Institutional Review Board Compliance Issues on Research Aspects of International Entrepreneurial Ventures

Carey Bell, Senior, International Politics
Rachel Dzombak, Junior, Bioengineering
Tara Sulewski, Graduate, Mechanical Engineering
Khanjan Mehta, Lead Faculty,
Humanitarian Engineering and Social Entrepreneurship (HESE), Penn State University

ABSTRACT
The Humanitarian Engineering and Social Entrepreneurship (HESE) Initiative at Penn State is engaged in several student ventures that integrate teaching, research and outreach to educate entrepreneurial global citizens and create sustainable value for developing communities. Engaging students in publishing the observations and results of these initiatives in peer-reviewed journals and conference proceedings is an explicit objective of HESE. The Institutional Review Board (IRB) is responsible for overseeing all research efforts that involve human subjects. IRB approval and subsequent compliance is essential to ensure appropriate research and conduct. This paper discusses the challenges faced and lessons learned while seeking approval from and ensuring compliance with the IRB on five distinct projects undertaken concurrently in Kenya in summer 2010. Unexpected situations that arose while gathering data and how they were resolved is also discussed. This paper aims to share insights into planning and executing research components of international entrepreneurial ventures undertaken by similar programs.

Introduction
Almost half of the world’s population lives on less than $2.50 per day. Millions of people do not have access to clean water, sufficient amounts of food, or adequate health care services (Shah 2010). Engineers have the power to ameliorate this situation by melding technological innovation with contextually appropriate design and commercialization. However, as it stands now, 90% of the world’s engineering efforts are aimed to impact only 10% of the world’s population (Smithsonian 2010). This discrepancy demonstrates the urgent need for more engineers to focus on areas where they can make the most substantial impact.

Humanitarian Engineering and Social Entrepreneurship (HESE) at Penn State engages students in technology-based social ventures in developing countries. The basic philosophy of HESE is the convergence of concepts, disciplines, cultures and countries towards a freer, fairer, friendlier and more sustainable world. HESE brings together students and faculty from various disciplines to develop innovative and practical technology-based solutions to address the most compelling challenges facing marginalized communities in the developing world. The quest is for solutions that meet the four hallmarks of sustainability: technologically appropriate, environmentally benign, socially acceptable and economically sustainable. HESE seeks the convergence of the tripartite university missions of teaching, research and outreach to educate globally-engaged social problem solvers and to create sustainable value for developing communities, while generating and disseminating knowledge and lessons learned. Forming long-term relationships with a diverse array of partners and leveraging indigenous knowledge to foster developmental entrepreneurship are the foundations of all initiatives.

HESE specifically emphasizes student research and scholarship to provide rigor to the larger program. This paper deals with the IRB approval process for research studies and issues encountered while conducting research in developing country contexts. The first section emphasizes the importance of research and publication in this field, while the second section discusses the IRB approval process. The next
section provides practical insights into real issues encountered while conducting multiple research studies in Kenya. Larger conflicts and challenges balancing the chaotic environment of entrepreneurial activity (especially in developing countries) and the precise deterministic environment desired for scientific research are discussed in the final section of the paper.

**Importance of “Research”**

In recent years, many different academic programs have been developed to help meet the needs of underserved populations. A number of them employ the pedagogy of service learning. Service learning helps students to broaden their understanding of their disciplines and course materials while also encouraging civic engagement and social responsibility. (Bringle, 1996) Programs like Humanitarian Engineering and Social Entrepreneurship at Penn State are also on the rise. The Humanitarian Engineering Leadership Projects program at Dartmouth, the D-Lab at MIT, the Humanitarian Engineering program at the Colorado School of Mines, Global Resolve at Arizona State, and the Mortenson Center in Engineering for Developing Communities at the University of Colorado at Boulder are specific examples. Students and faculty from these programs have been involved in myriad ventures such as working to provide clean water in regions of Tanzania and Kenya, generating solar power in Belize, designing solar ovens and drip irrigation systems, and producing hydroelectricity and biogas in Rwanda (Dartmouth Humanitarian Engineering Projects 2008; MIT: About D-Lab 2010; Humanitarian Engineering: Colorado School of Mines 2010).

While the work of many of these student programs has significant merit and could potentially contribute significantly to the academic community and practitioners, their work often goes unpublished. Often their experiences are shared at conferences through papers and presentations, but this information is ‘anecdotal’ and does not qualify as scientific research. For instance, of the publications cited by the Humanitarian Engineering Program at the Colorado School of Mines, four are journal articles while the other 30 are conferences and presentations (Humanitarian Engineering: Colorado School of Mines 2010).

The addition of a research component into student ventures adds academic rigor to the project by requiring an increased level of thinking and attention to detail. Anecdotal information can contain mistakes and lack professionalism but citable research by its very nature requires exacting research design, execution, and critical evaluation. Through publication, student teams can share their technologies and ventures so that others can build upon them. More importantly, they can share the lessons they learned applying those technologies in a specific context in order to improve future ventures. Publication helps to build a universal body of knowledge and ensure that mistakes are not repeated. This is especially true in the fields of humanitarian engineering and social entrepreneurship, which are in early stages of development.

Students are incentivized to publish by the opportunity of having peer-reviewed publications on their résumé. Through writing for publication, they develop the ability to analyze their efforts and share their knowledge in a meaningful way. Finally, research provides students with a compelling context in which to explore the complexities of social problems as well as develop, deploy and assess innovative and practical means of transforming the social scenario.

However, research of this nature is rare because of various fundamental challenges to its successful execution. In an effort to help other researchers surmount these challenges, Desai and Potter (2006) and Scheyven and Storey (2003) provide introductory guides to the numerous practical, ethical, and contextual issues of performing research in developing communities. Oakes (2002) and Gordon (2003) identify problems typically encountered by international researchers seeking IRB approval and ways to overcome them. Our paper builds upon these efforts by discussing and providing practical advice related to issues encountered in the IRB process and practical challenges of research undertaken in developing communities. In order to understand these challenges, it is necessary to first gain some understanding of IRBs themselves.

**The Institutional Review Board**

Institutional Review Boards (IRBs) are “responsible to review and approve, require modifications in, or withhold approval of research involving human participants” (IRB 2010). An IRB committee is composed of five or more individuals with diverse backgrounds. Though typically a part of a research organization such as a university, these bodies must operate independently from their parent structure and in compliance with federal regulations in order to maintain legitimacy (Oakes 2002).

**History of IRB**

IRBs arose out of the need to protect human research subjects. The initial drive for this type of regulation arose out of the horrors of Nazi experimentation revealed at the Nuremberg trials following WWII. In the wake of those trials, the Nuremberg Code was drafted to set guidelines for human research (Oakes 2002, 444). In 1964, the World Health Organization endorsed the use of review boards to protect human subjects
from risk in the Declaration of Helsinki (Hamburger 2004, 272). Pressure for human subject protections in the US grew as the public became increasingly aware of unsafe and unethical research practices then in wide use, particularly with the exposure of the Tuskegee syphilis study. Thus in the 1970s, the US government began to require research studies be granted IRB approval in order to receive federal support (Hamburger 2004, 272-273). Since then IRBs have proliferated and are now a mainstay at most research institutions (Oakes 2002, 444).

**Benefits of IRB**

Firstly and most obviously, IRB helps ensure the safety of human research participants, a consideration which should be foremost in the mind of any researcher. Furthermore, IRB helps to standardize research methods and protocols for addressing ethical dilemmas. IRB approval lends credibility to research and helps teach students proper research methods. Despite numerous efforts on the part of a team of investigators, subject risks and liabilities can find their way into the research design unnoticed. Teams may grow accustomed to examining a problem from the same perspective time and time again. In the case of international research, attention to cultural norms and local authority structures in experiment design is paramount and can be improperly treated as a result of unfamiliarity. Often, in the face of such myriad considerations, steps to ensure fundamental human subject rights such as voluntary informed consent can fall to the wayside. The IRB exists as a check against such naturally occurring lapses in judgment.

Ethical considerations are ultimately a subjective matter and what might be deemed appropriate by one team of researchers might be viewed differently by another team. The many current controversies surrounding practices in human subject research in the developing world point to the continued need for rigorous evaluation of proposed projects. The debates over proper research participation compensation and the use of placebo-controls in clinical trials like those employed US Centers for Disease Control and Prevention and National Institute of Health sponsored trials of ziduvudine (AZT) serve as prime examples (Shaffer 2006; Levine 1998). By applying uniform regulations drawn largely from the Belmont Report (Belmont Commission 1979) and federal guidelines, the IRB serves to eliminate discrepancies in the application of research protections which, if unchecked, could ultimately harm human subjects (Oakes 2002, 448). The exact number of IRBs currently in existence is unclear; however, Oakes cites Amdur and Bankert as putting the figure at over 4,000 in the year 2002 (Amdur 2002; Oakes 2002, 4). The growing use of IRBs as a means of research approval and standardization lends increasing credibility to IRB approved research while casting doubt on that without it. A 2001 report by the National Bioethics Advisory Commission called for an end to government funding of any clinical research in the developing world not approved by an ethics committee or nonconforming to a number of Belmont Report inspired, IRB-like regulations (NBAC 2001, 6). At Penn State, any research involving human subjects requires IRB approval and cannot be published unless the protocol was approved by IRB before the study was conducted.

Additionally, the IRB process helps students develop as researchers. By guiding students step by step through the design of a study, the IRB process helps teach students the fundamental steps and considerations in that process. As a result of the preplanning required by the IRB process, studies are better designed, and for those being conducted internationally, more ready for implementation immediately upon arrival in the host country. Through IRBs, students explore ethical considerations in real world scenarios. Finally, students have the opportunity to publish their work and contribute to the academic community, while adding something tangible to their own CVs.

**Critiques of IRB**

Despite the long and positive history of Institutional Review Boards in guiding research and protecting human subjects, much of the literature surrounding them focuses on ways that the regulatory efforts of these committees impede research, particularly in the social sciences. Part of this problem stems from the fact that the regulations upon which IRBs are based were written by biomedical researchers who considered only applications within their own field of research. This sort of regulation is in many ways less applicable to social science research (Oakes 2002, 447-449; Gordon 2003).

Some researchers fear that the labor-intensive IRB process could have a “chilling effect” on social science investigation by thwarting efforts at research, particularly those efforts of undergraduate and graduate students who find themselves under strict time constraints (Barzilai 2007, 6). The IRB approval process can take months and in some instances cited by Barzilai, years. As a result students might shy away from research for which they feel they cannot gain timely approval (Barzilai 2007, 6-7). Attempts to circumvent the IRB either by altering research methods or ignoring it altogether can create further problems through less accurate and less contextually and ethically appropriate research (Barzilai 2007).
Research in developing communities

There is growing concern that research undertaken by organizations from industrialized countries in developing communities exploits individuals in those communities. IRBs exist to review potential research initiatives and provide a check on this sort of exploitation. However, a number of key issues exist within this process. Researchers in both the US and those from developing countries have expressed concern that US IRBs are too procedurally oriented and focus less on content. Many cite IRBs’ frequent insistence on individual written consent forms as an example of this. Researchers have also questioned whether US IRBs are adequately familiar with the cultural contexts in these communities to effectively guide research. At the same time, researchers surveyed from the developing world overwhelmingly support the standard of ethics required by US IRBs. In essence, while US IRBs have proven largely effective, there remain areas in need of improvement (Hyder 2004; Kass 2003).

Related works have discussed many of the difficulties which can arise while conducting research in developing communities. Anokwa et al detail the most common challenges encountered by a group of nine North American researchers in these communities (Anokwa 2009). Chavan (2005) emphasizes the importance of contextually appropriate design and Russo and Boor (2003) provide insights into communicating through translation (Chavan 2005; Russo 1993). Other commonly highlighted issues include: written vs. oral consent, levels of risk, use of audiotapes, recruitment of subjects, vulnerable populations, de-identification and destruction of data. We encountered many of these issues within our own studies and will detail them later in the paper.

Navigating the IRB Process

In many ways, the frustration with the IRB process comes from an incomplete understanding of it. In an effort to help future researchers navigate the research design and IRB process, we have gone on to provide a roadmap of the issues we encountered, the lessons we learned and the larger conflicts we experienced. Our goal is not to detail our exact procedures but to share our best practices and knowledge of the IRB and research process derived from our experiences with the research community.

Types of review

There are three types of IRB approved studies: exempt, expedited, and full review. A study will be classified as exempt if it is essentially risk-free. It could involve conducting minimally invasive surveys, recording observations, or utilizing publicly available data. Exempt studies still require all recruitment materials, informed consent forms and interview outlines to be submitted.

The next level of examination is ‘expedited,’ which means the review process can take up to a month and require letters of support from partners. Only one or two members of the IRB committee are needed to conduct a review of an expedited study. A study can go through expedited review when it is classified as low or minimal risk. Low risk is defined as the conditions where the risks imposed by the study are no greater than those to be expected in everyday life (Oakes 2002, 456). Interviews, focus groups and taking non-invasive measurements with sensors are examples of low-risk studies.

The final category is full review, which means that the proposed study is scrutinized at a meeting of all the IRB committee members. Research involving invasive procedures requires full reviews. Both expedited and full reviews often require a number of re-submissions before the study is fully approved. Although IRB asks for input on what level of review the primary investigator believes is necessary, ultimately the committee has the final decision.

IRB structures and timeline

The IRB process can be extremely time-consuming. IRB committees at Penn State meet bimonthly and review a number of studies each time. As a result, reviews and modifications take weeks or months, not days. This is particularly true in the spring semester when IRB committees receive large numbers of submissions for research to take place in the summer. It is best to begin the IRB process as early as possible. An entire semester was spent preparing our projects and research design and gaining IRB approval. Over 80 students from seven different colleges within the university were involved in this process!

The development of an IRB protocol entails determining and specifying every question the study will ask, the logistics of where the study will take place, who the research subjects will be and a number of additional details. However, when working in a foreign context, nothing is completely predictable or controllable. No matter how many partners have provided advice and how much contextual research has been done, there will always be unknown factors. In spite of this, researchers preparing IRB proposals need to be able to answer these questions.

Research approval at the local level

As per federal regulations, the IRB application will require researchers to explain how they are gaining local approval for the proposed research. IRB will ask for documentation of this approval prior to the departure of the research team. This can prove exceedingly difficult as many cultures rely more on oral communication and face to face meetings than written letters and email.
After negotiations with the IRB, our projects were approved without these letters from local officials. However, the IRB was informed that our local partner at the Children and Youth Empowerment Center (CYEC) had obtained verbal approval from these officials prior to our approval and departure. Sometimes, conducting appropriate research requires going beyond IRB. Although we had already obtained verbal consent through an intermediary, our first step in Kenya before conducting any research was to meet with our local partners and local and provincial government officials. We brought a letter of approval which was signed by these officials and then forwarded to all local entities. Only then did we begin our research.

IRB also requires documentation of research approval from any local IRB or ethics committee and compliance with any established research protocols. In the absence of any such local body, IRB will require letters of collaboration from any local partners (Some institutions may require this letter regardless).

**Letters of collaboration**

Letters of collaboration are required to prove the understanding and willing cooperation of partners in the host country. This is often a difficult step as that level of understanding and cooperation can be difficult to adequately demonstrate in a letter. The letter must bear an original signature and that often proves problematic. When working in rural, developing communities, it may take a very long time to get a letter with an original signature; again, most IRBs function based on developed countries’ concept of FedEx and postal service. The IRB must also agree that the collaborator possesses adequate authority to consent and provide assistance to the research.

We obtained one letter of support from the authority at our primary research site. We were unable to provide additional letters of support because at the time of IRB application, we were unsure of what additional locations we might use.

**Location of research**

IRB requires that the exact location of proposed research be provided along with contact information. Determining research locations often requires coordination with local partners after arrival in the host country. In these instances, providing an exact location can be impossible.

We knew prior to departure that we would be working extensively at a specific site in Nyeri and we provided that information in our proposal. However, we knew that we would be holding clinics in additional locations to reach a larger and more diverse sampling of people. Our application stated that we would be conducting research in two additional locations and was approved. Without the one concrete address and contact, we doubt the proposal would have been approved.

**Biomedical devices and research**

When any sort of biomedical device is incorporated into research, IRB requires that a non-biased, non-affiliated expert write a letter certifying the device(s) as low-risk. In our case, an electrical engineer wrote a letter to validate our devices. IRB will also examine whether or not a device requires FDA approval to be included in the study. We were initially required to gain FDA approval for our devices. This requirement was removed once we explained that we would be using FDA approved devices to back up our own low-risk, proof-of-concept devices and that health information provided to participants would always be drawn from the FDA-approved commercial devices.

**Data storage, de-identification and disposal**

IRB requires that proposals describe the exact means of data storage, de-identification and disposal. These are seemingly small issues but procedures must be put in place for them to secure IRB approval. We detailed all of this including even the building and room number of the computer at Penn State where the data would ultimately be stored.

**Photos**

As part of this data disposal procedure, IRB requires that all photos taken of research participants be disposed of as well. However, photography is a standard expectation of international student ventures. There were numerous instances in Kenya where students took pictures of participants outside the context of the research either for personal reasons or because they were requested to by the participants themselves. These photos, such as the ones taken with the Maasai in the Ngong hills or Kimathi University students represent a priceless part of the student’s international experience. That aside, there is virtually no way to regulate student photography and ensure all pictures are destroyed.

**Issues Encountered while conducting study in Kenya**

**Recruitment and consent**

Consent forms and recruitment scripts are two critical parts of the IRB protocol. For each participant portion of a study, an individual has to be recruited, provided with all information about the study, understand the information presented, and agree to participate. Obtaining written consent is a general standard of IRBs but in the Kenyan context it was not appropriate to request signed consent because it would not be viewed as normal or appropriate in East African culture (Gordon 2003). Both Gordon and Oakes in their discussions of informed consent mention the Euro-centricity of the concept of written consent (Gordon 2003; Oakes 2002, 463). In this context, the use of written
While two US doctors and a local medical professional were with us at all times, our purpose was not treatment and this fact was not well described by us or those spreading the word about us. In that context, ‘clinic’ generally means doctors and medicine. We had numerous potential participants arrive with a completely inaccurate idea of why they were there. The word ‘clinic’ was often used to describe our activities.

The Mashavu message was now traveling from English to Swahili and other local languages through multiple intermediaries. As a result, participants were at work or school. This meant that our primary demographic for these clinics shifted from younger, English speaking community members to older individuals from rural areas who spoke significantly less English.

Students from the Children and Youth Empowerment Center, one of our main collaborators, facilitated the interviews but a number of communication errors still arose. Although a large portion of the Kenyan population speaks English, Kiswahili and a tribal language, many elderly community members speak only the tribal language. Since we hosted clinics in many different rural locations throughout central Kenya, the tribal languages spoken were often different from those of our partner students, leading to a total inability to communicate.

Even when the translator and interviewee spoke the same language, communication still occasionally faltered. At times, the patient would respond to a question with a long answer, sometimes speaking for over a minute, and the students would translate the response as “The patient said he liked it.” One might expect that in the face of this problem, translation would take place sentence by sentence, but this proved a difficult concept to explain and even more difficult to implement. All data obtained through incomplete or inaccurate communication was not included in our final data set.

Further issues lie within the very idea of translation itself. Ideas and expressions can be difficult to mold into exact translations and subject to different cultural interpretations and paraphrasing (Marshall, 89-90). As such, even seemingly flawless work with translators fluent in both languages can be subject to misinterpretations. Medical and technical terms were also a source of difficulty. Translators were at times unable to come up with an equivalent expression for some symptoms during the medical history portion of the exam or had difficulty describing the exact nature of a biomedical device. We had created multiple sets of interview questions as part of the research preparation and validated them with American doctors and professors, Kenyan students at Penn State, and our local partners in Kenya, including a local nurse. The nature of these questions had also been validated by Kenyan doctors in previous research efforts. In spite of this we were still forced to exclude some of the questions due to difficulties with medical terminology.

By far our smoothest clinics were conducted with students from the local universities. With these students there was no translation necessary and we received a great deal of valuable feedback from them.

**Community recruiters**

To mobilize research participants we met with local community leaders and explained our project and asked that they help us recruit participants. These community leaders were typically very excited about the project and helped to spread the word about it. However, the Mashavu message was now traveling from English to Swahili and other local languages through multiple intermediaries. As a result, we had numerous potential participants arrive with a completely inaccurate idea of why they were there. The word ‘clinic’ was often used to describe our activities, by us and by those spreading the word about us. In that context, ‘clinic’ generally means doctors and medicine. While two US doctors and a local medical professional were with us at all times, our purpose was not treatment and this fact was not well described to different cultural interpretations and paraphrasing (Marshall, 89-90). As such, even seemingly flawless work with translators fluent in both languages can be subject to misinterpretations. Medical and technical terms were also a source of difficulty. Translators were at times unable to come up with an equivalent expression for some symptoms during the medical history portion of the exam or had difficulty describing the exact nature of a biomedical device. We had created multiple sets of interview questions as part of the research preparation and validated them with American doctors and professors, Kenyan students at Penn State, and our local partners in Kenya, including a local nurse. The nature of these questions had also been validated by Kenyan doctors in previous research efforts. In spite of this we were still forced to exclude some of the questions due to difficulties with medical terminology.

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**Language barrier**

We realized very quickly upon our arrival in Kenya that we would require intermediaries who spoke both English and the local language to conduct our research. Our belief prior to arrival, and one that was largely validated, was that the majority of the younger generations of Kenyans spoke English. However, we did not consider that we would be hosting clinics primarily on weekdays, when most younger people were at work or school. This meant that our primary demographic for these clinics shifted from younger, English speaking community members to older individuals from rural areas who spoke significantly less English.

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communicated to people prior to their arrival. Another similar lapse in communication occurred when university students arrived expecting a discussion forum rather than a telemedicine ‘clinic’.

We solved this problem by communicating to everyone upon their arrival the exact nature of the project and their potential role as participants.

Involvement criteria
Completing an IRB application requires a detailed description of exactly who will participate in the proposed study. The proposed inclusion of anyone under the age of 18, currently incarcerated, sick, or pregnant, to name a few, will require explanation. We agreed not to include anyone of these and several other populations. We realized that the stipulation that no participants be under the age of 18 could create some issues as many of the elderly participants who are also the primary caretakers in the family would bring along a large number of children. To decline the children participation altogether would have been considered rude. To solve this problem, we wrote into our IRB proposal that we would set up a children’s clinic where they could “play” Mashavu and have their height and weight taken. None of these measurements were recorded. This simple, IRB-approved solution worked without problems.

Concept of operations
Crowd control and organization were two critical elements of Mashavu implementation. When 100 university students arrived at the clinic at one time, we needed a way to manage the influx of people and keep them engaged for the rest of the day. We could not make plans until the day before a clinic because there were so many variable factors, such as how many tables and chairs we would have, what space would be available and the number of people that would be attending the clinic. Working in an international context is as much about preplanning as it is about innovating on the go. In spite of having committed partners and numerous connections to the communities we worked with, our resources changed on a daily basis depending on our location and as a result we constantly had to adapt and adjust our plans. Without a well-developed but flexible concept of operations we would not have succeeded to the extent that we did in Kenya.

Research participation incentives
Incentives for participation in research studies might include the opportunity to further research, have a new experience or receive financial compensation. No federal guidelines exist in regards to financial compensation for research participation and the regulations of individual institutions vary.

In many contexts, subjects expect some form of compensation for participation. Local custom often dictates that a beverage or a meal be shared as part of the research participation. Many participants expect some sort of tangible result for their participation. Often we provided beverages as a part of the participation experience and we provided all Mashavu participants with a notecard detailing their health statistics.

However, is this compensation or simply adherence to local custom? The Mashavu IRB application described the process of providing a beverage but the other applications claimed that there would be no form of compensation. Clearly there were mixed interpretations within our own teams as well. No issues or expectations related to financial compensation were raised by participants.

One researcher interviewing street youth in Nairobi found that participants would often request an alcoholic beverage and he was forced to explain that the university did not allow him to provide that, though he could purchase something non-alcoholic. Also, even after it had been explained multiple times that there would be no official certificate of participation, most university students who participated in one of the studies expected one.

New Lessons Learned
Some key takeaways from our research experience include:

**Minimize risk in IRB application.**
If proposed research ventures contain multiple studies, divide those elements across multiple IRB applications. By spreading the aspects of the study across multiple IRB protocols, the risk posed by the rejection of one research study or procedure is minimized. Rather than an entire project being disapproved, only one portion of it will be. In our case, we prepared seven separate IRB protocols including Mashavu social science, Mashavu biomedical devices, WishVast social networking, anaerobic digesters, etc. Two of the studies were approved early on while the rest of the studies were approved only after we arrived in Kenya. If some of the protocols would not have been approved, we would have still been able to continue with the other aspects of our venture.

**Be concise and eliminate potential points of misunderstanding.**
Eliminating unnecessary explanatory tangents limits the misunderstandings that can occur because of what appears in the application. At the same time, it is important to be mindful of what doesn’t appear in the application. IRB committee members reviewing proposals are looking for instances of increased subject risk and other ethical violations. Failing to address contingencies and hypotheticals can allow re
viewers to imagine the worst and slow the process of approval. Consider potential concerns of reviewers as you edit your application and seek to address them. Not all concerns can be addressed on paper, but a thorough and well prepared proposal will go a long way towards speeding approval of an appropriate study.

**Meet with IRB staff prior to the submission of your application and continue to meet with them throughout the course of your proposal’s submission, revision, and modification.**

An initial face-to-face meeting will help to identify any early issues with your proposal. Eliminating this issue before your proposal goes under review can save valuable time. Furthermore, face to face meetings provide researchers with an opportunity to allay the fears and concerns of IRB reviewers as they arise. Reviewers are searching proposals for problems in order to alleviate them and ensure the safety of participants. For the most part, a written proposal cannot possibly dismiss every worst-case-scenario and contingency in a critical reader’s mind. Because reviewers cannot always pick up on the intricacies of your intentions, they might miss a critical component of a project and reject it due to lack of understanding.

For instance, one of the key problems identified with our proposal ended up being a non-issue once we were able to provide further explanation. Initially the IRB thought that we planned on having sick patients participate in the telemedicine clinic, which would not have been permitted by their standards. In fact, we intended only to provide personal health information to healthy patients. Once this was explained and a protocol was designed to properly provide for any sick individuals (outside of the research process) who arrived to participate, our proposal proceeded. Helping the IRB to understand your project beyond what simply appears on the page will go a long way in assuring its appropriateness and its ultimate approval.

**Do not overcomplicate your project.**

Decide on a goal, a procedure to obtain that goal, and then carry it out. Each complication of your procedure will bring on an entirely new series of questions and required explanations. Simple is better. We made the mistake of wasting time talking to IRB about issues that were not as important as others.

For example, we originally wanted to use tape recorders as another means of collecting data. Doing so, would have led to an entirely new set of protocols and procedures. In the end, we decided to take a different (easier) route and type the interview dialogue. This basic solution dramatically simplified our IRB process.

**Prioritize and take care of the most critical aspects of your project.**

Marginal issues such as the name of a certain subsection of your website can quite suddenly occupy an inordinate amount of time. While Mashavu excelled in networking and developing a strong concept of operations, we should have spent more time developing our interview questions and working with translators. In retrospect, developing translated sets of simpler questions would have dramatically improved the quality of our interview responses. We underestimated the importance of this area and it hindered our ability to get the necessary data.

**The option of gaining FDA approval for devices.**

The process to gain FDA approval can take anywhere from 6 months to several years, so before beginning this endeavor it is worthwhile to weigh the benefits and various problems associated with that process. If the goal of a venture is to sell a design to industry, then it may be worth the time to complete this process earlier, rather than shifting that task to a potential investor. The Mashavu team created proof of concept devices that were radical redesigns of commonly used devices such as thermometers, stethoscopes, and pulse oximeters among others. Therefore, FDA approval was not necessary for this study and also not practical because of time and resource constraints.

**Larger Conflicts and Challenges**

**Non-medical students and medically-oriented research**

Questions of a personal nature that would be medically necessary in a real world telemedicine scenario but not a research trial proved difficult because students were uncomfortable asking those sensitive questions. The doctors we were working with needed this information but the students required to ask those questions were unqualified to do so. We resolved this situation by having the doctors ask those sensitive questions if they felt them necessary following their examination of the participants’ health information. In a true trial of the system, the kiosk worker would have asked these questions but due to the nature of our research team, this was not feasible.

**The strictures of the IRB and those of a student research budget**

Conforming strictly to IRB regulations and the scientific method on the budget of a student venture is virtually impossible. In spite of numerous grants and an enormous level of self-funding, we found the goals of our research incompatible with the demands of the IRB. A perfect IRB application would have detailed exactly where all of our research would have taken place, exactly who would participate and included letters of support from all research sites and all relevant local officials. Due to cultural constraints previously mentioned, this
would have required placing a team in Kenya prior to IRB approval and the rest of the team’s arrival to conduct face-to-face meetings and secure this documentation. Even then, officials would likely not have signed any letters until the full team was in Kenya and a meeting had been held. Once we arrived in Kenya we did receive these letters of support and wholehearted collaboration and support at each of our research sites but to provide this documentation prior to our departure would have been completely infeasible.

The IRB asks if researchers speak the same language as participants. We responded yes, bearing in mind that we intended to communicate in English. However, English is not the first language of most Kenyans and this poses communication difficulties. All documents provided to participants should have been translated into Swahili and the local language of each region we intended on visiting (an additional three languages). Once more, finding fluent speakers of both English and each of these languages willing to aid our research would have proven a monumental and once again, almost impossible task.

The fact that the inherent unpredictability of research in the developing world renders procedures and protocols virtually irreproducible begs the question of whether this sort of research even constitutes generalizable research. Large corporations and governments are more capable of producing this sort of research because they have a higher level of funding. They can reach more people, leverage more technology, and apply protocol more strictly. Academic research on the other hand, operates on a much more limited budget and timeline. As a result research procedure can come to be dictated by necessary expedience rather than the scientific method and IRB regulation.

**The collision of circumstance and ‘appropriate research’**

Striking a balance between acting appropriately in an international context, conducting a scientific research experiment and carrying out an entrepreneurial venture can be a very complicated task. Each aspect is equally important and needs to be performed with the same amount of integrity. An IRB proposal strictly outlines the proposed research method. However, in the developing world, chaos pervades any sort of research experiment. Conditions and circumstances dictating the research effort change constantly. Despite all attempts to stick to the plan outlined within an IRB, it is not always possible.

Entrepreneurial ventures are chaotic by nature, requiring fast adaptation to changing circumstances and demands. Often in Kenya, we found ourselves under pressure to alter Mashavu IRB protocols in order to deliver a better product and be more efficient. However, IRB requires that any changes to the research plan be approved by committee, a time-consuming process. Often in the middle of a clinic, circumstances arose that required we somehow alter the procedure or risk neglecting the needs of clinic participants. The incredible flexibility required by entrepreneurial ventures and third world research directly contradicts the stringent requirements of the traditional research methods and the IRB.

For example, although we had developed numerous partners and connections in Kenya prior to our arrival, that process continued once we were on the ground. As a result we were presented with the opportunity to hold clinics in more locations than just the CYEC and the two other sites approved by IRB. This would have allowed us to spread Mashavu further and to collect a greater number of responses from a more diverse sampling of the Kenyan people. From a research and business perspective this would have been an enormous positive but it was not IRB appropriate. For a number of reasons, including the IRB, we were ultimately limited to three locations.

**Conclusion**

Student research ventures in developing communities like the ones we participated in this past summer in Kenya are growing increasingly common. This paper presented some of the lessons learned from that experience. Several larger themes emerge from these observations: the importance of contextual considerations in any research effort within a foreign culture, the importance of regulatory oversight for this kind of venture, and the inherent contradictions within that same guiding structure. It is our hope that this paper may contribute to the growing body of knowledge in this field and aid similar student ventures in the future.

**References**


