

The Ethics of Research and Clinical Trial Outsourcing

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The globalization of science and medical services is a double-edged sword. On one hand, the diffusion of knowledge and health amenities from industrialized to industrializing countries facilitates access to health care technologies for the populations most in need. On the other hand, the increasing ease of information and service exchange between countries allows scientists and pharmaceutical companies to tap into and take advantage of those needy populations for research and clinical trials. It is the latter consequence of globalization that treads the fine line between the need for scientific advancement and the need to safeguard human welfare. This moral quandary is not new, and ever since the Tuskegee syphilis experiment in Alabama revealed the horrors of withholding available treatments to unsuspecting test subjects, multiple regulatory measures have been implemented to prevent medical research from purposefully jeopardizing the health of human subjects.

In the international arena however, vague standards for research on human subjects and the different national policies for subject protection has made transgressing moral boundaries much easier. “Tuskegee-like” experiments can still be seen today. For example, in one study funded by the National Institutes of Health, investigators from University of Washington and University of Nairobi allowed HIV-positive pregnant women in Nairobi to go untreated in order to study the correlation between the viral loads in the mother’s genital tract and transmission of HIV to the offspring [1]. This study continued despite the availability of an antiviral drug called AZT that could have prevented mother-to-child HIV transmission. Certainly, such ethically questionable study would not have been done in the United States, but in African countries where regulatory measures are more lax, experiments like these are more common.

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The practice of extending biomedical research to developing countries in order to circumvent prohibitory ethical regulations is remarkably analogous to a common economic phenomenon known as job outsourcing, a strategy through which companies exploit cheap labor of populous countries to maximize revenue. From this comparison emerges a double-standard that scientists in these research projects could use to argue that researchers are not obligated to provide first-world treatment to third-world subjects. Just as science enlists subjects from countries with lax ethical regulations to generate new findings, so too does businesses take advantage of surplus labor in places with poor worker protection to churn out new products. Why are scientists obligated to assure the best proven diagnostic and therapeutic method to their foreign subjects while businesses are not required to adhere to the minimum wage and employee compensation standards of developed countries? What does it mean for human rights to be universal if they are not uniformly applied from business to science?

Proponents of subjects’ rights would probably respond by noting that the matter of life and death in research – especially in the HIV research in Africa – differentiates research from business. Because human life is at stake, researchers are morally responsible to enact the highest ethical values in spite of local standards. But how are scientists to judge

to what extent human life is at risk? How accurately can scientists assess the risk of harm or death in research in other societies especially since Institutional Review Boards (IRBs) have too little familiarity with developing countries? This nagging ambiguity suggests a clear-cut solution of doing unto others as we do unto ourselves may not practically or adequately redeem the shame of medical research.

In research with humans as subjects, one ideal is predominant: The well-being of the subjects should take precedence over the interests of science and society. However, in advocating for the uncompromising application of Western and American ethical practices to research in developing countries, we make the assumption that 1) Western and American ethical practices are the most ideal and 2) that uniform application of



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these practices in different societies is equally beneficial, or at least will generate the most beneficial outcome. Absent from his proposal is the consideration that local biologies and local moral worlds may affect the way human rights practices meet human rights standards.

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For instance, official Ugandan policy advises against partner notification when the other partner is tested as HIV-positive. In compliance with U.S. ethical practices, the uninfected partner would most likely be notified. However, in countries like Uganda that lack the same civil protections and HIV education as United States, labeling someone as HIV-positive could expose them to spousal abuse and severe

social injustices. In addition, when offering the best possible Western treatment (e.g., AZT) to subjects, scientists should take into account factors like the drug's toxicity and the need for constant medical monitoring in context with the work demands, living conditions, limited funds, and the local values of the native population.

This is where ethnography may aid in the most sensible application of human rights practices in research. Instead of complacently accepting the fact that IRBs are ill-equipped to differentiate among the values and customs of foreign societies and therefore broadly applying Western human rights practices everywhere, ethics committees should ethnographically understand the complex interplay between social and cultural values, and the impacts of Western-derived approaches in such context. While human rights standards are universal, practices that safeguard those standards are not. Hopefully, with ethnography, biomedical research in developing countries can achieve culturally pertinent benefits and turn research outsourcing into research outreaching. ■

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