### PART III

## THE HUMAN DEVELOPMENT APPROACH TO JUSTICE IN INTERNATIONAL RESEARCH

# Avoiding Justice: Research at the Auction Block

#### 8.1 Introduction

International research reveals fault lines in the foundations of research ethics produced by the tectonic friction between two metaphorical continents. One metaphorical continent represents orthodox research ethics in its domestic application in high-income countries (HICs) like the United States. Here, the principle of justice is, at best, woefully underdeveloped and, at worst, the subject of an almost principled aversion (e.g., \$1.2.7, \$2.5). Instead, the central focus is on ethical issues that can be most easily represented as falling within the confines of the IRB triangle. The other metaphorical continent is the domain of research conceived or funded by entities in HICs but carried out in low- and middle-income countries (LMICs).

On this second metaphorical continent, issues of justice rise to prominence and it becomes more difficult to shoehorn the relevant ethical issues into the narrow confines of the IRB triangle. In part, this is because it is difficult to ignore histories of unfair extractive relationships between HICs of the global north, many of whom are former colonial powers, and LMICs of the global south, many of whom are still dealing with the legacy of colonial rule. At a more practical level, disparities between the communities that sponsor and often drive the agenda for international research and the communities that host such trials calls into question background assumptions that are often taken for granted in the domestic context. With different burdens of disease from different sources of morbidity and mortality that must be addressed within different infrastructures and social systems, it is difficult to ignore the potential for disconnect between the questions international trials are designed to answer and the health priorities of host countries. As a result, issues about the relationship between research, local health needs, and health system capacity lie at the very heart of international research.

To address these issues, as we saw in §2.5-6 and §3.2.2, documents that provide guidance about the ethical conduct of international research include a series of requirements that address a group of stakeholders that are not typically the focus of discussion in domestic research. For example, at least some of the key stakeholders most directly able to influence whether research in low- and middle-income settings is responsive to the health needs and priorities of host communities fall outside of the IRB-triangle. These actors include international non-governmental organizations, foreign and domestic governmental authorities, and the agencies or entities that sponsor research. Similarly, whether a novel intervention will be made reasonably available to host communities after studies are concluded depends on the decisions and the conduct of a range of parties outside the IRB triangle, such as regulators, study sponsors, host governments, international organizations, or philanthropies that might help to fund access. Moreover, decisions or agreements that affect one or more of these issues might be made before stakeholders within the IRB triangle have been identified (before it is clear which team will carry out a research initiative or which communities will participate in the research) and some of their provisions will have to be effectuated by regulators, government officials, study sponsors, and others, after studies have been completed.

I have argued in previous chapters that research ethics in its domestic incarnation should embrace the relationship between research and the larger purposes of a just social order. Giving justice a more significant role in research ethics would, in effect, eliminate this tectonic friction by providing a unified foundation for a single framework of research ethics that can be consistently and coherently applied to domestic and international research. The next chapter shows how what I call the *human development approach* to international research can ground core requirements of international research in requirements of the egalitarian research imperative.

In this chapter, I examine the prospects of an alternative approach to reducing this tectonic friction that seeks, instead, to remain agnostic about larger issues of justice. It focuses on a process for ensuring that the microlevel transactions between the parties within the IRB triangle are fair and non-exploitative. This view aspires to eliminate what it views as a cumbersome mix of requirements on international research with their expansive scope in favor of a framework of procedures that render considerations of fairness more manageable within the confines of orthodox research ethics. In §8.2 I lay out the core claims of the *fair benefits approach* to international research (Participants 2002, 2004), including its use of collaborative partnership and transparency to ensure the fairness of the discrete transactions between study participants and researchers.

In §8.5–6 I argue that, despite its considerable appeal, this approach is deeply flawed. At best, it is underdeveloped at both a foundational and a practical level. At worst, I show that, as the view has been described, it serves to increase the efficiency of market forces that are likely to reduce the share of benefits that host countries secure from international research, driving a race to the bottom. Additionally, it is unlikely that the outcomes of this procedure will satisfy the criteria that its proponents require of fair agreements. In this sense, this view risks creating a kind of ethical Trojan horse in which a veneer of fairness and respect cloak the extent to which it allows powerful entities from HICs to advance their interests largely unconstrained.

Ultimately, I am concerned that the appeal to procedures as an alternative to substantive conceptions of justice embodies a romantic, pre-economic conception of procedures. An important lesson from the literature on procedures in economics—the area referred to as mechanism design—is that similar procedures can result in radically different outcomes and that the process of designing and selecting relevant procedures is often highly influenced by substantive values, including judgments about the appropriateness of their outcomes and the moral acceptability of the baselines from which the various stakeholders interact.

I conclude by arguing that it is more difficult than it might seem to remain agnostic about questions of justice in research ethics. Avoiding an explicit and systematic analysis of important background issues of social justice and, instead, hewing closely to the established values of research ethics does not represent agnosticism about issues of justice; instead it represents the tacit acceptance of what Brian Barry calls "justice as mutual advantage" (1982, 219–252). As a result, those who approach this topic wanting to remain agnostic about controversial issues may find themselves formulating the basic problem in a way that tacitly presupposes a particularly anemic theory of justice.

This chapter also illustrates how norms that govern the review and approval of research initiatives shape the strategic environment in which stakeholders interact. Creating a system of norms that focuses on individual transactions and benefits from research that are not directly related to the value of the information that research generates for host communities is likely to perpetuate an extractive system that deprives the most burdened populations of LMICs of the unique public good that can flow from research as a scientific activity. This public good is the information that local stakeholders require to expand the capacity of their basic social systems to effectively, efficiently, and equitably safeguard and advance the basic interests of that community's members.

#### 8.2 Fair Benefits and the Procedural Alternative<sup>1</sup>

#### 8.2.1 Exploitation as an Unfair Level of Benefit

The fair benefits approach begins from a premise that is widely shared, namely, that one of the most central ethical issues in international research is to avoid situations in which more powerful parties from HICs take unfair advantage of LMIC communities. Also, like numerous other accounts, this view treats unfair advantage taking as synonymous with exploitation. But proponents of this view argue that it is a mistake to see the cumbersome list of requirements elaborated in international guidance documents as necessary conditions for avoiding exploitation.

Their argument rests, in part, on Wertheimer's account of exploitation (Wertheimer 2008). On that view, exploitation is a property of micro-level interactions between individual parties to a discrete transaction. Although exploitative relationships can result in net harms to the exploited party, this need not be the case. It is an advantage of Wertheimer's view that it recognizes that agreements can be freely and knowingly undertaken and mutually beneficial while still being exploitative. In particular, even within a voluntary and mutually beneficial transaction, Party A exploits party B if party A receives "an unfair level of benefits as a result of B's interactions with A" (Participants 2004, 19). In this view, whether researchers and sponsors exploit study participants and their communities depends on whether the share of the benefits that these parties receive from hosting particular research initiatives is fair.

<sup>&</sup>lt;sup>1</sup> Much of the material in §8.2–8.7 originally appeared in London, A. J., & Zollman, K. J. (2010). Research at the auction block: problems for the Fair Benefits Approach to international research. *Hastings Center Report*, *40*(4), 34–45. It is revised and reprinted here with the generous permission of Kevin Zollman.

Additionally, proponents of this view follow Wertheimer in arguing that fairness is not ultimately an issue of "what" benefits host communities receive but of the "level" or amount of benefit (Participants 2004, 20). If this premise is accepted, then it follows that no particular benefit is a necessary condition for avoiding exploitation. Instead, exploitation is about how much benefit parties receive from a transaction. For this reason, proponents of this view argue that all types of benefits that might flow from research, not just access to the investigational agent, must be considered in determining whether the benefits are fair (Emanuel 2008, 724–725).

#### 8.2.2 Standards of Fairness

To identify exploitative relationships, we require a standard of fairness, now to be understood as a specification of the amount of benefit received by each of the parties to a discrete, micro-level transaction. But proponents of this approach also lament that:

(a) "Currently, there is no shared international standard of fairness; reasonable people disagree" (Participants 2004, 23).

Additionally, different individuals and different communities can have different valuations of the diverse benefits that might be on the table at any time. As a result, they go on to assert,

- (b) "Most importantly, only the host population can determine the value of the benefits for itself" (Participants 2004, 23). Therefore
- (c) "Ultimately, the determination of whether the benefits are fair and worth the risks cannot be entrusted to people outside the population, no matter how well intentioned" (Participants 2004, 22; 2002, 2134).

The claims in (a), (b), and (c) are quite strong and they provide the justification for the assertion that "the population being asked to enroll determines whether a particular array of benefits is sufficient and fair" (Participants 2004, 22).

These claims bolster the view, also adopted from Wertheimer, that fair distributions of benefits are defined by the results of free and informed transactions untainted by force, fraud, or deception. As they put the matter:

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(d) "[A] fair distribution of benefits at the micro-level is based on the level of benefits that would occur in a market transaction devoid of fraud, deception, or force, in which the parties have full information" (Participants 2004, 20).

Free agents with full information in a market devoid of force, fraud, and deception would evaluate the bundles of resources they can secure from alternative transactions and then choose according to their values. This reflects the sovereignty of host community values and the importance of a deep respect for their freedom and values.

Rather than specifying that host communities must be provided with a specific type of good, proponents of the fair benefits approach hold that a fair distribution is determined by requirements on the relative amount of benefits that relevant parties receive.

**Benefits must increase with burdens**: "As the burdens on the participants and the community increase, so the benefits must increase" (Emanuel 2008, 725; see also Gbadegesin and Wendler 2006, 251; Participants 2004, 22).

**Benefits must increase with benefits to others**: "Similarly, as the benefits to the sponsors, researchers, and others outside the population increase, the benefits to the host population should also increase" (Emanuel 2008, 725; see also Gbadegesin and Wendler 2006, 251; Participants 2004, 23.)

Benefits must track relative contributions: "The level of benefits that a community should receive to ensure a fair deal depends on the community's contribution relative to the contributions of all other parties that are involved in the research project, including sponsors, investigators, subjects, and other communities" (Gbadegesin and Wendler 2006, 251).

Against this background, proponents of the fair benefits approach have been staunch critics of the reasonable availability requirement on the grounds that it does a poor job of avoiding the problem of exploitation. First, in early-phase research, for example, or unsuccessful late-stage research, there is no intervention to make available to communities. In such cases host communities bear any costs or burdens of participation without receiving any offsetting benefits. Second, they argue that it is overly paternalistic to require host communities to accept, and perhaps even to pay for, the fruits of a particular research study when there may be different benefits that those communities would prefer (Participants 2004, 20; Weijer and LeBlanc 2006). Finally, reasonable availability is rejected because it doesn't track the criteria for fairness listed in the previous paragraph: "Reasonable availability fails to ensure a fair share of benefits; for instance, it may provide for too little benefit when risks are high or benefits to the sponsors great" (Participants 2002, 2133).

One particularly important implication of this reasoning is that if what matters is not the kind of benefit host communities receive but the amount, then if host communities are not interested in the information or the interventions that a study is designed to generate, and if it is not obligatory to provide post-trial access to the study intervention, then it is difficult to justify requiring cross-national studies to be aligned with or to focus on the urgent health needs or priorities of the host community. That focus itself appears to be overly narrow and perhaps also overly paternalistic because it focuses only on one way in which research can be responsive to interests of host communities (Wolitz et al. 2009).

#### 8.2.3 Collaborative Partnership

The fair benefits approach relies on two additional principles to produce outcomes that are fair. The first is called *collaborative partnership*. At the level of concrete action, researchers and host community members are to engage in a collaborative process of negotiation in which host communities and researchers agree on a specific division of benefits. Freed from the constraints imposed by international guidance documents, host communities are free to negotiate for studies that are responsive to their health needs and for post-trial access to novel interventions. But they are also free to negotiate for a different package of benefits, such as help in cleaning their water supply, constructing a road, or vaccinating their children.

Collaborative partnership is thus intended to be more responsive to a wider range of needs and preferences among host community members and to take advantage of the special knowledge and insight of host community members about how best to advance or improve their condition or circumstances. In light of the strong claims in (a), (b), and (c), it also reflects deference to autonomy of individuals in LMIC communities to make decisions for themselves about the conditions that would justify research participation.

#### 8.2.4 The Principle of Transparency

Collaborative partnership may help to ensure that agreements are mutually beneficial and therefore consistent with the requirements of beneficence. But Wertheimer holds that mutually beneficial transactions, freely entered, can still be exploitative. In part, that is because agreements in the real world can suffer from deficiencies that would not be present in a market in which all parties have full information and the transaction is free from fraud, deception, and abuse. Proponents of the fair benefits approach are particularly concerned about this problem in the international context. As they put it:

(e) "A population in a developing country is likely to be at a distinct disadvantage relative to the sponsors from the developed country in determining whether a proposed level of benefits is fair" (Participants 2004, 23).

The principle of transparency is supposed to structure the process of bargaining and negotiation in a way that approximates, as closely as possible, the conditions of such an idealized market. This involves creating a publicly accessible database of all benefits agreements between various research sponsors and host communities. This repository is supposed to be maintained by an independent party, such as the World Health Organization, with the expectation that various groups such as researchers, sponsors, governments, and potential host communities will have access to the data. In fact, their view requires that the database be advertised to potential host communities so that they can evaluate the various packages of benefits that have been exchanged in the context of other research projects.

How is this database supposed to ensure that agreements are fair? First, it reduces informational asymmetries between the host country and the researcher. This is required because fair outcomes must reflect agreements that would be struck under the condition in which the parties have full information (d).

Second, satisfying the requirement of full information is supposed to reduce the likelihood of fraud or deception by giving potential host communities access to information regarding a wide range of factors such as the costs of various aspects of research and the full range of benefits that might flow from a research project. Third, seeing what other communities received in the past should allow communities to assess the competitiveness of a proposed division of benefits. This, in turn, can be a point of negotiation in their determination of whether a proposed package is worth accepting.

Fourth, proponents of the fair benefits approach also claim that the principle of transparency is supposed to advance a regulative as well as informational goal. In particular, their approach has been criticized for not recognizing the extent to which inequalities in bargaining power will allow researchers and sponsors to exact hugely disproportionate benefits from the agreements reached in this process (London 2005). In response, proponents of the fair benefits approach have argued that:

- (f) "The criticisms seem to miss the fact that the fairness of agreements is not determined just by bargaining. The purpose of the transparency principle is to provide an external check that independently assesses the fairness of agreements" (Emanuel 2008, 725).
- (g) "Such information will facilitate the development of "case law" standards of fairness that evolve out of a number of agreements" (Participants 2004, 24).

It is this regulative goal that is referred to in (f) and (g) in which the database of prior agreements and the case law that it engenders function as an external check on fairness.

Ultimately, the principle of transparency is supposed to ensure that collaborative partnerships produce fair agreements by counteracting some of the informational defects that separate real-world negotiations from more idealized markets. As a regulative tool that can be used by international organizations, it is also supposed to correct for imbalances in power by ruling out offers that do not provide a sufficiently larger share of benefits to count as fair.

#### 8.2.5 Problems with Consistency?

The fair benefits approach has considerable allure, in part, because it appears to offer something for everyone. But a core question is whether this broad appeal reflects the merits of a view that coherently integrates different perspectives into a single framework or a vaguely articulated set of requirements that appeal to different constituencies but which, ultimately, cannot be reconciled.

Regulators and IRBs may be attracted to the prospect of reducing thorny questions of justice and fairness to terms that can be manageably addressed within the confines of the IRB triangle. This approach seems to embody the minimalist approach to questions of justice latent in the *Belmont Report* in which issues of justice are reduced to a function of beneficence and respect for persons (§2.5.3). However, it has the added attraction of recognizing the extent to which even voluntary and mutually beneficial agreements might reflect imperfections of real-world agents and, in this sense, fall short of fairness. So, it situates the minimalist's appeal to beneficence and autonomy within a more idealized context of full information and freedom from force, fraud, and deception. It thus holds out the promise of replacing the cumbersome mix of requirements enshrined in international documents with a single, seemingly much more manageable process.

Other stakeholders might be attracted to the fair benefits approach because they think that it will allow host communities to capture a much larger share of the benefits from international research. These parties might be attracted to the idea that benefits to host communities will increase with burdens and with benefits to others, and will track relative contributions. When LMIC communities host research that has the potential to generate hundreds of millions, if not billions, of dollars in revenue, then they might believe that host communities will be guaranteed to receive fairly substantial benefits in return for hosting the research. This prospect might be seen as justifying or rendering unproblematic the prospect that such research may focus primarily on HIC health needs or be designed to vindicate interventions that are unlikely to be used on a widespread basis in LMICs.

One question, then, concerns how the process of collaborative partnership and the transparency principle are to be structured so that they represent the conditions of an ideal market (d) while ensuring that agreements distribute resources in proportion to burdens, benefits to others, and relative contributions. In §8.4 we show that these two ideas are in fundamental tension and that ideal market transactions are unlikely to result in agreements that satisfy these conditions.

Other stakeholders may be attracted to the idea that LMIC communities must be the ultimate arbiters of what counts as a fair bargain as seen in (a), (b), and (c). They like the extent to which the fair benefits approach empowers LMIC communities to decide for themselves which agreements are worthwhile in a context free from force, fraud, and asymmetric information. But this strong commitment to the evaluative sovereignty of host communities might conflict with the substantive criteria for fair agreements if host communities are willing to accept a bargain in which the distribution of benefits does not vary according to one or more of those criteria.

In contrast, others might like the extent to which regulators or agencies like the WHO are empowered to play a regulative role in preventing LMIC populations from being offered unfair agreements, as reflected in (f), (g). These parties like the extent to which the bargaining power of researchers can be checked or constrained by outside parties who have the practical ability to police these agreements and ensure their fairness. But if outside regulators have the power to prevent mutually beneficial bargains that host communities are willing to accept under conditions of full information, devoid of force or fraud, then this seems to impinge on the strong commitment to the sovereignty of host community values in (a), (b), and (c).

Other stakeholders may like this approach because reducing inefficiencies in the market for research (d) and removing cumbersome requirements such as responsiveness and reasonable availability will allow firms from HICs to carry out a much wider range of research in LMIC communities. Offshoring research will result in considerable cost savings for firms and allow them to leverage supply and demand to capture almost all of the benefits from such transactions. Lowering the costs of research will, in turn, allow savings to fund more studies, thereby improving the overall rate of research.

Which of these assessments is correct? Well, it is difficult to say and, as a general point, that is itself part of the problem. We know so little about how the process of negotiation is supposed to be carried out that it is difficult to know how the market ideal in (d) is supposed to be reconciled with the distributional criteria for fairness. We know so little about how the database will influence this that it is unclear how to reconcile it with the strong claims in (a), (b), and (c).

#### 8.3 Collaborative Partnership Is an Auction

#### 8.3.1 Simultaneous, Iterated Bidding

How might the fair benefits approach be carried out in practice? We start from the idea that, ultimately, the focus of negotiations concerns how to divide the surplus value generated by research. Since this view is clear that the ultimate question is not "what" benefits are divided, but how much each party receives, this effectively focuses deliberations on the price that a community regards as fair for hosting a study, which is the cost to the researcher. We assume that every study has an expected surplus (the expected profits minus the cost of conducting the research), and that some of this surplus can be transferred to the LMIC host community. We also assume that there are some costs associated with hosting the research, and no community will agree to host research where its share of the surplus is less than its expected costs.

Consider first the situation in which researchers are free to negotiate simultaneously with as many interested parties as they like. In this case, researchers inform potential host communities about the various costs, risks, and potential benefits associated with a particular research initiative. After consulting their constituent members, each community proposes a basket of benefits that it would be willing to accept in return for hosting the initiative. Assume further that researchers are then free to inform each community of what the others are asking—as required under the principle of transparency and by the ideal of a competitive market. This would allow each community to compare a given level of benefit to what they perceive as their cost for hosting the research. At some point one community will be willing to accept a level of benefit that is less than what it would cost another community to host the initiative. At that point the latter community will withdraw from the negotiations. Other communities will consider whether the current "bid" is above their cost and, if it is, they will lower their bid. At some point negotiations will reach a level at which only two communities have a cost that is below the current offer. Negotiations will continue until the bid reaches the cost of the second-place community. That community will not lower its offer and the community with the lowest cost will reduce its bid accordingly. After this point there will be no more offers. The community with the lowest cost thus pays a fraction more than the cost of the second-place bidder. The division of benefits that results from this process will be such that the eventual winner gains the difference between its own cost and the cost to the second cheapest host community.

The process just described has the structure of a first price, open cry auction—those familiar to most of us from live and internet auctions. Instead of bidding larger amounts of money to purchase a commodity, potential host communities try to make themselves more attractive venues for research by

lowering the share of the surplus value generated by the research that they are willing to accept in return for hosting a research initiative. Negotiating this way allows researchers to choose the venue with the lowest costs, in effect, maximizing the surplus that they can expect to receive from the bargaining process.

It might be objected that this is not the kind of negotiation process that proponents of the fair benefits approach had in mind. However, nothing in the fair benefits approach prohibits this form of negotiation. In fact, this form of negotiating is consistent with the few features of this approach that its proponents do stipulate. That is, in this scenario researchers are negotiating directly with individual host communities about how much benefit each is willing to accept as a fair return to collaboration. It closely approximates the full information requirement for ideal market transactions by giving each community the chance to adjust their assessment in light of the current bid of other communities. Each community determines which offers they are willing to accept and if a community regards a proposed split as unfair, it is free to refuse. Likewise, the benefits from any agreement accrue directly to the eventual host community.

If the fair benefits approach wants to rule out using this kind of negotiating procedure, then it needs to be much clearer about either the way that procedure should be conducted, or about the properties that it should satisfy and how those properties rule out this kind of approach. Nevertheless, it is true that proponents of the fair benefits approach do not describe a process of repeated negotiation between communities, and although they stipulate that all parties must have access to the database of previous agreements, they do not state that each community must be aware of what other contemporaneous communities are willing to accept.

#### 8.3.2 One-Shot Bidding

So, we might imagine instead a process of negotiation in which researchers engage in a deliberative process with each community and then each has one opportunity to inform researchers of the amount they regard as a fair return. This eliminates the repeated process of negotiation or bidding and, in turn, eliminates the condition of perfect information that each community had in the previous scenario about the cost structure of other communities. Unfortunately, as long as each community knows that there are others that are interested in hosting the research, and each community knows that they have only one chance to submit an offer, then, on average, the outcome will be the same as the first price, open cry auction. That is because negotiations of this type also have the structure of an auction; in this case it is a first price, sealed bid auction. Variants of this kind eliminate the situation of perfect information, but not the incentive to make educated guesses about the cost structure of other bidders. Bidders simply have to base their negotiation strategies on those guesses. Sometimes they miscalculate and get less than they would in an open cry auction, other times they get lucky and get more; on average, however, the outcomes will be the same.

There are many ways in which these two processes of negotiation may differ. But the irrelevance of these differences is established by a powerful and elegant formal result, now well known as the "revenue equivalence theorem." What this theorem proves is that, given a particular set of constraints, the average amount paid in an auction (here interpreted as the amount of the surplus kept by the researcher) is the same (Myerson 1981; Riley and Samuelson 1981). On average the researcher will keep all of the surplus minus the average value of the second lowest cost.

The assumptions required for the revenue equivalence theorem to hold require very little from the structure of the interaction.<sup>2</sup> There must be an imbalance between supply and demand (modeled as multiple cites vying to host a single research initiative). Individuals who are bidding cannot enjoy taking risk for its own sake (although they may be willing to take risks). The structure of the process by which research is awarded must be such that the person who bids the lowest receives the research, even if they pay an amount different from their bid. If a community has the highest possible cost for hosting research, they must expect not to get any surplus. There are some restrictions on what communities believe about each other's costs, and all of this must be known by all parties.

Notice that many of the features we commonly associate with auctions are not required for the outcome to be equivalent to the outcome of an auction. The high bidder need not pay her bid, or even the bid of the second highest

<sup>&</sup>lt;sup>2</sup> We state these assumptions and defend their relevance to the fair benefits approach in Appendix A to London and Zollman 2010 available at: https://www.cmu.edu/dietrich/philosophy/docs/london/london-research-auction-supplement.pdf or from the author by request.

bidder. Bids can be made simultaneously or sequentially or any combination of the two. The result holds for an astonishing variety of ways of permuting the process of negotiation so that it differs from both first price, open cry or one-shot bidding auctions.

#### 8.3.3 Modified One-Shot Bidding

For instance, in an effort to remove some of the strategic element to the competitive bidding process, each community might engage with researchers in a process of deliberation knowing that, at the end of that process, there will be one chance to submit a bid and that although the lowest bidder will still win, that bidder will receive an amount of the surplus that is equivalent to the bid of the second lowest bidder. This is known as a second price, sealed bid auction. The strategic element to the bidding is removed but the result remains the same. The researcher expects to receive the same amount of the surplus as in the other cases: almost all of it.

#### 8.3.4 Commitment with the Option to Relocate

In fact, a negotiation process where there is not simultaneous competitive bidding can still function like an auction over time. Perhaps, for instance, host communities are first chosen on the basis of factors such as existing relationships, convenience, and ease of conducting the research. Assume, however, that at the completion of the study researchers have the option of locating subsequent studies elsewhere. As long as there are multiple potential host communities for each proposed research initiative then communities with a lower cost structure have an incentive to approach researchers, or their sponsors, in an effort to host a subsequent research study. As long as there is a realistic possibility that researchers will relocate, then the threat of being underbid in the future puts pressure on host communities to reduce their costs and, with this, the amount of benefit that they seek in return.<sup>3</sup>

<sup>&</sup>lt;sup>3</sup> For a brief overview of repeated auctions see Klemperer (2004, section 1.10.3).

#### 8.3.5 The Result of the Auction

Auction-like structures do an excellent job of realizing in practice the features of the ideal markets in (d) that are central to the fair benefits approach. What do these outcomes look like in practice?

Suppose that the anticipated benefits of a research project can be assigned a monetary value and that a particular project is expected to generate \$10 million in surplus. To model the results of this bargaining process, we assign each host community a cost for hosting this initiative by randomly drawing a number between \$100,000 and \$1 million. If we randomly assign costs in this range to two host communities and carry out the auction process over and over, the average split will be \$700,000 for the host community and \$9.3 million for the researcher. The average cost for the winning host community is \$400,000 so the average profit is \$300,000. If there are three communities, the average profit drops to \$225,000 (a \$550,000 / \$9,450,000 split). If there are nine, the profits are a meager \$90,000 (a \$280,000 / \$9,720,000 split).

What if we retain all of these assumptions, but we assume that instead of \$10 million dollars in surplus that the study is expected to generate \$10 billion dollars? In this case, the payouts to the host community remain the same. The additional profits are absorbed entirely by the sponsor.

What if research does not impose such steep costs on host communities? If we assume, as in the previous example, that the expected profit is \$10 million, but the costs to host communities are in the range of [\$0, \$100,000] then with two bidders the expected profit for the host community is \$33,333 (a split of \$66,666 / \$9,933,334). For three bidders the expected profit drops to \$25,000 (a split of \$50,000 / \$9,950,000), and if there are nine potential hosts the expected profit drops to \$10,000 (a split of \$20,000 / \$9,980,000).

Notice now one respect in which this approach can have some counterintuitive consequences. Suppose that the costs for host communities are as described in our first example, somewhere in the range of \$100,000 and \$1 million. Now suppose that altruistically motivated researchers want to help defray the costs that host communities might incur from hosting a research project. So they lobby the research sponsor to use more of their own personnel, defraying personnel costs, or to bring in a mobile laboratory, defraying infrastructure costs. This altruistically motivated act would in fact work against the interests of host communities and would capture a potentially sizable increase in profit for the research sponsor. This is because defraying costs to host communities reduces the range of potential hosting costs, thereby decreasing the distance between the cost of the winner and the cost of the second highest bidder. If costs could be reduced to the range of our second example, between [\$0, \$100,000], then the benefits to host communities would decrease to those listed in the second example. In other words, with three bidders the host community's expected profit drops from \$225,000 to \$25,000 and with nine bidders it drops from \$90,000 to a paltry \$10,000.

#### 8.4 Fair Benefits Cannot Achieve Its Own Benchmarks for Fairness

8.4.1 Participant Benefits Don't Increase with Burdens to Participants

This very brief modeling exercise allows us to answer some important questions that we raised in §8.2.5. For example, would the outcomes of this process satisfy the principles that benefits to host communities must increase with burdens and with benefits to others, as well as track relative contributions? Under auction-like structures it is unlikely that any of these desiderata will be satisfied.

The first principle from the fair benefits approach requires that the benefits to the host community must increase as the burdens to participants and the larger community increase. Under auction-like structures, however, the benefits that the host community receives (its profit) are not a function of the burdens that the research imposes on participants or the larger community. Sure, as costs for potential host communities rise, the size of the split that the host community receives will have to be larger in order to offset those costs. But "benefits" here are modeled as the share of the surplus that host communities receive that is over and above their costs. This is determined by the difference between the costs of hosting the research in the winning community and the costs of the community with the second lowest costs, and by the number of communities that are party to the negotiations.

Another way of putting this point is to say that trials that are more expensive cost more to conduct. But it does not follow from this that host communities will receive more benefit from this higher cost. Low-risk or less burdensome studies for rare conditions may reward host communities with sizable profits while high-risk or more burdensome studies for conditions that are quite common may produce minuscule profits for host communities. Our point is that under auction-like structures, the burdens that research participants or host communities bear do not directly influence the share of the benefits that they receive from hosting a trial. If outcomes of this process satisfy this condition, it will be as a result of happy coincidence and *not as a result of the structure of the negotiation process itself.* 

#### 8.4.2 Participant Benefits Don't Increase with Benefits to Others

The second principle states that the share of the benefits that host communities enjoy should increase as the benefits increase for other stakeholders, such as sponsors, researchers, and others outside the population. Under auction-like structures, however, the degree to which others profit from a community's participation is basically irrelevant to determining how the surplus is divided. In particular, if we hold fixed the costs of hosting a trial and the number of bidders, then it doesn't matter if the projected profit is \$2 million or \$20 billion dollars—the expected profit of the host community does not change. If the host community can expect to receive \$20,000 of benefit in the first case, that is what it can expect to receive in the latter. It is therefore important to recognize that auction-like structures function in a way that makes it unlikely that outcomes will ever satisfy this condition.

#### 8.4.3 Participant Benefits Don't Increase with Contributions

The third principle says that the benefits to host communities ought to be proportional to the community's contribution relative to other stakeholders. Unfortunately, the proponents of the fair benefits approach have not given us a clear account of what they mean by a "contribution" here. It should be clear from the previous analysis, however, that under auction-like structures, it is difficult to see how we could understand the contribution of the host community relative to those of researchers, sponsors, and others in a way that would make it relevant to determining the share of the benefits that host communities receive. Even if there are only two communities in the world that could host a particular trial, the magnitude of the benefits that the eventual winner receives will be a function of the difference between its cost and the cost of the other community. If the trial can be conducted with few costs, and the costs of the two communities are fairly close to one another, then the host community could expect to receive fairly meager benefits.

The upshot of this analysis is that there is little reason to believe that the process at the heart of the fair benefits approach will produce outcomes that satisfy the minimal conditions of fairness that the proponents of this view themselves endorse and certainly use as grounds for rejecting other views.

#### 8.4.4 A Race to the Bottom

This brief modeling exercise also demonstrates the potential for the fair benefits approach to result in a race to the bottom when implemented in practice. And, just so the point is clear, the process of negotiation does not have to be structured as a first-price, open cry auction in order for this result to obtain. The structural features that create the incentive for host communities to lower their bids are present even in the sequential case where researchers locate their study in a particular community but have the option of relocating for subsequent studies.<sup>4</sup>

Several additional factors increase the likelihood of a race to the bottom. First, as international research becomes increasingly mobile host communities may realize that they need to restrain their requests for benefits or risk having researchers relocate (Petryna 2007). This is because the outsourcing of clinical trials has effectively created a market for companies whose purpose is to match research initiatives with potential host communities (Petryna 2007; McManus and Saywell 2001). These contract research organizations (CROs) seek profits by reducing research costs and more efficiently matching research with host communities. These companies therefore have a powerful incentive to increase the size of their "portfolio" of potential communities that might host various research initiatives. This, in turn, makes the prospect of relocation very real for host communities. It also creates a market environment where host communities are more clearly competing with one another to secure access to research.

<sup>&</sup>lt;sup>4</sup> In fact, we argue in Appendix B to London and Zollman 2010 that even some fairly restrictive and unrealistic requirements aimed at equalizing the bargaining power of researchers and host communities would be unlikely to prevent a race to the bottom. This appendix is available at: https://www.cmu.edu/dietrich/philosophy/docs/london/london-research-auction-supplement.pdf or from the author by request.

The operation of CROs is thus making the marketplace for hosting research more competitive. Even if host communities are not bidding against one another each time they host a trial, the fact that the CRO can find a community that might be willing to host a similar study for less provides an incentive to reduce the size of the surplus that host communities seek to retain for themselves now.

What about the principle of transparency? It might come as a surprise to learn that it will do nothing to hinder the race to the bottom. This is largely because the race to the bottom is actually facilitated by the full information requirement of ideal theory that this principle is supposed to approximate.

Additionally, using the data from the repository of past agreements as a way to advertise research to eligible LMIC communities (Participants 2004, 23), would serve to increase the number of potential host communities by bringing new "buyers" into the market. Potential host communities could see what others have received in the past and enter the market armed with the information that they need to make competitive bids. After all, if one knows that researchers located an ongoing study in one place for some cost X, and one knows that one's community could host that research for considerably less cost than X, then one has an incentive to approach the researchers, their sponsor, or their CRO in an effort to host their next initiative. Even if the proponents of this approach do not intend the database to be used as a marketing tool to bring new host communities into the market, CROs have a powerful incentive to use it this way.

Rather than averting a race to the bottom or setting a floor for the benefits that host communities receive, the principle of transparency may actually place a ceiling on benefits as communities are forced by competition to seek less in return for hosting studies.

#### 8.5 An Independent Check on Fairness?

#### 8.5.1 Pure versus Imperfect Procedural Justice

One might object that this characterization of the fair benefits approach is overly pessimistic because we have left out the regulative aspect detailed in (f) and (g) (Emanuel 2008, 725). In this interpretation, the role of regulators might be to prevent a race to the bottom or to ensure that outcomes satisfy the principles that benefits to host communities must increase with burdens and with benefits to others, and must track relative contributions.

This objection dramatizes deep ambiguities within the fair benefits approach because it calls into question exactly what kind of procedural approach it is supposed to be. At some points, it sounds like it is supposed to be a *pure procedural approach*. Under a pure procedural approach, an outcome or a state of affairs is regarded as fair if and only if it is the result of a particular procedure. That is, the fairness of an outcome consists in the fact that it was arrived at or produced by a particular procedure. This view supports following (d) in defining fair outcomes as whatever "would occur in a market transaction devoid of fraud, deception, or force, in which the parties have full information" (Participants 2004, 20).

But, if the race to the bottom is prevented by a regulator imposing some constraints on which *outcomes* are acceptable, the fair benefit approach is not a pure procedural approach. How do we determine which restrictions should be imposed by the regulator? It cannot be from this *procedure*, since the regulator must now impose outcomes on the parties that differ from those that were arrived at by the relevant procedure.

At other points, the fair benefits approach seems like it is supposed to be an *imperfect procedural approach*. In an imperfect procedural approach, the special value of the procedure lies in its ability to produce, imperfectly, but more or less reliably, outcomes that are fair according to some independent standard or criterion of fairness. On this view, then, the fairness of the outcome is constituted by something other than its relationship to a particular process.

One such criterion requires that outcomes meet the conditions that benefits to host communities increase with burdens and with benefits to others, and that they track relative contributions. Moreover, the claim that "Reasonable availability fails to ensure a fair share of benefits; for instance, it may provide for too little benefit when risks are high or benefits to the sponsors great" (Participants 2002, 2133) seems to imply that satisfying at least the first two conditions is a necessary requirement for avoiding exploitation.

In light of the analysis presented here (§8.3-6) it is doubtful that proponents of the fair benefits approach can consistently endorse the more purely procedural criterion expressed in (d) and the more substantive criteria about the distribution of benefits relative to burdens and benefits and contributions. The reason is simply that transactions in a market of full information devoid of force or fraud are not likely to produce outcomes that approximate those substantive criteria.

#### 8.5.2 Incompatible Criteria for Fairness

There are two possibilities for eliminating the incompatibility between the pure procedural and imperfect procedural aspirations of the fair benefits approach. One is to argue that fair outcomes should at least approximate the principles that benefits to host communities must increase with burdens and with benefits to others, and they must track relative contributions. In that case, we now need a detailed account of the procedures that will be used to enable researchers and host communities to negotiate in such a way that they are likely to arrive at outcomes that approximate these conditions. We have argued that on a number of plausible ways of making operational the conditions outlined in (d), these outcomes are unlikely to hold. If the job of ensuring that these principles are met is supposed to fall to regulators, then this would require a significant diminution of the expansive role of host community autonomy expressed in (c). On this new proposal, regulators, not host countries, would decide if a bargain is ultimately fair. Moreover, their decision would be based on a substantive view of fairness. In particular, host communities might be willing to accept some mutually beneficial offers that regulators would prohibit on the grounds that they are unfair (since they deviate from the substantive criteria regulators are empowered to enforce).

While this is a tenable position, it is very different from the original presentation of the fair benefits approach since it dispenses with the strong claims outlined in (a), (b), and (c). This new position would require defense on substantive, rather than procedural grounds and an account of the procedure for negotiation that will approximate these outcomes. It is worth noting that the same argument that support Wertheimer's defense of the principle of permissible exploitation (§3.3–4) would challenge the consistency of this position.

A second alternative would be to stick with the market norms outlined in (d) and to jettison a commitment to the principles that benefits to host communities must increase with burdens and with benefits to others, and they must track relative contributions. Now, the role of external regulators would be to make sure that actual agreements approximate those that would have been reached in the ideal market. In this case, we need a more precise specification of what constitutes the idealized market. For instance, is the ratio of buyers to sellers in the idealized market the same as in the actual one? If it is the same, then we are back to the discussion of §8.3-4. That is, not only will the principles that benefits to host communities must increase with burdens and with benefits to others, and must track relative contributions, not hold, but regulators will not provide an external check on the bargaining process, other than ensuring that there was no deception, fraud, or concealment.

Interestingly, if the ratio of buyers to sellers in the ideal market is not the same as the actual one, then regulators might play the role of adjusting bargains to reflect this ideal ratio. Although this is also an interesting proposal, it would require additional, substantive arguments to (a) specify the ideal ratio and (b) justify using *this* feature to determine a fair distribution of benefits as opposed to some other view of fairness.

#### 8.6 Pure Procedural Justice Revisited

Perhaps we have underestimated the appeal of the fair benefits approach as a pure procedural approach to issues of fairness in this context. After all, collaborative partnership is a compelling ideal. What is there not to like about the idea that researchers and host communities should engage each other as "partners," "collaborating" to advance shared ends, in a way that is respectful of the autonomy of the host community and its distinctive values and ends? The relationship of moral equality implied by collaborative partnership also strikes a welcome contrast to ethical imperialism or the inequalities of the "white man's burden." Since the values of respect for autonomy and beneficence are the bioethics equivalent of mom and apple pie, perhaps we should follow them wherever they lead and simply call those outcomes "fair."

This sounds good. The problem is that endorsing these values does not entail that everyone who endorses them conceives of them in the same way. Nor does it entail that one has a set of procedures that are faithful to these values in practice. Both of these problems afflict the fair benefits approach.

The view contains within it several competing conceptions of the sense in which sponsors and host community members should be treated as equals in their "partnership." One ideal is grounded in the norms of the market. All parties should be equally free to make binding contracts in light of full information, free from fraud, coercion, and deception. Within those constraints, there is nothing unfair about participants using inequalities in urgent needs, endowments, and the like to their strategic advantage.

In contrast, different ideals of equality and partnership undergird the principles that benefits to host communities must increase with burdens, with benefits to others, and track relative contributions. Here, ideals of equal respect for welfare, partnership, and agency are conceived of in ways that differ from ideal market norms because they constrain the way that collaborators can use inequalities in endowments or urgency of needs to their strategic advantage.

The problem is not simply that these different ideals lead to incompatible outcomes, but also that the incompatibility of these outcomes reflects substantive differences in ideals of respect for others as moral equals.

Before we can know whether we should follow the procedures of the fair benefits approach wherever they lead us, therefore, its proponents need to (i) specify a consistent set of ideals that these procedures are supposed to track or embody, (ii) justify the claim that these are the relevant ideals, and (iii) demonstrate that their procedures for realizing these values in practice are faithful to those ideals, properly understood. Our claim is not that this can't be done—it is that there appear to be several, potentially incompatible, ways of doing this, and each represents a significant departure from the original ambitions of the approach.

For example, sticking with their claim in (d) that "a fair distribution of benefits at the micro-level is based on the level of benefits that would occur in a market transaction devoid of fraud, deception, or force, in which the parties have full information" (Participants 2004, 20), proponents might simply embrace the claim that auction-like structures represent the best way to ensure that real-world negotiations satisfy these conditions. If this process results in highly disproportionate divisions of benefits and if LMIC communities wind up receiving a lower level of benefits than they would have received under reasonable availability, then this simply shows that such outcomes are not exploitative, not that the fair benefits approach is somehow faulty.

If proponents want to move in this direction then they should drop the misleading language of collaborative partnership. After all, there is a sense in which online auction sites like eBay respect the autonomy of participants and treat them as morally equal. But nobody is confused into believing that whether they get the item at the end of that process depends on the reasons that they offer to their "partners" in some collaborative, deliberative interaction. This is because there is a more important sense in which auctions, and markets in general, are designed to harness the power of *competition*, not collaboration. More importantly, they would then need to provide substantive arguments to justify what would at least now be explicit claims about the status of research as a commodity and market norms as the relevant criteria of fairness.

#### 8.7 Models and Empirical Assumptions

At various points in our analysis critics might object that we have relied on questionable empirical assumptions. For instance, we note that even if researchers are committed to conducting research in a particular community, others that could host future research projects at a lower cost have an incentive to recruit researchers away. But it might be objected that hosting a trial can give that community an advantage over other communities and make it more likely that they could retain future research initiatives while still increasing the benefits that they receive. So, things might not turn out as badly as our model predicts. Perhaps this is the case with other features of our model as well.

Several responses to are in order. First, our analysis is intended to illustrate the importance of providing stakeholders with some framework for assessing the normative claims that one makes on behalf of a proposed procedural approach. This framework should clarify for stakeholders how the proposed procedures are likely to behave, given realistic assumptions, and it should help stakeholders understand the variables that will determine how the approach performs in actual practice. Proponents of the fair benefits approach have not done this. We have tried to fill this gap. If proponents of the fair benefits approach have a different model to propose, they are welcome to elaborate it. But it is not a vindication of their approach, as it has been articulated to date, to leave our model and its general conclusions unchallenged and simply to hope that something will happen in actual practice that will avert its predictions from coming to pass.

Second, one advantage of articulating a model of the form that we provide is that it makes such questions more tractable by bringing into focus the set of factors or variables that are relevant to the model's predictions. In this case, for example, whether researchers are likely to relocate can depend on the extent to which the relevant stakeholders view research as just another form of economic exchange. Research sponsors, after all, are under constant pressure to cut costs and to make their basket of resources stretch farther. We suspect that, if anything, the Fair Benefits Approach contributes to the view that research is an economic opportunity that is rightly governed by market norms. As such, the widespread endorsement of this view might reduce the inhibitions of various stakeholders to relocate research when doing so can be justified on economic grounds.

Third, in all cases, the probability that researchers will relocate in the future hinges on whether other communities can make themselves more attractive hosts. It would be a mistake to understand this claim as somehow imputing crude or insensitive motives to researchers. This reflects one of the recurring themes of this work, namely, that the motives of various parties may matter much less than structural features of the social system in which those parties are constrained to act. The myopic focus of orthodox research ethics screens out the larger, social dynamics that influence the terms on which research is carried out. Researchers may have deep commitments to host communities, but they may not be able to live up to those commitments if they are under pressure from sponsors or others to relocate in order to cut costs. In fact, we have shown that the way that a particular system is structured can have such far-reaching consequences that it can create situations in which altruistically motivated acts have unintended, deleterious consequences (§8.3.5).

Nothing in our analysis presupposes that stakeholders have unsavory motivations. Nevertheless, it is important to recognize that there are armies of well-paid professionals who make their living analyzing systems and figuring out how to maximize the returns of their firms. "Gaming the system" may be frowned upon in some forms of "collaborative partnership," but in the market, the ability to work the system to one's advantage is regarded as a virtue rather than a vice. Since market norms play such a pervasive role in the fair benefits approach, these concerns are centrally relevant.

One implication of the analysis presented here is that the fair benefits approach could easily function in practice as a kind of ethical Trojan horse. Ambiguities and inconsistencies at the conceptual level make it attractive to a broad range of stakeholders, each of whom has a different view of how to understand and reconcile its core commitments. But when it is carried out in practice, this view may simply entail that LMICs are free to "collaborate" in research that advances the health interests of HIC populations while HIC sponsors are free to use their considerable bargaining power to capture almost all of the benefits generated by such collaborations.

We have also argued that in order to clarify the normative content of their position, proponents of this approach cannot avoid engaging substantive issues of fairness and justice. In this regard, both proponents and critics of the fair benefits approach need to pay greater attention to a move that the fair benefits approach uses to shape the terms of the debate, but for which we can find no explicit argumentation. Recall that Wertheimer treats exploitation as a micro-level concern. It is a property of discrete interactions between individual actors and it is supposed to be independent of broader background concerns about rights and justice. As we mentioned earlier, the key issue on this view is not which benefits are received, but how much. This in turn motivates the view that whether a particular research project is aligned with and focused on the health needs of the host community is less relevant (if it is relevant at all) than the question of whether they receive a sufficient level of benefits in return for hosting the study. And this leads to a view that effectively treats research as a commodity whose distribution is rightly governed by market forces.

But even if one were to agree, for the sake of argument, that Wertheimer's view of exploitation is the correct view of that concept, this does not establish (1) that the most fundamental or important ethical issues in the context of international research are those that occur at the micro-level, (2) that researchers (as opposed to other stakeholders such as governments, nongovernmental organizations, or funding agencies) should be seen as the primary duty bearers in this context, or (3) that researchers should be treated essentially as private parties with no prior obligations that are relevant to the exchange.

As we saw in §3.7, questions about the funding, regulation, and conduct of international research are issues of institutional design. But concerns about the fairness of *institutional systems* cannot be accommodated within Wertheimer's account of exploitation since his view applies only to the discrete interactions of individuals and not to the operation of institutions. Once again, the myopic focus on discrete interactions between a narrow set of stakeholders is insufficient to capture the way that the incentives that these actors face are structured by the rules and norms of larger social systems.

#### 8.8 Why Minimalism about Justice Is Problematic

#### 8.8.1 Allowing Power to Define the Space of Equality

In research ethics, the desire to avoid controversial commitments and protracted debates about justice motivates what I have called a minimalist approach to this principle. It is minimalist in the sense that it offers a thin conception of justice in which the real evaluative work is done by the more well-defined and well-understood values of beneficence and respect for persons. Part of the allure of the fair benefits approach is that it purports to offer a procedure that can be used in the face of disagreement about difficult questions of justice to ensure that research agreements are voluntary, mutually beneficial, and fair.

Despite appearances, this approach does not avoid entanglements with controversial conceptions of justice. Instead, its conditions together represent an example of what Brian Barry calls "justice as mutual advantage" (Barry 1989). In seeking to avoid the controversies associated with thick conceptions of justice, the minimalist approach covertly elects a particular account of justice to govern international research initiatives without explicitly having to defend this approach as a particular conception of justice.

In justice as mutual advantage, the parties to a transaction bargain to ensure that each is made better off as a result of the interaction. The requirement that acceptable bargains must provide each party with a net benefit, even if agreements must be reached under conditions of full information devoid of force and fraud, is perfectly consistent with agreements in which the distribution of those benefits is hugely disproportionate. This is in part because the way benefits are distributed reflects inequalities in the power of the bargainers.

Justice as mutual advantage does not deny that, from the moral point of view, equals should be treated equally. But it allows equality to be defined, often implicitly, by the capacity of individuals to help or harm others. Those who are equally situated in their capacity to help or to harm receive equal treatment while those in a less advantaged position receive proportionately worse treatment. Lopsided agreements between parties of unequal power are not only to be expected but track the underlying inequalities that define the space of equality.

Allowing inequalities in power to legitimate inequalities in entitlements effectively accepts Hobbes's view that "the value or worth of a man is, as for

all other things, his price, that is to say, so much as would be given for the use of his power; and therefore is not absolute, but a thing dependent on the need and judgment of another" (Hobbes 1985, X, 16). Far from agnosticism about justice, this position tacitly embraces the view that the value or worth of a person is a function of their use value to a potential bargainer seeking to maximize her own share of the surplus of cooperation. Disease and lack of access to medical care effectively function as valuable commodities whose use value to researchers or sponsors from HICs gives some a place at the bargaining table. The more widespread a particular condition of sickness and disease, the less power individuals or communities of individuals with that condition have since those who hold out for more can be replaced by those willing to accept less.

Individuals and communities who lack the "good fortune" to suffer from a condition that is of interest to scientists and companies in HICs have no seat at the bargaining table. Their plight is of no use value to researchers and so they are consigned to die in silence because the power differential in their case is so great that they cannot either help or harm potential collaborators. As Barry notes in a discussion of principles of reciprocity or fair play in general, while they specify terms that cooperative endeavors must meet in order to be fair, they do not "say that it is unfair for a practice that would, if it existed, be mutually beneficial, not to exist" (Barry 1982, 231). In other words, when justice is framed as a fair exchange, it does not recognize any obligation to engage in cooperation where cooperation does not yet exist.

This has a profoundly distorting effect on our approach to LMIC health needs. Those who care about the plight of disadvantaged people simply because they are fellow human beings are forced to resort to eloquent attempts to portray rampant sickness and disease as a threat to global prosperity or national security—to the affluence and security of more powerful parties who already have a seat at the bargaining table (Heymann 2000). Highlighting the potential for disease to cross borders and to transgress socioeconomic, racial, and ethnic boundaries represents a way of pleading the case for the plight of groups who might otherwise not be recognized as having moral standing. In effect, this tactic seeks to make the plight of the least advantaged salient by emphasizing its instrumental importance to the people who are tacitly treated as really mattering, the more powerful groups whose interests might be impacted by unchecked disease that flows from conditions of deprivation.

Focusing primarily on transactional fairness also encourages a piecemeal and ad hoc approach to the needs of LMIC communities for two reasons. First, it allows decisions about research priorities, which strategies to pursue and where research should be conducted to be determined by the nearly unchecked discretion of the stronger party. Second, it allows the stronger party's interests to dictate the terms on which bargains can be carried out. As a result, there are no grounds internal to this view on which to object to interactions with LMIC communities that are initiated by and structured entirely around the needs and interests of HIC firms or entities. Nor are there grounds, inherent to this approach, to differentiate between the types of need that research might address, whether research addresses root causes of problems or is orthogonal to the priority health concerns for host populations.

#### 8.8.2 Screening Out Morally Relevant Information

Avoiding broader questions of justice carries with it a larger risk to which the parochialism of orthodox research ethics is already prone. Focusing narrowly on micro-level transactions between a narrow set of parties screens out as irrelevant some of the very questions that lie at the heart of justice, understood as a value of social institutions.

First, this approach treats the status quo as the relevant moral baseline against which possible actions are to be evaluated. Against this baseline, the only actors whose conduct is relevant to assessment are the parties to the specific micro-level transaction under consideration. These assumptions cast international research initiatives in terms that fit easily within the conceptual ecosystem of orthodox research ethics. But, in doing so, they risk begging the very questions that make such initiatives so morally fraught.

Second, this narrow frame effectively excludes as irrelevant the character and quality of past relationships of extraction and domination that might have contributed to social conditions of poverty and deprivation in which sickness and disease flourish. But past relationships of injustice, or the failure to discharge important social responsibilities can give rise to obligations to provide more or better than what is reflected in the status quo.

Finally, this narrow frame treats the relationship between the health needs of individuals and the broader social, political, and economic context that structure and shape those needs as morally unproblematic. But the health of individuals and their ability to influence their own health status is fundamentally shaped by the way basic social structures promote or frustrate the capabilities of, and the range of opportunities open to, the individuals whose lives they govern. Abstracting the health needs of a community from this larger context therefore excludes the information necessary to evaluate the extent to which important rules, practices, and social structures influence those needs.

Treating the organization of the basic social institutions of a community as given elides the distinction between cases in which populations suffer because of the failures of less-than-decent social structures and cases in which decent social structures are overwhelmed by natural disasters. This obscures some of the grounds on which individuals in the host community might have a legitimate claim against one another, or against their own government to better conditions. It also obscures the grounds on which the influence of third parties, such as foreign governmental and corporate entities, on the community's basic social structure might generate obligations to go above and beyond the status quo.

How power is distributed, the terms on which social authority is exercised and the purposes for which shared social resources are expended are issues that fall under the purview of a theory of justice (Freeman 1990). These questions structure the context in which research transactions take place and that determine who has the ability to negotiate for particular ends, on particular terms. But they also have a profound impact on other fundamental aspects of human agency and experience that provide far less arbitrary grounds for claims to equal consideration from the moral point of view.<sup>5</sup>

When we approach the problem of assessing potential collaborative research initiatives from this broader perspective, therefore, we must at the very least leave conceptual room to consider whether the interests that are frustrated or defeated by less-than-decent social structures are so fundamental as to generate a duty on the part of others to assist them.<sup>6</sup> In the next chapter I argue that claims of justice limit how research can be organized within national boundaries and how it can permissibly be organized when it reaches across national boundaries.

<sup>&</sup>lt;sup>5</sup> On different efforts to define the space of moral equality and for a defense of a particular version of the capabilities approach see Anderson (1999).

<sup>&</sup>lt;sup>6</sup> This point is dramatized by proponents of the so-called interest theory of rights. For example, Raz (1984, 195) argues that "'x has a right' if and only if x can have rights, and other things being equal, an aspect of x's well-being (his interest) is a sufficient reason for holding some other person(s) to be under a duty." See also Nussbaum (1999, 236).