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MORALITY AND LAW

See Law and Morality.

MORALITY AND RELIGION

See Ethics, *article on* religion and morality.

MULTINATIONAL RESEARCH

"Multinational research" refers to biomedical research that involves investigators and subjects from more than one nation. Here we will consider the most typical—and most problematic—type of multinational research: that in which the investigators come from a developed country (the "sponsoring" country) and the subjects are located in a developing country (the "host" country). Multinational research of this type poses several ethical problems in addition to the standard issues in research involving human subjects (Levine, 1986). Of particular concern is the possibility of dissonance between the fundamental ethical concepts of investigators and subjects from different cultural backgrounds.

Ethical dissonance raises a basic question with important theoretical and practical implications: Can one formulate ethical rules governing the conduct of investigators from one cultural background performing research on subjects from another? At the heart of this question is the problem of ethical universalism versus pluralism—the belief that the ethical standards governing the conduct of research are the same wherever research is conducted versus the contention that since ethics is socially constructed, it will vary according to the cultural setting in which it is formulated (Kunstadter, 1980).

Two trends bring concern about biomedical research ethics in a multinational context to the fore: (1) the increasing prominence of biomedicine in non-Western settings and (2) the increasing movement of biomedical investigators across national boundaries. These trends, which tend to increase the contact between investigators from developed countries and research subjects from developing countries, have been accelerated by the AIDS pandemic.

International standards

The first international code of ethics for research involving human subjects, the Nuremberg Code, was drafted in 1947 at the Nuremberg trials as a reaction to atrocities committed by Nazi physicians in the conduct of experiments on inmates of concentration camps (United States Department of Defense, 1947). The goal of the code was to acknowledge the importance and necessity of clinical research while providing a universally applicable standard for condemning the conduct of Nazi physicians. The Nuremberg Code, which consists of ten concise principles, was soon recognized as an authoritative statement of the fundamental rights of research subjects in all nations. The first principle of the Nuremberg Code is "The voluntary consent of the human subject is absolutely essential." This is elaborated to require that the subject be free from constraint or coercion and that the subject have "sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." Other principles in the Nuremberg Code require that the proposed research be meaningful and essential, be based on prior animal experiments, and "avoid all unnecessary physical and mental suffering and injury."

The Declaration of Helsinki, first promulgated by the World Medical Assembly in 1964 and revised in 1975, 1983, and 1989, adapted the principles of the Nuremberg Code to fit the empirical realities of biomedical research; for example, it provides for the authorization through proxy consent of the participation in research of less than fully autonomous subjects (World Medical Assembly, 1989).

The Nuremberg Code and the Declaration of Helsinki were written on the presumption that their ethical standards were universally applicable, and for many years they were widely regarded as such. However, with the proliferation of multinational research, this presumption of universality came to be challenged (Levine, 1982). In order to interpret the standards of the Declaration of Helsinki so that they would be applied correctly, particularly in technologically developing countries, the Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization jointly developed and promulgated a new set of international guidelines in 1982 that have become the leading articulation of ethical standards for multinational research (CIOMS, 1982). Subsequently, CIOMS extensively revised these guidelines (CIOMS, 1993) and also issued guidelines for the ethical review of epidemiological studies (CIOMS, 1991).

The CIOMS guidelines state that when research is conducted by investigators of one country on subjects of another, the "sponsoring agency should submit the research protocol to ethical and scientific review according to the standards of the country of the sponsoring agency, and the ethical standards applied should be no less exacting than they would be in the case of research carried out in that country" (CIOMS, 1993, Guideline 15). The stated purpose of these guidelines is to "indicate how the fundamental ethical principles that guide the conduct of biomedical research involving human subjects, as set forth in the Declaration of Helsinki, [can] be applied effectively, particularly in developing countries, taking into account culture, socioeconomic circumstances, national laws, and executive and administrative arrangements" (CIOMS, 1993, p. 8).

The CIOMS guidelines include provisions that address two problems perceived to be very important: (1) that multinational research might be exploitative, in that it might serve the interests of the initiating agency rather than those of the host country, and (2) that not all prospective subjects in developing countries or underdeveloped communities are so situated as to provide informed consent that meets the standards of the Declaration of Helsinki. However, the CIOMS guidelines, while commendably expressing concern for cultural specificity, nevertheless still reflect, perhaps unavoidably, a Western bias. Inherent in these guidelines is the assumption that the circumstances in the developing world are special and those in the developed world are the norm. Thus, the developed world is envisioned as more advanced, not only technologically but also morally.

Crossing national boundaries: Universalism or pluralism?

Because it brings investigator and subject together across a cultural boundary in a real research situation, the conduct of multinational research gives the theoretical tension between ethical universalism and ethical pluralism a palpable, practical significance. Psychiatrist and anthropologist Arthur Kleinman argues that

> Clinical investigations in developing societies must be understood as taking place within the particular contexts of practical, everyday beliefs, values, and power relationships that constitute local cultural systems and [must be understood] as creating potential conflicts between these non-Western systems and the Western cultural conceptions and norms that are a usually unrecognized part of clinical research projects and the expectations and behaviors of clinical researchers. . . . (Kleinman, 1979, p. 1)

There is considerable controversy regarding how such conflict should be resolved (Christakis, 1992). Some contend that all research, wherever it is conducted, should be justified according to universally applicable standards. Those opposed to this position, while sometimes accepting certain standards as generally applicable, argue that most standards must be adapted to accommodate the mores of particular cultures; they argue for ethical pluralism. Pluralists commonly refer to the universalist position as "ethical imperialism," while universalists often call that of their opponents "ethical relativism."

Universalists endorse uniform international standards because they are concerned that investigators from industrialized nations may go to developing countries to test therapeutic innovations not only for appropriate reasons (e.g., to study a disease where it is indigenous, to obtain a scientifically appropriate study group) but also for inappropriate ones (e.g., to take advantage of the less sophisticated regulatory systems typical of developing countries). Requiring investigators to conform to the ethical standards of their own country when conducting research abroad is one way to restrain exploitation. Universalists point to the Declaration of Helsinki as a widely accepted standard for biomedical research that has been endorsed both by technologically developing countries that lack indigenous standards of research ethics and by technologically developed countries where, in general, complex regulations are patterned after the declaration.

Pluralists join with universalists in condemning exploitation of technologically developing countries and their citizens. Unlike the universalists, however, they see the imposition of ethical standards for the conduct of research by a powerful country on a developing country as yet another form of exploitation. In their view, it is tantamount to saying, "No, you may not participate in the development of this technology, no matter how much you desire it, unless you permit us to replace your ethical standards with our own." Pluralists call attention to the fact that the Declaration of Helsinki reflects a uniquely Western configuration of a number of key ethical points; in particular, the declaration has a largely Western view of the nature of the person and, as such, it does not adequately guide investigators to show respect for persons in non-Western settings. Pluralists point to findings in the fields of medical sociology and medical anthropology regarding the culturally dependent variability in medical care, ethical practice, and conceptualization of personhood.

Role of the AIDS pandemic

The AIDS pandemic has provoked critical scrutiny of the universalistic, Western conception of clinical research ethics. AIDS research of various kinds by Western investigators in non-Western settings—such as epidemiological studies, vaccine trials, and drug trials—has raised specific, thorny challenges to such a presumption. Certain research protocols that are unacceptable in developed countries have been seen as acceptable in developing countries and vice versa. Difficulties have arisen in satisfying conflicting ethical expectations. Many AIDS researchers have stressed the importance of sensitivity to local culture in general and local ethics in particular, and they have advocated local community involvement in the ethical design of research.

For example, one American investigator described a research project in Tanzania in which the ethical expectations of the investigators' and subjects' cultures clashed. In this study of the prevalence of HIV antibodies, maternal and infant blood was to be sampled at the time of birth. The investigator's home institutional review board, as part of its approval, had required that subjects give informed consent to participate and also that subjects be told their test results. Tanzanian authorities, however, had a conflicting set of requirements: worried that the results could cause psychological trauma, and cognizant of the fact that no meaningful therapy was available for HIV-positive individuals in Tanzania, they insisted that the researchers not tell their subjects either the reasons for or the results of the blood tests. This study, which both the host nation and the investigator judged to be valuable, was abandoned because of this conflict (Barry, 1988). In other situations, disagreement between local ethics committees and those of the international body funding the research have forced local investigators to change the research protocol in ways that were meaningless in the cultural and economic circumstances of the host country (Hall, 1989). Some would regard such examples as ethical imperialism; others, as the worldwide elaboration of appropriate universal standards.

Another example is provided by a case involving the use of placebos. A Brazilian investigator proposed to compare the drug dideoxycytidine with a placebo in order to assess the efficacy of this drug in prolonging survival in HIV-infected patients. This trial was also intended to determine if a financial investment by the Brazilian government in this drug would be worthwhile. From the perspective of orthodox Western research ethics, this study raised two major problems: Is it ethical to conduct a placebo-controlled trial when effective therapy for HIV infection (i.e., zidovudine) exists? And is it ethical to design a clinical study to answer an economic question? (Christakis et al., 1991). From the perspective of many Brazilians, but probably not from that of a developed society, the answer to each of these questions is affirmative.

The informed consent debate: Personhood in multinational perspective

The brisk debate about the permissibility of multinational variability in informed consent is particularly illustrative of discrepancies that may arise between ethical expectations in Western and non-Western societies and of the need for sensitivity to local culture. The debate has focused on three problems: (1) the extent to which *informed* consent is achievable; (2) the extent to which *individual* informed consent is necessary; and (3) the extent to which *free* consent is obtainable in the developing world.

With respect to the first problem, it is clear that the type of consent practiced in the West, with the signing of an informed consent document, is inappropriate for illiterate or semiliterate peoples. Moreover, in some cultural settings, it may be extremely difficult to convey an accurate understanding of the concept of randomization, the passage of time, the spontaneous remission of disease, or other essential concepts. Indeed, there may be cultural variation in the understanding of diseases, at odds with Western scientific notions, that makes truly *informed* consent (as configured in the West) impossible (Ekunwe and Kessel, 1984). However, illiteracy and poverty are all too often confused with passivity and stupidity, and many commentators have argued for better efforts to make the informational content of consent accessible to indigenous peoples.

The problem of individual consent is even more difficult, both philosophically and practically. The requirement for individual informed consent is grounded ethically in the principle of respect for persons, one of the posited universal ethical standards. When stated at the level of formality employed by Immanuel Kant, it is easy to apply universally and difficult to envision people who would disagree: "So act as to treat humanity, whether in thine own person or in that of any other, in every case as an end withal, never as a means only." When one goes beyond this level of abstraction, however, the principle begins to lose its apparent universality (Levine, 1991; 1982).

A very fundamental problem arises in the application of the principle of respect for persons because of cross-cultural variation in the definition of personhood (De Craemer, 1983). Western societies stress the individualistic nature of a person and put much emphasis on the individual's rights, autonomy, self-determination, and privacy. But this is at variance with the more relational definitions of a person found in many non-Western societies that stress the embeddedness of the individual within society and define a person by means of relations to others. The Kongo of Lower Zaire, for example, have conceptions of illness that "consistently [draw] the effective boundary of a person differently, more expansively, than classical Western medicine, philosophy, and religion. The outcome is usually disconcerting or unreal to Western medical observers . . ." (Janzen, 1978, p. 189).

Important practical implications arise from this variation in the definition of a person. Since the notion of persons as individuals is undermined, the consent of the individual may not be viewed as paramount in certain cultural settings. Indeed, the focus of the consent process may shift from the individual to the family or to the community. In the context of research, it may be necessary to secure the consent of a subject's family or social group instead of or in addition to the consent of the subject.

An additional practical problem in some areas of the developing world is that of establishing personal identity. Records of vital events are often spotty and kinship designations are sometimes ambiguous, thus making positive identification of research subjects difficult. Particularly when research participation involves an immediate benefit (e.g., a monetary reward for a blood specimen), villagers may replace one subject with another when the former is away from the village. Such practical issues have obliged creative solutions that might not stand up to an ethical review in a developed society. For example, in a trial of hepatitis vaccine involving more than one hundred thousand people in The Gambia, investigators found it necessary to produce a scar on the recipients' bodies in order to identify them positively (Hall, 1989).

Variations in the definition of personhood between societies may also find expression in precisely who is thought to have the authority to give informed consent for others. This is acknowledged in the CIOMS guidelines: When individuals cannot be made "sufficiently aware of the implications of participation to give adequately informed consent, the decision . . . on whether to consent should be elicited through a reliable intermediary such as a trusted community leader" (CIOMS, 1993, Guideline 8). There will be considerable variation by culture as to who is acknowledged as a "community leader" and whether such an individual can be considered a reliable intermediary. The requirement for community leader consent, however, may be the only alternative, albeit unsatisfactory by Western standards, to individual consent in many cases in which beneficial research is essential. But this alternative may not necessarily be ethically disturbing within the society of the research subject. Of course, a necessary presupposition regarding such proxy consent is that the leader will act in good faith for the benefit of the community. The possibility for abuse in such situations is quite real.

The CIOMS guidelines also respond to the problem of obtaining proxy consent for women in cultures where women's rights to exercise self-determination are not acknowledged. Recognizing that women who have serious illnesses should not be deprived of opportunities to receive investigational therapies when there are no better alternatives, the guidelines strive to strike a balance between, on the one hand, strictly individualistic—and, under such circumstances, therefore prohibitive—interpretations of individual informed consent and, on the other hand, potentially abusive interpretations that grant too much authority to the person giving the proxy consent. The guidelines note that "Efforts must be made . . . to invite [women] to decide whether they wish to accept the investigational therapy, even though the formal consent must be obtained from another person, usually a man. Such invitations may best be extended by women who understand the culture sufficiently well to discern whether [they] genuinely wish to accept or reject the therapy" (CIOMS, 1993, Guideline 11). The CIOMS guidelines are the first code of ethics to address this difficult problem explicitly.

Thus, some American observers have argued that, in certain developing world settings,

> Seeking informed consent to research [participation] from individuals may tend to weaken the social fabric of a non-individualistic society, forcing it to deal with values it does not hold, and possibly sowing disorder that the community will have to reap long after the investigators have gone home. . . . It is questionable that [our vaunted Western individualism] has been an unmitigated good for our own civilization and very questionable that it is up to standard for export. We ought, in truth, to be suitably humble about the worth of procedures [i.e., individual consent] developed only to cater to a very Western weakness. . . . How can it be a sign of our respect for people, or of our concern for their welfare, that we are willing to suppress research that is conducted according to the laws and cultures of the countries in which it is being carried out? (Newton, 1990, p. 11)

Other observers have argued that "Ethical standards in medicine . . . cannot be relative; they must be judged by their substance. The force of local custom or law cannot justify abuses of certain fundamental rights, and the right of self-determination, on which the doctrine of informed consent is based, is one of them" (Angell, 1988, p. 1082).

Research in developing countries, particularly when conducted by investigators from relatively powerful developed countries, raises difficult questions regarding how *free* consent can be in such circumstances. This problem has two parts: possible coercion by insiders and possible coercion by outsiders.

Many non-Western countries have complex social systems governing the exchange of gifts that, in the context of clinical investigations, would be interpreted in American culture, for instance, as problematic conflicts of interest. Describing Japan, clearly both a developed and a non-Western society, for example, the sociologist Willy De Craemer states,

> A continuous, gift-exchanging-structured flow of material and nonmaterial "goods" and "services" takes place between the members of the enclosed human nexus to which each individual belongs. . . . [A] web of relations develops . . . [that] binds donors and recipients together in diffuse, deeply personal, and overlapping creditor-debtor ways. Generalized benevolence is involved, but so is generalized obligation, both of which take into account another crucial parameter of Japanese culture: the importance attached to status, rank, and hierarchical order in interpersonal relationships. . . . (De Craemer, 1983, p. 30)

It is easy to imagine how a research ethics committee in the United States would evaluate such a custom of exchange of gifts—both material and nonmaterial—in a system that recognizes the legitimacy of "status, rank, and hierarchical order." Attention would soon be focused on the problems of "conflicts of interest," "undue inducement," or what the Nuremberg Code calls "other ulterior forms of constraint or coercion" that would invalidate informed consent. Such discrepant cultural perceptions would pose significant ethical problems in the context of a particular multinational research project.

Western investigators must thus appreciate that what appears to them to be coercion may, from the perspective of local inhabitants, represent cooperation and identification with the group to which the individual belongs. However, this does not relieve Western investigators, who are perforce not members of the host country, of the responsibility to avoid coercion arising from their own actions. They must be aware that coercion is difficult to avoid in most settings where clinical investigation in the developing world is conducted. Subjects with relatively little understanding of the medical aspects of research participation, indisposed to resisting the suggestions of Western doctors, perhaps operating under the mistaken notion that they are receiving therapy, and possibly receiving some ancillary benefits from participation in the research, are very vulnerable to coercion.

The CIOMS guidelines recognize that sponsors and investigators may have great difficulty in understanding and responding to cultural norms and traditions in developing countries:

> The ability to judge . . . ethical acceptability . . . requires a thorough understanding of a community's customs and traditions. The ethical review committee must have as either members or consultants persons with such understanding, so that the committee may evaluate proposed means of obtaining informed consent and otherwise respecting the rights of prospective subjects. Such persons should be able, for example, to identify appropriate members of the community to serve as intermediaries . . . , to decide whether material benefits or inducements may be regarded as appropriate in the light of a community's gift-exchange traditions, and to provide safeguards for data and personal information considered by the subjects to be private or sensitive. (CIOMS, 1993, Guideline 8)

The justification and regulation of multinational research

Multinational research also raises troubling ethical questions pertaining to the motivations behind it and the purposes to which it is directed. What are the ethics of collaboration between nations in clinical research? How are its costs and benefits to be apportioned among the collaborators?

The conduct of collaborative, multinational AIDS research in Africa—generally involving African subjects and American, European, and African investigators—is illustrative. Both Western and African nations urgently require the development of effective means of AIDS prevention and therapy. For both practical and scientific reasons, Africa has been identified as an ideal site for clinical trials of vaccines and other pharmaceuticals (Christakis, 1988). The developed world needs access to large populations of prospective subjects with a high prevalence of HIV infection, such as those found in certain African nations. And these African nations, lacking both well-developed research institutions and adequate funds, need the involvement of the developed world.

But there has been widespread concern that differences in economic and political power might lead to abuse of the poor by the rich and of the weak by the strong. For example, many African critics have been concerned that Western investigators, unchecked by foreign or local supervision, might conduct "savage experiments" in Africa. Many Africans have voiced the concern that Western science often goes to Africa with "dirty hands," and that Africans are serving as subjects for research deemed too risky to be conducted in the West (Fortin, 1987; Christakis, 1988).

African concerns about Western research transcend concerns that subjects might be treated inhumanely or unethically. Some Africans have voiced the more general concern that they do not derive significant benefit from their contribution to collaborative research efforts. Indeed, they sometimes feel harmed (Beiser, 1977). African physicians have complained that "Some of the Western press and researchers have used the . . . data we supplied, but instead of putting HIV under the microscope, they have put our society, our customs, even our love life under the lens. . . . We give you information and so often you seem to turn it against us" (Sabatier, 1988, p. 89). Practical and scientific reasons for the conduct of AIDS research in Africa, they argue, are not sufficient to justify using African subjects, especially if such subjects bear the burden of the research risks but do not reap the benefit from any advances.

In this context, some commentators have argued that sponsoring countries or corporations be required to develop enduring infrastructures (such as medical clinics or research facilities) in the host country as part of the process of conducting research (Gostin, 1991). Suggestions that sponsor countries provide lasting benefits to host communities are motivated in part by a concern for the equitable distribution of burdens and benefits that, in the West, is ordinarily understood as a question of distributive justice. According to the CIOMS guidelines, for example, external sponsors are expected to employ and, if necessary, to train local personnel to perform various functions in conducting the research (CIOMS, 1993, Guideline 15). Sponsors are also expected to provide facilities and personnel to make necessary health-care services available during the conduct of the research. However, provision of such services beyond what is necessary for the conduct of the research is described in the CIOMS guidelines not as obligatory but as "morally praiseworthy." Indeed, some commentators have argued that such costly requirements may simply prevent the initiation of important and desirable research in developing countries.

Sponsors of multinational research have also been criticized for their tendency to select research topics that are either irrelevant to local health needs or not integrated with follow-up health care delivery. For example, expensive pharmaceutical products are sometimes imported to developing countries in order to be evaluated, but alternative and cheaper drugs or methods of disease control, lacking sponsorship, are not tested (Abdussalam and Osuntokun, 1991).

Implementation of international standards at a local level (if one adopts a universalist perspective) or discovery and implementation of local ethical standards (if one adopts a pluralist perspective) each requires some formal institution to attain the objective. No matter where clinical research is conducted, some responsible body must articulate and implement ethical standards. In many developed countries, elaborate systems of review committees and legislation exist to achieve this. The emergence of multinational research has revealed the relative absence of such institutions (or appropriate substitutes) in the developing world. Problems have arisen in defining who should regulate research in such settings and how they should do it. The assertion of the necessity for local review assumes a local institution capable of carrying out such a review. Solutions to these problems are partly predicated on addressing whether exogenous, international standards or indigenous, local standards should be used in a given research setting. A significant part of the problem will be to identify local ethical expectations, and the medical social sciences can make a meaningful contribution in this respect (Kleinman, 1979; Kunstadter, 1980; Lieban, 1990; Hoffmaster, 1990; Christakis, 1992).

Proposed international procedural standards

Existing international ethical codes and guidelines cannot be a mechanism for the resolution of conflicting ethical expectations, especially under circumstances where the universal applicability of the standards is not recognized or where the standards are insufficiently specific or where the standards conflict with each other. Therefore, some authors have argued for a shift from content-based international ethical standards toward procedure-based protocols.