

AMSA Global Health Research Ethics Pre-Departure Workshop Student Resource Guide

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Introduction, Cases and Discussions adapted from Provenzano AM, Graber LK, Elansary M, Khoshnood K, Rastegar A, Barry M. Short-term global health research projects by US medical students: Ethical challenges for partnerships. *The American Journal of Tropical Medicine and Hygiene* 2010;83:211-4

Objective

This resource guide includes cases with accompanying discussion for future reference. An annotated reference list is provided for optional further reading.

1. Research Priorities: Who Decides?

Chris is a medical student applying for an international research grant. He wants to study HIV. Chris's advisor approves his proposal and put him in touch with his colleague Dr. K who runs a clinic in Vietnam. Dr. K tells Chris that patients have become wary of Westerners studying HIV, and some have complained that only HIV-positive patients benefit from research. Dr. K suggests that Chris develop a project focused on heart disease, which is an increasing concern in the community. Chris is reluctant to start over on his research proposal and feels that his HIV project is the more desirable for his own professional development.

Sample Discussion:

Medical students undertaking international research projects must ensure that their work serves the needs of the community where the research is to occur. Often, projects are developed without the input of local partners. Rightly, this has been referred to as a form of neo-colonialism,¹ and is reflected broadly in the lack of representation of researchers from developing countries as first authors in academic journals and on editorial boards, even those specializing in tropical medicine.² Furthermore, US-based medical students and their medical schools should avoid the trap that some well-intentioned Western aid organizations fall into by only offering research opportunities for certain specific diseases. This can contribute to a perverse internal form of brain drain, where experts at the site of research work on those specific topics that outsiders deem important rather than on diseases important to that researcher's community.³ In response to this phenomenon, community engagement or community consultation in the proposed research project has emerged as a requirement for ethical international research.^{1,4} Such engagement might include focus groups of community members discussing areas of research interest or the inclusion of community members in the oversight of a research project. Importantly, it has been shown that cross-cultural research methods that involve greater community collaboration and

participation are more likely to provide long-term benefits to the community.⁵ The ethical guidelines of the Council for International Organizations of Medical Sciences (CIOMS) stipulate that international research “is responsive to the health needs and the priorities of the population or community in which it is to be carried out” and that “any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.”⁶

Funding from a student’s medical school should be incumbent on that student choosing a project targeting the research priorities articulated by the host institutions. Furthermore, students should strive to include international partners in the data collection, interpretation, and publication of the research. As Edejer³ points out, key principles of a true research partnership include shared responsibility for the project as well as capacity building among international researchers.⁴ US-based medical schools have the responsibility to impart these ethical considerations to nascent global-health researchers.

2. Burdens of the host

Qing received an international research fellowship from her medical school. The Liberian physician sponsoring her spent hours assisting with the paperwork for her visa, arranging accommodations for her, and hiring a car to pick Qing up from the airport. Qing faces a series of logistic problems in setting up the study, and it takes longer than anticipated to get her research underway. Qing’s sponsor spends one to two hours per day away from patient care helping her mitigate these difficulties, which disrupts the clinic and causes irritation among the clinic staff.

Sample Discussion:

Medical students face many difficulties in performing short-term research in low-resource settings. These challenges range from negotiating cultural and linguistic barriers to logistic questions such as where to obtain materials that may be required for the study. Already overburdened local staff may be forced to expend significant amounts of time and energy to orient student researchers and assist them with these problems rather than focusing on serving their patients, as occurred in this vignette. As Crump and Sugarman⁷ rightly point out, these impositions on a health system that is already strained by a lack of resources may cause tension between the host and the sending institution and make such research projects ethically questionable. Furthermore, host institutions may be hesitant to address concerns with the wealthier, sending institutions to avoid jeopardizing the partnership between the two bodies.⁷ Benatar and Singer⁸ have also discussed this phenomenon, and they have suggested that one requirement for ethical international health research should be “ensuring [that] existing disparities are not more deeply entrenched by inappropriate deflection of local human or material resources away from the health care system in the host country towards the research project.”⁸

Medical students from the United States and their medical schools have the ethical responsibility to critically assess whether a research project may cause harm by necessitating the diversion of material or human support from the host institution. For example, students can choose to work with US-based faculty advisors who frequently visit or have lived and worked in the intended site of research and who can advise students on the logistic and cultural barriers that may exist at the site. Furthermore, US-based students traveling to the same site to perform short-term research projects may collaborate, allowing for a longer period of data collection and higher quality research. Students should also feel empowered to question their university to enable partnership and bilateral capacity building. For example, funding for exchanges to allow students and researchers from the hosting institution to travel to the partner institution in the United States can further develop a fruitful collaboration.

3. Informed Consent

Amit, a fourth-year medical student, travels to Peru to work on a research project. He and his advisor hire several Peruvian research assistants from the community to perform interviews. After the project is underway, Amit realizes that the assistants often paraphrase the questions and sometimes gloss over the informed consent form. When Amit asks one of the research assistants about it, he shrugs and says, “I am sure they understand ok.” Amit is unsure what to say to his Peruvian supervisor or his advisor back in the United States. He decides not to say anything, because his Peruvian advisor is heavily burdened with clinical duties and his advisor from the United States is counting on this data for a publication.

Sample Discussion:

The issue of informed consent presents a great challenge to all researchers, not simply student researchers carrying out short-term projects. It is standard practice in international research to solicit IRB approval from both the host institution at the site of data collection and the collaborating institution in the United States. In some countries, a national regulatory body further oversees biomedical research, and so, researchers must be aware of host-country national guidelines for research approval. It is further expected that the IRB review include an examination of the informed consent process for the proposed study.⁹ Given the history of Western researchers exploiting vulnerable subjects, researchers rightly continue to analyze factors influencing the process for obtaining informed consent from research subjects in low-resource settings.¹⁰ Part of the ongoing challenge, as is clear in Amit’s situation, is how the informed consent process can be translated from the theoretical and abstract domain of Western academic institutions (where much of the research performed in the developing world originates) to the realities of the field. As Benatar suggests, informed consent must be obtained “within the linguistic and cultural framework of research subjects” to function as desired.¹¹ In this vignette, Amit is witnessing a violation of informed consent, and data in the study described would be unethically obtained. If Amit’s medical school were involved in a standing

collaboration with his host institution in Peru, this sort of situation could more easily be avoided and resolved. The hosting institution would receive compensation for the time that the advisor spent working with Amit on the study, thus freeing scarce resources to assist students in trouble-shooting problems as described above. Furthermore, in such a partnership, Amit's advisor in the United States would have familiarity with the specific logistical and cultural barriers to informed consent that may exist in the host country, thereby allowing him to serve as a true resource for the student researcher. Additionally, any comprehensive partnership should include pre-departure training for US-based medical students to prepare them to grapple with such ethical questions, should they arise, as well as cultural sensitivity training and if possible, even language training. Ideally, the collaborating institutions should arrange for individuals from the hosting institution to travel to the United States and facilitate such trainings for US-based students and faculty.

4. Clinical Care versus Research Priorities

Andrew, a first year medical student from the U.S, is doing a summer research project on latent tuberculosis infection among HIV positive prisoners in Singapore. His faculty advisor at his medical school has been working with colleagues in Singapore and facilitated this research project.

Dr. H, a local physician, accompanies him to his study site for one week to help set up the study. During the first week, the prisoners share their other health concerns with Dr. H who treats them with the prison's limited medical supplies. After Dr. H. leaves, the prisoners expect that the research team will be able to continue treating their health problems, not only latent TB. Andrew is faced with having to tell the prisoners that he is not properly trained to give medical care. Andrew later realizes that many of the prisoners are identified with latent TB and he is concerned about the other prisoners who he is not screening. He also learns that there are not enough medications to treat the prisoners after his study ends, nonetheless the prisoners who are not screened in his study. Andrew is overwhelmed and frustrated that he cannot provide more help to the prisoners.

Sample Discussion:

While attempting to help Andrew set up his research project, Dr. H provides needed medical care to several prisoners over the course of a week. After he leaves, however, the prisoners are not only again without health care, but they are also left with expectation. This scenario provides an example of ancillary care, defined as care needed by research participants but not necessary to ensure scientific validity, prevent study-related harms, or address study-related injuries.¹² While there is ongoing academic debate on the exact ethical justifications for ancillary care obligations^{13,14}, ethicists agree that researchers and sponsors conducting health research in developing countries have some obligation to consider the unmet health needs of research participants. In this

scenario, it is clear that the research team did not plan for ancillary care, develop partnerships with local medical staff to provide necessary care, nor did they make practical provisions to offer ancillary care throughout the duration of the study.

Moreover, Andrew plans to initiate treatment for latent TB infection, which likely lasts for longer than his proposed research project. As with several medical research projects, Andrew's research is contingent on treatment or follow up services that a foreign, short-term researcher will not be able to provide. Disregarding the paucity of medication that limits his treatment of the population in need, Andrew's plan to initiate a course of TB treatment is a complex task as it relies on local infrastructure to ensure its completion. As suggested by Emanuel et al., collaborative partnerships are necessary for multinational clinical research trials as "without the engagement of researchers and health communities in the developing country, a study is unlikely to have any lasting impact, and, without the investment of makers of health policies, the research results are unlikely to influence policy making and the allocation of scarce resources."¹⁵

This case is further complicated by the fact that while Andrew and the research team are screening prisoners for latent TB, there is not enough medication for them to be appropriately treated. There has been much debate about the responsibility to research subjects from the Global South in the medical literature^{4,16-20 3,21,22}, particularly in research projects that involve the trials of new treatment regimens. As described in the Declaration of Helsinki, an outline of ethical principles for conducting research with human subjects²³, subjects in a research trial should benefit from their participation in the trial. However the standard of care that subjects should receive has been debated, as healthcare in the Global North and healthcare in the Global South often differ dramatically with regards to available resources and health care providers. This debate becomes further compounded when the results of the study potentially have impact on future medical care. As Marcia Angell writes, "One reason ethical codes are unequivocal about investigators' primary obligation to care for the human subjects of their research is the strong temptation to subordinate the subjects' welfare to the objectives of the study. That is particularly likely when the research question is extremely important and the answer would probably improve the care of future patients substantially."²²

In this case, while Andrew had planned that the prisoners identified with latent TB would be treated, the prison could not provide this service. In many respects, Andrew had tried to set up his research study appropriately in that he was working with a local physician and had been informed that the prison clinic would be able to treat patients. As it is the responsibility of the research team to ensure that each participant in the study receives benefit, Andrew should report his concern to Dr. H and his research mentors at home. The research study

should potentially be put on hold while the team reassesses what care they can provide the participants. Regular collaboration between the prison, Dr. H, and Andrew's home institution may have prevented this situation from occurring, as there potentially would have been more explicit conversation about the use of prison medications and provisions for ancillary care.

Annotated Reference List for Further Reading

1. Provenzano AM, Graber LK, Elansary M, Khoshnood K, Rastegar A, Barry M. Short-term global health research projects by US medical students: ethical challenges for partnerships. *The American Journal of Tropical Medicine and Hygiene* 2010;83:211-4

This pre-departure global health ethics training is based upon this article. It contains cases similar to those discussed in the training session, accompanied by discussions that summarize current thought on the subject matter.

2. Shah S, Wu T. The medical student global health experience: professionalism and ethical implications. *Journal of medical ethics* 2008;34:375-8

Given the rapid increase in the number of medical students having global health experiences, this article discusses some ethical considerations and recommends that students undergo ethical and professional education before having these experiences.

3. Edejer TT. North-South research partnerships: the ethics of carrying out research in developing countries. *BMJ* 1999; 319: 438-411.

This article reviews some of the ethical issues in North-South research partnerships.

4. Langer A, Diaz-Olavarrieta C, Berdichevsky K, Villar J. Why is research from developing countries underrepresented in international health literature, and what can be done about it? *Bulletin of the World Health Organization* 2004;82:802-3.

This article provides a thoughtful discussion of the lack of representation among developing country authors in global health literature.

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