

Involving Communities in Deciding What Benefits They Receive in Multinational Research

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There is wide agreement that communities in lower-income countries should benefit when they participate in multinational research. Debate now focuses on how and to what extent these communities should benefit. This debate has identified compelling reasons to reject the claim that whatever benefits a community agrees to accept are necessarily fair. Yet, those who conduct clinical research may conclude from this rejection that there is no reason to involve communities in the process of deciding how they benefit. Against this possibility, the present manuscript argues that involving host communities in this process helps to promote four important goals: (1) protecting host communities, (2) respecting host communities, (3) promoting transparency, and (4) enhancing social value.

Keywords: *benefits, clinical research, exploitation, risks*

I. INTRODUCTION

Protecting participants from exploitation is one of the primary ethical challenges posed by clinical research. This concern has received substantial attention in the literature, especially when sponsors and investigators from higher-income countries conduct clinical trials in lower-income countries (Angell, 1997; Lurie and Wolfe, 1997; Varmus and Satcher, 1997). It is widely agreed that, in order to address the potential for exploitation in this setting, host communities should benefit from the trials in which they participate (Shapiro and Meslin, 2001). Consensus on this point has led to debate over

how best to decide what benefits host communities receive (Ballantyne, 2010). Perhaps the most important practical challenge in this regard is to determine what role, if any, the host community should play in deciding what benefits it receives (London and Zollman, 2010).

The present manuscript argues that including host communities in the process of deciding what benefits they receive helps to promote four important goals: protecting host communities, respecting host communities, promoting transparency, and enhancing social value. This analysis suggests that, except in rare cases, host communities should be involved in deciding what benefits they receive in the context of multinational research. Future research should evaluate which methods for involving host communities best promote these goals.

II. BACKGROUND

Exploitation involves inappropriately using or taking advantage of an individual or group for the benefit of others. According to an influential account, exploitation occurs when one party to a project or transaction fails to receive a fair level of benefits, given the risks and burdens the transaction imposes on them and the extent to which others benefit from the party's involvement in the project or transaction (Wertheimer, 1996). Simply put, if, in the course of a joint project, you do all the work and I receive all the benefits, you have been exploited. To remedy this wrong, you would need to receive a fair level of benefits, given the work you did and the extent to which others benefit from your efforts.

Historically, concern regarding the potential for exploitation in clinical research has focused on the potential exploitation of individual subjects. Indeed, some commentators have argued that the paradigm of clinical research—investigators perform research interventions on subjects which pose risks and burdens in order to collect data that might benefit others—represents a paradigmatic example of exploitation (Jonas, 1969). To address this concern, some commentators and guidelines have specified that subjects should receive sufficient benefit from their research participation. For example, the 2008 version of the Declaration of Helsinki mandated that patients who participate in clinical research studies should “share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits” (World Medical Association, 2008, paragraph 33). Sharing in benefits helps to protect research subjects from exploitation. However, some commentators express concern that offering benefits to individual subjects may represent an “undue inducement.” That is, the offer of benefits may undermine potential subjects’ ability to determine whether it is reasonable for them to enroll in the research. For example, to address concerns over exploitation, study investigators might

offer significant benefits to individuals who enroll in a study. Yet, an offer of significant benefits may lead individuals to ignore the risks that the research poses and thereby enroll in a study that is clearly contrary to their interests. The current literature focuses on how best to balance these two concerns, making sure that individual subjects are not exploited while protecting them from offers that might undermine their ability to make good decisions.

More recently, commentators have argued that clinical research can exploit host communities. This worry has become more prominent as funders increasingly conduct clinical research in lower-income countries. Specifically, there is concern that funders will take advantage of groups and communities in lower-income countries to conduct trials of medications and interventions that will then be made available only in higher-income countries. To address this concern, it is argued that host communities should benefit from their involvement in multinational clinical research. For example, the current version of the Declaration of Helsinki states that medical research with vulnerable groups is justified only when they “stand to benefit from the knowledge, practices or interventions that result from the research” (World Medical Association, 2013, paragraph 20). The claim that research subjects should benefit from their participation in clinical research seems plausible, given that subjects clearly face risks and make important contributions to research projects. It is less clear why host communities should benefit (Hughes, 2012). One argument is that host communities, like individual subjects, accept risks and burdens and make contributions to clinical trials (Gbadegesin and Wendler, 2006).

For present purposes, we will assume that host communities should benefit in at least some cases. This assumption raises the question of how and to what extent host communities should benefit. One of the earliest ethical requirements intended to ensure that host communities in multinational research benefit sufficiently has come to be known as the requirement for “reasonable availability” (Cleaton-Jones, 1997). This requirement was first emphasized in 1993 by the Council for International Organizations of Medical Sciences (CIOMS) and is described in their revised guidelines of 2002 as follows:

As a general rule, the sponsoring agency should agree in advance of the research that any product developed through such research will be made reasonably available to the inhabitants of the host community or country at the completion of successful testing. (CIOMS, 2002)

Although this requirement is stated as a general rule, it came to be regarded as the preferred, and sometimes even as a necessary means to avoid exploitation (Annas and Grodin, 1998). Unfortunately, reliance on reasonable availability alone to address the potential for exploitation raises several concerns (Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries, 2004). Insisting on a specific type of

benefit—availability of the tested product—seems to ignore the fact that the best way to meet the needs of host communities may vary depending on their circumstances. As a result, offers that provide sufficient benefit to one community may be insufficient for others.

More importantly, many clinical trials, including early phase trials, observational studies, and trials testing products which prove to be ineffective, pose risks and burdens but do not yield a successful intervention. And some clinical trials fail to recruit sufficient numbers of participants or fail to yield meaningful results. Exclusive reliance on the reasonable availability of products that are shown to be effective and/or the knowledge gained by the study offers no way to protect communities from exploitation in these trials. This is a serious concern, given that trials which do not yield a successful intervention may well represent the majority of clinical trials.

To ensure that the potential for exploitation is addressed in all trials, recent commentators have endorsed several alternative approaches to reasonable availability. First, some endorse the “fair benefits” framework. The fair benefits framework determines what benefits host communities should receive based on the nature of the individual studies in which they are involved. Specifically, the fair benefits framework maintains that host communities should receive a fair level of benefits. It further maintains that what level of benefits is fair depends on the risks and burdens to which the host community is exposed, and the extent to which others benefit as a result of the community’s involvement in a given study ([Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries, 2002](#)).

Second, a number of commentators have argued that the level of benefits the host community receives should be determined by what is needed to adequately address the conditions of oppression in the host community ([Lavery et al., 2010](#)). Third, other commentators have argued that determining what benefits host communities receive based solely on the risks and benefits of individual studies, as the fair benefits framework does, is too narrow. These commentators hold that, in order to avoid exploitation, the decision of what benefits host communities receive should take into account the conditions of background injustice that are present in the host community ([Arras, 2004](#)). Fourth, it has been argued that addressing the potential for exploitation requires a proper distribution of the added benefits which are gained from conducting the study in the lower-income country, as opposed to conducting the study in a higher-income country ([Ballantyne, 2010](#)).

All of these approaches face important theoretical challenges. The fair benefits approach and the focus on a proper distribution of the added benefits produced by a given trial do not seem to offer any way to determine what level of benefits is fair in individual cases. How do we determine whether an offer to establish and fund a health clinic offers sufficient benefit for hosting a phase 2, placebo controlled, randomized study of a new malaria vaccine? Without further elaboration, then, it is unclear whether these approaches

provide a sufficient way to address the potential for exploitation. Even more worrisome, the claim that addressing the potential for exploitation of host communities requires addressing the conditions of oppression, or addressing the background conditions of injustice, seems to misunderstand the nature of clinical research. Consider a lower-income community that hosts a clinical trial to assess the impact of a new experimental treatment on some condition or disease. The potential for exploitation in this case arises from the risks and burdens that hosting the trial places on the community, and the extent to which others benefit from the trial. It is not clear that the conditions of oppression or injustice that existed in the community prior to the initiation of the study are even relevant to determining what constitutes a nonexploitative study.

Proponents might respond that everyone who interacts with those in lower-income communities has an obligation to address the conditions of oppression or injustice that exist in those communities. Or, it might be argued that, as a matter of historical fact, individuals in higher-income countries have benefited from prior oppression and exploitation of those in lower-income communities. Hence, individuals in higher-income countries have an obligation to benefit those in lower-income communities. While these claims may be right, they are not specific to clinical research, but apply to everyone in higher-income countries. As a result, the details of individual studies seem irrelevant to determining, on these views, the extent to which host communities should benefit. Instead, one needs some theory for the extent to which individuals from higher-income countries in general have an obligation to assist those in lower-income communities. Finally, these views seem to pose significant challenges for determining what constitutes an appropriate level of benefits. How does one determine to what extent a given company in the United States, say, has benefitted from the historical abuse over the past 500 years of individuals in lower-income countries and to what extent this company thereby has an obligation to help these individuals?

Recognizing that all four approaches face significant challenges, it seems unlikely that any of them will gain consensus support in the near future. At the same time, clinical studies continue to be conducted in lower-income countries. Thus, the challenge of determining how and to what extent host communities should benefit cannot simply be postponed until we reach theoretical consensus. With the need for some practical solution in mind, notice that all four approaches agree that those in lower-income countries should receive a sufficient level of benefits. These four approaches thus all raise the challenge of identifying a method which can be used in practice to determine which offers of benefits are sufficient. Specifically, no matter which approach one endorses, the challenge remains of determining in specific cases for specific trials whether a given offer of benefits to a host community is sufficient to address the potential for exploitation.

III. IDENTIFYING APPROPRIATE BENEFITS

The extant approaches provide little guidance on which method or methods should be used to determine in practice whether a given offer to a host community is sufficient to address the potential for exploitation. The claim that the host community should receive a level of benefits that is sufficient to address the conditions of oppression in the host community does not provide a method for determining in practice which offers satisfy this condition. Similarly, the claim that the benefits which host communities receive should be sufficient to address the background conditions of injustice provides no way to determine which offers meet this standard. How should the relevant stakeholders determine the extent of background injustice in the host community? How should they determine when a level of benefits is sufficient to address the background conditions of injustice? To what extent does this determination depend on whether the funders and sponsors are from a country which oppressed the host community or country in the past? The fourth approach—addressing the potential for exploitation requires an adequate distribution of the surplus benefits of a study—offers the most specific proposal for determining what benefits should be provided in practice.

Surplus Benefits

Proponents of the fourth approach argue that the host community should receive *essentially all* the added benefits that are gained from conducting the study in the lower-income country rather than conducting the study in a higher-income country. While this proposal is clear and specific, proponents do not provide any reason to think that this specific distribution of the added benefits is the appropriate one to avoid the potential for exploitation. This lack of guidance is problematic, given that there are many ways to distribute the added benefits that are derived from conducting a study in a lower-income country. The host community might receive an equal share of the added benefits, or 75 percent, or a share that is a function of the burdens the study poses on the host community. In the absence of a compelling argument for why one of these options is preferable to the others (Wertheimer, Millum, and Schaefer, 2010), those who rely on this approach will need some method to determine in practice what portion of the surplus benefits are provided to the host community.

A more fundamental problem with this approach is that a focus on surplus benefits is unlikely to address the potential for exploitation in many cases. Consider a study that generates enormous profits overall, but the profits generated by conducting the study in the lower-income community are similar to the profits that would have been generated by conducting the study in a higher-income community. In this case, the present approach seems to imply

that the host community should be offered essentially no benefits, even if they made a significant contribution and experienced substantial burden. The problem here is that the surplus benefit approach focuses on the *difference* in benefits that result from conducting the study in a lower-income country rather than conducting it in a higher-income country. This approach thus addresses the potential for exploitation of host communities only to the extent that it traces to the host community being relatively impoverished and the study thereby producing increased profits for others. This approach does not address the potential for exploitation of host communities in other cases.

Ideal Markets

Some commentators have essentially endorsed the fair benefits framework and then argued that the correct method for determining what counts as a fair level of benefits is whatever would be provided in an ideal market (Phillips, 2011). In an ideal, or perfectly competitive market, everyone has complete information, there are no barriers to entry or exit, and the number of transacting parties is so high that no one party can control prices. For the purposes of trying to protect host communities, these conditions offer the important advantage of eliminating several potential sources of exploitation, such as differences in levels of information between the contracting parties. As a result, no party will be in a position to take “special unfair advantage of particular defects in the other party’s decision-making capacity or special vulnerabilities in the other party’s situation” (Wertheimer, 1996). For example, specifying that everyone in an ideal market has complete information eliminates the possibility that funders can use their greater information to take advantage of host communities.

The fact that no party is able to control the outcome in an ideal market is an important virtue of this approach. It almost certainly increases the chances that the agreements that result from this approach will be fair compared to any approach that does not address these imbalances. At the same time, it does not follow that whatever offer results in an ideal market will necessarily avoid exploitation. Put differently, eliminating several potential sources of exploitation decreases the chances that the resulting outcome will involve exploitation; it does not eliminate that possibility. The prevailing circumstances might lead to an exploitative outcome, despite the fact that no one party is able to determine the outcome. The exploitative outcome may trace not to defects in one party’s decision-making capacity or to special vulnerabilities in the party’s situation, but to the circumstances in which the parties find themselves. This seems to be a particularly salient concern in the present context, given that lower-income countries are worse off.

The possibility that an ideal market might lead to ethically unacceptable outcomes is underscored by the fact that the parties in an ideal market

are assumed to be motivated purely by self interest. They are motivated to achieve the best deal for promoting their own interests, irrespective of moral considerations and the impact that the outcome has on others. The level of benefits that a host community receives in an ideal market might thus be very low, even though no individual party is responsible for this outcome. It might simply be a result of the ideal market itself, the fact that everyone is looking out for themselves and no one is motivated by moral considerations. Parties who are motivated to do the right thing might recognize the unfairness of the outcome dictated by the ideal market and choose to provide host communities with greater benefits (Arneson, 2011). Finally, even if one insists that the results of an ideal market are necessarily fair, we have no way to determine in practice what the results of such a market would be. Hence, this approach, like the others, will have to rely on some method or methods to determine what benefits are provided to host communities in practice.

Responses

Someday an algorithm might be developed that could be used to determine what benefits should be provided to host communities. For example, someone might develop an algorithm which takes as inputs the facts of the individual case that are relevant on the theory one endorses and outputs precisely what benefits need to be provided to address the potential for exploitation. Such an algorithm might take as inputs the measures of injustice in the host community, the extent to which the funders are responsible for and have benefitted from the conditions of injustice, and output what benefits must be provided. If such an algorithm were developed, there would be little or no need for the relevant stakeholders to use their judgment to determine what benefits are provided to host communities. Instead, a technician could simply input the relevant data and receive a computer-generated determination of what level of benefits should be provided to the host community in that case (although concern might remain over whether the correct data were entered and whether the program is working properly).

Until such an algorithm is developed, there are at least four options that one might endorse. First, one might argue that investigators and entities from higher-income countries should be prohibited from conducting research in lower-income countries on the grounds that there is no way to ensure that such research will avoid exploitation. While this approach makes sense, and it certainly will protect host communities from being exploited by funders and investigators, it also prevents them from the benefits that might result from participating in clinical research. This is especially a problem, given that research on many of the conditions which affect lower-income countries must be conducted there. For example, a stipulation that research cannot

be conducted in lower-income countries would make it extremely difficult, if not impossible, to conduct research to develop treatments for neglected tropical diseases.

Second, one might stipulate that all the benefits gained from clinical trials conducted in lower-income countries should be given to the host communities. While this approach clearly protects host communities from exploitation, it fails to recognize the legitimate claims that others have to the benefits resulting from such trials. While sponsors should not exploit host communities, they have a legitimate claim to benefit from their efforts in the study. That is, concerns regarding exploitation do not apply only to the host communities. It is possible that funders can be exploited as well if they incur significant burdens and costs, but receive no benefits.

Third, one might argue that, absent some algorithm which identifies a fair deal in all cases, reliance on free market mechanisms provides the best chance to address the potential for exploitation. Unfortunately, history provides compelling reason to be skeptical. In particular, reliance on the free market alone, without any oversight, regulation, or guidelines, has frequently led to significant levels of exploitation. One reason for this is that current markets are decidedly less than ideal. Another is that reliance on markets tends to increase the advantages that the rich and powerful have over others, a concern that is especially pressing in the present context.

A fourth option is for some party or parties to use their judgment to decide in practice what benefits the host community should receive. If one adopts the view that the benefits provided to the host community should address the conditions of oppression, some individuals will have to decide which packages of benefits best realize this goal. Is the offer to build four schools to empower a new generation sufficient to address the conditions of oppression? Does the answer to this question depend on the nature of the individual study, such as the risks, potential benefits, or number of individuals from the host community who enroll?

To determine which method is best for deciding how the host community should benefit, many questions will need to be answered. At a theoretical level, the method might be designed to minimize instances of exploitation. On this approach, deals could be regarded as acceptable only when they certainly or almost certainly provide the host community with a sufficient level of benefits. Alternatively, the method might be designed to increase opportunities for host communities. In this case, deals could be regarded as acceptable unless they certainly or almost certainly *do not* provide the host community with a sufficient level of benefits. With respect to implementation, who will fund the determination of what benefits should be provided to the host community in a given case? Should there be an appeal mechanism?

All of these questions are important. However, for present purposes, the central point is that, whatever method is adopted, the decision of what

benefits the host community receives ultimately will depend on the judgment of some party or parties. This finding suggests that, in terms of practical consequences, the primary challenge will be to determine *who* should be involved in deciding what benefits are provided to the host community.

IV. PROCEDURAL FAIRNESS

As we have seen, the fair benefits framework maintains that the key to addressing the potential for exploitation in multinational research is the level or amount of benefits that the host community receives, given the risks and benefits of individual studies. Absent a definitive theoretical account which clarifies precisely which levels of benefits are fair in which cases, the fair benefits framework describes a three-step method for making this determination:

1. Comprehensive delineation of the benefits to participants and the population.
2. Free, uncoerced decision making by the community about whether the benefits are sufficient to justify participation in the proposed research.
3. Transparency in the arrangement for provision of benefits to the population in order to subject these arrangements to independent evaluation and to accrue a “case law” set of standards for determining fair levels of benefits.

The second requirement mandates the inclusion of the host community in deciding what benefits it receives. However, no clear argument is provided for why the community should be involved. One possibility would be to defend this requirement by arguing that the host community should be involved in determining what benefits it receives because the agreement of the community *determines* which offers are fair. However, there are a number of problems with this view (Ballantyne, 2008).

Most importantly, host communities in lower-income countries are likely to have less information and less power compared to the sponsoring entities in higher-income countries. As a result, the host community might agree to a deal which, in fact, is unfair (it is just these types of imbalances that appeal to the ideal market attempts to eliminate). Communities in lower-income countries also may recognize that a given offer is unfair, but nonetheless accept it because they lack any better alternatives. The possibility that host communities might agree to offers which are unfair reveals that the agreement of the host community does not necessarily determine that a given offer is fair. This conclusion reveals that appeal to a “procedural” theory of fairness—a fair deal is whatever deal the host community happens to agree to—will not address the potential for exploitation in multinational research.

The conclusion that the community does not determine which agreements are fair is important. At the same time, it is important to be clear regarding the implications of this conclusion. In particular, absent clarification, this conclusion may encourage the view that there is no reason to involve the host community in the process of determining what benefits it receives. If the agreement of the host community does not determine that a given deal is necessarily fair, why should investigators and funders consult the community at all when determining what benefits to provide?

It is important to distinguish two questions: (1) what is the principle or basis that determines what benefits host communities should receive and (2) in practice, how should it be determined what benefits the host community receives? For example, one might stipulate that the host community should be involved in deciding what benefits it receives. However, if it is not clear that this claim is made in response to the second question, readers might assume that it amounts to an endorsement of a process account of fairness. Similarly, rejections of process accounts of fairness do not determine whether the community should be involved in deciding what benefits it receives. One way to understand this point is in terms of the fact that principles do not implement themselves. Hence, even if one has a preferred principle for what determines the extent to which host communities should benefit, one still needs a method or process by which the principle is implemented in practice. It follows that rejection of process accounts of fairness in favor of one of the other extant views leaves open the question of whether the community should be involved in determining what benefits it receives.

V. REASONS FOR INCLUSION

Involvement and agreement of the host community do not imply that a given deal is necessarily fair. Even with the involvement and agreement of the host community, it is possible that mistakes will be made and bad deals will be accepted. At the same time, involvement and agreement of the host community help to promote four important goals. This analysis suggests that, except in rare cases, the host community should be involved in determining what benefits it receives.

Protecting Host Communities

What benefits individuals or a community (what promotes their interests or makes them better off) and what harms individuals or a community (what sets back their interests or makes them worse off) depend to some extent on what they value (Griffin, 1988). For example, the offer of medications which include bovine-derived products might promote the interests of a Christian community, but set back the interests of a Hindu community. It follows that an accurate understanding of the host community's values is vital for

determining which offers will benefit the host community, and which offers pose risks.

While it may be possible to obtain an understanding of the community's values from outsiders, the most reliable source typically will be members of the community. This consideration provides an important reason why the method for determining which benefits are provided to the host community should include the community itself. Inclusion of the community increases the chances that offers will reflect an accurate understanding of the risks and potential benefits for the community. This, in turn, increases the chances that the final offer will successfully address the potential for exploitation.

Respecting Host Communities

One of the most important ways in which we respect others is to allow them to determine the course of their own lives (Raz, 1986). The benefits provided to host communities are intended to have an impact on them, and may in some cases have a substantial impact. For example, whether the community receives training of new clinical investigators or construction of a new medical clinic could have a substantial impact on life in the community. Including the community in deciding which benefits it receives thus offers a way to allow the community to help to shape its future.

The conclusion that involving the community will promote respect is supported by the fact that, absent an algorithm to determine which deals are fair, some individuals will have to use their judgment to decide what benefits the community receives. Given the need to rely on some individuals, a method which did not include the community would be exclusionary and might inadvertently signal that the community is not thought capable of helping to make these decisions. Even when it is well intended, making the decision of what benefits the community receives based solely on input from the funders and the ethics review committee suggests that the views of the community are not valued, and not valuable.

Promoting Transparency

Clinical research is supported by society and depends for its success on the continued support of the public. Therefore, it is not sufficient to put in place a method which in fact ensures that individual studies satisfy the relevant ethical requirements. Whatever method is used also should provide assurance to the public that the relevant ethical requirements have been satisfied. In multinational research, it is vital to provide assurance that the method used to decide which benefits the community receives is appropriate. Specifically, it should be clear to the relevant stakeholders, and to the public, that the method took into account the relevant considerations, weighed them adequately, and was not swayed by irrelevant considerations.

The need for transparency is especially important in contexts in which there is no agreed-upon method for determining which offers are appropriate. In these cases, it can be difficult for third parties to evaluate whether a given proposal is fair. An important way to provide assurance in these cases is to make clear that the method by which the final offer was determined was itself appropriate. Perhaps the best way to provide this assurance is to require that the community be involved in the negotiation process. It seems less likely that sponsors will be able to steer the results in ways that favor them and disfavor the host community if the host community is involved.

Enhancing Social Value

Presumably, individuals and communities are more likely to drop out of studies they regard as unfair. However, if communities frequently drop out, studies will be slowed and may even be halted, increasing the costs and reducing the value of research studies. One way to minimize this possibility, and maximize the social value of research, would be to put in place steps to increase the likelihood that the host community will regard as fair the benefits it receives. Mandating that the community be part of the process of determining what benefits it receives should increase chances that the final deal will be regarded as fair by the host community. In this way, inclusion of the community should increase the chances that the community will support and continue to participate in the study.

VI. REMAINING CHALLENGES

The fact that the involvement of the community helps to promote four important goals—protecting host communities, respecting host communities, promoting transparency, and enhancing social value—raises the possibility of tension between these goals in individual cases. In principle, there might be conflicts between any of the four goals. Some studies might pose a conflict between promoting transparency and enhancing social value. For example, the success of some types of research depends on the community not knowing the procedures or purpose of the study. Assuming that ethics review committees are involved in approving the research in question, these independent actors will have to consider what their role should be and whether the social value of the study provides sufficient reason not to use a fully transparent process that involves the community.

Conflicts may be especially likely between the goals of protecting and respecting the host community. Such conflicts could arise when protecting the host community provides reason not to accept its view on the appropriateness of a given study. Consider a case in which a community very much wants to participate in a study and regards the sponsor's offer as fair, but the research ethics

committee regards the deal as unfair to the community. This conflict arose in the context of an HIV treatment trial proposed in South Africa in the 1990s.

In this case, the host community wanted to participate in the study, but the research ethics committee rejected the trial as unethical. The research ethics committee based this claim on the fact that, by failing to provide antiretroviral therapy after the study, the sponsor was failing to offer the community sufficient benefits. The sponsor pointed out that it would have to buy drugs from competitor companies to ensure post-trial access, and it was unwilling to do so (Tucker and Slack, 2003). The community argued that providing therapy within the trial was a considerable benefit and that a successful trial might ultimately lead to acceptance and availability of HIV treatment in South Africa.

Respect for the self-determination of the community suggests that its decision should be accepted and the study should be allowed. In contrast, emphasis on protecting the community's interests suggests that the research ethics committee should block the study based on its judgment that the offer of benefits was insufficient. In the actual case, the research ethics committee was ultimately convinced by the community that the benefits were very valuable and allowed the trial to proceed. This case provides insight regarding how research ethics committees should handle conflicts that arise between the goals of protecting and respecting the host community.

The research ethics committee in this case recognized that individuals and communities can make mistakes, and the charge of protecting them includes the occasional need to protect them from the effects of their own mistakes. This possibility suggests that, in evaluating which offers are fair, representatives of all major stakeholders should be consulted. Discussion with these groups could include comparison of the proposed deal to previous deals that were similar and determined to be fair. Ideally, this consultation process will result in the identification of an offer which is fair, and which all parties agree is fair.

In cases where the community regards the deal as fair, but the ethics review committee does not, the committee should consider whether it is making a mistake. Perhaps the committee has insufficient understanding of the needs or values of the community. If, after thorough evaluation and consultation, the ethics review committee continues to believe the offer is unfair, it should explain its reasoning to the community and attempt to come to an agreement.

If this approach fails, the ethics review committee should next evaluate how bad the offer is. If the offer is regarded by the committee as unfair, but not excessively so, it should approve the study, assuming the community continues to support it. When the benefits being provided are close to a level that would be fair, the committees should default on the side of respecting community self-determination. However, if the committee finds the deal to be substantially unfair, it should not approve it, despite the agreement of

the community. Where to draw this line will require the judgment of a dedicated, informed, and supportive ethics review committee.

A second type of conflict between protecting and respecting host communities might arise when even just consulting with the community might undermine the chances that it will benefit. This possibility might arise in cases of severe strife in the community, as well as cases in which there is good reason to believe that the appointed representatives of the community are not trying to promote its interests. The standard approach in these cases should be to identify a different community to host the research. However, there may be very exceptional cases where the benefits to the community are significant and very much needed.

In these cases, it might make sense for the ethics review committee to agree to go ahead with the study in that community, despite the fact that the community is not involved in deciding what benefits it receives. In these cases, ethics review committees should institute other protections to help to ensure that the study is appropriate. In particular, it will be important to consult with others who are knowledgeable and disinterested and can provide input on behalf of the community. For example, the committee might consult with individuals who have extensive experience working with the community. The committee also might consider consulting with similar communities to see whether they regard the study as appropriate.

The present analysis suggests that the community should be involved in deciding what benefits it receives. Future research will be needed to assess how best to involve the community for this purpose. Of note, community consultation is often regarded as an ethical requirement for clinical research (Weijer and Emanuel, 2000). This view argues that the community should be involved from the beginning stages of developing and implementing studies. In addition, a number of groups have developed guidelines on how best to obtain community input for different types of research (Tarantola et al., 2007; UNAIDS, 2011). While a good deal more work will be needed, these proposals provide a starting point for future research to determine how best to involve the community in determining what benefits it receives.

VII. CONCLUSION

Addressing the potential for exploitation is vital to ensuring the appropriateness of multinational research. To avoid exploitation, it is widely agreed that host communities in lower-income countries should receive sufficient benefits. Regardless of what account of benefit sharing one endorses, the present analysis suggests that involvement of the host community in deciding what benefits it receives promotes four important goals: respecting the community, protecting the community, transparency, and enhancing social value. Importantly, the conclusion that involvement of the community should help

to promote these four goals does not depend on the acceptance of a particular account of what constitutes an appropriate offer of benefits to the community. It does not depend on endorsing the fair benefits framework, or the view that what benefits should be provided depends on the conditions of background injustice or oppression in the host community. Of particular note, the present arguments for involving the community do not depend on the mistaken belief that community consent determines what is fair and thus necessarily ensures a fair distribution of benefits. Rather, this analysis suggests that no matter which approach or approaches are ultimately found to be best for addressing the potential for exploitation, host communities should be involved in determining what benefits they receive in the context of multinational research.

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