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We're Not the Enemy!: Mending Fences Between Researchers and the IRB

2012-09-22 16:19:45

By Ita Irizarry

I would like to respond to Kimberly Sue's recent post on Somatosphere ("Are IRBs a Stumbling Block for an Engaged Anthropology?"). Since I do not know the full nature of Ms. Sue's research or experience working with IRBs, I can only respond to what she wrote in her post. I have experience on both sides of the IRB divide: I am currently a manager at Brown University's IRB, with extensive background in human subjects regulation for both biomedical and behavioral research; I hold a MA in anthropology, have experience designing research protocols and conducting fieldwork.

I applaud Ms. Sue's intended research on women's experiences in and out of prison. This subject is one that our researchers at Brown have been working on throughout Rhode Island and Massachusetts, and it is not one that is easily covered. That being said, I found Ms. Sue's piece to be very problematic, as it suggests a misunderstanding of the role, function, and purpose of any institution's IRB.

Ms. Sue wrote that she "submitted … to various institutions across the state in order to conduct my research" and has "seen a wide-range of concerns." First, the federal government defines the regulations to which all IRBs (national and international, if receiving US monies) must comply: Policy for Protection of Human Research Subjects (45 CFR 46). It is colloquially known as the "Common Rule," but IRBs consider it their Bible. It only has five sections: one section on the basic policy, three sections on vulnerable populations, and one section for registering IRBs. If there are any discrepancies or irregularities between IRBs, they are institution-specific. This Code of Federal Regulations is available on the Health and Human Services (HHS) website and is the foundation upon which each institution may build upon to better fit its needs.

Second, it is helpful when working with IRBs, to understand the language and terms used. As with any discipline, HHS has its own jargon. If researchers can speak the language of "research" as the federal government defines it, they will travel through research regulations and IRBs more smoothly.

For example, “vulnerability” does not mean the same thing to an anthropologist as it does to an oncologist, or a priest, or an IRB member. When IRBs refer to “vulnerability,” they are not talking about “life history” and “social support” (as Ms. Sue states), but in the case of prisoners (45 CFR 46, subpart C), a person’s ability to decide, of their own free will, to participate in research. In the case of prison studies, IRBs cannot review a study and assess participant vulnerability without a qualified prisoner advocate. There will never be an IRB reviewing a study involving prisoners without the advocate’s input. In addition, an approved prisoner study must be submitted by IRBs to HHS’s Office for Human Research Protections (OHRP) with a Prisoner Certification Letter. OHRP will review the IRB’s determination and the research. Without OHRP’s final determination, that study cannot be approved to enroll prisoners. So, when Ms. Sue wrote that an IRB told her to report any participant who becomes incarcerated when she is not approved to enroll prisoners, the IRB is not being punitive. Rather, it is ensuring that Ms. Sue and the IRB are overseeing research with a strong participant protections policy and not in violation of federal regulations.

It is extremely important not to confuse federal regulations on research with regulations prisons have for their own institutions. IRBs do not have any control over prisons or whether or not wardens or prisoners wish to work with researchers. Behavioral and biomedical research have bad reputations among prison officials and prisoners – one that is, unfortunately, well-deserved by years of ethically-questionable research. IRBs place enormous trust in their prisoner advocates, require letters of support from prisons, and expect that researchers comply with the “Common Rule” for conducting research in prisons. Again, IRBs will never prevent a researcher from conducting research in a prison setting if federal regulations are met and the prison supports the research. The onus of gaining access to prison facilities, however, is on the researcher, and IRBs cannot approve research if officials of these organizations refuse or are slow to agree to participate in research.

One thing Ms. Sue wrote did strike me as particularly concerning: “I felt somehow at fault for not explaining the nature of anthropological inquiry in adequate language for a lay audience.” This is a key point for researchers. It is difficult to do, at first, but not impossible. But, researchers must remember, that their audience is not the IRB, but their potential participants. These participants are a “lay audience” and if researchers are unable to explain their study to an IRB, they will not be able to explain it to participants in a language that enables truly informed consent. If researchers need help with this task, I urge them to talk to their IRB. They can rest assured that their IRB has read more research proposals and consent documents than researchers could ever hope to write.

Ms. Sue wrote that she does not understand why her IRB requested revisions for her research. If this is the case, again, she should ask. If she does not know what reporting, as she writes, a “changed status regarding incarceration” involves, she should ask. It is the best way for a researcher to learn research regulations, and the best way to create a strong rapport with an IRB. Contrary to popular opinion, we are genuinely interested in making sure that research progresses with as little trouble as possible. On a personal level, remember that as with most people, IRB staff will be even more willing to help researchers, if they believe researchers are actually respectful of what they do.

Recommendations by IRBs should not be taken lightly. IRBs are composed of groups of people who have “been there, done that” and, together, have a combined knowledge of research and scientific literature that surpasses individual researchers. If they suggest a revision to study design or exclusion criteria, researchers should consider it thoughtfully. If the IRB did not provide a reason for their recommendation (and they should), the researcher should ask. The IRB may be aware of something which a researcher is not, and researchers do nothing for their study if they remain voluntarily and willingly ignorant of relevant information.

Please also know that researchers are never required to implement every revision that an IRB requests. Remember, in most cases, they are *recommendations*, not stipulations. It is in a researcher’s best interest to genuinely consider IRB recommendations for merit and appropriateness to their study. All that is required is a response. If a researcher disagrees, they should explain why and, importantly, try to cite any “Common Rule” regulations, literature or other research that backs-up their decision. The IRB may disagree with a researcher’s answer, but can be swayed by a valid, well-stated, and defended argument.

Most IRBs list the names and professions of their members. Researchers should see who sits on their IRB, find out what their backgrounds are, and ask them questions. They may be surprised to find that one or two of their colleagues or mentors are IRB members. If, indeed, there are no IRB members from their discipline, a researcher should ask to be present when the IRB reviews their study. Most IRB meetings are open forums. Researchers will be asked to leave the room during deliberation, but when IRB members can meet with and speak to a researcher, in person and in real time, it makes a huge difference in their understanding of the study.

If researchers truly want to make a difference, they could go a step further and consider joining the IRB as a member representing their own discipline. I promise the IRB will never turn down a person who is truly interested in participating in the review process. Some universities even offer professional incentives for working with IRBs. If nothing else is

gained from the experience, it will give greater insight into the process and, perhaps, make writing future proposals that much easier.

Most importantly, I want to encourage all researchers to work *with* their IRB, and not against them. The IRB is not an adversary, nor are they all-powerful gatekeepers, terrifying bogeymen, or oppressive Big Brothers. Use the IRB as another guide, or even a mentor, for research. Members of IRBs have research and field experience from a multitude of disciples and have worked all over the world. They are scientists, social workers, ethicists, and clergy. They are doctors, lawyers, schoolteachers, and parents. It is in their best interest to serve a researcher's best interest, and it does nothing for them or their institution to stand in the way of research. Even if most interaction with an IRB takes place online, make an effort to talk to them. Ask them questions. They have good advice. But, do not fear them or get frustrated, or as Ms. Sue wrote, "gird" herself "for a battle." *Remember that IRBs are designed to be tools to assist researchers with research compliance.* If researchers do not use IRBs, their guidance and expertise, researchers voluntarily give up a valuable resource. In doing so, the process will be unnecessarily frustrating and research, or worse, participants, will be hurt in the end. And nobody – not Ms. Sue, not her advisor, not her department, not her university, and certainly not her IRB – wants that outcome.

Ita Irizarry is an IRB Manager at Brown University's Research Protections Office. She was previously an IRB Coordinator and Regulatory Analyst at the Colorado Multiple Institutional Review Board (COMIRB) with the University of Colorado Denver – Anschutz Medical Campus. She has a MA in anthropology from the University of Denver.

AMA citation
Irizarry I. We're Not the Enemy!: Mending Fences Between Researchers and the IRB. *Somatosphere*. 2012. Available at: http://somatosphere.net/?p=4044. Accessed September 22, 2012.

APA citation
Irizarry, Ita. (2012). *We're Not the Enemy!: Mending Fences Between Researchers and the IRB*. Retrieved September 22, 2012, from Somatosphere Web site: http://somatosphere.net/?p=4044

Chicago citation
Irizarry, Ita. 2012. We're Not the Enemy!: Mending Fences Between Researchers and the IRB. Somatosphere. http://somatosphere.net/?p=4044 (accessed September 22, 2012).

Harvard citation
Irizarry, I 2012, *We're Not the Enemy!: Mending Fences Between Researchers and the IRB*, Somatosphere. Retrieved September 22, 2012, from <http://somatosphere.net/?p=4044>

MLA citation
Irizarry, Ita. "We're Not the Enemy!: Mending Fences Between Researchers and the IRB." 22 Sep. 2012. Somatosphere. Accessed 22 Sep. 2012.<http://somatosphere.net/?p=4044>