Okukkera Ng’omuzungu (Lost in Translation): The Challenges of Making Meaning in Global Health Research

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Paper presented at workshop:

Values and Moral Experiences in Global Health: Bridging the Local and the Global

Humanities Center, Harvard University
May 24-26, 2007
http://www.fas.harvard.edu/~valuesgh/

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1.) Introduction

On May 27, 2006, the World Health Assembly, the supreme decision-making body for the World Health Organization (WHO), passed a resolution introduced by two of its 192 member states, Kenya and Brazil, to set up a new intergovernmental working group focused on reforming the global system for supporting medical research and development (R&D). Many argue that this initiative has the potential to create an unprecedented global framework to stimulate health R&D not through the profit motive but by “medical priority” (Love 2006). Although the bulk of the resolution focuses on overturning strong patent protection and market driven R&D priorities as identified by the WHO’s Commission on Intellectual Property Rights, Innovation and Public Health, it also seeks to create a new global framework for essential health research. This will have broad implications for the conduct of social scientific health research in resource-poor settings by identifying new R&D priorities, promoting new research methods, and advocating for new sources of increased funding.¹ The passing of the resolution signals a recognition at the global level that health research and development in resource-poor settings must be prioritized in a new way: that is, by local needs and not by profit or other priorities. Since 1993, the Council on Health Research for Development (COHRED) has focused efforts on strengthening human resources for health research (HR-HR) to facilitate health research priority-setting in resource-constrained environments. A July 2006 conference, Human Resources for Health Research: An African Perspective, argued the need to develop and support a new “research culture” that encouraged a “habit of inquiry, evidence evaluation, experimentation, and redirection” and reiterated the importance of communities not only as subjects of research but as drivers of the research agenda (COHRED 2006:x; 6). But how are those needs to be assessed and by whom? What will be role of local research participants and their communities in this global initiative to re-prioritize health research? And is there a need to examine the structure of health research itself?

As major global governance entities begin to re-assess the structure and goals of health research in resource-poor settings, it is time for social scientists to follow suit. Most studies of the conduct of externally-funded health research in resource-poor settings, especially HIV/AIDS research in Africa, have focused on three central issues: IRB procedures and research design (for example, standard of care and use of placebo), equity in collaboration between the funding PIs (usually Americans or Europeans) and local researchers, and participant comprehension of the consent form. An exception is a very recent trend to document local expectations of benefits and, more specifically, expectations of continued or expanded access to anti-retrovirals for research participants and their partners and families. However, the majority of work on the ethics of health research in Africa continues to focus on the instrumental and

¹ According to a briefing by the Council on Health Research for Development (COHRED), the work of the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property has not yet produced any concrete action. But web-based public hearings will be held in August and September 2007, and the Working Group will present its final report to the WHO Executive Board in 2008 (COHRED 2007a).
procedural aspects of informed consent (Chokshi et al 2007). That is, accurately measuring comprehension of scientific concepts in the informed consent form (placebo, genome, randomization, etc) and improving comprehension through new communication techniques (visual aids, question and answer format, recall exercises, etc). Without a doubt, the focus on the content and conduct of informed consent is essential for ensuring the highest ethical standards of human subject research. However, this improved content flows in only one direction—from the researcher to the participant—and fails to consider broader conceptual issues related to the conduct of research and the value of the research encounter for local communities and for the participant. Local meanings and interpretations of scientific concepts embedded in the consent form, such as risk, or even the definition of research itself, go unexplored. Local motivations for participation are rarely explored; and while expectations of benefits in recognition of participation often exceed those allowed in the research protocol, little is done to close this gap. All of these issues speak directly to two of the core principles of informed consent – establishing a shared understanding of the nature of the research encounter between the informant and the researchers and a clear understanding of the risks and benefits of participation for the informant. This has a significant impact on the quality of the consent and calls into question the legitimacy of the consent we do obtain with current protocols and regulations.

2.) Background

The central goal of this project is to analyze indigenous definitions of western-derived concepts of bioethics, such as autonomy, beneficence, risk, and respect, as described in the 1978 U.S-authored Belmont Report, in the context of HIV/AIDS research in Uganda (National Commission 1978). In 1974, the National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to identify the basic ethical principles that should guide the conduct of biomedical and behavioral research involving human subjects. Those ethical principles were identified by the Commission at a February 1976 conference held at the Smithsonian Institution’s Belmont Conference Center and later during monthly meetings held over a period of nearly four years. The Belmont Report is a summary of those deliberations.²

All research with human subjects funded by an agency of the U.S. Department of Health and Human Services (such as the NIH), and regardless of the location of the study site, must comply with Federal Regulations 45 CFR 46. 45 CFR 46 is the DHHS Federal Policy for the Protection of Human Subjects and it describes the guidelines researchers must follow to (a) protect the private identifiable information gathered from research subjects (b) give assurance that Institutional Review Board review of research protocols were successfully completed prior to research subject recruitment and data collection and (c) demonstrate appropriate procedures for informed consent. The Belmont Report identifies three “general prescriptive judgments” as core principles for

² For a recent retrospective of the Belmont Report, consult Childress, Meslin, and Shapiro, eds., 2005.
the conduct of human subjects research: respect for persons (autonomy to consent to participate in research), beneficence (do no harm and maximize benefits for research subjects), and justice (fair distribution of the burdens and benefits of research). In the Belmont Report, these three basic principles are described as “generally accepted in our cultural tradition...and...particularly relevant to the ethics of research involving human subjects” (emphasis mine). When collaborative, international research with human subjects is funded by the DHHS, it must comply with 45 CFR 46. Not surprisingly, complications immediately arise. The bulk of the objections to this legislation focus on the injustice and scientific imperialism of the U.S. federal regulations which prescribe specific protocols for research conducted in foreign countries (refs). However, it must be said, we don’t necessarily need to draw on case studies of informed consent outside the USA to encounter these contradictions; there is compelling evidence documenting the difficulties of fully implementing informed consent in domestic research in the USA (refs). Most importantly, however, no guidance is offered as to how to coordinate American “cultural traditions” and foreign “cultural traditions” within the context of these legally mandated, non-negotiable parameters for the conduct of research outside the USA. My concern here is to examine the contradictions that necessarily follow from mandating legislation based on the unexamined category of “our cultural traditions” in the Belmont Report.

3.) Study Description

The study described here offers one of the first rigorously designed and sampled, in-depth qualitative study of the ethics of health research in Africa from the perspective of the individual research participant. Uganda is an especially rich place to explore this issue because HIV/AIDS in Africa was first identified here (Serwadda et al 1985) and the country has the longest on-going national HIV/AIDS sero-prevalence and community-based intervention studies of any country in Africa (Uganda AIDS Commission 2001). AIDS vaccine trials began in Uganda in 2000, and the evidence for one of the most widely adopted behavioral intervention, the currently contested A-B-C approach, originated here. Table 1 lists basic demographic indicators for Uganda for 2005. This project explores many themes related to the experience of participation in intensive health research: for examples, opinions of the value of research, motivation and preparation for participating in research, actual experiences of participating in research, comprehension of the consent process, local definitions and concepts of consent, risk, individual autonomy, and benefits, and perspectives on the ethics of research. However, this paper will present only a small subset of the results concerning local definitions of autonomy, risk, and research, and the impact of participation in long-term, intensive medical research in a resource-poor setting on notions of research as community development.
Methods

Study design and sample

The study was conducted in three locations in Uganda using an observational case-comparison study design. The case group is located in Rakai District, comparison group 1 is located in Kalangala District (Ssese Islands), and comparison group 2 is located in a Rakai District community which borders the case group (add map here). The key inclusion criterion (Table 2) for the case group was at least three years of concurrent participation in intensive health research, while the key inclusion criterion for the comparison groups was never participating in any research that required completion of an informed consent form. In fact, no one in either of the comparison groups ever had participated in any research.

The cases were randomly selected from a list of current research participants living in one of the 56 communities involved since 1988 in a population-based cohort and intervention research initiative to study and reduce transmission of HIV/AIDS in rural southwestern Uganda (Wawer et al 1994; Wawer et al 1999). Twenty years of research at Rakai Health Sciences Program is described at http://www.jhsph.edu/rakai/.

Comparison group 1 was comprised of residents in an interior farming community on a remote island in Lake Victoria where no formal health research has ever been conducted. Comparison group 2 was randomly drawn from a community which neighbored the case group but which did not participate in the HIV/AIDS intervention study. Because neither census data nor neighborhood lists were available to us, we could not randomly sample comparison group 1. Instead, the study communities were informed of our project by local leaders and villagers freely decided to participate. In an attempt to minimize the bias that was likely introduced into this self-selected group, we purposively sampled the self-selected participants to create a balance of gender and age. In any case, there was little to no significant difference between the three study groups according to type of residence, economic activity, education, or other basic demographic variables as listed in Tables 2 and 3.

Table 3 lists some of the basic socio-demographic characteristics of the survey participants. The total sample size, \( N = 102 \), from which I randomly chose a subset of

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3 Nelson Sewankambo (2000), Dean, Faculty of Medicine, Makerere University is co-PI on this Fulbright-funded New Century Scholars study. We thank Maria Wawer (1999) and Ronald Gray (2001), co-PIs with Sewankambo on the Rakai Health Sciences Program, for allowing us to interview participants from the CHER sub-study of the Rakai Health Sciences Program. Since 1990, the Rakai Health Sciences Program has enrolled over 10,000 study participants in a variety of epidemiological, clinical, and behavioral studies. Major funding for the Rakai Health Sciences Program comes from NIAID, NICHD, and NIMH. Many thanks also to Jennifer Wagman for her invaluable logistical support in Kalisizo, Uganda. Special thanks to my fabulous ethnographic research team for unflagging enthusiasm for the project: Catherine Bbosa, William Ddaaki, Immaculate Nakiyingi, and Richard Sekamwa. Many thanks to the administrators and people of the towns of Katana and Mugoye for participating in these discussions and generously offering their time to help ensure that the research did not “flop.”
62 interviews for the analysis here, allowed for robust non-parametric (chi-square) analysis of significant associations between multiple variables.

**Instruments and interviewing**

All study instruments were translated from English into Luganda with considerable attention to accuracy, meaning, and local idiom common in the rural interview sites. A language specialist at Makerere University back-translated the materials and we pre-tested and piloted all instruments. The survey included basic demographic information, closed- and open-ended questions about research, and semi-structured discussions of several short stories, or scenarios, regarding local concepts of risk and autonomy. Case and comparison group 2 interviews were conducted in a private spot in or near the participant’s home while comparison group 1 interviews were conducted in private locations in or near the local health clinic during non-business daylight hours. The tape-recorded interviews ran for 60-90 minutes and were transcribed and translated from Luganda into English by local research staff trained in both survey and ethnographic research methods. I personally observed a short segment of each interview. Neither me, nor my research assistants, observed any of the clinical interviews associated with the case group, nor did we have access to any personal health information of any participant in any of the study groups.

**Ethical considerations**

This study was approved after full review by the Ethics Review Committees of the Uganda National Council for Science and Technology (Kampala, Uganda) and Northwestern University (Chicago, USA). The time to complete the consent process varied between 10 and 25 minutes. All survey participants received a bar of soap ($0.25) which is the standard compensation for the Rakai Health Sciences Program. Refusal rate for the case group was less than 2%. All participants who began the interview completed it.

4.) **Results and Discussion**

**Theoretical Framework for Understanding Informed Consent**

As early as the 1980s (refs), American researchers realized that the process of obtaining informed consent from research participants went well beyond following the three major principles enshrined in the Belmont Report. Delivering essential information about the research project or clinical trial to the participant and, without coercion, obtaining their signature to indicate willingness to participate was essential, but not sufficient. Poor comprehension and recall, reluctance to question the researcher
administering the consent, and sheer boredom were just a few of the first signs of trouble with the emerging practice of informed consent (refs). Responses to these problems over the past two decades are classified here in three chronological stages: instrumental, processual, and rights-based or social-justice approaches. All three stages are essential for improving the validity of the consent obtained from research participants.

This paper argues, however, that all three stages in the development of the informed consent process failed to recognize that to improve informed consent we must ensure that both the researcher and the participant have analogous understandings of the meanings of both the individual language terms used in the consent form and the broader social categories to which the language terms might refer. We must also take into account not only what is said, but how it is said, and most importantly, by whom it is said (Sankar 2004). Recent research even demonstrates the impact of the “neurobiology of social cognition” in how research subjects decide to participate in research (Charuvastra and Marder 2006). Literal translation/back translation of terminology in the consent form may result in a technically correct translation of the consent form, but it does not constitute a meaningful translation. For example, the confidence in translation/back translation assumes that there is a single word or phrase in each language which directly corresponds to one another and that the task in translating a consent form is simply to choose the right or best translation of the term. This approach also overlooks the possibility that the various other words and phrases which were not chosen as the “correct” translation might still have salience for the participant and not choosing them might create some confusion in the mind of the participant. For example, when translating risk from English to Luganda, the researchers might prefer the legal term in Luganda for risk, but merely choosing the legal term because it best fits our understanding of risk does not solve the problem that there are multiple meanings of the concept of risk in Luganda, and the legal term is just one of many possible choices. (This is discussed in more detail below.) According to Wallace and Atkins in a classic early paper on formal semantic analysis, translation/back translation is an attempt to achieve truth, accuracy, and predictability in the translation of discrete terms, but does not attempt to convey meaning; it concerns taxonomy but not nomenclature (1965: 245-246). They conclude: “merely structurally valid statements are true statements about a society; psychologically valid statements are true statements about a society and also are true statements about individuals’ cognitive processes” (1965:246). In an attempt to address this problem, this paper will tentatively explore Mikhail Bakhtin’s work on how meaning is created through dialogue in order to suggest a new theoretical framework for improving informed consent.

The first, and up to today, most common response to difficulties in obtaining informed consent was to focus on instrumental improvements in the consent form. Simplifying language to a 10th or 8th grade level was the first step in improving comprehension of the form for the participants, although some recent studies indicate a 4th or 6th grade level is more appropriate in the USA (Paasche-Orlow et al 2003). Borrowing readability tests developed by psychologists and educators, these tests count the number of syllables in each word in the consent form and produce a score based on
the simplicity of the language used; for example, the Fry Readability Test, or the Flesch–Kincaid Grade Level Score which is more widely used because it is packaged with Microsoft WORD. Another early instrumental response was to shorten the length of the form and standardize content. This response meant that all research with human subjects would use the same wording in the same order to explain risk, benefit, adverse outcomes, etc. This option led to the development of the widely accepted boilerplate approach to consent forms. Favoring by most Institutional Review Boards at medical schools in the USA, this approach streamlines the review process but, as some argue, it is primarily a legal strategy for protecting the sponsoring institution from litigation (Beyer et al 2003).

When instrumental adjustments to the informed consent form did not significantly resolve comprehension problems, researchers reasoned that the problem was not with literal translations, but with the process of informed consent itself. Thus the often quoted expression: “informed consent is not a product but a process.” Researchers recognized that more than merely improve the language of the form, they needed to understand the process of obtaining consent, particularly the power dynamic in play when a research professional explains the research and secures participation from a participant in a health care setting. Many of these insights were developed as a result of US and European researchers collaborating overseas with in-country elites in rural, resource-poor settings and on a chronic, but infectious, disease: HIV/AIDS. Similar to Moore’s argument that Africa was the “growing field for a bountiful harvest” of new theoretical projects in social anthropology in the 20th century (1994:1), HIV/AIDS research in Africa has delivered a new harvest of innovative directions for health behavior change theories, vaccine development, improving adherence to HAART, and especially health research ethics. But with the new directions also came new challenges. For the first time since the Tuskegee scandal broke in the late 1960s, American researchers working in Africa were confronted by the implications of a titanic imbalance in literacy and access to resources between the researchers and the African research community. This was further compounded by issues specifically related to HIV; for example, confidentiality and, early on, lack of treatment options for research participants. The difficulties in obtaining informed consent in clinical trials in rural Africa were some of the first indications that this power differential could seriously undermine the scientific validity of the research outcomes and recommendations. The highly publicized debate over which standard of care to offer research participants in the NIH-funded 076 AZT mother-to-child-transmission trials in Uganda was a clear indication of the dangers of applying different research designs in the developing and developed world (refs).

I want to suggest we look to the literary philosopher Mikhail Bakhtin for guidance in thinking about these issues. Why Bakhtin? Because his philosophy of heteroglossia and dialogic thinking most closely approximates what I understand to be the elemental state of the consenting process (1981; 1986). That is, a researcher, a potential participant, a text and: (a) the presence of many voices and perspectives (heteroglossia) both coming together and flying apart in one place at the same time (centripetal/centrifugal) (b) the possibility for understanding and meaning which exists
only at the interface of people in the act of dialogue (dialogism). This new perspective calls for a shift from representational or monologic understanding to responsive, interactive communication. It is clear from the shortcomings of the instrumental and processual approaches to improving informed consent that we should not, in fact can not, strive towards a single perfect document. Bakhtin helps us to see that heteroglossia is a permanent condition, and therefore researchers must reconceptualize consent as an alliance of different voices and experiences. But most importantly, health researchers must learn to tolerate the simultaneous presence of multiple intentions and interpretations while informed consent is being delivered, pondered, accepted or rejected. Advocating for the tolerance of a diversity of meanings in the consent process is certainly a radical suggestion that goes beyond mere methodological changes and it appears to be contrary to its core intention of obtaining a signature to represent a singular understanding of the nature of the agreement between researcher and participant. However, I believe it is a reasonable one, which once accepted, can move us forward to more meaningful consent. How? Observing the consent process through the dialogic model opens new, and more realistic I believe, expectations of what the consent process can achieve. Bakhtin is helpful if we imagine the informed consent process to unfold with a plot, dialogue, and characterization as we would analyze a novel. For Bakhtin, monologic characters are static and predetermined, they lack creativity and function as a mouthpiece for the authors’ (read funders’) ideological viewpoint. We can clearly see the informed consent process is a closed system; it is self-referential. Following Bakhtin, we would acknowledge the essential monologic and authoritative nature of the consent process, but we would also struggle to build dialogic possibilities for consenting. This might be to actively seek out the participant’s reactions and responses to the form, and not necessarily to see conflict in diversity, but to find correspondence, to negotiate a new meaning of the consent form for the researcher and participant. It is our ethical duty to seek out the meaning of the form for the participant: to do anything less, is to fail to obtain truly informed consent.

Another response to the broader issue is to borrow techniques for community participation from the WHO literature on rapid assessment and the work of Robert Chambers on participatory rural appraisal (refs). Focus group discussions with the community both alerted the participant community to the goals of the research project and explored community ideas and expectations about research. New methods to encourage participant willingness to ask questions during the delivery of the informed consent or to assess comprehension and recall were developed [refs]. Researchers came to understand the tremendous power of a signature or a thumbprint on a printed piece of paper and how illiterate participants often feared revealing their inability to sign their name while others feared police action if they didn’t sign their name and agree to participate. Engaging the local community as well as mitigating the power differentials between the researcher and the participant significantly improved the delivery of informed consent, it also transformed the conduct of research because it could now (theoretically) integrate more of the community’s own concerns into the research goals and design.
Some critics advocate for a more explicitly participatory approach to health research. Polanyi and fellow Canadian researchers and bioethicists who focus on health as a human right (Benatar, Daar, Singer), practicing physicians and medical anthropologists (Farmer, Molyneux, Marshall), and social justice philosophers (London), all share a common vision to move away from rigid positivist-based public health and biomedical research towards a model in which new knowledge is created through an interactive, collaborative, interdisciplinary, reflexive conversation that addresses local needs first, and positivist research requirements second (Chung and Lounsbury 2006). Health research now becomes a social and democratic project bouncing back and forth amongst researcher, practitioner, community, participant, policy-makers and resources.

**Autonomy and Consent**

Autonomy (respect for persons) is a central concept in health research, particularly in the context of the process of informed consent. As described in the Belmont Report, an autonomous person is “an individual capable of deliberation about personal goals and of acting under the direction of such deliberation.” The report continues very simply by stating “that individuals should be treated as autonomous agents” and notes that researchers are bound by the “moral requirement to acknowledge autonomy” through the process of obtaining informed consent for healthcare or medical research. Two conditions are essential to establish an individual’s autonomy: liberty or “independence from controlling influences” and agency or “capacity for intentional action” (Beauchamp and Childress 1994:121). The three core features of informed consent are: providing necessary and sufficient information about the treatment or research to enable the patient or potential participant to accept or decline; sufficient comprehension by the patient or research participant of that information to assess their own risks and benefits; and voluntariness in the individual’s consent to treatment or to be a study participant. The Nuremberg Code is the first modern legal doctrine to mandate the central roles of autonomy and consent in medical treatment and research. However, much has been made in the bioethics literature of the deep and uniquely Western roots of the concept of autonomy reaching back to Enlightenment thought about individualism and reason. This historical legacy is the precursor to the current rights-based or patient-centered approach to healthcare in the USA (refs). In this framework, then, the autonomous person is “conceptualized as possessing a sphere of protected activity or privacy free from unwanted interference…able to exercise his or her liberty…which express[es] the patient’s right of self-determination of his or her body” (Kuczewski 1996:8).

What are the implications of these core “cultural traditions” and in some cases, legal formulations, for the American regulation of informed consent overseas? First, is a tenacious belief that only westerners make medical or research-related decisions independent of consultations with individuals other than their physician. This is held in stark contrast to non-westerners, in particular sub-Saharan Africans, who are

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4 This paper will not discuss informed consent or assent for vulnerable populations, such as children or prisoners, or diminished autonomy of mentally incompetent persons.
stereotyped to have an underdeveloped sense of individuality that is subordinated to their communal identity. If Africans could, the thinking goes, they would prefer to make medical or research-related decisions communally; that is, a chief would make the decision to participate in research on behalf of his community and a husband would make the decision to participate on behalf of his wife. I argue that this unexamined myth has misdirected researchers for decades, causing them to focus their efforts to improve informed consent on establishing the voluntariness and autonomous decision to participate by the fact of collecting a single signature at the end of a complicated and contradictory legal form.

Data cited below are analyzed in light of Beauchamp and Childress' two essential conditions for establishing an individual's autonomy: liberty or "independence from controlling influences" and agency or "capacity for intentional action" (1994:121). We clearly see strong evidence of an indigenous sense of the necessity for the autonomy of the individual in decision making, and a conviction that one can refuse to make a decision even when others attempt to persuade or force a decision. Therefore, the conditions for liberty are met.

Informant 7: I have left my home and come here. I have decided to come myself. Nobody has forced me and I have put down my signature that I have agreed to participate in the research you have told us about.

Informant 1: A female decides and gets married to the man she feels like marrying and then refuses one that she is being forced to marry.

Informant 8: Someone can decide to stand for the post of chairman without being forced by anyone or without anyone deciding for him or her. He or she consents for self.

Female opinion leaders from non-research community  
FGD/02/12-13

Informant 4: Consenting is when you are ready to decide. For example, your parent may be doing some problems for you at the early stage. Time comes when you can decide alone and weigh what shall benefit you and what shall not. At that point you decide to do something you shall benefit in and leave what you may not benefit.

Informant 5: When there is no force and you eternalize the issue within your heart and nobody is forcing you. Okay you may be forced to accept, that can happen, but after none has forced you it has been your own will.

Male youths from non-research community  
FGD/03/8-9

Agency is also clearly understood and valued in decision making.

Moderator: What do you understand by consenting in daily life?

Informant 1: It refers to making a decision from the bottom of my heart about anything I may be doing at that time and I have done it.
Informant 3: I would say consenting is all about pronouncing your decision and opinion because consenting come from the heart. [He beats his chest in emphasis] You then make your mind known to other people…at first we had our own mind/opinion about this very research when you asked us to sign the consent. I got some concerns internally in fact you twice gave me the pen and I twice refused because I had some ideas internally which I wanted clarification about before I could sign the consent. I asked the question and other people heard it. Then you clarified it and I made a consent and this is an example of consenting. So after making a decision within your heart, you show it to the rest by signing to indicate that we have consented.

Male opinion leaders from non-research community
FGD/01/8-10

As with informant three above, the quality of information determines a person’s ability and willingness to comfortably give consent.

Informant 8: A person consents based on an idea that is well explained to him. Once he is satisfied, he consents accordingly.

Male opinion leader from non-research community
FGD/01/8-10

Informant 7: To me consenting means that you have been read every single thing in a document, which everything you have understood very well and following your proper understanding of everything do take a decision after even consulting your heart “okwebuza ku mutiam gwo” on whether to accept something or to refuse it but that only follows your proper understanding of everything.

Male opinion leader from research community
FGD/05/7

It is clear that the concept of individual autonomous consent is a strong one in Uganda both for daily life and in research and it appears to conform closely to Euro-American ideals of consent. The broad process of informed consent is also generally well understood. In fact, the evidence from both the case and control communities is equally strong and consistent across gender, age, education, and residence. This suggests that ideas of the autonomy of the individual in decision making are deeply embedded in an Ugandan worldview and is independent of exposure to research. Then why does the literature generally present the process of informed consent as a problematic one in resource-poor countries? I would argue that the problem is not a conceptual or philosophical issue of the autonomy of the individual or the role of the community, but a problem with the mode of communicating content or information from researcher to participant. What is missing is sufficient time to convey the details of the study in a variety of different modes – verbal, pictorial, interactive (role-playing), written. Lindegger et al recently explored this issue in the context of HIV vaccine trial participation in South Africa and concluded that a variety of formats are essential to improving comprehension of clinical trial participation (2006). Fitzgerald et al come to similar conclusions based on research conducted by the Haitian Study Group on Kaposi’s Sarcoma and Immunodeficiency Disorders, but more important, they argue, is the need to assess measures of the “autonomy of study participants to give consent freely in the context of severe poverty, sex inequality, and little access to basic health care” (2002:1302). Another approach is to explore local definitions of the concept of
risk and understandings of local options to mediate exposure to and consequences of risk.

**Okukkera Ng’omuzungu⁵ (Lost in Translation): Risk**

The Belmont Report advises that a “systematic, nonarbitrary analysis of risks and benefits” which could result from participation in research should be clearly explained to the participant during the informed consent process. 45 CFR 46.116 outlines the general requirements for the informed consent document and specifies it must include a “description of any reasonable foreseeable risks” and an explanation of compensation for research “involving more than minimal risk”. Risk is a central, but largely unproblematized, concept in public health. In an editorial in the *Journal of the American Medical Association*, the former Director-General of the World Health Organization asserted that the world is “living dangerously” due to increased risks to health and called on governments to implement “risk-reducing” interventions to improve health outcomes globally (Brundtland 2000). In this public health context, risk is expressed primarily as a numeric assessment of the probability of a certain health outcome; for example, a 1 in 6 risk of cancer. However, as the Belmont Report acknowledges, not all risk is equal. For example, the term “small risk” indicates a low probability that harm will come to the research subject as a result of participating in the research. The term “high risk” more often refers to the severity or magnitude of the probable harm, not simply an increased probability that harm will come to the participant. In other words, the single term, risk, in English carries multiple meanings: probability or chance of an adverse outcome and the severity of that adverse outcome. The imprecision of the language term, whose meanings are embedded in a probabilistic framework, complicates the legal regulations of 45 CFR 46 which mandate a very precise, but also very peculiarly American, treatment of the concept of risk in the informed consent document. Van Ness suggests that the persistence of pairing the terms, “risk and benefits,” in English is a reflection of the ambivalence people feel about chance and uncertainty in their lives (2001:369). Certainly this tendency is also culturally bound and demands careful analysis when translating the text and the multiple meanings of risk into a local language. Risk reduction is generally presented as a matter of changing individual behavior or introducing new government regulations; for example, lowering salt intake or increasing taxation on tobacco products. But is the concept of risk and the process of risk reduction similarly understood by individuals outside this public health context? Do sub-Saharan Africans, for example, and Ugandans in particular, discuss the likelihood of certain health outcomes in numeric, probabilistic terms? Do they believe that they can change their individual health by virtue of changing their own behaviors?

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And in the context of global health research, what are the implications of multiple interpretations of risk?

Determining the most meaningful translation of “risk” presents significant challenges. The process of translating terms such as risk, autonomy, and beneficence between LuGanda and English is difficult and imprecise. Of the seven major published LuGanda dictionaries, the most recent LuGanda - English / English - LuGanda dictionary is the 1925 publication by Kitching and Blackledge (revised primarily for orthography in 1952 by Mulira and Ndawalu).

<table>
<thead>
<tr>
<th>Dictionary Language</th>
<th>Publication Date</th>
<th>Type of Dictionary</th>
<th>Author</th>
</tr>
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<td>General</td>
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<td>L-E</td>
<td>1921</td>
<td>Medical Phrases</td>
<td>Cook</td>
</tr>
<tr>
<td>L-E</td>
<td>1967</td>
<td>General</td>
<td>Snoxall</td>
</tr>
<tr>
<td>L-E</td>
<td>1972</td>
<td>General</td>
<td>Murphy</td>
</tr>
<tr>
<td>E-L</td>
<td>1992</td>
<td>Law</td>
<td>Nsereko</td>
</tr>
</tbody>
</table>

There is no up-to-date, single source for moving back and forth between English and LuGanda. Therefore, the most common approach to preparing informed consent forms is to compose them first in English, translate into Luganda, and then back translate into English relying on research field assistants or professional linguists at Makerere University. This introduces tremendous variability into the process and leads to unstable and unreliable translations.

However, even if we were to rely only on Luganda dictionaries, other problems emerge. For example, “risk” in the English section of Mulira and Ndawalu is translated as -egabula, -etunda, -evuubiika, and -tunda omwoyo (1952:203). When we back translate these terms using the same dictionary, we immediately recognize the variety of meanings that the English work “risk” gives us in Luganda, for example, to voluntarily bring risk or danger to your body or life by ignorance or by compulsive behavior. By 1992, our only contemporary option for translating “risk” from English is to consult Nsereko’s Law Dictionary. Nsereko translates “risk” as “akabi akayinza akugwawo” (1992). However, to completely understand Nsereko’s translation, we must then refer to the Snoxall 1967 LuGanda-English dictionary to back translate. Snoxall gives a separate translation of each of Nsereko’s terms “akabi akayinza akugwawo”: (a) “akabi” is harm, danger; (b) “–bi” is bad, evil, dirty, dangerous; (c) “–yinza” is to be able, to have power and authority, to make possible; (d) “–gawo” is to give to, to distribute. The literal translation of “risk” or “akabi akayinza akugwawo” is “it gave to you the power to do evil or harm.” Therefore, if we use Nsereko’s legalistic term for “risk” we convey a negative
and dangerous meaning that carries the additional gloss of power and authority and is further complicated by the reflexive verb.

If we choose the standard, more conversational usage of “risk”, which is also the most common translation of risk on consent forms – “buzibu” – we find the same sense of negativity, but not danger, and certainly not power and authority. Buzibu means “difficulty” or “big problem.” It correlates only to a negative outcome, but most importantly, it does not carry any sense of probability of outcomes, whether they are good or bad, as the English use of the word “risk” does in consent forms. An alternative approach would be to analyze a set of conceptually related words to establish a continuum of meaning that forms the cultural universe of “risk” for LuGanda speakers.

- katyabaga risk, trouble, difficulty, endangering situation
- Omukisa good luck, high chance, probability, unexpected good fortune
- Omukisa omuni bad luck
- Ekisirani bad luck, fate due to God’s will, loss of life
- Ekiizi problem
- Buzibu risk, difficulty, bad situation
- Nteekateeka ya katonda God’s will

We see that buzibu is the result of human action, but it always results in bad outcomes and therefore is an inappropriate term for the informed consent document. Mukisa is often translated as “chance” or “probability” or ”luck” and is used to convey that sense, but as we see from the discussions below, mukisa carries a sense of divine intervention. Omukisa, however, is a means for accounting for seemingly random outcomes – why one person dies in a bus accident, while another did not. Women offered a similar analogy related to pregnancy outcomes. Omukisa also has a sense of unexpectedness, an inability to predict the possibilities of, or even prepare for outcomes.

Informant 7: Risk [buzibu] is what puts into problems but chance [mukisa] is what uplifts you from danger.

Male opinion leader from research community
FGD/05/15

Informant 1: “Omukisa gujira mulamu:” Chance is for the living. Provided you are still alive, chance can always come your way.

Moderator: Where does chance come from?

Informant 5: “Mu bajjaja” From the traditional gods, I give them offertory and then open up my way for chances.

Informant 6: I can also wake up in the morning, get ahold of my “sapuli” (rosary), pray to God and he deals me with chances and luck.

Moderator: Where does risk come from?

Informant 5: In most cases, it is we who fetch danger or risk to ourselves.

Male opinion leaders from research community
Moderator: What other words do you use which mean “omukisa”?

Informant 6: Also at times we can all be “bazitto” [literally: heavy, colloquial for pregnant], we can all go to hospital to deliver, they may deliver my friend with a cesarean case, and for me I deliver normally. That is “mukisa.”

Female youth from non-research community
FGD/04/13

Moderator: What is the other example of “omukisa”?

Informant 1: When one gets something good which he never expected. Like if I have been walking and I came across a million shillings.

Informant 6: I could have failed to conceive for a long time until I even separated, but on getting another man, then I get a baby. Wouldn’t that be a “mukisa”?

Female opinion leaders from non-research community
FGD/02/22

Early in the project, when my research assistants began to realize the difficulty of translating “risk,” they summed up the problem as Katogo! Literally translated, katogo means the leftovers you eat for breakfast, but metaphorically it indicates a mess, or a situation that is all mixed up. It is clear that there is no single word, in either English or LuGanda, that conveys all the meanings of “risk” according to the criteria of the Belmont Report. A more effective strategy would be to translate bundles of concepts, rather than single words.

Effects of Participation in Research on Definitions of Research

The data reported in Table 4 address another central research question: What is the effect of long-term participation in externally-funded, collaborative HIV/AIDS research on study participants’ definitions, understandings, and expectations of health research in a resource-poor rural community in Uganda? We glossed the English word “to research” in Luganda as “okunoonyereza” for which the literal translation is “to look for diligently, to investigate thoroughly” (Murphy 1972). The question posed to the participants in Table 4 was, “According to you, what is research? Can you please explain it to me?” Answers were followed up with probes, such as: “Can you give me a few examples of this? Which of these examples has been good? Or bad?” “Is it important? Why or why not?”

Identifying the four response categories in Table 4 followed the first step in Glaser and Strauss’ (1967) (Glaser and Strauss 1967) grounded theory approach for the analysis of qualitative data. After reading transcripts of open-ended responses, broad themes and concepts emerge to suggest response categories for the tables. In our case, after summarizing and coding several pages of text per informant in which they define research and benefits, four distinct response categories clearly emerged: (1) discovery by experts of new knowledge to improve the general quality of life for rural
Ugandans (2) discovery by experts of a treatment or cure for HIV/AIDS (3) seminars or projects led by experts and offered to community members to help them address specific local development problems (4) personal material gain, such as money from research participation, improved seeds and fertilizer, building materials for a household latrine, etc.

In Table 4, 75% of those who had participated for at least three years in intensive health research (“research experienced”) defined research specifically as the search for, or work towards, a cure or treatment for disease and specifically named HIV/AIDS in their response. The remaining 25% defined research as the discovery of new, general knowledge or the process of community development. It is notable that no one in the “research experienced” group mentioned personal material gain when defining research. The two comparison groups gave remarkably similar responses. Almost two-thirds of all those with no research experience defined research as the discovery of new, general knowledge. One-quarter to one-third defined research as community development, with a small percentage mentioning a cure for HIV/AIDS or personal material gain as the definition of research.

The following quotes are representative of responses reported in Table 4. On defining research in response category 1, a 25 year-old man from the Ssese Islands with no experience with research defined it this way: “Research involves going to a place, making a study on an issue, and then giving a feedback about what you did the research about” (03). A 65 year-old man from the same area explained: “Research is finding by discovering what has not been worked on…They [scientists] may make research by asking themselves questions like, ‘What causes plants to appear like this?’” (09). Compare this with answers in response category 2 by those who participated in intensive health research. A 30 year-old woman replied: “Research is treating people so that they are healthy enough, mainly research on HIV/AIDS” (047). Another woman reported: “Research is the health workers getting blood from us to find out the diseases (HIV/AIDS) that we could be having” (060). This response by a 35 year-old male resident of the Ssese Islands is typical for response category 3, community development: “Research may prove that there are no schools here in Ssese. Schools may then be constructed” (020).

Effects of Participation in Research on Expectations of Research Benefits

Table 4 also offers a quick and compelling assessment of the powerful, and unexpected, effects of participation in health research on local ideas, norms, and expectations. We anticipated that the definition of research described by those who had participated in research would more closely reflect the western scientific ideal of research than those who had never participated in research. However, the data do not confirm this. In fact, those with no research experience were anything but “naïve” in their understanding of the basic goals and methods of research. They clearly, and often elegantly, articulated a vision of research as the systematic search for new, but general,
knowledge. Where members of both comparison groups listed a variety of topics in reference to their definition of research, such as agriculture, education, crime and transportation, research participants focused primarily on HIV/AIDS. Long-term participation in intensive health research appears to have narrowed the frame of reference for defining what research is or could be, to a focus on, or a mimicking of, the specific goals of the project in which they were participating.

It might seem reasonable to attribute the much higher rates of HIV/AIDS in Rakai vs. Kalangala to the observed differences. However, the similar responses of the two comparison groups weakens this explanation and suggests that participation in research accounts for this transformation. This shift is another reminder of the powerful impact a large-scale health study exerts on an individual participant’s understanding of and expectations for research. It suggests we need to increase our qualitative assessment of informants’ commitment to a study to ensure that their expectations remain reasonable and reflect an informed assessment of the risks and benefits associated with their continued participation.

On a more expansive note, the testimonies of informants with no research experience reveal a noble and hopeful vision for future research. Many in the comparison groups explained that research should be an active and collaborative relationship between scientists and participants. Some suggested that truly meaningful new knowledge could come only when researchers listened to, and followed up on, the research priorities of their local informants. Furthermore, they did not see the conduct of research as a value-free, neutral enterprise and emphatically noted that they did not want to waste local resources (i.e., their time and effort as participants) on research that did not have the direct application of productive knowledge to local development as one of its central goals. For informants in the comparison groups, research clearly facilitated the distribution of scarce resources and was described as a political process.

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6 There are no statistically reliable sero-prevalence rates by district in Uganda. The only district level sero-prevalence data are from select sentinel ante-natal sites, and neither Rakai nor Kalangala are sentinel sites. The most reliable, population-based data come from the 2006 joint report by the Ministry of Health Uganda and ORC Macro which disaggregates HIV/AIDS sero-prevalence rates only to the regional level and both Rakai and Kalangala are included in the same region. That study estimated current country-wide rates for men at 5.0% and for women at 7.5% (MOH-ORC, 2006:101). However, as a rough comparison, a good, early measurement would be “Distribution of Clinical AIDS Cases by District of Residence, prior to 1998,” in which Rakai District reported 2,163 AIDS cases prior to 1998 and Kalangala District reported 17 AIDS cases prior to 1998 based on clinical symptoms (STD/AIDS Control Programme, 2003:50-51). The most recent data is based on HIV testing and is available from The National Health Data Bank of Uganda (NHDB-U), a unit of the Uganda Ministry of Health, <http://www.healthdata.go.ug/>. Between May 2004, when HIV testing was first made available in Kalangala, and August 2005, 520 HIV positive cases above age 5 were confirmed in Kalangala. For the same time period in Rakai, 2620 HIV positive cases above age 5 were confirmed. Many thanks to Herbert Mulira of NHDB-U for providing these raw data for comparison purposes of this paper only.
**Therapeutic Misconception**

The following section is very preliminary

More serious, perhaps, than the effect of longterm participation in research to shift the definition of research from a general search for new knowledge to a focus on a cure for HIV/AIDS, is the therapeutic misconception. First described by Appelbaum and colleagues in 1982, the therapeutic misconception occurs when the research participant transfers their understanding of the therapeutic role of the physician in the clinical setting to that of the healthcare-investigator in a trial or research setting. Whereas the physician is obligated to act in the best interests of their patients, the physician-investigator is obligated to uphold the research protocol, which may or may not be in the best interests of the research participant. Over two decades later, this classic interpretation of the therapeutic misconception is still reported in research settings in both resource-rich and resource-poor settings (Fairchild and Leach 2006a and 2006b; Hyder and Wali 2006; Krosin et al, 2006; Marshall et al, 2006; Molyneux et al, 2004; Moodley et al, 2005; Onvomaha-Tindana et al, 2006).

However, the therapeutic misconception is neither static nor do all examples follow this classic description. Belkin argues that the therapeutic misconception developed as a distinct phenomenon not because the practice of medicine or medical research became more moral whereby practitioners finally recognized the ethical challenges of the therapeutic misconception, but because the practice of research and medicine became more distinct, “more capitalized, industrialized, standardized, and thus more easily and necessarily organized in predictable and generalizable routines” (2006: 83). As the relationship between research and treatment continues to change, we can expect the contours of the therapeutic misconception to also change. For example, increased access to knowledge about clinical HIV/AIDS trials changed the relationship between trial participants, particularly in the USA, and their physicians and physician-investigators. By the early-1990s participation in clinical HIV/AIDS trials was seen as superior to the therapy offered by a physician and HIV-positive patients actively sought participation in clinical trials to supplement or even supplant their physician’s care. Rebecca Dresser identifies a new “therapeutic misconception”, one in which cancer and AIDS patients seek out participation in phase one trials of experimental therapies, hoping for a therapeutic effect, even when the research design specifically indicates a low chance of such an effect (2001; 2002).

Why does the therapeutic misconception persist in time and across space? Is it simply a matter of ineffective communication between researcher and research participant, a miscommunication which can be addressed in the same vein as the process of improving informed consent? Or do we see evidence that goes beyond a “miscommunication” to indicate different worldviews and moral imaginations about the value of health research, especially in resource-poor settings? Do African research participants who describe research in the classic formulation of the therapeutic misconception engage with research as treatment not in a misunderstanding of these two separate activities, but because their lived experience of health research is that it is
their only option for treatment in a resource-poor setting? Or perhaps because African research participants observe that research subjects receive more efficacious and consistent care than those who seek treatment at public clinics? And what of the apparent conflation of health research with community development or education? Is this another example of miscommunication? Or is it a reflection of fundamentally different expectations for health research shaped by local access to resources? Western researchers typically define the contours of their relationship to their research subjects through the consent process and understand it to be transactional in nature. African research participants expect the conduct of research in their community to be transformative and to develop and sustain new networks of reciprocity. We clearly see the emergence of a different moral economy of research for a poor rural community in Uganda. To address this problem, Lavery et al suggest a new approach to critically examining the norms of multinational health research and offer a framework for a new “mutual aid principle of clinical research” (2007: 191-192). However, according to Marilyn Strathern, the problem goes deeper than improving the terms of collaboration, it is embedded in a social situation that is neither defined by nor controlled by the parties involved (2006).

Therefore, we must conclude that resolving these different viewpoints and expectations requires more than “better” communication or collaboration. It demands recasting the therapeutic misconception literature within a classic debate in the anthropological literature on African health systems: the false dichotomies of science and folk systems, empirical observation and magic, biomedicine and traditional herbal healing, open (dynamic and testable) and closed (static and non-empirical) knowledge systems. The explanatory power of the therapeutic misconception is increasingly limited by its commitment to the false dichotomy of research and treatment. In a recent article on therapeutic choices among the Ghaambo of Tanzania, Steven Feierman revisits this debate and argues that failing to move beyond such dichotomous frameworks “described in terms of stark and immutable contrasts” means we ultimately fail in our ability to understand and interpret local judgments of (to cite our case study here) the practice of health research in a resource-poor setting (2000: 343-344). Feierman describes the search for diagnosis and treatment by a woman named Asha Abedi. Her biomedical diagnosis was hookworm, but her description of her symptoms focused on her social marginality. In fact, she did not separate the two domains and “she expected a course of therapeutic action to address the whole of her condition” (Feierman 2000:334). Diagnosis reflected the “logic of social relations” and treatment was expected to address the moral economy of local resources (Feierman 2000:332). In this context, where existing treatment options are limited and often unsuccessful, the therapeutic misconception needs to be recast away from research and treatment to one of research and development (either personal or community).

Feierman’s framework helps us to understand that what on first glance appears to be a classic case of therapeutic misconception is actually a reflection of the logic of local expectations of new social relationships from participation in research. Motivation to participate in research and expectations of benefits from participation for the Rakai case study group (longterm participation in clinically-intensive health research) primarily
focus on material goods – blood tests, access to ARVs, health check ups, etc. The classic features of the therapeutic misconception which mark the Rakai group are not confusing the therapeutic role of the investigator-practitioner with that of a private-practitioner, but rather clearly distinguishing the spheres of research and treatment by participant access to personal health resources. ARVs, other essential drugs, and HIV testing are goods consumed by and benefitting only the study participant. The focus for the Rakai group is on the dyad of health practitioner and participant. In contrast, for the other two study groups – Ssese Islands and neighbors to the Rakai project – motivation and expectations reflected a more complicated calculus of personal benefit that almost always was in the service of a larger purpose of community benefit. The research dyad of physician and patient was merely the starting point for amplifying and distributing the resources that came into the community as a result of the research project. Access to research meant access to increased personal knowledge and health education that must then be shared with others in the community. Research participants gained a new visibility and personal authority by virtue of their exposure to the research project and research personnel that was also to be used in service to the community.

Below are a few preliminary pieces of evidence that demonstrate a “therapeutic misconception” whereby research participants link the goals of research with the goals of community development. The comments below are from those with no research experience, that is the Ssese and Rakai neighbor groups. The comments are in response to questions about motivation to participate in research.

The foundational step in community development is access to new knowledge, which research projects provide.

“I expected to get knowledge. We said that we shall go and get knowledge. More so, like us who never went to school.” (Q514, respondent 6)

“Having knowledge. You know there is a saying: Ndimugezi nga mubuu liri (I am a clever person, but only after I am informed).” (Q501, respondent 9)

“Because an educated person does not suffer much with this world” (Q501, respondent 12)

Control of new knowledge is not only for personal benefit, but for community development.

“It is because I wanted to get messages to take to fellow youth back in the community” (Q502, respondent 3)

“I need to learn something…so that I can in turn teach others…this is the truth!” (Q501, respondent 19)

“I have always wished to be working with an NGO in Rakai District. Before coming here I stayed in Mukono (a nearby large town) for sometime and people in Mukono have so many NGOs giving assistance to people with AIDS. But when I came here I realized that there is no such group in this area. So when I heard about this chance I even gave in part of my time that I would be using for prayer, so as to participate in this research.” (Q501, respondent 87)
“I know that my district and country will certainly gain from this research. Secondly, to be invited as an individual to participate in an activity of this nature, it becomes a prestige to you. That is, you are a special person amongst the many. You certainly have the credibility and can be consulted by other people.” (Q518, respondent 21)

“Somebody comes and asks you questions about yourself and your area, why don’t you become happy since they have considered you among the knowledgeable?” (Q518, respondent 23)

A few examples of the specifics of community development.

“I expected that research is being done on how to improve people’s living standards by availing us health units and seminars on health to help us learn more about good health.” (Q514, respondent 20)

“I had an idea that our only road running through Kalangala is very narrow. Wooh! If this road could be made wide, it would reduce road accidents here.” (Q515, respondent 20)

“I had an idea that they could give us oxen to help us in fetching water for those people with disabilities, like old people and those who are seriously sick. That would benefit us all.” (Q515, respondent 77)

5.) When Rules are Not Enough: The Making of a Moral Imagination

The hypothesis that attracted funding for my dissertation research in medical anthropology was: staying in school has a protective effect on sexual risk-taking among youth, especially girls, in rural western Uganda (Stewart 2000). It was an important question to ask at that time because the HIV virus in Uganda was shifting from urban to rural areas and from the over-18 to the under-18 age group for the first time anywhere on the African continent. AIDS prevention and education programs in Africa were modeled on American public health theories of risk behavior change and targeted primarily urban adults. The existing demographic studies rarely surveyed adolescents, the most recent cultural descriptions of sexual debut in rural Uganda were over 30 years old, and it was widely believed that girls who attended school were at higher risk of HIV transmission than other girls because they spent more time away from their homes. How could we develop effective interventions to change sexual behaviors, protect young women against predatory men, and interrupt those alarming new trends in the transmission of the HIV virus? The first step was to conduct a research project that simultaneously collected a biological marker (HIV serostatus), a sexual behavior survey stratified by school experience, and a qualitative study of youth sexual cultures. For those who tested HIV+, our most critical group of interest, the blood test offered a unique and accurate method to test the internal validity of the self-reported sexual behaviors. The unstructured, open-ended interviews were linked directly to the biological marker and survey data, thereby increasing the use value of qualitative data for the public health and biomedical researchers who dominated the HIV/AIDS research scene in Uganda in the 1990s. Triangulation of results across these three domains, I argued, was certain to improve our understanding of HIV risk for young people in Uganda.
The human subjects research review process for this study spanned almost four years. The study passed through a variety of formal reviews at my university (University of Florida), my funders (NIMH, NSF, and Wenner-Gren), the Uganda National Council of Science and Technology (UNCST), the AIDS Research Sub-Committee of the UNCST, the Makerere Institute of Social Research (MISR), and the District Medical Officer for the area where I conducted the study. Although cumbersome and lengthy, the process dramatically reduced the level of research risk for the study participants, improved the scientific validity of the research design, sharpened my qualitative study focus, and made the project more relevant to local research concerns. During two country visits, I consulted with researchers and health professionals outside the formal review committees and applied their recommendations to the study. I knew of no other graduate student who devoted so much time and effort to getting their study right. Therefore, when we did begin data collection, I was absolutely certain that, with the help of so many dedicated people, I had developed the most technically compliant and ethically rigorous study possible of rural youth sexual behavior. I set off for my research site with an exhilarating sense of achievement, a certainty that my study would not repeat the many research misdemeanors and ethical transgressions I observed on other similar projects, and a very deep sense of satisfaction that my faithfulness to getting the study right meant that no harm would come to those young people who volunteered to participate in my study. Finally, I thought, my moral vision prevailed.

It prevailed for about two weeks. Once I began the process of recruiting participants, I discovered an irresolvable conflict between maintaining the integrity, and therefore the scientific value, of my research design, upholding my responsibility to follow the three basic principles of the Belmont Report (respect for persons, beneficence, and justice), and fulfilling my moral vision of conducting research as free of risk as possible. The most serious problem that emerged was with respect for persons, the core value of the process of informed consent: “An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons’ considered opinions and choices.” (National Commission 1978) The most original aspect of my research design was the simultaneous collection of survey and biological data in a random stratified sampling design. The most important quality of informed consent is autonomous consent, free of any undue influence or coercion. Our selection protocol was to approach potential school-going participants at school, school drop-outs in town, and non-school-goers on their farms in a rural area outside town. When knocking on our first door in the rural area, I suddenly recognized that the informed consent we obtained first to collect survey data required a much lower threshold of autonomous consent, and represented a categorically different quality of research risk, than the informed consent required to collect blood for a diagnostic HIV test. Many informants were already familiar with survey research, whether directly or indirectly, and their consent to the survey indicated that they did not find it objectionable to participate. However, I was not convinced that those who freely consented first to the survey would distinguish it from the second stage of informed consent for the diagnostic HIV test. Nor was I convinced that the willingness to accept the blood test after a short counseling process in situ could satisfactorily indicate a fully deliberate and independent decision.
immediately suspended data collection and retreated to my house to consider the situation.

What were my options? (1.) Change nothing and be confident that the human subjects review process which unanimously approved the design, found no rules or regulations violated, nor anything unethical about the project, was sufficient? I canvassed many colleagues; all but one urged me to continue, arguing that the value of the information, particularly at that point in the epidemic, was so critical that my personal concerns about the sufficiency of the review process should be suppressed. Others felt I was over zealous in my interpretation of the meaning of autonomy and that my test for autonomy was unrealistic, needed too much evidence, and over-stated the harm that could come to someone who accepted an HIV test without previously considering it independent of the research team approaching them. In any case, most argued, the participants were not required to receive their results and could therefore opt out of their results at the hospital. It was the argument for the greater good over the lesser evil. (2.) Consider technical fixes that would allow me to maintain those critical research design features while addressing some of my own worries? For example, I considered a two-stage design, whereby potential participants were properly counseled about HIV testing on one visit and then were approached at a second visit for consent to both the survey and blood draw. This solution introduced some sampling bias; but more importantly, confidentiality would be virtually impossible to guarantee in a small village where the study goals would be known to everyone by the time we returned for a second visit. Other complicated issues were at play: the age of the informants, a general reluctance to refuse the requests of researchers, the remoteness of the research site hindered the local availability of HIV testing which made travel to a testing clinic for an alternative to participating in the project prohibitively expensive, the ethics of collecting blood when not much follow up support was available, etc. (3) Change the research design to meet my higher standards of the principle of autonomous consent, but in doing so, break the direct temporal link between the survey and biological data that promised to produce original and important data? It also meant failing to fulfill my obligations to the funders and reviewers who approved the project for this very specific reason. Yet, was it more wrong to abandon such promising research for the remote possibility of protecting a participant who consented to an HIV test under less than optimal circumstances? Was I being too paternalistic by denying the community the option of choosing for themselves to participate in a research project that many villagers told me had significant and personal relevance for them? Where did my ultimate allegiance lie: to the individual participant? the greater good of the community? funders? or even more remotely, the promise the science held for my professional community and perhaps my own career?

Solomon Benatar recently suggested that a lack of moral imagination is the greatest challenge to improving global health (2005). Mark Johnson identifies three components in the development of a moral imagination: (1) simultaneously recognizing

7 Many of these concerns are no longer an issue: door-to-door testing is now routinely conducted in Uganda, access to testing facilities is greatly improved, stigma against testing is reduced because of the availability of ARVs, etc.
a variety of interpretations or choices (2) developing new solutions and (3) evaluating those new solutions from a new moral place where new ideas lead to new actions (1993:202). Moral imagination, therefore, is the ability to see contextual factors, to reframe problems from a variety of perspectives and interests, and to envision, act on, and justify the solution to the problem. In my view, this defines best practice for many anthropologists. In the end, my determination to do the right thing was not a matter of rules and regulations, but a matter of moral imagination. Rules and regulations guided the research protocol, but I needed moral imagination and an experience of the local context to make the right judgment and resolve the dilemma. According to Arthur Kleinman, this is the “close-up world” (2006: 232) of the anthropologist where the intersection of ethical principles and moral experience defines what matters most – to both the anthropologist and the informant (Kleinman 1997, 1999, 2006; Yang, Kleinman, and et al 2007). I sensed that my “moral environment was wrong” because the rules and principles which initially shaped my project were set in a context of experience that was external to the local experience (Kleinman 2006: 3, 25). What guided my final decision? the principle of utility? scientific accuracy? justice and human rights? Ultimately, my decision rested on my training as an anthropologist and the value I respond to most as an anthropologist: the honesty of my personal relationship with my informant. What mattered most in my case was to be able to take full responsibility for everything that happened to the informant as a direct result of participating in my project. I decided my primary responsibilities were to the person in front of me who was to be affected immediately from my direct actions or presence. I calculated my action on direct and immediate effects – not the longterm, or the greater good. My reasoning was that I could return to the longterm concerns in the future, but right now, I needed another approach. I decided to take the most conservative route and separate the collection of the survey and HIV data in both time and place. Participation in one phase of data collection was now totally independent of participation in another. This meant three new paths to becoming an informant: (1) participate in the survey but do not go to the district hospital to obtain the blood test; (2) obtain an HIV test at the hospital but decline to answer the survey questions; (3) complete both parts of the study. Yes, I altered the critical design of the simultaneous collection of survey and biomarker, but I was now confident that every HIV test result delivered to a research participant was delivered to someone who completely consented to it in the fullest possible sense of consent. But, I didn’t stop there. I wanted to understand how the review process had failed me and my informants. This experience inspired the next project, the one I describe above.

6.) Concluding Reflections

From the individual participant, to WHO policy-makers, to the new model of transparency and collaboration promoted by the Gates Global HIV Vaccine Enterprise in July 2006, there is increased scrutiny of health research, especially research on global health problems. Global health research is now a global public good with high social value. How can we harness this current focus on global health research to maximize benefits for resource-poor settings? Perhaps if we deploy social science to listen to the
participants themselves, then one emphatic suggestion is to more explicitly link health research to local development.
### 7.) Tables

**Table 1**

Demographic Indicators, Uganda 2005

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<th>Value</th>
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</thead>
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<tr>
<td>Total Population</td>
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</tr>
<tr>
<td>Births per 1,000 pop</td>
<td>47</td>
</tr>
<tr>
<td>Deaths per 1,000 pop</td>
<td>13</td>
</tr>
<tr>
<td>Rate of natural increase</td>
<td>3.5%</td>
</tr>
<tr>
<td>Life expectancy at birth</td>
<td>51 yrs</td>
</tr>
<tr>
<td>Infant deaths per 1,000 live births</td>
<td>68</td>
</tr>
<tr>
<td>Total fertility rate (per woman)</td>
<td>6.7</td>
</tr>
<tr>
<td>GNI per capita (US$)</td>
<td>$240</td>
</tr>
<tr>
<td>Rural Population</td>
<td>88%</td>
</tr>
<tr>
<td>Total Adult Literacy Rate</td>
<td>67%</td>
</tr>
<tr>
<td>Adult HIV prevalence rate</td>
<td>4.1%</td>
</tr>
<tr>
<td>(15-49) range: 2.8%-6.65)</td>
<td></td>
</tr>
</tbody>
</table>

UNAIDS, 2003
<table>
<thead>
<tr>
<th>Table 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Survey research design and inclusion/exclusion criteria, total N = 102</strong></td>
</tr>
<tr>
<td><strong>Case group, Rakai District, southwestern Uganda, N = 39</strong></td>
</tr>
<tr>
<td>&gt;18 years old</td>
</tr>
<tr>
<td>Health research study participant ≥3 years</td>
</tr>
<tr>
<td>Previously consented to blood draw for HIV testing as on-going research subject</td>
</tr>
<tr>
<td>Primary language: Luganda</td>
</tr>
<tr>
<td>Main economic activity: small-holder subsistence farmer</td>
</tr>
<tr>
<td>Resident in a rural, agrarian village</td>
</tr>
<tr>
<td><strong>Comparison group 1, Ssese Islands, Kalangala District in Lake Victoria, N = 40</strong></td>
</tr>
<tr>
<td>&gt;18 years old</td>
</tr>
<tr>
<td>No previous research experience</td>
</tr>
<tr>
<td>Primary language: Luganda</td>
</tr>
<tr>
<td>Main economic activity: small-holder subsistence farmer</td>
</tr>
<tr>
<td>Resident in a rural, agrarian village</td>
</tr>
<tr>
<td><strong>Comparison group 2, Rakai District, southwestern Uganda, N = 23</strong></td>
</tr>
<tr>
<td>&gt;18 years old</td>
</tr>
<tr>
<td>No previous research experience</td>
</tr>
<tr>
<td>Primary language: Luganda</td>
</tr>
<tr>
<td>Main economic activity: small-holder subsistence farmer, possibly supplemented with fishing</td>
</tr>
<tr>
<td>Resident in a rural, agrarian village</td>
</tr>
</tbody>
</table>
Table 3
Socio-demographic characteristics of survey participants, $N = 102$

<table>
<thead>
<tr>
<th>Variable</th>
<th>(%)</th>
<th>Variable</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>49</td>
<td>Literacy</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>51</td>
<td>None</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Some</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Full</td>
<td>64</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td>Birthplace</td>
<td></td>
</tr>
<tr>
<td>18-29</td>
<td>32</td>
<td>Rakai District</td>
<td>50</td>
</tr>
<tr>
<td>30-39</td>
<td>37</td>
<td>Ssese Islands</td>
<td>20</td>
</tr>
<tr>
<td>40-49</td>
<td>19</td>
<td>Masaka District</td>
<td>20</td>
</tr>
<tr>
<td>50 and older</td>
<td>12</td>
<td>Other</td>
<td>10</td>
</tr>
<tr>
<td>Religion</td>
<td></td>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>Catholic</td>
<td>68</td>
<td>None - Primary 4</td>
<td>29</td>
</tr>
<tr>
<td>Anglican</td>
<td>13</td>
<td>Primary 5 - 7</td>
<td>50</td>
</tr>
<tr>
<td>Islamic</td>
<td>7</td>
<td>Secondary 1 - 4</td>
<td>18</td>
</tr>
<tr>
<td>Charismatic</td>
<td>3</td>
<td>Post High School</td>
<td>3</td>
</tr>
<tr>
<td>Other</td>
<td>9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 4

Results: Effects of research participation on definition of research, $N = 62$

<table>
<thead>
<tr>
<th></th>
<th>Discovery (General) (%)</th>
<th>Discover, treat, or cure HIV (%)</th>
<th>Community Development (%)</th>
<th>Personal Material Gain (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research experienced (Case group)</td>
<td>20</td>
<td>75</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>No research experience (Isolated: Ssese Islands) (Comparison group 1)</td>
<td>59</td>
<td>4</td>
<td>32</td>
<td>5</td>
</tr>
<tr>
<td>No research experience (Neighbor of case group) (Comparison group 2)</td>
<td>60</td>
<td>10</td>
<td>25</td>
<td>5</td>
</tr>
</tbody>
</table>

.000 significance (Pearson Chi-Square, df6)
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