

AMSA Global Health Research Ethics Pre-Departure Workshop Facilitators 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

Objectives:

1. To think about the potential ethical dilemmas that may arise in short-term global health research¹, based on experiences of prior students.
2. To discuss means of mitigating these dilemmas and means of seeking support when doing research internationally.

Preparation:

Recruit students with prior global research experience and a faculty member when possible to serve as workshop leaders.

Recommended Materials:

Nametags, copies of Student Handout, copies of Student Resource Guide, copies of Student Evaluation

Workshop Content (Approximately 90 Minutes):

- I. Introduction (10 minutes)
 - a. Greet participants, identify goals of the workshop (10 minutes)
 - b. Ask each person to 1) introduce themselves, 2) their research question, and 3) identify what they hope to get out of this workshop
- II. Group case discussion (10 minutes)

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.

¹ Research sponsored/funded by institutions in wealthy countries and conducted in resource-constrained settings

Questions for discussion:

1. How should Chris approach this situation?
2. How important are Chris' priorities in comparison to Dr. K's?
3. What if Chris didn't find this out until he was in Vietnam?
4. How could Chris' advisor support him in this research?

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.

III. Small group break out sessions (20 minutes)

- a. Small groups of 4-5 students will discuss one of the following cases

- b. Ideally, one faculty member or workshop leader can be present in each group to provide support and reflection

a. 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.

Questions for Discussion:

1. What are reasonable expectations for a student to have while on an international clinical rotation in a developing country? What are reasonable expectations of the host clinic of the student?
2. Are there ways to minimize the diversion of time and resources to foreign trainees like Qing?
3. What are the responsibilities of the student's medical school, both to the student and to the clinic or hospital hosting the American student, when sending one of their students on such an international rotation?
4. Should Qing be concerned with relative cost-benefit of her presence? Can Qing objectively assess her hopes for service to the community and her actual ability to give back?
5. At the end of her visit, Qing feels badly that she has not given money to the NGO to cover her housing and other administrative costs of having her. She mentions this to her friend back home, who replies that Qing has served as a "free consultant" since she was not paid and that this was more than enough. What do you think?
6. Upon return to the United States, Qing feels an overwhelming need to give back to the community in Liberia where she worked. What can she do now that she has returned?

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.

b. 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.

Questions for Discussion:

1. Should Amit say something? If so, what should Amit say to the Peruvian physician? What should he say to his advisor at home?
2. If Amit does not feel comfortable speaking with either of his research advisors, whom else could he approach with these issues?
3. What could have been done to prevent this situation?

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.

C. 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.

Questions for Discussion:

1. What are the ethical dilemmas in this case?
2. How do you think the research team is perceived by the prisoners?
3. How should Andrew and his advisor balance the clinical care needed by the prisoners and their research objectives?
4. What should Andrew do when he sees referrals made to the medical clinic for urgent concerns go unresolved?

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.

IV. Concerns, conflicts and advice (15 minutes)

- a. Each group will then report back to the larger group addressing the concerns, conflicts and advice that they discussed in their small groups.

V. Ethical dilemmas anticipated in your projects (20 minutes)

- a. Divide into new small groups
- b. Ask each student to briefly explain their project and to identify two things that they think could be a challenge with their project. What advice will you give each other?
- c. What information/support do you need from your advisor on the ground?
- d. Who will you go to when you need help?

- e. How will you recruit participants?
- f. How will you talk to your participants about informed consent?
- g. How is your study situated within the larger context of disease burden in your host country?
- h. How will you share your results with the community after you have left?
- i. What additional supports do you need in working on your project?

VI. Future Steps (2 minutes)

- a. Announce the plan for a post-return ethics workshop, focused on the experiences of students during their clinical electives.

VII. Evaluation (5 minutes)

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