

“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…”

Some participants at Moi University 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 must be different in Kenya due to varying degrees of illiteracy, poor understanding of research, and an unwillingness to sign consent forms.

“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 their 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.”

Apparent institutional differences regarding informed consent.

In response questions about using different informed consent processes at the two institutions, participants at IU expressed no concern. However, when asked if there were any differences apparent between the two institutions regarding the informed consent process, the overwhelming majority acknowledged that they would prefer to defer to written consent. 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.”

Most of the discussion by MU participants centered around the difference between using verbal and written consent. A majority of participants believed that it was necessary to include verbal consent as an option in the informed consent process to accommodate African culture. One participant noted:

“In the IRB 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.”

Remuneration

When asked about remuneration of IRB/IREC members, there was general consensus at Indiana University 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 reviewed for promotion. Respondents expressed concern over conflict of interest if IREC members were to receive financial remuneration.

“…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.”

Most respondents at Moi University indicated that a form of remuneration could be offered for participation in the IREC. 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. One participant noted:

“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 are people with credibility in the institution, and I don’t think a small allowance could compromise their judgment.”

Identified Needs

The Key Informant Interviews and Focus Groups 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 suggestions for how those needs should be addressed, participants identified a number of needs in common
between the two universities. The following areas were identified as key points for further study and/or intervention.

Perceived Needs Common to Both Universities

- Cultural differences between the U.S. and Kenya have an impact on the conduct of research at IU and MU. For example:
  - Investigators at IU and MU consider cultural and related values when designing, conducting research.
  - IRB and IREC members consider such values as part of their “local” review and approval of protocols.
  - There is a recognized need to identify the most appropriate method for obtaining informed consent in specific settings.
- Different institutional policies, procedures and practices have an impact on the conduct of research at IU and MU. For example, there is a need to:
  - Increase investigator and IREC/IRB member awareness of the general review policies, procedures and practices at each institution.
  - Develop procedures and mechanisms at both universities for enhancing training and education of IREC/IRB members.
  - Discuss the development of compensation policies for members of both the IREC and the IRB.

These common needs provided a rich source of data and suggestions for how to proceed. Our recommendations and next steps provide a plan of implementation based on the data collected.

Recommendations

This needs assessment provided a useful first step to operationalize and implement the Memorandum of Understanding that was agreed to by Moi University and Indiana University in February 2003.

As such, it gives rise to many potential next steps as both universities 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. We note however, that many of the recommendations provided below, while arising from the needs assessment carried out at Moi University, may apply equally well to other universities with which IU has collaborative relationships. In some instances, we suspect that some of the practices we recommend are already in place. If not, we encourage their consideration. Similarly, Moi University may currently have or may intend to develop relationships with universities other than IU. In such situations, we encourage Moi University to consider whether and to what extent any of the recommendations proposed here can be applied to those partnerships.
1. Communication/Dissemination

1.1. This report should be distributed for “comments” from participants involved in the needs assessment, all IRB/IREC chairs, the IREC administrator, the Dean and Director at Moi University, and the Vice Chancellor for Research at Indiana University. The comment period will be three months. Comments will be considered in preparing a final report.

1.2. The IU-Kenya Partnership should be encouraged to provide investigators at both MU and IU with sufficient information about the procedures, guidelines and policies that are used to review collaborative research protocols, whether they (a) originate at IU and are conducted at MU, (b) originate at IU and are conducted at MU and IU, (c) originate at MU and are conducted at IU, or (d) originate at MU and conducted at MU and IU. Such efforts might include: circulating this report, or creating an additional orientation package for IU and MU investigators relating to research ethics that outlines the procedures at both institutions.

1.3. The Office of the Vice Chancellor for Research at IUPUI, and the Office of the Dean at Moi University Faculty of Health Sciences should develop a process for establishing exchange programs between IREC and IRB members to facilitate and enhance communication. This may require identifying specific funding opportunities for this exchange. The Office of International Programs at IU/IUPUI may be useful in this regard.

1.4. The Office of the Vice Chancellor for Research at IUPUI should develop (or designate a delegate to develop) a process for establishing regular communication between the relevant IU IRB chairs and the IREC chair, and between relevant administrators and secretaries of the respective committees.

1.5. The two institutions should convene a workshop to follow-up on the February 2003 within one year of the dissemination of this report as a way to continue the momentum already underway.

1.6. The IUPUI/Clarian IRBs (including the Executive Committee) and MU IREC should be briefed on the content of this needs assessment.

2. Education/Training

2.1. Leaders of the IU/MU Partnership should include specific information about ethical issues in international research ethics, an overview of IREC, and related issues in the orientation package given to all IU students/trainees/investigators/visitors intending to visit Moi University.

2.2. The Office of the Dean at MUFHS (or its designee) should include specific information about ethical issues in international research, an overview of the IRB, and related issues in an orientation/education program or orientation package given to all MU students/trainees/investigators/visitors intending to visit IU.
2.3. Both institutions should require all IU trainees, investigators, and staff involved in international research activities to demonstrate a proficiency in international research ethics issues. This may include being required to complete specific questions on the Human Subjects Protection Test that is required for Protection of Human Subjects in Research Certification at IUPUI (See Rec 2.4).

2.4. Develop a distinct training module based on the international SOP (See Rec. 3.1).

2.5. IU and MU investigators should continue to seek out external funding opportunities to support research and development of research ethics capacity building. The IU-Kenya Partnership should make available information on funding opportunities (from local, state, federal, private and philanthropic sources).

3. Policy/Procedures

3.1 IU and MU should collaborate on development of a Standard Operating Procedure that specifically addresses issues in international collaborative research (with particular emphasis on collaborative research involving MU). This SOP should, at a minimum address the following issues:

- Format a flow chart for submission of proposals to the IRB and IREC
- Accepted methods of obtaining and documenting informed consent
- Mechanisms for anticipating and addressing areas of conflict or disagreement
- Remuneration/Incentives/Recognition of IREC/IRB members
- Interactions between US federal research regulations and international guidelines

**Final Summary**

The results of this needs assessment provide Moi University and Indiana University with knowledge related to both individual and common institutional needs in their ever-expanding collaboration. Based on the data gathered we propose that the three focus areas outlined above be addressed in order to improve collaborative research efforts as well as better insure human subjects protection in these efforts. We respectfully request, that the leadership at both institutions will review these recommendations with implementation in mind.
Appendix A: Memorandum of Understanding

Memorandum of Understanding Between
Moi University College of Health Sciences/Moi Teaching and Referral Hospital
and
Indiana University
Regarding Research Ethics

Preamble

Recognizing the important contributions that have resulted from the existing partnership between Moi University College of Health Sciences (MUCHS) / Moi Teaching and Referral Hospital (MT&RH) and Indiana University (IU), and now recognizing the value to both organizations from extending the spirit of this collaboration to the many research activities undertaken by IU and MUCHS, we today agree to the following Memorandum of Understanding (MOU). The purpose of this MOU is to describe the common principles that will guide those relationships and activities of the relevant review bodies at both institutions, namely the Institutional Review Board(s) at Indiana University, and the Institutional Research and Ethics Committee (IREC) at Moi University College of Health Sciences/Moi Teaching and Referral Hospital.

This MOU follows a three-day workshop, convened at Moi University College of Health Sciences, Eldoret, Kenya, from February 3-5, 2003. The workshop was attended by representatives from three institutions and full list of the participants is found in the Appendix.

General Principles

The following general principles guide the Memorandum of Understanding:

That there is mutual recognition of the important contributions that the institutions have made, and will make, towards advancing knowledge in the health sciences;

That it is anticipated that this MOU will enhance the capacity for collaborative research;

That respecting and recognizing integrity and authority of each institution is indispensable;

That ongoing communication and consultations are important means for anticipating and addressing issues of mutual interest;

That different, but mutually acceptable policies and procedures may be developed or adopted by each institution to guide the conduct of research, ethical review and other matters related to this collaboration.

In the event that disagreements or conflicts arise, the institutions will strive to resolve them amicably and respectfully.
Specific Issues Identified

The following three areas were identified as being of interest at this time. These issues are not exhaustive of the possible topics that may arise from time to time in the course of future collaborative studies. We are committed to identifying other issues that should be addressed, and have a mutual commitment to continue ongoing consultations in an effort to strengthen this MOU and the collaboration as a whole.

Informed Consent

Informed consent is a process. It may be satisfied in different ways in different settings such as, verbal, written or a combination. Both the content of informed consent and the process by which it is obtained are important. Moi University/Moi Teaching and Referral Hospital and Indiana University are committed to developing the criteria and mechanisms necessary to satisfy the conditions for these different approaches to informed consent.

We recognize that various steps including community and family entry may be required to satisfy local customs or norms, before informed consent can be sought.

We recognize and affirm the importance of and respect for the autonomy of individual research participants.

Equity

We are committed to working towards mechanisms to provide fair distribution of benefits for individuals, communities, and institutions involved in research.

We recognize that determining equity in research projects must be considered within the context of the longstanding IU-Moi University Partnership.

We recognize that inequities may be identified within an institution or between institutions. Although we agree that this MOU is not an appropriate means to redress these inequities, we agree that any such inequities should be addressed by an appropriate institutional framework.

IREC and IRB Standard Operating Procedures (SOPs)

We agree that all collaborative research proposals will be independently reviewed by the IREC and IRB. Each proposal can be reviewed either simultaneously or sequentially.

We recognize that much can be gained from the expertise that both institutions have in developing policies, procedures, and training materials. We are committed to sharing these materials and to working together to develop policies and SOPs.
The Way Forward

It is expected and intended that among the actions arising from this MOU will be the development of policies, Standard Operating Procedures and other resources that will address specific issues not mentioned here. This MOU is developed in the spirit of respect and mutual trust. This MOU collaboration will foster continuing excellence in research.

Moi University Signatory

Moi Teaching and Referral Hospital Signatory

Indiana University Signatory

Date  Date  Date
Appendix B: Existing SOPs at IU

IU SOPs (drafted, approved, or in revision)

1. Auditing of Research Involving Human Subjects
2. Collection, Storage, and/or Use of Biological Specimens for Research
3. Conflict of Interest Reporting to the IRB
4. Data Management
5. Emergency Use of and Planned Emergency Research with Investigational Agents or Devises
6. Exempt and Expedited New Study Approval Process
7. Handling Humanitarian Use Device
8. Handling Serious and/or Continuing Noncompliance with Human Subjects Regulations
9. Handling Unanticipated Problems Involving Risks to Subjects and Protocol Deviations and Violations
10. Human subject Identification, Selection, and Recruitment
11. Investigational Device Accountability
12. Investigational Drug Accountability
13. Involving Minors (Children) in Research
15. Involving Prisoners in Research
16. IRB Operations and Study Approval Process
17. Obtaining and Documenting Informed Consent
18. Policies and Procedures for the IUPUI/Clarian SOPs
19. Reporting Adverse Events to the IRB
20. Research Personnel Qualifications and Training Documentation
21. Responsibilities of Principal Investigators
22. Safety/Risk Assessment and Oversight Plan for Research Involving Human Subjects
23. Security of Research Data
24. Student Research Involving Human Subjects Subject Confidentiality and Privacy

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1 Found at http://www.iupui.edu/%7Erespoly/human-sop/human-sop-index.htm
Appendix C: Existing SOPs at Moi University

1. Role of IREC
2. Membership
3. Terms of Reference
4. The Executive Committee
5. The IREC Secretariat
6. Functions and Responsibilities
7. Regular IREC Meetings
8. Conduct of Meeting
9. Submission of a Research Proposal
10. Communication of Review Decisions
11. Expedited Review
12. Monitoring and Evaluation of Research

2 Found at http://www.bioethics.iu.edu/IREC.doc
Appendix D: Existing Human Subjects Protection Test

Please select the best option for each question.

Note: In all questions, "IRB" refers to the Institutional Review Boards at IUPUI and the Human Subjects Committee at IUB.

1. Which of the following statements is not true?

Any negative event that might be related to a research project and

a. ☐ is fatal or life-threatening is considered a serious adverse event.
b. ☐ qualifies as a serious and unexpected adverse event must be reported to the IRB.
c. ☐ is not covered by the subject's health insurance is considered a serious adverse event.
d. ☐ is not described as a possible side effect or outcome in the documentation provided to the IRB is considered an unexpected adverse event.

2. On a project that has been approved by the IRB, changing recruitment methods from posted notices to e-mail solicitations

a. ☐ needs IRB approval.
b. ☐ should be noted in the PI's continuing review form.
c. ☐ is inconsequential and can be done without IRB approval.
d. ☐ can be reported to the IRB after implementation.

3. Which of the following defines when IRB approval must be obtained?

a. ☐ Before the protocol is written.
b. ☐ Before the grant is funded.
c. ☐ Before data collection begins.
d. ☐ Before the study is published.

4. In the context of research with human subjects, 'continuing review' means

a. ☐ the PI must be aware of the progress of the research project at all times.
b. ☐ the IRB must review every active protocol at least once a month.
c. ☐ the IRB must review every active protocol at least once a year.
d. ☐ the PI must submit weekly progress reports to the IRB.

5. Research classified as 'exempt'

a. ☐ may be conducted before submitting the study to the IRB.
b. ☐ does not need to be reviewed by the full IRB.
6. The Institutional Review Board at IUPUI and the Human Subjects Committee at IUB are responsible for protecting the rights and welfare of human research subjects
   a. includes all studies regardless of funding source.
   b. only in studies funded by the Federal Government.
   c. only in studies funded by the National Institutes of Health.
   d. only in studies that are funded by not-for-profit or government entities.

7. Which of the following must be in an informed consent document?
   a. A description of risks and benefits to the subject.
   b. The researcher's home address and telephone number.
   c. A description of the methods of statistical analysis to be used in the research.
   d. A waiver of the right of the subject to sue for damages incurred in the research.

8. Which of the following statements best describes the purpose and scope of informed consent?
   a. Consenting a research subject involves securing his or her signature on the informed consent document.
   b. Informed consent is an ongoing process to ensure that subjects participate voluntarily, with a good understanding of the risks and benefits of participation.
   c. The primary purpose of informed consent is to limit the legal liability of the researcher and the institution sponsoring the research in the event that harm accrues to research subjects.
   d. Informed consent is only necessary for research involving substantial risk of greater-than-minimal physical harm to the human subject.

9. Every investigator who undertakes research with human subjects should seek approval from the IRB because
   a. failure to do so could jeopardize the researcher's work and lead to the suspension of all human subjects research at his or her institution.
   b. it is every researcher's moral obligation to protect the human subjects involved in his or her research.
   c. federal and institutional rules require it.
   d. all of the above.

10. When soliciting human subjects for and enrolling them into research projects,
    a. risks and benefits should be spread equitably across society.
    b. risks should be concentrated in as small a population as possible.
c. benefits should be carefully targeted to a specific population.

d. risks and benefits are not a significant factor.

11. In research with children,

a. parental consent never overrides the child's clear desire not to be involved in the research.

b. research involving greater than minimal risk is never acceptable.

c. written parental permission is generally required.

d. written parental permission is always required.

12. Who bears ultimate responsibility for the conduct of human subjects research, including ensuring that the protocol is followed and kept up-to-date?

a. Every member of the research team.

b. The university.

c. The IRB.

d. The principal investigator.

13. For a study using an existing computerized database, no IRB approval is necessary

a. if the PI has an access code to the database.

b. if the database is accessible to the public.

c. if the subjects are not individually identified and the information is being used for internal quality assurance.

d. if the information in the database is about your patient you are enrolling in a study.

14. For regulatory purposes governing research with human subjects, which of the following is least likely to be considered an example of human subjects research?

a. Surveys or polls.

b. Research on tissue samples from an identifiable person.

c. Interviews intended only for printing in a local newspaper.

d. Telephone interviews with no physical contact between the interviewer and the persons interviewed.

15. Indiana University graduate and undergraduate students

a. may not conduct human subjects research.

b. may only be subjects in research conducted by their own teachers.

c. must obtain IRB approval for human subjects research that they plan to publish.

d. never need IRB approval to undertake human subjects research that is part of a class assignment.
16. Any changes (amendments) to an IRB approved research protocol
   a. must be reported to the IRB, no matter how minor.
   b. require re-submission of the entire application form, suitably altered.
   c. must be reported to the IRB only if they increase the risk to human subjects.
   d. must be reported to the IRB within thirty days after the changes are initially implemented.

17. Which of the following must be in an informed consent document?
   a. Investigator's signature.
   b. Investigator's credentials.
   c. Name and address of the subject.
   d. A statement that subject can withdraw from participation at any time.

18. The principle of justice, as identified in the Belmont Report, demands that
   a. everyone is free to become a human subject in any research project of his or her choosing.
   b. risks and benefits of human subjects research should be spread evenly through society.
   c. people who may be harmed by research should be excluded from volunteering as research
      subjects.
   d. only people who can directly benefit from a research project should be used as human
      subjects in that project.

19. Which of the following is least likely to require local IRB approval?
   a. Data collected in a classroom at Indiana University by a researcher from another University.
   b. Data collection for a state agency to evaluate a state program.
   c. Student research for class projects which do not involve more than minimal risk but will be
      presented at a regional conference of anthropologists.
   d. Less-than-minimal-risk observational research intended for publication.

20. The following studies are all intended for publication in peer-reviewed research journals. For
    regulatory purposes governing research with human subjects, which one does not constitute research
    involving human subjects?
   a. Non-therapeutic research on blood samples from living, identifiable cancer patients.
   b. Research on bone samples from a Revolutionary War battle site.
   c. Oral history interviews about a County Fair.
   d. Therapeutic research on cancer patients.