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

Volume II: The Responses

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Outline

This volume provides further data and information from the Key Informant and Focus Group Interviews. In particular, it includes key representative responses from participants as well as a description of the approach used to organize the responses.

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.

- 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 differences in policy and practice between institutions that affect the conduct of international research.

- Key Informant Interviews (KII) with administrators, researchers and committee members gathered information 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 individuals who set policy within the institutions was imperative however when provided in the setting of a focus group may have inhibited 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.
Focus Groups and Key Informant Interviews

All interviews were conducted with one or more of the Co-Investigators and a research assistant. A detailed interview guide consisting of 19 questions was designed to be for both interviews and focus groups, and at both IU and MU. However, following the first focus group interview, the investigators decided to omit 2 questions (#13 and #16) because they were found to be redundant and inhibited the flow of discussion. These questions were, however, asked of MU participants. All interviews were tape recorded and transcribed by a professional transcriptionist.

Once the transcribed interviews were reviewed and edited by a research assistant, they were distributed to Drs. Meslin, Sidle, and Wools-Kaloustian in order to begin a simultaneous analysis process for transcripts from each institution. This occurred in three “rounds”.

- First Round

  Each analyst chose three key representative phrases from each of the nineteen questions.

  The key representative phrases were then compared (in nearly all the cases the analysts had chosen the same phrase) and brief discussion on differing phrases took place to come to an agreement on the phrase to be used.

  Once the phrases were in place, the respondent’s answers were then summarized, with a conscious effort to include all differing perspectives.

- Second Round

  Analysts reviewed the summaries and agreed on the content.

  The key phrases and the summaries from each institution were then placed into one document.

- Third Round

  For each question, a “take home point” that summarizes the main idea from both institutions and an “action item” that aided in the creation of our recommendations was inserted.

  Analysts reviewed each “take home point” and “action item” and agreed on the content.
The Responses

Below we provide the 19 questions and their responses. We have included many of the key representative quotes. It is from these lists of representative quotes that we selected one or two for inclusion in Volume I.

Prior Knowledge of the System

1. Prior to being contacted for this interview / discussion, were you aware of the Memorandum of Understanding (MOU) regarding research ethics between Moi University Faculty of Health Sciences (MUFHS) and Indiana University (IU)?

Aware

(IU) “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.”

(IU) “I suppose it was to make sure that we had a common launching point, or a common framework for the way forward as they you know using sort of some of the vernacular that our friends at MOI University use”

(IU) “…it had several purposes but one of the major ones was to try to reach some kind of an understanding between our two institutions as to what roles each needed to play in supervising research conduct, particularly research that was initiated or at least participated in from the Indiana side and conducted in Kenya since those types of relationships sometimes get to be one-sided and to make sure that the needs of the Kenyan side were taken into consideration and also to some extent to try to streamline the process as much as possible to make it relatively easy to conduct research at the same time protecting the interest of particularly the Kenyans but obviously on both sides providing protections for research subjects and allowing investigators to do what they needed to do as easily as possible.”

(IU) “The longer term goal was to stimulate a dialog. A dialog on, among the researchers for two reasons. One is, I mean the wider goal was to if we’re going to be collaborating with researchers just any excuse to get us to talk together is a good thing. But the narrower goal was that there are a lot of issues on research and research ethics in the developing world that are a moving target at this point and we could either be reactive or we could be proactive…”
"I guess I more thought of it as I guess already as a memo of understanding that you know we all have some basic principles in mind...."

"In view of the existing partnership between Indiana University and Moi University, it was necessary to have a memorandum of understanding to outline the nature of the partnership and general rules to govern the partnership."

"I think the purpose was to institute a formal arrangement between IRB and REC, 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 institutions and how together we can resolve those."

"I gathered that the MOU was supposed to ensure that research undertaken at Moi University in collaboration with the Indiana University counterparts get approved by both the IRB in Indiana and the IREC here at Moi and that each of the IRB's would independently review the protocols and make a decision and even after that the collaborating institution has to also go ahead and do their own review. I think the idea also was to ensure that there is some similarity or rather comparability between the activities of IREC and the IRB at IU."

"My understanding is that any collaboration, any research between Moi University and Indiana University is something which must be agreed mutually...”

Not aware prior to interview

"....that it’s to lay out the fact that you respect each other’s respective IRB processes and they’re both important and that to do collaborative research you have to understand and accept you know the other IRBs take on things and reach consensus when you

"don’t agree and it just laid out a nice tone for developing that process but it doesn’t lay out any specifics about the process.”

"....it is not terribly clear to me yet as a non-institutional person and not research oriented, why it is important for these two groups to connect in this kind of Memorandum of Understanding.”

Summary from IU interviews: A substantial number of the individuals interviewed 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. There was one individual concerned about why the development of such an agreement between two independent bodies was needed.

Summary from MU Interviews: All participants interviewed had prior knowledge of the MOU. For all but one of the participants, who was concerned because he had not had the chance to
review the MOU before the meeting, the attitudes were positive. The general consensus was that the purpose of the MOU was to find a mutual agreement between the two collaborating universities, more particularly an understanding between the IREC and the IU IRBs.

**Take Home Point:** While the majority of IREC members/Kenyan researchers are aware that a MOU related to research exists between Indiana University and Moi University, the majority of IRB members/U.S. researchers were unaware of such an MOU.

**Action Item:** Members of the IRB and researchers participating in projects related to the Eldoret site need to be educated about the relationship developed between the Moi University IREC and the Indiana University Research and Sponsored Programs office.

**2. What is your understanding of the IU IRB procedures for reviewing an international protocol?**

(IU)“…our struggle is that “Are we approving an informed consent that is, will be well understood by the common person in Kenya?” And so we felt like why should we be reviewing it? Why shouldn’t it be a board that is you know familiar with the language and review it in Swahili rather than in English.”

(IU)“.We don’t have any policies on this as you know and that’s certainly something that we need to work on so it’s more of a gut check kind of reaction to things but for the most part I would say that the additional piece that comes about with international studies are the issues of the local contacts. How people will be approached. What's acceptable in these other nations and then also the issue of frankly that the mundane sorts of things like what language is the consent form going to be in and is it translated accurately and how are we going to go about insuring that?”

(IU)“…you have two different review bodies reviewing the same document. They always have different things that they want to have done and so there are always issues of reconciling as well that come into play but they do have to approve the final document.”

(IU)“We just had a deeper discussion about you know what was the culture issues and some of the safety issues of the participants that they were freely speaking about.”

(IU)“I know we were very concerned with the consent and this whole idea of written consent because in a lot of cases the moment you have a written consent and that person’s name is on a paper that is what you know ties them to having participated”

(IU)“I think that the general elements certainly are the same. Subject protection, informed consent and no coercion at all. I think that there has been and obviously sensitivity 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 conformed consent may not be the appropriate vehicle to obtain that.”

(IU) “So I think that there’s been a dialogue frankly between investigators and IRB members that for international studies that often exceeds that dialogue for you know non-international studies and in terms of being much more explanatory about what the needs are and what the concerns are.”

(MU) “Well I have looked at the documents and I must say that it is not clear within the IU procedures whether they are reviewing international protocols. I think the IRB in Indiana is looking at, was basically set up to review US based research and in my view there is very little incorporation of international research. I think these SOP’s are intended to fill that gap because of the lack of information of the IRB.

(MU) “It could be possible that they are trying to develop one for foreign policies, foreign organizations but I can’t remember seeing any, yeah…IRBs at the states have established so far is good in that first, you’re giving your home institution the mandate to determine if this research is ethical, ethically right, so to say, and that can be done within this home base. So I think that first step is key other than that the procedures that should just be the same as they are now…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, yah.”

(MU) “Yeah, it was specific because I mean it was a big document I had to go through—very big actually—and there were lots of—but it was very clear—lots of instructions what to do.”

(Moi) “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.”

(MU) “Yeah. I had the opportunity to visit Indiana and have a meeting with the Chairman of the IRB. So I was really fascinated by the elaborate arrangement they have in IRB where they are able to look at proposals internationally. So they do conform to the international guidelines; like CIOMS, the Helsinki, and the WHO. Of course they have put into the context of the of the Indiana system.”

(MU) “That is a very easy question. Actually I don’t know them.”

Summary from IU Interviews: The majority believed that International Protocols are reviewed at IU 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. Respondents expressed concerns about protocols being culturally appropriate and acknowledged that there is frequently more dialogue with the PI for international protocols and that the R&SP provides experts to review issues of language. The issue of accurate translation
of consent was also a concern. There was also some discussion of the method of consent. There was acknowledgement that International Investigators had to complete the Human Subjects Protection test for IU.

Summary from MU Interviews: A few participants believed that the procedures for reviewing an international protocol were the same at each institution. One participant did not know the procedural relationship between the two universities. Some participants commented on the “elaborate arrangement” and “large document” the IU IRB had concerning international reviews. 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. Others just simply admitted that they were not aware of the procedures.

Take Home point: While the majority of IU IRB members/U.S. researchers working in Kenya are aware that international protocols are reviewed in a manner similar to that of domestic protocols, IREC members/Kenyan investigators were generally unaware of how the US IRB handles these protocols.

Action Items: 1) IREC members and Kenyan researchers doing collaborative work with Indiana University should be educated about how the IRB handles international protocols. 2) An SOP for the review of international protocols should be developed in order to provide a resource for education.

3. What is your understanding of the MUFHS IREC procedures for reviewing a protocol?

What are the procedures...

(IU) “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.”

(IU) “Things take a little bit longer to get through their IRB for a couple of reasons. One being that at one point, I don’t know about now, but at one point it was meeting quarterly so the response time was down a little bit. And they have the same problem that a lot of IRBs have only more so and that is it's very difficult for them to get a quorum at meetings.”

(IU) “…they do have a somewhat different format for how they want things submitted to the IREC compared to our IRB so that projects that are submitted to both have to be kind of reshuffled and have the submission put in their format for the IREC to get it in a form that they like to see it in just in terms of physical way it’s presented to the committee. And again because of the less frequent meetings the turnaround time tends to be a bit longer…”

(MU) “I don’t think there are any 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 its 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, then its up to the secretariat to determine it its going to go for full review, expedited review or if its going to be given exempt status as of yet.”

(MU) “Currently there are procedures, but my understanding has been that they are evolving and there has been a lot of input from Indiana University to see if they can complement the current procedure.”

(MU) “What I know is that they have a format that they expect researchers to adhere to, and it’s like I remember they gave me just one page with sections…So I think it is very important to have a structure that everybody must follow, and I want to believe if a protocol comes in and if get everything is everywhere, it should just be returned with that one page from Christine saying ‘Please can you just organize our material in this format and make it easy for everybody’…”

(MU) “…I think the only difference is that you might not get back the results of what you expect in the time that you expect, so I think that is the only shortcoming that we seem in that Standard Operating Procedures.”

What procedures should be in place…

(IU)“ I think the constitution of the committee is important that you have someone who understands the issues involved in the IRB review and that you have local people on the board and that you don’t have conflict of interest.”

(IU)“I think conflict of interest you have to be very careful that you don’t have the investigator and the 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 I 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.”

(MU) “But as a requirement I think if it is an international sort of proposal there should be a local co-researcher to work with. Sort of a Kenyan researcher.”

Summary from IU Interviews: The majority of the participants were unaware of how the IREC functioned. For those aware of the procedures for IREC, they felt 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. There were some suggestions as to what the members of the U.S. IRB would consider important for another IRB; these would include the constitution of the other IRB, procedures for dealing with conflict of interest, policies and procedures for informed consent, and provision of continuing education to IREC members.

Summary from MU Interviews: All of the participants were aware that the IREC had specific procedures for reviewing a protocol. Several participants described the IREC procedures in detail.
Some participants acknowledged that IREC procedures were currently evolving as more reviews were being completed. One respondent suggested that IREC procedures and guidelines should require a Kenyan co-investigator on international protocols.

**Take Home Point:** The majority of IU IRB members/Researchers were unaware of how the IREC functions including their procedures for reviewing protocols, the constitution of the committee and their procedures to deal with conflict of interest.

**Action Item:** 1) IU IRB members/Researchers need to be educated about how the IREC functions including procedures for protocol review, constitution and methods for resolving conflict of interest issues. 2) All protocols initiated from the IU side of the collaboration should be required to include a Kenyan counterpart on the protocol.

5. Which individuals (or groups) within your institution:

   a. have primary authority over decisions about cooperation between these two collaborating bodies?

   b. should have primary authority over decisions about cooperation between these two collaborating bodies?

   c. should facilitate communication between the IRBs and the IREC? (b and c are areas of need however their responses are mixed in with a and so they are addressed here)

   (IU)“But if, for instance, 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.”

   (IU)“It's become clear that the faculty are frustrated with, not just the IRB process but in sort of an undifferentiated way with the whole contracting, IRB review, blah, blah, blah and you probably where have all these tasks forces and committees that have been formed to look at all this? Some of the stuff that I'm hearing suggests that there is a push being made to perhaps use one of these sort of independent IRBs for review of certain protocols and that they would not be reviewed again by our IRB.”

   (IU)“What really kind of catches my attention with that is if we would agree that the two Vice Chancellors are the you know are the decision-makers what catches my attention is do we at this point need to have some foresight of who might that third party be? Who might the tie-breaker be?”

   (MU) “See, at the moment, the Ethics Committee is based in the hospital, and the IRB is based at Indiana University; but the collaboration is between Indiana University and Moi University. So that means that the Director…and whoever is
responsible on this side should be responsible. And then other people come in, and most of the researchers also, come from the Faculty of Health Science.”

(MU) “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.”

(MU) “I believe that’s solely the responsibility of the secretary of IREC. Yeah. Currently Dr. Were. It should be his responsibility to ensure that any communication is done.”

(MU) “So I want to believe the Director and the Dean and of course the IREC committee or at least a core group in the committee should be the group, and I think these are the individuals who should be involved. And someone like Nyandiko now who has an office director of research in AMPATH, when such an individual gets an office of that title he should be involved. He should be involved in IREC.”

(MU) “I thought that falls under the auspices of the Human Subjects Office…”

Summary from IU Interviews: The majority of those interviewed indicated that the Vice Chancellor for Research for the medical school should be responsible for these decisions with or without input from the executive committee. One individual noted that if the Vice Chancellor of Research at both institutions was responsible for this process then who else should be involved as the neutral third party if a tiebreaker were necessary. Some participants indicated that administrators in Bloomington might also need to be involved but this was not warmly embraced because of their distance from the investigator. 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. In addition, there was some discussion of total deferment to other IRBs for selected protocols (it is unclear what the future of this will be). One individual felt that it was the responsibility of the PI to reconcile the input from the two IRBs.

Summary from MU Interviews: The majority of participants 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 IU and MUCHS. 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 authority the majority of participants interviewed believed that it should be granted to the IREC and/or the chairman of the IREC. When asked who should facilitate communication between IU and MU the majority indicated the IREC Secretariat. Other answers included the Projects office, the IREC Administrator, and the chairman of both the IREC and the IRB. One of the participants suggested that the Director of research in AMPATH be involved in the IREC.

Take home point: There are varying opinions both within and between institutions about how conflicts should be resolved and communication should be handled.
**Action Item:** An SOP should be developed to address conflict resolution between the IU and MU IRBs including designation of the individuals responsible for initiating this communication.

**Specific Issues--IRB Activities**

6. We are interested in hearing your opinions about the interactions between the IREC at MUFHS and the IRBs at IU:

   a. To your knowledge, is there any interaction between the IREC at MUFHS and the IRBs at IU?

   (IU)“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.”

   (IU)“…since we have this agreement where, or the memo of understanding at least that both sides are going to review the same study it would make sense that we would have some dialogue or at least the sharing of approval documents or sharing at least of discussions during meetings about what the different IRBs had concerns about because I would bet my bottom dollar that we have different concerns coming from different perspectives so certainly that would make sense …”

   (IU)“Now when Christine Chuani (the IREC Administrator) visited here she certainly spent some time with Shelly (the IRB Administrator) and other IRB staff members to try to develop a relationship there and she may feel like she can talk to people there direct if there’s a need …”

   (IU)“A lot of their (IU) studies are multi site studies and I can tell you that there are always difficulties in the clashing, you know just the non-synchronization of IRBs and to be honest with you it was harder between here and the University of Washington than here and between IREC”

   (MU) “Ya, umm there is some interaction…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. That is one interaction, at least Indiana University has assisted us by giving us expertise in terms of resource persons…Also, like when it comes to test yeah you will realize that for us people here at IREC we have not developed a test of our own but not for human subjects but we have come to an understanding with the Indiana University IRBs that we can use their test, you know, when our researchers need to show that they have done some ethical tests they can just access the Indiana University test and do it and they have availed us with that. And they have also provided us with lots and lots of material that we use for reference here and there and they are there….there has been quite a bit of interactions since the time I joined IREC between our IREC and the IRBs in the USA for Indiana University.”
“I would say yes, because the IREC through this interaction has seen the training of Christine to be able to run the IREC Office more efficiently. So Christine had to go to IU and spend some time at the IU Human Subjects’ Office for her update herself and to understand. To me that is an interaction between the IRB and the IREC.”

“I don’t know how much there is, because after that workshop I would have expected exchange of information between our IREC and the Indiana IRB, but since I am not involved in the day to day basis with the IREC perhaps there is communication which I am not aware of…”

“Well apart from the countries, apart from the three-day workshop, personally I have not been able to realize a difference, which originates from Indiana, but I have been able to see some papers, some proposals, which came from Indiana group…the only collaboration or the only way of improving this is I think form time to time, we should be having some kind of a joint meeting. It shouldn’t be one way, I mean, if we are able, if three or four of you come from Indiana, I don’t see any reason why three or four from here can’t go to Indiana if the funding will allow. Sort of to see really on the spot what happens.”

“I think the emails going through the secretariat…”

**Summary from IU Interviews:** The majority of participants were unaware of any formal interactions between the two review bodies. However, there was support for future interaction. Some individuals were aware that the IREC Human Subjects Administrator had made an observational visit to the IRB at Indiana, and some were aware that Indiana had assisted the Moi Faculty of Health Sciences IREC in developing their current structure. There was some indication that the interactions between the IREC and the IRB were easier than interactions with other U.S.-based universities.

**Summary from MU Interviews:** The majority of the participants 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 being the training of the IREC Human Subjects Administrator at the IU IRB. Two participants noted the presence of IU faculty members on the IREC. One noted the MOU as an interaction. Another noted the IU Human Subjects Training, which is being used at MUFHS. A small number of participants believed that there was no practical increase in interactions between the IREC and the IRB since the meeting that formed the MOU. One suggested a way of improving collaboration between the two institutions would be to implement a bilateral exchange of IRB and IREC members.

**Take Home Point:** There are varying opinions both within and between institutions about the level of interaction that currently exists between the IRB and IREC.

**Action Item:** Develop a plan for regular communication between the IREC and the IRB. This may include joint educational programs, exchange of IREC and IRB members, and workshops to address issues related to international research which may be of concern to both the IREC and the IRB.
Specific Issues--Informed Consent

9. Do you think that informed consent should be handled in the same way at both institutions?

(IU)“Now people in the United States are used to signing forms and sometimes it’s a barrier and sometimes it’s not. But if it’s culturally a barrier in another country then that’s where their IRB board has precedence understanding that.”

(IU)“Not necessarily. I mean I think we have to follow the 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 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....”

(IU)“...I think it’s more important that we have a mechanism where we show that the details of the protocol was well explained to the patients and the side effects and whether it’s verbal or other mean of communications but you know you can tape it you can you know some sort but I don’t think it should be the same standard I mean it’s a totally different culture.”

(IU)“...I think the informed consent should be reviewed by people on the ground you know who are familiar with the culture of the language.”

(MU) “I don’t think the process in the U.S. is the same as here. But you can have a broad definition of the process, but the specifics should be left to the respective institutions.”

(MU) “...No. You see, the consent is generally written...Now a lot of people that we would be requiring to give a consent may be illiterate or may not understand sufficiently the translation, particularly into Swahili, to be sure that they are giving informed consent...”

(MU) “In principle it should. The only thing is that the level of understanding and appreciating research in this country is not as high as in the US, 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 statement because of their some of their reservations regarding signatures. So I think I principle yes, but I think we have to make sure that it is customized to the area you are working in.”

(MU) “...we should stamp the Informed Consent document process and make sure that it is used...other than that, I think the informed consent is the same: it is a process that should be followed, structured across the world so the document that is there just needs to be restructured to fit Kenyan needs, you know,
translations...yeah?...clearer understanding depending on the people who you are dealing with, but the content matter should be the same at the end of the day.”

(MU) “Not necessarily”

Summary for IU Interviews: The majority of respondents indicated that they found no difficulties arising from the consent process being different in Kenya than in the U.S. They emphasized that a way must be found to document an individual’s understanding of the research and their willingness to participate. One individual indicated that if a protocol were conducted simultaneously in the U.S. and Kenya then the consent process for the two sites should be similar.

Summary for the MU Interviews: Some participants believed that the process of informed consent could be similar at both locations, but most stressed that the 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. One participant felt that both institutions needed to clarify the meaning of informed consent because a signature doesn’t necessarily signify a complete understanding.

Take Home Point: There appears to be a general feeling that the consent process can be different at the two sites but that insuring that subjects do provide informed consent is important.

Action Item: The IREC might consider the development of an SOP for informed consent (written and verbal). This SOP could be used to inform and educate other review bodies about what is considered to be the standard for obtaining consent in western Kenya and in what situations written vs. verbal consent would be most appropriate.

10. In your opinion, are there particular issues about informed consent differ between the IU IRB and the MU IREC?

(IU)“I mean my own view is that written informed consent is probably the standard on the to obtain informed consent and I think again the investigator has an opportunity to make that argument.”

(IU)“…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.”

(IU)“I mean I think for some research where the risk would have to be, would be considered greater I think it would be more difficult to rely on non-written consent than for research that is relatively minimal risk.”

(IU)“Part of my education in doing research in Kenya is understanding that the default way of obtaining consent there is verbal and not written.”
(MU) “I think the main one is consent issues, which we have discussed even before. And you find that some, sometimes in our community, when you ask somebody to append their signature somewhere, it sounds like you are tying them to something unknown. But the requirement for consenting also from the other side is much more rigorous than we do around here, so that is the main difference.”

(MU) “I think the basic principle is just the same whether it is that side or here. Yeah, the detailed explanation will take into account the people’s differences, but I think that should really make us focus on what the informed consent should be.”

(MU) “I think the context here, we have to accommodate verbal consent more much as we insist on signatures.”

(MU) “The whole area of the approval process. One area is the informed consent for instance. In the IRB system they require the written—the individual must give written consent by signing. However in the African set up, we have socio-cultural factor 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.”

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

Summary for MU Interviews: Most of the discussion 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 the African culture.

Take Home point: Generally the respondents from the U.S. were more comfortable with participants providing written informed consent while the respondents from Kenya were more comfortable with the concept of verbal consent.

Action Item: The IREC and the IRB should jointly explore ways of obtaining non-written informed consent which would be acceptable to both review bodies.

11. A research project is being proposed for rural western Kenya in which subjects will be interviewed about their health and economic status in their homes.

   a. The protocol requires that the permission of the village elder be sought prior to entry into the community. Does this requirement concern you?

   (IU)“They’re (Physicians are) acting as a gatekeeper and we have many gatekeepers here in the United States. Almost every study you have a gatekeeper. I mean we could philosophically talk about whether that was appropriate or not.”
“...I think that we should defer to what the sort of local perspective is and that’s a case where I don’t think to the extent possible that if that study were being conducted here certainly our autonomous participants would not want any sort of elders deciding for them and we couldn’t make that a requirement here but or even entertain it here I don’t believe but there you have to think about realities.”

“Kind of akin to I need permission to go into your practice to enroll patients and the practice requires permission of the practice director so in that particular instance I don’t have a problem with it.”

“I mean it’s really analogous to an individual physician allowing you know consent to or the access to their patients, I mean it’s really not substantively any different than that......I mean again I think physicians and it sounds like the elder has some feeling of responsibility to their charges and wants to you know maximize benefit and minimize risks of their population so I think that that’s a threshold that I think that we all have to get over when we’re pursuing research and I suspect it’s the same threshold in Kenya.”

“It doesn’t pose a problem because it seems to be consistent with the culture and it would be required and all that but this discussion brings up another side that I just have to mention is that the elders in their particular positions will be, have another interesting challenge and it’s the challenge of incentives …”

“I mean from an IRB’s perspective I think it’s again it’s another barrier to enter research but at least from an IRB perspective additional barriers are not really my primary concern.”

“I guess it doesn’t bother me because I’m on the behavioral IRB and so many of our subjects are prisoners or they’re children or they’re persons who may lack the mental capacity to give consent for themselves or they’re students and we’re talking about a principal and teachers so that it seems like we have, it would be, it’s the less likely case where we only have the one person can sign, it seems like we have to get multiple people involved.”

“So to me it should not just be a requirement in this particular research, but it is a procedure of getting to the community and that facilitates the smooth entry of the researcher into the community and also the ease of getting information because that way the community knows when they see their chief or their village elder, then they know this person who is with this person must be an ok person---they will feel secure.”

“If one person mobilizes the community against the researcher, then you’re going to be wasting your time. You might not even get the right answers from that community...they would have their own person they would trust; usually it would be the Traditional Birth Attendant (TBA) or somebody like that. But the village elder is in a position of authority, so it is important that he is also brought on
board. You must also look for two opinion leaders in that community, and that will assist the researcher tremendously.”

(MU) “I think it should be mandatory for all community-based service because as you said the people do not really comprehend research as much, and I think the presence of people asking information in the community can be misinterpreted and can also be used against the researchers. So I think for purposes of ensuring not just the safety of the researcher but also the safety of the respondent, it is good to ensure that the village elder, the community leader are informed, and they communicate to the people in the village what is going on, and that will facilitate the data collection process.”

(MU) “Fine, he is a gatekeeper in the particular community. But there are many other gatekeepers, people who are of significance in any community and not all villages are the same…If he has his own personal idiosyncrasies and like I said attitude towards scientific work, he may say no and a whole village misses out on something very important. But on the other hand depending—I guess it is a fifty fifty answer…personally I believe in going to a community and asking who is a significant gatekeeper here. An not necessarily so that they can consent for the community and then I go and meet individual people and now they consent at that level, but just so that they can give me ideas as to how I can go about doing my study.”

(MU) “No, they don’t need to sign, but you need to get to that community through seeking their consent.”

Summary from IU Interviews: Some individuals believed that the use of a village elder was similar to the use of a primary care provider as a gatekeeper. Others found it culturally different but acceptable, and they believed that it was necessary to work within the cultural system. There was some discussion that a threshold of a gatekeeper feeling responsible for other individuals should be used. There was also concern that this practice could increase barriers to research and some concern over the issue of whether incentives would be provided to the Elders.

Summary from MU Interviews: For most participants it did not concern them if the village elder was sought prior to conducting research in a community. Many participants acknowledged that this was a procedure rather than a requirement. Others believed that if the researcher did not speak to the village elder prior to research, the likelihood of acquiring information from the community was nearly impossible. The other participants that were concerned believed that the entire community, rather than only the village elder, should be sought prior to research. Another suggested that the researcher speak with the Traditional Birth Attendant (TBA) and two opinion leaders in the community in addition to the village elder.

Take Home Point: In general IU participants believed that involvement of village elders as gatekeepers should be respected if this were culturally appropriate. Participants at Moi University seemed to agree that involvement of an accepted opinion leader from the community was necessary prior to undertaking community-based research and that this procedure is an expected, though not a required, part of any protocol.
**Action Item:** For any community-based research planned in Kenya, Kenyan investigators should guide the protocol with respect to appropriate community entry.

b. *if the protocol did not require the permission of the village elder prior to entry into the community, would this concern you?*

(IU) “I think it depends upon the likelihood of the person you’re approaching being harmed or upset by you’re approaching them.”

(IU) “It depends on whether or not it’s expected by the community. If it’s a community where it’s appropriate to get the relationship of the community members to its elder is that it is appropriate to go through the elders and you don’t do it, then it’s inappropriate not to do it.”

(IU) “Not understanding the culture probably not but this is exactly why I think there are local IRB rules so that you know hopefully the people in MOI will say look this isn’t going to work, we need to do this and again…”

(MU) “I think it would because it is just like doing a research at the hospital here, and then you say you are going to do the research—it might not be related at all to the Director’s office—you’re going to say do it at the blood bank, but the blood bank is part of the teaching and referral hospital and you decide to go and do it without telling the director. If he was to hear that you are doing that research somewhere, he would feel very offended…If you can go ahead and seek permission from the DC and the DO, then why leave out that village elder and these are his villagers. I think it would concern me a lot. It is just order that you should do it.”

(MU) “I don’t know whether it should be part of the protocol. But part of the approach should include that.”

(MU) “I think the point there is that the researcher is the one who is who is going to suffer the consequences of not using the culturally acceptable way of entering the community. So whatever research they are going to do, if they don’t put in place entry into the community as part of their procedure, then they are going to fail in whatever research they are doing.”

**Summary from IU Interviews:** Respondents agreed that this was an expectation of the culture that they would feel uncomfortable if this were not included in the protocol. However participants indicated that they are frequently unaware of the cultural norms when reviewing an international proposal and must rely on the local IRB to inform them.

**Summary from MU Interviews:** The majority of respondents said that it would concern them if the protocol did not require the permission of the village elder for the same reasons that were stated in the previous sub-question. One mentioned that they were not sure if it needed to be in the protocol, however it should be the approach of the researcher. Those who said it would not concern them cited reasons such as: it would be foolish not to obtain permission, it would be
expected to be done, and that the elder needs to only be informed rather than asked permission of entry.

**Take Home Point:** In general IU participants felt that involvement of village elders as gatekeepers should be respected if this were culturally appropriate. Participants at Moi University seemed to agree that involvement of an accepted opinion leader from the community was necessary prior to undertaking community-based research and that this procedure is an expected, though not required, part of any protocol.

**Action Item:** For any community-based research planned in Kenya, Kenyan investigators should guide the protocol with respect to appropriate community entry.

c. **The protocol requires that the permission of the head of household (usually the most senior male living in the compound) be sought prior to interviewing any member of the household. Does this requirement concern you?**

(IU)“Not if that’s the custom and if you approach someone without that consent that it would make them uncomfortable.”

(IU)“Obviously I don’t like that system but who am I to say what is the right thing? I mean if I, I'm conducting a research that will benefit that populations and I think this is the best way to bring something new and novel that will improve the health of that society despite my dislike of their system I think if that’s what the requirement then it doesn’t bother me.”

(IU)“Yeah, I think for the project you described I think that would be appropriate. I think there are times when that sort of requirement would be a little bit concerning to me.”

(IU)“No, it’s also, I think it’s also the kind of information you are seeking so in that sense the risk I think figures into it as well because again it’s appropriate I think from the kind of information you’re seeking to go that route and to discuss with these people.”

(IU)“No, as a basic tenet it doesn’t bother me to get permission from the household. In specific instances it bothers me because there are certain issues related to gender roles, etc. that would be very impossible to study if you have to go through the male head of household.”

(MU) “Actually I think that is necessary…Because I know decision making in the home, actually it’s the man. Most of the time the women just suggest stuff. They really can’t make a decision, although we are trying to change things, but it is taking forever.”

(MU) “That requirement does not concern me because it is in order. Given our cultural orientation, you cannot go into somebody’s household and start interviewing any member of the household without consent of the head of the
household. So it is like just recognizing, the structure of the household because that can cause problems.”

(MU) “No. You see, in some of the communities there, the women will not give you any information. Not to say that they don't have authority, but that is how the community is organized--that they will not give you any information unless the head of the household knows.”

(MU) “…there is a lot of movement towards that, the empowerment of women and I think if women could participate…As well so that, if it is accepted, this is the women’s issue and that is when women come in because it has come from some structure. Otherwise, I think unless you are dealing with really doctors, nurses, senior people in society, the elite, right now if I went to Mrs. Owino to interview her, I don’t think she will say, my husband has to be here.”

**Summary from IU Interviews:** Some participants were uncomfortable seeking permission from the head of the household in all instances. For this protocol there were no major objections to seeking permission from this individual.

**Summary from the MU Interviews:** All of the participants acknowledged that in order to do research at the household level, permission from the head of the household must be sought. However, several participants (both male and female) reported that society needed to move towards more autonomy for women. One participant pointed out that among the elite and the well educated, there was no need to seek out the head of the household to talk amongst the women of the household. However, others stressed that for the household studies, this requirement was needed to ensure the participation of the woman, protect the household from conflict, and protect the researcher from disfavor.

**Take Home Point:** In general, IU respondents believed that permission should be sought if this were culturally appropriate, but expressed concern that perhaps this was not appropriate in all instances. Kenyan participants acknowledged that women in Kenya need more autonomy, but despite some changes for women in Kenyan society, permission from the head of household must still be sought.

**Action Item:** The IREC should advise the IU IRB on the most culturally appropriate method of entry into the household for all research project conducted in Kenya.

d. **If the protocol did not require the permission of the head of the household would this concern you?**

(IU)“Even though this is the way, so you’re saying for example, if this is the normal process within…The region. I think the way that it normally happens here and I think this is the right way is that if the IRB knew that for example they would ask for a pretty lengthy justification for why the investigator thinks that in this case even though this is the norm we don’t think it would fit this situation and the IRB should make a determination on a case by case basis”
IU)“If the protocol did not require it but it was optional to get it then it would not bother me. If the protocol said I was not allowed to get it and you know don’t get it and in this particular culture it’s appropriate to go through the head of household that would bother me.”

(MU) “It does. It is part of the entry process into a household. As we said the first entry process is into the community or the village. But as you enter somebody’s home, I think it is good to talk to the head of the household.”

(MU) “Yeah. If it is a family. If it a question about family issues, I believe the head of the household has must be, his consent must be sought…When I talk about the head of the household in a marital situation it could also be a brother in-law…But if we want to ask questions at an individual level just about the lady and her own life and all that stuff, then if she’s married and the husband is present then you must first seek his consent.”

(MU) “…from the village point of view knowing Kenya’s culture you have to ask for permission—you just have to.”

Summary from IU Interviews: The general consensus was that they would have a problem with not asking permission from the head of household if they were aware that it was a cultural norm.

Summary from MU Interviews: All participants would be concerned if the husband was not sought prior to interviewing. They noted that this was the acceptable and respectful practice within the Kenyan culture.

Take Home Point: In general, IU respondents felt that permission should be sought if this were culturally appropriate, but expressed concern that perhaps this was not appropriate in all instances. Kenyan participants acknowledged that women in Kenya need more autonomy, but despite some changes for women in Kenyan society, permission from the head of household must still be sought.

Action Item: The IREC should advise the IU IRB on the most culturally appropriate method of entry into the household for all research project conducted in Kenya.

12. A clinical trial of a new birth control method is being conducted in a clinic in western Kenya. Women who present to the Family Planning Clinic seeking contraception will be eligible for the study.

   a. The protocol requires the husband’s consent for participation, in addition to that of the eligible women. Does this requirement concern you?

   (IU)“A like situation here is kids, adolescents can go to family planning without the consent of their parents and we have approved research without parental consent for these people that’s related to family planning because if parental consent were required then the parent would find out that the adolescent you know was getting birth control and it might cause more of a problem then, I think it depends upon
the risk of the study. The higher the risk in terms of physical problems or things that would affect the partner then I would be more inclined to say yeah you should have both consent. For instance if one of the risks were sterility.”

(IU) “I don’t see why there’s a problem. I mean it’s a birth control issue it’s you know both subjects are involved in that you know issue so I would think it’s fair requirement, I think.”

(IU) “I would certainly expect that the IRB would explore the reasoning for that. I don’t think they would just take it at face value. I don’t think they should take it at face value. I think they should require the investigator to explain why that would be acceptable. Yeah, I could see where the IRB could buy an argument.”

(IU) “You put forth that this is an individual who is coming to a fertility clinic to begin with so there was some seeking out of that individual of information that surrounded fertility and I’m not sure what the rule set would be under the ability for that person to be seen under that context. I would probably try to match to best degree whatever social norms existed surrounding the flow of information surrounding fertility decisions. “

(IU) “Things where the husband’s involvement might interfere and again like Bill said my cultural sensibilities of not wanting to have women completely subjugated and allowing them to get, to be able to consent to getting things on their own I would not want to require the husband’s consent for these kinds of studies.”

(IU) “Cause it, fundamentally it doesn’t bother me that the culture is that the husband signs. The problem is is that birth control is considered a reason for beating women in Kenya. So that the family planning clinic has a back door the women go into and a back door that they come out of or a side door they come in from their, where they, they go in with their babies that men never go in where the mother takes the baby to the, there’s a side door that goes into family clinic and a back door that comes out of it so that women can’t be seen coming and going from it to get Depo-Provera shots so that their husband doesn’t, don’t know that they’re getting family and it’s because family planning is really taboo…”

(IU) “I have the same reaction that it’s an additional barrier to research and additional barriers I can think of a lot of reasons why that may be important to actually complete the study so an additional barrier to research doesn’t particularly bother me.”

(IU) “I would say that if it’s their culture that it’s not required that the husband needs to consent then I would say that just the woman needs to consent.”

(IU) “Well I don’t see it as an IRB question that we have to decide that so in that sense I guess it’s not a concern. I think on the human reality of a marriage or sexual relationship that’s a different question but it’s not a question for the IRB.”
(MU) “No. Again it is just like what we have discussed about, because you are recognizing the head of the household and his role.”

(MU) “…Yes to a certain extent, cause I believe very strongly that the large percentage of the women who go for family planning do not tell their husbands…I think the most important person to ask is the lady…”

(MU) “I’ve heard of women who use market days. They pretend they are going to shop and they actually go to get a depo or something because the husband does not want her to have or to use a family planning method. So if you want to do anything concerning reproductive health in Western Kenya then the man should be involved. But on the other had you should be ready for, what’s the word, lack of cooperation…”

(MU) “Yeah, so I would say it is of no concern…Either way would have been fine they can ask the woman and ask the man that is ok, yeah as long as they ask both of them, that is cool because you are talking about children. I don’t think the woman has the sole responsibility of deciding whether she wants to have these children or not. She should consult from her husband if he wants to have these children or not.”

(MU) “While it is absolutely necessary to get the consent (of the husband), we must ask what effects it will have on the research if it attracts hostility from the other partner.”

**Summary from IU Interviews:** There was significant variation in the responses given for this question. Some individuals felt strongly that if this was the cultural norm it should be used. Others felt that if would interfere with participation in the study and were concerned that if the spouse knew about participation there might be some level of risk. Some felt that since it was a birth control issue (something that impacts both partners) it was acceptable. However, they indicated that in other situations if would not be acceptable.

**Summary from MU Interviews:** There was a variation in the responses given for this question. Some participants believed that as stated in the previous head of the household questions, referring to the husband, he should be or must be consulted, to first speak to his wife. There were also participants that believed this should occur due to the fact that there is family planning involved which will affect everyone, not just the woman. On the other hand, some participants believed that the husband may not be as willing to speak nor support family planning and in these cases, the woman would be the best person to consult.

**Take Home Point:** There was a lack of consensus at either institution on the appropriate way to handle informed consent for women involved in studies on family planning methods.

**Action Items:** 1) The IREC should advise the IRB on the most culturally appropriate method of consent in studies involving women and family planning in Kenya. 2) Issues of consent surrounding family planning methods should be considered as a specific topic within future workshops between IU and MUFHS investigators.
b. If the protocol did not require the consent of the husband would this concern you?

(IU) “Well I think the language of the consent should say you know if you have chosen to use birth control pills and you know and you, this is an alternative then that mean that the issue has been discussed you know in the family and that’s an acceptable choice then I don’t see a reason why he need to.”

(IU) “Yeah, I would say probably not but if the IRB knew enough about the situation where if the IRB knew that in this society this was the MO normally then I would certainly expect them to at least question it.”

(IU) “…I think that as the potential for benefit becomes larger the less I become morally and ethically desirable of having the other individual required to consent, as simple as that is.”

(IU) “… it certainly wouldn’t bother me to not have the consent of the husband in this situation.”

(IU) “That may be more problematic to me depending on what’s involved and what the other dynamics are. You could I think perceive a situation where that might actually endanger the subject. That it would actually increase the risk of the research so I know you’d have to know what the protocol is and some of the other dynamics but you could certainly understand how that might increase the risk beyond what is apparent from whatever the procedure is.”

(IU) “What I was saying is that I think obviously one of our goals is for people to understand the full risks of their participation in research and I think it seems to me that not, participating in the study of birth control without your husband’s consent or perhaps even knowledge might actually increase the risks of and I think you know it would at least be important for women to understand that.”

(MU) “I would be very concerned, yes. I would have preferred that the husband is involved for the success of the family planning.”

(MU) “I don’t think we need his informed consent. We just need to inform him of what you want to do.”

(MU) “I think we should involve her but involve a counselor to help her give her tips or guidelines of how to break the news, you know, disclosure?”

Summary from IU Interviews: Again there was a significant variation in the responses given for this question. There was considerable discussion of risk versus benefit and consideration that each study needed to be weighed separately in order to determine the level of risk. There was discussion that if consent of the spouse was not obtained that there should be information given to the participant about the fact that they should consider discussing their participation in the project.
Summary from MU Interviews: Again there was variation in the responses to this question. The participants that were concerned asking for the husbands consent believed that it was important for the husband to be involved in family planning. One individual indicated that involving the husband was the right thing to do, unless there was an extreme situation in which the husband does not consent and the wife is in need. Participants that were not concerned about obtaining consent from the husband believed that there was a distinction between informed consent and simply informing him about family planning decisions. They felt that the latter of the two was necessary rather than the former. One participant suggested that a counselor be involved to help the woman “break the news” to her husband.

Take Home Point: There was a lack of consensus at either institution on the appropriate way to handle informed consent for women involved in studies on family planning methods.

Action Items: 1) The IREC should advise the IRB on the most culturally appropriate method of consent in studies involving women and family planning in Kenya. 2) Issues of consent surrounding family planning methods should be considered as a specific topic within future workshops between IU and MUFHS investigators.

Equity

14. A concern expressed by some ethics review committees, is whether members should be remunerated for their time and participation. Do you think that ethics review committee members should be remunerated?

(IU)“I think it depends upon the workload and what the culture expects out of people if it in fact is given you know it’s in your faculty position you do have time to do service and it’s counted positively towards merit or whatever then that’s different.”

(IU)“…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 they need to you know I think you know it doesn’t have to be money. I mean if percent effort whatever the department feel is appropriate then they need to be compensated for that.”

(IU)“Then I don’t know that that money has to be, I don’t think that it necessarily has to be in the form of currency but I think the local norms should decide that. I think our issue is more that they should be at least given some release time and not expected to fulfill the same number of clinical duties if they serve on the IRB or that their department gets paid in some way for the time that they’re out of a clinic rather than it directly going to people who are already fairly well off.”

(IU)“So in the end I don’t think that money remuneration in terms of money as its pure definition is what’s necessary but the recognition of the workload and expertise should be recognized in some manner so again I’ll say, don’t need money, many places do it, but recognition may substitute for that or at least credit for time served in some way which may be paid for in some aspect.”
Now in Kenya there may be difficulties figuring out a way to do that appropriately because their salary structures are very different from ours in the way they’re paid and everything is very different. And so there may be, that may be the only practical way to do it there would be to actually provide them with some direct payment for participating in review activities and I again, I think compensation of some sort is appropriate for ethics review and I think as I say I prefer non-monetary compensation but if that’s the only way it can be practically accomplished I think it’s not inappropriate to do it.

(IU) “I don’t have a problem paying for the Kenyans to participate in the IRB and interestingly they do in IREC, that when we have this discussion they were worried that being paid to do it might change how you respond to the different protocols. I would argue that you just pay generically, then you, you know do a good job and it’s not tied to whether you approve a protocol or not.”

(IU) “I’m also concerned a lot with conflict of interest, not only in terms of having been on a committee at the campus that’s drafting the conflict of interest and conflict of commitment policies.”

(IU) “However I do think that there’s greater recognition that some aspects of service involve much more time and much more intellectual input than just going and sitting in a committee meeting and I think one of those is definitely IRB service and I see more and more people setting out kind of that service as being you know going above and beyond not only in terms of time but also in terms of you know intellectual ability and you have to study and read and participate and the serious responsibility.”

(MU) “I don’t think so; this is part and parcel of what they are paid to do.”

(MU) “The remuneration should be like a recognition of the service rendered. …the minute you start remunerating people, you might see a lot of interest, but that could compromise the review process, so that somebody is more inclined to review more proposals…I would not want to call it remuneration per se, but some kind of appreciation for what has been done…”

(MU) “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. So yes, I would like some recognition and appreciation, but the mechanism of how that can be done and implemented is something we should work out.”

(MU) “I don’t think so. I see research as part of the responsibility we have in the academic institution, and it should be seen in that line.”
(MU) “My thinking was that the committee members probably should have what we call their honoraria. It is not like you are paid on a daily basis or you are paid according to work done, but probably once a year they should have a token payment to appreciate this if the money was raised.”

(MU) “…I think I would like to be compensated because it means that even when you invite me for a meeting I don’t know whether I will reach there.”

(MU) “When you have your monthly meetings, or when IREC has monthly meetings, I think it’s just fair that you compensate people for time they spend there. But I think for the review process, I mean for reviewing the proposals, I see a conflict of interest if you actually paid people…”

Summary from IU Interviews: There was general consensus 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.

Summary from MU Interviews: There was general consensus 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 proposals. Two participants noted that remuneration could possibly take the form of non-monetary benefits. Two other participants considered IREC participation to be part of academia or “part of what they are already paid to do.”

Take Home Point: There is general consensus at both sites that time spent in IREC/IRB activities should be acknowledged in some way.

Action Item: Both institutions should consider developing policies on IREC/IRB compensation (monetary vs. comp time vs. other acknowledgement)

15. An important development in the conduct of clinical trials is whether there are obligations to provide certain benefits to research subjects after the trial is complete, (e.g., provision of established effective treatment, continued monitoring, etc.) Do you think this is an important issue. If so why, if not, why not?

(IU) “I think it needs to be addressed probably before the IRB even gets it. Well in the proposal itself and before you know when it’s being reviewed if in fact they’re going to go in and give a drug for six months and they find it’s effective and everyone feels better and then it’s withdrawn because they have no means to sustain that, I think that’s an ethical issue. What are you going to do about providing or the mechanisms to provide if this drug works out the drug for people long term? Is it going to be an informed consent? If you don’t have a mechanism that they may have benefit and then it’s you know after the trial’s over they
wouldn’t have access to it. I think then if the participants understood that before they agreed to be on trial, that would be crucial, the informed consent.”

(IU)”Yeah I think there are, if there are benefit of what you’re doing and there’s no alternative that is equal I think we have to provide that. If there is a drug that benefiting a patient and the only, and it’s not available, I think it’s the obligation of the person who’s conducting and sponsoring the trial to provide that treatment. I mean that’s the fair thing to do.”

(IU)”I guess I do have some problems with the potential for creating coercion by providing certain benefits at the end. I might be convinced if there are some examples that are not coercive but right now I would proceed on the potential for coercive nature and prefer not to structure something along that line.”

(IU)”….I think that the true feasibility of this in the future or the commitment would appear to be out of the range of the ability to sponsoring agents to really commit to if we in fact feel we’re going to reach more patients with research. So, I guess from an ethics viewpoint I do not feel that it is necessary. From a personal viewpoint in order to approve a study or for that study to be ethical I think it would be desirable for that individual to be able to access, I would hope that that individual could access that medication based on provisions through their own country in some manner but at this point in time I do not see it ethically as an absolute.”

(IU)”I think that certainly a couple of years ago when anti retro viral therapy was just impossible for people to access locally because of the cost then I would view it as being very questionable to be able to go in and do a six month trial where somebody gets highly active anti retro viral therapy that is then withdrawn completely because the study ended but and they have no way of continuing to treat and that bothers me from an ethical standpoint on the other hand there are practical issues about what kind of a commitment you can provide beyond the study and I think some type of compromise is probably appropriate where some duration of post treatment coverage is provided but perhaps not indefinite or almost certainly not indefinite because that’s not practical.”

(IU)”….fundamentally I think the idea is that people should not be provided with something that they can’t otherwise access and then have it completely taken away from them so there has to be some way of expecting that some of the benefits of the study can be continued beyond the duration of the study whether that be provided directly by the funders of the study or through other mechanisms available in the country.”

(IU)”I think it’s appropriate to compensate people appropriately for their time and any risk they take in a study. Whether, I don’t think at these days it’s going to mean lifelong therapy I think because we can do these things within funded treatment programs. In the past it was a much, much bigger issue.”
(MU) “Yes. Given the economic standards of living in Kenya, if research leads to a benefit, it should be shared with the community from a moral point of view.”

(MU) “I think it is difficult, and given that the people who have participated in the clinical trial have consented to do that, so they understand that they are in a trial for that duration of time and once it is over, it is over. So there is that understanding from the beginning up to the end.”

(MU) “I think the participants should be made aware of what the trial is all about and the obligations on their apart and the obligations on the part of the researchers and the sponsors.”

(MU) “Well—yes and no. Yes in the sense that if you have been undertaking a controlled trial to be able to monitor the subjects for a certain length of time which I hope will be indicated within the protocol how long you are going to follow the subjects for after the end of the study. But no in the sense that a research is still trying to find out what works, And it would be inappropriate to make it sort of a standard procedure that every research find out…I think really the best thing is to make sure that what you—the results you get from the research can be disseminated to a large scientific society and thereafter a decision can be made where to incorporate your research finding into service delivery to be implemented. I think it would be, in my view I think it would be expecting too much for a researcher to offer service at the expiry of the research period.”

Summary from IU Interviews: There were very mixed responses to this question. Some individuals believed very strongly that post trial treatment should be made available through the sponsor, some believed that it was the community’s or country’s responsibility to take over this burden after the trial. Some felt that it was not feasible for the sponsor to take over responsibility for post-trial care. There was discussion that whatever the approach to post trial care that this should be very clearly stated in the initial consent process.

Summary from MU Interviews: Everyone agreed that the issue of benefits after a clinical trial was in fact an important one. However, there were various responses that even occurred within one answer as to how and even if benefits should be implemented after the trial is over. Some participants believed that the benefits should be shared with not just an individual, but also the entire community. Others believed that as a patient that has participated in the study there is a sense of contribution and entitlement to receive continuing beneficial treatment. A few participants indicated that the patient should be aware of all aspects of the study obligations before they agree to enter the trial, clearing up any confusion during the termination of the trial.

Take Home Point: There is a great deal of ambivalence about post trial benefits.

Action Item: Both institutions should consider developing policies on post trial benefits.

16. Equity is seen as important in collaborations between researchers from developing and developed countries. What are some of the equity issues you believe should be addressed by MU and IU?
(MU) “I think when people conceive the ideas, it is important that at that level, the two see each other as partners and as they grow, they should be honest… the group should actually from the beginning reason together, and conceive the idea and actually know their strengths and what they are bringing to research…”

(MU) “…I now know what am work according to the KIPRA an institution that was given the mandate by the government to actually determine what our worth is…Yes, and its sad and unfortunate that our universities cannot afford to remunerate its work force at the level that they should right now, which puts us rather in a tight spot.”

(MU) “…the other resource is in terms of equipment…if your research is going to pull resources, don’t leave us just with refrigerators and, you know, such like (MU) things. Lets leave the place better than we found it, and they should be sustainable resources.”

(MU) “So sometimes a project may be frozen simply because the person on this side is not considered an equal to the person on the other side that they want to work with…Because if we decide that we are going to wait until we have an equal number of professors to run projects on either side, at IU and in Moi, we will delay a lot of projects. Or are we going to start involving professors who are less interested because they have a title—and that has happened already by the way.”

(MU) “So I think that if there is an issue of equity it should be based on the same rates of the accepted levels in IU for instance. So if the equity is 10% of your salary and it is so much, I think that 10% should be interpreted differently here.”

Summary from MU Interviews: There were various concerns of equity issues raised by MU participants. Issues included maintaining a partnership mentality, remuneration, equipment and sustainable resources, and research delays due to interest and title equality between the two institutions.

Take Home Point: There were many equity issues raised by respondents that need to be examined cooperatively between the two institutions.

Action Item: Issues of equity should be acknowledged and considered at both institutions.

Areas of Needs/Proposals

4. We are interested in hearing your opinions about the interactions between the IREC and MUFHS and the IRBs at IU

b. In what area(s) do you think that cooperation between the IREC and the IRB need(s) to be improved or consolidated?

(IU)“I think that as the amount of work increases it might be necessary in the future to have some more scheduled or at least a means identified for conflict
resolution in a rapid manner but right now I don’t know that the entire system’s been tested to its full capacity at this point”

(IU) “I think number one is that they, we really do need a set of international SOPs here and I think MOI university needs one as well and they need to agree. …The second thing is that when we have something that’s been submitted to both sites neither one wants to see the paperwork that’s going to the other site and I think that’s a mistake. Very easy to copy the IREC’s submission to our IRB and copy our IRB submission there so at least if they don’t use the same forms, they might be gathering the same information, they know what the other one is seeing because I think that can help overcome some of the miscommunications that are involved…”

(IU)“I think formal communication, one way by just making sure everybody sees what’s being submitted to everybody else. And having SOPs that are at least compatible so that the processes are similar and then beyond that, this notion of whether or not to have formal regular communication, I think if these other things were done I think that probably could be you know kind of informal, irregular. In other words if you were having this problem let’s talk about it as opposed to we’re going to talk every month”.

(IU)“I think as the volume of research increases, which we all hope it will, that there may be more of a need for regular communication just because you know if there are things that are going to be looked at on a regular basis and by each group by the new submissions or any reviews or whatever there may be a need for some more formalized, that kind of means of communication.”

(IU)“I would comment that might be specifically needed would be some issues related to the consent document or the consent process and particularly a willingness and I think this exists but I think a willingness on the part of again particularly on the IU side being willing to defer to the MOI University committee what constitutes appropriate consent in that setting.”

(IU)“ our IRB seems to treat consent as a form and it was nice early on in the discussion at MOI University and it reflected in the first bullet point that informed consent is a process not a form and everybody agreed with that and I think that everybody in IRB is going to agree with that and I think it often gets lost in focusing on the form.

(IU)“The second thing that is becoming a bigger deal with our own research and it doesn’t affect Kenya is HIPAA. I mean the HIPAA rules don’t count in Kenya and our IRB recognizes that but there’s no way to fill out our local forms that are appropriate for Kenya.”

(IU)“ HIPAA law doesn’t exist and yet the basic tenets of privacy do and so it’s, that interchange is a little bit I think still a work in progress that the Kenyans want to make sure, like when it came up with the discussion that we had about biological specimens. It didn’t really understand that you could save a specimen and not let
the information out and was still protected if it, you know, and no one could get at it unless you wrote a protocol to get the information that got passed by the IRB that worried about things like privacy and stigma and things like that and it took the clinicians really several days to get that notion.”

(MU) “…One of the things that we don’t do here is conducting continuing review and I think because this committee has not bee doing this, it could be useful if we could learn from the IRB’s at the IU how to conduct continuing review. Secondly, another very critical issue is monitoring of approved protocols. So fat we don’t have a mechanism of which we monitor the protocols that we approve… I think the third aspect is in relation to training of IRB members. Maybe because of the limited connectivity that we have at the faculty, not all IREC members may have done the necessary evaluations that are required for any scientist or IRB member to do, which are online….So because there are new developments all the times, the IRB’s in IU might be having some more up-to-date information with regard to requirements and training of IRB members, which it would be nice for us to share so that we also keep current.

(MU) “…we should have common policies and procedures umm borrow some from Indiana and borrow some from IREC that will be acceptable to both institutions so that when looking at protocols for research we don’t have to follow different laid down procedures.”

(MU) “Frequent meeting or visit exchange of staff from both institutions I thin I necessary. I also think that participation at workshops is important to follow-up on the one that we initiated last year. I hope also that we can have mechanisms of training personnel at all levels. So in this way Indiana can assist in training of our staff.”

(MU) “I think the one key are that I could say we could improve well on is SOPs, you know…So if we are up standards and say this is what we are going to do for internationally approved protocols, they are reviewed at this end first then, Indiana University just checks to make sure that we followed the protocols as it is in our Standard Operating Procedures then it wouldn’t have to be reviewed twice and what would save us a lot of time in terms of research.”

(MU) “One of the things that I have seen here increasingly being put emphasis is a secretariat that is functional and that corresponds to say the other partner in Indiana…”

(MU) “For review. For instance someone who wants ethical clearance and has submitted a proposal and that proposal is to do with maybe molecular pieces or molecular biology or and you have a member of IRB through IRB IU, you know someone who is an expert in that field if we don’t have that expert over here, can we approach the IRB of IU to approach that expert to review that proposal—at no cost of course, because we are not paying.”
Summary from IU Interviews: Many participants believed that more scheduled communication, and the development of international SOPs were necessary to address the needs of international research. At least one individual indicated that the IRB needed to express a willingness to defer to IREC on consent issues. Another individual indicated that the forms needed for the IU IRB because HIPAA issues where not a consideration in Kenya and the forms allow this be addressed. One individual brought up the Issue of specimens and the fact that the Kenyan’s are having difficulty figuring out how to deal with controversies over issues of stored specimens.

Summary from MU Interviews: There were various suggestions of improvements and consolidations. Several participants expressed a desire to see more infrastructure development assistance from Indiana directed towards the MU IREC.

Take Home Point: There were many suggestions from respondents from both IU and MU about what could be done to improve cooperation between the review bodies.

Action Items: 1) Consider the development a mechanism for formal/regular communication between IREC and the IRB 2) Consider the development of joint educational programs between the IREC/IRB 3) Consider the development of an exchange program between IREC/IRB 4) IREC needs to develop a continuing review process and develop ways to monitoring on-going protocols. IRB could assist in this development by providing a model, educational materials and training personnel 5) IREC needs to consider developing its own investigator human subjects protection program which is tailored to the issues encountered in Kenya. IRB could assist with program development by providing a model, educational materials and training personnel 6) The IREC needs to develop a policy about retained clinical specimens. IRB could assist with policy development. 7) Consider developing a program expertise support program for the IREC (A panel of experts in various fields that could be called on to review protocols for which the IREC has no expertise).

8. When conflicts arise in policy between the ethics boards of the two universities, what do you think would be the best way to resolve them?

(IU)“I guess the question you’re asking me is how does one best anticipate those problems and when one anticipates a problem do you deal with that working through some committee made up of the partnership or do you work it through the team leader who speaks with the dean or the team leader who speaks with a director of research and the director of research goes and talks to the IRB chair. Yeah and I choose the latter”

(IU)“…if there are differences between the two boards and we don’t understand why they want this extra hoop then we need to attend their meetings and try to understand because we, I don't feel that we can force our approval on someone else, especially someone in a different culture.”

(IU)“Well I think it’s probably you need to have some sort of board that consists of member of the Kenya program and member of the IU program where they can discuss it and resolve it.”
“...clearly even more in Kenya I think that here if you can anticipate it and reach an agreement and put it in writing I mean that is the most powerful tool that you’ve got. I mean things in writing are, I mean those are weapons.”

“I would think that I mean there’s one IRB at MOI so it would be sort of probably that IRB interacting with the executive committee.”

“How about an executive committee made up of from both places so that they can represent both sides

“I mean they may well have policy differences but that’s never really been the discussion at the IRB level. I mean basically it’s left to the investigator. They have to satisfy the concerns of both IRBs and however that is they just, it’s basically thrown back into the lap of the investigators.”

“If something is beyond the University, then both Indiana University and IREC need to be aware of the limitations there. Talk about it. Understand the dispute. Try to find common ground.”

“I think the best way would be through dialogue… I think initially, of course, this should be discussed by the committee members—full committee—and through that there should be some decision made. I think once the decision has been made by the committee, then this the decision of the two committees if they’re not at variance, they’ll just be communicated to, the decision from here communicated to the IRB or IRBs in IU ad the same from the other end communicated to us. But if it gets to a level where the committees are not able to resolve that, then I would say higher authorities should be able to address, although I do not know what kind of conflict would really get to that level.”

“I think the fundamental issue here is really from the policy level. The two institutions should be able to have certain policy...really at the implementation level, how do you say now that if there is conflict on culture, if there is conflict on
then how do you address it and who is supposed to address it in very specific issues and putting what you are saying as the mechanism and addressing it in very specific issues and putting what you are saying as the mechanism and addressing each of these very beautiful statements per item.”

Summary from IU Interviews: There was discussion about communication between the IREC and the IRB using conference calls or teleconference as a means of communication. Solutions to conflict were wide ranging from it was up to the investigator to resolve the problem, to the IU Team leader to intervene and talk to the Chairman of the research committee to the development of a committee composed of representatives from both the IREC and the IRB to a visit of members of the IRB to IREC to understand more about how they review protocols and conduct meeting.

Summary from MU Interviews: Most of the participants indicated that any conflicts could be solved through simple communication/dialogue between the IREC and the IRB. Some believed that further measures were in order suggesting higher authority or administration involvement, ad hoc committees or a commission of inquiry and policy.

Take Home Point: The key to conflict resolution identified from both Moi University and Indiana University respondents was the need to communicate and the need for a formal policy on conflict resolution.

Action Item: 1) Consider the development of a joint SOP on conflict resolution 2) Develop a plan for regular communication between members of the IRB and IREC.

13. If disagreements over the general issues of informed consent arise between the IREC and the IRB how do you think those should be resolved?

(MU)“Bring them here and let them enter that community through us.”

(MU)“But I think the IRB and the IREC need an exchange program.”

(MU)“...if they came, the IRB members, if they came, participated and actually saw getting an informed consent is ok, is genuine, people participate...Let them come and see how easy or difficult it is when you explain to somebody, and that they accept.”

(MU)“...the Indiana University IRB sends a request that this is what our informed consent process should contain...And what would be part of the IREC secretariat to make sure that they look at that informed consent in detail and give feedback to the IU IRB and say that we are confident that this can be used very well in that kind of a setting where the villagers do not understand this science and stuff like that.”

(MU)“I think we need a super committee just looking, but really all the time take care of the local interest which doesn’t need money it needs more than dignity most of the time its dignity more than anything else.”
(MU) “Another conflict that would arise probably is this whole squabble of where--now that is an internal conflict probably—of where IREC lies. You know that is probably something we should look at before we ever go international.”

(MU) “I think the IRB in IU should really rely on the IREC here to give them guidance and advice on how to handle the local situation. And maybe for the informed consent issue for international research, the final authority should be left with the local IREC, which will of course make approval after considering all the relevant factors.”

(MU) “It should be resolved at the committee level, so that if there is the lack of that understanding, maybe on the part of one committee, the other committee should be able to explain clearly why things are done in a certain way and not in the other way.”

Summary from MU Interviews: All MU respondents agreed that if the IU IRBs were exposed to or educated about the community and cultural issues surrounding informed consent then issues could be easily resolved. Manners of exposure and education included: an exchange program between the IU IRBs and the MU IREC, a super committee made up of both IU and MU ethics committee members and communication between committees.

Take Home Point: MU respondents believed that interaction, communication, and exchange between the IU IRBs and the MU IREC could resolve issues of informed consent.

Action Item: Develop an IRB/IREC exchange program.

17. Are you aware of any Standard Operating Procedure (SOP) for review of international research at IUPUI?

(IU) “And you know it would be really interesting to do it and if for no other reason it allows us to hash out some of these ambiguities from our perspective and come forth with some, maybe not iron-clad principles, hopefully they won’t be because if they are I think we’ll set ourselves up for failure. But guiding principles that allow us to frame a relationship with a collaborating international institution…”

(IU) “I think I need some guidelines to help me.”

(MU) “No. Prudence and practicality would say that we should have different SOPs and as the relationship develops the aim should be to have a common standard SOP so that it is the experience both IU and MU that one SOP can be developed.

(MU) “I think as I was reading the SOPs they look fairly the same…There is actually nothing—even when you read through the guidelines and even what was developed which said yes protocols that involve different countries must be
reviewed in the two countries…the SOPs should just reiterate that once a protocol has to been approved by an IRB at IU, and that protocol has to be implemented in another country, then the IRB from the host institution where that protocol is going to be implemented should review and approve that protocol independent of the decision of the IRB at IU.”

(MU) “I have looked at the standard operation procedures of IU and I think they have incorporated most of the international guidelines. So to me the IU SOPs are comprehensive and really reach the international standard…”

(MU) “No…But I want to believe honestly what we are doing in international, there should be.”

Summary from IU Interviews: Everyone except one individual correctly identified the fact that there were no IRB SOPs for international research. However, the general consensus was that there should be some guidelines for the conduct and review of international research which might include issues related to consent, conflict resolution, risk/benefit, and consensus and communication between IRBs.

Summary from MU Interviews: There was confusion from two participants about the existing SOPs and whether they covered international protocols. The remaining participants agreed that they were not aware of any international SOP. In addition, they believed that an international SOP was needed.

Take Home Point: There are no SOPs for international research at either institution however respondents from both Indiana University and Moi University believed international SOPs should be developed.

Action Item: 1) Develop SOPs for international research at both institutions 2) Consider making this SOP development a collaborative process.

18. Do you think that the current human subjects training required by IU is adequate and appropriate for:

   a. Indiana researchers conducting research in Kenya
   b. MU researchers conducting research at IU
   c. MU researchers conducting joint projects with IU in Kenya
   d. U.S. Investigators in Kenya

(IU)“I think it’s an understanding of history and of culture and of traditions and a respect for history and culture and traditions and you don’t get that in a one-day orientation or a one-hour orientation.”

(IU)“I think the minimum level is not very great as long as they’re tied to a mentor. I think the mentor is just so important. And by mentor I mean a mentor who
knows how to conduct research in a place like Kenya. Or at the very least knows how to conduct themselves in a place like Kenya.”

(IU)“Really what we’re looking for though are people who have some element of cross-cultural competence and I think if you can demonstrate cross-cultural competence then the amount of orientation that you need is going to be significantly less. And I would say that would apply for researchers, clinicians, for anyone.”

(IU)“I mean I think again I mean it (the Human Subject Protection curriculum) has to contain information about the local customs, culture, mode of communications, expectation of the subjects you know and so I think probably it needs to be expanded.”

(IU)“I mean I think we need to recommend that they establish some form of proficiency testing in Kenya and I think we’ll sign off that. I mean if the person can, able to understand how to conduct research in Kenya then you know we should be alright.”

(IU)“I mean I think more of a maybe even more of an awareness document rather than an SOP for exactly how to proceed but some items or elements that they should be aware of prior to embarking on a research study.”

(IU)“I think that we do need if we are going to have U.S. investigators involved in research in Kenya and other foreign countries that I think we do need to have an extra module or an extra training available for people doing that …”

(IU)“I don’t think it would be a bad thing to require people to do something extra for, if they’re going to be involved in international studies.”

(IU)“I mean clearly international education could be part of that in terms of if you are proposing a study an international study then you have to actually complete the educational requirement for that.”

(IU)“I think an overarching theme is the constant need for education and heightened awareness of what the IRB is and why it's necessary and also what it's not.”

(IU)“I’m sure it just has to do with numbers but why maybe new researchers don’t maybe in short term have to even just cycle through an IRB.”

(IU)“I don’t know whether we mentor new researchers in more than just a mentor being on paper but do we actually truly do some mentoring that involves some of these processes.”

(MU) “I think so…It is adequate and appropriate because it is based on the basic fundamental principles that govern the conduct of research.”
(MU) “I think it has been the assumption that the researchers are well grounded and they are going through the protocol training ad therefore they are well versed in the area of research. But we haven’t put in place mechanisms to evaluate them, and I think maybe it is important that as we collaborate we put in mechanisms to evaluate such individuals at the end of their training to see whether actually they are competent. Although I do appreciate that the training at IU is comprehensive and this is something that probably should also be extended to Moi University.”

(MU) “It is a very elaborate test, and what they need to do is to have a similar sort of training done here. Very similar, perhaps the same, and then let let us locally identify where the gaps are which we can add to what already you are doing.”

(MU) “Maybe they should throw in a few questions like the ones you are asking us on research protocols…I think there should be questions that focus on culture and see what views people should consider when they are…because its international…I mean and your dealing with people of different cultures and that also should apply to the Kenyans on this end.”

(MU) “…most of them (questions) applied to circumstances that would have occurred in the states…”

(MU) “Yeah, I think it’s basic but it’s to the point…It’s not specific to the Kenyan situation like I say for…but generally about protecting the subject it makes a lot of sense and it is straight forward…It was educative and all that but I still felt that it was very American.”

Kenyan Investigators in U.S.

(IU)“Certainly I don’t think that our IRB is adequate for to understand Kenyans. Someone from Kenya doing research here if they read it and I think they would need to attend meetings, a couple of meetings to to really understand what was going on.”

Kenyan Investigators in Kenya/U.S.

(IU) “You know IU’s doing it and without you know suggesting to them that they should do it maybe they’d seize on the you know the opportunity to have us assist them build a module that would help them educate their own researchers on basic principles and wow what a wonderful opportunity for discussion on some of the things that should be presented to everybody would ensue.”

(MU) “What I’m not sue is whether our researchers have really gone through this training, and I believe they should.”

(MU) “It is appropriate, but it is not adequate. I think we should end up having more training for joint researchers, both for the Moi and IU guys. When they come to do research that is going back and forth, I think it wouldn’t hurt to give them, aside from giving them the test and the cause outline to read through, it wouldn’t
hurt to have continuous seminars developed to train researcher on conducting research.”

Summary from IU Interviews: U.S. Investigators in Kenya: Most of the discussion centered around whether or not U.S. investigators were well enough educated to conduct research in Kenya. There was some discussion about the need for investigators to probe culture competency and a discussion about the need for a mentor in this new environment. Some individuals indicated that the current HSP curriculum was adequate to provide a foundation but that additional education material needed to be added from those who were planning on conducting research internationally. There was some frustration expressed by various IRB members about investigators attitude toward the IRB (even with investigators just conducting research in the U.S.) and some discussion about the fact that all investigators should have to rotate through the IRB in order to understand it. There was some discussion of an awareness document (outlining cultural norms and procedures in Kenya) Kenyan Investigators in the U.S.: One individual indicated that Kenyans conducting research in the U.S. should have to rotate through IRB meetings prior to initiating research. Kenyan Investigators in Kenya/U.S.: One individual believed that the Kenyans should develop an HSP curriculum for themselves with our assistance.

Summary from MU Interviews: U.S. Investigators in Kenya: All of the participants that replied believed that the current training was both adequate and appropriate. Some discussion was focused on additions that could be made involving cultural issues such as the ones that were discussed throughout the interview (head of the household, village elder, gender issues, etc.). There was also mention of creating a similar training and test in Kenya, if not the same test. One participant indicated that in order to maintain collaboration there needed to be a formalized arrangement to review research training. Kenyan Investigators in the U.S. There was discussion about the training being too ‘American’ due to the focus the cases presented. There was also a suggestion to include more recent cases (instead of the 60’s syphilis case) as well as international cases and cultural issues. One participant believed that the test was not all-inclusive and one could learn a lot through simple contact with IU researchers. Kenyan Investigators in Kenya/U.S. One participant believed that Moi should write their own model. Another believed that the model currently in place was based on research in affluent countries, excluding circumstances that may occur in Kenya within structured communities. One participant indicated that in order to make the training adequate there should be ‘continuous seminars’ including researchers from both institutions. Another participant felt that the committee (IREC) should make the training mandatory for all researchers conducting research alone or with an IU partner.

Take Home Point: Respondents at both institutions discussed the need to expand the education of investigators in various ways.

Action Item: 1) IREC needs to consider developing its own investigator human subjects protection program which is tailored to the issues encountered in Kenya. IRB could assist with program development by providing a model, educational materials and training personnel 2) IRB needs to consider expanding its human subjects protection training to cover issues encountered in International Research. The IREC could assist with program expansion by providing insights related to conducting research in the developing world.
19. In your opinion, what needs to be done to operationalize this MOU between the two universities?

(IU) “Well I think if an SOP were developed or maybe it is I’m just ignorant of it that that would you know as soon as people get used to using those, they’re fairly new, that would probably help and it would help guide other research also, international research.”

(IU) “I think it would go a long way toward probably advancing the delegated authority concept if they did sit across the table and our folks understood that there is a high degree of sophistication among our collaborators at MOI and the collaborators at MOI sat down and understood that our IRB reps are just genuinely interested not about being bureaucrats or pointy headed you know oversight people but that they just want to make sure that you know they have reserved for the benefit of the IRB that they don’t really think in terms of Indiana University.”

(IU) “I think that’s what you have to have to be able to operationalize something like that so you’d certainly have to bring the right administrators and IRB chairs to the table to make sure it’s going to work for both places and they have to be at the table the same time.”

(MU) “We need exchange programs so that review of the MOU is an ongoing process of ensuring that the MOU works.”

(MU) “And the only thing that I would like to request is the facilitation of training of our IRB members.”

(MU) “I would say that it would be good to have the new person, the new human subjects administrator sit with the people in IU and get some orientation so that they can be proficient and knowledgeable about human subjects protections.”

(MU) “I thought probably the appointing authorities should ensure that the MOU is implemented through IREC and the IRB. I think a meeting should be held soon to see how we should go about operationalizing it.”

(MU) “I think what needs to be done is to make people aware of what the MOU is and how it is implemented. And this can be done by having some periodic regular seminars and meeting so that we won’t just develop SOP’s and lock them in the drawer or the shelf. We need to make sure that everybody is aware.”

**Take Home Point:** Many suggestions were made from respondents from both institutions about how to operationalize the MOU.
**Action Items:**

- Educate the U.S. IRB about Kenyan IREC
- Develop an International SOP at IU
- Develop communications between IREC and IRB (regular or irregular)
- Consider Developing an Exchange program between the IRB and IREC
- Consider Setting-up a specific office or mandate an existing office to monitor how research processes within the MOU are being addressed at each institution.
- Develop a plan to facilitate training of IREC members
- Assist the New Human Subjects Administrator at Moi University to receive training at IU
- Consider developing a method for follow-up between the chairmen and the secretaries of IREC and IRB
- Consider developing a shared format for guidelines and proposals
- Consider conducting another meeting/workshop (move forward-develop SOPs)
- Promote institution-wide awareness of the MOU and SOPs (for both institutions)
- Create a more functional structure for the MU IREC office.
Appendix A: Interview Guide

1. Prior to being contacted for this interview/discussion, were you aware of the Memorandum of Understanding (MOU) regarding research ethics between Moi University Faculty of Health Sciences (MUFHS) and Indiana University (IU)?

   Prompt: *If yes, what was your understanding of the purpose of this document?*

   Prompt: *If no, did you have time to read the MOU prior to this interview?*

   Prompt: *If yes, what are your thoughts about this document?*

   Prompt: *If no (Note to the interviewer: review the document with the participant(s). After reviewing the document return to prompt above)*

2. What is your understanding of the IU IRB procedures for reviewing an international protocol?

   Prompt: *Do you think that the IU IRBs use a specific set of guidelines?*

   Prompt: *Do you think that there are specific procedures for reviewing a protocol?*

3. What is your understanding of the MUFHS IREC procedures for reviewing a protocol?

   Prompt: *Do you think that the Moi IREC uses a specific set of guidelines?*

   Prompt: *Do you think that there are specific procedures that must be followed?*

4. We are interested in hearing your opinions about the interactions between the IREC at MUFHS and the IRBs at IU

   a. To your knowledge, is there any interaction between the IREC at MUFHS and the IRBs at IU?

      Prompt: *If yes, what is that interaction?*

      Prompt: *If no (Note to interviewer: Discuss the history of interaction between the IRB and the IREC including the workshop held in Eldoret in February 2003)*

   b. In what area(s) do you think that cooperation between the IREC and the IRB need(s) to be improved or consolidated?

      Prompt: *What needs to be done in these areas to improve or consolidate cooperation between the IREC at MUFHS and the IRBs at IU?*

5. Which individuals (or groups) within your institution:
a. have primary authority over decisions about cooperation between these two collaborating bodies?

b. should have primary authority over decisions about cooperation between these two collaborating bodies?

c. Should facilitate communication between the IRBs and the IREC?

6. Are you aware of any current conflicts or difficulties between the policies of Moi University and Indiana University regarding research and research ethics?

Prompt: Can you describe the nature of this (these) conflict(s)?

Prompt: In your opinion, how should this (these) conflict(s) be resolved?

7. Do you foresee any potential conflicts over international research between the Moi IREC and the Indiana IRB?

Prompt: If yes, what conflicts do you foresee? How should these conflicts be resolved?

Prompt: If no, is there a reason(s) that you don’t foresee conflicts arising? What are they?

8. When conflicts arise in policy between the ethics boards of the two universities, what do you think would be the best way to resolve them?

Prompt: Who should be responsible for resolving these issues?

Prompt: What should be the mechanism for resolving these issues?

MOU Related Questions:

The MOU specifically noted 3 initial areas of interest: Informed Consent, Equity, and the Standard Operating Procedures (SOPs) of the review bodies at each university. The following questions address issues related to these areas.

9. Do you think that informed consent should be handled in the same way at both institutions?

Prompt: Do you think that both institutions should require that research protocols use written/signed consent forms?

If yes, why?
If no, why not?

10. In your opinion, are there particular issues about informed consent that differ between the Indiana IRB and the Moi IREC?
Prompt: If yes, in what areas do you perceive differences?

Prompt: How can these differences be reconciled between the two institutions?

Note to interviewer: Explore the areas identified by the focus group or the key informant and then move to the prompts below.

Prompt: How should the IU IRB approach issues related to comprehension of research by individuals with limited educational background and little exposure to scientific thought, an issue which is of concern to the Moi IREC?

11. A research project is being proposed for rural western Kenya in which subjects will be interviewed about their health and economic status in their homes.

   a. The protocol requires that the permission of the village elder be sought prior to entry into the community. Does this requirement concern you?

      Prompt: If yes, why?

      Prompt: If no, why not?

   b. If the protocol did not require the permission of the village elder prior to entry into the community, would this concern you?

      Prompt: If yes, why?

      Prompt: If no, why not?

   c. The protocol requires that the permission of the head of household (usually the most senior male living in the compound) be sought prior to interviewing any member of the household. Does this requirement concern you?

      Prompt: If yes, why?

      Prompt: If no, why not?

   d. If the protocol did not require the permission of the head of the household would this concern you?

      Prompt: If yes, why?

      Prompt: If no, why not?

12. A clinical trial of a new birth control method is being conducted in a clinic in western Kenya. Women who present to the Family Planning Clinic seeking contraception will be eligible for the study.
a. The protocol requires the husband’s consent for participation, in addition to that of the eligible women. Does this requirement concern you?

Prompt: If yes, why?

Prompt: If no, why not?

b. If the protocol did not require the consent of the husband would this concern you?

Prompt: If yes, why?

Prompt: If no, why not?

13. If disagreements over the general issues of informed consent arise between the IREC and the IRB how do you think those should be resolved?

Prompt: Who should resolve them?

Prompt: By what mechanism should they be resolved?

14. A concern expressed by some ethics review committees, is whether members should be remunerated for their time and participation. Do you think that ethics review committee members should be remunerated?

15. An important development in the conduct of clinical trials is whether there are obligations to provide certain benefits to research subjects after the trial is complete, (e.g. provision of established effective treatment, continued monitoring, etc.) Do you think this is an important issue? If so why, if not, why not?

16. Equity is seen as important in collaborations between researchers from developing and developed countries. What are some of the equity issues you believe should be addressed by Moi and IU?

17. Are you aware of any Standard Operating Procedure (SOP) for review of international research at IUPUI?

Prompt: If yes, What are these procedures? Who is responsible for overseeing the proper administration of this SOP?

Prompt: If no, Do you think there should be an SOP? If so, what issues should it address?

18. Do you think that the current human subjects training required by IU is adequate and appropriate for:

a. Indiana researchers conducting research in Kenya
Prompt: If yes, why is it adequate/appropriate?

Prompt: If no, why isn’t it adequate/appropriate? How should it be changed to make it adequate/appropriate?

b. Moi researchers conducting research in OR at IU

Prompt: If yes, why is it adequate/appropriate?

Prompt: If no, why isn’t it adequate/appropriate? How should it be changed to make it adequate/appropriate?

c. Moi researcher conducting joint projects with IU in Kenya

Prompt: If yes, why is it adequate/appropriate?

Prompt: If no, why isn’t it adequate/appropriate? How should it be changed to make it adequate/appropriate?

19. In your opinion, what needs to be done to operationalize this MOU between the two universities?