JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 3, No. 7, July 2007 "Can You Handle the Truth?"

A Right to Benefit from International Research: A New Approach to Capacity Building in Less-Developed Countries

By Mary Terrell White

Abstract

This article proposes a means by which benefits provided in international research collaborations might be employed to strengthen health care, research, and other capacities in less-developed countries. The Declaration of Helsinki and CIOMS Guidelines define certain expectations of benefits, but these requirements are ambiguous, logistically problematic, and studies suggest they are inconsistently upheld. Drawing on the principle of respect for persons, a right to benefit from hosting externally-sponsored research is proposed. This right guarantees host communities benefits of a certain value, the nature and use of which is controlled by indigenous personnel. Suggestions are made as to how implementation of this right, using structured incentives, may systematically promote capacity building in host communities.

Introduction

The inability of most foreign development assistance to effectively improve economies, health care, and education in African nations has long been recognized. The shortcomings of investments in global health have been recently characterized as lacking coordination, being tied to narrow interests, held hostage to political values and the whims of donors, and lacking measures of their efficiency or efficacy. By focusing on specific health measures, long-term comprehensive goals such as infrastructure development and capacity building are neglected. Most importantly, "Virtually no provisions exist to allow the world's poor to say what they want, decide which projects serve their needs, or adopt local innovations" (Garrett, 2007).

Some argue that the failures of foreign aid are due to fundamental cultural underpinnings of contemporary Africa rooted in the predominance of personal rule of "big men" over the rule of law and professional values, the extraction economies that diminish incentives to develop national infrastructures, and the absence of significant involvement of indigenous personnel in project design. As a result, development investments often fall prey to corruption and fail to develop local infrastructures and a professional class capable of maintaining development achievements (Leonard and Strauss, 2003, Chapter 1; Easterly, 2006, Chapter 1).

In this article, I propose a way in which international biomedical research may be used to strengthen local health care capacities and community infrastructure while simultaneously addressing some of these issues. This proposal emerges from a sabbatical I spent in Uganda where I observed many of the challenges to economic development as well as the opportunities international collaborations can offer individuals, institutions, and communities. International research is in many ways an ideal vehicle for development assistance as it involves long-term relationships between external and host collaborators. As outlined here, the goal of successful research partnerships would be to promote the development of local infrastructures and health care capacities, drawing on the leadership and skills of indigenous professionals. Central to this proposal is the establishment of the right of less-developed countries to benefit from hosting research. While Uganda provides the backdrop for my thinking, the development framework outlined here may be appropriate for most of the African continent and other less-developed countries globally.

In Part I, I review the benefits requirement for international research as articulated in the World Medical Association's (WMA) Helsinki Declaration (WMA, 2004) and the International Ethical Guidelines for Biomedical Research Involving Human Subjects developed by the World Health Organization's Council for International Organizations of Medical Sciences (2002, hereinafter CIOMS Guidelines). In Part II, I develop an ethical argument for establishing host countries' right to benefit from hosting externally-sponsored research, and conclude with suggestions as to how this right might be implemented.

International Research Guidelines and Host Country Benefits

In international research, less-developed countries provide a number of opportunities and services to Western researchers, including settings where certain diseases are prevalent, participants are easily found and are likely to be free of confounding medications, and where research can often be conducted more quickly and at lower cost than in developed countries. Depending on the type of research, host communities may provide support staff, space, and a variety of other resources. In return for these opportunities and services, external researchers are expected to provide certain benefits to their host participants and communities. These benefit expectations are delineated in the Helsinki Declaration (WMA, 2004) and the CIOMS Guidelines. Three forms of benefit are identified: 1) the responsiveness of research to host country needs and health care priorities; 2) the contribution of research to capacity building; 3) benefits to participants and host communities during and after a study is completed. The specific guidelines pertaining to each of these benefits are reviewed below, accompanied by data from a major study of American and international researchers that suggest the extent to which these principles are realized in practice.

Responsiveness of Research to Host Country Needs and Health Care Priorities

As in all medical research involving human subjects, externally sponsored research is expected to be responsive to the health needs of the subject population. The Helsinki Declaration (WMA, 2004) states: "Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research" (Article 19). The CIOMS Guidelines also affirm this expectation in the following statements:

> The health authorities of the host country, as well as a national or local ethical review committee, should ensure that the proposed research is responsive to the health needs and priorities of the host country and meets the requisite ethical standards. (Guideline 3)

> Before undertaking research in a population or community with limited resources, the sponsor and investigator must make every effort to ensure that the research is responsive to the health needs and the priorities of the population or the community in which it is to be carried out. (Guideline 10)

These guidelines clearly require that research be directed toward generating knowledge that will contribute directly or indirectly to some aspect of health care in the host community. The commentary for Guideline 10 adds that "responsiveness" includes an element of negotiation, and that any such negotiations must include host country representatives from various levels of government, the medical profession, the scientific community, and the subject population.

In 2001, the National Bioethics Advisory Commission published the results of a major study that explored the extent to which international research ethics guidelines are upheld in practice (hereinafter the NBAC Study). This study solicited perspectives of approximately 300 American researchers and 200 international researchers by means of surveys and focus groups (Kass and Hyder, 2001). Among the primary concerns of this study were the three types of benefits identified in research guidelines: responsiveness to host country needs, capacity building, and benefits provided during and after a study is completed. With regard to responsiveness, results were mixed. Although 87% of the US respondents claimed to include host collaborators in developing study design (Kass and Hyder, 2001, p. B-44, Table C.4.2), over half of both American and international respondents claimed as true the statement, "Research priorities of outside funding agencies that are funding the study are not congruent with the top priorities of the developing country" (Kass and Hyder, 2001, p. B-93). One international respondent added, "U.S. investigators have all the power, since they had the idea for the study, they wrote the grant . . . They therefore assume that they need to control all aspects of the study." (Kass and Hyder, 2001, p. B-44).

In a report on research conducted between 1993-1997 by the Uganda National Health Research Organization (2000; hereinafter, UNHRO Report), 99% of a total of US$11,683,660 spent on health research during this period was attributed to external sources (UNHRO, 2000, p. 19). The report also noted the following:

> The dependence on external funding sometimes leads to distortion of national priorities and uncertainties in planning. . . Foreign funding for research in the form of projects, especially short-term projects, has led to fragmentation of research programs and institutions and the imposition of foreign research agenda[s] on national priorities. . . Uganda researchers should be involved in the planning of externally funded health research projects so as to address priority areas of health research of the country. (UNHRO Report, p. 44-45)

This and the NBAC Study provide a very mixed picture of the extent to which host collaborators are included in research negotiations. But the widespread perception that a substantial amount of research is not addressing local needs suggests the negotiating strength of host partners may be limited.

The Contribution of Research Benefits to Capacity Building

The role of research benefits in capacity building is clearly recognized in CIOMS Guideline 20, which states the following:

> In externally sponsored collaborative research, sponsors and investigators have an ethical obligation to ensure that biomedical research projects for which they are responsible in such countries contribute effectively to national or local capacity to

design and conduct biomedical research, and to provide scientific and ethical review and monitoring of such research.

Capacity-building may include, but is not limited to, the following activities:

- Establishing and strengthening independent and competent ethical review processes/committees
- Strengthening research capacity
- Developing technologies appropriate to health-care and biomedical research
- Training of research and health-care staff
- Educating the community from which research subjects will be drawn

The commentary for this Guideline requires that the benefit contribution should be "proportional" to the magnitude of the study, specific objectives being negotiated with host-collaborators and included in the protocol.

In the NBAC Study, assessments of capacity building efforts focus on the involvement of host collaborators in research activities and infrastructure development. Most of the American and international respondents (80-98%) reported that host personnel were involved in research through training, involvement in study design, subject recruitment, obtaining consent, drafting manuscripts, and authorship of articles, with somewhat fewer participating in data analysis and grant writing (NBAC, p. B-44, Table C.4.2; p. B-96, Table D.4.8). Most respondents also reported that collaborations substantially contributed to infrastructure development, leaving trained personnel, medical, laboratory, or office equipment, computers or data management systems, and organizational structures for health care or research in the host country after the study was completed. Somewhat fewer respondents (40-50%) claimed buildings or laboratory facilities, power equipment, water systems, and vehicles remained (Kass and Hyder, 2001, p. B-45, Table C.4.3; p. B-96, Table D.4.9). What these data do not tell us is whether these benefits were negotiated, how well they were integrated into existing resources, and whether they were effectively used to improve health care and research capacities.

One significant consequence of externally-sponsored research that is overlooked in international guidelines is its impact on local hospitals and clinics (Edejer, 1999). Externally-funded researchers often employ indigenous health care and administrative staff who can serve as translators and provide clinical skills and administrative support. But in the effort to find and retain qualified staff, sponsoring researchers may offer salaries that far exceed those offered by government and NGO-funded health care agencies (Davey et al., 2006). While these opportunities are one of the benefits offered by externally sponsored research, the loss of skilled health care personnel in local communities can be profound. In Uganda, the UNHRO Report notes this loss as follows:

> If foreign funded research projects do not help to build indigenous research capacity, their externally imposed research priorities may overwhelm an already stretched pool of researchers, dissipating their focus on productivity. One of the major objectives of capacity building efforts is to create and strengthen a critical mass of human resources, capable of planning and implementing research projects that address national health needs. (UNHRO, p. 44)

An internal brain-drain, coupled with decades of loss of trained nurses and physicians to wealthier countries (Pond et al., 2006), may significantly handicap the ability of less-developed countries to provide care for their own people. How research staff should be recruited and compensated and host communities compensated for the loss of trained personnel merits consideration in study planning and design.

Benefits to Participants and Host Communities During and After a Study is Completed

Research subjects may also benefit from their participation, most often from access to health care and medications that are otherwise prohibitively expensive or unavailable. However, subjects may sometimes be harmed, either directly as a result of participating, or indirectly by developing dependence on a drug provided during a trial that when discontinued at the study's end is experienced as a harm. CIOMS Guideline 21 states the following:

> External sponsors are ethically obliged to ensure the availability of:
>
> - health-care services that are essential to the safe conduct of the research;
> - treatment for subjects who suffer injury as a consequence of research interventions; and,
> - services that are a necessary part of the commitment of a sponsor to make a beneficial intervention or product developed as a result of the research reasonably available to the population or community concerned.

The Helsinki Declaration similarly states, "At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic, and therapeutic methods identified by the study" (Article 30). A "Note of Clarification" is added:

> The WMA [World Medical Association] hereby affirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review. (WMA, 2004)

In the NBAC study, 47% of the U.S. researchers in less developed countries claimed to offer participants medical care in the form of disease prevention, diagnostic testing, or treatment interventions (Kass and Hyder, 2001, p. B-38). That the possibility of receiving health care may serve as an inducement to participate was recognized by 64% of U.S. respondents, while 33% felt that "participants have unrealistic hopes about personal benefit from participation" (Kass and Hyder, 2001, p. B-37). The question of whether consent in a less developed country can be either voluntary or informed in the sense that we expect in western industrialized countries is beyond the scope of this article. It is, however, carefully explored in the NBAC Study and elsewhere (Macklin, 2004; Kass and Hyder, 2001, pp. B-27-29, 81-82, 115-119; Loue et al., 1996; McGrath et al., 2001; Molyneaux 2004). Suffice it here only to note that in a context of poverty, where health care is limited or nonexistent, research may offer an attractive, if temporary, opportunity for participants to receive desired care.

Both the Helsinki Declaration and the CIOMS guidelines claim that research participants and/or host communities deserve some sort of health benefit after a study is completed. These expectations and claims raise numerous questions: What should this benefit consist of? If a research product, who is responsible for benefit distribution and medical follow-up, and who pays for the intervention and the infrastructure necessary for its distribution? Drugs for chronic diseases suggest the need for a longer term commitment than is necessary for short-term therapies; finding and training personnel to manage new medications takes time and money, and whether the benefits should go to the research subjects, the host community or an entire nation raises questions of cost, logistics, and equity. The CIOMS Guideline 21 speaks of making the product "reasonably available" to the host community, but years may pass between the conclusion of a study and the

development of a marketable product. Moreover, what it means to be "reasonably available" seems deliberately ambiguous, avoiding issues of cost and intellectual property rights. And what is owed participants in research that yields neither useful information nor a useful product? Most importantly, restricting the scope of benefits to specific medical interventions provided by sponsors ties host communities to products they may not want, and denies them a voice in determining the benefits they would find most valuable.

Despite these difficulties, 53% of U.S. researchers in the NBAC study felt that "Research to test an intervention should not be carried out in a developing country unless the intervention, if found to be successful, will be made available to that country after the conclusion of the study" (Kass and Hyder, pp. B-39, B-60). As of this writing, data are not available that address the extent to which products of research are successfully provided after studies are concluded.

A Right to Benefit

As we have seen, the Helsinki Declaration and CIOMS Guidelines establish a range of benefits for international collaborations. The NBAC study suggests that at least a strong subset of researchers is committed to meeting these expectations. But it also appears that the relationship between external and host collaborators is uneven. Those who have funding drive research agendas, choose how their international partners will participate, and what kinds of benefits, if any, will be provided during and after the study. As a result, benefits are unlikely to be coordinated in a way that can effectively strengthen local capacities.

In what follows, I propose that that international guidelines be revised to establish that less-developed countries' have a right to substantial benefits from hosting research. This right would be guaranteed, regardless of whether research produced any useful knowledge or product. The purpose of this right is to strengthen host partners' standing in the collaborative relationship so that they may advocate for meaningful benefits. In order to justify such a right, a number of questions must be addressed: First, what ethical justification underlies this right and who are the rightful recipients of research benefits? Second, how might such a right be implemented - how would the value of research benefits be assessed, and who has the duty to provide the benefits? Finally, how might establishing this right productively contribute to capacity building efforts? I address each of these questions in turn.

What Ethical Justification Underlies a Right to Benefit?

Diverse interpretations of the principle of justice support host countries' right to benefit from the opportunities and services they provide (Macklin, 2004, pp. 75-82), the most persuasive being the notions of justice as reciprocity and "just deserts" (Macklin, 2004, pp. 80-81; NBAC, 2001, p. 59). Reciprocity may be understood broadly as the duty to reward those who have made a contribution to society in some way. "Just deserts" are generally understood as the duty to provide appropriate compensation for services rendered. As we have seen, these ideas are reflected in the Helsinki Declaration and CIOMS Guidelines, however they are ambiguously stated, not enforced, and in some circumstances, logistically impossible to implement.

While the duty of sponsoring researchers to provide benefits is well established, the proper scope and purpose of the benefit are contested questions. Whether one appeals to notions of individual rights, humanitarian concerns, reparations for past or present injustices or recognition that uncontrolled disease constitutes a threat to political stability and national security, any such grounds are ultimately matters of interpretation. Two very different approaches to these questions are offered by an international panel of researchers and ethicists (Fair Benefits Framework) and Alex John London (Human Development Approach),

and illustrate some of the challenges involved in justifying the scope of the duty to provide a benefit and the difficulties of translating theory into practice.

The "Fair Benefits Framework" is founded on the claim that if an arrangement is considered "fair" and acceptable to both external researchers and their hosts, then exploitation does not occur (Emanuel et al, 2004). In this framework, determinations of fairness occur at a "micro-level" between negotiating partners, ignoring background factors of historical exploitation and political oppression, and are based on ideal market forces. Fairness is achieved by inviting research participants - those who undertook the risks - to determine what benefits are sufficient and how they shall be allocated. An obvious difficulty with this approach lies in determining what level of benefits is fair. In order to provide host negotiators with a reasonable benchmark, the Fair Benefits Framework recommends the development of an international databank of benefit agreements that could be accessible to researchers, participants, and others, as a means of ensuring transparency.

The Fair Benefits approach is responsive to host communities in that it recognizes that a range of benefits may be preferable to a specific research product and that appropriate benefits are best identified by the people who will use them. It is problematic, however, in that it is difficult to imagine that fairness can be attainable when negotiating partners occupy profoundly unequal political and economic strata and determinations of fairness essentially rely on market forces. Lacking negotiating power, host negotiators may settle for relatively limited benefits, while external researchers retain the freedom to seek the least demanding host partners. Given the disparities between external researchers and those in less-developed countries, it is unlikely that an international repository of benefit agreements will ensure fairness; rather, it will merely record what has been negotiated, which may more accurately reflect levels of desperation.

At the other end of the spectrum, Alex John London proposes a macro-level approach to benefits that embraces background issues of exploitation and oppression and tries to develop a means by which benefits may contribute to broad goals of social justice (London, 2005). London is critical of the Fair Benefits Framework, arguing that by ignoring the larger issues of social justice, it eliminates concern for historical grievances and ongoing social, political, and economic forces that perpetuate poverty and ill health. In this way, the Fair Benefits framework takes the conditions on the ground in the host country as normative and excludes questions of whether external researchers, as members of institutions and countries associated with those sources of oppression, have any duty to try to improve conditions beyond this level, or to provide benefits beyond those demanded by market forces.

The "Human Development" approach is premised on the notion that justice is most properly understood in terms of the extent to which social and political structures enable human flourishing. In this approach, healthy communities are those that offer their citizens education, employment, health care, political representation, and uphold basic human rights. Research benefits can contribute to these goals by providing health care interventions and capacity building efforts. Appropriate goals include health care interventions as well as capacity building efforts to meet these needs. London claims that researchers are uniquely positioned to "investigate ways of filling the gaps between a community's health needs and the capability of its social institutions to meet those needs" (London, 2005, p. 34). As such, ethical researchers must anticipate in their protocols what kinds of research will most effectively address local needs, and how research benefits can best contribute to the larger goals of human and community development. How research will do these things should also be considered in the approval process.

London has high ambitions for research, but it is difficult to imagine how his approach might play out in practice. Too much responsibility seems to lie with researchers, who are tasked not only with developing responsive research protocols, but also with figuring out how their efforts can intersect with local capacity needs and the matrix of national and international governments and NGOs that are also engaged in development efforts in the region. The role of host partners, institutions, and communities is rarely mentioned, nor does London include any discussion of the significance of cultural differences or the challenges of working in countries with limited or non-existent infrastructure and ineffective or corrupt governments. While London's goals are laudable, it is not clear how the Human Development Approach will surmount the obstacles that development experts have been struggling with for decades.

What is missing in both the Fair Benefits and Human Development approaches is acknowledgment that host collaborators are the experts in the needs of their communities and institutions. Yet due to the differences in social, economic, and political power between external and host country researchers, it is virtually impossible for host personnel to negotiate for more than external researchers are willing to give. This dynamic not only creates opportunities for exploitation; it also handicaps the ability of host personnel to use research benefits in capacity building efforts. What is needed is a shift toward a more equal balance of power in the relationship. Such a shift may be leveraged by establishing that host communities have a right to benefit from externally sponsored research.

Current research guidelines largely construe benefits in terms of something that is owed to individuals in return for specific types of sacrifices. But entire communities may be impacted by research. External researchers draw on local human and material resources, creating various kinds of dependencies and expectations - of jobs, access to medications, lifestyles - and they sometimes leave shattered economies when they depart. Rewarding only select individuals thus does not reflect the scope of the research impact. Moreover, in most of Africa and many less-developed countries around the world, the dominant social ethic is communitarian, in which the primary concern is the welfare of the community as a whole. Consistent with a communitarian ethic, the right to benefit envisioned here would be dedicated to developing and enhancing existing health care and research capacities at host institutions, which would directly and indirectly benefit the entire community.

This right, if included in international research guidelines, would require that external partners provide their hosts with benefits up to a certain predetermined cash value. With this assurance, the content of negotiations will focus on what benefits are most desired. This will not ensure that research is responsive to host country needs - for that, the external researchers' review committees are responsible. Indeed, whether research is responsive may matter less to host collaborators than the prospect of benefits they may receive by hosting the project. But the right to benefit will nonetheless guarantee that whatever the purpose of a protocol, the host community will receive benefits in return for the opportunities and services it provides. Most importantly, the right offers host partners the opportunity to select the benefits they wish, and plan how they will be used.

This right to benefit is chiefly derived from the principle of respect for persons. Respect for persons appeals to the dignity and respect owed individuals in any meaningful, long-term relationship in which the sustenance and value of the relationship depends on the ability of both partners to feel their needs are understood and attended to. This view of persons was articulated in the early days of contemporary bioethics by such figures as Paul Ramsey (1970) and Jay Katz (1984), who observing the excesses of paternalism in clinical practice and research, compelled a shift to a new medical culture in which patient autonomy became the paramount moral value and shared decision-making the ideal. Today, in Western medical practice and research, respect for persons is formally recognized as the right of individuals to informed and voluntary consent to treatment.

In fleeting transactions, the substance of an interpersonal relationship is minimal and duties to respect persons in such transactions extend largely to matters of courtesy and adherence to the law. But research collaborations generally involve long-term relationships that involve face-to-face contact between people with shared aims, who work together over time. If the relationship is to flourish, respect for persons demands attention to the dignity and needs of the other. Whether the other is socially, politically, and economically disadvantaged makes no difference; all people in such relationships deserve such respect and attention. Failure to demonstrate respect leads to abuse, exploitation, and corruption. In biomedical research, history has repeatedly shown that failure to respect persons threatens the integrity of the entire enterprise.

In international collaborations, respect for persons serves much the same purpose for the host community as the doctrine of informed consent does for individuals. Both strengthen the negotiating power of the less-advantaged partners in the relationship and in that way affirms their dignity, autonomy, and rights. By establishing that host communities deserve to be substantially rewarded, a right to benefit reduces risks of exploitation and in that way helps to preserve research integrity. Given the conflicts of interest and high stakes inherent in biomedical research today, affirming such a right may be essential to maintaining research integrity in international collaborations. And by predicating benefits on capacity-building expectations, this right may offer new leverage to development efforts.

How Might a Right to Benefit be Implemented?

To formalize host countries' right to benefit, I propose the following text be added to international research guidelines:

> Communities hosting externally sponsored research have a right to benefit from the partnership. This benefit shall be equivalent to a cash value of between 10%-50%, of research funding and must be directed toward strengthening capacities in health care, research, and related community needs. Benefits will include cash, educational materials, basic medical supplies, drugs, technology, infrastructure development, and training.

The right to benefit proposed here thus imposes a duty on external researchers to provide benefits valued at a specific cash value, regardless of whether research generates useful products or knowledge. The challenge, as we have seen, is to determine what level of benefits is fair. Given the range of research conducted abroad, this value may best be determined by an algorithm - ideally developed by development economists at an international health organization. This algorithm would balance factors such as the type and duration of the study, the source and magnitude of funding, the likelihood of marketable products to emerge from the study, the GDP of the host country, and the resources requested from the host community (skilled personnel, space, and number of participants) to calculate a range of benefit rates. Rates would be lowest for short-term, minimal risk studies, and highest for industry-based research involving clinical trials, especially those in Phase III. The range of 10%-50% given here is admittedly arbitrary, intended only to suggest that the benefit should be substantial enough to make a meaningful contribution to capacity building.

The benefit would function essentially as overhead on research budgets. Host institutions would receive cash and other benefits directly from external researchers or when applicable, as part of the indirect funds provided by research funders to researchers' home institutions. (Indeed, transfer of indirect funds is already being done in a partnership between Indiana University School of Medicine and Moi University in Kenya, cf. Sidle, et al., Manuscript). Other kinds of benefits would be provided during or after the research is complete, subject to negotiations. While external researchers and their sponsors would initially be responsible for ensuring benefits are provided, should this approach prove an effective development

strategy, global aid organizations and government agencies might eventually provide supplemental funds for benefit support.

How Might a Right to Benefit Contribute to Capacity Building Efforts?

The strength of this approach is that it places responsibility for the use of benefits in the hands of host personnel with the understanding that benefits should be primarily directed toward improving local health care and research capacities at local hospitals, universities, and clinics. If other community needs are pressing, as in the event of a natural disaster or political conflict, benefits may be used for this as well. But the first priority, given the expertise of the external researchers, should be health care and research. Key indigenous personnel will include representatives from the host research team, institutional leadership, the medical community, local government, and research participants. Between them, they will need to identify capacity building priorities, develop a long-range plan, negotiate benefits with external researchers, identify and supervise those who will be responsible for implementation, and demand accountability. This effort will require leadership skills, teamwork, creativity, and the commitment of people at all levels of participating institutions. There are many in the development field who believe that the culture of personal rule and corruption in Africa preclude the possibility of such extensive strategic planning and for this reason have denied indigenous personnel these opportunities. There are others who claim that African professionals possess the necessary knowledge, talent, and motivation but lack the opportunities, structures, and incentives to develop a managerial class (Leonard and Strauss, 2003, Ch. 3). International research is an ideal context for introducing this kind of indigenous development effort largely because it is in the interests of external researchers for the project to succeed. Because they are on-site, have long-term relationships with local personnel, and are familiar with the culture and local resources, they are ideally situated to provide mentoring support and professional reinforcement for the initiatives undertaken.

Importantly, this approach provides incentives for accountability. Because research is more easily conducted where infrastructure is in place, those institutions that effectively use benefits to strengthen their capacities and infrastructures will be attractive to future researchers, who will in turn provide more benefits. Those who waste their benefits will be less likely to be approached the next time. The fact that external researchers or their representatives will be on-site will also lend a measure of support and accountability. Thus structured, the right to benefit should discourage capricious appropriations and reward effective management, eventually leading to regional centers of strength in health care and research. In this way, even if only on a small scale, research collaborations can serve to develop local capacities while furthering the development of an indigenous professional culture.

As alluded to above, the challenge and opportunity here lie in each host institution's ability to develop an incremental long-range plan and stick to it. Implementing long-term strategic plans in less-developed countries is fraught with challenges as immediate needs risk thwarting any such plans and traditional approaches toward resource use may undermine institutional goals. National and local government support for research-sponsored capacity building efforts is therefore essential, especially as a source of supplemental funds once projects are under way. Mentoring relationships and consultants may be helpful, and could be included as part of the benefits package. Strong leadership must be encouraged, recognized, and rewarded locally and through increased international investment. Broad-based commitment across institutions will need to be developed through culturally appropriate incentives. Developing networks of professionals through media and conferences will add valuable support, as would invitations to conferences to share successes and obstacles. This is an enormously challenging proposal, and progress will be

uneven. But if indigenous capacity building efforts are ever to take root in Africa, collaborative research offers a promising arena in which to start.

Critics will protest that establishing a formal right to benefit will excessively burden externally sponsored researchers by raising the costs of research to prohibitive levels. But when there are vast economic disparities between sponsoring and host countries, such claims are not credible. Once the right to benefit is established, it will simply become part of the cost of doing business. It is also possible that in many cases the increased cost of this benefit will not be substantial. Many of the benefits provided by this means may already be accounted for in research budgets and if not, could be managed by reallocating funds within these budgets. Supplemental public or private funding may be a realistic expectation, if this approach proves effective.

A more serious criticism is that some host institutions' research review committees may find the prospect of benefits so appealing that they will approve research that poses serious risks to patients. This is possible, but since any externally-funded research protocol must be first approved by the research review committee at the researchers' home institution, studies that pose an unfavorable risk-benefit ratio should be identified at that point and rejected (Emanuel, 2005). Failures of the research review process are not unknown, however. Were such protocols to slip through the approval process, one would hope that the public nature of research would act as a further constraint. Regrettably, this risk cannot be fully eliminated.

The "right to benefit" described here thus establishes that a primary ethical responsibility of externally sponsored research projects is to contribute to development goals in host communities. By guaranteeing the right of host collaborators to a certain level of benefits, and requiring that they choose which will best serve their institutions and communities, they are affirmed as equal partners whose expertise and involvement are essential to capacity building efforts. By providing benefits directly to host institutions and individuals with the understanding that future collaborations will be contingent on how they are used, incentives are in place to reward responsible use and further the growth of a managerial class. Research sponsors may also gain moral satisfaction from contributing tangibly to host country development - a recent disclosure by Novartis suggests that genuine efforts to meet the needs of people in developing countries offers a number of rewards, including enhanced public relations and employee morale (Herrling, 2006). Ideally, establishing the right of host communities to benefit in this way will lead to thoughtful and sustained research partnerships that will eventually strengthen global health and health research worldwide. Failure to recognize such a right, however, will permit externally sponsored research to continue to capitalize on the desperation of poor nations and peoples, remaining an essentially exploitive enterprise.

Acknowledgments

I am grateful to Dr. Jerome Kabakyenga, Dean of the Medical School at Mbarara University of Science and Technology, for hosting my sabbatical in Uganda, and to Solomon Benatar, Andrew Jameton, and anonymous reviewers for their thoughtful comments on earlier drafts of this paper.

References

1. www.cioms.ch/frame_guidelines_nov.2002.htm - Council for International Organizations of Medical Sciences (CIOMS). (1993/2002). International Ethical Guidelines for Biomedical Research Involving Human Subjects

2. Davey, G., Fekade, D. and Parry, E. (2006) Must aid hinder attempts to reach the Millennium Development Goals?. The Lancet 367, pp. 629-630.
3. Easterly, W. (2006) The White Man's Burden Penguin Press, New York
4. Edejer, T. T. (1999) North-South research partnerships: The ethics of carrying out research in developing countries. BMJ 319, pp. 438-441.
5. Emanuel, E. (2005) Undue inducement: nonsense on stilts?. American Journal of Bioethics 5:5, pp. 9-13.
6. Emanuel, E. and Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries (2004) Moral standards for research in developing countries. Hastings Center Report 34:3, pp. 17-27.
7. Garrett, L. (2007) The challenge of global health. Foreign Affairs 86:1, pp. 14-38.
8. Herrling, P. (2006) Experiments in social responsibility. Nature 439:19, pp. 267-268.
9. Kass, N. and Hyder, A. A. (2001) Attitudes and experiences of U.S. and developing country investigators regarding U.S. human subject regulation. Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries II, National Bioethics Advisory Commission, Bethesda, MD
10. Katz, J. (1984) The Silent World of Doctor and Patient The Free Press, New York
11. Leonard, D. K. and Strauss, S. (2003) Africa's Stalled Development Lynne Rienner Publishers, Boulder, CO
12. London, A. J. (2005) Justice and the human development approach to international research. The Hastings Center Report 35:1, pp. 24-37.
13. Loue, S., Okello, D. and Kawuma, M. (1996) Research bioethics in the Ugandan context: A program summary. Journal of law, Medicine and Ethics 24, pp. 47-53.
14. Macklin, R. (2004) Double Standards in Medical Research in Developing Countries Cambridge University Press, Cambridge
15. McGrath, J. W., George, K., Svilar, G., Ihler, E., Mafigiri, D., Kabugo, M. and Mugisha, E. (2001) Knowledge about vaccine trials and willingness to participate in an HIV/AIDS vaccine study in the Ugandan military. Journal of Acquired Immune Deficiency Syndromes 27, pp. 381-388.
16. Molyneux, C. S., Peshu, N. and Marsh, K. (2004) Understanding of informed consent in a low-income setting: three case studies from the Kenyan coast. Social Science and Medicine 59, pp. 2547-2559.
17. National Bioethics Advisory Commission (NBAC) (2001) When research is concluded - Access to the benefits of research by participants, communities and countries. Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries I, p. 59. National Bioethics Advisory Commission, Bethesda, MD
18. Pond, B. and McPake, B. (2006) The health migration crisis: The role of four Organization for Economic Cooperation and Development countries. The Lancet 367, pp. 1448-1455.
19. Ramsey, P. (1970) The Patient as Person Yale University Press, New Haven, CT
20. http://idea.iupui.edu/bitstream/1805/633/1/Meslin - Sidle, J. E., Were, E., Wools-Kaloustian, K., Chuani, C., Salmon, K., Tierney, W. M., and Meslin, E. (Manuscript). A needs assessment to build international research ethics capacity at Moi University and Indiana University.
21. health.go.ug/docs/unhro_analysis.pdf - Uganda National Health Research Organization (UNHRO). An Analysis of Institutions Doing Health Research in Uganda - Year 2000
22. 23. www.wmc.net/e/policy.63.htm - World Medical Association (WMA). (1964, revisions in 1975, 1983, 1989, 1996, 2000, 2002, 2004). Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects

Note

U.S. Department of Health and Human Services. (1981). Title 45, Code of Federal Regulations, Part 46. Protection of Human Subjects

Author

Mary Terrell White, PhD is Associate Professor and Community Health Director in the Department of Community Health, Boonshoft School of Medicine, Wright State University. Contact her at 1.937.775.3167 or mary.t.white@wright.edu.

