

Justice and the Human Development Approach to International Research

9.1 Introduction

The previous chapter illustrates how efforts to avoid difficult questions of justice in research ethics have not succeeded. At best this aversion has built up an unresolved “tectonic friction” between the way that orthodox research ethics deals with domestic research in high-income countries (HICs) and the set of issues and stakeholders that are salient when research is funded and conducted by entities from HICs but carried out in populations from low- and middle-income countries (LMICs). At worst, rather than preserving agnosticism about potentially controversial issues, the field’s general aversion to questions of justice and reliance on other foundational principles of bioethics and research ethics has resulted in the default acceptance of one particularly narrow conception of justice from a much larger space of possible alternatives.

In this chapter I argue that the best way to eliminate this tectonic friction is to reconstruct the foundations of research ethics on terms that reflect the requirements of the egalitarian research imperative. The lesson to learn from recent debates about the ethics of international research is not that we need to purge international frameworks of appeals to requirements that are grounded in justice and that implicate a wider range of stakeholders. It is that we need to recognize justice as the first virtue of social institutions, acknowledge that research with humans is a scheme of social cooperation involving a wide range of stakeholders that both calls into action and feeds into important social institutions, and we need to hold both domestic and international research to the requirements of the egalitarian research imperative. I refer to the resulting view as the *human development approach to international research*.

Although the human development approach deals specifically with international research, it is important to emphasize that it extends into

the international context the egalitarian research imperative outlined in chapter 4, the integrative approach to research risk in chapter 6, and the non-paternalistic approach to research oversight in chapter 7. In §9.2 I provide a brief overview of the key claims of the human development approach. I then elaborate and defend particular aspects of this view in more detail. In §9.3 I show how this approach situates research within a larger project of human development that is focused on ensuring that the basic social structures of a community function to secure the fair value of the basic interests of community members. Then in §9.4 I argue that this position supports a duty to promote research that fulfills this social mission.

Within this context, the duties of responsiveness and post-trial access operate at two levels. At the system level there is a duty to shape the incentives of the research system so that it promotes the conduct of research aimed at generating the knowledge needed to expand the capacity of basic social institutions in LMIC communities—including their systems of individual and public health—to more effectively, efficiently, and equitably meet needs that represent development priorities for that community's members. Post-trial access ensures that this knowledge and the interventions, practices, and procedures that it supports are incorporated into the basic social institutions of the host community. At the level of research review these requirements should be enforced to prevent powerful parties from advancing their own interests at the expense of the common good of LMIC communities.

In §9.5 I argue that only the local *de jure* standard of care allows studies to advance the common good while respecting the status of participants as free and equal persons. To substantiate this claim I show how this interpretation of the standard of care dovetails with the requirements of the integrative approach from chapter 6 and how alternative interpretations of the standard of care can fail to track the requirement of social value or the principle of equal concern. This chapter then closes with some comments about the challenges associated with linking the conduct of research to philosophically contentious positions about domestic and international justice.

9.2 Overview of the Human Development Approach

The human development approach to international research is a framework for organizing and evaluating research that crosses national boundaries or that takes place within a single nation but involves funders, researchers, or

other actors from other nations or from extra-national entities such as governmental or non-governmental international organizations. It is particularly relevant to research that takes place in LMIC communities that is funded, organized, conducted, or otherwise influenced by entities from HICs.

This framework is grounded in the same concern for the basic interests of persons that defines the basic interests conception of the common good and that motivates the egalitarian research imperative. It holds that in every community, individuals have a just claim to basic social structures that are organized around and function to secure the common good of that community's members. On the basic interest conception of the common good, this means that community members have a just claim to basic social institutions that function to secure for all community members the fair value of the basic intellectual, affective, social, and physical capacities they need to formulate, pursue, and revise a life plan on terms that are consistent with equal regard for the interest of their compatriots to do the same.

Because the basic social structures of most communities fall short of the requirements of justice, the members of every community have a claim on one another and their social authorities to support a larger program of human development. This is a multisectoral process of promoting and reforming the terms on which their basic social structures function so as to more closely approximate the requirements of a just social order for all community members. This includes a claim on local authorities to use existing knowledge and resources to advance the basic interests of that community's members. Internationally, residents of affluent countries, government officials, and stakeholders in private and public organizations also have a duty to contribute to this process of human development in LMICs.

In both domestic and international cases, the human development approach holds that the obligation to promote human development extends to a duty to discharge the egalitarian research imperative. This involves helping LMIC communities to create a certain division of social labor among one set of basic social institutions that has as its ultimate goal the improvement of a related set of basic social institutions. In particular, this is a division of social labor in which stakeholders and institutions employ the distinctive scientific and statistical methods of research to generate the knowledge and the means necessary to bridge shortfalls or gaps in the ability of that community's basic social structures (such as their systems of individual and public health) to effectively, efficiently, or equitably safeguard and advance the basic interests of that community's members.

A shortfall of this kind obtains when a threat to the basic interests of community members cannot be more effectively, efficiently, or equitably addressed through the application of existing knowledge and resources. Such threats may be novel in the sense that their cause is unknown or there are no established effective means of addressing them. Alternatively, such threats can be novel in the sense that established effective means of addressing them exist, but there is significant conflict or uncertainty about their relative merits under conditions that are attainable and sustainable in the host community.

The human development approach to international research retains the responsiveness requirement, recast to reflect a broader scope for research ethics and its role in shaping the strategic environment in which various parties to the research enterprise interact. Within this framework, the responsiveness requirement operates on two levels. At the system level it is understood as a duty that applies to a wide range of stakeholders to create and sustain a system of knowledge production in which the strategic environment aligns the interests of stakeholders with research that addresses those shortfalls in the basic institutions in LMICs that represent development priorities for host communities. This includes strengthening the capacity of LMICs to conduct research that addresses their distinctive development priorities. At the level of research review, the human development approach endorses a strong but defeasible requirement limiting research initiatives in LMIC contexts to those that are organized, designed, and conducted to produce the information necessary to expand the capacity of the host community's basic social structures to address threats to the basic interests of community members that constitute development priorities for those communities.¹

The human development approach also retains the requirement of reasonable availability. At the system level, this is understood as a broad-based duty that applies to a wide range of stakeholders to ensure that resources of various kinds are in place so that the knowledge and the means that are developed in research can be incorporated into the basic social structures of host communities. At the level of research review, this translates into a duty to verify that such prior agreements are in place.

Finally, the human development approach holds that research must be conducted on terms that respect the status of study participants and host community members as free and equal persons. To do this, research must be consistent with the principle of equal concern (§6.2.2). The local *de jure*

¹ For a slightly different defense of a similar claim, see Flory and Kitcher (2004, 38–39).

interpretation of the standard of care holds that study participants should not receive a level of care for their basic interests that falls below what experts judge to be the most effective strategy for addressing the need in question under conditions that are attainable and sustainable in basic social systems—such as the local health systems—where the intervention in question will be deployed. Research in which the standard of care provided to participants satisfies this requirement is consistent with the principle of equal concern and is thus consistent with equal respect for the status of study participants and community members as free and equal persons.

Studies that meet the conditions of responsiveness, with credible assurance of reasonable availability, and that provide at least the local *de jure* standard of care satisfy conditions of justice. They represent an avenue for advancing the common good of LMIC community members on terms that respect the status of those who make these advances possible as free and equal persons.

9.3 Basic Interests and Moral Claims on Basic Social Institutions

9.3.1 Justice and Basic Social Structures

In contrast to the myopia of orthodox research ethics, in which the research activity is severed from its relationship to larger social structures and purposes, the human development approach understands research as an activity that calls into operation basic social institutions in a community and that has as its proper moral function generating the information those institutions need to better fulfill their proper social function. Research is thus a cooperative social activity that is constrained by and beholden to prior moral claims of justice on the part of the community members whose basic interests it shapes and impacts.

The human development approach treats justice as fundamentally concerned with the basic social structures of a society and whether they work to secure for all community members the fair value of their basic human capacities (Rawls 1971; Korsgaard 1993; Anderson 1999; Nussbaum 1999; Sen 1999b). It also recognizes, however, that in the nonideal world in which we live, the basic social institutions of most communities fall short of the requirements of justice. This shortfall is the motivation for a larger project of human development that takes these basic social structures as its focus.

In particular, the goal of this long-term, multisectoral project is to establish and foster, for every community, basic social structures that are organized around, and function in the service of, the common good of that community's members (Nussbaum 1999; Sen 1999b).

There are two reasons why the human development approach requires that international research initiatives must be evaluated in terms of the way they draw on and impact the basic social institutions of a community.² I state these reasons briefly here and then elaborate on each in §9.3.2 and §9.3.3.

First, the basic social structures of a community consist in the political, legal, social, economic, and health-related institutions that determine the distribution of fundamental rights and liberties and that set the terms on which individuals can access all-purpose goods and resources such as food, shelter, education, and productive employment, as well as health services necessary to protect, preserve, or restore the ability to function. These institutions are basic because they represent the background institutions, rules, entitlements, and restrictions within which other social interactions take place (Rawls 2001, 10).

These institutions have a deep and pervasive impact on the life prospects of those they govern because they regulate how rights and liberties are distributed and the terms on which community members can access individual and social opportunity. They determine the terms on which community members have access to education, productive employment, to the political process, control over their person and their personal environment, and protection of their basic human rights. As a result, how these structures operate is an important social determinant of health (Sen 1981, 1999b; Drèze and Sen 1989). More important than the sheer economic wealth of a community is whether the community directs its resources to creating and sustaining social conditions that promote the ability of community members to develop and exercise their basic intellectual, affective, and social capacities in the service of formulating, pursuing, and revising a life plan of their own (Daniels et al. 1999; Sen 1999b). Because the health

² It is worth emphasizing again that the human development approach is not a quixotic effort to lump the moral responsibility for addressing all injustice onto the shoulders of researchers or the research enterprise (see chapter 4 note 23). Rather, the goal is to specify the unique role that research can play in within a just division of social labor and to articulate criteria that can be used to promote research that advances those ends and to avoid research that detracts from them.

status of individuals is affected by a matrix of political, social, and economic factors, the project of creating and sustaining the conditions that foster health requires a coordinated, multisectoral approach that is sensitive to these interrelationships.

Second, this network of social institutions itself represents a division of social labor in which responsibility for safeguarding the basic interests of people in different spheres of life (e.g., education, health care, criminal justice) is delegated to identifiable parties. If all persons are morally equal to the extent that they share the same higher-order interest in having real freedom to formulate, pursue, and revise a reasonable life plan of their own (§4.5.3), then every community bears a responsibility of justice to ensure that its educational, economic, legal, political, criminal justice, and health-related social institutions work to realize this goal for all community members. In every community, in other words, there is a duty to ensure that this division of social labor works to produce what Henry Shue refers to as “full coverage” to the legitimate claims of community members (1988).

International research is to be evaluated against this background conception of justice and human development. It advances the goals of human development when it works to expand the capacity of a community’s basic social systems to more effectively, efficiently and equitably secure or advance the basic interests of its members.

9.3.2 Social Determinants of Health and Prior Moral Claims

Members of a community have prior moral claims on the basic social structures of their community because those structures have such a profound impact on their rights, liberties, and health. Social structures that are not organized around or that do not function in the service of the common good create conditions in which some are denied effective opportunities to develop and exercise their basic capacities while others enjoy a rich array of opportunities and resources that support individual achievement (Daniels et al. 1999; Marmot and Bell 2012). Very often, these are also the conditions under which avoidable sickness, disease, and premature mortality flourish (Marmot and Wilkinson 2005; Commission on Social Determinants of Health 2008). When individuals in such conditions lack access to the basic building blocks of social and economic opportunity and healthy living, the harms that result cannot be dismissed

as accidents of nature or justified by reference to the common good. They represent a failure to use the state's control over basic social structures to advance the interests of community members. Those who suffer in these cases can legitimately claim, as a strict obligation of justice, an entitlement to relief from such hardships.

To illustrate this point, consider some parallels between the health needs of LMIC populations and Amartya Sen's groundbreaking work on famine (Sen 1981; Drèze and Sen 1989). Famines are commonly viewed as natural disasters caused principally by a combination of poverty and poor food production. Sen showed, however, that these factors alone do not account for the occurrence of famines. For example, in 1979–1981 and 1983–1984, Sudan and Ethiopia experienced declines in food production of 11% or 12% and, like a number of other countries in sub-Saharan Africa, suffered massive famines. During the same period, however, food production declined by 17% in Botswana and by a precipitous 38% in Zimbabwe, yet these countries did not suffer the ravages of famine (Sen 1999b, 178–180).

According to Sen, the reason for this difference in outcomes can be traced to differences in the social and political structures of these countries. Botswana and Zimbabwe had rudimentary democratic social institutions that enabled them to stave off famine. They implemented a series of social support programs targeted at enhancing the economic purchasing power of affected groups while also supplementing food supplies. Mass starvation occurred in Sudan and Ethiopia because the dictatorial regimes in those nations failed to take such relatively simple social and economic steps to safeguard their citizens' interests.

These lessons should inform our view of sickness and disease more generally (Benatar 1998, 2001, 2002, Van Niekerk, A. A. (2002).). For example, HIV/AIDS has had a devastating impact on many populations in sub-Saharan Africa. In some nations, during the 1990s, as much as 30% of the population was HIV positive. In sharp contrast, during that same period, Senegal was able to limit both the prevalence of HIV/AIDS and the rate of new infections to about 1% of the population. The principal cause of Senegal's success lies not in advanced technology or great wealth, but in the government's long-standing, grassroots investment in its human resources. In Senegal, information about HIV/AIDS and many other sexually transmitted diseases has been disseminated through an assortment of educational programs. Empowering individuals with information and opportunities for activism enhances the public's capacities for communal interaction, free expression, and political

participation and so creates a social context in which people can more effectively safeguard and secure their welfare.

This focus on education and activism has been further enhanced by the judicious use of scarce resources. Senegal closely monitors its blood supply and distributes millions of condoms free of charge. It invests in monitoring and treating many sexually transmitted diseases, especially in target populations such as commercial sex workers, young people, truck drivers, and the spouses of migrant workers. Additionally, as part of a program of perinatal care, it was one of the first countries to offer antiretroviral drugs to pregnant women, although on a very limited basis. This multisectoral approach to HIV/AIDS, and to public health in general, has halved HIV prevalence and illustrates the positive health effects of policies that strive to protect citizens' basic capacities for agency and welfare (Kharsany and Karim 2016).

The terms on which the basic social structures of a community are organized have a profound and far-reaching effect on the ability of community members to secure and advance their basic interests. Because every community member is equal insofar as they share the higher-order interest in having real freedom to formulate, pursue, and revise a life plan of their own, every community member has a moral claim to a set of basic social structures that are organized around the goal of securing this interest. As a result, resources that domestic authorities are willing to make available to various actors—including the parties who would use those resources for research purposes—may not be “available” in a more fundamental moral sense: those who control them have a prior moral obligation to deploy them in the service of ends that better advance the goals of human development (§4.8.2).

The same is true for other ways in which authorities might use the power of their offices. Regimes can fail to serve the common good by neglecting basic social institutions altogether, by misappropriating or misdirecting the time and energies of their personnel, or by inappropriately restricting or occupying important institutional spaces. These failures can violate prior moral claims that constrain the ways in which important social institutions can exercise authority and allocate various human and material resources (Gostin 2010). These prior claims—of all citizens to a set of basic social structures that secure and advance their basic interests, and of citizens whose interests are set back by failures or deficiencies in these basic social structures—shape and limit the terms on which research in a community can be conducted.

9.3.3 Full Coverage to Moral Claims

Because the basic interests of community members define the space of equality and because those with equal claims are equally deserving of assistance, efforts to secure and advance these interests must strive to satisfy the requirement of full coverage. A social arrangement, a policy, or an initiative satisfies the condition of full coverage to the extent that it addresses the interest of every party with a legitimate claim. As Shue (1988) notes, the duty of full coverage is often best achieved through a division of social labor in which specific parties are assigned particular duties and prerogatives that are jointly necessary to meet the conditions of full coverage.

For Rawls (1971, 7; 2001, 10), the basic social institutions of society represent exactly this sort of social division of labor. Their purpose is to assign specific responsibilities, duties, permissions, and prerogatives to identified parties who are delegated specific tasks for meeting particular needs under specific terms and constraints. This division of labor thus seeks to increase the coverage of rights, resources, services, and opportunities provided to community members to secure their higher-order interest in having real freedom to formulate, pursue, and revise a life plan on terms that are consistent with the real freedom of their compatriots to do the same.

The health-related institutions of a community, including its public health and healthcare institutions, contribute to the process of human development in two fundamental ways. First, sickness, injury, and disease can undermine the ability of persons to exercise those basic cognitive and affective abilities they need to take full advantage of opportunities in various spheres of life, such as personal, social, economic, and political spheres (Daniels 1985). Sickness and disease can hinder education, frustrate full participation in the social and political life of a community, and reduce access to employment and economic opportunity. These deprivations, in turn, can produce compounding effects that hamper a person's ability to advance their own interests, including their health, educational, social, and economic interests (Bloom and Canning 2000; Jamison et al. 2013). Health systems promote human development through prevention efforts to reduce the probability that health-related threats materialize, through ameliorative efforts to mitigate the harmful effects of sickness and disease when they do occur, and by making available the knowledge and the means that individuals, clinicians, policy makers, and others require to make decisions about how to effectively safeguard and advance the basic interests of persons.

Second, although other elements of the basic social structures of the community provide individuals with important social determinants of health—education, nutrition, employment, access to social and political opportunity, and respect for basic human rights—health-related institutions address the health needs of individuals that persist in the face of these social determinants. Even if a just social order produces widespread health benefits for community members (Daniels et al. 1999; Sreenivasan 2007), residual sickness, injury, and disease can nevertheless impair the ability of afflicted individuals to realize the fair value of their basic abilities. The systems of individual and public health provide an infrastructure for addressing these residual needs.

To meet the duty of full coverage, health systems must be configured to make effective, efficient, and equitable use of existing knowledge and resources. Efforts to advance the goals of human development in health should first seek to close gaps in the ability of health systems to safeguard and secure the basic interests of community members by expanding their capacity to make use of existing knowledge and resources. Even a relatively modest increase in international aid targeted this way would transform the health needs of LMIC communities (Pogge 2002, 79). Roughly 90% of the avoidable mortality in LMICs stems from a handful of causes for which effective interventions already exist (Jhah et al. 2002). Making those interventions available through local health systems would have a transformative effect on individual health and opportunity (Jamison et al. 2013).

Even if these efforts are undertaken with new urgency and commitment, two broad categories of research with humans have an important role to play in advancing the goals of human development.³ The first deals with the development of diagnostic, prophylactic (especially vaccine research), therapeutic, and vector control interventions. These interventions target health needs that persist in the face of such development efforts or represent strategies for addressing health needs that would significantly advance the ability of health systems to contribute to development goals. This type of research focuses on conditions of special importance to LMICs including HIV, malaria, tuberculosis, typhoid, kinetoplastids, parasitic worms, staphylococcal

³ Discussing the increase in average life expectancy in LMICs and the decrease in cross-country inequalities in the last half century, Jamison et al. note, “Of much greater quantitative significance, however, have been the generation and diffusion of new knowledge and of low-cost, appropriate technologies. Increased access to knowledge and technology has accounted for perhaps as much as two-thirds of the impressive 2 percent per year rate of decline in under-five mortality rates” (2006, 4).

infections, diarrheal disease, and strategies for improving the ability of women and girls to avoid unplanned pregnancy and to reduce maternal and infant mortality (PATH 2014). It is also important to produce interventions that can be implemented at scale under conditions that are attainable and sustainable in LMIC contexts. An example of research of this kind in the context of vaccines includes research to produce formulations that require fewer doses; that are stable under hotter temperatures; that are effective against multiple strains of a pathogen, such as influenza; or that offer combined protection against multiple pathogens, such as a combined diarrheal vaccine against rotavirus, enterotoxigenic *Escherichia coli*, typhoid, and shigella (Jamison et al. 2013, 1940–1944). As the health needs of LMICs shift and non-communicable diseases account for an increasingly large share of the burden of disease, it will be important to develop interventions with similar utility for LMIC health systems.

The second category is health policy, health systems and implementation research. Establishing that interventions are effective against a particular condition is only a small part of the knowledge needed to use a set of interventions to improve the health of people on a large scale. Research in this category is necessary to determine whether and under what conditions interventions, whether newly developed or already established effective in a different context, can be deployed at scale in LMIC contexts in ways that increase the effectiveness, efficiency, or equity with which health systems are able to address the health needs of their populations. The same applies to research on individual and public health policies, programs, and health systems (Haines et al. 2004; Paina and Peters 2012; Alonge et al. 2019; Sheikh et al. 2020). This includes identifying and closing gaps in service provision; identifying and addressing impediments to intervention uptake, utilization, and adherence; and identifying and addressing shortfalls in the ability of current systems to secure and advance the health needs of populations that are marginalized, subject to exclusion or prejudice, or in some other respect historically underserved (Pratt and Hyder 2015).

9.3.4 Research and Basic Social Structures

The prior moral claims that citizens have to basic social structures that secure and advance the common good motivate the egalitarian research imperative and constrain the terms on which research with humans is morally

permissible. In part, this is because research is a scheme of social cooperation that stands in a special relationship to the basic social structures of a community. Because of this relationship, research is entangled in a network of moral claims that shape both the permissible goals of research and the conditions on which research can be permissibly carried out.

First, as we saw in § 4.7.2–3, research stands in a special relationship to the basic structures of a community because it produces a unique public good. This public good is the information and means necessary to understand threats to the basic interests of community members, the causal processes involved in the lifecycle of such threats, to understand and develop alternative means of addressing those threats, and to clarify the relative merits of possible preventative or restorative strategies. The ability of a community's basic social structures, such as its institutions of individual and public health, to effectively, efficiently, and equitably secure and advance the basic interests of community members thus depends on how the research enterprise is structured and functions (Easterlin 1999). In part, this is because myriad stakeholders rely on the information produced in research to make decisions that impact health and welfare, the use of scarce social resources, and the entitlements of community members.⁴ It is also because research is often the only way to produce the information and the means necessary to bridge gaps in the ability of a community's basic social structures to safeguard and advance the basic interests of that community's members.

Second, the research enterprise calls into action the basic social institutions of a society.⁵ This can involve legislative action or rule making to support research through public financing or to shape intellectual property rights or conditions for market access in order to align the incentives of private actors with the common good. Similar legislation or rule making might create

⁴ A key insight of Wenner (2018) is that failure to enforce requirements that research must produce social value for host communities has led to the concentration of power in the hands of private actors to shape the system of evidence production in ways that advance their own interests, and the interests of a narrow band of identifiable parties, to the detriment of a wider swath of the population whose health needs are deemed less lucrative or otherwise less worthy of investigation.

⁵ For arguments to the effect that considerations of justice arise from the fact that research frequently relies on social resources and that this is true even for research conducted by private entities, see London (2005), London et al. (2010), and Wendler and Rid (2017). Wenner (2018) associates these arguments with a transactional view of research which she rightly rejects. The point I want to emphasize here is that these resources are made available, not just to support individual research transactions, but to create the kind of infrastructure that supports research and that shapes the terms on which it is conducted. It raises issues of justice, then, because it represents the use of social authority and the creation of rules, institutions, and social systems that shape an activity that has the kind of profound impacts that Wenner describes.

social institutions with the mandate to conduct research, to support the conduct of research by others, to regulate the products of research, or to oversee different elements in the lifecycle of knowledge generation and product development, licensing, marketing, and sales. This can include enacting rules and regulations that set standards for regulatory approval or for ensuring the ethical conduct of scientifically sound research. It can involve shaping educational institutions and curricula to train and educate actors capable of engaging in research or engaging in one of the allied disciplines that support the research enterprise or take it as its subject matter.

All of these activities require the exercise of social authority for the purpose of creating a system of rules and institutions that allocate rights and privileges, divide responsibility, and allocate scarce material resources, human time, and attention to support research activities. The exercise of this authority and the institutions, laws, rules, and investments that it produces must be justifiable to community members as serving and advancing the common good.

Finally, in addition to being a form of social cooperation that serves important public purposes and requires the exercise of social authority and various forms of public support, research is also an activity that directly affects the basic interests of participants. For all of these reasons, it must be organized and carried out on terms that respect the status of its various participants as free and equal persons. In part, this reiterates the logic of appeals to the common good, namely, that social activities undertaken to advance the common good must be carried out on terms that respect the common good (§4.5.5). So, research activities undertaken with the goal of enhancing the ability of health systems to protect, restore, or promote the basic interests of community members must be carried out on terms that reflect equal concern for the basic interests of research stakeholders, including study participants.

In light of these moral claims, the human development approach holds that the research enterprise must function as part of a division of social labor in which it is the purpose of the basic social institutions of a community to discharge the duty of providing full coverage to the basic interests of community members. The distinctive role that research can play in this division of social labor is to use scientific and statistical methods to target and investigate the means of filling gaps in the ability of those social structures to meet those needs.⁶ The research enterprise represents a permissible use

⁶ Wenner makes a similar point when she says that “Clinical research is one aspect of an institutional structure that governs the health systems that are available to individuals, that individuals

of a community's social authority and scarce public resources and is a permissible target of social support when it functions to expand the capacity of the basic social structures of that community to more effectively, efficiently, or equitably safeguard and advance the basic interests of that community's members.

When it is not possible to address every such knowledge gap then the stakeholders who shape the direction and focus of research have a duty to ensure that mechanisms are in place to focus research activities on knowledge gaps that represent priorities for human development. Because this is a claim about the way that research must relate to the basic social institutions of a community, it holds for all research, including domestic research carried out in HIC contexts. In the context of international medical research, the human development approach holds that stakeholders who shape the direction and focus of scientific research have a duty to promote research that targets the priority health needs of LMIC populations and to ensure that all research is carried out in a way that is responsive to and aligned with those needs.

Recognizing the importance of research to development underscores that the egalitarian research imperative requires that HICs support the ability of LMICs to carry out research of this kind for themselves. In other words, it is not sufficient that research resources and expertise be controlled by HIC sponsors and deployed in LMIC settings (Sitthi-Amorn and Somrongthong 2000; Nuyens 2005). Rather, the goal is to create and sustain the infrastructure in LMICs to support research that addresses their development priorities (Pratt and Loff 2014; Pratt and Hyder 2015).

9.4 The Duty to Promote Human Development

9.4.1 Avoiding Three Moral Pitfalls

In chapter 3 I argued that Wertheimer's radical proposal to permit relationships of exploitation, unfairness and injustice was motivated, in part, by a frustration over the way that orthodox research ethics navigates three

cannot opt out of, and that will have deep and lasting impacts on their life prospects, their final ends and purposes, and the way that they think of themselves" (2018, 31).

moral pitfalls. In particular, when the requirements of responsiveness and reasonable availability are applied by IRBs at the time of protocol review, they can prevent LMIC populations from engaging in research that might offer those populations a net benefit without ensuring that a better alternative is waiting in the wings. The concern, then, is that strong prohibitions against exploitation and unfairness might avert unfair or disrespectful relationships while leaving host communities vulnerable to the ravages of lethal neglect.

Alternatively, efforts to avoid neglect by requiring researchers to discharge a duty to aid or a duty to rectify past histories of injustice appear to arbitrarily saddle a narrow group of actors with a demanding duty to rectify unjust conditions that are not of their making, or that are not solely of their making. Because the decision-making of parties such as lawmakers, ministers of health, regulatory agencies, or private philanthropies who shape the research agenda is treated as falling outside the purview of orthodox research ethics, there is a kind of conceptual pressure to revise research ethics standards in international research in a way that allows host communities to advance their interests to the greatest extent possible, given the offers they are likely to receive.

The human development approach rejects the presumption that IRBs represent the most appropriate institutional focus for issues of justice in research ethics and that the stakeholders who are party to the IRB process exhaust the set of stakeholders who bear important duties in this realm. Instead, it expands the purview of research ethics to consider the role of research as an element in a just social order and the requirements on its design and conduct necessary to fill this role. The goal is then to advocate for institutional frameworks, laws, policies, incentive structures, partnerships, treaties, and any other viable means necessary to bring the conduct of research in practice into better alignment with these conditions (Benatar and Singer 2000). The stakeholders who bear responsibility for these goals include political leaders, policy makers, corporate leadership, trade organizations, professional societies, international organizations, philanthropies, and others.

In that regard, the primary goal of this framework is not to limit research in LMICs but to expand it. It seeks not to articulate conditions for the ethical conduct of international research and then to hope that stakeholders are motivated to propose research that satisfies those criteria. Rather, the goal is to establish that there is a moral imperative to promote research that satisfies these criteria grounded in the ability of research to produce a unique public good that is intimately tied to the ability of a

community's basic social structures to discharge their responsibilities to that community's members.

9.4.2 Human Development and the Egalitarian Research Imperative

The imperative to support research that advances the goals of development is grounded in the relationship between research and the basic social institutions of a community and the moral imperative to undertake a process of human development that takes those social institutions as its target. Every community has a strong moral obligation to support and promote the larger process of human development. This obligation has two foci. The first is inward looking and encompasses the obligation to ensure that the basic social structures of their own community are designed and function on terms that preserve and advance the fair value of every community member's basic interest in having real freedom to formulate, pursue, and revise a life plan of their own (Gostin 2010).

Even technologically advanced HICs have a duty to engage in a domestic process of human development because the rights of women, racial and ethnic minorities, people with disabilities, or other marginalized groups are often unrecognized, or may be recognized on paper but disregarded in practice in ways that detract from the ability of individuals in these classes to realize the fair value of their basic interests. In such cases, unequal treatment for basic interests and the profound consequences this can have for the life prospects of individuals translate into a duty of justice to reform laws, social policies, and institutional arrangements around the goal of securing the fair value of the basic interests of all community members. The same considerations apply to domestic authorities within LMICs who must often discharge this responsibility against a background of severe resource constraints.

The second focus is outward looking and encompasses the obligations that communities have to one another. This obligation has three components. I state each component briefly and then elaborate on them in turn. First, all communities have an obligation to respect and not to undermine just social arrangements, wherever they exist (Rawls 1971, 334; Simmons 1979, 147–156). This obligation is grounded, at least in part, in the important role that the basic social institutions of other communities play in securing the basic interests of the individuals in those communities. Since the basic interests of

individuals define the space of moral equality, there is no reason that membership in one community should empower its members to be indifferent to, or malevolent toward, the social arrangements that influence the ability of others to enjoy the fair value of their basic interests.

Second, when a set of communities interact on terms that undermine the capacity of the basic social structures of a subset of communities to advance the common good of their constituent members, the communities that are advantaged by such interactions incur a duty to rectify the consequences of these interactions. Such duties of rectification can stem from ongoing relationships of explicit domination and extraction. They can also arise from social arrangements that may not have been intended to advance such goals but that nevertheless have created a niche that powerful parties have been able to exploit to these ends.

Third, independently of prior relationships, countries with sufficient wealth, political power, and influence have an obligation to assist other communities in creating and sustaining basic social arrangements that satisfy conditions of justice and advance the project of human development. This obligation stems from the importance of the basic interests that are frustrated by less-than-decent social institutions and the ability of affluent and influential communities to encourage and promote systems that better provide full coverage to the claims of those who suffer and toil under adverse social, economic, political, and health conditions.

The human development approach regards each of these outward looking considerations as sufficient to establish a duty to support the larger project of human development in LMICs. We can start with the third consideration and work backwards. Moral frameworks that take human welfare and agency as sources of moral claims recognize that claims of assistance can be grounded in the importance of the basic interests of persons that are frustrated by less-than-decent social institutions (Ruger 2018; Cullity 1994; Sen 1999b; Nussbaum 1996, Ashford 2003). Such frameworks can be consequentialist in nature, but they need not be since they can also ground rights-based frameworks, including accounts of the source and nature of human rights.⁷ Likewise, although the importance of these interests is emphasized

⁷ Sen (1999b) offers an account that has both consequentialist and rights-based components. Proponents of the interest theory of rights, such as Joseph Raz, argue 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” (1984, 195). Nussbaum argues that capabilities needed to live a distinctively human life ground human rights claims (1999).

in global egalitarian conceptions of justice (Beitz 1979; Nussbaum 1996; Shue 1996; Brock 2009; Jones 1999; Pogge 2002, 1994; Caney 2005) the moral importance of these interests are often recognized even within state-based or nationalist conceptions of the global order. From the claim that individuals and states might owe special duties to their fellow citizens (e.g., Tamir 1993, 2019; Miller 1995, 2007; Gans 2003), it does not follow that such individuals or states do not also have a duty to aid others. For example, although Rawls rejects a global egalitarian framework that would extend justice as fairness to all people, regardless of national borders, he still holds that well-ordered societies have a duty to assist burdened peoples (Rawls 1999, 105–113).

Moreover, the importance of different aspects of what I am calling the basic interests of persons are reflected in the mission statements of international organizations and help to motivate global development initiatives, such as the millennium development goals, where research has also been recognized as an important element for advancing those goals (Jamison et al. 2013; PATH 2014). In that respect, the moral imperative to respond to threats to the basic interests of persons—whether formulated in consequentialist terms or in human rights language—is already recognized in some international policy and programs. In this respect, the human development approach seeks to bring research ethics into better alignment with ethical considerations whose relevance to policy and practice is already recognized though imperfectly supported and realized in practice.

The duty to aid is bolstered by prior relationships that generate special duties of rectification.⁸ Many LMICs continue to struggle from the legacy of extractive relationships including colonial rule and post-colonial turmoil. Part of the enduring legacy of colonialism is the extent to which the interests of colonial powers shaped local policies and institutions in colonized territories, often to the detriment of those populations (Turshen 1977; Manderson 2002; Pearson 2018). To amass wealth and secure access to natural resources and raw materials, colonial powers co-opted the social structures of colonized peoples and fostered social divisions that could be exploited to prevent unified insurrection. Although foreign governments were most directly

⁸ This argument is briefly explored in the context of international research in Crouch and Arras (1998) and Benatar (1998, 2001). For a clear exposition of duties of rectification, see Nozick (1977).

involved in colonial rule, the focus of that rule was often geared at enabling firms to exploit the material and human resources of colonized peoples. The extractive economic systems that colonial powers created were thus exploited by a range of stakeholders, from foreign trading partners to private firms across a variety of industries.

For example, recognizing and supporting what Pogge calls the “international resource privilege” creates a strategic environment in which any group that succeeds in wresting control of the national government in a developing country is recognized as having the legitimate authority “to borrow in the name of its people and to confer legal ownership rights for the country’s resources” (Pogge 2002, 73). The existence of this privilege provides not only a powerful incentive for the unscrupulous to seize power, but also a convenient mechanism for consolidating power and then wielding it for the enrichment of a privileged few.⁹ Employing power in this way saddles LMICs with disastrous long-term debt and prevents most of the population from sharing in the benefits generated by their country’s natural resources. Instead, the benefits are enjoyed primarily by ruling elites and by governments and corporations in HICs who prop up such regimes in exchange for strategic alliances, the sale of military equipment or other large-industry commodities (e.g., airplanes, oil and gas services), and cheap access to raw materials and human resources. Although the global resource privilege is a policy of governments to recognize the authority of other governments, it enables trade among private firms who sell their products and services.

Similarly, one reason drugs are so scarce in LMIC populations is their cost. Many individual pharmaceutical companies played an active role in the negotiation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement) at the World Trade Organization. The pharmaceutical lobby has used its considerable influence on US and EU trade representatives to enforce patent protections and intellectual property rights even though the TRIPS agreement allows countries to produce or import generic versions of beneficial medications in cases of national emergency. The pharmaceutical industry has aggressively pressed for trade sanctions or taken legal action against countries that have tried to implement this emergency clause (Barry and Raworth 2002; Schüklenk and Ashcroft 2002). In doing so, it has blocked legitimate efforts to provide

⁹ Pogge (2002b, chapters 4, 6).

medicines to some of the populations that need them most (Pierson and Millum 2018).

Although specific governments and corporations may owe particularly strong duties of rectification to specific groups whom they directly wrong, the policies and practices of colonial rule and post-colonial exploitation have provided, and in some cases continue to provide, benefits to a wide range of governments and private entities. This includes the citizens of the countries in whose name colonial rule was undertaken and the shareholders in the firms in whose interests profits were maximized.¹⁰

Because duties of rectification are also owed equally to all parties who are affected, and because the effects of these systems have been widespread, priority should be given to strategies for redress that provide full coverage to those who have been affected. At a minimum, the targets for such a duty include eliminating the global and domestic structures in LMICs that perpetuate extractive relationships and establishing in their place structures that promote human development.

This view of development also provides a needed corrective to what amounts to an inappropriately narrow focus on inequalities in income or wealth in the literature on global justice. For example, a common theme in this literature is that international development requires a significant transfer of wealth from developed to developing nations. Transferring a greater share of wealth to LMIC populations would supposedly alleviate the conditions of poverty that provide the ecological niche in which sickness and disease flourish. Similarly, greater economic prosperity would provide the extremely poor with a broader range of opportunities and the resources necessary to meet more of their most basic needs.¹¹ To be sure, the development and maintenance of basic social structures are not cost free, and failure to provide monetary and socio-political support for the reform or expansion of such structures will impede a community's ability to achieve full coverage. But whether a transfer of resources will improve the social and economic

¹⁰ Statist or nationalist theories of global justice hold that inequalities between states are not morally impermissible, as such, since these inequalities can reflect morally important differences, such as the willingness of certain people to invest time and effort in practices or innovations that turn out to be particularly advantageous. But Miller argues persuasively that such a view of national responsibility is a double-edged sword: it protects advantages won through fair means, but it renders citizens of such states liable for remedial duties tied to past state action (Miller 2007, 265–266).

¹¹ Sreenivasan claims that “Any plausible and complete ideal of international distributive justice . . . will at least require better-off states to transfer *one percent of their gross domestic product (GDP)* to worse off states” (2002). See also Pogge (2001).

conditions of community members depends crucially on the ends to which such resources are employed.

Without reforms to global institutions and the basic structures of LMIC communities, filling the pockets of regimes that do not employ existing resources to safeguard and secure the basic interests of all citizens does not guarantee that additional resources will trickle down to community members. For these reasons, even if those in the developing world are owed a greater share of global resources, international aid and development must target more than financial transfers. It must focus on improving those elements of the host community's basic social structure that affect individual agency and social opportunity, while taking interim steps to mitigate the adverse effects of existing social structures on the health and welfare of those who are subject to them. This dual focus on resources as well as individual agency and social opportunity is central to the kind of multisectoral approach that defines the human development view.

Finally, even if one does not recognize a duty to aid, or if one recognizes such a duty but believes it will not soon be honored on a large scale, the human development approach provides a more equitable foundation for collaborative partnership between communities. It permits research that targets knowledge gaps in HIC health systems to be carried out in partnership with LMICs under the conditions that the host community suffers from the same knowledge gap, regards its closure as an important policy goal, that the strategies or interventions being evaluated can be implemented on terms that are attainable and sustainable in LMIC communities, and there are reasonable commitments in place to ensure that the knowledge, policies, practices, or interventions vindicated in such research will be incorporated into the health systems of LMIC partners.

Together, concern for the basic interests of burdened peoples and recognition of the complex of extractive relationships that are part of the legacy of colonialism and post-colonial exploitation provide a network of reasons for policy makers in HICs to take affirmative steps to support and advance the basic social structures of LMICs. Although the bulk of these efforts should focus on the provision of existing knowledge, practices, and interventions, research with human participants still has a valuable role to play in this process. But it cannot play that role without concerted effort on the part of a range of stakeholders whose duties, obligations, and influence on research are not traditionally represented within research ethics (Pratt et al. 2012).

9.4.3 Responsiveness and Reasonable Availability as System-Level Concerns

Within the human development approach, the responsiveness and reasonable availability requirements help to ensure that research satisfies the social value requirement and so discharges the first part of the egalitarian research imperative. In this view, a necessary condition of responsiveness is that research must be designed to produce the information and the means that are necessary to expand the capacity of host community health systems to more effectively, efficiently, or equitably safeguard or advance the basic interests of that community's members. In this regard, the 2016 CIOMS guidelines are correct when they assert that, "Where communities or policy-makers have determined that research on particular health needs constitutes a public health priority, studies that address such needs seek to provide social value to the community or population and are therefore responsive to their health needs" (CIOMS 2016, Guideline 2). The cognate requirement of reasonable availability is necessary to ensure that research of this kind translates into concrete improvements in the capacity of local health systems to advance the basic interests of that community's members.

Even when research is designed to expand the capacity of local health systems to address local health needs, those needs can vary in terms of their importance. Earlier versions of the CIOMS guidelines required research to be "responsive to the health needs and the priorities of the population or community in which it is to be carried out" (CIOMS 2002, Guideline 10). But the 2016 revision of those guidelines holds that research must be "responsive to the health needs or priorities of the communities or populations where the research will be conducted" (CIOMS 2016, Guideline 2). The open question is whether research satisfies the condition of responsiveness if it is designed to generate "new knowledge about the best means of addressing a health condition present in that community or region" even if that health condition does not constitute a public health priority for the relevant communities (CIOMS 2016, Guideline 2). From the language of the commentary in the CIOMS guidelines, it appears that it can.

Within the human development approach, the responsiveness and reasonable availability requirements operate on two levels. At the system level, they reflect the imperative to strengthen research capacity in LMICs, to increase the amount of research that addresses shortfalls in the ability of local health systems to address needs that represent priorities for development,

and to ensure that processes are in place to translate new knowledge and interventions into improved practices and procedures. This focus on capacity building and priority health needs reflects the strong claim on the part of community members to basic social systems that provide full coverage to the basic interests of all community members. When all such needs cannot be met, then these moral claims translate into a requirement to ensure that development efforts address needs that represent priorities for development.

This moral claim operates at the system level in the sense that it indicates the goals that should be advanced by incentives that structure the strategic environment in which various stakeholders in research act. I have argued here that research ethics plays a critical role in shaping the strategic environment in which various parties act. It does this, in part, by influencing the rules and the terms on which various practices or conduct is permitted. In chapters 2 and 8, for example, we saw that the conditions for permitting various kinds of studies can alter the portfolio of research proposed in a community because those conditions play a direct and an indirect role in determining whose interests drive the research agenda. In chapter 7 we saw that prospective review before committees of diverse representation alters the incentives that researchers face in ways that can improve the quality of research and its ethical acceptability. But we also saw that IRB review is not a viable forum for addressing all of the incentives that shape the research enterprise (e.g., §4.9).

Promoting responsiveness at the systems level requires engaging a wider range of stakeholders about questions that must be addressed long before individual protocols are composed and submitted for IRB review. A significant portion of these efforts should focus on promoting a legitimate process of priority setting for research and developing mechanisms for global health governance within which stakeholders can be accountable for funding research that addresses these priorities (Ruger 2018). For at least three decades, some organizations and communities have advanced a process of priority setting under various headings (Dye et al. 2013) including “essential national health research.”¹² In this process, stakeholders seek to identify and prioritize research according to a range of relevant factors including prevalence, severity, economic impact, cost effectiveness, effects on equity, social justice, and so on. This process has met with varying degrees of success (McGregor,

¹² Commission on Health Research for Development (1990), World Health Organization (1996), Council on Health Research for Development (2007), Dye et al. (2013), and McGregor et al. (2014).

Henderson, and Kaldor 2014) and faces numerous challenges, including ensuring that such processes are representative and fair (Pratt, Zion, and Loff 2012; Pratt and de Vries 2018).

Nevertheless, promoting this process is important to enable communities to exercise important rights to self-determination in forging a strategy to advance the goals of development. Such rights are not unlimited, since they are constrained by the prior claims of community members and the recognition that those who suffer the greatest shortfalls in their basic capabilities can have a strong claim to approaches that give priority to their basic interests. Nevertheless, even within these constraints there is likely to be a range of strategies for promoting development that are not clearly dominated by some viable alternative. Within this range, communities have an interest in determining their own development priorities. This latitude stems from several sources of legitimate diversity.

The first involves diversity in metrics that assign value to various aspects of health problems and procedures for decision-making that take these valuations as inputs. Quality-adjusted life years (QALYs) and disability-adjusted life years (DALYS) are two examples of metrics that are sometimes used to assign value to health states. These particular metrics assign value in a way that allows the relative value of all health states to be compared. However, their valuations do not always agree. These measures also have ethical shortcomings that are widely discussed (Arnesen and Nord 1999; Gold et al. 2002; Anand and Hanson 2004), and many alternatives have been proposed. Similarly, cost-effectiveness analysis (CEA) is an example of a procedure for combining this information in order to make decisions. Despite its popularity, CEA is a largely consequentialist framework that has been subject to criticism for its propensity to produce results that conflict with considerations of equity (Brock 2004). After reflective consideration of these issues, different communities might reasonably adopt different metrics for valuing health states and different procedures for decision-making (McGregor et al. 2014).

A second kind of diversity relates to diversity in the strategies available for advancing health-related goals. Some health conditions may be more amenable to control through prevention and improvements in the social determinants of health than others. In such cases, communities may have to determine how to divide social resources between broad-based improvements in living conditions, prevention measures that involve investments in social determinants of health, prevention measures that are

more directly medical in nature, treatments for those who contract or develop the health problem in question, and steps that can be taken outside the realm of health care to support the ability of persons to function in the face of disability. Because the adverse effects of health conditions on the ability of persons to function can depend on the availability of various kinds of support or alternative means of restoring functioning, health conditions can differ in terms of the variety of options available for mitigating their effects or restoring lost functions associated with the condition, and these conditions can vary across different communities both within LMICs and across them.

These various considerations can overlap with social and political background conditions to create a matrix of combinations in which some health needs can raise special issues of equity and social justice. For example, health conditions that are prevalent in children from predominantly poor neighborhoods populated by groups who have traditionally been subject to social exclusion or oppression may affect only a subset of the population, but if they produce long-term harms that reinforce particularly pernicious histories of neglect or persecution then addressing those health conditions might be of particular urgency from the standpoint of equity in human development.

A third kind of diversity relates to the reasonable diversity of values regarding strategies for development. For example, Drèze and Senn (1989) distinguish two broad strategies for reducing mortality and fostering human development in LMIC settings. A “growth-mediated” process aims to encourage economic growth in order to generate the means to reinvest into basic social services. On this approach, social resources are invested in expanding the social and economic opportunities available to those who can seize them, and the benefits of increased economic activity are used to build out social services to expand the share of the population who is capable of taking advantage of these opportunities. In contrast, a “support-led” process focuses on expanding educational opportunity and access to individual and public health services with the goal of enhancing the ability of individuals to create and take advantage of social opportunities.

Between the extremes of growth-mediated and support-led approaches to development lie a range of alternatives that assign differential relative importance to investments in particular social sectors. It may be the case that some health conditions are so important to a particular community that they will remain priorities for research no matter which approach a community adopts for reducing avoidable morbidity and mortality. It may also be the

case that different health conditions will emerge as more or less important under different approaches to human development.

Even if a set of countries shares the same health needs, differences in infrastructure, technological development, and other aspects in this matrix of features, along with the reasonable pluralism of values in decent societies, might entail that if those communities engage in a fair process of priority setting for research, they would generate different lists of research priorities. In such cases, different knowledge gaps might emerge as more or less important depending on the strategies such societies pursue for advancing human development.

At the system level, the responsiveness requirement represents a goal to be advanced through institutional design, incentive systems, capacity building, and global health governance. This reflects the role of reasonable pluralism in determining permissible strategies of development and the autonomy interest of communities in selecting development strategies from this range of permissible options.

Ensuring that research can satisfy this requirement, and that research that satisfies this requirement actually advances the health needs of host communities requires strengthening the capacity of LMICs to complete the arc of translation. This is the process in which new knowledge, practices, or procedures are propagated through health systems to improve their ability to secure and advance the basic interests of community members. Such capacity building requires establishing or strengthening the institutions, norms, material, and human resources necessary to complete the arc of translation. It also requires a system of global health governance with established pathways to support this process.

It is the nature of some branches of research, such as new product development, given the current state of scientific knowledge, that the majority of studies do not establish that a novel intervention is sufficiently safe and effective that it merits use in clinical practice. As a result, the proponents of the fair benefits approach are correct when they assert that many studies, especially early phase research, will not produce a product that can be made reasonably available to host community members. But this does not mean that such studies only have social value if they serve as a conduit to some other, more tangible range of benefits. Rather, it shows only that the application of science in these areas often takes time to bear fruit and that new medical interventions are more like a pearl that results from the gradual accretion of knowledge over time, than they are like products manufactured in a factory.

The important point is that medical and public health knowledge is a public good and that communities with the capacity to produce this knowledge over time, especially when it is relevant to the health priorities of that community, benefit from this gradual and continual improvement in knowledge. These benefits include an increased knowledge base that supports further intervention development activities and that supports the decision-making of policy makers, practitioners, and patients. In this respect, well-designed studies that produce negative results are nevertheless a crucial part of the intervention development process, generating information that can be relevant to future development efforts and also to clinical practice (London and Kimmelman 2015; Kimmelman and London 2015).

When research is organized as an ongoing portfolio of inquiries in which individual studies are part of larger trajectories of inquiry, it is easier to ensure that early phase studies, and individual studies that produce negative results nevertheless contribute to an important public good for host communities. That is because the knowledge these studies produce contributes to a larger ongoing inquiry that takes place against a credible background assurance that the knowledge they produce and any practices, procedures, or products they vindicate will be incorporated into local health systems. When these conditions are met, such studies satisfy requirements of justice because they represent important elements within the kind of extended and careful study that is necessary to close shortfalls in the ability of that community's basic social systems to secure the basic interests of community members.

9.4.4 Misaligned Research and Injustice

At the level of protocol review, the human development approach recognizes a strong but defeasible requirement to limit research in LMIC settings to studies that address shortfalls in basic social systems that represent priorities for development. This requirement reflects the prior claims of community members, as outlined earlier, but it also reflects the role of protocol review in influencing stakeholder behavior. In particular, as we saw in chapter 7, the knowledge that protocols will be evaluated using particular criteria shapes the strategic environment in which researchers and sponsors act. The terms on which studies of various kinds are approved and permitted thus influences the nature of the protocols that are likely to be submitted for review.

Prohibiting research that does not align with the development priorities of host communities is not sufficient to promote research that does align with those priorities—that is a goal that must be addressed at a system level. But such a prohibition is likely necessary to reduce the use of LMICs as locations for research that perpetuates the fundamentally extractive practice of co-opting the basic social institutions of host communities to generate evidence and information that, if it is of genuine social value at all, is of value for communities that already enjoy extensive benefits from the fruits of scientific inquiry.

When research is untethered from the common good of host communities or the explicit project of generating the information necessary to aid less-advantaged communities in the process of human development, it can perpetuate injustice. In part, this is because clinical trials play a critical role in generating medical consensus, influencing practice behavior, and shaping patient demand (London, Kimmelman, and Carlisle 2012).

This is powerfully illustrated by Adriana Petryna's portrait of the ways in which communities that host international research are not simply temporary homes for transient research projects; they are also emerging markets for new interventions. In such contexts, clinical trials are not merely exercises in scientific inquiry; they are powerful tools for shaping the opinions, preferences, and behavior of physicians, patients, and a nexus of other actors—such as lawyers, judges, and politicians—who administer or oversee entitlement programs or other mechanisms by which citizens make claims on shared health resources. Nor are research environments separate ecosystems from the local medical and public health systems of the communities in which such trials take place. Rather, they are the means by which information is generated that is supported by and that feeds back into those social systems. As a result, Petryna argues that clinical trials are “operative environments that redistribute public health resources and occasion new and often tense medical and social fields” (2009, 30).

One particularly powerful illustration of the dangers of research that is misaligned with local priorities occurs when communities are used to “salvage” interventions whose therapeutic potential has been cast into doubt. Petryna reports the case of the pseudonymous Brazilian researcher “Dr. Santos” who was tasked with the job of securing approval for a new antidepressant that had failed to show superiority to a placebo in a phase III trial. At first, Dr. Santos planned to double the dose of the drug and combine it with a powerful hypnotic. However, this possibility was foreclosed by

the passage of a Brazilian law prohibiting such combined drug formulations. Instead, Dr. Santos worked to place the drug on the Brazilian market for the treatment of “a mild form of depression—a ‘made-up’ illness as she called it” (Petryna 2009, 124).

Even if study participants, researchers, and host communities were to benefit from hosting and participating in such research in ways that do not derive from the social value of the information it produces, such research is morally objectionable. Private parties syphon scarce social resources to their own purposes while producing evidence that hampers the efficacy of care that health systems provide. Diversifying treatment practice without the benefit of increased efficacy hampers the efficiency with which health systems can address the many health needs of community members. Directing resources away from more effective avenues of care can also exacerbate inequities within health systems, especially if such decisions reduce the resources available to meet the needs of underserved populations.

Enforcing the requirement of reasonable availability without a credible assurance that research is responsive to the priority shortfalls of host community social systems would produce a similar effect. It would require expending resources and allocating time and effort to procuring and delivering an intervention that may not produce sufficient social value to justify these efforts. Doing so allows individual actors to profit from activities that subvert the prior claims of community members to basic social systems that are effective, efficient, and equitable.

It might appear possible to avoid these pitfalls by permitting research to be carried out in LMICs without the goal of influencing local health systems and without a requirement of reasonable availability. But this proposal faces several problems.

First, even if such studies are not intended to influence local health systems, they are conducted with the goal of influencing the decisions of providers, policy makers, and other stakeholders, even if those stakeholders do not reside in the host community (Wenner 2018). The globalization of clinical research allows contract research organizations to shop for populations of research participants with very specific disease characteristics. This makes it possible to quickly execute in practice trials that generate information from populations that can have very different characteristics from the patients likely to be the ultimate recipients of the intervention in the target population—the population where the intervention is likely to be sold

and utilized. This can leave significant uncertainty about the external validity of this information for target populations—uncertainty about whether therapeutic or protective effects seen in such trials will materialize in populations with different comorbidities, whether adverse events in such populations will alter the net clinical value of the intervention, whether additional interventions are necessary to promote the clinical value of the intervention in the target population, and whether the intervention has sufficient clinical value relative to established alternatives that it ought to be incorporated into practice. Firms may have an interest in quickly generating a signal of efficacy so they can reap the benefits of earlier market access. But if this process offloads the costs and risks of reducing significant residual uncertainty onto the health systems of the target community, then such research can be objectionable on the grounds of justice (§4.9).

Second, such activities are often not separate from local medical and public health ecosystems. They frequently draw scarce social, material, and human resources away from prevention, primary care, and public health (Sithi-Amorn and Somrongthong 2000). Lucrative ecosystems that support research activities unmoored from the goal of expanding the capacity of local health systems to address local health needs can subvert the common good of both host and target communities. In the worst cases, such trials enable sponsors to assemble what amount to made-up populations to produce interventions for what amount to made-up diseases, drawing real resources from the health systems of both host and target populations in order to generate unbelievable profits for pharmaceutical companies.

Finally, even in the best case, this proposal perpetuates a strategic environment in which parties who already play an outsized role in shaping the global research agenda are permitted to use LMIC populations to produce information that primarily benefits already advantaged populations. As long as this remains an option, powerful parties who stand to profit from its exploitation will allocate time, energy, and resources to doing so. As I indicated previously, forbidding such practices alone does not ensure that these resources are redirected in ways that promote human development for LMICs. But independent efforts to promote human development in LMICs, including efforts to focus research on LMIC priorities, may be hampered if such practices are sanctioned and permitted.

Requiring studies to generate information that addresses a shortfall in LMIC health systems is sufficient to rule out studies like the Surfaxin trial (§2.6.8). Although that study focused on a need that is represented in host

communities, it was not designed to generate information that was necessary to close a knowledge gap necessary to enable health systems in those communities to better address acute respiratory distress in premature infants. Those communities lacked effective treatments for that condition that could be effectively and efficiently implemented under conditions that were attainable and sustainable. Several surfactant replacement treatments had been established as effective for treating acute respiratory distress in premature infants in HIC settings. But a variety of factors, including poverty and lack of infrastructure, prevented those countries from implementing those treatments on a widespread basis. There was nothing about Surfaxin or the question the trial was designed to answer that would generate information that would enable LMIC health systems to better address this medical need on a widespread basis.

Nevertheless, the requirement that research be responsive to health needs that represent development priorities for host communities is defeasible in that the presumption in favor of this restriction might be relaxed under certain conditions. One such condition obtains when communities have not articulated actionable research priorities. This may be because they have not articulated priorities for research or because those priorities are so vague that it is not clear how they provide actionable guidance to stakeholders. In such cases, review committees should, nevertheless, require assurance that the study or studies under review are part of a larger trajectory of research that is likely to advance the capacity of local institutions to safeguard or advance the basic interests of community members and that communities regard such research as sufficiently important that they are likely to support its uptake into local health systems if it is successful.

Another condition might include research that represents a low-cost, fortuitous opportunity. For instance, in the course of a research partnership that is responsive to a shared research priority of a set of communities, an opportunity to study a new question might be identified. Given existing research infrastructure it would be relatively easy to study this new question. It is possible that the new question is a research priority for some but not all of the communities with centers participating in the initial collaboration. It is also possible that this isn't a research priority for any of these communities but that it nevertheless addresses a knowledge gap that they share. Such research might also arise because the science in a particular area has matured to the point where it might be possible to close a knowledge gap that doesn't fall under any existing research priority.

Within the human development approach, such research might be permissible, but only under the conditions that permitting it does not undermine or impede the ability of host communities to mount and to secure support for research that addresses their research priorities, and that conducting such research in the presence of a requirement of reasonable availability does not detract from the ability of local health systems to function effectively, efficiently, or equitably. Having said that, the close connections between research and the institutions of individual and public health in a community provide important reasons to be wary of attempting to increase the benefits that are available to communities or study participants by permitting the conduct of research that does not address a question that represents a health priority for the host community.

9.5 The Standard of Care

9.5.1 The Local De Jure Standard of Care, Social Value, and Equal Concern

It is an advantage of the human development approach that it uses a single coherent framework to evaluate domestic research in HICs, domestic research in LMICs, and cross-national research between entities from HICs and populations in LMICs. In all of these cases, research should represent an avenue through which community members can advance the common good under terms that provide credible social assurance that their status as free and equal persons will not be compromised in the process. In chapter 6 I argued that the integrative approach to risk assessment and management provides a framework for ensuring that research designed to satisfy the social value requirement is consistent with the principle of equal concern (§6.2). Research is consistent with the principle of equal concern if it satisfies the requirements of no unnecessary risk (§6.3.1), special concern for basic interests (§6.3.2), and social consistency (§6.3.3). The human development approach makes clear that, in all cases, these criteria are to be understood against the background of the local de jure standard of care.

The local de jure standard of care states that participants in research are entitled to a level of care for their basic interests that does not fall below what experts judge to be the most effective strategy for preserving or advancing those interests under conditions that are attainable and sustainable in their

community (§2.6.2). This phrasing reflects the fact that there may be reasonable diversity among experts about which practices, policies, or interventions represent the best way of preventing, treating, or ameliorating a threat to a person's basic interests. In such cases, respect for the status of individuals as free and equal persons requires that their treatment not be substandard or inferior to the options that are regarded as best by at least a reasonable minority of experts.

This interpretation of the standard of care reflects the deep moral claim that all community members have to conditions that provide real freedom to formulate, pursue, and revise a life plan and the special role that the basic social structures of a community play in meeting this claim. Individuals have a just claim on the basic structures of their community to use established knowledge, practices, policies, and interventions to safeguard and advance their basic interests on terms that reflect the duty of full coverage. This just claim correlates with a duty on the part of the basic social institutions of their community to provide the best means of safeguarding and advancing their basic interests, consistent with the equal regard for this same interest on the part of their compatriots.¹³

The requirements of the integrative approach are to be understood against this baseline set of claims. In particular, special concern for basic interests holds that if the basic interests of research participants are threatened or impaired (for example, by sickness, injury, or disease), participants must be provided a level of care and protection for their basic interests that does not fall below what at least a reasonable minority of experts in the relevant field(s) (e.g., experts from the medical or public health community) would regard as the most beneficial method of response. When there is uncertainty or conflict in the expert community about how best to secure and advance the basic interests of persons, research that is designed to resolve this uncertainty has a strong, *prima facie* claim to social value. When the uncertainty in question relates to a shortfall that represents a development priority for host communities, and research takes place in a context of credible assurance of reasonable availability, then research satisfies conditions of justice.

Within the cognitive ecosystem of orthodox research ethics, the idea that domestic research in HICs is governed by the local *de jure* standard of care may seem odd. But this does not reflect a shortcoming in that standard of

¹³ For a comprehensive and insightful discussion of the relationship between this formulation of the standard of care and the rights of community members see MacKay (2018). See also Kukla (2007).

care; it reflects the difficulties of understanding the role of research in a just social order within the parochialism of orthodox research ethics.

It is worth emphasizing, therefore, that only the local *de jure* standard of care ensures that research tracks both the social value requirement and the principle of equal concern. One fundamental reason for this is that knowledge about how to safeguard and advance the basic interests of persons cannot achieve that goal under the requirement of full coverage if it does not augment the capacity of basic social institutions. This is because these institutions are responsible for dividing social labor and using social authority and resources to safeguard and advance the basic interests of community members. Both the local *de facto* and the global *de jure* standards of care permit research that violates these principles and that is therefore objectionable on the grounds of injustice.

9.5.2 The Local *De Facto* Standard of Care and Prior Moral Claims

The local *de facto* standard artificially separates current practice from the knowledge regarding the way the various resources in a community—including existing medical knowledge—could be used to effectively, efficiently, or more equitably safeguard the health interests of individuals in that community. As a result, studies designed to test interventions against this baseline can deviate from both the social value requirement and the principle of equal concern.

Studies that use the local *de facto* standard of care can lack social value, in part, because conditions reflected in current practice may not reveal knowledge gaps at all. To see this, consider that marginalized or oppressed groups are often denied access to practices, policies, or interventions that are safe and effective and that could be deployed within the economic and infrastructure requirements that prevail in the larger community.¹⁴ In such cases, the local *de facto* standard of care falls below what could be achieved by extending existing services and the various benefits of social inclusion to members of these groups.

To the extent that health problems in a group or population are the product of prejudice, antipathy, neglect, or exclusion, they represent the

¹⁴ See Annas and Grodin (1998) for some examples.

ravages produced from denying individuals various forms of social support (including equitable access to health services) and not uncertainty about how best to secure the interests of those people. Designing a study to assess whether some intervention A is superior to the local de facto standard of care B will not be relevant to the host community if there is an alternative C (extending existing social and health services to members of this disadvantaged group) that is preferable to both and that could be safely and effectively implemented under conditions that are attainable and sustainable in the host community.¹⁵

Moreover, this is the case even if C is not currently provided to individuals with the particular condition in question. If it is clear that C is the best alternative for addressing a problem and that the conditions necessary for its safe and effective delivery are attainable and sustainable in that community, then there is no knowledge gap to fill. The local de facto standard of care cannot capture this insight since it presupposes that the relevant normative baseline against which proposals are to be evaluated is the state of affairs that would obtain if no research were to be conducted.

Similarly, randomizing individuals to the local de facto standard of care can violate the principle of equal concern. When the status quo reflects antipathy, indifference, or deprivation, replicating that level of care within a study perpetuates the larger deprivations those groups experience in society. Doing so shows less concern for the basic interests of participants (and for members of marginalized groups outside of the trial) than for members of more advantaged groups who live under the same social institutions. In such cases, study participants have claim to more or better than the local de facto standard of care precisely because better alternatives are attainable and sustainable under social arrangements in which their basic social institutions better approximate the demands of full coverage.

9.5.3 The Global De Jure Standard of Care Is Fundamentally Confused

In §2.6 we saw that arguments against the local de facto standard of care are often seen as favoring the global de jure standard of care, which uses the judgments of experts to determine the baseline level of care that must be provided to participants in research using global centers of excellence as the

¹⁵ Such studies violate concern for welfare (§6.2.1) and the principle of equal concern (§6.2.1).

relevant reference point for such assessments. One rationale for this choice of reference point is that it allows us to distinguish situations in which we do not know how to solve a problem (and therefore require new knowledge) from those cases in which we possess the know-how but lack the resources to put this know-how into practice. So understood, a focus on what can be achieved in global centers of excellence is intended to help stakeholders avoid conducting research that exploits conditions of poverty and deprivation.

However, although the motivation for this interpretation is important, the concept of a global *de jure* standard of care is fundamentally confused. It artificially separates research from its relationship to the basic social structures of a community that are required to translate knowledge, interventions, and practices into actions that secure or advance the basic interests of individuals. As a result, either it ignores the extent to which every community, including those that are home to global centers of excellence, must meet the basic interests of community members under resource constraints, or it incorrectly assumes that what can be achieved under one set of such constraints should be normative for all communities, regardless of the constraints under which they must meet the basic interests of their members. We can elaborate each horn of this dilemma in turn.

On the first horn of the dilemma, if the global *de jure* standard is interpreted as identifying the best level of care that can be attained in global centers of excellence regardless of resource constraints, then it is not normative for any community. Framed in these terms, this formulation of the standard of care would include practices that require all resources to be dedicated to solving a single problem. Clearly, tremendous strides could be made in reducing HIV transmission, for example, if all resources were dedicated to this end. But the practices that would bring about these achievements are not normative as a baseline standard of care even in HIC centers of excellence. The reason is that every community must use its scarce social, human, and economic resources to address the full range of threats to the ability of individuals to develop and exercise the capacities they need to formulate, pursue, and revise a reasonable life plan. Moreover, health-related social structures are only one element in a larger network of social structures that must work together to safeguard the basic interests of community members. Not only would it be unjust for communities to dedicate all of their resources to addressing a single problem, but also they must not focus solely on problems in one particular domain, such as health.

Turning to the second horn of the dilemma, if the practices and interventions labeled as the global *de jure* standard of care are normative for

the communities that are served by global centers of excellence, then this status is explained by the fact that they constitute the local *de jure* standard of care for those communities. Individuals in those communities would be wronged if they were denied such interventions or practices because those practices can be effectively implemented on a sustainable basis within the health systems of those communities.

To use an example from chapter 2, the 076 protocol became the standard of care in HICs because it represented the most effective intervention for preventing perinatal HIV transmission that could be deployed under conditions that are attainable and sustainable in those countries. Moreover, it had this status, in part, because the protocol was formulated against a background set of assumptions that hold, or can be established, in the HICs that hosted that research. These assumptions include the economic conditions and the type of infrastructure that would be available in the contexts in which this intervention would be delivered. Against this background, for example, early identification of pregnancy is consistent with routine medical practice. Intravenous medication can be delivered safely and effectively on a routine basis. The widespread availability of clean, potable water allows women who refrain from breast feeding to provide safe alternatives to their infants.

The status of the 076 protocol as the local *de jure* standard of care for HIC communities explains the conditions under which using this intervention as the normative baseline for research supports the social value requirement in those communities. The 076 protocol could be safely and effectively implemented in health systems in HICs to reduce perinatal HIV transmission. To expand the capacity of those health systems to better address this health need, a comparator would have to offer a more effective, efficient, or equitable way of addressing this same health need. If there is credible uncertainty or conflicting expert judgment about the relative merits of the 076 protocol in comparison to an alternative or a set of alternatives, then research that reduces or resolves this uncertainty can play a valuable role in enhancing the capacity of those health systems to better meet the needs of the people who rely on them.

Treating this intervention as the normative baseline for research in HICs also satisfies the principle of equal concern. But it does so because it satisfies the conditions of the local *de jure* standard of care, namely, it reflects the judgment of the relevant experts about the best diagnostic, prophylactic, or therapeutic intervention for this condition that can be delivered effectively under conditions that are attainable and sustainable in the target population. It does

not violate the principle of equal concern to allow participants to be randomized to a set of interventions as long as there is conflict or uncertainty among the relevant set of experts about the relative merits of the interventions in that set and the local *de jure* standard of care. In other words, nobody in such a trial is made worse off relative to the other participants in the trial or to the members of the larger community who rely on this set of health systems to safeguard and advance their basic interests.

It would violate the principle of equal concern, however, if some study participants are randomized to interventions or practices that fall below the local *de jure* standard of care. The reason is that all community members have a just claim on the basic social structures of their community to practices that safeguard and advance their basic interests, consistent with the requirement of full coverage.

Now consider some community that is not served by one of these global centers of excellence. Does it make sense to hold that the same interventions that are required in those centers of excellence must also be provided to individuals in different communities? The answer is clearly “yes it does” if it is the case that the same intervention can be safely and effectively deployed in this new community under conditions that are attainable and sustainable in that community. But this is simply to say that when another community can attain and sustain the conditions necessary to safely and effectively deliver that same practice, procedure, or intervention then using it as a comparator against which new interventions are tested ensures that those studies satisfy the social value requirement and the principle of equal concern. The same intervention must be provided to study participants in these two different communities for the same reasons, and these reasons are captured by the local *de jure* standard of care.

In contrast, the global *de jure* standard of care says that an intervention that experts judge to be the best way of safeguarding the basic interests of individuals in one place, under one set of background social, economic, and political conditions, must be provided to study participants in any community, regardless of differences in the background social, economic, or political conditions in the target community. So, even if it is not the case that the intervention in question can be safely and effectively deployed under conditions that are attainable and sustainable in a different community, the global *de jure* standard of care says that it must still serve as the comparator against which any alternative intervention will be tested. But, in doing so, this requirement is now divorced from both the social value requirement and the principle of equal concern.

It is divorced from the social value requirement because the global *de jure* standard of care effectively requires every social community to test new interventions, policies, or practices against a baseline that can be wildly different from what can be attained and sustained in that community. If the information that is generated from such studies is relevant to any community, it is most likely to be relevant to the already more advantaged communities that are served by those global centers of excellence. This not only permits research in LMIC settings that is designed to produce information to expand the capabilities of social structures that advance the basic interests of already more advantaged communities, it prohibits research that does otherwise (§2.6.4). This standard of care effectively prohibits communities from conducting research that is most directly relevant to the capacity of their own health systems to safeguard and advance the basic interests of their own community members.

This argument also assumes that it would be possible to implement the intervention that serves as the global *de jure* standard of care in all studies, regardless of background social, economic, or epidemiological conditions, in a way that would preserve its safety and efficacy. In other words, if an intervention was shown to be safe and effective in resource-intensive HIC contexts, then this position assumes that it is possible to create a comparable clinical context in LMIC settings that preserves the intervention's safety and efficacy. But this may not be possible. For example, if the background health status of HIC and LMIC populations is sufficiently different—if LMIC residents have higher rates of medical conditions that were absent in trials of the intervention in question in HICs—then the rate of adverse events may differ significantly between these two populations. Such a difference can affect both the safety and efficacy profile of the interventions provided. If this is the case, then a study that compares a novel intervention against the global *de jure* standard of care might generate information that is not relevant to any community. In particular, if we cannot ensure that the conditions necessary to preserve the safety and efficacy of the control intervention are in place, then it is difficult, if not impossible, to interpret the findings of such a study. In the worst case, for example, if the control intervention is positively harmful, then the investigational intervention might appear to be superior even though it is merely ineffective.

Studies that use the global *de jure* standard of care are disconnected from the principle of equal concern to the extent that the interventions provided to at least some participants far exceed what is attainable and sustainable in the

larger community. This might not appear to be a significant problem since providing higher-quality care to study participants advances the interests of those individuals, and prohibiting this merely out of a concern for equality might represent a morally objectionable instance of “leveling down.” As long as nobody in a study is denied a level of care and concern to which they are entitled, then we should be very careful about forbidding the provision of extra benefits to some study participants (MacKay 2020).

Although concerns about leveling down are legitimate, it is important to bear in mind three points. First, it is worth emphasizing that this argument is most compelling when the relevant baseline is set by the local *de jure* standard of care. If inequalities in the standard of care provided to study participants or between study participants and community members are permissible as long as nobody is deprived of a level of care to which they are entitled, then we need an independent account of the baseline of care to which study participants are entitled. The local *de jure* standard provides a compelling account of that entitlement.

Second, the local *de jure* standard reflects the claims that community members can make against their shared social institutions given the duty of full coverage. If some study participants occasionally receive a higher level of care for their basic interests than what is attainable and sustainable in the broader community, such isolated cases may not result in others being denied a level of care or concern to which they are entitled.

However, the systematic provision of a standard of care that is higher than the local *de jure* standard raises questions about the extent to which the research enterprise is functioning on terms that are consistent with the duty of full coverage. The local *de jure* standard of care and the principle of equal concern help to ensure that the research enterprise functions efficiently and equitably within a larger social division of labor in which scarce social resources are enmeshed in a network of prior claims. If such a system prevents more research from being conducted, or siphons resources from the provision of goods or services to which community members are entitled, then the higher standard of care may benefit participants but at the price of leaving other legitimate claims of community members unmet or addressed with less efficacy or efficiency than is feasible.

Finally, it is also worth emphasizing that the principle of equal concern is closely connected to the epistemic goals of research and the social value requirement. Evidence generated against a baseline that more closely reflects what is attainable and sustainable outside the trial is likely to have

greater direct relevance for the stakeholders who rely on this information to discharge important social responsibilities. These responsibilities include making decisions about how to use scarce time, effort, and human and material resources to effectively, efficiently, and equitably address the many different needs of community members. If the standard of care within a trial is not normative for the host community, then establishing the merits of alternative interventions relative to this baseline does not directly address the uncertainties that are most relevant to the decisions facing key stakeholders in that community (§6.6).

In many ways, these points reiterate key themes that run throughout this book. First, the provision of benefits to study participants raises issues of fairness, but those issues are not simply a matter of the amount of benefit provided. The social function of research is to produce information that is a public good and the social value of that information for host communities depends on its alignment with and relevance to a normative baseline that reflects the prior moral claims of community members. These prior moral claims implicate issues of justice because they relate to basic social institutions that have a responsibility to make effective, efficient, and equitable use of existing knowledge and resources. The local *de jure* standard of care tracks this baseline.

Second, research ethics needs to be sensitive to the way that the parochial interests of different parties to the research enterprise can align or conflict with the common good. Enriching the standard of care available in individual trials can be a way of inducing people to participate in studies they might not otherwise consider. But if the baseline created in such trials is most directly relevant to more advantaged communities, then such research can represent an extractive relationship in which social arrangements in less advantaged communities are co-opted to generate social value for already more advantaged groups.

9.6 Justice and the Process of Human Development

9.6.1 The Standard of Care and Just Moral Baselines

We said in chapter 2 that debates about the standard of care sometimes feel like proxy wars for larger philosophical positions that exert their influence from offstage. The arguments from the previous section allow us to explain

one way in which this might be the case. This, in turn, can help to avoid an important confusion and to bring into better focus distinct ways in which research activities can contribute to the process of moving toward a more just social order.

The confusion in question involves the following distinct claims. The first claim is about the relationship between the standard of care and the basic social structures of the communities that are affected by that research. In particular, I argued in the previous section that only the local *de jure* standard of care ensures that research advances the common good of host communities while respecting the status of study participants and community members as free and equal persons.

The second claim is about whether the conditions that are attainable and sustainable in a community are themselves morally defensible. In particular, we saw that the local *de facto* standard of care was problematic because the level of care that individuals actually receive in a community might not reflect the level of care that is attainable and sustainable under a social order in which the community's basic social institutions make more efficient and equitable use of existing knowledge and resources. But, in a world of widespread injustice, there may be an analogous gap between the conditions that can be attained and sustained in a particular community if its basic social structures made a more effective use of existing knowledge and resources and the conditions that could be attained and sustained if that same community also enjoyed a larger and fairer share of resources.

This last point might be seen as calling into question the normative status of the local *de jure* standard of care. For example, if one held a strict, global egalitarian view according to which national boundaries are morally arbitrary and there is a strong duty to redistribute global resources, then one might think that this would entail support for the global *de jure* standard of care. The reason is that equalizing resources would equalize the baseline of care that individuals receive, regardless of where they are located, and that the global *de jure* standard of care might be expected to capture this baseline.

It is a mistake to think that the second claim stands in this relationship to the first. To begin with, the global *de jure* standard of care is still vulnerable to the original dilemma that I posed earlier. Either that position can identify practices as the standard of care that would not be normative for any community or it identifies standards that are normative but only to the extent that it effectively uses the local *de jure* standard of care for some paradigm community as the normative standard for all other communities. Global egalitarian

theories of justice seek to reduce the gap in infrastructure between HICs and LMICs. Even so, the specific interventions, policies, or practices that constitute the local *de jure* standard of care for one community would only be normative for those other communities if they also share priority health needs.

It is true, however, that vindicating the local *de jure* interpretation as the best way of understanding the standard of care does not settle the issue raised in the second claim. In particular, what is attainable and sustainable in a community depends on the resources that can be allocated to solving a problem and this, in turn, can depend on at least two factors. One is the share of resources a community can legitimately claim and legitimately expect to receive within the relevant window of time. The other is how those resources can be legitimately used to address the problem in question, given that communities can adopt different strategies for development in light of the factors discussed in §9.4.3. Different theories of global justice can have important consequences for this first factor since they might entail that communities have a just claim to greater or lesser shares of resources.

The point I want to emphasize here is that the close connection between what is attainable and sustainable in LMIC communities and larger theories of global justice does not undermine the status of the local *de jure* interpretation of the standard of care. That is because the local *de jure* standard captures the important relationship between the principle of equal concern and the background conditions against which communities are constrained to safeguard and advance the basic interests of their constituent members. The fact that changes in the resources available to LMICs might alter this baseline underscores the importance of situating international research initiatives within the larger context of human development and the efforts to improve the baseline circumstances in LMICs that it entails.

9.6.2 Research on the Way to a More Just Social Order

In previous chapters we said that the minimalist approach to justice is latent in the conceptual ecosystem of orthodox research ethics and that this is due, in part, to the desire to preserve the practical utility of research ethics. If perennial questions of global, social, and distributive justice have to be settled before questions of research ethics can be addressed, then the worry is that the urgent business of regulating research with humans will be undermined. Because the approach to research ethics outlined in this book explicitly

situates research within a larger conception of political and distributive justice, the concerns of the last section might seem to pose a particularly urgent and thorny problem.

It is fitting to close this discussion, therefore, by addressing these worries. I will begin by addressing the narrow issue raised in the previous section and then turn to more general concerns.

The first point I want to make is that the human development approach and the egalitarian research imperative understand research as one social activity within a much larger, multisectoral division of labor aimed at moving communities toward a more just social order. In particular, research plays this role when it addresses uncertainty or conflicting expert assessments about the best ways to secure and advance the basic interests of persons. These questions must be formulated relative to what is attainable and sustainable within the basic social institutions of the host community for the very pragmatic reason that those institutions structure the environment within which individuals are constrained to live and to act and against which public officials, healthcare providers, public health agents, and others must discharge their concrete social and moral obligations to community members.

In that respect, the focus of the human development approach and the egalitarian research imperative on eliminating shortfalls in the capacity of a community's basic social institutions to secure and advance the basic interests of that community's members does not necessarily presuppose the truth or falsity of any particular conception of global or distributive justice. Even if global egalitarians are correct and there is nothing morally sacrosanct about national boundaries or national identities, it does not follow that education, security for basic rights and interests, environmental and public health, and the panoply of health services on which individuals depend can be delivered independently of the basic social structures of society on terms that satisfy the requirement of full coverage. Rather, it follows only that the vast majority of the world has a strong moral claim to basic social structures that do a much better job of advancing their basic interests than they do now.

The second point I want to make is that because the human development approach recognizes a moral responsibility, both domestically and internationally, to engage in a larger process of human development, arguments about the extent of such duties—about when such duties have been fulfilled and about the extent of the transfers that this requires—do not pose a radical challenge for the application of this framework. In part, this is because the process of meeting development goals and discharging duties of justice

is likely to be extended over time. Additionally, the entitlements that are in force for decisions within research ethics must reflect the extent to which what *ought* to be done is constrained by what *can* be achieved within relevant time horizons.

Host communities face uncertainty about how best to meet the distinctive needs of their members as the development process unfolds, including how best to allocate new resources for advancing development goals across different sectors. Because there is likely to be room for reasonable pluralism about alternative strategies for achieving development goals, as we argued in §9.4.3, this point illustrates the importance of foregrounding discussions about development priorities and identifying knowledge gaps that are likely to persist across sufficient periods of time for research to represent an attractive strategy for closing those gaps.

During this process, communities must still strive to provide full coverage to the basic interests of their members. In that respect, there may be cases in which the rate of social and economic development calls into question the social value of research that is too closely tied to a baseline of care that is likely to be superseded before such research could meaningfully advance the goals of human development. In other cases, however, differences in endemic diseases, infrastructure, and development priorities might entail that particular research initiatives represent a valuable investment in an effort to address threats to the basic interests of persons that might frustrate development and that are unlikely to be met more quickly, more easily, or more equitably through the application of existing resources.

To use a concrete example, imagine a case similar to the short-course zidovudine studies discussed in chapter 2. In that context, Crouch and Arras (1998) argued persuasively that in order to determine the standard of care for a short-course zidovudine study, it is not sufficient to establish that there are circumstances under which an intervention like the 076 Protocol could be effectively deployed in LMIC settings. This is not sufficient, they argued, because such conditions might be attainable, but not be sustainable in the sense of being consistent with a just allocation of resources in that community. Moreover, they argued that this might be the case even if we grant that such communities are entitled to a larger share of resources than they already enjoy.

To simplify matters, we can say that if a community would not implement the 076 Protocol in the near future, even if the process of development were accelerated, because of concerns about that community's ability to meet the

relevant need on terms that satisfy the requirements of full coverage, then it would be permissible to compare the short-course against whatever intervention is regarded as the best alternative under those conditions. If no such alternative exists, then the claim is that if it is morally permissible for that community not to implement the 076 Protocol in practice, even under a more just resource allocation, then it is morally permissible to evaluate the merits of a short course against a placebo control, as long as it is the case that the host community is prepared to implement this alternative intervention if its merits are confirmed in testing.

The point for our present purposes is that this reasoning may play out differently for different communities. For LMICs with a more robust health infrastructure, the 076 Protocol might be both attainable and sustainable under social and economic circumstances that are likely to prevail in the near term. In that case, it might be permissible to test a short course against the 076 Protocol in a trial designed to establish whether a cheaper, more portable, easier to implement alternative might represent a more effective and efficient way to address perinatal HIV transmission on terms that are consistent with full coverage. Here, the difference is that if the short course fails to meet the relevant benchmarks, the host community is committed to implementing the 076 Protocol on a widespread basis.

This last point illustrates that the application of the same normative requirements (using a single moral standard to make different decisions) can produce different outcomes in different cases. It is not an embarrassment that a placebo control may be morally permissible in research that is carried out in one place but not in another if this result follows from the sound application of just moral principles. The example provided a moment ago is intended to illustrate merely how such variation in what is morally permissible might be possible. In contrast, it is an embarrassment to require that clinical trials adopt the same design if this comes at the cost of frustrating the morally legitimate goals of human development.

The idea that judgments about what is attainable and sustainable in a community must be made against a larger background understanding of the development priorities of a community may be particularly jarring to Americans. In part, this is because Americans are particularly resistant to recognizing the extent to which healthcare budgets are limited. Nevertheless, public entitlement programs, such as Medicare or Medicaid, and private insurance plans may not cover certain forms of treatment because such decisions conflict with the efficient and equitable allocation of shared

resources. Citizens of nations with national health services are more familiar, and often more comfortable, with the idea that not all established effective interventions must be provided in such systems.

If it is consistent with principles of justice to limit access to established effective care out of concerns for the just allocation of scarce resources, then it must also be consistent with principles of justice to ensure that research is carried out against a moral baseline that reflects the legitimate entitlements of community members (London 2019).

Finally, one of the main contentions of the present work is that research with humans has an important role to play in improving the ability of social systems, such as public and individual health systems, to effectively, efficiently, and equitably advance the basic interests of community members. Failing to appreciate the relationship between the research activity and these larger social structures can undermine and frustrate these goals. It allows powerful parties to co-opt social resources and social systems to advance the parochial ends of profit, promotion, or individual benefit without a guarantee that these rewards attach to activities that also promote the common good. Although this is dramatized by research that crosses national boundaries, the same concerns apply to domestic research as well.

Situating research within a larger social context, where it is evaluated in light of and beholden to larger social purposes, is more demanding. It will require a reconceptualization of the audience that research ethics addresses and the social institutions and stakeholders who fall within the legitimate boundaries of the field, and a widening of the menu of mechanisms that might be used to shape stakeholder behavior. Nevertheless, this complexity is not an avoidable nuisance. It reflects the complexity of the social systems within which research is embedded, into which it feeds, and that influence the incentives for stakeholders who advance the many different objectives out of which the larger tapestry of cooperation is woven.