

PART II  
RESEARCH AMONG EQUALS



# 4

## The Common Good and the Egalitarian Research Imperative

### 4.1 Revisiting the Common Good

Orthodox research ethics has largely rejected the idea that there is a social imperative to support and carry out research with human participants. We canvassed some of the practical and philosophical reasons for this in chapter 2, including Hans Jonas's influential argument that the ordinary toll of sickness, injury, and disease is not a threat to society, but to the interests of individuals and that, as such, medical research is not grounded in a social imperative (Jonas 1969). As a result, orthodox research ethics tends to treat research as an optional activity that stakeholders are free to undertake, if they choose, as part of their personal, private projects. Appeals to the common good as a ground for a social imperative to carry out research are now rare and are likely to be greeted with skepticism as rhetorical excess or as an ambiguous façade obscuring less meritorious motives.<sup>1</sup>

In this chapter I argue that both proponents and critics of a research imperative have presumed a particular conception of the common good, which I call the *corporate conception*. Jonas was correct in his assertion that there is no moral imperative to undertake medical research as a way of securing the corporate conception of the common good. However, both sides of this debate were mistaken in thinking that this is the only or the best way to understand the common good.

<sup>1</sup> Arendt expresses this skepticism succinctly when she says, “the liberals’ political philosophy, according to which the mere sum of individual interests adds up to the miracle of the common good, appeared to be only a rationalization of the recklessness with which private interests were pressed regardless of the common good” (1973, 336). See also Nozick (1974, 33) for the idea that talk of a social good “covers up” the fact that something is done to one person for the sake of a benefit to another.

As an alternative, I describe and defend what I call the *basic* or *generic interest* conception of the common good and argue that this grounds what I refer to as the *egalitarian research imperative*. In contrast to the parochialism of orthodox research ethics, the egalitarian research imperative recognizes that various forms of research with human participants are part of a larger division of social labor. Because this division of labor draws on and influences the capacity of institutions that impact the basic interests of community members, there is a social imperative to carry out research that generates the evidence needed to enable a community's basic social systems, such as a community's medical and public health systems, to effectively, efficiently, and equitably safeguard and advance the basic interests of that community's members. This imperative is grounded in a fundamental concern for the status of each community member as free and equal, and this grounding shapes both the goals and purposes of the research enterprise as well as the terms on which it is to be organized and conducted.

To make this argument, in §4.2 I elaborate the pragmatic value of appeals to the common good and explicate the way that the implicit structure of such appeals shapes moral decision-making. In §4.3 I describe the corporate conception of the common good and show how this is the focus of Jonas's famous critique, and I bolster criticisms of this view in §4.4. In §4.5 I describe the basic or generic interests conception of the common good and in §4.6 demonstrate how it can be formulated within a diverse range of ethical and political frameworks.

In §4.7 I argue for the egalitarian research imperative and show how it grounds both the purpose of research, and the terms on which it can be carried out, in respect for the status of individuals as free and equal. In §4.8 I show how the resulting position expands the scope and purview of research ethics with some illustrative examples provided in §4.9.

## 4.2 The Structure of Appeals to the Common Good

### 4.2.1 Pragmatic Value

Normative appeals to the common good have a pragmatic value that derives, at least in part, from their implicit moral logic or structure. In particular, appeals to the common good often play a special role in securing individual and collective action. If some action, policy or other instrument can

be successfully portrayed as necessary to support or preserve the common good, then this constitutes a strong, *prima facie* reason for individuals and groups to support it. Moreover, appeals to the common good can build on and marshal prior commitments and shared understandings, or they can function as a conduit through which such understandings can be forged or built.

Appeals to the common good that are invoked within communities that share a history or identity often portray some action or undertaking as having special importance in relation to the shared purposes of this common identity. In contrast, appeals to the common good can also secure collective action in the face of moral and political pluralism. When individuals or groups are not part of a discrete community or do not share a common comprehensive conception of the good, appeals to the common good highlight an action or undertaking as important relative to some underlying, shared interest. For example, prior to the Persian Wars around 492–449 BCE, ancient Greek city states shared a common language but no national identity. They were, instead, divided by rivalries and sharp cultural differences. However, they were able to unite in response to the threat from Persian forces because they could see external invasion as a threat to interests they shared in common—political sovereignty and territorial integrity—even if those interests were not connected to membership in some prior political community.

This pragmatic flexibility reflects a logic to such appeals that is independent of substantive conceptions of the good or comprehensive moral or political doctrines that might provide the content to such claims. As a result, competing substantive political or ethical doctrines can each use appeals to the common good to package their key commitments in an effort to support collective action among their adherents. At the same time, successful appeals to the common good can also indicate that some value or interest is of sufficient importance that it must be explained or accounted for within the framework of a particular comprehensive doctrine. For example, if security is recognized as a sufficiently widespread interest that it can support collective action, then different moral or political theories might seek to account for and explain the moral or political significance of this interest. As a result, appeals to the common good can reflect explicit tenets of widely held comprehensive doctrines or they can enjoy a kind of pre-theoretical intuitive force that different comprehensive theories might try to capture and to formulate more precisely.

### 4.2.2 The Implicit Structure of Appeals to the Common Good

Although the implicit structure of appeals to the common good is rarely explicated, it plays an important role in organizing moral decision-making. For our present purposes, we can begin with a common normative claim involved in appeals to the common good:

**Normative Claim (NC):** There are circumstances in which the interests of individuals may permissibly be subordinated to the common good.<sup>2</sup>

For example, McDermott's claim that "to ensure the rights of society, an arbitrary judgment must be made against an individual" (1967, 40) can be read as asserting that the greater good of society outweighs and legitimates the subordination or abrogation of individual rights and welfare.

Second, we require some specification of the circumstances under which this normative claim applies. The weakest, and therefore least controversial, specification simply asserts that the normative claim is most likely to be operative in cases where there is a clear and present threat to the common good itself.

**Triggering Condition (TC):** The presence of a clear and present threat to the common good constitutes a circumstance in which it may be permissible to subordinate the interests of individuals to the common good.<sup>3</sup>

Finally, these two claims together entail that efforts to promote the common good must remain within certain boundaries.

**Practical Constraint (PC):** The means used to pursue or secure the common good must not themselves conflict with or subvert the common good.

<sup>2</sup> Jonas's argument clearly presupposes this claim. Pettit is committed to this view when he asserts, "there is a big difference between constrained interference that is designed for a common good—say, the interference of a law that no one contests—and arbitrary interference" (1997, vii, see also 68). Aquinas articulates this claim when he says, "the common good should be put before the good of an individual" (2005, 213). See also Harris, for example, who says "It is widely recognized that there is clearly sometimes an obligation to make sacrifices for the community or an entitlement of the community to go so far as to deny autonomy and even violate bodily integrity in the public interests and this obligation is recognized in a number of ways" (2015, 244).

<sup>3</sup> This condition is explicitly discussed by Jonas. Harris appeals to this condition when he says, "medical research is a public good, that may *in extremis* justify compulsory participation" (2015, 245).

Although this is only a schematic representation, it enables us to clarify two points. First, appeals to the value of certain individual rights, such as civil liberties, may not be an appropriate response to arguments of this type because the NC does not deny that individual rights or civil liberties are important to the interest of individuals. It claims only that it is sometimes acceptable to limit or otherwise subordinate individual interests to something of equal or greater importance. If individual rights or civil liberties are in the class of individual interests, then an appeal to the common good represents an intuitive way to formulate a permission to override or abrogate them. Unless one is prepared to argue that such rights or liberties are absolute and inviolable, the case for overriding or breaching them becomes more compelling as the perceived threat to the common good becomes more severe.

The second point is that, as we will see in a moment, different substantive accounts of what constitutes the common good will license different actions in the NC, determine what sort of concrete threats are sufficient to meet the TC, and what substantive PC limit the means that may be used in pursuing the common good in practice. In order to avoid equivocation, one must ensure that each of these claims is explicated in terms of the same substantive account of the common good. Formulating the NC in terms of one conception of the common good and grounding the TC or the PC in a different conception would break the justificatory link between these claims. To evaluate the soundness of arguments of this type, we require detailed information about what the common good is in defense of which it may sometimes be permissible to subordinate or curtail individual interests.

### **4.3 The Corporate Conception of the Common Good**

#### **4.3.1 Interests Distinct from Individuals**

The NC draws a contrast between the interests of individuals, on the one hand, and the common good, on the other. However, there are at least two ways of drawing this contrast that yield importantly different conceptions of the common good.

One fairly natural way to draw this contrast is to identify the common good with the good of the community conceived of as an entity that exists in its own right, persisting through time, with interests that are in some meaningful sense distinct from those of its individual members. On this view, the

NC draws a fairly blunt distinction between the good of two different parties. One party is monadic—the individual agent—and the other is corporate—the collective agent or the body politic.<sup>4</sup>

Aquinas appears to have this conception of the common good in mind when he says, “There is also a common good that relates to one person or another qua part of a whole; for example, to a soldier qua part of the army, or to a citizen qua part of the city” (Aquinas 2005, 131).<sup>5</sup> Similarly, in his testimony before the tribunal at Nuremberg, the defendant Dr. Karl Brandt seems to have this view in mind when he says that the Nazi party imposed a system in which “the demands of society are placed above every individual human being as an entity, and this entity, the human being, is completely used in the interests of that society” (Tribunals 1949, 29).

When Jonas asserts the normative claim that it is sometimes permissible to subordinate the interests of individuals to the common good, he notes correctly that “the common or public good” represents an unknown element in this equation. He then goes on to assume, at least for the sake of the argument, that the common good represents the good of society as something “distinct from any plurality of individuals” (1969, 221).

It is against the backdrop of this assumption that Jonas argues that most common illnesses, such as “cancer, heart disease, and other organic, noncontagious ills,” do not pose a threat to the common good because the normal death rate from these causes does not prevent society from “flourishing in every way.” As he puts it, “a permanent death rate from heart failure or cancer does not threaten society” (1969, 228). These are not threats to the common good—to society as a corporate entity—but to the lives of individuals. From the standpoint of society, as a body politic that persists as different individuals are born, live, and die, the goal of finding treatments to ameliorate sickness, injury, and disease does not benefit the corporate entity, but only the parts from which it is composed. Because the whole can survive the normal death rate from these causes, medical progress is an individual rather than a common good and is therefore morally optional.

<sup>4</sup> This is what Brennan and Lomasky describe as a strongly irreducible social good, which they define as, “G counts as a common good for society S if (1) G is good for S and (2a) G is not good for all or most of the citizens of S or (2b) G is good for S irrespective of whether G is good for the citizens of S” (2006, 223).

<sup>5</sup> As Thomas Williams explains, for Aquinas “Human beings are parts of a whole; that whole is the community. And parts exist for the sake of the whole. Just as you should not impair the body’s integrity for just any old reason (chop off your hand just because you feel like it), but you should amputate if that is the only way to save the body, so also you should excise dangerous people if that is necessary for the safeguarding of the community” (Aquinas 2005, xviii).



The argumentative strategy that Jonas adopts reveals the logic of appeals to the common good. Given the corporate conception, in order to pose a threat to the common good (to meet the TC) something must endanger the continued existence, proper functioning, or collective welfare of society as a whole. Jonas's strategy is to argue that under "ordinary" circumstances, most common diseases and ills threaten the lives and interests of individuals, not of the community as a whole. Without a threat to the common good, the TC has not been met. Without meeting the TC, the NC has not been grounded or justified. Absent such a justification, researchers are not empowered to ignore, override, or subordinate the rights and welfare of individuals to the larger social goal of advancing the common good.

Notice, however, that if something *is* deemed to constitute a threat to the common good, this view yields only the weakest possible PC on the steps that can be taken in response. That is, if the common good is identified with the continued existence or collective welfare of society as a whole, then the PC states that the means that are used to pursue or secure the common good must not themselves conflict with or subvert the continued existence or collective welfare of the community as a whole.

Something that poses a threat to "the whole condition, present and future, of the community" may create a state of emergency "thereby suspending certain otherwise inviolable prohibitions and taboos" (Jonas 1969, 229). Once the TC has been met, violations of civil liberties and harms to individuals would have to be egregious in scope and deleterious in their direct and indirect effects before they would threaten to undermine this view of the common good. After all, just as ordinary sickness and disease are not a threat to the community before the TC has been met, the violation of individual rights and liberties and a loss in individual well-being do not threaten the existence of the community after the TC has been met.

What Jonas seems to recognize so keenly is that the corporate conception yields a surprisingly broad permission for authorities to subordinate the interests of individuals to the common good once the TC has been met. Notice too that concealing harms to individuals that are justified by appeal to this conception of the common good makes it less likely that the PC will be violated. As such, this conception of the common good seems to underwrite less than transparent and perhaps overtly deceptive social practices in order to ensure that public scrutiny does not threaten to destabilize the community.

This last point explains why McDermott, Lasagna, and others who saw researchers as empowered to make "arbitrary judgments" against specific

unlucky individuals also argued that this sacred trust must remain sufficiently private or discrete as not to threaten or undermine the ability of researchers to produce these social benefits. If sickness and disease threaten society, then society can take whatever steps are necessary to secure its preservation, as long as those steps remain within the bounds of the PC.

Because the corporate conception of the common good yields such a weak PC, this framework tends to focus debate on whether or not the triggering conditions for the normative claim have been met. As a result, this conception of the common good makes it difficult to locate a middle ground between the following two extreme interpretations of the TC).

### 4.3.2 Strict Triggering Conditions

Jonas endorses what we might call “strict conditions” on when the TC has been met. On this view, common and pervasive threats to the welfare of individual agents such as most major diseases and illnesses, most criminal activities, and fairly steep social and economic inequalities, do not pose a threat to the common good. It is only in the most extreme cases—cases in which plague, famine, anarchy, or revolution threaten health and safety on a grand scale—that such conditions threaten the persistence, proper functioning, or aggregate welfare of the community as a whole.

On the view that Jonas adopts, efforts to ameliorate or address the ordinary, common causes of avoidable suffering, loss of functioning, or death for individuals cannot draw their support from an appeal to the common good. They are not sufficient to activate the TC and justify the NC. If efforts to address these conditions require concessions from individual agents, then the strict position Jonas adopts either prohibits them, or requires that the justification for seeking them be drawn from an appeal to something other than the common good.

By adopting the strict position on when the TC is met, Jonas shields individual interests against the potential for overreach and abuse latent in appeals to the common good and the NC. In doing so, he also rebuts the claim that there is a social imperative to carry out research with human participants. This shifts the justification for this activity outside the public sphere and into the private sphere of individual interest.<sup>6</sup>

<sup>6</sup> The logic of the move Jonas makes is recognized even by critics who seek to revive the idea that the status of medical knowledge as a public good is sufficient to ground a research imperative. In the

### 4.3.3 Lenient Triggering Conditions

In contrast, what I will call the “lenient position” on the TC is more willing to view “ordinary” sources of individual morbidity and mortality as threats to the common good as defined by the corporate conception.<sup>7</sup> This position is lenient in the sense that it sets a lower bar for the triggering condition. To do this from within the corporate conception of the common good, it has to focus less on the persistence through time of the community and more on its aggregate welfare or, as Arendt phrases it, “the sum total of individual interests” (1973, 152).<sup>8</sup>

Certain forms of utilitarianism support a view in which the sum total or aggregate social welfare is created by combining the gains and losses to individual welfare at a particular time without keeping track of how those changes in welfare affect the life of individual agents across time. For example, Parfit describes a view that rejects the idea that there is a deep metaphysical or moral truth to the personal identity of individuals over time. On this view, what matters are the quality of the experiences that occur in the lives of persons at a given time, not how those experiences are connected to past or future experiences. As Parfit puts it, “If we cease to believe that persons are separately existing entities, and come to believe that the unity of a life involves no more than the various relations between the experiences in this life, it becomes more plausible to be more concerned about the quality

hands of these critics, the research imperative is no longer a social imperative to carry out research of a certain sort. Rather, it is framed as a moral imperative that individuals participate in research. Nevertheless, as one group puts it, “If it turned out that biomedical research with human participants was not that important after all—that society would not be much worse off if all research on humans were to cease—there would be no obligation to participate” (Schaefer et al. 2009, 68).

<sup>7</sup> Harris notes that communities sometimes have “an entitlement to go so far as to deny autonomy and even violate bodily integrity in the public interest,” (2005, 244), and although he seems to think that this should be reserved for cases of “extremis,” he seems to have a lower threshold for appeals to the common good to override individual interests than Jonas. Similarly, in 1997, the Secretary of Health and Human Services, Donna Shalala, testified before congress that the traditional requirement of patient consent for disclosure of medical information must give way to “our public responsibility to support national priorities—public health, research, quality care, and our fight against health care fraud and abuse.” Critics of this proposal saw it as an instance of the subordination of human subject protections to the “interests of science and society” pointing to what they saw as “Shalala’s willingness to use bureaucratically designated ‘national priorities’ as a rationale for overriding a traditional patient right and, potentially, patients’ civil rights as well” (Woodward 1999).

<sup>8</sup> Arendt argues that imperial powers saw economic and political expansion as a way to serve the common good because, although different individuals have different interests, they share common economic interests that were advanced by expanding economic opportunities. Such powers thus saw expansion as a way to increase the sum total of individual interests in their community (Arendt 1973, 152).

of experiences, and less concerned about whose experiences they are” (1984, 346).

On such a view, “the impersonality of Utilitarianism is therefore less implausible than most of us believe” (Parfit 1984, 346). The view is impersonal in the sense that it assigns value to the net utility of states of affairs regardless of how the underlying utilities (pleasures and pains or whatever metric is used to define the good) are distributed across specific individuals. This creates a corporate conception of the common good because the community’s welfare is an aggregation of the pleasures and pains of its constituent members at a given time, without concern for how those pleasures and pains are distributed across its members.

On this view, the TC can be more lenient, as anything that avoidably reduces aggregate welfare might trigger the NC. To the extent that preventing, curing, or ameliorating sickness, injury, or disease on a large scale increases aggregate welfare, then the means of effectuating these gains can be viewed as helping society to avoid a collective threat—the loss of social utility that avoidable morbidity and mortality bring.

When Eisenberg asserts that “the decision not to do something poses as many ethical quandaries as the decision to do it,” he appears to be making a clearly consequentialist claim. This underwrites his assertion that, “the systematic imposition of impediments to significant therapeutic research is itself unethical because an important benefit is being denied to the community” (1977, 1108). Here it is unlikely that he is referring to the community in the corporate sense. When he says that “there is a clear moral imperative in developed nations for medical research in tropical diseases, to seek to permit two-thirds of the world’s population to share in the freedom from pain and untimely death we have achieved for ourselves” (1977, 1109), it is the magnitude of the benefits to the welfare of large numbers of people that seem to underwrite the moral imperative.

Adopting a more lenient TC has the potentially attractive feature of grounding a social imperative to support the research enterprise. But because the corporate conception of the common good yields such a weak PC, the willingness to exact even the most profound sacrifices from the individual, or a minority of individuals, in order to secure the good of the majority may turn out not to be a moral failing, but a requirement of civic virtue in such a view. When the aggregate welfare is impersonal, there is no constraint against increasing it in ways that exact a heavy toll from individual agents. The only practical constraint on exacting sacrifices from individuals

in the name of the common good is that any harms or wrongs must be compensated for sufficiently by the increase in aggregate well-being.

Some utilitarians were at pains to prevent this kind of conflict between the interest of the individual and the demands of the collective by stressing that the way welfare is distributed across the life of a particular individual matters morally.<sup>9</sup> These theorists are thus sensitive to the potential for utilitarian theories to run roughshod over what most political liberals regard as a foundational requirement of morality, namely, the need to respect the sanctity or dignity of the individual person, what Rawls calls the “separateness of persons” (Rawls 1971, 22–33).

It is not surprising that those with a more utilitarian bent are likely to be unpersuaded by Jonas’s argument. Jonas mounts his defense of individual rights and welfare with an argument in defense of the strict position on when the NC is triggered. That position was motivated by a conception of the community, as an enduring entity, reflected in Nazi ideology, and represents a natural interpretation of claims about the right of humanity or the state to medical progress. But that view requires a strict interpretation of the TC and it is this view that Jonas exploits. In contrast, a more permissive view of the triggering condition is likely to be adopted by utilitarians who think that they have sufficient information to make interpersonally comparable assessments of aggregate social utility of a fine enough grain to determine when social policies that adversely impact the rights or welfare of individuals generate a sufficient amount of welfare to offset those losses.<sup>10</sup>

<sup>9</sup> Sidgwick says, “It would be contrary to Common Sense to deny that the distinction between any one individual and any other is real and fundamental, and that consequently I am concerned with the quality of my existence as an individual in a sense, fundamentally important, in which I am not concerned with the quality of the existence of other individuals: and this being so, I do not see how it can be proved that this distinction is not to be taken as fundamental in determining the ultimate end of rational action for an individual” (1930, 498). Parfit frames his discussion of the separateness of persons as a response to Sidgwick: “Sidgwick held this view because he believed the separateness of persons to be a deep truth. He believed that an appeal to this truth gives a Self-interest Theorist a sufficient defense against the claims of morality. And he suggested that, if we took a different view about personal identity, we could refute the Self-interest Theory. I have claimed that this is true” (1984, 329).

<sup>10</sup> See Hardin (1998) for an insightful discussion of the way that the presence or absence of information about interpersonal comparisons of utility alters the norms that can be grounded in a consequentialist framework.

#### 4.3.4 Diversity and (Spurious) Consensus

I suggested previously that arguments about the common good are somewhat independent of comprehensive moral and political theories. It is worth reiterating, therefore, that communitarians who are comfortable treating the state or the community as a distinct entity that persists through time, and utilitarians who hold that communities are nothing more than collections of individuals, may disagree about strict and lenient interpretations of the TC. But such disagreements can take place against the shared background assumption of the corporate conception of the common good.

During times of relative peace or security, disagreement over strict and lenient positions may flourish between proponents of such different comprehensive views. In a time of social crisis, however, these divisions are more likely to collapse. The larger the social threat, the more difficult it will be to resist the claim that the TC has been met. Proponents of different comprehensive moral and political theories may suddenly find themselves in agreement because the fact that they share the corporate conception of the common good is obscured by the more salient or prominent division over the stringency of the TC. As a result, in times of national crisis, both communitarians and liberals may find themselves embracing the same NC and therefore willing to tolerate fairly high demands on some, so long as those demands do not violate the same fairly weak PC).

Understanding the logic behind such a convergence is particularly important for two reasons. To begin with, if proponents of different comprehensive views find themselves converging in the way I just described, they may perceive this as an overlapping consensus that therefore takes on special epistemic, or at least political, credence. Additionally, if the role of embracing a corporate conception of the common good in forging this consensus is not subjected to explicit reflection, it may become increasingly difficult to see dissenters as rational or reasonable. Without seeing the possibility of an alternative conception of the common good, the only way to interpret continued dissent within this framework is to see it as a claim that the (TC) has not been met. As fear of calamitous consequences render such a position more difficult to make, however, it also becomes harder to see dissenters as rational.

The corporate conception of the common good, however, is only one possible way of construing the relationship between individual interests and the common good. In §4.5 I will outline an alternative way of construing this relationship that yields very different normative conclusions. First, however,

I want to note some of the reasons why we ought to be skeptical of the corporate conception of the common good.

#### 4.4 Problems with the Corporate Conception

To begin with, the corporate conception of the common good is overly broad in what it recognizes as threats. For example, it would include as threats to the common good cases where the persistence of a community is threatened by causes that do not endanger the moral rights or welfare of its individual members. Such cases might include the dissolution of the community through mass emigration, peaceful succession, or pervasive civil reforms in which central social and cultural structures are dissolved and replaced by alternatives. In such a case, the threat of the dissolution of the community could activate the TC and justify state action that would adversely impact the rights or welfare of community members, even though the threat the state is facing would not adversely affect the rights or welfare of *any* of its constituent members.

Similarly, if the focus is the aggregate welfare of the community, this conception of the common good can still be overly broad in what it recognizes as a threat. For instance, imagine a large population of people, each of whom has a relatively low level of individual welfare. Reducing the size of the population through emigration or lower fertility rates will reduce the overall aggregate welfare of the community simply by reducing the number of people. Policies that reduce population size threaten the common good by lowering aggregate welfare, even though it is possible to reduce aggregate welfare in ways that harm no one and lead to a state of affairs in which the welfare of every remaining individual increases.<sup>11</sup>

On the other hand, this conception of the common good also appears to be overly narrow in what it recognizes as potential threats. On the corporate conception of the common good, the preservation of features that constitute

<sup>11</sup> As a simple example, consider 100 people, each of whom has a utility of 60. If emigration and lower fertility rates reduced the population by half and increased the welfare of the remaining 50 people by a positive amount that is less than 30, the aggregate population level will decrease while the welfare of every individual will increase. This is a strong result because every remaining individual is strictly better off than they previously were. A weaker version would hold as long as some people are made no worse off and others are made better off as a result of a decrease in population. In this way, exceedingly large populations might decline in ways that reduce overall, aggregate welfare without making anyone worse off but also making some people strictly better off. Nevertheless, such trends would constitute threats to the common good and so be targets for state action.

the identity of the community as a whole can justify acts or policies that reduce the rights and welfare of community members. This can happen, for example, when a culturally, politically, and economically dominant class exacts heavy sacrifices from individuals in marginalized groups to secure the transmission of culture and the maintenance of social order that perpetuates the exclusion or subjugation of marginalized groups. Worries of this kind likely motivated Jonas's critique.

Likewise, policies that increase overall utility may have a deleterious effect on the welfare of the individuals who comprise the relevant community. The clearest example of this occurs from absorbing or adding new members, either through population increase or immigration, in a way that increases aggregate welfare while diminishing individual welfare. Here again it is possible to increase the total social welfare while making every individual in the community worse off.<sup>12</sup>

In these cases, the corporate conception of the common good can accept, and may even require, significant compromises to the rights or welfare of fairly sizable portions of the population, so long as those compromises do not threaten the persistence of the community as a whole or the aggregate welfare of its members.

The corporate conception faces these problems because it treats the community as something whose perfection or proper function is in a meaningful sense distinct or uncoupled from the flourishing or proper functioning of its members. Given this divergence, however, it becomes unclear why the perfection, proper function or flourishing of this corporate entity should take normative precedence over that of the individuals that comprise it.<sup>13</sup>

Such worries are exacerbated by the tendency for the pursuit of such non-personal ideals to require significant personal sacrifice, often from

<sup>12</sup> For instance, adding  $n$  people with a total utility of  $y$  to a population of size  $m$  will increase the aggregate utility of the population while making every individual worse off as long as the decrease to each individual's utility is greater than zero and strictly less than  $(n + m)/y$ . These objections are an instance of what Parfit refers to as the "repugnant conclusion" (1984, 381–390).

<sup>13</sup> Brennan and Lomasky make a similar argument when they argue that strongly irreducible social goods are "irrelevant to rational political activity" because the community and the individual are each treated as separate entities that can fare well or fare badly and there is "no special connection between their farings" (2006, 224). They point out that such a special connection cannot be established by appealing to the fact that individuals can value the fact that their community embodies some irreducible social good because this grounds the importance of the common good in the prior value of individual preferences or commitments. It is also worth mentioning that Jonas (1969, 221) raises related concerns about what I am calling the corporate conception. It is therefore appropriate to read Jonas's argument as dialectical in nature. That is, he is claiming that even if we assume the corporate conception of the common good we can still provide a sturdy foundation for informed consent for most peacetime circumstances.



members of the most vulnerable classes. They are also exacerbated by the convenient congruence between the needs of these ideals and the protection, enrichment, entertainment, and general aggrandizement of a powerful, prosperous few.<sup>14</sup>

For these reasons, the corporate conception of the common good provides a poor framework within which to evaluate important normative questions. It is insufficiently responsive to the interests of individual community members and it places inordinate emphasis on establishing that the TC has been met. Within this framework, for example, debate will focus on whether a public health emergency represents a clear and present danger to the common good. Establishing that this is the case allows us to treat basic rights and liberties and the traditional principles of research ethics as peacetime luxuries that can be abrogated in this time of crisis. What this framework does not provide is any sense of a principled way to make specific decisions about when or to what extent such traditional protections may be modified. It simply enunciates the permissibility of setting them aside.

The potential for abuse that is latent in this position can therefore lead reasonable people to avoid acknowledging a health emergency as a threat to the common good, even when such a threat adversely affects the health and welfare of potentially sizable groups of individuals. This fosters zero-sum thinking and can therefore exacerbate conflicts over controversial cases. It is also extremely difficult within this framework to draw support from a concern for the common good for specific, substantive limits on permissible means in a way that is sensitive to the interests of the individuals involved. This adds to the difficulty of finding integrative or win-win solutions to conflicts that do arise within this framework.

## **4.5 The Basic or Generic Interests Conception of the Common Good**

### 4.5.1 Personal Interests

It is crucial, therefore, to consider another way of distinguishing individual interests from the common good. What I call the “basic or generic

<sup>14</sup> See note 1 in this chapter.

interests” view draws a distinction, not between the interests of individuals, on one side, and groups or communities on the other, but between two sets of interests that can be attributed to every individual.

One set of interests is individual or personal. These include the goals and ends that derive from the particular life plan an individual has adopted, as well as interests that derive from the various ways that a person’s life can go better or worse relative to that plan. These are first-order interests in the sense that they are interests that one has in virtue of the particular life plan one has adopted, including a conception of a good or flourishing life.

Talk of “adopting a life plan” is likely to be misleading to the extent that it gives the impression of a single moment in which an agent performs a self-conscious act of deciding to pursue a discretely formulated and clearly articulated plan or script for a life. In reality, this process is often inchoate, extended across time, and undertaken tacitly and implicitly. Children are often raised to have certain values and aspirations that structure their activities and pursuits, along with their conceptions of success and failure, without questioning the values they have effectively inherited from their parents, friends, and community. At other times in life—after a traumatic event or a major transition such as graduating or ending a relationship—individuals sometimes do reflect on the values and ideals after which they strive: whether those values and ideals are defective or wanting, whether they would be better served, in some meaningful sense, by editing and revising some aspect of their goals, values, ambitions or criteria for success and failure.

Regardless of the extent to which a life plan is explicit or implicit, such a plan represents a set of values and a conception of the human good or human flourishing that provides a structure for evaluating opportunities and determining the magnitude of a benefit or a harm. For example, a person who organizes her life around hiking and mountain climbing may value striving for excellence in physical strength and endurance, cultivating the mental toughness necessary to resist fatigue and the desire to quit, and appreciating the beauty and grandeur of nature. For such a person, sitting inside at a desk all day, typing at a computer, might seem like a hellish existence, even if it came with lucrative remuneration. In contrast, the novelist or academic who enjoys reading and writing for long hours may view the hardships and inconveniences of camping and hiking as precisely the kind of drudgery that modern conveniences were invented to obviate. They would prefer to

sit at a computer, exploring new ideas, crafting elegant prose, or insightful arguments to trudging up a muddy hillside and sleeping on wet grass without a shower.

The point of these stereotypical examples is merely to illustrate how the values, aspirations, goals, and ideals that a person embraces can shape a life in which activities that would be of low value to one person can be deeply meaningful and valued by another. The interest that these parties have in spending long hours on the trail or at a desk, in having a membership at a gym or a subscription to a literary magazine, are all personal interests in the sense that they derive their value from their place in a particular life plan.

#### 4.5.2 Basic or Generic Interests

Personal interests are distinguished from basic or generic in this sense: although individuals may differ widely in their particular tastes, preferences, career choices, and personal ideals—their individual or personal conception of the good—they each share a general interest in being able to pursue whatever life plan they have adopted. Rawls refers to this as a higher-order interest in the sense that it takes a person's first-order interests as its object (1982, 164–165). At an even more general level, this shared higher-order interest is the subject of what Rawls refers to as a person's highest-order interest (164–165). This is their basic or generic interest in being able to develop and exercise their basic intellectual, affective, social, and physical capacities in order to be able to formulate, pursue, and revise a meaningful life plan, including forming and maintaining relationships of significance with others.

During periods of growth or change, people sometimes adopt this kind of higher-order perspective or they seek the help of a counselor or advisor who provides assistance in assuming this perspective. In such cases, people consider what their talents and aptitudes are; what activities draw on those aptitudes in a way that might create a sense of fulfillment and accomplishment; and how those aptitudes or activities might align with career plans and vocational options, hobbies and avocational opportunities, social movements and volunteer opportunities, or other forms of association that are available in their society. At such a time it would not be uncommon for such a person to say that they are looking for the same thing as everyone else—a life plan that fits their personality, gifts, proclivities, and limitations

that they might inhabit and within which they might grow and find a sense of meaning and belonging.<sup>15</sup>

The stockbroker, the triathlete, the chemist, the sculptor, the musician, and the soldier may have radically different conceptions of what activities and accomplishments are worthwhile, of the prospects that are to be feared or avoided, of the resources that are valuable for advancing their ends, and of the criteria for success and failure. Nevertheless, with reflection each can see the others as fundamentally the same as them in this basic respect, namely, that each shares the generic interest in being able to develop a life plan of their own, to be able to revise it in light of reflection and experience, and to be free from arbitrary interference so that they can undertake these pursuits on terms that are consistent with the equal ability of their compatriots to do the same.

### 4.5.3 Justice and the Space of Equality

What I call the basic or generic interests view identifies the common good with this set of basic or generic interests. One of the goals of a just political order is to secure the common good in the sense that a just political order is one in which the basic institutions of society are designed and function to create and maintain social conditions in which every one of its members can develop and exercise their basic intellectual, affective,

<sup>15</sup> As Mill puts it:

There is no reason that all human existences should be constructed on some one, or some small number of patterns. If a person possesses any tolerable amount of common sense and experience, his own mode of laying out his existence is the best, not because it is the best in itself, but because it is his own mode. Human beings are not like sheep; and even sheep are not undistinguishably alike. A man cannot get a coat or a pair of boots to fit him, unless they are either made to his measure, or he has a whole warehouseful to choose from: and is it easier to fit him with a life than with a coat, or are human beings more like one another in their whole physical and spiritual conformation than in the shape of their feet? If it were only that people have diversities of taste that is reason enough for not attempting to shape them all after one model. But different persons also require different conditions for their spiritual development; and can no more exist healthily in the same moral, than all the variety of plants can in the same physical atmosphere and climate. The same things which are helps to one person towards the cultivation of his higher nature, are hindrances to another. The same mode of life is a healthy excitement to one, keeping all his faculties of action and enjoyment in their best order, while to another it is a distracting burden, which suspends or crushes all internal life. Such are the differences among human beings in their sources of pleasure, their susceptibilities of pain, and the operation on them of different physical and moral agencies, that unless there is a corresponding diversity in their modes of life, they neither obtain their fair share of happiness, nor grow up to the mental, moral, and aesthetic stature of which their nature is capable. (1880, 39–40)

and social capacities in order to form, pursue, and revise a reasonable life plan.<sup>16</sup>

Basic interests help to define the sense in which a just social order treats people as free and equal. A just social order treats people as morally free when it recognizes their status as individuals “who exist for their own sake and not for the sake of someone else” (Aristotle 982b25–27). This status is reflected in the interest that individuals share in being able not only to form and pursue, but also to revise, a life plan. Individuals can take on a wide range of commitments within their personal projects, and those projects can entail differences in rank or standing or accomplishment relative to the criteria within those shared projects. But those distinctions must not compromise the deep interest that individuals retain in being able to reassess their commitments and projects and memberships and to act on those revised assessments. Honoring or respecting moral freedom requires concrete social action to secure for all community members, across a complete lifespan, the personal and social conditions necessary to realize this interest in practice.<sup>17</sup>

Basic interests define the sphere of moral equality because they represent the common, highest-order interest that all persons share in being able to forge and pursue a life of personal meaning and interpersonal connection and importance. Relative to these interests, there are no grounds for discriminating or favoring individuals. Whether a life plan is reasonable or not is to be judged from this highest-order standpoint and hinges on the extent to which it is consistent with a social order that recognizes all other individuals as having the same generic interests, and therefore as having the same moral and political standing. A life plan of patriotic service to one’s particular country may be reasonable, in this sense, because it is consistent with the equal status of others to develop and pursue a life plan of their own. In contrast, a life plan that involves pursuing the supremacy of one racial or ethnic cast and the domination or systematic oppression of other racial or ethnic

<sup>16</sup> This point about the relationship between basic interests and the basic social structures of a community is taken up again in chapter 9.

<sup>17</sup> It is noteworthy that Pettit identifies freedom as non-domination with the common good (1997, 120–126; see also 2004). In other words, the purpose of a republic is to provide a social order that protects individuals from arbitrary interference from others and in which their dignity and status as the moral equal of their compatriots is recognized in law and in practice. This is a common good, for Pettit, both in the sense that being free from arbitrary interference is an interest shared by all persons and in the sense that this good can only be realized by action taken at the community level. This notion of community level action—embodied in the rule of law and checks and balances of institutions—is captured here in the idea that the basic structures of a society must function so as to preserve for individuals the real freedom to formulate, pursue, and revise a life plan.

casts is not reasonable because it denies to others the ability to develop and exercise the basic interests that all people share.

Given the generic interest conception of the common good, the NC that the interests of individuals may permissibly be subordinated to the common good is to be understood as holding that an individual's pursuit of his or her individual or personal good must sometimes be subordinated to, or constrained by, the basic interests that individuals need in order to form, pursue, and revise a life plan. In this regard, the claim that a White supremacist ideology is unreasonable and therefore should not be tolerated in a just society represents an instance of the NC—the ability of a person to identify with and to promote personal projects, including the formation of relationships and identities of interpersonal meaning and significance, must be constrained by the legitimate interests of others in being free to develop and exercise the very intellectual, social, and emotional capacities that are presupposed in that person's pursuit of his or her own particular ends. Because the White supremacist embraces an identity that denies the equal moral status of others—their generic interest in being free to develop and pursue a life plan of their own without arbitrary social interference—a just social order can use social authority to deter the dissemination, cultivation, and pursuit of this identity.

#### 4.5.4 Threats to Basic Interests

Many more things pose a threat to the common good on this view than on the corporate conception. Premature mortality and severe morbidity threaten the integrity of a life by shortening its duration or reducing the extent to which a person can develop and exercise their particular talents and abilities. To formulate, pursue, and revise a life plan, individuals draw on a network of intellectual and affective capacities. These capacities can be hindered or undermined by injury and disease including various forms of physical and mental illness. A person's ability to pursue a reasonable life plan can also be frustrated by impediments to or restrictions on the capabilities they use to navigate the physical world, to engage in social life, to enter public and private spaces, and to convert resources into the functionings necessary to take advantage of social opportunity (Sen 1999b; Nussbaum 2000).

The ability to formulate, pursue, and revise a life plan of one's own is not solely a function of an individual's physical or mental condition. Individuals

can be prevented from exercising those capacities in practice if the laws or social norms to which they are subject prohibit their participation in society on equal terms with their compatriots. Racism, sexism, ableism, and other forms of discrimination frustrate the generic interests of individuals by preventing their development or preventing their exercise in practice. Restrictions on access to education, for example, prevent individuals in targeted classes from developing their basic intellectual, affective, and social capabilities and also deprive them of access to a social space in which the exercise of those abilities is a gateway to additional social, economic, and political opportunity.

The basic or generic interest of individuals in being able to formulate, pursue, and revise a life plan can thus be set back by a range of factors that detract from the fair value of this interest. To enjoy the fair value of this interest, it is not sufficient to recognize individuals as free and equal on paper. Rather, to enjoy the fair value of their basic interests, individuals require the freedom to exercise the intellectual, affective, and social abilities necessary to advance those interests; they also require social protections for that exercise and access to the opportunities in which those capacities can be deployed (Sen 1999; Nussbaum 2000). When individuals have the resources, protections, and opportunities to realize the fair value of their basic human capacities then we can say that they have the real freedom to exercise these capacities in the service of a meaningful life plan.<sup>18</sup> Given the diversity of individual capability sets, this can include access to equipment (e.g., braces, wheel chairs, Braille text) or supports (e.g., translation or transcription services) that enable persons with disabilities to function in ways that are necessary to take advantage of opportunities that would be open to them in light of their various talents, abilities, and interests.

Because the way that social systems are ordered has such a profound impact on the basic interests of persons, the common good should be understood as a set of shared interests that encompass both the ability of individuals to develop and exercise their basic intellectual, affective and physical abilities and their shared interest in being subject to social arrangements that foster and promote their capacity to translate these abilities into the functionings needed to formulate, pursue, or revise a life plan of their own. The members of a community have a claim on the basic structures of their community that

<sup>18</sup> On this idea in the political theories of Locke, Kant, and Mill, see Korsgaard (1993) and Anderson (1999). For the link between the concept of “fair value” applied to basic liberties and human capabilities, see Korsgaard (1993), Rawls (2001, 175), Nussbaum (2000), and Sen (1999a and 1999b).

they function on terms that give each person an effective opportunity to cultivate and use their basic intellectual, affective, and social capacities to pursue a meaningful life plan.

The generic interest conception of the common good thus yields a TC that is easier to meet because many more things threaten the common good, so conceived. This means that social undertakings aimed at ameliorating or addressing a much wider range of social and biological ills draw their normative support from safeguarding and advancing the common good.

#### 4.5.5 Internal Constraints

However, the generic interests conception also yields a PC that provides much more substantive and robust limits on the way that efforts to address these conditions may permissibly be carried out. In particular, efforts to safeguard and secure the generic interests of people must not themselves violate or trample on the basic interests of individuals.

Just as the effects of disease, for example, do not need to be widespread to pose a threat to the common good so conceived, neither does a contemplated abrogation of individual rights or basic liberties. Just as all individuals have an interest in being free from or protected against the possible ravages of injury and oppression, so too do they have a generic interest in knowing that their control over their person will be safeguarded and respected as the community strives to provide such protections. As a result, efforts to provide the social, material, environmental, and medical conditions necessary for individuals to enjoy the fair value of their basic interests must be designed and carried out in ways that respect the basic interests of the people who carry out this effort.

One key means of advancing the common good within these constraints is to encourage a division of labor in which different tasks associated with advancing the common good can be formulated in terms that are attractive to community members as arenas in which they can pursue goods, ideals, or values that are salient within their personal conception of the good. For example, in a decent society, children require education. To advance this basic interest, educational careers should be formulated on terms that attract individuals who can see in this form of public service an arena in which to develop and exercise their love of learning, their enjoyment of performing, or numerous other traits or commitments.



The goal of such a division of social labor is to create opportunities for individuals to take up, as part of their first-order life plan, activities, and roles that are necessary to secure the basic interests of community members. In some cases, these activities and roles take the form of career opportunities, as when individuals become teachers, adopting as part of their first-order life plan the project of providing a service and a good (teaching and knowledge) that students require in order to be able to develop and exercise their basic interests in being able to formulate, pursue, and revise a life plan of their own.

In the case of medical research, being a researcher has long been seen as a pathway for advancing the common good. The view I defend in the rest of this and the next chapter is that there is an imperative to treat study participation in a parallel fashion, not as a career but as a social opportunity open to community members through which they can contribute to the common good with credible public assurance that, in doing so, their own basic interests will not be knowingly compromised in the process.<sup>19</sup>

This way of distinguishing individual interests from the common good avoids the zero-sum thinking of the corporate conception which distinguished all of an individual's interests from the distinct interests of the community. When individuals come into conflict over the pursuit of their individual goods, the goal is to resolve the conflict in a way that is maximally responsive to the common good—that is, to the shared basic interests of each in being able to develop and exercise the basic intellectual, social, and affective capacities they need to formulate, pursue, and revise a life plan and to pursue relationships of meaning and significance. In other words, the goal is to resolve conflicts at the level of the individual good by searching for *integrative solutions*—modifications in individual goals and ends that enable each party to pursue and exercise their shared basic capacities for agency and welfare. When goals or ends conflict, an integrative solution is one that modifies those goals and ends so as to meet or satisfy the underlying legitimate interests that provide the rationale or motivation behind those goals or ends.<sup>20</sup> In the next two chapters, when we explore how it is possible to

<sup>19</sup> Whether research participants should be treated like volunteers, similar to volunteer fire fighters or paramedics, or paid as professionals is the subject of vigorous debate. In this work I lean toward the view that they should be treated as volunteers. To make this the case, a range of steps should be taken to relieve any burdens, hardships, and expenses that participants might incur through research participation. For the debate about whether research should be treated as a paid profession see Dickert and Grady (1999), Lemmens and Elliott (1999), Anderson and Weijer (2002), Lynch (2014), Różyńska (2018), and Malmqvist (2019).

<sup>20</sup> For a more detailed discussion, including types of integrative solutions, see Rubin, Pruitt, and Kim (1994, 168–195).

implement such requirements in practice, I develop what I call the integrative approach to risk assessment and management. That approach is integrative in this sense: it resolves conflicts over the reasonableness of risks in research by distinguishing these two sets of interests and allowing individuals greater discretion over the risks they face to their personal interests while requiring that research respect a principle of equal concern when it comes to their basic interests.

## 4.6 Multiple Instances of the Generic Interests View

### 4.6.1 A Communitarian Formulation

Like the corporate conception, the generic interests view can be formulated within a variety of theoretical frameworks that are separated by some of the most commonly disputed issues in moral and political philosophy. For philosophically minded readers, it can help clarify the content of the generic interest view to see how it can be formulated within different traditions of social and political justice that begin from different starting points and appeal to a range of different moral considerations. Readers who are less interested in the way this view can be formulated in different philosophical traditions should feel free to skip this section.

For instance, Charles Taylor is a communitarian in the sense that he thinks community membership and social obligation have a certain kind of priority over individual rights. As a result, he has argued that individualist or atomistic political theories that postulate pre-societal or pre-political rights rest on a mistaken view of the basic capacities of agents (Taylor 1979). Granting a certain priority to the community and to obligations of membership does not rule out the generic interests view of the common good, however.

On Taylor's view, what makes some social arrangements preferable to others is the extent to which they create the conditions in which individuals can develop the deliberative and social capacities necessary to entertain alternative forms of living, to engage in a vigorous public debate, and the extent to which they ensure participation in the ongoing development and improvement of the community. The perfection of the community is therefore defined by its responsiveness to the generic interests that its members share in being able to develop and exercise their basic deliberative and social capabilities.

The social obligations that have priority over individual rights are obligations to respect in others the same set of generic interests that are presupposed in one's pursuit of one's own particular projects and relationships. For Taylor, this means that some of one's particular ends (accumulating a vast personal fortune, for example) may have to be modified to accommodate a commitment to sustain the social institutions that create the conditions in which members of the community enjoy the freedom to develop and exercise the very capacities that make the pursuit of these particular ends possible.

Taylor is also a communitarian in the sense that he thinks the development of our individual human potential cannot be achieved outside of some social matrix, some prior set of social structures and practices that countenance certain identities and certain possibilities for self-development as practical possibilities. There is a sense in which this social matrix precedes each of us—we are born into it and our development is shaped by it—and makes a claim on our allegiance.

But, on Taylor's view, we have a duty to belong to a certain sort of society only because it is within such social arrangements that we can develop the fundamental capacities for reflection and agency that we exercise in formulating and carrying out a life plan. Taylor rejects the contractualist idea that a just state derives its moral authority from the voluntary consent of the governed, arguing instead that its moral authority derives from its justice. Nevertheless, he holds that the justice of a social order, on this view, consists in its being organized around creating and supporting citizens who enjoy the fair value of their ability to formulate and carry out a reasonable life plan of their own.

Although the norms and institutions of society precede us, Taylor argues that their purpose does not lie in the impersonal perfection of the state or the community *per se*. Rather, the fundamental purpose of the state and the community lies in cultivating and supporting the basic interests of the individual human persons who constitute its constituent members. Taylor emphasizes that one of the reasons that individuals need the capacities that a just state cultivates is to be able to engage in the civic life of the community and preserve the justice of the state. But the capacities that individuals require to engage in public deliberation and the civil life of the community are the same capacities we use to contemplate our personal projects and plans and to communicate and form bonds of intimacy with our friends and loved ones.

Taylor's communitarianism is a form of perfectionism—a view that morality and justice are ultimately grounded in a certain conception of human nature. As such, it is what Rawls refers to as a comprehensive doctrine, an account of human nature and the human good that competes on the same level with all other such comprehensive views. But this comprehensive, communitarian view locates the common good of community members in the basic intellectual, affective, and associative capacities that citizens exercise in the public life of the state and that free and equal individuals employ to formulate, pursue, and revise a life plan of their own.

#### 4.6.2 A Purely Political Contractarian Formulation

In contrast, John Rawls rejects Taylor's perfectionism and his communitarianism. Rawls offers, instead, a contractarian theory of justice in which the generic interests conception of the common good is presented as a purely political conception of persons that is used to define the constraints on constitutional essentials that can be supported in a democratic society by an overlapping consensus of reasonable comprehensive theories. On Rawls's view, members of society may differ in their comprehensive theories of the good—they identify with different groups, support diverse causes, value competing goals, and endorse different standards for honor, success, beauty, achievement, and other thick aesthetic and moral concepts. Despite this diversity in their first-order conceptions of the good, Rawls argues that these individuals can see themselves as sharing the common higher-order project of formulating and pursuing a life plan. As such, they can recognize a shared, highest-order interest in being able to develop and exercise what Rawls refers to as their two moral powers: their capacity to form a substantive conception of the good and their capacity to regulate their conduct by principles of right (1971, 19, 504–510).

Unlike Taylor's perfectionism, Rawls grounds what I am calling the generic interests conception of the common good in a purely political standpoint. This is a standpoint that is available to members of a pluralistic modern society from which they can see themselves as sharing in a common project—developing and exercising their basic moral powers in the pursuit of a personal, first-order conception of the good life. This highest-order standpoint doesn't compete with the comprehensive views that individuals formulate and embrace as their first-order conception of the good.

Rather, the interest in being able to formulate, pursue, and revise a life plan is presupposed in the pursuit of any first-order life plan and, with this, the interest in having the basic or generic capacities that are presupposed in the formulation and pursuit of any such first-order conception.

In Rawls's political theory, these generic interests set the terms for the just operation of the "basic structure" of society, a term that Rawls uses for "the way in which the major social institutions distribute fundamental rights and duties and determine the division of advantages from social cooperation" (1971, 7). These interests ground the constraints that members of a liberal democratic community can accept for determining the constitutional essentials of society (Freeman 2000). Within what Rawls calls "justice as fairness," securing the generic interests conception of the common good for all citizens is given strict priority over the pursuit of the particular, personal goals that constitute each individual's personal conception of the good. In other words, the basic interests of some individuals cannot be compromised or traded in order to achieve greater personal good for other members of the community.

#### 4.6.3 A Natural Law Formulation

The claim that frameworks can share a commitment to a particular conception of the common good while differing in their background commitments is further illustrated by the defense that natural law theorist John Finnis offers for what I am calling the generic interests conception of the common good. Finnis, like Taylor, embraces a realist, perfectionist view of the common good. He says, "there is a 'common good' for human beings, inasmuch as life, knowledge, play, aesthetic experience, friendship, religion, and freedom in practical reasonableness are good for any and every person" (2011, 155). Also like Taylor, Finnis argues that the "point or the common good" of the political community is securing the "ensemble of material and other conditions that tend to favour the realization, by each individual in the community, of his or her personal development" (2011, 154).

Like Rawls, Finnis treats certain goods as fundamental because of the critical role they play in realizing the personal development of the individual. This shared interest in personal development grounds a claim to access these goods and constitutes the focus for social collaboration. In this sense, we might say that Finnis offers a view that is both political and metaphysical. It is

political in the Rawlsian sense of offering a set of reasons that have purchase on, or constitute reasons for, reasonable individuals who are pursuing diverse conceptions of their individual good. But it is metaphysical in the sense that personal development is treated as an objective good that is enriched by the constitutive goods of life, knowledge, play, aesthetic experience, friendship, and so on. In this regard, Finnis can be seen as holding that the highest-order standpoint that Rawls regards as a purely political perspective represents a deep moral insight into the human good—that is, into the nature of the first-order life plans that individuals should be encouraged to adopt and pursue.

For my present purposes the point is that, despite this disagreement, these thinkers can be seen as supporting a version of what I am calling the basic or generic interests conception of the common good. In different ways, they each recognize that individuals share in common a set of fundamental interests that relate to their ability to formulate, pursue, and revise a life plan and to engage in relationships of meaning with others and that it is the purpose of a just social order to provide the supports necessary for individuals to enjoy the fair value of this capacity.

#### 4.6.4 An Institutional Utilitarian Formulation

Finally, in different ways, each of the thinkers just mentioned argues against the adequacy of purely consequentialist moral or political theories. Nevertheless, the generic interests conception of the common good can also be formulated within a broadly consequentialist framework. For brevity I mention two strategies for doing this. The first is what Russel Hardin calls institutional utilitarianism (Hardin 1988). This is a form of utilitarianism in that it holds that the goodness of outcomes is the foundational concern of morality and that the good should be understood in broadly welfarist terms. However, unlike traditional act utilitarianism, which brings this foundational concern to bear directly on the evaluation of individual acts, institutional utilitarianism brings this foundational concern to bear on the choice of institutions that are to regulate social interaction.

Hardin justifies this focus on institutions on several grounds. One is the common assumption that individuals are generally better judges of their interests than third parties and that institutions that empower individuals to advance their own welfare will produce a greater net utility than institutions that attempt to allocate advantages and burdens directly to individuals.

A second, and related, ground is that we often lack the information necessary to make meaningful interpersonal comparisons of welfare.<sup>21</sup> This ground can have two interpretations. On the contingent interpretation, such information is available in principle but gathering and processing it in practice would be so expensive and morally intrusive that it is either infeasible or possibly self-defeating. On a more substantive interpretation, such information is unavailable because it simply doesn't exist. This can be because there is no way to construct a single, coherent interpersonal utility that can preserve the many different valuations of the diverse individuals in a society. But even if this skeptical view is mistaken, it is not sufficient to establish that such a utility function is possible. Rather, it must also be the case that there is a single, unique way of constructing such a utility. Otherwise, the problem is that there are too many ways of doing this and there are no value-neutral grounds for preferring one representation over another.

In the absence of social consensus regarding the information that should be used to generate interpersonal welfare comparisons, Hardin argues, we should seek to design institutions that “secure mutual advantage for all even though there can be no interpersonal weighings of advantages” (1988, 76). We do this by erecting institutions that protect certain basic interests of persons, securing the integrity and security of their person, their holdings, their privacy, and securing their ability to speak, associate, and form relationships of meaning and significance.

The argument for basic rights in this approach is Paretian: guaranteeing basic rights makes no one worse off and creates the institutional setting in which individual and collective action can take place through which persons can advance their own interests as they understand them. Rights are essential to addressing collective action problems that would arise without the security they provide. As a result, on this view, “We constrain individuals’ choices of strategy in order to produce a better outcome than would have resulted from unconstrained choices” (Hardin 1988, 80).

Institutional utilitarianism supports the generic interest conception of the common good to the extent that it marks out certain interests of individuals as sufficiently fundamental that we are justified in erecting social institutions to safeguard and advance their cultivation and pursuit. Moreover, social institutions are to safeguard these interests not for a select few, but for every person.

<sup>21</sup> I discuss the issues raised in this paragraph in more detail in §6.7.3.

#### 4.6.5 An Objective Consequentialist Formulation

A different, although not mutually exclusive, way to formulate the generic interests view of the common good within a broadly utilitarian framework is to deny that the good is a single dimension onto which the diversity of all value can be mapped. If there is a diversity of goods that cannot be commensurated onto a single scale of comparison, then there is no single domain of goodness for decision-makers to maximize. At best, there is a set of dimensions of goodness, each of which is capable of ranking or ordering alternatives for choice, but which cannot be reconciled into a single, all-things-considered utility function.

There is a sense in which Henry Sidgwick was a pluralist of this sort in that he argued that there is no single standpoint from which to integrate or reconcile the claims of individual self-concern and impartial social concern. This is analogous to positing two goods, each of which make normative claims on us, but whose respective demands cannot be reconciled in a single perspective—such as a weighted average.

Sidgwick represents the subjectivist wing of utilitarian theories. In contrast, David Brink (1989) has defended what he refers to as “objective utilitarianism,” where the modifier “objective” is intended to provide a contrast with subjective theories that reduce human welfare to mental states such as pleasure or desire satisfaction. Brink claims that it is this subjectivism that makes classical utilitarian theories prey to objections concerning the distribution of welfare because the subjective mental states of each individual are summed together to give a single aggregate utility score to the community. Instead, he proposes a non-reductive, naturalistic account of human welfare whose primary components include the reflective pursuit and realization by agents of reasonable life projects and the development of personal and social relationships of mutual concern and commitment.

Brink argues that his objective account of the good is distribution-sensitive because basic goods such as health, nutrition, and education are either necessary conditions for the existence of value, or they are all-purpose means that enable individuals to pursue a wide range of individual life plans (1989, 272). Brink’s theory is still utilitarian, in that it is consequentialist and welfarist—it is just that this view treats welfare as a set of objective goods that cannot be reconciled into a single higher-order good. By defining welfare in terms of the development and exercise of certain basic intellectual and affective



capacities, he argues that objective utilitarianism does not permit trade-offs between access to basic goods for increases in social utility.<sup>22</sup>

The point of these remarks is to illustrate that the generic interests conception of the common good can be formulated within a variety of theoretical frameworks and that within these different frameworks those interests help to define the terms on which the basic social institutions of a decent society should be regulated and organized. It is also helpful to survey the justificatory strategies that different approaches use in supporting institutions that safeguard and advance these generic interests, since many of these justificatory strategies can be deployed outside of the narrow frameworks in which they are discussed here.

For instance, the arguments deployed by institutional utilitarians are available to a wide range of non-utilitarian frameworks. This is because other frameworks often recognize the importance of consequences, individual welfare, and collective action, even if they also recognize as fundamental other normative claims that utilitarians reject or view as derivative from specifically utilitarian assumptions.

In the course of the present work, I gravitate toward Rawls's purely political presentation of the highest-order perspective from which individuals

<sup>22</sup> See Brink (1992). One reason that this conception of the common good may go unrecognized, or may be greeted with skepticism, is that certain of its formulations are easily confused with the corporate conception. Classical utilitarianism resembles the corporate conception because it identifies the good with a subjective mental state, such as pleasure, and then evaluates states of affairs in terms of the net utility score of the social aggregate. One of the basic objections to classical utilitarianism is that its focus on aggregate utility makes it insensitive to questions of the distribution of welfare between individuals. In principle, if persecuting a minority yields a higher aggregate utility score than a policy of equal treatment, then it would be justifiable. As Rawls puts it, "classical utilitarianism treats the political community as a single entity, thereby focusing moral and political deliberation on how best to maximize the overall well being of this corporate individual" (1971, 22–33). What is important for our present purposes is not the accuracy of Rawls's objection, but the fact that it appears to target what I am calling the corporate conception of the common good.

Other versions of utilitarianism, however, attempt to avoid this pitfall.

This is a generic interests conception of the common good, then, in the sense that it defines the common good in terms of a set of interests that members of the community share and have reason to promote both in their own case, and with respect to every other member of the community as well. On this view, pursuit of the common good involves creating the personal and social conditions that enable agents to develop and exercise these basic capacities, including steps to provide agents with access to the basic material resources and conditions required for the exercise of these capacities.

Brink's objective utilitarianism is an ambitious attempt to provide a thick, non-reductive, naturalistic account of human welfare that can serve as the centerpiece of a consequentialist moral theory. Contractarians who embrace the generic interests conception of the common good reject consequentialism and its derivation of the right from the good. They are also deeply impressed by the pluralism in contemporary society surrounding thick conceptions of the good and are, therefore, dubious of the prospect of achieving societal consensus about such complex issues. Whereas Brink deploys his arguments as part of a larger program of naturalistic moral realism, Rawls sees these constraints as constructs that result from an overlapping consensus.

can see themselves as sharing a set of basic interests. This is because I take this approach to have the broadest appeal in the sense that it presupposes the weakest premises. That is, this purely political perspective allows us to identify interests that others may wish to ground in more metaphysically baroque frameworks, or within larger traditions that Rawls regards as comprehensive conceptions of the good, without having to take a stand on which of those comprehensive theories of the good is correct. I am not opposed to efforts to vindicate such theories; I merely regard them as relying on stronger premises than are needed for the purpose of the argument I am making here.

Finally, I gravitate also to Hardin's institutional utilitarianism since it allows us to consider and respond to collective action problems while recognizing that in a pluralistic society in which there are potentially as many ways of making interpersonal comparisons of welfare as there are distinct conceptions of the good life, we should evaluate the effects of social institutions on terms that respect the highest-order interests of each person in having real freedom to pursue the projects and plans from which they derive personal welfare or well-being.

## 4.7 The Egalitarian Research Imperative

### 4.7.1 Stating the Imperative

Traditional proponents of a research imperative equated the common good with the corporate conception. By arguing that "ordinary" sources of avoidable morbidity and mortality do not pose a threat to the common good, Jonas relegated research with human subjects to the realm of the private ends of private individuals. In light of the analysis provided here, we can say that Jonas was correct to argue that there is no social imperative to carry out research grounded in the corporate conception of the common good.

In contrast, the generic interest conception of the common good does ground a social imperative to support a wide range of research, not only in the sphere of individual and public health but with respect to the operation of any social institution that impacts the basic interests of that community's members. Because this imperative is grounded in the fundamental interests of individuals and not in the role-related obligations of any profession, it is binding on, and applies to the conduct of, a much wider range of stakeholders than frameworks in orthodox research ethics. However, because the PC on the pursuit of the common good is much more robust,

this research imperative does not empower professionals to make arbitrary judgments against research participants. This is because the research enterprise itself must be consistent with respect for the generic interests of both the stakeholders to the research enterprise and the members of the larger community in whose name research is carried out and who are expected to be the eventual beneficiaries of the advances it creates.

To unpack these various claims, it is useful to begin by formulating what I call the egalitarian research imperative:

**The Egalitarian Research Imperative:** There is a strong social imperative to enable communities to create, sustain, and engage in research understood as a scheme of social cooperation that respects the status of stakeholders as free and equal and that functions to generate information and interventions needed to enable their basic social systems to equitably, effectively, and efficiently safeguard and advance the basic interests of their constituent members.

Clarifying how this imperative is grounded in the basic interests conception of the common good will enable us to justify its particular relevance to health-related social systems, to explain the sense in which research must be understood as a scheme of social cooperation between free and equal people, and to explain two senses in which this is an egalitarian imperative.

#### 4.7.2 Grounding the Imperative

The egalitarian research imperative is grounded in three claims. The first is that a decent social order strives to preserve and advance the common good, understood as the set of basic interests that individuals require to be able to formulate, pursue, and revise a life plan. These interests can be set back or thwarted by ignorance, poverty, crime, oppression, social exclusion, lack of access to economic opportunity, environmental hazard, contagion, sickness, and disease. To avoid these pitfalls and to realize the fair value of these interests, a decent social order will include a wide range of social institutions designed to safeguard the basic interests of individuals across this diversity of spheres and domains.

Because the basic interests of individuals can be set back by sickness, injury, disease and other threats to individual and public health, a just social order will include social institutions for safeguarding and advancing the

basic interests of individuals in the sphere of public and individual physical and mental health. These social institutions include health care systems, such as hospitals, clinics, and similar venues for health care delivery, as well as the various organs of public health and health policy within a community.

The provision of medical and public health services is thus part of the basic structure of a just society because the provision of these services is necessary to preserve or to realize the ability of community members to function as moral and political equals—to have the real opportunity to exercise their moral powers, free from arbitrary social interference, to formulate, pursue, and revise a reasonable life plan. Rawls makes a similar point when he argues that the provision of medical care falls into the category of a primary good—a good that is valuable to individuals because of its ability to support the generic interests needed to pursue any from among a wide range of life plans. As he puts it,

provision for medical care, as with primary goods generally, is to meet the needs and requirements of citizens as free and equal. Such care falls under the general means necessary to underwrite fair equality of opportunity and our capacity to take advantage of our basic rights and liberties, and thus to be normal and fully cooperating members of society over a complete life. (2001, 174)

Second, the egalitarian research imperative is grounded in the claim that the generic interests of individuals define the space of moral and political equality. Because individuals share the generic interest in having the real freedom to formulate, pursue, and revise a life plan and because these interests are fundamental to the agency and welfare of individuals, these interests define the respect in which community members have equal claim to equal treatment. Every community member has an equal claim on the basic social institutions of their community that function to secure and preserve the fair value of their basic interests.

As a result, there is a moral and a political imperative that social institutions that affect the basic interests of community members function effectively, efficiently, and equitably. The imperative that such systems function effectively is grounded in the importance of the basic interests of individuals to their ability to function as agents and to shape and pursue a life plan of meaning and significance. It is not sufficient that such institutions be designed with the intent or the purpose of securing the fair value of these interests. They

must possess the knowledge and the means of intervening in the world to bring about these ends in actual practice.

There is a moral and a social imperative that those institutions function efficiently, in the sense of securing and advancing the basic interests of community members with as little wasted effort and the fewest wasted resources as possible. This imperative derives from the fact that these institutions must meet the needs of all community members within resource constraints. These resource constraints can derive from various sources, including the fact that just limits must be set on the share of social resources dedicated to social systems in different spheres. No community can dedicate all of its social resources to education or to health care. Rather, every community is constrained to secure and advance the basic interests of its members across a range of spheres, including education; protecting and promoting safety, security, and human rights; and ensuring fair equality of opportunity in social and economic spheres and in the realm of health. Reducing wasted time, effort, and human and material resources allows institutions to achieve better outcomes or to achieve the same outcomes for more people with the same bundle of resources.

Finally, there is also a moral and political imperative for the basic social institutions of a community to function equitably—to preserve and advance the generic interests of all community members with equal safety and efficacy. The imperative of equity derives from the equal claim that all community members have on the basic structures of their society. Disparities in the ability of basic social institutions to advance this end for different members of the community in one sphere can translate into disparities in the ability of those community members to take advantage of opportunities in other spheres (Bloom and Canning 2000; Jamison et al. 2013). This includes increasing the burden of avoidable sickness, injury, disease, and premature mortality (Dwyer-Lindgren et al. 2017; Forde et al. 2020). If such disparities are not addressed, they can produce gaps in opportunity for affected community members that persist and compound over time (Jamison et al. 2013; Bloom and Canning 2000; Ridley et al. 2020).

For example, disparities in access to nutrition or basic public or individual health services can prevent individuals from taking full advantage of educational opportunities. Shortfalls in each of these areas can translate into a lack of effective access to social and economic opportunities that would otherwise be available to the individuals in question. Physical environments that exclude persons with disabilities reduce their ability to access opportunities

in a range of spheres, including education, health care, participation in social life, and the ability to participate meaningfully in the political process. Even when such exclusions do not result from social animus, they can produce cascades of deprivation that prevent individuals with particular traits from being able to enjoy the fair value of their basic interests in being able to formulate, pursue, and revise a life plan.

In other cases, disparities in the operation of a community's basic social institutions stem from and perpetuate histories of unequal treatment rooted in prejudice, domination, and abuse (Cogburn 2019). Racism, sexism, ableism, and other forms of unfair and oppressive treatment deny the moral equality of individuals on the basis of an arbitrary characteristic and translate into social practices that deny and erode the freedom of individuals in those groups to enjoy the fair value of their most basic interests.

The imperative that the basic social institutions of a community function with equity entails a moral and political responsibility to identify and then to address gaps in the ability of these institutions to secure and advance the basic interests of community members. This imperative is particularly strong in cases where patterns of disparity persist through time and reflect histories of indifference toward, or unjust treatment of, individuals in particular groups, such as groups defined by racial or ethnic characteristics, religious or sexual orientation, gender, or disability status.

Thirdly, the egalitarian research imperative is grounded in the intimate connection between the evidence and information that research produces and the ability of the basic social systems of a community to effectively, efficiently, and equitably safeguard and advance the generic interests of the individuals and groups who depend on them. In particular, how to safeguard and advance the basic interests of persons involves inherently causal questions, and in areas such as individual and public health, the state of current knowledge is not sufficient to support the development of safe and effective interventions (understood broadly to include policies, practices, procedures, drugs, and devices) without carefully controlled empirical testing. As a result, research with human participants is often the only way to generate the knowledge necessary to understand the factors in a particular sphere that influence the basic interests of individuals and to understand the relative merits of different strategies for securing or advancing those interests for the diverse constituents of a community.

The imperative to ensure that a community's basic social institutions can safely, efficiently, and effectively secure and advance the basic interests

of its members combined with the dependence of such efforts on carefully designed empirical testing entails a social imperative to use social authority and resources to promote research that generates the information necessary to improve the ability of basic social institutions to fulfill their special moral purpose.

Moreover, because the research enterprise is understood broadly, as a division of social labor among a wide range of parties, this imperative is also understood broadly. It includes investing social resources, founding institutions, and establishing the rules and norms that are necessary to promote scientific research across the full lifecycle of knowledge development and deployment. It also includes the use of social authority to align the incentives of a wide range of actors who produce health-related information with the common good. Intellectual property laws, patent protections, the evidentiary thresholds necessary to secure regulatory approval, and the scope of the indication for which interventions can be marketed and sold are a few examples of policy decisions that shape the incentives of funding agencies, private sector firms, researchers, regulators, and other actors. Because these activities involve the exercise of state authority and because these decisions impact which questions are likely to be investigated in research and whether gaps in the ability of basic social institutions to advance the basic interests of community members are widened or closed, they implicate questions of justice and must be justifiable to community members as advancing the common good.

How the research enterprise is organized is a question of justice because that enterprise calls into action the social authority, institutions, and resources of the state to create a division of social labor that must advance a particular social purpose. This moral purpose is generating information that is necessary to close gaps in the ability of the basic social institutions of a community to secure and advance the basic interests of its members. The point is not that health or health-related research is a key to solving or resolving all social ills—it is not.<sup>23</sup> Rather, the point is that the ability of individuals to be

<sup>23</sup> Discussing my human development approach to international research, Shamoo and Resnik characterize my view as holding that researchers have a duty to do more than ensure fair benefits: “They must rectify past injustice and promote social, economic, and political development in the host nation” (2009, 335). I discuss the inadequacies of the fair benefits view in chapter 8 and elaborate the human development approach in chapter 9. Shamoo and Resnik appear to confuse two ideas that are related to the current discussion. The first idea is that the entitlements of community members are shaped by a range of background considerations of justice. In particular, community members have a claim on one another to social institutions that advance their common good, and the organs of research are such institutions. Additionally, inadequacies in the capacity of a community’s

able to formulate, pursue, and revise a life plan is affected by the way a variety of social arrangements are designed, implemented, and regulated. The health-related institutions within a community are one element within this larger social division of labor, and their ability to fulfill their special social mission effectively, efficiently, and equitably is closely connected to the terms on which the research enterprise is organized.

Additionally, the moral and social imperative to support research with humans represents the fact that the evidence and information that it produces is an important public good on which a diverse array of stakeholders rely to discharge important moral and social responsibilities. To illustrate this point, it is worth considering the sense in which knowledge is the most important output of research with human participants, the sense in which this knowledge represents an important public good, and how myriad stakeholders rely on this good to discharge important responsibilities.

### 4.7.3 The Knowledge Research Produces Is a Public Good

Although it is common to speak about drugs, devices, policies, or practices as the units of translation—as the entities that move from the bench to the bedside and that are the fruits of research—this view is fundamentally inadequate (Kimmelman and London 2015). In particular, although the drug, device, or other intervention may be the most tangible product of research, these concrete products alone have no social utility. A drug, for example, is merely a substance that at one concentration may be effectively inert and at

basic structures to fulfill their social purpose is often a major source of avoidable morbidity and mortality in a community and such inadequacies can result from a variety of causes, including domestic injustice and unjust dealings with foreign entities. The second idea is that these background considerations have to factor into our evaluation of cross-national research initiatives. Shamoo and Resnik assume that this second idea entails that researchers alone are responsible for rectifying all of the injustices in a community. This erroneous interpretation of my view results from trying to shoehorn questions of justice, at a social level, into the narrow confines of the IRB triangle. The obligation to ensure that the basic structures of a community fulfill their social mission is shared by a wide range of parties. But researchers are not charged with rectifying all past wrongs in a community. Rather, they have a duty to ensure that research with humans addresses the priority health needs of host communities and expands the capacity of their health-related social systems to advance the common good. They share this duty with numerous parties, including local governments. Recognizing that research is part of a larger social system, recognizing that how research functions can affect the operation of key aspects of these social systems, and requiring researchers to take this into account when planning and engaging in research activities is not the same as holding that researchers have the kind of expansive duty that Shamoo and Resnik infer.



other concentrations can be lethal. A device alone is a piece of hardware. In order for these things to produce a net advantage—a benefit that is sufficient to offset any attending adverse effects—they must be used properly. For simplicity, we can limit our discussion to drug development, but the claims here generalize.

The true product of drug development is not a compound or an artifact; it is the knowledge of whether and how a particular chemical compound can be used to provide therapeutic or prophylactic advantage to patients. This knowledge is critical to the ability of actors who consume this information to make decisions that implicate the use of scarce social resources and that affect the basic interests of community members.

The knowledge about whether and how a substance can be used to produce beneficial effects includes the set or “ensemble” of factors that modulate its effects in use (Kimmelman 2012; Kimmelman and London 2015). This set of factors includes how to distinguish the population of patients that the drug can help from those it cannot. This is often referred to as the indication for a drug, and it includes understanding how an intervention’s effects might differ in patients with various clinical characteristics and which features of patients might put them at elevated risk of experiencing adverse events. This set of factors also includes the knowledge of the dosage at which a drug must be given to unlock its therapeutic potential and the window outside of which it is either ineffective or harmful. It includes the frequency or schedule for delivering a drug to ensure the proper concentration and the window outside of which the drug is likely to again be ineffective or harmful. It includes any special diagnostic steps that might be needed to monitor recipients and any co-interventions that are required to amplify benefits or to mitigate adverse effects. It also includes an understanding of how that drug interacts with other treatments, including which combinations of drugs to avoid because of their potential for producing adverse events.

This practical knowledge is not the only fruit of clinical translation. The results of research also provide information that supports or undermines the larger theories of disease pathophysiology and intervention mechanism that drove the development of that intervention and that are likely to drive further development activities (Kimmelman and London 2015). In particular, intervention development is often driven by background theories about the pathophysiology of disease, factors that increase or mitigate susceptibility or disease progression, and the ability of interventions of a certain kind to alter mechanisms that are important to the lifecycle of disease.

These theories often drive drug development by highlighting mechanisms to exploit and suggesting pathways through which those mechanisms might be influenced with the fewest adverse events. Repeated failures to develop interventions that leverage these insights for therapeutic benefit cast doubt on the credibility of those underlying theories. Likewise, practical success in exploiting such insights reinforces the utility of particular models and encourages their use in understanding the source and nature of disease and how it might be delayed, reversed, or cured in both future research and in clinical practice.

Although a drug or a device may consist of materials that are scarce or that constitute the intellectual property of a particular person or firm, the practical knowledge necessary to unlock its therapeutic or prophylactic potential and the evidence this provides about broader understandings of sickness, injury, or disease constitute a public good. It is a public good because a wide range of stakeholders rely on this knowledge to discharge socially important obligations or to carry out activities that relate directly to the common good and so are the subject of a just social order. It also has features of a public good in the economic sense (Schaefer et al. 2009, 68). This information is non-rival, meaning that these stakeholders can rely on and make use of it without thereby diminishing its content or value or reducing the share of information that is available to those other stakeholders. It is also difficult to exclude others from using that knowledge once it has been disseminated. On the one hand, a drug or a device cannot produce practical benefits without the knowledge of how to use it. On the other hand, the (un)successful development of a particular drug necessarily provides evidence about the utility of the broader theories of disease and drug mechanism that contributed to the intervention's development.

How the research system is organized thus has a profound effect on the ability of a wide range of stakeholders to discharge their moral responsibilities (London 2005, 2019; London, Kimmelman, and Carlisle 2012; Wenner 2016, 2018). These stakeholders include policy makers, health systems, individual health care providers, patients, and the other scientists who build on this information.

Policy makers depend on reliable medical information to determine which health practices to promote or discourage, which public and individual health goals to prioritize, which mix of strategies to adopt to advance those priorities, and where scarce health resources can best be invested in order to promote the efficacy, efficiency, and equity of health systems.

Health systems cannot make an efficient use of scarce resources without information about how best to prevent, diagnose, and treat the wide range of afflictions likely to be represented in the populations they serve. Because of the variability of disease, uncertainty about its etiology, and the likely effects of different strategies for preventing or otherwise intervening on those conditions, carefully controlled trials in humans are often the only way to generate this information.

Individual providers within health systems are similarly dependent on research findings to discharge their fiduciary duties to patients. Their ability to advance the medical interests of patients, consistent with the way those patients understand those interests within their larger conception of the good and their broader life plan, hinges on the quality of the information they possess about the relative merits of interventions and practices available to them.

Likewise, patients cannot effectively engage with health systems and providers to protect and advance their own interests without reliable medical information. This includes the information they need in order to understand their health status, to understand medical conditions they experience, and to comprehend the relative merits and demerits of the options available for prevention, diagnosis, or treatment.

Finally, the process of drug development is itself a collaborative activity that is extended across time in which medical evidence is produced and consumed by a wide range of actors. For example, the information produced in pre-clinical research can have implications for the use of a drug in clinical practice, but it is most directly relevant to other researchers who are also conducting pre-clinical research or who will conduct early phase studies in humans. Similarly, early-phase studies in humans explore the various parameters of a drug's use that must be understood in order to unlock its therapeutic potential. These studies too can be relevant to clinical practice, but their primary and most direct purpose is to identify elements within the ensemble of knowledge and practices that are necessary to use a drug to produce clinical benefit. Once these various elements have been identified, ensembles of materials, knowledge, and practices can be subjected to confirmatory testing in large late-phase trials. These trials are crucial to establishing the relative therapeutic or prophylactic merits of an intervention, and the information that they produce is the most directly relevant to the widest range of stakeholders. Nevertheless, these studies build on a prior network of research and contribute to the evidence base that supports subsequent investigation.

The ability of these various stakeholders to safely, effectively, and efficiently address the health needs of community members in practice, or to carry out the research that is necessary to effectuate this goal, depends critically on the quality of the evidence that is generated in research and its relevance to the ability of that community's basic social structures to secure and advance the basic interests of that community's members. Poor quality research that generates misleading or biased information detracts from the ability of stakeholders in basic social institutions to effectively and efficiently secure and advance the basic interests of community members. Similarly, disparities in which health needs are the subject of research and investigation can create or exacerbate disparities in the ability of these different stakeholders to meet the needs of community members, or to meet those needs with equal efficacy, safety, or efficiency (Dresser 1992; Weijer and Crouch 1999; London and Kimmelman 2016; Basu and Gujral 2020).

The egalitarian research imperative reflects the status of the information that research produces as a public good and the moral importance of ensuring that this information is of sufficient quality, reliability, and relevance that it can advance the moral mission of research. How the research enterprise is organized—from the questions that are chosen for investigation to the methods that are used to generate answers—is bound up with requirements of justice because these issues determine whether this activity can be justified as advancing the common good of community members. In other words, considerations of justice are raised by decisions that determine whether research contributes to improving or reducing the efficacy and the efficiency of practice and whether it serves to reduce and eliminate, or to create and exacerbate, disparities in the ability of health systems to meet needs of community members that relate directly and indirectly to their ability to formulate, pursue, and revise a reasonable life plan. I return to some concrete examples that illustrate these points in §4.9.

Although I have focused on health in this exposition, health systems are not the only social system that affects the basic interests of individuals. As a result, it is important that a framework for research ethics be of sufficient generality that it can apply to a wide range of research involving human participants (London 2005, 2006a, 2009; Kukla 2007; MacKay 2018). For example, both Kukla (2007) and MacKay (2018) discuss research that falls under the umbrella of social systems outside of the health sector, narrowly conceived. These include the effect of early education on opportunity, access to supplemental nutrition within social safety net programs, and the relative

efficacy of different policies to prevent homelessness. As I have framed it here, the same arguments that support the egalitarian research imperative in the sphere of health would apply to any other context in which a social system has a direct impact on the basic interests of community members.

#### 4.7.4 Egalitarian in Two Respects

The research imperative articulated here is egalitarian in two respects, each of which is grounded in the idea that free individuals “exist for their own sake and not for the sake of someone else” (Aristotle 982b25–27). It is egalitarian in the first respect in that the interests that it targets are shared by all community members. All community members depend on a variety of social systems, including health systems, to safeguard and advance their basic interest in being able to formulate, pursue, and revise a reasonable life plan. In order to be responsive to the moral and political status of individuals as free and equal persons, social systems must strive to eliminate gaps in the efficacy and efficiency with which they are capable of responding to the basic interests of the individuals in the community they serve. The normative force of the egalitarian research imperative derives from the importance of the needs that basic social systems address and the unique ability of the research enterprise to produce the information that enables those social systems to equitably, safely, and efficiently fulfill their social purpose.

This research imperative is also egalitarian in a second respect. This same concern for the basic interests of individuals that triggers the NC also provides the content to the PC on the forms of social interaction that are permissible means of advancing this goal. Coercion, domination, exploitation, neglect, abuse, and other forms of harmful or unfair treatment violate the practical constraint on acceptable ways of attempting to advance the common good because they undermine the status of the affected individuals as free and equal. They compromise the moral freedom of individuals to the extent that they secure access to their person or their participation in an activity without regard to the place of that activity in the plans or projects of that individual. They undermine their status as moral equals because they treat the interest of some as sufficient to license showing lesser regard to the basic interests of the affected parties.

It is a particular strength of this view that this practical constraint is not an exogenous value imposed on research from the outside. Rather, it is

internal to the conception of research as a social undertaking that requires the sustained and voluntary collaboration and cooperation of many different stakeholders over time. The generic interests of the diverse parties who participate in and make this undertaking possible merit equal respect. There are thus no grounds to justify a division of social labor in which some stakeholders are empowered to show less moral concern for the basic interests of others or to relegate them to a position of subordination or domination. The egalitarian research imperative thus does not justify empowering researchers to conscript unwitting participants into medical research as “soldiers of science” or to “play god” by selecting small samples of individuals whose interests can permissibly be sacrificed to the greater good (McDermott 1967, 39).<sup>24</sup> In chapter 6, I outline a framework for evaluating research risks that reconciles promoting the common good with the requirement to show equal regard for the basic interests of study participants in the process.

In the previous chapter I argued that Wertheimer’s principle of permissible exploitation (PPE) revealed fault lines running through the foundations of research ethics. One of these consists in the asymmetric treatment of the interests of various parties. In orthodox research ethics, even when individuals suffer from health problems that threaten their capacity to form, pursue, or revise a reasonable life plan, this is not sufficient to generate a duty on anyone’s part to carry out research of any kind. Research, even if it would address such basic needs, is treated as a largely optional, private undertaking. Nevertheless, if those same individuals are involved in research, then their basic interests ground robust deontological protections that place what Wertheimer sees as significant limits on the liberties of both researchers and participants. This creates an inefficiency that PPE attempts to resolve by weakening constraints on exploitative, unfair, or disrespectful treatment. As we saw, PPE could be seen as sanctioning some wrongdoing in the form of exploitative, unfair, or unjust research relationships as a way to remedy the overly permissive attitude in orthodox research ethics to the neglect of important health needs without creating an overly demanding set of moral requirements in the process.

<sup>24</sup> In this regard, the view I defend here captures the insight of Jonas that “human experimentation for whatever purpose is always also a responsible, nonexperimental, definitive dealing with the subject himself and not even the noblest purpose abrogates the obligations this involves (1969, 220) and Kukla’s claim that “the research enterprise gives investigators no license to compromise citizens’ moral entitlements to justice, respect, and welfare protection” (2007, 184).

The egalitarian research imperative rejects the fundamentally asymmetric view of the basic interests of persons shared by both orthodox research ethics and PPE. Rather than empowering a few to dominate their compatriots in order to promote social progress, the egalitarian research imperative enjoins communities to provide various social supports for, and to encourage the development of, a division of social labor in which free and equal individuals can serve the common good by voluntarily cooperating within a social system that is arranged to ensure that their cumulative efforts produce an important public good. The same fundamental concern for the basic interests of persons that grounds the imperative to generate the knowledge needed to bridge gaps between the basic interests of persons and the ability of the basic social institutions in their community to meet those needs grounds a social imperative to ensure that these social systems are designed to attract the voluntary participation of study participants, just as it attracts the voluntary participation of researchers and other stakeholders.

The idea that a just community can discharge its responsibilities to citizens without abrogating the rights of its constituent members is neither radical nor new. In the *Politics*, Aristotle argues that “constitutions that aim at the common advantage are in effect rightly framed in accordance with absolute justice,” because a polity is a “partnership of free persons” (1279a17–22). Democracies require representatives and leaders, but candidates for these positions are chosen from volunteers who see public service as part of a rewarding personal life plan. Just states need physicians and teachers, researchers and engineers, lawyers and judges, and a dizzying array of professionals who discharge important responsibilities of basic social institutions. A just state cannot operate without these professionals, but they are selected from the ranks of volunteers who see in such careers opportunities to develop their talents and abilities, earn a living, join a profession, and contribute to the common good.

Promoting a system of research involving human participants requires the thoughtful implementation of concrete social incentives that encourage a diverse set of parties to take up, as part of their individual life plan, advancing an important element or component of this larger division of social labor. It also involves providing a system of concrete social assurances that this division of social labor will not be co-opted for parochial or partisan purposes and that in voluntarily participating in this scheme of social cooperation, no stakeholder will be subject to deception, injustice, or abuse (see chapter 7).

## 4.8 A Scheme of Cooperation among Free and Equal Persons

### 4.8.1 To Whom Does the Imperative Apply?

At the most general level, the egalitarian research imperative applies to all of the individuals who comprise a community. The reason for this is that it is individual community members who owe duties of justice to one another. However, as we saw in §4.6, a just social order represents a division of social labor through which free and equal people divide responsibility for securing the basic interests of community members. Individual community members thus bear a responsibility to create and to support a division of social labor that advances the common good. One of the ways that individuals discharge the egalitarian research imperative is by delegating to government the critical responsibility to create and maintain the infrastructure, rules, and resources that comprise a functioning research system.

Even if we view individuals as delegating this responsibility to government, they retain at least three important residual obligations. The first residual obligation is to hold political leaders accountable for fulfilling their moral and political obligation to discharge this duty. The second is to refrain from acting in ways that conflict with, subvert, or undermine the ability of the various parties to this division of labor to discharge the responsibilities they take on within this scheme of social cooperation. The third is to be prepared to support the activities of these stakeholders, especially when this can be done in a way that does not require a significant compromise in one's basic or personal interests.

On this view, the primary responsibility for discharging the substantive requirements of the egalitarian research imperative in practice falls to governments. Governments are responsible for allocating resources and creating the institutions and systems of rules that are necessary to effectuate three goals. The first is to ensure that the research enterprise functions to generate the knowledge needed to bridge gaps between the basic interests of community members and the ability of the basic social institutions in their community to meet those needs. The second is to ensure that the system of norms, rules, and incentives that govern the research enterprise align the personal and parochial interests of stakeholders with the promotion of this end. This includes providing credible public assurance to all stakeholders that no party has the ability to co-opt this division of social



labor to exclusively advance their own parochial interests. The third is to provide credible public assurance to all stakeholders that as each seeks to pursue their personal interests in this arena—to seek profit, career advancement, or access to novel medical interventions—no party will be subject to domination, exploitation, abuse, or other forms of unfair or harmful treatment.

Exactly how this social division of labor should be organized is a question of mechanism design. Moreover, it seems reasonable that different communities could adopt different approaches that rely, to greater or lesser degrees, on public and private entities. At one extreme would be an effort to fund, regulate, and carry out research entirely with public funds and within public institutions. At the other extreme would be an effort to create a public system of rules and regulations within which the various activities in the research enterprise are carried out entirely by private enterprise. In the United States and most other economically developed nations there is a mix of public funding and public infrastructure, such as governmental agencies and institutions, that interact with a range of private entities in a regulated market. The point I want to emphasize for present purposes is that, however this system is organized, governments retain a duty to monitor and adjust the system of rules and norms that create the strategic environment in which the various stakeholders to the research enterprise interact, with the goal of ensuring that this system advances the goals described in the previous paragraph.

Although national authorities should be regarded as having the default responsibility for fulfilling the egalitarian research imperative, the just and legitimate division of social labor within states entails that responsibility for carrying out particular strategies necessary to satisfy the egalitarian research imperative sometimes fall to regional, provincial or local health authorities. Similarly, it is possible that the community that is bound by the research imperative may be larger than the individual state. This is most clearly the case when states form larger bodies bound by common laws and policies that regulate the provision of individual or public health or the process of research and development. The European Union may represent such a body to the extent that its member states share common structures for drug development regulation and approval.

Larger collectives of this type can be bound by the egalitarian research imperative, but to the extent that national governments delegate responsibilities to such entities, they would nevertheless retain duties that are analogous to the duties that individuals retain when they delegate responsibility

for fulfilling the egalitarian research imperative to states. Additionally, such extra-national agreements often utilize the local institutions of the states that are party to the collaboration and rely on the legal authority and enforcement mechanisms of those states to ensure compliance with agreed upon norms (Freeman 2006). Because extra-national agreements often supervene on the structures, rules, and authority of cooperating nations, national governments should still be seen as the default bearer of the responsibility for discharging the substantive requirements of the egalitarian research imperative. How this default is affected by factors such as prior histories of unjust interaction is dealt with in chapter 9.

In this respect, MacKay is correct to say that governments bear key duties in this area, since they have “duties of justice to provide their residents with access to particular types of goods, and/or to realize particular outcomes” (2017, 3). But it would be a mistake to assume that governments are the only parties who bear duties of justice that relate to the organization and functioning of the research enterprise. In particular, citizens retain the three obligations I described previously and private entities that conduct research have a responsibility to ensure that their activities contribute to the common good on terms that respect the status of other participants in this social undertaking as free and equal.

#### 4.8.2 Prior Moral Claims

I argued in chapter 2 that orthodox research ethics tends to treat research as a private activity in the sense that it is not clearly constrained by its relationship to larger social purposes. I also argued that this view is bolstered by the tendency to conceptualize research as a set of goals and purposes that can be taken up by individuals and that stand in contrast to the goals and purposes of medical practice. As a result, orthodox research ethics tends to locate the moral epicenter of research in the IRB triangle, the discrete relationships between researchers and study participants.

The arguments I have presented here offer a very different account of research and its relationship to the larger purposes of a just social order. In particular, it is worth emphasizing that, on the view I am presenting here, the egalitarian research imperative enunciates a duty to create a certain kind of institutional order. This is an institutional order in which a broad range of stakeholders can collaborate in ways that produce an important public good.

This public good is the knowledge and the means necessary to effectively, efficiently, and equitably bridge gaps in the ability of that community's basic social structures to secure and advance the basic interests of that community's members.

Understanding research as a scheme of social cooperation invites us to consider the social arrangements that are necessary to identify priority knowledge gaps of this kind, understand the source and nature of the problems to which they relate, formulate strategies and interventions for addressing them, evaluate the relative merits of those strategies and interventions and then to make this knowledge and these interventions available on a widespread basis so that they can be incorporated into basic social institutions that are charged with securing and advancing the basic interests of community members. These social arrangements include the training of investigators, mechanisms for funding research, the terms on which interventions can be marketed and sold, the standards of evidence required to establish safety and efficacy, and so on.

This perspective also invites us to consider the wide range of actors who play a role in this division of social labor. Beyond the players within the IRB triangle, the stakeholders whose activities affect the ability of research to advance the common good include policy makers who shape intellectual property laws or in other ways influence funding allocations and priorities. It includes biotech companies, pharmaceutical firms, philanthropic organizations, and public institutions that sponsor research or carry it out. It includes regulators in the various institutions that set or enforce the rules for research oversight, and the bodies that perform research oversight functions including regulatory bodies that determine the standards for intervention approval and market access. It includes administrators in health systems and clinics where research is carried out and medical societies and professional organizations that set standards for medical practice and for professional conduct. It includes journal editors and bodies who create publishing guidelines that determine the standards of quality and for disclosure that research must satisfy in order to warrant publication. It includes patient advocacy groups whose lobbying, advertising, or funding activities influence politicians, study participants, clinicians, or other stakeholders.

The imperative to ensure that this division of social labor produces an important, public good entails that prior moral claims constrain how the infrastructure of the research enterprise can be used. The institutions, rules, and human and material resources that facilitate this scheme of social

cooperation are not free for entrepreneurial agents—investigators, sponsors, regulators, consultants, or participants—to utilize solely to advance their private purposes, without regard for the way those purposes align with the common good.

Open societies are free to harness the power of the private sector and the profit motive to secure financing and to drive innovation, but it remains a duty of government to ensure that the rules, incentives, and constraints in this system align the parochial interests of these parties with the common good. Private firms may own the resources that they invest in the research enterprise, and public firms may invest resources that are derived from the investments of shareholders to whom they owe a fiduciary duty. But this is consistent with the claim that such resources cannot be deployed in the research enterprise solely to advance the parochial interests of these parties. Rather, engaging in the research enterprise entails a duty to ensure that human and material resources, and the infrastructure on which they rely, are used in the service of ends that contribute to identifying, investigating, and closing gaps in the ability of a community's basic social structures to secure and advance the basic interests of its respective members.

Private individuals and entities, academic researchers, academic medical centers, medical associations, disease advocacy groups, and pharmaceutical firms can play an important role in this division of social labor, but they do not have unlimited discretion over the way this system is used. This is because the prior claims of community members to social systems that safeguard and advance their basic interests constrain the goals that this system can be used to advance and the means that can be used to advance those goals.

Similarly, individual researchers, investors, and biotech or pharmaceutical firms may be drawn to research as an area in which they can use their intellectual, material, and human capital to secure profit, notoriety, and any number of private goods. All of these private goods and the motives that attach to them represent levers that can be used to incentivize participation in this division of social labor. But it is the responsibility of all of the stakeholders in this enterprise, including policy makers and regulators, to ensure that the strategic environment in which these parties interact aligns these parochial motives with the common good and constrains the extent to which those motives might undermine or subvert this end.

Finally, just as prior moral purposes constrain the ends to which the infrastructure of research can be used, the products of research are not a purely private good. Private firms may have intellectual property in the compounds

and devices that represent the most visible fruits of research efforts. But, as I argued in §4.7.3, the knowledge that research produces is a public good on which myriad stakeholders rely to discharge important social and moral responsibilities. The conditions under which firms can market and sell products and the quality of the information needed before a product can be approved for use are centrally relevant to research ethics.

Because orthodox research ethics is so centrally focused on protecting the rights and welfare of study participants, it can be difficult to motivate concerns about the quality and relevance of the information that research is likely to produce if the studies in question do not place study participants at elevated risk. On the view I am articulating here, questions about the quality and relevance of the information generated in research, and about the efficiency with which that information is generated are centrally relevant to research ethics because they raise questions of justice. It is worth concluding with some brief examples that illustrate this point.

#### 4.9 Examples of Neglected Issues

Three brief examples illustrate the way in which the activities of what are traditionally seen as private actors in this context raise questions of justice. These examples are drawn from work I have done with Jonathan Kimmelman and are presented in schematic form for brevity. Nevertheless, they provide an important contrast to the parochialism of orthodox research ethics.

Prior to regulatory approval of a new drug, private firms have a strong incentive to quickly conduct well-designed clinical trials. The reason is that they cannot market and sell their product—and thus reap a return on their investment—without generating evidence that establishes its safety and efficacy for a particular indication. The standards for approval set by regulatory agencies like the US Food and Drug Administration (FDA) thus play a critical role in determining the extent and the quality of the evidence that is available to clinicians, patients, policy makers, and health systems about the efficacy of a drug and its anticipated side effects in patients with a wide range of clinical characteristics. As a result, FDA standards for drug approval determine whether a new drug is tested in a narrow and homogenous population or whether it must be tested in more diverse populations that better reflects the characteristics and demographics of the population in which that drug is likely to be used.

Recently, the United States has seen a concerted push on the part of various stakeholders, including patient advocacy groups and pharmaceutical firms, to lower the evidentiary requirements necessary to secure drug approval in order to speed drugs to market. The moral arguments offered in support of such policies focus on the needs of patients who currently lack access to effective interventions and their interest in being able to accept greater risk in return for earlier access to novel interventions.

Reducing drug development timelines in this way, however, raises questions of justice that are difficult to frame within orthodox research ethics because they fall outside the confines of the IRB triangle (London and Kimmelman 2016). In particular, one of the easiest ways to compress development timelines is to test drugs in increasingly homogenous populations. In the United States this often means populations that are Whiter, younger, and healthier than the populations who are likely to use the intervention in practice. Another way is to rely on surrogate endpoints that allow studies to be completed in a shorter time. For example, a cancer trial might use tumor shrinkage over a period of months as a primary endpoint rather than waiting years to collect data about overall mortality.

Within the narrow confines of orthodox research ethics, any objection to proposals to shorten drug development timelines would likely have to be framed in terms of the rights and interests of study participants. But if the individual protocols for such studies are scientifically sound and pose only reasonable risks to participants, then orthodox research ethics would likely have no grounds for concern with such proposals.

Yet, such proposals raise questions of equity and justice to the extent that they allow interventions onto the market when they are supported only by direct evidence about their effects in populations of patients drawn from groups that are already advantaged within the medical system. Younger, Whiter, healthier patients face fewer risks in accessing these interventions in clinical practice than patients who differ from them. This includes much older and much younger patients, patients with additional common medical problems, patients using other medications, and patients from minority populations who are already historically underserved in health systems.

These groups face higher risks when accessing such interventions because their effects have not been established in groups with co-morbidities, who concomitantly use other medications, or whose bodies process medications differently because they are older or younger than trial participants. Uncertainties about dosing, schedule, and effects in such patients elevate

risks to patients, both in terms of their expected efficacy and whether they provoke adverse events that reduce their net therapeutic advantage in these different groups. Speeding drugs to market can thus exacerbate inequities in health systems.

Additionally, these efforts offload the burden of generating the evidence necessary to rectify such inequalities from the stakeholders who profit from their sale to the patients, providers, and health systems that pay for them. This is inefficient in that it takes longer, and thus it takes more instances of harm to patients, to detect differential effects of such drugs in other populations when those effects have to be detected in clinical settings. Clinical settings are noisy in the sense that there are many sources of variation that can impact patient health other than the beneficial or adverse effects of the drug in question. Similarly, offloading the cost of generating this information onto consumers and health systems raises questions of fairness since their budgets already strain to meet the full range of health needs in the community.

The standards of evidence that the FDA requires for drug approval thus raise important issues of justice because they impact the extent to which health systems function effectively, efficiently, and equitably. Proposals to reduce drug development timelines may advance the interests of a narrow set of patients, but they also reduce the bandwidth of information that is available to other stakeholders including health systems and clinicians who care for patients who are already not well served by existing health systems. These proposals raise issues of justice that are largely invisible within orthodox research ethics, in part because they involve stakeholders outside of the IRB triangle. But this is also because they implicate issues relating to the quality of the information produced in research that are difficult to make salient within a cognitive ecosystem that is heavily focused on protecting study participants.

The standards regulatory agencies use for intervention approval are a mechanism for influencing the incentives of powerful actors whose decisions determine the bandwidth of information available to stakeholders, how uncertainty is distributed across the different segments of the population, and how the costs and burdens of addressing residual uncertainty are shared across different social institutions. These issues bear on the ability of social institutions to function effectively, efficiently, and equitably, and they would be difficult to address at the level of IRB review. Broadening the scope of research ethics brings these decisions into the purview of the field. It creates conceptual space in which issues of justice can be articulated and it situates

those discussions within an institutional context in which mechanisms are available for shaping the incentives of key actors.

As a second example, once drugs are approved for sale, the incentive for firms to fund additional studies attenuates dramatically. In fact, firms may be reluctant to fund additional studies because adverse events or information about an intervention's clinical merits relative to a competitor's alternative put their profits at risk. When post-marketing studies are conducted, however, they are often carried out in ways that are designed more to advertise a drug and to tout its merits than to generate new medical evidence.

If post-marketing studies generate flawed or biased information without imposing risks on study participants, then orthodox research ethics has a difficult time capturing the ethical issues at stake in those studies (London, Kimmelman, and Carlisle 2012). But this parochialism ignores the extent to which a range of stakeholders rely on the evidence that is generated from research. Companies may use private funds to conduct such studies, but the information they generate is a public good, and co-opting this public good allows firms to increase their profits without advancing the medical interests of patients, the evidentiary interests of other scientists, or the informational needs of policy makers and health systems. These practices thus raise important questions of justice that are also largely invisible within orthodox research ethics.

Finally, even when practices do impact the health and welfare of study participants, the parochialism of orthodox research ethics makes it difficult to frame and address the relevant issues. This happens when scientific and ethical issues arise from practices that happen at the "portfolio-level" (Kimmelman et al. 2017). Within orthodox research ethics the unit of evaluation is the individual study protocol. But groups of similar studies constitute a portfolio of trials, and how such sets of studies are organized and which methods they employ determine the bandwidth of information that is produced, whether that information is most relevant to the needs of subsequent researchers or to practitioners, how uncertainty is distributed over different treatment populations, how burdens are distributed across study participants, and how much profit sponsors are able to generate relative to the value of the information their studies produce (London and Kimmelman 2019).

To use a single example, consider a case in which four interventions ( $w$ ,  $x$ ,  $y$ ,  $z$ ) appear promising as treatments for a particular disease. For simplicity, let's assume that all are owned by a single firm. Orthodox research



ethics effectively regards the decision about how to test these different interventions as a private consideration for this private actor. But the alternative approaches a firm might take can influence the bandwidth of information that is available to stakeholders, its relevance to those stakeholders' informational needs, as well as how many study participants are likely to be harmed in order to generate the same quantity of information.

In particular, a firm might decide to evaluate these interventions by testing each in a separate trial in which participants are randomized to the investigational intervention or to usual care. The result is four different trials, each of which must recruit a particular number of participants in order to detect a particular effect at a predetermined level of statistical significance. Orthodox research ethics would look at each of these protocols and require that they meet particular ethical standards: subjects must provide free and informed consent and risks must be minimized and must be reasonable in light of the evidence studies are likely to produce. If each individual protocol passes muster on these grounds, they will each be approved.

Orthodox research ethics operates on the background assumption that if each protocol is approved, then the set of protocols must be ethically permissible. But this assumption is false. To see this, consider the bandwidth of information produced from these distinct studies compared to a possible alternative approach. In particular, it is possible for firms to design each of these studies so that a finding that *x* is superior to usual care and *y* is superior to usual care may not reveal much about the relative merits of *x* and *y*. One factor, for example, concerns the extent to which usual care in these two protocols is standardized so that it is effectively the same. If what constitutes usual care differs between the trials, then a firm might be able to sell more than one intervention as an effective treatment for the condition in question without ever generating evidence that supports a reliable comparison of the relative merits of *x* and *y*.

In contrast, if the firm were to run a trial in which *w*, *x*, *y* and *z* are all compared against one another and against a usual-care control arm, then it could generate a wider bandwidth of information while subjecting fewer participants to the risk of harm. The bandwidth of information is wider because such a design allows for a determination not just about whether both *x* and *y* are better than usual care, but about the relative merits of *x* and *y*. This information is more relevant to stakeholder needs because it eliminates the inefficiency associated with deploying two interventions in clinical practice in those cases where one provides a superior net therapeutic advantage to

patients over the other. Additionally, fewer patients might be harmed in such a trial because the overall population needed to generate this evidence can be smaller than the total population in the four pairwise trials described above.

The approach in which all of these interventions are tested within a unified study design shows more respect for the health and welfare of participants, makes a more efficient use of their time and commitment, and better addresses the informational needs of a wide range of stakeholders. But using this approach can conflict with the firm's pecuniary interests. If fielding two interventions allows a firm to maximize profits by better segmenting the market, then this more unified approach jeopardizes profit. In cases where  $x$  is owned by one firm and  $y$  is owned by another, this more unified approach is in direct conflict with the financial interests of each firm. Each might prefer to split the market rather than take the gamble of losing out altogether.

Orthodox research ethics doesn't address such portfolio-level questions—they fall outside of the IRB triangle and they implicate questions of justice that revolve essentially around questions that are difficult to frame within the paternalistic focus of orthodox research ethics. Nevertheless, these decisions affect how effectively health systems meet patient needs and how efficiently they use scarce resources. As a result, they raise issues of justice and the framework articulated here captures the key respects in which those issues are morally salient.

#### 4.10 Conclusion

Orthodox research ethics has avoided connecting research to larger social purposes, in part, from fear that those social purposes might license the abrogation of individual rights and the denigration of individual welfare. In this chapter I have argued that there is a conception of the common good that grounds a social imperative to carry out research that is designed to close knowledge gaps between the basic interests of community members and the ability of that community's basic social structures to safeguard and advance those interests. However, because this imperative is grounded in a concern for the basic interests of individuals, it requires that research be organized as a scheme of social cooperation that respects the status of its various stakeholders as free and equal persons.

I also showed that although this conception of the common good is capable of grounding such a social imperative, it is not uniquely dependent on

a single, substantive conception of the good or on a particular philosophical approach to social or political philosophy. Rather, this conception of the common good can be formulated within frameworks that span important philosophical divides, including communitarian or liberal starting points and contractarian or consequentialist frameworks.

Finally, the egalitarian research imperative has important implications for the range of issues that fall into the scope of research ethics and the range of stakeholders whose conduct is a legitimate target for assessment. As we will see again in subsequent chapters, this framework provides a more unified and consistent foundation for some established requirements in research ethics while drawing coherent connections to a broader range of issues that are more difficult to formulate and address within the narrow confines of orthodox research ethics.