

THE ETHICS OF RESEARCH  
INVOLVING HUMAN  
SUBJECTS:  
Facing the 21st Century

Edited by

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Maryland

# The Distinction Between Ethical Pluralism and Ethical Relativism: Implications for the Conduct of Transcultural Clinical Research

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## INTRODUCTION

Transcultural research refers to clinical biomedical research that involves subjects and investigators from different cultures. The most typical—and most problematic—type of transcultural research is that in which the investigators come from a developed country and the subjects are located in a developing country. The possibility of dissonance between the ethical expectations of the researchers and the subjects from different cultural backgrounds raises the following fundamental practical question: Is it possible to justify ethical rules to govern the conduct of investigators from one cultural background who are performing research on subjects from another? This question has been raised most commonly in the setting of AIDS research, but it is not limited to it.<sup>1</sup> Current debate about this question typically construes it within the frameworks of ethical universality versus relativity—the belief that the ethical principles governing the conduct of research are the same wherever research is conducted versus the contention that ethical principles vary according to cultural setting.

Because it brings investigator and subject together across a cultural boundary in a real research situation, the conduct of transcultural research gives the theoretical tension between ethical universality and ethical relativity palpable, practical significance. The psychiatrist and anthropologist Arthur Kleinman has argued 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 usually an unrecognized part of clinical research projects and the expectations and behaviors of clinical researchers. . . .<sup>2</sup>

There is considerable controversy regarding how such conflict should be resolved and regarding which system of ethics should govern the conduct of multinational, transcultural clinical research. Some contend that all research, wherever it is conducted, should and can be evaluated by universally applicable standards.<sup>3</sup> Others contend that universal standards are possible, but must be flexibly implemented and conceived.<sup>4</sup> Still others contend that, at best, few standards are universal and that ethical rules are and should be culturally relative.

Virtually always, however, solutions to the question are framed within the extremes of universalism and relativism. But there is another framework which provides a more workable solution to the question: ethical pluralism. Ethical pluralism addresses many of the problems inherent in the relativist and universalist positions. Its superiority arises from two attributes: it acknowledges the key position of culture in shaping both the content and form of ethical rules and it includes a mechanism of dispute resolution through mutual evaluation and negotiation.

#### UNIVERSAL STANDARDS FOR CLINICAL RESEARCH ETHICS ARE PROBLEMATIC

International guidelines regarding clinical research ethics, such as the *Nuremberg Code*,<sup>5</sup> the *Declaration of Helsinki*, 1964 and 1975,<sup>6</sup> and even the *Guidelines of the Council for International Organizations of Medical Sciences (CIOMS)*,<sup>7</sup> are problematic on two broad levels.<sup>8</sup> First, by asserting their universality, international guidelines obscure real and legitimate cross-cultural differences in ethical expectations. International guidelines seek to make homogeneous something which is not necessarily so. Second, existing international guidelines are ambiguous about their objectives and

purposes. On the one hand, guidelines are structured as a set of goals and are largely aspirational in language and content. But on the other hand, the guidelines assume a normative character, by providing a set of standards to judge and, if appropriate, to sanction investigators' conduct. Consequently, international guidelines and their application may unavoidably and wrongly marginalize alternative visions of what is ethically correct, and they may therefore proscribe or be used to proscribe necessary investigations in certain locales that are conducted by local investigators in good faith and with local community approval. Indeed, there have been several examples of research that both subjects and investigators wished to conduct that were abandoned for nonconformity to international guidelines.<sup>9</sup>

There are two broad ways that a universal system of research ethics might be developed.<sup>10</sup> One way—the only way so far employed—is to use Western research ethics as the international standard. However, this solution does not speak to non-Western ethical expectations. Moreover, such an outright application of Western research ethics is confounded by serious cultural variation in the interpretation of certain essential ideas (such as personhood, disease causation, and randomization). Another way is to abstract a new system of research ethics through cross-cultural examination of systems of medical ethics. But this is complicated by the lack of other research traditions. Where present, other systems of medical ethics are largely professional in nature and, in a fundamental way, do not speak to the concerns of the Western tradition of clinical research. Both ways, in other words, are practically unworkable.<sup>11</sup>

A particularly good illustration of the debate between the positions of relativism and universalism is found in disagreements over the extent to which variability in individual informed consent is permissible. Articulate proponents of the universal nature of informed consent correctly argue that neither the difficulty of achieving informed consent in the developing world nor the urgency of conducting research justify compromising ethical principles.<sup>12</sup> But the argument about the need for individual informed consent is also often extended to include moral justifications for the universality of individual informed consent. Universalists argue 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."<sup>13</sup> They argue that individual informed consent "expresses important and basic moral values that are universally applicable, regardless of variations in cultural practice."<sup>14</sup> These arguments reflect the belief that, since one aspect of modern medicine is to prescribe its cure for patients, why not prescribe its morality as well? Arguments for the universalism of Western research ethics often seem to conflate technological superiority with moral superiority.

A further problem with the universalist position is that it does not seem to recognize that the requirement of first person informed consent is deeply imprinted with the emphasis on individualism and individual rights that is paramount in Western culture and that in many ways is peculiar to it. Moreover, the universalist perspective is disrespectful of the more social conceptions of the person that prevail in most regions of the world.

The Western principle of informed consent is predicated upon the notion of respect for persons and upon the notion of individuals as autonomous agents.<sup>15</sup> However, a fundamental problem arises in the application of the respect for persons principle because of cross-cultural variation in the very definition of personhood. Western societies stress the individualistic nature of the person and put much emphasis on the individual's rights, autonomy, self-determination, and privacy. This is at variance with more pluralistic definitions of the person found in other societies which stress the embeddedness of the individual within society and define a person by his relations to others. The Kongo of Lower Zaire, for example, have conceptions of illness and medicine 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. . . ."<sup>16</sup> The very definition of "body" by the Kongo embraces "constant reference to social relations."<sup>17</sup>

Anthropologist Clifford Geertz provides another example in his consideration of the nature of personhood in Bali; Geertz notes: "One of these pervasive orientational necessities is surely the characterization of individual human beings. Peoples

everywhere have developed symbolic structures in terms of which persons are perceived not baldly as such, as mere unadorned members of the human race, but as representatives of certain distinct categories of persons, specific sorts of individuals."<sup>18</sup>

The teknonymous Balinese system, moreover, leads to ongoing shifts in how members of this society are given names during the individual's lifetime, depending on their social position. In general, the definition of a person and of the self is more fluid, more expansive, and more relational in that it depends on the relatives of a given individual; the definition, that is, depends on *other members of the society*.<sup>19</sup>

Important practical implications arise from this kind of 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 essential in certain cultural settings. Indeed, the focus of the consent process may shift from the individual to the family or to the community; for example, in contemporary China, consent for a procedure might be first elicited from relatives who would in turn persuade the individual of the virtue of the proposed intervention.<sup>20</sup> Thus, 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 himself.

The question of whether individual informed consent is universal across all cultures is indeed amenable to cross-cultural empirical research. But it seems unlikely—should such research be undertaken—that individual informed consent will prove to be universal across all cultures akin to, say, the incest taboo. On the contrary, much research suggests that conceptions of individual consent and of the "person" are highly variable.<sup>21</sup> If anything, the American view is in the minority.

Indeed, even in our own society, informed consent is not exclusively individualistic. For instance, although the Uniform Anatomical Gift Act has made it legal for individuals to give consent for *post mortem* organ donation, physicians and other healthcare providers almost always request the written consent of the cadaveric donors' families before they harvest organs for this purpose. It would seem that in the face of a surgical act that they still consider extraordinary, however routinized it may have

bec The factual evidence [regarding the existence of variation in values] is beside the point. The relativists make the error of deriving an 'ought' statement from an 'is' statement. To say that values vary from culture to culture is to describe (accurately or not) an empirical state of affairs in the real world, whereas the call for tolerance is a value judgment of what ought to be, and it is logically impossible to derive the one from the other. The fact of moral diversity no more compels our approval of other ways of life than the existence of cancer compels us to value ill-health.<sup>25</sup>

Though on liberal, humanistic grounds tolerance has some appeal, critics of relativistic thinking, Hatch included, have pointed out that tolerance should not be extended beyond its limits. But there is no uniform way to decide at what point tolerance should stop.

### ETHICAL PLURALISM

Most of the problems with both the universalist and relativist positions on clinical research ethics arise from a maladroit handling and incomplete recognition of the influence of culture upon the question at hand. The pluralist position is fundamentally based on the fact that culture shapes (1) the content of ethical precepts, (2) the way ethics as a concept is configured (that is, the form of ethical precepts), and (3) the interaction between conflicting ethical expectations (that is, the way ethical conflict itself is handled).

Addressing the first issue (how culture shapes ethical rules) requires careful analysis of indigenous ethical expectations.<sup>26</sup> It is in many respects the easiest of the three. Addressing the last two issues, however, is more difficult: it requires the development of a special perspective on ethical systems. Orthodox Western bioethical approaches may well be inadequate to deal with not only the manifest variability in the ethical norms of differing cultures, but also the differing ways ethics is understood and ethical conflicts are handled in other cultures.

Medical ethics is not the same kind of thing in all societies. Sociologists Renee Fox and Judith Swazey have argued, for example, that the Chinese "medical morality" is *not* equivalent to Western "bioethics."<sup>27</sup> More generally, ethics do not just regulate

behavior, they construe it. Ethics are a form of "local knowledge," which Geertz has described as "local not just as to place, time, class, and variety of issue, but as to accent-vernacular characterizations of what happens connected to vernacular imaginings of what can."<sup>28</sup> As local knowledge, ethical systems are highly variable and situation-specific. Geertz observes that a paradox arises when we conceptualize systems of ideas with the realization that "socio-political thought does not grow out of disembodied reflection but 'it is always bound up with the existing life situation of the thinker.'<sup>29</sup> The solution to this problem, Geertz argues, lies in a more adroit handling of socio-political thought by conceptualizing it as an ordered system of cultural symbols. That is, it is not the ethical rules themselves which are so important, it is their *meaning* within respective cultures. The rules, in a sense, may be taken to reflect how a given culture perceives that human beings should be treated by others, how investigator and subject should communicate, or how medical knowledge is to be acquired. Medical ethics may also be different in respective cultures in part because of the activities ethics is viewed as appropriately governing. For example, the distribution of resources that maintain or restore health is configured as necessarily a moral problem within contemporary Western medical ethics. Yet, in other societies, the distribution of such resources might not be configured as a moral issue at all.<sup>30</sup>

A culturally sensitive perspective on systems of medical ethics has a further consequence. According to the prevailing view, medical ethics, as part of a positivist tradition in Western philosophy, consists of rules and principles directed at what ought to be the case. An alternative, contextualist, view of medical ethics, however, focuses on accounting for the *phenomena* of medical ethics. It seeks to understand the practice of medical ethics by locating its cultural context.<sup>31</sup> A contextualist perspective on morality offers a way out of the thorny methodological and substantive issues raised by a positivist—and culturally myopic—perspective on morality, issues brought to the fore by the conduct of transcultural clinical research.

A contextualist approach also contributes to a solution to the problem of determining which ethics should govern transcultural research, because the contextualist approach broadens the

philosophical basis of research ethics. Part of the problem with current analysis of the problem—even from a Western point of view—is that the full richness of Western philosophy itself has not been tapped.<sup>32</sup> Bioethics has, until very recently, based itself almost exclusively on Anglo-American analytic philosophical thought and largely ignored other Western philosophical traditions, such as phenomenology, virtues theory, existentialism, communitarianism, social ethics, and the like.

Present American concepts of medical ethics are too detached from the clinical reality in which ethics come into play. A significant source of ethical meaning is the particular situation in which ethical issues are raised. Clinical research ethics have a concrete existence, expressed in each research setting. Ethical rules such as those pertaining to clinical research, like other socio-political and religious thought, are constructed, fashioned, made. And since both the maker and the situation in which they are applied vary, so will the product. In order to resolve the troubling problems raised by the conduct of transcultural clinical research, an ethnography of the practice of morality in medical contexts in general and in transcultural clinical research in particular will be needed.

Indeed, the Western system of research ethics is, itself, a recent creation, largely articulated since World War II. It rests on a medical ethic that was exclusively doctor/patient oriented and which, under pressure of the research endeavor, was expanded to accommodate the investigator/subject relationship. Western medical ethics, that is, were at the outset based on the Hippocratic tradition, and were largely *professional* in nature, meaning that they pertained largely to matters of professional decorum. The concept of essential patient rights, which in themselves create obligations for professionals, is alien to the Hippocratic ethical tradition. This concept found its first important expression in the West in the *Nuremberg Code*. The *Nuremberg Code* abandoned the notion that experimental subjects are protected by professional standards and replaced it with the notion that subjects have intrinsic rights. In short, there has been an evolution in medical ethics—in response to the existence of research and to the abuse of research subjects in certain settings—in the West. The indigenous ethics of non-Western cultures, as they apply to professional etiquette or clinical care, are also capable of evolution. Of course,

the form of research ethics that systems of non-Western medical ethics ultimately achieve might be quite different from Western research ethics.<sup>33</sup> But the emergence of non-Western systems of clinical research ethics, such as they might be, must be expected and understood. In view of the importance and proliferation of collaborative research efforts between developed and developing countries, an understanding of the emergence of research ethics in non-Western countries is of enormous practical significance. Moreover, as traditional medical practices converge with Western biomedicine around much of the world, clinical research ethics will be under increasing pressure to adapt to local circumstances and local cultures.<sup>34</sup>

Thus, culture shapes both the content and form of ethical systems. It can also be seen to shape how the existence of conflicting ethical expectations is construed and handled. In the United States in particular, we often seem to expect that a solution to ethical problems is indeed possible, if only we were clever or persuasive or patient enough. The expectation, tempered by our culture, is that ethical dilemmas have a transcendent solution. However, not all conflicts, especially in such a complex area as research ethics, are resolvable. This problem is compounded in the conduct of transcultural clinical research: it is not just ethical principles themselves that might conflict, it is also the interests of varying cultures. Resolving ethical conflict is apt to be especially unlikely when non-casuistic, systematic solutions—those divorced from actual, clinically and culturally specific situations—are applied. American bioethics has an inherent bias in that there is an expectation that final and transcendent resolution of ethical disputes is indeed possible. In the United States, we seem to hesitate to accept inherent ethical irresolvability. Ethical systems, however, do not exist only to eliminate ethical problems. They also exist to provide a framework for such problems—a framework for the confrontation of particular situations that pose ethical dilemmas.

#### PRACTICAL IMPLICATIONS OF PLURALISM

Such a casuistic, pluralistic view of medical ethics has three major practical implications. The first implication is that an



understanding of the *relevant* and *specific* ethical expectations of indigenous peoples will be a prerequisite of transcultural clinical research. It is not, after all, the existence of moral standards that varies cross-culturally, it is their form and content. This pluralistic approach to the problem is different from the approach of ethical relativism in four critical respects: (1) an ongoing *dialogue* between ethical systems is inherent in it; (2) a *negotiation* between ethical systems about a *particular situation* takes place; (3) proponents of both the dissonant ethical systems *assess* the other and their own ethical systems; and (4) a rationale for *tolerance* is thus provided, namely, that ethical conflict is sometimes irresolvable but must nevertheless be handled.

These features lead to the second practical implication of ethical pluralism. From a pluralist perspective, the ethical conduct of transcultural research is dependent upon the negotiated settlement of ethical disputes rather than upon the rigid application of previously formed international ethical rules or the lax acquiescence to all systems of clinical research ethics. The kind of negotiation between equals that this approach entails would admittedly be difficult to attain in many settings in the developing world where research is conducted—if, for no other reason, because of tremendous differences in education, wealth, and power between investigators and subjects. A paternalistic feeling on the part of the investigator that the ethical expectations of the subjects have been met is not enough. The difficulty in achieving such a cross-cultural negotiation, however, does not mean that efforts should be abandoned. In such a negotiation, the involved parties must accept the existence of alternative ethical systems, and, while not forswearing assessment of the other systems, must still negotiate with them. Such negotiation and mutual understanding also provides the practical advantage of providing a mechanism for dispute resolution.<sup>35</sup>

With an eye toward respecting the local ideals of both subject and investigator, I have previously proposed the following protocol.<sup>36</sup> This protocol would encourage a negotiated settlement of ethical differences, so that both parties, researchers and subjects, might be comfortable with the proposed research, ethically and clinically.

1. The host country for the research, or, more specifically, the representatives of research subjects, should have a presumptive claim to ethical guidance. In the event of a conflict, the host country's ethical standards, if they are more restrictive, should always prevail.
2. A researcher retains an allegiance to his or her own community. To the extent a researcher's community views the research as unethical, the researcher should not go forward irrespective of what the host nation says, unless the ethical dispute can be negotiated.
3. To the extent that any nation or institution adopts ethical guidelines, including any internationally promulgated guidelines, it should be bound by those guidelines irrespective of to whom they are being applied within the nation.
4. When research that is considered desirable by either party is proscribed by existing international standards or by either party's own standards, formal negotiations between the parties to understand the source of disagreement and to arrive at a consensus, if possible, should take place. Relevant international standards might here serve as aspirational guides. If a consensus is reached, the research should be viewed as necessarily ethical, its deviation from any international standards notwithstanding. The negotiations, of course, must be fair.

Ideally, negotiation would take place between true representatives of those who wish to conduct the research and those who would be the subjects. Such negotiations would not necessarily be based on national boundaries and could conceivably take place within a given country as well as between two countries. Implicit in this position is support for an ongoing international dialogue that privileges all perspectives on the ethics of clinical research (not just Western perspectives). In this regard, the question of the composition of international bodies and the ability of alternative voices to be heard is critical. To date, international bodies have tended to mirror the distribution of power within the world. The more powerful, principally Western nations have dominated the debate. Although Western representatives are often commendably sensitive to the concerns of the developing world, this is no substitute for actual participation by those nations themselves.

The quintessential dilemmas in such a protocol thus become (1) to discover local ethical expectations, (2) to assess the good faith and legitimacy of the representatives, and (3) to ensure adequate expertise on the part of the subject representatives.

These requirements, finally, lead to the third practical implication of ethical pluralism. Pluralism suggests a shift from current content-based international ethical standards towards procedure-based protocols directed at addressing the above three dilemmas. Such procedural guidelines would specify how transcultural ethical disputes in transcultural research projects, if they arise, might be mediated, rather than specifying *a priori* which ethical rules should be followed. And they would be concerned with the specification of fair procedures for negotiation rather than the articulation of principles of research ethics.

Ideally, such guidelines would encourage a negotiated settlement of ethical differences, so that both parties—researchers and subjects—might be comfortable with the proposed research, ethically and clinically. But a necessary predicate to the fair application of such guidelines is the legitimacy and good faith of local representatives and the integrity and fairness of the dialogue between the parties.<sup>37</sup> Cultural sensitivity and the privileging of local ethics should not be used as a shield to abuse developing world citizens as research subjects. I emphasize that the legitimacy and good faith of local representatives is fundamental to the process. I am not advocating the view that the assertion by a host nation regarding these matters is perforce acceptable. Otherwise, for example, it is easy to envisage the selective abuse of minorities within host nations or bad faith actions by research subject representatives. This type of evaluation is analogous to the inquiry common in human rights investigations. Monitors of international bodies are not ordinarily satisfied by a mere formal adoption of applicable human rights covenants by a given nation.<sup>38</sup>

Indeed, there are many egregious examples of the abuse of research subjects in the developing world, and they are to be strongly condemned. For example, one researcher outlined high risk experiments conducted in Bangladesh that would “not have been passed by ethics committees elsewhere.” This research involved cholera patients and included administration of radioactive materials and withholding of proper treatment (leading

directly to a death in at least one case).<sup>39</sup> Other cases have emerged during the development of contraceptive medicines; critics argued that coercion to participate in the research was rife and that the Third World poor might become “the guinea pigs or beagle dogs for the world’s contraceptive testing.”<sup>40</sup>

Yet another, more recent, problematic case is that of an AIDS vaccine trial conducted in Zaire in the late 1980s. Africans were concerned that they were serving as subjects for research deemed too risky to be conducted in the West, with good reason. An unidentified source close to the research group conducting the trial informed a *New York Times* reporter that “It was easier to get official permission here [in Zaire] than in France.”<sup>41</sup> It later emerged that the research subjects were mostly minors. African critics were also concerned that Western investigators, unchecked by foreign or local supervision, might conduct “savage experiments” in Africa.<sup>42</sup> There was a feeling that “Western science often comes to Africa with dirty hands.”<sup>43</sup>

Such examples warrant caution and safeguards when reviewing the conduct of multinational research. But the history of the abuse of research subjects in the developing world (and in the developed world) does not mean that we necessarily abandon a sociologically informed, pluralistic research ethic, replacing it, presumably, with a narrow, Western-based ethic which is not necessarily representative of the wishes of the research subjects it allegedly is protecting. Indeed, it may even be true that it is not ethical codes themselves—even Western or “universal” ones—that truly protect research subjects. It is not, in other words, necessary to adopt a universalist position on transcultural research ethics in order to support high standards of ethics. Ethical behavior and philosophical outlook are distinct. No system of rules alone, no matter how extensive or enlightened, will completely protect subjects from unscrupulous investigators.<sup>44</sup> Instead, research subjects may perhaps best be protected by being involved as equals in the conduct of research. This, of course, is largely equivalent to arguing that local culture should inform the ethics of clinical research trials.

Since systems of ethical rules are socially constructed, they will vary according to the cultural setting in which they are formulated.<sup>45</sup> This fact suggests that *both* cultural analysis and



moral analysis should be part of ethical research. Indeed, it is not possible for moral analysis to be totally acultural, even if this were desirable. Pluralism challenges the presumption that cultural analysis is not integrally related to moral analysis.

It has become apparent that existing international standards of research ethics are not a mechanism for the resolution of conflicting ethical expectations under circumstances where the universality of the principles articulated within them is not recognized, where the principles as articulated are insufficiently specific, or where the principles articulated within the standards conflict with each other. Ethical relativism, on the other hand, is essentially nihilistic: it does not provide a solution because it is non-evaluative and because it does not offer a means for the resolution of conflict. Pluralism does away with the most troubling aspect of both universalism and relativism: namely, the lack of critical appraisal of one's own and the other ethical system. Pluralism is an intermediate solution to the problem of which ethics should guide the conduct of transcultural clinical research, a solution that sits between the autocracy of universalism and the anarchy of relativism.

#### NOTES

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5. U.S. Department of Defense, "The Nuremberg Code," in *U.S. v. Karl Brandt, Trials of War Criminals before Nuremberg Military Tribunals under Control Law No. 10* (Washington, D.C.: U.S. Government Printing Office), 2: 181-83. This code is replicated in this volume's Appendix A.

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8. N.A. Christakis and M.J. Panner, "Existing International Ethical Guidelines for Human Subjects Research: Some Open Questions," *Law, Medicine & Health Care* 19 (1991): 214-21.

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11. *Ibid.*

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13. M. Angell, "Ethical Imperialism?" 1082.

14. C.B. IJsselmuiden and R.R. Faden, "Research and Informed Consent in Africa: Another Look," *New England Journal of Medicine* 326 (1992): 830-33.

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No. (OS) 79-12065 (Washington, D.C.: U.S. Government Printing Office, 1979), 4; reprinted in this volume's Appendix C.

16. J.M. Janzen, *The Quest for Therapy in Lower Zaire* (Berkeley, Calif.: University of California Press, 1978), 189.

17. *Ibid.*, 169.

18. C. Geertz, "Person, Time, and Conduct in Bali," in *The Interpretation of Cultures* (New York: Basic Books, 1973), 363.

19. The nature of personhood has, among other things, come increasingly to be the focus of "new" ethnography. See G.E. Marcus and M.M.J. Fischer, *Anthropology as Cultural Critique, An Experimental Moment in the Human Sciences* (Chicago: University of Chicago Press, 1986), especially 45-73.

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27. R.C. Fox and J.P. Swazey, "Medical Morality Is Not Bioethics—Medical Ethics in China and the United States," *Perspectives in Biology and Medicine* 27 (1984): 336-60.

28. C. Geertz, "Local Knowledge," in *Local Knowledge: Further Essays in Interpretive Anthropology* (New York: Basic Books, 1983), 215.

29. C. Geertz, "Ideology as a Cultural System," in *The Interpretation of Cultures* (New York: Basic Books, 1973), 194.

30. Lieban, "Medical Anthropology and the Comparative Study of Medical Ethics," 227-28.

31. Hoffmaster, "Morality and the Social Sciences."

32. Fox and Swazey, "Medical Morality Is Not Bioethics," 358.

33. Christakis, "Ethics Are Local."

34. N.A. Christakis, N.C. Ware, and A. Kleinman, "Illness Behavior and the Health Transition in the Developing World," in *Health and Social Change in International Perspective*, eds. L.C. Chen, A. Kleinman, and N. Ware (Cambridge: Harvard University Press, 1993), 233-56.

35. Christakis and Panner, "Existing International Ethical Guidelines."

36. *Ibid.* See also Levine, "Informed Consent: Some Challenges," for another set of procedural guidelines.

37. Many formal methods to ensure fair and open dialogue exist. For example, see B.J. Broome and N.A. Christakis, "A Culturally Sensitive Approach to Tribal Governance Issue Management," *International Journal of Intercultural Relations* 12 (1988): 107-23.

38. D. Orentlicher, "Bearing Witness: The Art and Science of Human Rights Fact Finding," *Harvard Human Rights Journal* 3 (1990): 83-136.

39. See, for example, a series of letters published in *Lancet* in 1978 regarding diarrheal research in Bangladesh: W.H. Mosley et al., "International Research Laboratory in Bangladesh," *Lancet* no. i

(1978): 602-3; C. McCord, "International Research Laboratory in Bangladesh," *Lancet* no. *i* (1978): 768 (containing the allegations of ethical misconduct); C. McCord, "Cholera Research in Bangladesh," *Lancet* no. *i* (1978): 1207; D.R. Nalin, "Cholera Research in Bangladesh," *Lancet* no. *ii* (1978): 102-3.

40. D.P. Warwick, "Contraceptives in the Third World," *Hastings Center Report* 5 (August 1975): 9-12; see also, M. Potts and J.M. Paxman, "Depo-Provera: Ethical Issues in Its Testing and Distribution," *Journal of Medical Ethics* 10 (1984): 9-20.

41. "Zaire, Ending Secrecy, Attacks AIDS Openly," *New York Times*, 8 February 1987. The results were published as D. Zagury *et al.*, "Immunization Against AIDS in Humans," *Nature* 326 (1987): 249-50. Prior news reports regarding this vaccine trial had appeared: P. Newmark, "First Human AIDS Vaccine Trial Goes Ahead Without Official OK," *Nature* 325 (1987): 290; and, "AIDS Immunization Tested in Humans," *New York Times*, 17 December 1986.

42. "Special SIDA: Des Millions d'Africains condamnés à mort?" *Jeune Afrique Magazine* (February 1987): 87. See also "Who Will Volunteer for an AIDS Vaccine?" *New York Times*, 15 April 1986.

43. A.J. Fortin, "The Politics of AIDS in Kenya," *Third World Quarterly* 9 (1987): 906-19.

44. Indeed, the doctrine of informed consent does not adequately protect research subjects in American society; moreover, the *practice* of informed consent in American society seems often to be so substandard as to not adequately protect research subjects.

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## 12

## Medical Research and the Principle of Respect for Persons in Non-Western Cultures

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### INTRODUCTION

Should the principle of respect for persons be viewed as morally relative when Western researchers conduct medical research in another cultural setting, or should this principle be regarded as universally valid? And, if its application is to be modified, how should it be changed and who will decide on these changes?

Limiting this discussion to first-person informed consent in cross-cultural research, this paper examines the arguments favoring substantial modifications to the Western notion of informed consent: the obligation to obtain first-person informed consent from competent adult subjects of research. By demonstrating that these arguments are incomplete and deficient and by placing research back in the context of the overall endeavor to improve the human condition, this paper defends the position that Western first-person informed consent requirements should be adhered to in cross-cultural research. If first-person informed consent cannot be obtained for studies where the "unit of measurement" is the individual, then such research should not be undertaken, except in the case of medical or health emergencies.

The obligation of scientists to obtain first-person informed consent from research subjects, grounded in a general moral principle of respect for persons, has developed through philosophical and religious reflection on the scientist-subject relationship, through the medical research establishment in the pursuit of protecting study subjects and, therefore, in the pursuit of a