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Assuring Adequate Protections in International Health Research: A Principled Justification and Practical Recommendations for the Role of Community Oversight

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Assuring Adequate Protections in International Health Research: A Principled Justification and Practical Recommendations for the Role of Community Oversight

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The analysis presented here lays out the ethical warrants for requiring community oversight of health research conducted in international settings. It reviews the inadequacies with the current standards of individual informed consent and research ethics committee review, and then, shows how a broader population-based public health perspective raises new demands on justice involving due consideration of the rights, harms and benefits to the community as a whole. As developed here, an ethical standard that requires community oversight of health research is justified on three principled grounds: respect for community autonomy and their right to self-determination; due consideration of the consequences of the research for the community as a whole; and, a more complete understanding of human autonomy. The paper concludes with practical recommendations regarding the composition of Community Advisory Boards to ensure that they have legitimate decision-making authority in diverse socio-cultural contexts.

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Introduction

Since the conduct of the controversial HIV–perinatal transmission trials in the early 1990s, debates have raged about the ethics of international health studies. In that research, pregnant women in low-income countries were given low doses of AZT to determine whether a less expensive alternative could be developed to prevent mother-to-infant transmission of HIV (Angell, 1997, 2000; Lurie and Wolfe, 1997). The research raised serious questions about the potential for exploitation and the adequacy of present protections for participants in international health research.

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In response to these controversies, a number of bioethicists have recently issued calls to mandate com-

munity involvement in decision-making about the conduct of health research (Weijer and Emanuel, 2000; Emanuel *et al.*, 2004; Brody *et al.*, 2005). One major concern raised by these analyses is whether Research Ethics Committee (REC) reviews and individual informed consent provide sufficient ethical safeguards in all contexts (Macklin, 2004).

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Key issues left unresolved by these calls are both the theoretical foundation that could provide the ethical justification for community monitoring and practical strategies for instituting an oversight process with legitimized authority. To advance the development of sound context-appropriate ethical standards, this paper presents a principled justification for the ethical assessment of international health research protocols by community representatives. In addition, recommendations

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regarding a feasible process for achieving community oversight are provided.

105 From the outset, it is important to address potential concerns that requiring an additional layer of review might impede the timely conduct of research (Berkley, 2003; Dawson and Kass, 2005). A vastly disproportionate share of the world's research resources is now allocated to studies on diseases that affect only a minority of the global population (Global Forum, 2004). Additional review requirements on international health research would be unjust if the net result served only to decrease access to the benefits of research further for the majority of the world's population.

115 Our view is that, requiring another level of review is necessary, not only to ensure ethically appropriate oversight, but also to facilitate the conduct of research by building trust in its safety and importance. In Western industrialized nations, there has been a 'paradigm shift' in public attitudes toward research participation, where the weight of concerns has shifted from apprehension about the risks of research participation to an appreciation of the potential benefits (Kahn *et al.*, 1998; McCarthy, 1998; Powers, 1998; Buchanan and Miller, 2006a). With the onset of the AIDS epidemic, the urgent need for effective treatments led many people to view research participation not as a pernicious threat, but as an opportunity to obtain the most scientifically advanced therapies possible. Since community monitoring should reduce the threat of exploitation and thereby increase trust in its potential benefits, specifying clear policies with respect to the purpose and parameters of community review should bolster confidence among potential research volunteers, and thus facilitate the conduct of research in these settings.

130 The paper starts with a synopsis of concerns that have been raised about the processes of individual informed consent and REC review. We then examine recent issues that have emerged from the field of public health ethics regarding the adequacy of currently accepted ethical review procedures, which were designed primarily to monitor clinical treatment trials, and growing recognition of the need to take into account population protections. Building on that framework, we present the ethical rationale for community involvement in assessing the ethical conduct of health research. Community oversight refers to a process of engaging community members equitably in monitoring health intervention research to ensure that ethical standards are upheld and the interests of community members protected. The paper concludes with practical recommendations regarding issues of representation to ensure fair community participation in monitoring health research.

Problems with Individual Informed Consent

155 A number of concerns have been raised about the adequacy and appropriateness of the individual informed consent standard in the context of international health research. These concerns include: the definition of 'informed' and criteria for assessing its attainment; the cultural appropriateness of individualistic decision-making processes; concerns about the priority of individual autonomy over other moral considerations; questions about the utility of individual informed consent *per se*; and, finally, reconsiderations of the overarching purpose of informed consent requirements.

160 Faden and Beauchamp (1986) make a distinction between 'philosophical' and 'policy-oriented' definitions of informed consent. A philosophical definition refers to a substantial understanding of the overall research process and its implications for human interests. A policy-oriented definition refers to the legal requirements enumerated in state law, such as the US Code of Federal Regulations (45 CFR 46.116(c) and 45 CFR 46.116(d)), which denotes eight elements (see box) that must be presented in written informed consent documents.

Eight Elements of Informed Consent

180 The eight required elements of informed consent that have been defined by US federal regulations [45 CFR 46.116(c) and 45 CFR 46.116(d)] are

- 185 1. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental
- 190 2. a description of any reasonably foreseeable risks or discomforts to the subjects
- 195 3. a description of any benefits to the subjects or to others which may reasonably be expected from the research
- 200 4. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subjects
5. a statement describing the extent, if any, to which confidentiality of records identify the subjects will be maintained
6. for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if

- 205 so, what they consist of, and where further information may be obtained
- 210 7. an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subjects
- 215 8. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subjects is otherwise entitled, and the subjects may discontinue participation at any time without penalty or loss of benefits to which the subjects is otherwise entitled.

220 While some legal provisions are designed to foster the conditions in which the substantive philosophical ideal can be attained, there are currently no established standards or criteria for determining the degree to which individuals truly understand what their participation entails.

225 Critically, there is a much greater distance between the philosophical ideal and the reality of individual comprehension in contexts where participants may lack formal education, be illiterate, live in poverty, be malnourished or face other stressful life conditions. Furthermore, researchers and others have noted that many languages do not have words or equivalent concepts for basic terminology such as 'research' or 'hypothesis,' let alone more technical scientific language such as 'placebo,' 'false positives,' and 'randomization' (Ekunwe and Kessel, 1984; Bayer, 1998; Moodley, 2002; MacQueen *et al.*, 2004; Molyneux *et al.*, 2004; Dawson and Kass, 2005). More broadly, many socio-cultural conceptual frameworks regarding the etiology of disease are incongruent with Western scientific explanations. In such contexts, while the eight elements of informed consent can perhaps be satisfactorily explained to potential participants (thus fulfilling the policy-oriented definition of informed consent), it is difficult to maintain that they have a proficient understanding of the nature, goals and risks of the research, which is fundamental to providing one's permission for researchers to proceed with the experiment. The common requirement that informed consent documents be written in plain language fails to address this important ethical problem.

250 Issues have also been raised about the imposition of Western norms of individual decision-making in contexts where such practices are foreign (Moodley, 2002; Dawson and Kass, 2005; Woodsong and Karim, 2005). The (Western) concern that others may exert undue influence may be based on the questionable assumption that the interests of the individual and the community

are inherently in conflict. In different cultural contexts, however, social relationships may be understood to be (at least partially) constitutive of one's identity; for example, the traditional African concept of 'ubuntu' has been defined as 'umuntu ngumuntu ngabantu' – 'you are who you are because of other people' (Biko, 1978). In the West, Sandel (1982) has described this broader self-understanding as a shift from thinking in terms of 'I' to 'we,' where one's sense of identity is bound up with the realization of a common way of life, the reproduction of valued social practices, and the sense of community in which one takes pride. In such contexts, not only are the interests of the individual and the community commonly perceived to be synonymous, but the notion that persons *should* make decisions independently, divorced from their social relationships, is a patent violation of accepted social norms. The current push for requiring individual informed consent in all contexts appears to be based on the tacit assumption that low-income countries are traditional societies that have not yet attained a modern, enlightened mindset, in the sense of the emancipation of the individual and valorization of individual rights (Mamdani, 1996). This trajectory is apparently presumed to be unilinear, universal and normal, rather than historically contingent or problematic, where the possibility of developing ethical norms along divergent lines might remain open. In light of these opposing considerations, the proposed standards presented here seek to achieve an appropriate balance between concerns about the potential for individual exploitation and the need for respecting beneficent cultural practices.

Critics have also questioned the near-absolute priority placed on the principle of respect for individual autonomy (from which the mandate for individual informed consent derives) over other moral considerations in the brief history of bioethics, as it developed in the US (Weijer, 1999; Rhodes, 2005). As Levine (1986) notes, the work of the 1978 US National Commission must be seen in context of its time and thus can be faulted now for its overemphasis on individual rights, to the neglect of obligations to the larger community. More strongly, Taylor (1985) has assailed the central tenet of liberalism, which he calls the 'primacy of rights,' referring to the moral view that individual rights have priority over all other moral considerations, such as obligations to contribute to the collective good. However, as the well-known 1905 US Supreme Court ruling in *Jacobsen v. Massachusetts* made clear, the principle of individual freedom cannot take absolute precedence over other moral principles. On the contrary, since the potential benefits to society and future generations are significant, other ethicists have taken the position that citizens *should* be morally obligated to

participate in research, in order to advance the common good, distribute risk equitably, and mitigate the free-rider problem (Caplan, 1984; Harris, 2005; Orentlicher, 2005; Rhodes, 2005).

Moreover, Truog and his colleagues (Truog, Robinson, and Randolph, 1999) have questioned the ‘blind insistence’ on obtaining individual informed consent. As they state, ‘There is little evidence to support the claim that informed consent, as currently practiced, provides protection against the exploitation of patients in research. Studies have shown that patients rarely have an adequate understanding of consent forms and often do not understand the meaning or implications of randomization.’ In its stead, they propose the use of a ‘reasonable person standard’, which could be achieved by ‘the involvement of the community through the representation of people without medical backgrounds’ on ethical review boards.

Finally, while great emphasis has been placed on the need for demonstrating respect for individual autonomy, another key purpose of informed consent has centered on reducing inequalities of power and knowledge (President’s Commission, 1982). As described below, when novel interventions hold the potential for affecting the community as a whole, there is a critical need for putting processes in place that reduce inequalities of power between research institutions and communities targeted as potential pools for participant recruitment and eventual dissemination. Current interest in USA in Community-Based Participatory Research (CBPR) appears to be directly related to reducing power differentials and mitigating these ethical concerns (Wallerstein *et al.*, 2005; Buchanan *et al.*, 2007). In many types of research, it is the community as a whole that both bears the risks and stands to gain the potential benefits of newly developed interventions. New policies are thus imperative for redressing power imbalances and giving due consideration to the community’s right to self-determination.

Problems with Research Ethics Committee Review

A number of concerns have also been raised about the adequacy of the research ethics review process, including the composition, training, scope of authority, accountability and allegiance of review boards (Emanuel *et al.*, 2004). The following analysis focuses primarily on the US system of Institutional Review Boards (IRBs), and thus is limited to USA and other countries that have adopted similar systems of research ethics review.

In a policy formulation that has since been called into question, the US Congress passed regulations that cre-

ated a decentralized system of ethical review boards and that enumerated only minimal requirements regarding the composition of local IRBs. According to these regulations, IRBs must have at least five members ‘with varying backgrounds to promote... sensitivity to such issues as community attitudes’, ‘at least one member whose primary concerns are in non-scientific areas’, and ‘at least one member who is not otherwise affiliated with the institution’ (US 45 CFR 46.116). In practice, this has generally meant that institutions appoint one outside community member to sit on a board with 10–12 other members recruited from the ranks of experienced researchers employed by the university or research organization. As a result, Marshall (2007, p. 17) notes that ‘most are dominated by scientists who are responsible for reviewing the research protocols of colleagues and friends.’ US regulations do not provide any further guidance with respect to how members should be selected.

Until quite recently, there were no requirements in the US regarding the training or qualifications of IRB members. In the wake of widespread public outcry over the deaths of two research participants several years ago, however, the US Office of Human Research Protections instituted regulations that now require all researchers to gain certification in research ethics; this training is generally provided by new, on-line certificate programs, which take about 1 hour to complete. Otherwise, IRB membership is open to people with no specific knowledge, training or experience in conducting ethical reviews.

Regarding the scope of their authority, one major concern is that IRBs in USA derive their regulatory power from the conditions attached to federal funding; hence, privately funded research does not fall under the purview of IRB review but fall only under FDA inspection as it pertains to applications for licenses to sell new drugs or devices (Berg *et al.*, 2001). Currently in USA, the volume and investment of health research conducted by the pharmaceutical industry exceeds that of publicly funded research (Bodenheimer, 2000; Rettig, 2000). While many private corporations have voluntarily adopted the federal code of ethics regulating health research, they are not mandated by law. In a recent report, Levinson (2007) found that FDA regulators do not know how many clinical trials are being conducted, audit less than 1% of the testing sites, and have only 200 inspectors to police an estimated 350,000 testing sites. Oversight of drug trials funded by private pharmaceutical companies in international settings is even less well monitored.

Critics have also pointed out that IRBs are accountable to no one, except the courts in instances when the institution is sued by participant(s) to redress allegations of harm (Berg *et al.*, 2001). Presently, if researchers,

410 participants, community members, or other third parties disagree with the decision to approve or not to approve the research by the IRB, or with any stipulations that are attached or not attached for modifying the protocol, there are no provisions or standing body for appeal where they can plead their case and seek remediation.

415 Finally, largely as a result of the cumulative impact of the above factors, concerns have also been raised about the allegiance of IRBs. Faced with growing fears of litigation and liability, several commentators have noted that IRBs appear to have adopted a narrow 'regulatory model', focusing on meeting the letter of the law (e.g., ensuring that all eight elements are spelled out in an approved consent form), which appears to be aimed primarily at providing legal protection for the institution (London, 2002; Dawson and Kass, 2005). Capturing these
420 concerns, in ruling on a lawsuit pressed by two families against Johns Hopkins' Kennedy Krieger Institute in their controversial Lead Paint Abatement Trial, the Maryland Court of Appeals issued a blistering critique that referred to the Hopkins IRB as 'in-house agents' who were not 'as sufficiently concerned with ethicality of the research as they were with the success of the experiment' (Maryland Court of Appeals, 2000).

435 In succinct summary, the Office of the Inspector General of the US HHS issued a report on IRBs that concluded: 'IRBs are reviewing too much, too quickly, with too little expertise; conducting minimal continuing review of approved research; facing conflicts of interest that threaten their independence; and providing little training for clinical investigators and board members' (Brown, 1998).
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An Emerging Public Health Ethics Perspective

445 In recent years, there has been growing attention to ethics from a public health perspective (Kass, 2001; Childress *et al.*, 2002; Buchanan and Miller, 2006b; Buchanan and Miller, 2006c). Where medicine focuses on individual health, public health is concerned with the health of the entire population. Thus, in contrast to a fiduciary duty to the individual patient, public health ethics is founded on societal responsibility to protect and promote the health of the population as a whole. The moral obligation to protect population health holds important implications for identifying appropriate ethical norms to guide
450 research ethics, including that conducted in international settings.

The emerging public health ethics framework builds on a line of reasoning that has focused on the role of justice in evaluating the conduct of health research; in so

460 doing, it gives greater weight to concerns for the collective good relative to the current emphasis on individual rights (McCarthy, 1998; Kass, 2004). As mentioned, observers have noted a 'paradigm shift' in the evolution of public concerns about health research in USA, moving from a preoccupation with protecting participants from
465 harm to an interest in improving access to clinical trials (Powers, 1998). In the historical context of public outrage at the egregious misconduct of researchers at Tuskegee and other research scandals, the Belmont Report concentrated accordingly on justice considerations internal
470 to the research process (National Commission, 1979). Although concerns about distributing the benefits of research fairly in society are presented, the report focused primarily on protecting research participants from harm and exploitation. Over time, however, the weight of public
475 moral concerns has shifted, from worries about the risks of participating in research to greater recognition of the potential benefits. For example, the research community once thought that women should be excluded from health research due to a perceived greater vulnerability. Later, they recognized that it was unfair to conduct
480 research only on men, since the benefits of the research for women would remain uncertain and justice demands that the benefits be distributed fairly (Dresser, 1992; Kahn *et al.*, 1998; Weijer and Crouch, 1999). Thus, the inclusion of various population groups is now seen to be
485 obligatory. The demands of justice have expanded the range of parties that ought to be considered morally relevant beyond the participants alone in determining the acceptability of the research under consideration.
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From a public health perspective, the range of risks and benefits that are considered ethically significant must be extended to take into account the social impact of the research (Buchanan and Miller, 2006b, 2006c). In ethical
495 reviews, research is ultimately justified on the basis of its social value; research without any social or scientific value cannot be justified because it would place participants at risk for no reason, that is, without compensating social benefit (Emanuel *et al.*, 2000). To determine the social
500 value of research, a comprehensive analysis should then consider not only the risks and benefits to the research participants themselves, but also the benefits and risks to the population as a whole. Adopting a public health perspective thus entails the moral obligation of researchers to consider the interests of the community as a whole as
505 well as the individual research participants.

A public health perspective on research ethics is based on due recognition of the inherently social purpose of health research. The evolution of ethical standards regulating health research (which has been dominated historically by clinical medical research) can be traced directly
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to the Hippocratic Oath and the decree that physicians have an unqualified duty of fidelity to each individual patient (Miller and Brody, 2003; Miller and Rosenstein, 2003). Due to its historical development within the context of clinical medical trials, the currently prevailing research ethics framework has focused virtually exclusively on protecting and benefiting individual participants, to the neglect of weighing the consequences of the research for the community as a whole. While this standard may be appropriate in the context of providing medical care, research results have implications for the whole of society. Unlike the clinical context of providing personalized doctor–patient care, in the context of conducting research, the moral consequences of inadvertently inflicting harm—of conducting a trial that turns out to increase risk of serious morbidities or death—extend beyond the individual to the community at large. The consequences of the conduct of the research include, for example, the perceived trustworthiness of health research, the perceived value of health science, and the likelihood of community-wide adoption of a new intervention (e.g., HIV vaccine), should one eventually become available. In contrast to basing standards on ethical norms appropriate to providing individual medical care, a public-health perspective provides the theoretical foundation for incorporating due consideration of community interests in setting ethical standards for the conduct of health research.

The Ethical Justification for Community Oversight

As developed here, an ethical standard that requires community oversight of health research is justified on three principled grounds: respect for community autonomy and their right to self-determination; due consideration of the consequences of the research for the community as a whole; and, a more complete understanding of human autonomy. Respect for community autonomy entails the fundamental right of community members to exercise a meaningful role in determining the conduct of research that affects their lives (Buchanan *et al.*, 2007). Vaccines, for example, are designed not only to protect individuals but to protect the community as a whole, including unvaccinated individuals via herd immunity, but this can be achieved only if a large proportion of the population gets vaccinated. Requiring community review is warranted on the basis that communities are distinguishable entities with interests that are distinct from individual interests and that must be protected accordingly (Weijer, 1999; Brody *et al.*, 2005).

The principle of respect for community autonomy acknowledges that the community has a non-negligible stake in the decision to conduct research on its membership. The community, for example, has a collective right to participate in decisions regarding the use of limited fiscal or social resources (e.g., health clinic personnel and facilities). Since justice demands that resources be allocated fairly, the community must have a say in determining whether scarce resources are being diverted from more pressing priorities or result in other potentially important opportunities being lost (Brody *et al.*, 2005). This right encompasses protection against exploitation, where exploitation is defined as one party taking unfair advantage of another. As Wertheimer (1996) explains, for exploitation to occur, it is not necessary for one party to harm another—only that the benefit to one side be disproportionate compared to the benefit to the other. Given the enormous power of the pharmaceutical and academic health research enterprise, it is critically important to establish a body with sufficient standing to set fair terms of participation and protect against the potential for exploitation. For our purposes here, it is worth recalling that, etymologically, the word ‘autonomy’ originally referred not to individuals but to relationships among city-states and communal independence from imperial domination (Hill, 2001).

In addition to problems of diverting scarce resources and exploiting community assets, the community bears other types of risks that cannot be reduced to the individual level. The success of many health interventions depends on their adoption by the population. To the extent that the conduct of the research reinforces negative attitudes (e.g., human beings as ‘guinea pigs’), it undermines trust in Western health science, which will impede the adoption of effective interventions. Likewise, the community as a whole must understand the implications of participation in certain types of research; seroconversion due to participation in HIV/AIDS vaccine trials, for example, has high potential for family, workforce and community disruption if there is not a widespread understanding of its significance. The use of public resources also calls for public accountability, a standard that transcends individual consent and is not now part of REC review. If researchers claim that making referrals to a research project will not take an inordinate amount of staff time, a body is necessary to monitor whether it is interfering with the timely care of patients waiting for an appointment.

The community should also have the capacity to determine the fair terms of benefits in return for their participation. The so-called ‘ancillary duties’ of researchers have received increasing attention in recent years, taking

up questions about the extent of researcher obligations, for instance, to share the results with the community, to offer related health services (e.g., HIV testing and counseling), and to provide medical care for the participants (Belsky and Richardson, 2004; Macklin, 2004). The key point here is that the scope of fair, nonexploitative benefits can be decided and endorsed neither by individual participants nor by research institution-based RECs but only by the community itself.

Finally, the ethical justification for community oversight can be established on the basis of a more complete understanding of human autonomy, in particular, as it relates to conceptualizing human identity. In liberal Western societies, starting in the writings of Hobbes and Locke, conceptions of personhood have evolved in the direction of a radically individualistic, atomistic view of the human condition (Taylor, 1985). In this line of thinking, society and social cooperation come to exist only for the instrumental pursuit of individual interests, and social norms are perceived to be fundamentally antagonistic towards the unfettered quest for maximizing personal pleasure. This set of assumptions about human identity presses toward the position that the only right that warrants recognition is the right of individuals to choose not to participate.

In contrast, a number of other schools of thought, including communitarianism, feminism and non-Western traditions of communalism, have underscored the incoherence of such assumptions, noting that an individual's sense of identity is inextricably bound up with social relationships and membership in groups (Weijer, 1999; Lindegger and Richter, 2000; Moodley, 2002). This broader view gains traction starting with the fact that any expression of self-understanding can be articulated only in terms provided by a situated linguistic community. It is only through participation in the life of a community that one gains access to and learns the linguistic practices that make possible perceptions of self and the value of certain activities and ways of life. The very language used for claiming that one wants to do something for some reason (e.g., choosing to participate in research or not) presupposes membership in a community in which those terms have meaning. But if one can perceive certain desires only within a given cultural context, then one must have an obligation to preserve the larger social grouping and ensure its continuing vitality, for otherwise the community that reproduces the concepts that enable one to make sense of one's decisions (e.g., by discerning value in select activities) would be lost. As Taylor (1985) and others have argued, we find here a duty to protect the community in which membership provides the capacity

to find satisfaction and fulfillment in proffered ways of life.

On the other side of this same coin, individuals are systematically identified by their classification into social categories; thus, individual agreements to participate in research inevitably raise questions about stigmatizing identifiable social groups (Brody *et al.*, 2005). For example, the higher prevalence of HIV/AIDS found in Africans, which provides the primary justification for targeting Africans in AIDS prevention research, has been widely assumed to be attributable to promiscuous sexual practices, rather than other possible explanations (Epstein, 2007). In multiracial, multiethnic or otherwise diverse societies, the targeting of one group over another carries many meanings, about which the community identified for inclusion should be entitled to decide whether they find the implications of their participation acceptable. Hence, in direct parallel to the justification for respect for individual autonomy, the community has a right to protect itself against potential injuries to its self-understanding and self-respect (Taylor, 1992).

If one accepts that communities per se deserve protection and have a right to self-determination, then standards must be set to ensure community engagement in monitoring the conduct of health research. Based on the principle of community autonomy, we argue that the community is the best judge of its own interests; this position is analogous to the principle of individual autonomy, where respect is afforded the individual's right to determine his or her own best interests. Hence, a process must be put in place whereby the community can meaningfully deliberate about the implications for its own interests of participating in a research project. One process for achieving such community oversight is establishing Community Advisory Boards (CABs) (Buchanan *et al.*, 2007). Under the conditions specified below, CABs provide a sound mechanism for securing community ratification indicating that the research goals are valuable and methods acceptable to the community, before the research is allowed to proceed.

Practical Recommendations for Securing Legitimate Community Oversight

Currently, many CABs are set up for the express purpose of gaining access to groups targeted for recruitment purposes, and individual CAB members are identified and selected by the researchers for their 'gate keeping' ability to open doors and provide entry to these populations (Cox *et al.*, 1998; Strauss *et al.*, 2001; Morin

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715 *et al.*, 2003; Reddy *et al.*, 2007). In contrast, once the
 ethical imperative for community oversight is acknowl-
 edged, then two key issues must be addressed. First, the
 body charged with responsibility for assuring commu-
 nity oversight must be vested with legitimate authority
 720 duly recognized by the community affected by the re-
 search to make decisions on their behalf. The second issue
 of critical concern here is specifying how community is
 defined.

725 While space constraint requires precluding a full dis-
 cussion, in general, the two most common sources of
 legitimate civil authority are divine right and demo-
 cratic procedures (Weber, 1915/1946; Friedman, 1990;
 Raz, 1990; Weijer and Emanuel, 2000; Richardson, 2002).
 To set up bodies with valid decision-making power, ex-
 tant community norms and practices cannot be cir-
 cumvented; unless decisions are made by a recognized
 source of legitimate authority, they will not be consid-
 ered binding on community members. Thus, it is es-
 sential that researchers work within the existing system
 735 of power and authority at both the national and local
 levels.

740 The second major issue is the question of defin-
 ing a community. A starting point for this discus-
 sion is the well-known distinction between geographic
 and sociological definitions of community (Clark, 1973;
 Plant, 1974). Health research projects have geographic
 locations¹; the catchment area(s) for participant recruit-
 ment are defined in the research protocols. The re-
 search protocols will also specify the inclusion and exclu-
 sion criteria for participation, which provide the criteria
 745 for defining community sociologically (e.g., ethnic, cul-
 tural, linguistic, religious, gender, age, sexual orientation,
 racial, etc.).

750 Thus, we see two major sources of authority (leaders
 with inherited power and democratically elected repre-
 sentatives) and three major constituencies (existing au-
 thorities, residents, and potential participants) that must
 be acknowledged when vesting CABs with legitimate au-
 thority. Based on the preceding considerations, we make
 755 three recommendations with respect to instituting com-
 munity oversight of international health research.

760 The first is that national health ministries and national
 legislatures enact policies that require community review
 of health research. These national policies should specify
 the type of authority that will be recognized in consti-
 tuting CABs, the level of geographic specificity, and the
 types of sociologically defined communities that merit
 protection against potential exploitation, and thus, rep-
 resentation on CABs. The national assembly should also
 765 establish an appeals process for groups not previously
 recognized to petition for inclusion.

The second recommendation is that the make-up
 of CABs should accord with existing social practices
 for making communally binding decisions.² In contexts
 where customary inherited authority is recognized, re-
 searchers must respect their executive agency and gain
 770 their approval and authorization to proceed. The ruling
 authority should be empowered to designate an agent or
 agents who will provide permission, approval and agree-
 ment on the terms and conditions of local participation.
 National legislation should stipulate whether any fur-
 775 ther community review is required at the local level. In
 other locales, there may be well-established practices of
 democratic decision-making and representation. There,
 we recommend that CAB members should be elected by
 both geographic and sociological community members
 780 (see below).

Many countries have coexisting systems of rule by
 inherited power and democratic plebiscites. The South
 African Constitution, for example, provides one model
 for achieving an appropriate balance between political
 785 rights to vote for representatives to legislative bodies and
 recognition of the authority of traditional leaders on mat-
 ters at the local level. In such contexts, we recommend
 that both sources of communal authority be consulted.
 The issue of whether the respective approval processes
 remain separate, or be combined, leads into our final
 790 recommendation.

795 Third, we recommend that one of the two following
 models of representation on CABs be adopted at the lo-
 cal level. In Model A, the CAB is composed of equal
 numbers of representatives of the traditional authorities,
 democratically elected residents, and participant repre-
 sentatives. The CAB will deliberate as a whole to de-
 termine whether the research should be approved, not
 800 approved, or how it should be modified to make it ac-
 ceptable to each of the three respective constituencies. In
 Model B, there are two separate CABs, one composed of
 traditional authorities, and the other of equal numbers
 of geographically representative residents and targeted
 805 participants. Since many sociological communities may
 not be formally organized, we recommend soliciting vol-
 unteers. If more people volunteer than there are seats on
 the board, we recommend a process of random selection
 to ensure fairness.

810 Discussion

815 The ethical foundations of health research are currently
 in a state of disequilibrium, both in international settings
 and in industrialized nations. Appeals to the established
 practices of Research Ethics Committee review and indi-
 vidual informed consent are inadequate, unquestionably

in developing countries, but largely so in developed nations as well. A growing appreciation of the impact of health research on the community as a whole is precipitating a reassessment of the relative weight and understanding of the different ethical principles involved in protecting populations from exploitation. We have demonstrated here how new claims on justice oblige that the rights, harms and benefits to the community as a whole be taken into account in deliberations about the ethical propriety of research in international settings, but the analysis holds equally important implications for research in USA and other industrialized nations. To regain reflective equilibrium, an ethical framework based on a public health perspective yields a more satisfactory balance between the goals of gaining new knowledge and providing adequate protections in conducting health research for countries across the entire development spectrum.

An ethical standard requiring the establishment of CABs raises a host of issues, some of which cannot be decided a priori but will have to evolve pragmatically through experience and practice. One crucial issue that needs to be addressed immediately is the operational independence of CABs. Currently, CABs are largely set up and run by the individual research projects, which are responsible for providing trainings or other resources for their operations. This relationship of dependence is untenable. In consultation with community representatives, national governments and international sponsors need to begin discussions about sufficient set-asides to ensure the CABs' functional independence. The level of resources necessary to make CABs operationally effective and the responsibility for its provision are issues that will likely vary from setting to setting, but must be addressed as policies instituting their establishment are enacted.

The full scope of powers of CABs may also evolve in practice, probably in relation to the setting and type of research proposed (e.g., experimental versus epidemiological). At a minimum, CABs should have the same scope of powers of Research Ethics Committees in conducting prior review of research protocols, and stipulating provisions to meet recognized ethical standards. But over time, we envision that CABs play an appropriately more active role in securing greater community involvement, in making the monitoring of the research in progress more consistent, and in demanding greater accountability after the research has formally been completed. For example, there are already evolving practices of CABs calling for more in-depth assessments of community perceptions of the acceptability of the goals and methods of research, through processes such as community forums, key informant interviews, focus groups, community surveys,

and so on. The reliance on such practices is now seen as part and parcel of community empowerment, respect for human rights, support for self-determination and the promotion of civic responsibility for the justice of extant living conditions in the population. It is important that these practices be periodically reviewed and the best practices codified into policy statements.

In contrast, one can readily imagine proposals to empower CABs to waive the right to individual informed consent (or assent), by appealing, for example, to new forms of proxy decision-making. Given the long track record of historical abuses, we cannot find support for this position at this time. In conclusion, the preceding analysis has shown how community oversight is ethically imperative to protect against exploitation, to minimize potential misunderstandings about the intent of the research, and to ensure fair terms of cooperation and standards of care.

Notes

1. The growing use of internet-based research belies this statement to some extent, suggesting a seemingly boundary-less domain. However, since the issue of concern here is specifying an identifiable community, questions raised by the use of the internet may be moot, as any meaningful sampling process capable of being generalized will require the same specification of geographic and sociological parameters (e.g., physicians practicing in the US).
2. The issue of conducting research in nations with despotic regimes and a history of human rights abuses is complicated. To the extent that CABs are permitted because they are perceived as politically neutral and non-threatening, they may foster the growth and vitality of civil society, which may prove to be beneficial for the country in time. Thus, we would not dismiss the possibility out of hand.

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