oped countries. Globally, heart disease is now the most common cause of death. The globalization of disease is a message that must be clearly understood by medical schools, research funding bodies, industry, and governments of rich countries.

The development of effective and equitable research partnerships between developed and developing countries will not only help to combat the global inequity of health care, but will also be of enormous mutual benefit to both parties. As Donald Kennedy, editor-in-chief of *Science*, aptly and succinctly put it, "What can First World science do, not for the West, but for the Rest."[18] ■

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This article was accepted April 11, 2002.

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Ethical Oversight of Public Health Research: Can Rules and IRBs Make a Difference in Developing Countries?

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Controversies in the conduct of international research continue to pose challenges for the system of ethical review, particularly for developing countries. Although the concept of vulnerability is key to addressing these challenges, ethical review has typically ignored the agency of vulnerable participants and groups in determining what kind of review process is needed. Concurrent with developments shaping the new public health that seek to operationalize empowerment of communities by placing them as initiators and organizers of their own health, ethical review of public health research must find ways to recognize the agency of vulnerable individuals, groups, and communities in the review process if it is to address effectively the ethical dilemmas currently evident in collaborative international research. (*Am J Public Health.* 2002;92:1079–1084)

ALTHOUGH THE CONTROVERSIES over the ethical conduct of international research have in recent years generated increasingly copious[1–9] and at times acrimonious[10–12] debate, there is little doubt that many key issues remain unresolved,[13] particularly for developing countries.[14] Even in developed countries, the track record of ethical review remains open to criticism, particularly around the disputed definition of what constitutes "minimal risk."[15]

The current institutional framework for collaborative international health research stems largely from US government–driven directives to establish ethical oversight over research involving human subjects, most particularly in the form of federal regulations, and systematized in the form of institutional review boards (IRBs).[15–17] While the role of an IRB is viewed as having broad responsibilities for considering all ethical dimensions of a research protocol, it is recognized that IRBs in practice tend to focus on informed-consent documents.[14,16,18] Indeed, rules-driven ethical oversight[19] has created a disjuncture between ethical codes, which are essentially standards for professional behavior with limited ac-

countability, and legal standards, which have the potential for high levels of sanction and enforceability.[13] As a result, the system has driven a concern about procedural correctness[19] rather than a substantive approach to ethical reasoning.[13]

It is particularly in the setting of international collaborative research, involving researchers from developed and developing countries, that the fault lines have been most exposed.[1,4,13,18,20–23] For example, cross-country research protocols (i.e., research conducted in developing countries by developed country researchers) have set regulation-driven US standards against local interpretations of ethical codes, with the former routinely superceding the latter because of regulatory requirements that substituted provisions must be "at least equivalent" to those in US policies.[16] The responsibility of the IRB—or of its equivalent in a developing country—to span the tension between "legalist" and "ethical" reasoning approaches to safeguarding the rights and welfare of participants is complicated where there are profound cross-cultural differences, inadequate health care provision, high levels of social inequality, and social systems that fail to respect human rights.[16]

It is perhaps not surprising that, in considering ethical oversight, informed consent is most typically identified as the area on which "local" expertise is best placed to comment,[16] rather than on issues of the ethics of study design or justice. For example, locally specific cultural values are said to be more likely to influence preferences in how a study should be conducted (recruitment, disclosure, consent) than to influence the "overall acceptability" of a study.[14] Centers for Disease Control and Prevention (CDC) IRB interviewees expressed the view that national ethics committees were better placed "to address political and cultural acceptability" while CDC IRBs were better placed to address research design and biological risk.[24]

Accordingly, informed consent has become a particularly important focus of attention in ethical considerations in international research. One the one hand, this is welcome. Careful and culturally sensitive attention to matters of consent and confidentiality is essential for protecting the rights and welfare of study subjects[16,18,23,25,26] and finding fair resolution to the problems associated with interpreting what constitutes meaningful informed consent across different cultures.[14,16] However, the requirements of federal regulations and donor agency "rules"[27] have also resulted in the application of extremely detailed and elaborate procedures for consent that, from the point of view of researchers and subjects in developing countries, may simply be inappropriate in their assumptions and expectations of what research participants would see as important protections of their rights. It is not surprising that these stringent rules of consent may be seen as primarily protection for the researcher or institution rather than the study subject.[24,25,27] Even where consent is carefully addressed, it is usually in the design and planning, with little or no attention to monitoring actual implementation or how effective the consent is.[18,26]

Furthermore, as many commentators have pointed out,[13,15,18,26,28] reliance on procedural aspects of consent is wholly insufficient to guarantee ethical standards in research, and such narrow interpretations of ethical obligations have often had disastrous consequences for subjects in developing countries. Concentration on procedural aspects of consent to the exclusion of issues of distributive justice[13,18,21] makes it easier to justify or overlook exploitative research.

VULNERABILITY AND AGENCY

The concept of vulnerability of study populations, and the corollary obligations of the researchers, is central to the well-grounded fear of the exploitation of study subjects—particularly in, but not limited to,[26] developing countries. Traditionally, ethical codes have viewed the inability or incapacity to make independent decisions as the cornerstone of vulnerability[29,30] and characterized vulnerable populations by their need for special protection.[29,31]

Such formulations, while intended to redress imbalances in power underlying conditions of vulnerability, do not necessarily recognize the mutuality of the researcher–subject relationship,[26] inherent in newer conceptions of public participation[32,33] and community agency in determining need[34] in public health. The process of "speaking for others," so central to IRB processes in relation to vulnerable groups,[17] is coming under increasing criticism in development-related analyses of public heath where the "need for people to negotiate their own inclusion"[33] is critical to the success of the new public health.

For example, Eckenwiler[17] defines vulnerability in terms of threats to self-development, self-determination, and equality that exist independent of research and suggests that variables other than those "traditionally" cited in research codes (gender, disability, children, poverty, etc.) should be considered within the ambit of vulnerability, based on an analysis of the participant's own experiences and their particularity. Similarly, Zion et al.[26] define vulnerability in terms of the lack of basic rights and freedoms required for participants' free choices. Brody[25] has argued that failure to make informed consent meaningful has occurred because of a preoccupation with autonomy as a right rather than as a value, resulting in an ethical principle that generates no obligation on the part of the researcher to help the participant make autonomous decisions.

Institutional review processes, therefore, need to develop new ways to recognize and strengthen the agency of individuals, groups, and communities, whom institutional review has thus far only viewed as candidates for protection.[35] As in broader public

health policy, rather than "doing things *for* or *to* the poor, [ethical review should] start strengthening the capacities of the poor *to do* things themselves."[36] By asking difficult but appropriate questions of researchers relating to the role their research will play in facilitating empowerment of vulnerable groups, ethical review should aim to strengthen the connection between autonomy and freedom.[26]

For example, reproductive health studies that have the potential risk of gender violence could, if appropriately planned and managed, afford significant opportunities for intervening to reduce vulnerability and empower marginalized women, both within and outside of the study. Researchers should recognize a positive obligation to actualize participants' autonomy[25] and therefore improve the situation of vulnerable populations. Underresearching of the problems of vulnerable communities is itself an ethical issue that should not be aggravated by the very process of ethical review. The recognition of, and opportunity to support, participants' agency potentially turns institutional review into a mechanism for redress of inequality, rather than framing ethical discourse in relation to vulnerable populations as a negative conditionality (i.e., in terms of conditions under which research might be "ethically acceptable"[26]). Clearly, designing and implementing such studies demand additional resources and represent the added costs of community participation and empowerment. However, in evaluating the ethics of a study, public health research should not accept resource constraints as a given, and certainly should not allow such acceptance to set the terms in which ethical questions in public health research are resolved.

Moreover, one of the implications of the biomedical community's embrace of the randomized controlled trial as the core criterion for any public health evidence base is that other kinds of research, better suited to empowering vulnerable communities and groups, may be systematically neglected. For example, participatory action research[37,38] and social epidemiology[39] are research methods more attuned to assessing community harms and benefits and empowering study subjects. In examining challenges facing public health in developing countries, the strongest evidence for people-driven development in public health is often to be found in case studies,[33] replete with internally subjective assessments of success. Yet such evidence rarely meets traditional standards for scientific objectivity. If ethical review processes are to take seriously the participation of those who are labeled vulnerable, it has to address the passivity imposed on subjects by the objectification of participants inherent in many research designs.

PARTIALITY AND POWER

Linked to the positivist framework of most biomedical research is the view that ethical review requires careful assessment by an impartial external agency. However, commentators have observed that, in reality, the very process of ethical review is often replete with partiality[17] and—in Africa, for example—the colonial legacy leaves significant potential for personal bias.[23] Moreover, decisions of IRBs take place in the context of significant differences in interests among stakeholders, which include governments, funders, academic institutions, researchers, and communities, both within countries and between countries.[26] These interests, depending on the particular context, are expressed through uneven power relations between stakeholders,[40] between stakeholders and IRBs,[8,20,23,40,41] between IRBs and researchers in developed and developing countries,[16,27,42] and even within IRBs.[14,16]

Money, power (political or economic), prestige, custom, indifference, or even simple lack of awareness may all influence, sometimes decisively, the decisionmaking process of ethical review, frequently complicated by conflicts of interest (situations of dual loyalty) in which researchers[17,18,40,41] or IRB members[17,22,23,40,43] might find themselves. It is not uncommon for developing-country IRBs to be pressured by funders or researchers to approve the local arm of a multicenter study that has already met with approval in the funder's home country. Financial incentives to researchers and whole institutions may be sufficiently powerful to shape entire research agendas in the developing world[18,20–22,42] and the developed world.[18,40,41] Thus, while an idealized view of IRBs holds that their decisionmaking is always independent of influence, the reality may often be very different.

Some critics have argued that impartiality in ethical review is simply not possible and that claims for impartiality are in fact part of the problem.[17] What enables differences in power to persist, and to insert themselves into institutional review, is largely the lack of explicit recognition of these diverse and often powerful sectoral interests by the review process. Eckenwiler[17] has referred to the "flattening" process that occurs within IRBs that results in the hiding of inherent subjectivities, prejudice, and misunderstandings in the review process. Therefore, different frameworks for adjudicating conflicting interests, which are perhaps more effective at making the implicit explicit, may be useful if integrated in ethical review. Specifically, human rights approaches, by setting clear terms of reference for adjudicating conflicting rights in relation to widely accepted human rights standards, rely on exactly that process of making diverse and potentially divergent interests explicit, so that value judgments can be applied within a framework that has credibility with all stakeholders.[44,45] So, for example, rights analyses may help to clarify diverging interests, allowing greater weighting to be placed on the rights of participants from vulnerable groups, and thereby making the work of IRBs easier.

Such approaches may also be useful in helping to answer an-

other difficult controversy—to whom are IRBs accountable when funders, governments, participants, and researchers all look to IRBs to ensure that in the process of ethical review, their particular interests are met? IRBs can only balance these diverse pressures by making such pressures explicit, and negotiating a priori how consideration should be given to different kinds of stakeholders in the context of prioritizing the interests of study participants, particularly those from vulnerable groups. However, in the absence of any organized, credible, representative structure, often the interests of the participants are represented in the abstract, by consultants, or by token participation from individuals said to be representing the patients/participants.[8,16,35,43] Here again, the need to recognize the agency of vulnerable groups in representing themselves is paramount.

The problem of "moral relativism"[14,16,18,46] remains a serious obstacle in resolving Western vs non-Western differences in interpreting ethical standards. For example, how should consent be operationalized in societies that do not share Western constructions of autonomy?[14,16,18] How do different values influence the judgments made regarding the justice of the distribution of burdens and benefits in a particular study?[13,18,21,46] For research located in a developing country, US IRBs may be at a substantive disadvantage, having little familiarity with some of the key contextual issues in a developing country needed for assessing the ethical standing of a study.[13,16] Indeed, IRB members may have little if any knowledge about people who enroll in studies, whether in developing or developed countries.[17]

Arguments that it is "ethical imperialism" for outsiders to dictate ethical standards to African researchers and IRBs[12,13,14,47] are correct in drawing attention to uneven power relations between Northern and Southern institutions and researchers. However, such arguments ignore the heterogeneity that exists within countries, within committees, between researchers and communities, and among researchers and among communities. Moreover, the use of these arguements as a sole criterion for ethical justification of studies represents a false "procedural defense"[13] that opens the door further to the internalization of power differentials within the work of IRBs, rendering them more vulnerable to exploitative practices. Adherence to study procedures is a necessary but insufficient condition for the ethical conduct of a study,[13] as much in developed as in developing countries.

Finding an institutional system for ethical oversight that is able to account for all morally relevant factors particular to a local situation[46] without imposing "Western" rules, and in a way that affirms the agency of vulnerable participants, is hugely challenging. One suggestion to address cross-cultural differences in interpreting ethical principles has taken the form of a negotiated ethical standard that recognizes the "important truths" reflected in both approaches based on moral relativism and those based on moral fundamentalism.[16] However, even in its careful algorithm seeking to adapt "Western standards" to best protect the interests of local study populations, the core requirement is still to "satisfy Western standards of respect for persons, beneficence, and justice," which implies that "the sponsoring IRB should have the last word on whether the protocol is approved."[16]

MAKING THE DIFFERENCE

What, then, can be done? The work of IRBs in both developed and developing countries could be greatly facilitated by the establishment of effective and timely independent mechanisms for monitoring the conduct of research[8,18,28,48] and the availability of whistle-blower mechanisms to protect individuals who identify system failures.[18,48] Increasing the transparency of IRB decisions by opening IRB meetings to members of the public[8,14,28] and allowing public access to records of IRB decisions could be effected without compromising proprietary information or professional integrity. Most importantly, expanding IRB membership to include participants specifically drawn from vulnerable communities[14,28] would contribute significantly to critical and challenging perspectives being heard, which could also ensure the incorporation of "particularity into the review process."[17]

Of course, community participation is fraught with complexities; it may end up that only the most powerful—or minority—voices in heterogeneous communities are heard,[16,37] particularly where communities lack the infrastructure or organization to manage outsiders' requests for participation.[16] Recruitment of "lay" participants tends to privilege participants of higher educational and social standing,[16,17] and there is evidence that nonscientist members tend to be less active and to lack influence in ethical review processes.[14,17] Therefore, expanding IRB membership to include significant participation from groups that include vulnerable populations will be effective only if complemented by active steps to empower nonmedical participants in the review process.[35] Complementary to general calls for ethical training of developing country research ethics committees[6,18,43,46] should be measures that enhance nonmedical participants' understanding of how to organize themselves to offer ethical input that "empower[s] citizens to understand and utilize their potential for participating."[17] Moreover, such training must be situated within a context of policy and legislative changes to strengthen the role of civil society in ethical oversight.

The concept of vulnerability has been extended to apply to governments in developing countries, in recognition of the growing inequities generated by the process of globalization and the implications for health-related research.[49] Is it ethically tolerable that only 10% of global

spending on health research is directed toward diseases that contribute 90% of the global burden of disease?[50] And is it the task of the IRB system to address what Benatar[18] has called "macro issues"—the best interests of whole populations and science that concerns itself with the amelioration of "the miserable conditions in which the majority of the world's population live"? A narrow view might regard the IRBs' responsibilities as solely to protect human subjects from the risks posed by their participation in research.[14] However, such an exclusive focus is to lose sight of the broader challenges facing public health research. Vulnerable groups, vulnerable communities, and vulnerable countries will remain passively "in need of protection" until they gain the type of agency "that locates organized and active communities at the center as initiators and managers of their own health."[33] The process of ethical review in public health research must facilitate such agency if it is to address effectively the ethical dilemmas currently emerging in collaborative international research. ■

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This article was accepted April 18, 2002.

Acknowledgments

The Fulbright Foundation and the Takemi Program at the Harvard School of Public Health provided support for this work.

The comments of Louis Reynolds, Marietjie de Villiers, and Peter Lurie are gratefully acknowledged, as is the encouragement and support of Sofia Gruskin in the completion of this work.

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