

# 3

## The Anvil of Neglect and the Hammer of Exploitation

### Fault Lines in Research Ethics

Given the nonideal background conditions under which people find themselves, there should be a very strong presumption in favor of principles that would allow people to improve their situations if they give appropriately robust consent, if doing so has no negative effects on others, and this even if the transaction is unfair, unjust, or exploitative. (Wertheimer 2008, 84)

#### 3.1 Three Moral Pitfalls

If research ethics is to provide sound normative guidance to decision makers constrained to act in our non-ideal world, it must help them navigate three moral pitfalls: sanctioning neglect of the most vulnerable (sanctioning neglect), saddling those who seek to be ethical with an overly demanding set of moral requirements (demandingness), and justifying widespread wrongdoing as the lesser of the available evils (sanctioning wrongdoing).

In chapter 2 we saw how early defenders of the research imperative viewed research with humans as a way to advance the common good by creating the knowledge and means necessary to avert human suffering and premature mortality. We also saw how these same proponents understood this social imperative as inconsistent with equal regard and the sanctity of the individual within the domain of research with human participants. If embracing the research imperative avoided the pitfall of sanctioning neglect, it purchased this at the price of sanctioning wrongdoing. Given the moral dilemma perceived as lying at the heart of medical research, this

social imperative placed hefty demands on a few study participants against whom researchers would be permitted to make arbitrary judgments to meet the needs of the many.

In reaction, orthodox research ethics has practically defined its moral mission as constraining the extent to which social demands for medical progress can be used to justify perpetrating wrongs or harms on research participants. Influenced by Jonas's bold argument that the normal burden of suffering and disease is not a threat to the community, orthodox research ethics has tended to deny that there is a social imperative to advance the common good through research. If research is a morally optional undertaking, then the motivations that lead researchers or sponsors to conduct research are beyond the scope of the field.

From a certain practical standpoint, this approach makes a fair amount of sense. If researchers and sponsors have powerful pecuniary motives to undertake research, then one might think that research ethics does not need to articulate a moral imperative to conduct such inquiry. If the scientific enterprise contains within it the inherent potential for overreach and abuse, however, then research ethics can leave grand questions about the goals of science to others and focus instead on upholding strong constraints on the way that individual researchers can interact with study participants inside the IRB triangle.

The current equilibrium in research ethics emphasizes protecting study participants from wrongdoing, but these protections should not be purchased at the cost of sanctioning neglect. If research is an optional social undertaking and there is no moral impetus for powerful parties outside of the IRB triangle to carry out certain kinds of research, then erecting protectionist fortifications around the rights and interests of study participants ensures that the poor and the marginalized are not subject to exploitation, commodification, or other forms of injustice or abuse. But it does nothing to protect those same groups from the ravages of indifference.

Faced with this problematic tradeoff, a group of critics have recently challenged the protectionist stance of orthodox research ethics. They are concerned that the strong moral constraints at the heart of orthodox research ethics disadvantage study participants who would be willing to accept forms of study participation that are excluded by current protectionist norms. As a remedy, these critics question whether a research ethics that is suited to the non-ideal world in which we live should instead try to avert the harms of widespread neglect by weakening some of the demands of morality and

permitting the violation of norms against exploitation, unfairness, and injustice.<sup>1</sup> Perhaps the most rigorous and compelling of these is Alan Wertheimer's defense of what he refers to as the principle of permissible exploitation (PPE), which is glossed in the quote with which this chapter begins.

PPE is so heterodox that many in research ethics may have difficulty taking it seriously. As a policy proposal, this skepticism is warranted. As I argue in a moment, PPE permits more wrongdoing than its proponents recognize; rather than making morality less demanding, it shifts those demands onto the shoulders of the worst off; it represents a highly asymmetric concern for the status of different moral agents; and, from a policy standpoint, these problems are likely to lead to consequences that even proponents of PPE want to avoid.

However, reflecting on PPE as a piece of philosophical reasoning is a valuable diagnostic exercise. Part of what makes this proposal so fascinating is the way that it draws on and repurposes premises that are woven into the foundations of contemporary research ethics. This makes it surprisingly easy to defend this view by drawing on familiar claims in the conceptual ecosystem of orthodox research ethics. As a result, I hope to show that many of the problems with PPE are not merely problems with this heterodox view; they reflect a larger instability in fault lines that run through the foundations of research ethics.

## 3.2 The Targets of PPE

### 3.2.1 Norms of Respect

Although PPE focuses on exploitation, Wertheimer is clear that the argument for this claim generalizes to other forms of unfair or unjust treatment. In fact, the logic of this position is sufficient that it would apply to any instance of what I will call "norms of respect." This is a class of norms that deal with a person or people's interest in being treated as having a certain moral status, such as being recognized as the moral equal of others or as an agent whose worth is not solely a function of the goals and projects of others. Norms in this class include prohibitions on exploitation, domination, manipulation, commodification, unfairness, and injustice.

<sup>1</sup> The clearest example is Wertheimer (2008). See also Cooley (2001).

Norms of respect can implicate welfare in various ways. For example, being coerced into performing a demeaning act can both reduce a person's welfare and represent a violation of their status as a person whose rights and interests should be respected. But particular circumstances, social arrangements, or offers might pit these aspects against one another. For example, if performing a demeaning act represents a way for the agent to secure a net increase in welfare, then welfare-oriented considerations might conflict with the fact that the demeaning act continues to be problematic insofar as it represents a diminution or transgression of a norm of respect.

Similarly, distributive justice and fairness may require that in addition to being mutually beneficial, agreements or social arrangements must reflect the moral status of individuals. If, in a given case, fair wages require equal pay for equal work then a fair arrangement of wages must not simply provide workers with a net benefit, but that benefit would have to reflect the background status of equality among workers who perform the same tasks. Imagine now a toy case in which a firm could hire a new worker but only if it paid that worker half the salary of those already doing the same job. The proposal might be advantageous to both the firm and to the worker in terms of its impact on welfare, but it would be objectionable on the grounds that it violates the stipulated requirement of fairness.

Even if forms of disrespectful treatment do not result in a net reduction in a person's welfare, they might be wrong because they involve treating a person as lesser, as inferior, as subservient, or as an object whose value derives from its usefulness to others. PPE does not deny that such treatment is wrong. Instead, it holds that whether norms of respect should be upheld, or their violations should be permitted, depends on the effect that such permission or prohibition will have on the welfare of the individual in question.

### 3.2.2 Responsiveness, Reasonable Availability, and the Standard of Care

As pharmaceutical research has grown into one of the most profitable industries on earth it has also become an increasingly international endeavor (Glickman et al. 2009). Entities from high-income countries (HICs) now routinely sponsor clinical trials of new medical interventions in low- and middle-income countries (LMICs; Rehnquist 2001; Thiers et al. 2008).

LMIC populations are often attractive to researchers because they include large numbers of people with specific medical conditions, many of whom are “treatment naïve,” meaning that they have not had access to effective medical care in the past (Petryna 2009).

The disparity between sponsors and host communities in wealth, medical and public health infrastructure, access to medicine, and other social determinants of health has generated concern that individuals and populations in LMICs not only will be harmed and abused, but also subject to forms of treatment that violate norms of respect. At the end of the last chapter, we saw how several guidance documents enumerate moral standards that are grounded in justice or fairness, with the goal of averting these problems. Three requirements common to such documents are in the crosshairs of PPE.

One is the requirement that all members of a trial, including members of the control group, should receive a “standard of care” that is consistent with the current best practices for the treatment or prevention of the condition in question. People in resource-poor communities often lack access to a wide range of established, effective treatments for health problems. This requirement is meant to prohibit studies that randomize some participants to a placebo, or to some other form of care that is less effective than an available alternative that could be made available to participants in the host community.<sup>2</sup>

Insofar as this requirement holds that the standard of care must go beyond what is necessary to ensure that study participants are not made worse off and also receive some positive benefit from study participation, it is in the sights of PPE. Even if the placebo control used in the Surfaxin study was unethical because it violated the standard of care, PPE asserts that such a study should not be prohibited if doing so would leave vulnerable participants worse off.

The “responsiveness” requirement holds that studies in low-resource communities should be responsive to the health needs and priorities of those communities and the requirement of “reasonable availability” states that, prior to the initiation of a study, there must be an agreement in place that would make any intervention vindicated in the trial available to members of the host community. To the extent that these requirements are grounded in justice they may reflect important ideals

<sup>2</sup> This requirement is discussed at length in chapter 9.

of equal partnership, respect between individuals in communities that are separated by disparities in wealth and power, and requirements on the fairness of agreements.

PPE holds that studies that are not responsive to host community health needs and priorities and that are conducted without assurances of posttrial access may be morally wrong but that we should nevertheless permit them as long as study participants or host communities would voluntarily agree to them because they offer benefits that will avert worse outcomes.

PPE is thus distinct from the view we examine in chapter 8, the so-called fair benefits view, which challenges some of these same requirements on different grounds. In particular, the fair benefits view holds that if exploitation is about ensuring that less advantaged parties receive a fair *amount* of benefit, rather than a particular *kind* of benefit, then we should dispense with the responsiveness and reasonable availability requirements in favor of a process that allows host communities to negotiate for a larger share of a wider range of benefits (Participants 2002, 2004; Wolitz et al. 2009). This view holds that exploitation and unfairness are wrong and that exploitative and unfair agreements should be prohibited, but it challenges the criteria that have been articulated for these requirements and proposes an alternative set of criteria for these requirements. In contrast, PPE holds that agreements that are exploitative, unfair, and so on, are wrong but that we should sometimes permit these moral wrongs if doing so represents a way of respecting the decisions of disadvantaged parties about the best way to improve their circumstances.

Additionally, PPE must not be confused with skeptical views that deny that violations of respect are actual moral wrongs. PPE does not deny that exploitation, unfairness, injustice, and the like are moral wrongs. Nor does it hold that these norms are not violated if people voluntarily consent to be treated in ways that would otherwise transgress these norms. For Wertheimer, someone in a sufficiently dire situation can freely and knowingly consent to a deal that is exploitative, and the moral wrongness of that exploitation is not eliminated by the presence of voluntary consent.

What makes PPE distinctive is its focus on the *moral force*, weight, or significance that should be assigned to violations of norms of respect. It holds that mutually beneficial transactions, freely entered by informed parties, should not be prohibited, even if they involve exploitation, unfairness, or injustice and are therefore morally objectionable or wrong.

### 3.3 The Justification for Permitting Violations of Respect

Here is the argument in favor of PPE, altered to reflect its general application to norms of respect.<sup>3</sup>

1. Afflicted is in sufficiently dire circumstances that neglect will result in Afflicted suffering significant harm or disadvantage.
2. Better-off has the resources and ability to interact with Afflicted in a variety of ways, including ways that would make Afflicted significantly better off.
3. Better-off has “no obligation to transact with A [Afflicted] on any terms” (Wertheimer 2008, 82).
4. Better-off is only willing to engage in an exchange with Afflicted that would be regarded as morally wrong in that it involves a violation of respect (it is exploitative, commodifies Afflicted, involves the domination of Afflicted, treats Afflicted unfairly or unjustly . . .).
5. If Better-off cannot engage in an exchange with Afflicted on the above terms, Better-off will opt not to transact with Afflicted at all.
6. Afflicted would, with full knowledge of the relevant facts, freely engage in such a transaction with Better-off in order to receive what Afflicted judges to be a worthwhile benefit, even though the exchange subjects Afflicted to a violation of respect.
7. Neglect is therefore worse for Afflicted than being morally wronged.
8. Prohibiting violations of respect makes Afflicted worse off than permitting them.
9. Therefore, prohibiting violations of respect works to the disadvantage of the person whose interests protectionist norms against violations of respect are supposed to safeguard.
10. Therefore, Better-off ought to be permitted to perpetrate a violation of respect against Afflicted, so long as the following “proviso” is met: permitting this conduct has no negative effects on others.

Perhaps paradoxically, the upshot of PPE is that enforcing norms of respect leads to a situation where Afflicted would have been better off if those moral requirements were not enforced and both Afflicted and Better-off were permitted to engage in a voluntary transaction that violates a norm of respect.

<sup>3</sup> For example, see Wertheimer (2008, 82).

In effect, the claim is that constraints against violations of respect are self-defeating in the sense defined by Applebaum (1999, 38–152). They are supposed to protect individuals from unfair, degrading, or abusive treatment but merely ensuring that individuals are not so treated does not entail that a better deal is available to them. Because we are stipulating that Afflicted faces bleak alternatives that will result in significant harms (premise 1), enforcing norms of respect impedes, rather than advances, the interests of the very persons these norms are supposed to protect.

When the enforcement of moral norms is self-defeating, the proponents of those norms can be decried for frustrating the cause of the downtrodden and those who seek to act immorally can claim the righteous mantle of assisting those in need (Zwolinski 2007). What is perhaps worse is that there is a kernel of truth in this perversity. Those who never venture out among the poor may not treat them unfairly or treat them with disrespect, but their high-minded neglect may also be disastrously lethal. Otherwise, premise 6 would not be true and people like Afflicted would not vote with their feet and agree to be exploited, commodified, or treated unjustly.

PPE is thus most charitably read as a reaction to the concern that orthodox research ethics leaves the most vulnerable prey to lethal neglect by placing fairly demanding moral requirements in the way of agents like Better-off who might actually interact with the vulnerable and advance their welfare. If the responsiveness requirement prevents Better-off from conducting a clinical trial in some population because the knowledge it will generate is only relevant to HICs, then Better-off cannot offer Afflicted the chance to participate and possibly receive benefits that Afflicted would like to enjoy. These benefits might include access to medical care that Afflicted would not otherwise have received, or the provision of food, transportation, or direct remuneration.

So, too, if Better-off is required to provide members of the control group with the standard of care that is available in HICs, or to provide the study intervention after the completion of the trial to host-community members at steep discounts, Better-off may not conduct the trial. This may prevent unfair treatment, but it also deprives some people of potentially significant benefits that they may have been willing to accept. Unlike proposals to revise the content of requirements regarding the standard of care or posttrial access (see chapters 8 and 9), PPE assumes the content of these norms as stated in guidance documents and argues that even if they are morally sound, they should not be enforced because they are morally self-defeating.



In effect, PPE views norms of respect as creating an inefficiency in a market—individuals who would freely engage in mutually beneficial transactions are prohibited from doing so. To solve this problem, PPE reduces the demandingness of moral requirements grounded in norms of respect by permitting some wrongdoing if doing so enables those who are worst off to advance their welfare interests and avoid the ravages of neglect.<sup>4</sup>

### 3.4 Repurposing Shared Values

#### 3.4.1 Beneficence

Although the conclusion of the argument for PPE is a radical departure from orthodox research ethics, the argument in support of that conclusion draws heavily on one implicit and two explicit aspects of the conceptual ecosystem of orthodox research ethics. The explicit aspects are the centrality of the twin pillars of research ethics: beneficence, operationalized as concern for welfare, and respect for autonomy, operationalized as informed consent. The implicit aspect is the idea that researchers and participants are in a private relationship and engage in private transactions, unfettered by larger duties of obligations.<sup>5</sup> Recognizing that PPE draws from the same well of concerns and the same structure of values used in orthodox research ethics is necessary to appreciate how PPE reveals a larger tension in the field. Because there is something unsettling about the different ways in which orthodox research ethics and PPE seek to resolve this tension, it is important to understand the structure of the values that create it in order to motivate the search for a better way forward.

First, although the argument for PPE is about the force of certain moral wrongs, and not about whether violations of respect are actually moral wrongs, the considerations it uses to establish the relative weight of the wrongs in question reflect a welfare consequentialist conception of beneficence. They are *consequentialist* because premises 7, 8, and 9 each focuses on the consequences associated with the salient alternatives. The central reason

<sup>4</sup> Strictly speaking, PPE rests on an empirical assumption regarding the extent to which enforcing norms against exploitation would raise the price of carrying out research in LMICs to a point where it is no longer attractive to firms from HICs. If the cost savings to firms from relocating research to LMIC settings is great enough, then enforcing norms against exploitation might not deter such research. For a defense of this possibility, see Wenner (2016) and Ballantyne (2010).

<sup>5</sup> Wenner (2016) explores this point in greater detail.

that Better-off's unethical conduct should be permitted, in this view, is that permitting it brings about better consequences for Afflicted than prohibiting it. They are *welfarist* because PPE focuses on, and assigns overriding importance to, the welfare of Afflicted. Exploitation may be worse than neglect in terms of the respect that is shown to Afflicted as a moral agent, but PPE treats the diminution in welfare that derives from neglect as worse than the loss of status that might attend violations of respect.<sup>6</sup>

The appeal to consequences and welfare in PPE is not an appeal to an exogenous value that has to be imported into research ethics from the outside. It is, rather, an appeal to one of the core principles of orthodox research ethics: beneficence. PPE hinges on the fundamental idea that the welfare of others represents a moral reason in favor or against actions that will help that person or harm them, respectively. Its conclusion hinges on the idea that, as long as the proviso is satisfied, those reasons should be decisive in determining the conduct of agents who can help, including the relative weight that regulators or other outsiders assign to violations of respect.

### 3.4.2 Respect for Persons and Consent

Second, because PPE requires that violations of respect be permitted only when transactions are voluntary and informed, its proponents can claim, at the very least, that their position is consistent with a very basic but fundamental commitment to respect for persons. Those who find themselves in difficult circumstances are often faced with difficult decisions, but the proponents of PPE hold that we should not deny them meaningful avenues

<sup>6</sup> In order to avoid begging thorny questions about the relationship between welfare and Afflicted's status interests, premises 7–9 would have to be reformulated and an additional premise added:

- 7\*. Neglect is therefore worse for Afflicted (with respect to welfare) than being morally wronged.
- 8\*. Prohibiting the moral wrong would make Afflicted worse off (with respect to welfare) than not prohibiting it.
- 9\*. Therefore prohibiting the moral wrong works to the disadvantage of the person whose interests moral protections are supposed to safeguard (with respect to welfare).
- 9.5. In the presence of free and informed consent, violations of respect should not trump or prohibit benefits to welfare.

There is a serious concern that such claims simply assert what is at issue—namely, that serious threats to welfare are worse, all things considered, than serious threats to the status of a person. On this question, see Athanasiou et al. (2015).

for advancing their own welfare if they view those avenues, once all things are considered, as their best available alternative.

A more extreme position holds that PPE alone shows adequate respect for the autonomy of people like Afflicted because the ultimate purpose of rights is to protect a person's interests and it should be up to that person to decide whether their interest in respect is more important than securing some possible benefit. Taking this choice from Afflicted, in other words, not only deprives Afflicted of possible benefits, but it unduly restricts Afflicted's autonomy.<sup>7</sup>

The force of PPE thus derives from values that constitute the twin pillars of orthodox research ethics: respect for autonomy and beneficence or concern for welfare. But these values are repurposed to make an antipaternalistic argument against norms that are traditionally grounded in the value of justice and norms of respect. If the norms of research ethics are fundamentally grounded in, and intended for, the protection of individuals like Afflicted, pointing out that people in Afflicted's position may prefer exploitation or injustice to lethal neglect challenges the paternalism of protectionist norms on their own ground—their impact on the interests of the very people they are supposed to protect.

### 3.4.3 Options and the Private Sphere

The third commonality between the argument for PPE and the commitments of orthodox research ethics is less explicit. To see it, consider how odd it is that both accept the truth of premise 3, namely, that Better-off does not have a prior obligation to provide assistance to Afflicted, given the centrality of beneficence in both orthodox research ethics and the argument for PPE.

If a framework for moral decision-making includes beneficence, then, if all else is equal, that framework would seem to be committed to what I will call “weak consequentialism.”

**Weak Consequentialism:** There is a standing duty to benefit those in need (like Afflicted), as long as it imposes only minor costs to the welfare of agents

<sup>7</sup> On the role of respect for autonomy in PPE, including the extent to which PPE is intended to be anti-paternalistic, see Wenner (2016).

who incur the duty (such as Better-off) or to their ability to pursue their (otherwise) morally permissible projects and plans.<sup>8</sup>

If weak consequentialism is the only principle in a moral theory, then the theory itself is consequentialist. More commonly, a claim like this is likely to figure in a broad range of theories that are pluralistic in the sense that they include a consequentialist component (such as a commitment to beneficence) while also embracing constraints on its reach (in the form of rights, for example).<sup>9</sup>

In orthodox research ethics, both justice and respect for persons give rise to prohibitions that serve as constraints on the pursuit of beneficence. If justice requires that groups that are already marginalized or burdened in some way must not be involved in research that does not address their specific health needs, then recruiting such participants is forbidden, even if doing so would be a way to produce more good in the long run. Likewise, if respect for persons requires that no participant be recruited into research without having first given their free and informed consent (or having a proxy decision maker do so if they lack capacity to make that decision for themselves) then it is impermissible to conscript participants into research without their free and informed consent, even if doing so would produce important social benefits.

Although constraints fence in and limit the extent to which beneficence can require acts that are morally problematic in some other regard, constraints do not limit the demands of beneficence when it does not come into conflict with some other value. As a result, even though orthodox research ethics contains a number of constraints on the reach of beneficence, its commitment to beneficence should entail that considerations like those in weak consequentialism require the rejection of premise 3. Better-off would be obligated to interact with Afflicted, and to advance Afflicted's interests as much as possible, so long as there is not another action available to Better-off that would bring about a greater good and the costs to Better-off do not exceed the relevant threshold.<sup>10</sup>

<sup>8</sup> Compare this to Singer's strong altruistic claim: "if it is in our power to prevent something bad from happening, without thereby sacrificing anything morally significant, we ought, morally, to do it." And to Singer's weak altruistic claim: "if it is in our power to prevent something very bad from happening, without thereby sacrificing anything of comparable moral importance, we ought, morally, to do it" (Singer 1972).

<sup>9</sup> For a useful primer on consequentialism and constraints, see Kagan (1997).

<sup>10</sup> If there is some way that Better-off could bring about more good by not interacting with Afflicted, then Better-off would be obligated to adopt *that* course of action, and 3 would still be false. Strictly speaking, weak consequentialism supports a duty to aid people like Afflicted in most cases,

However, both PPE and orthodox research ethics reject the claim that Better-off has a duty to assist Afflicted. As such, they must share a further commitment that tempers the reach of principles of beneficence in cases where Afflicted and Better-off could transact without any violation of a norm of respect. The only way for such theories to reject the stronger claim of a duty to aid in this circumstance is to recognize what are sometimes called “options.”<sup>11</sup>

An option is basically a permission or a liberty right to act in ways that bring about less good than the agent could bring about through another feasible course of action. Frequently the existence of options is grounded in the idea that it is morally permissible for agents to avoid acts that require that they take on morally significant burdens. To be morally significant, burdens to the agent, understood in terms of her own interests or her ability to advance those interests, must be sufficient to outweigh, override, or otherwise mitigate the claims that the interests of others place on the agent.

There are significant disagreements about where to locate the threshold on the costs that an agent can be required to bear in the service of morality.<sup>12</sup> In part, these disagreements reflect deeper divisions over the role of morality in human life, and the force of moral reasons. But the proponents of options argue that there is in fact such a threshold and that it is necessary to preserve a “zone of moral indifference” within which the conduct of agents is not subject to the demanding assessment of morality (Fishkin 1982, chapter 4).

A different way of stating this idea is that options protect a sphere of “moral autonomy” within which agents have the permission or the liberty to shape their own life and conduct according to their own values, goals, and aspirations, free from demands that would be placed on them by a fully impartial responsiveness to the interests of others (Kagan 1997, 236). Options

because instead of a single best or optimal option, Better-off might be faced with a set of alternatives that are “maximal” in the sense that there are several actions that are not dominated by a better act but which are superior to all other possibilities open to Better-off. If interacting with Afflicted is a member of this maximal set, but so are alternatives that involve not interacting with Afflicted, then Better-off would be at liberty to choose not to interact with Afflicted in the sense that Better-off could choose another act from the maximal set. If Better-off chooses to interact with Afflicted, however, then Better-off would then be obligated to help advance the welfare of Afflicted as much as possible.

<sup>11</sup> My use of the terms “option” and “constraint” follows that of Kagan (1997, chapter 3).

<sup>12</sup> See Cullity (2004).

are sometimes referred to as “agent-centered prerogatives” to reflect the idea that they grant the agent the prerogative to give disproportionate weight to her own interests (Scheffler 1994). In each case, the salient question concerns the point at which the agent can no longer remain indifferent to others or at what point those interests can legitimately restrict or intrude upon her sphere of moral autonomy.

If both orthodox research ethics and PPE treat agents like Better-off as having no duty to aid or assist people like Afflicted, then the interactions between researchers and participants fall into a private sphere of moral discretion. In other words, they reflect the widely accepted idea that research with humans is a morally optional undertaking, unconstrained by larger social purposes, in which the primary ethical considerations are limited solely to the terms of the discrete transactions between the parties within the IRB triangle.

The idea that the interactions between researchers and participants fall into a private sphere of moral discretion is bolstered by the proviso in premise 10. PPE holds that conduct that violates norms of respect should be permitted so long as it remains confined to the discrete interactions of researchers and study participants. If permitting such violations were to have a larger social effect of making other parties worse off, then the proviso would kick in and violations of respect would be prohibited.

There is thus an important sense in which PPE challenges orthodox research ethics for not being sufficiently responsive to its own values.<sup>13</sup> In the private transactions between researchers and study participants, the welfare consequentialist concerns of beneficence provide the moral force for permitting violations of respect and define the limits on their permissibility. If individuals like Afflicted freely choose to be wronged in order to advance their welfare interests, then the paternalistic prohibition of such interactions is self-defeating.

<sup>13</sup> In this regard, the critique involved in PPE is simply a variant of the more general critique that consequentialists make against deontological rights or constraints of any kind: they are suboptimal. That is, constraints against violations of respect prevent people like Afflicted from enjoying gains in welfare that people like Better-off could bring about by violating such norms. Sophisticated welfare consequentialists agree that often we should respect the rights of agents, not because such rights have intrinsic moral value, but because such rights function as heuristics that mark out as salient courses of action that tend not to be optimistic over the long run. In cases where we can be confident that violating a right will produce more good than respecting it, however, the welfare consequentialist will claim that respecting the right makes no sense.

### 3.5 Permitting Too Much

#### 3.5.1 Undermining Consent

The analysis of the previous sections represents PPE as reorganizing core commitments of orthodox research ethics in a way that strikes a different (and, according to its proponents, a better) balance between the demandingness of morality and the perils of neglect. Because it is built out of many of the underlying commitments of orthodox research ethics, this proposal is more of a challenge to the status quo than it might first appear.

In particular, without a clear and explicit account of justice to ground prohibitions on unfair and unjust relationships, those practical requirements dangle in the moral wind. They appear arbitrary at best and misguided at worst precisely because the neglect of their grounding or justification or the location of that justification in the distribution of benefits and burdens create a conceptual ecosystem in which the other commitments of the field can be marshalled to support permitting their violation.

Nevertheless, there are a number of grounds for concern over the way PPE tries to reconcile the pitfalls of sanctioning neglect, justifying wrongdoing, and the demandingness of morality. To begin with, the logic of the PPE justifies more wrongdoing than its proponents want to permit. For example, proponents of PPE want to ensure that violations of respect are limited to cases in which agents like Afflicted give their free and informed consent. But since informed consent is itself grounded in a norm of respect, the logic of PPE seems to extend to violations of this requirement as well.

First, recall that PPE presupposes options of sufficient weight that even minor burdens to Better-off are capable of outweighing or trumping Afflicted's welfare interests. We are committed to this by the supposition that Better-off has an option not to interact with Afflicted, if doing so is burdensome to Better-off, even if this would provide Afflicted with significant welfare benefits. If Better-off did not have an option of this kind, then premise 3 would be false.

Second, the requirement to seek informed consent imposes costs on Better-off. Consent forms have to be created. They have to be translated at an accessible educational level, in the local dialect, and then work has to be done to overcome various barriers to communication including educational gaps and cultural differences. During the consent process, people sometimes say, "no." Perhaps Afflicted doesn't fully understand the extent

to which study participation would be an avenue to improving Afflicted's situation. Perhaps Afflicted doesn't want to be a participant in research, or doesn't want to be a subject in exploitative research. Whatever the reason, when potential participants refuse to participate, Better-off faces the extra costs and work of having to seek out and approach additional people and seek their consent.

Third, informed consent is itself a requirement that is grounded in a norm of respect—respect for the status of a person as morally sovereign over decisions that impact the shape and course of their life. PPE views constraints against violations of respect as inefficient to the extent that they prevent Afflicted from securing welfare benefits. Constraints against transgressing norms of respect can be outweighed by Afflicted's welfare interests. If Better-off could involve Afflicted in research without Afflicted's knowledge—perhaps by hiding the fact that Afflicted is participating in research—and if Afflicted is likely to receive a net welfare benefit from the interaction, then by transitivity Better-off should have the option to violate the constraint against exploiting Afflicted without Afflicted's consent. Doing so may be wrong—just as exploitation with Afflicted's consent is wrong—but PPE seems committed to the conclusion that it should not be prohibited.

### 3.5.2 The Participant-Centered Version

To be clear, there are at least two versions of this argument. The “participant-centered” version focuses on the impact of being exploited without consent on Afflicted's well-being. It holds that Better-off should not be required to secure the informed consent of Afflicted to be exploited or treated unfairly if seeking that consent would impose a cost on Better-off and if Better-off's exploitation of Afflicted would still leave Afflicted better off than would be the case if there were no interaction. After all, recall that Afflicted faces the prospect of serious harm outside of any transaction with Better-off and in the world of non-ideal agents, many in Afflicted's situation may not recognize that they would be better off being wronged than being neglected. The recipient-centered version of the argument thus allows Better-off to exploit Afflicted without Afflicted's permission so long as Afflicted receives a net benefit from the interaction.

If the participant-centered version of this argument sounds familiar, that's because it shares common features with traditional arguments in favor of



medical paternalism—with some notable differences, however. In medical paternalism, the clinician had a strong duty to act in the best interests of the patient grounded partly in the patient's dependence on the specialized medical knowledge the clinician possesses and the patient lacks. Consent was regarded as unnecessary because it might cause distress or lead the patient to deviate from the clinician's recommendations about how best to promote the patient's medical best interests (Goldman 1980).

In the patient-centered extension of PPE, the more powerful party need only have a strategic commitment to Afflicted's best interests. This commitment is strategic in that it is necessary for Better-off to achieve Better-off's ultimate goals. Similarly, permission to violate the requirement for informed consent is grounded in the importance of the benefits Afflicted stands to receive from the transaction and the fact that Better-off might deny those benefits to Afflicted if Better-off is required to incur the costs of securing Afflicted's informed consent. Ironically, in both Hippocratic paternalism and the patient-centered extension of PPE, it is concern for the welfare of Afflicted that underwrites the permission to violate a key requirement of respect for persons.

### 3.5.3 The Impartial Version

The impartial variant of the previous argument shifts its focus from the welfare of Afflicted to the welfare of some larger group. This transition is facilitated by noting that, in research ethics, risks to particular participants do not need to be offset by benefits to those same participants in order to be permissible. Rather, risks and burdens to study participants can be justified by the prospect of future benefits to other people.

With this premise in place, the impartial variant permits Better-off to exploit, wrong, or commodify Afflicted without consent, so long as this imposes fewer costs on Better-off than the alternatives and creates social benefits sufficient to outweigh the burdens to Afflicted. The impartial version of this argument looks very similar to justifications for conscripting participants into research that are grounded in some larger research imperative. In particular, both arguments entail that researchers should be permitted to involve participants in research without their informed consent.

Nevertheless, these arguments differ significantly in their structure. The argument that attempts to justify conscription on the basis of a larger social

obligation to facilitate research is inconsistent with the claim that Better-off is free to interact with Afflicted on whatever terms Better-off wants. In other words, that argument does not recognize a robust sphere of moral autonomy for Better-off. As a medical researcher, Better-off would not be free to determine whether and how to interact with Afflicted by consulting her personal interests, and the justification for abrogating informed consent is not grounded in costs to Better-off. Rather, Better-off is only justified in abrogating informed consent, on this model, to the extent that doing so is necessary to discharge the researcher's prior obligation to advance the common good.

In contrast, Better-off is able to dictate the terms on which Better-off is willing to interact with Afflicted within the argument for PPE because that position recognizes a robust sphere of moral autonomy on the part of Better-off. The impartial extension of PPE allows Better-off to abrogate the requirement of informed consent if doing so produces a large enough social benefit, *but there is no independent obligation to bring about this social benefit*. Better-off happens to pursue a private project in which Better-off takes on the personal goal of producing a social benefit. But Better-off has ultimate discretion over when, whether, and how to pursue Better-off's personal goals. This includes the moral discretion to determine when the costs to Better-off of pursuing this goal are sufficiently high that Better-off does not want to transact with someone like Afflicted. Enforcing the requirement of informed consent imposes a burden on Better-off's ability to advance Better-off's personal projects. If increasing the welfare of others is capable of justifying violations of norms of respect, then that justification would appear to extend to the abrogation of informed consent.

Interestingly, Wertheimer and colleagues have argued that because research is an activity that produces an important public good, there is a general duty to participate in research (Schaefer et al. 2009). They explicitly reject arguments that would ground this obligation in beneficence because, on their view, beneficence is too demanding. Instead, they argue that the generalizable medical information that research produces is a public good and it remains a public good even if it is produced by private companies or private individuals (2009, 68). This produces a kind of moral asymmetry. Private entities are at liberty to decide which projects to undertake—they are not fettered by obligations of justice or beneficence—but there is a duty to participate in research that flows from the status of this information as an important public good.

Wertheimer and colleagues argue that this duty to participate is not so strong that individuals can be compelled to participate in research. But PPE is not about whether, in this case, compulsion is morally permissible. It is about whether, given that compulsion would represent a moral transgression of an individual's interests in retaining sovereignty over their person and autonomy over their various life choices, we ought to enforce that moral prohibition. My point is that the same argument that justifies permitting the moral wrong of exploitation in research would also permit the moral wrong of conscripting individuals into research in which the information they help to generate contributes to the public good of generalizable medical information.

The impartial variant of PPE is constructed from premises that are shared by orthodox research ethics and by PPE. It recognizes a strong sphere of moral autonomy that protects individuals in their private pursuits while recognizing the fundamental moral importance of individual welfare. But there is also a sense in which the robust sphere of personal autonomy serves as a shield to Better-off against the claims that people in Afflicted's position might make against them for assistance and for fair, non-exploitative, non-demeaning treatment. When Better-off has as a personal project advancing the welfare of large numbers of future patients, this allows Better-off to both remain indifferent to Afflicted's plight (this follows from the claim that Better-off enjoys a sphere of autonomous choice protected by an option and is required in order for premise 3 to be true) and to justify exploiting, dominating, commodifying, or demeaning Afflicted for the benefit of future people.<sup>14</sup>

The arguments I just presented challenge PPE on its own terms because they use the concern about inefficiencies associated with norms of respect that motivate PPE to show that those concerns also justify adopting an even less demanding morality that permits more wrongdoing than even proponents of PPE want to allow. The welfare consequentialist elements of

<sup>14</sup> Wenner (2016, 43) raises a distinct argument that is worth noting in this context as well. Suppose that with the cost structure imposed by fair agreements, Better-off could conduct one research study with Afflicted but that if we permit Better-off to exploit Afflicted then Better-off would have the resources to conduct an additional study involving a second population, so long as we permit this second study to also be conducted on exploitative terms. In this case, although welfare consequentialist concerns are not strong enough to create a moral obligation for Better-off to interact with afflicted on fair terms, it would support a moral obligation on regulators not just to permit, but to maximize, the frequency of mutually beneficial and voluntary exploitation. Proponents of PPE might respond that they can resist this implication because it violates the proviso in premise 10. I consider the problematic implications of this response in §3.7.

PPE also facilitate the transition from the participant centered to the impartial variant of the position. In both cases, Better-off's decision about who to interact with, and on what terms, remains a private matter, shielded from outside interference by a fairly strong agent-centered prerogative. Given the logic of PPE, preventing research that imposes burdens on people who are already in a terrible situation doesn't improve the lot of those people, but it does deprive both researchers and future populations of people of potentially valuable medical resources.<sup>15</sup>

It might be objected that my critique is faulty because it misrepresents the role of consent in PPE. The claim would be that PPE is not committed to holding that Afflicted's welfare interests outweigh Afflicted's interests in respect, but only that we should respect Afflicted's determination, as expressed through informed consent or refusal, as to the relative importance of Afflicted's welfare and Afflicted's interest in respect.

This is a plausible objection, but it misses a key point. PPE is a position about the moral force of violations of respect and not about whether or not such a violation has occurred. As such, PPE is itself predicated on the claim that even if Afflicted consents to being exploited or degraded, Afflicted is still wronged by the subsequent exploitation and degradation. This is why PPE is committed to the idea that Afflicted's welfare interests should be allowed to trump Afflicted's interests in respect and why PPE is distinct from positions that hold that the agent's consent has the morally transformative effect of rendering what would be exploitative or morally degrading conduct non-exploitative or non-degrading. The point of my critique is that exploiting Afflicted without Afflicted's consent is wrong, but the logic of PPE justifies permitting this wrong as long as the resulting act provides Afflicted with benefits that leave Afflicted better off than Afflicted would otherwise have been (the patient-centered extension of PPE) or if the benefits that Better-off can produce for others are sufficient to outweigh the costs to Afflicted (the impartial extension of PPE).

<sup>15</sup> The impartial position comes exceedingly close to embracing a full-blown consequentialist position, but it falls short of that in a critical respect that relates to the demandingness of the position. That is, consequentialism is more demanding in that it imposes a duty on agents to promote the welfare of others, and if it were the case that the only way to do that was to exploit a certain population of people in clinical research then, as long as all else was equal, researchers would be obligated to do that. The impartial position considered above is less demanding in that it does not endorse such a duty. So it does not *require* anyone to exploit others. It simply says that if large numbers of people can benefit from such research and there are agents like Better-off who are willing to conscript vulnerable people as "soldiers of science" to do it, then we should not stand in their way.

### 3.6 (Un)Equal Respect

#### 3.6.1 Threats to Autonomy and the Integrity of a Life

Although it permits certain transgressions against Afflicted, PPE appears to do so against a more fundamental background of equal moral regard: Afflicted and Better-off are each moral agents who should be seen as sovereign over their own life and whose free and informed decisions should be respected. Limiting violations of respect to cases in which Afflicted consents to the violation might thus be seen as affirming this more fundamental value of equal respect.

The appearance of a strong commitment to equal regard, however, is misleading. Any concern for the autonomy of agents like Afflicted that grounds the requirement of informed consent in PPE is at best a dim simulacrum of the profound regard PPE shows for the autonomy and integrity of the life of agents like Better-off. Recall that we began this section by noting a tension in PPE between the welfare consequentialist elements of the argument on which it rests and the fact that weak consequentialism would provide grounds to reject the claim that Better-off has no prior obligation to transact with Afflicted. We noted that the permission in premise 3 might reflect the common view that weak consequentialism is an implausibly high moral standard because it forces agents like Better-off to compromise the integrity of their lives in order to help those like Afflicted. As such, we suggested that premise 3 might be grounded in an option or agent-centered prerogative whose moral importance is grounded in preserving the integrity of Better-off's life and Better-off's sovereignty over it.

But if we are genuinely concerned about autonomy and the integrity of an individual's life then we should question the grounds on which this concern is applied to the demands that morality and policy might make on the life of Better-off without being applied with equal force to the demands that such a weaker moral framework places on Afflicted. As David Sobel has argued, "costs that a moral theory permits but does not require are sometimes relevant to the demandingness of that theory" (Sobel 2007, 13).<sup>16</sup> Afflicted's autonomy and the integrity of Afflicted's life are threatened by moral frameworks (such as those common to orthodox research ethics and PPE) that sanction the indifference of others to Afflicted's basic needs and by the

<sup>16</sup> Similar ideas are elaborated at length in Nagel (1991) especially chapter five.

proposal embodied in PPE to empower others to breach norms of respect in order to further advance their own personal projects.

From the standpoint of agents like Better-off, PPE is less demanding than consequentialist views that would entail the rejection of premise 3 and current ethical frameworks that include options but that enforce norms of respect. From the standpoint of agents like Afflicted, however, PPE is an incredibly demanding theory. In this case, however, the objectionable burdens come not from what morality requires agents like Better-off to do in order to help others, but for what it requires agents like Afflicted to suffer and to lose in order to ensure that agents like Better-off are not fettered in *their* life plans by duties to help others.

The point is that in order for Better-off to have an option of the force we have been considering here—one that outweighs or trumps significant and avertable threats to the welfare of others—there has to be a strong moral ground of respect for Better-off's autonomy and the integrity of Better-off's life. But a symmetrical application of this concern for the autonomy and integrity of Afflicted's life undermines such a strong option and entails the negation of premise 3—that is, it entails a duty on the part of parties like Better-off to aid or assist parties like Afflicted precisely because parties in Afflicted's position are in dire circumstances that threaten their ability to pursue their life plans. If we want our moral frameworks to be responsive to the autonomy of agents and their ability to maintain the integrity of their life, then in situations where that ability is threatened for agents like Afflicted, and agents like Better-off can help to avert such a loss at little personal cost, we should require more from agents like Better-off than either PPE or orthodox research ethics recognize. Since norms of respect are tied closely to the value of autonomy and concern for the integrity of each individual's life, there is a strong case for requiring Better-off to interact with Afflicted on terms that advance Afflicted's interests in both welfare and respect.

If this is correct, then PPE is not entitled to the defense that the permission to wrong takes place against a deeper recognition of moral equality. Rather, PPE shows asymmetric concern for the interests of Afflicted and Better-off in that it is more sensitive to the way that moral constraints and consequentialist requirements to provide aid to people like Afflicted threaten Better-off's autonomy and sovereignty over Better-off's life than it is to the way that taking this very position threatens those same interests on the part of Afflicted.

At this point, it is important to remember that the main reason for focusing on PPE is for what it reveals about fault lines running through

orthodox research ethics. The argument examined in this section holds that PPE should be palatable because it is limited in its scope, sequestering violations of respect to contexts in which individuals autonomously accept such treatment. The problem with this move is that it obscures the way that the agency of some parties is protected and advanced at the expense of others. This asymmetric concern belies the idea that PPE preserves something like a baseline of moral equality against which a standard contractual relationship plays out. This asymmetric concern for autonomy, respect, and moral equality is not unique to PPE, in that this asymmetric concern is grounded in premises and features that it shares with orthodox research ethics.

### 3.6.2 Providing Assistance and the Fair Division of Moral Labor

It might be objected that even if we grant that sickness, injury, or disease can undermine Afflicted's autonomy and that Afflicted therefore has a claim to assistance, it doesn't follow that Afflicted would have that claim specifically against Better-off. This is probably correct, as far as it goes. In other words, we need to know more about the relevant division of social labor and about Better-off's role in it, before we could make such a determination. But I take this point to reinforce the poverty of the parochialism of orthodox research ethics. If, for example, there is a social obligation to promote the common good through medical research and if this places Better-off under a moral obligation to conduct research that advances this goal, then there may well be circumstances under which premise 3 is false; Better-off has a duty to carry out research that involves parties like Afflicted; and those parties have an enforceable claim to conditions that satisfy norms of fairness, justice, and respect.

In the next chapter, I make the case for just this position. There is a moral imperative to advance the common good through research and this imperative includes an obligation to adhere to strong norms of respect. The point of the analysis presented so far is not to identify the values that will provide the foundation for the positive view I will develop in this book. It is, instead, to illustrate that PPE repurposes the core values of orthodox research ethics in ways that reveal fault lines in the field. These fault lines concern the way that research is treated as a private undertaking of individuals with no explicitly defined and well-delineated social obligations whose interactions are to be

regulated primarily by the values of beneficence and respect for persons. PPE marshals these commitments to undermine not just the paternalism of orthodox research ethics but the moral force of its already anemic commitment to justice.

### 3.7 Violating the Proviso

In the previous section I argued that PPE tells us something important about the status of the conceptual foundations of research ethics. There is another respect in which a flaw with PPE reveals a problem with orthodox research ethics: namely, both tend to portray research as a largely private interaction between two parties—researchers and participants. There is no sense that this interaction takes place within a larger social division of labor, that this division of labor is structured by social aims and constrained by rules that must govern similar interactions for a range of different parties in different contexts, times, and places. This decontextualized view is illustrated most dramatically in the inclusion of the harm proviso in the argument for PPE.

In contrast to what is portrayed as the self-defeating character of theories that prohibit violations of respect, PPE is supposed to represent a way of empowering the downtrodden to advance their welfare interests in the limited context of mutually beneficial and voluntary interactions. The hope is that benefits that would not have materialized under a strong prohibition of violations of respect will materialize if those prohibitions are weakened and the harm proviso is obeyed—namely, “if doing so has no negative effects on others.”

How likely is it that the proviso would be violated? Here we face a tension between the context in which PPE is enunciated and the nature of the specific examples used to motivate the principle. That is, PPE is enunciated in the context of a longstanding debate within research ethics about the rules, principles, and requirements that ought to govern research that is sponsored by entities from HICs and carried out in LMIC populations. This longstanding debate is fundamentally a dispute over institutional design. At issue are the norms, goals and constraints that should govern the interactions between a range of stakeholders—from researchers, participants, and host communities, to funding agencies of various sorts including national and local governments, non-governmental organizations, and corporations—across time and different places.



In contrast to the debate over institutional design, the argument in favor of PPE outlined above depicts the discrete interaction of two seemingly isolated individuals. To some degree, this also reflects the traditional focus of orthodox research ethics. Orthodox research ethics is overwhelmingly concerned with the ethics of the researcher-participant relationship.<sup>17</sup> Similarly, the central mechanism for putting the norms of research ethics into practice is the IRB, an oversight body that reviews individual protocols. But the situation of a private individual conducting an isolated private transaction with another private individual is very different from policy questions about how the institutions of scientific research ought to be designed and regulated. These norms and institutions govern the interactions of a wide range of parties, some of which are repeated interactions over time. The probability that the proviso will be violated differs substantially between these two situations.

In particular, it is difficult to see how an institutional design that incorporated PPE as an explicit policy would not violate the harm proviso. The reason is that the system in which violations of respect are officially prohibited effectively places a floor on the “price” that researchers and sponsors have to “pay” in order to secure the cooperation of host communities without wronging them. From the standpoint of PPE, this price is too high because there may be some agents, such as Better-off above, who are “priced out” of the market—they choose not to interact rather than to pay a non-exploitative price.

Adopting PPE as a principle, however, would remove this floor on prices and destabilize the current price equilibrium. Those who are currently paying, or who would have paid in the future, the higher, respectful, price would face competitive pressures not to “overpay” as prohibitions are removed against either demanding a lower price to carry out the same transaction or simply finding someone else to transact with at the lower price. As a result, those communities currently hosting clinical trials on fair, non-exploitative, or respectful terms would stand either to lose out on hosting future studies that they would otherwise have hosted, or to be pressured to accept less than they would otherwise have received. I elaborate these arguments in detail in chapter 8.

<sup>17</sup> As we will see in chapter 5, this is the central focus of Fried’s (1974) classic work on equipoise, and the entire debate over the requirement of clinical equipoise has revolved around reconciling the clinician-researcher’s obligations to safeguard the welfare of individual participants with the demands of scientific research. See for example Marquis (1983), Miller and Weijer (2003), and Miller and Brody (2003).

These concerns are particularly relevant to the case of international research since this is a highly dynamic enterprise that is driven in large part by the potential for cost savings. Research sponsors are continually seeking ways to reduce costs so that they can minimize expenses and maximize profits. So-called “contract research organizations” (CROs) are corporations that have emerged with the explicit goal of making a profit by more efficiently matching research with host communities. Their emergence has made international research highly mobile, increasing competition between potential host communities and giving CROs the leverage to lower the costs of conducting research in order to capture profits for themselves.

In this context, endorsing PPE as a rule would put those who operate on fair terms of cooperation at a strategic disadvantage (see also Wenner 2016). Given the imbalance in supply and demand between the vast pools of sickness and disease in LMICs and the comparatively small number of clinical trials, market forces would drive research sponsors to make more exploitative offers in order to remain competitive.

Because implementing PPE as a principle that defines the permissible operation of the institutions of international research would result in some research participants being worse off than they otherwise would have been, such a use of PPE would violate the harm proviso. At best, therefore, PPE would have to be interpreted as a principle of individual morality that governs the conduct of researchers as private individuals. Whether this interpretation of the principle avoids violating the harm proviso will depend on a variety of factors including the degree of publicity associated with such choices and the willingness of third parties to enforce a division of labor and social norms that encourage or discourage it. In this regard, the motives of efficiency and competitive advantage would provide powerful incentives for sponsors and CROs to “encourage” researchers (through incentives such as profit sharing or punitive measures such as negative evaluation or reductions in funding for researchers whose activities are viewed as unnecessarily costly) to alter existing or future conduct in ways that are currently regarded as impermissible but that would be sanctioned under PPE. The same shift in equilibrium that would result from adoption of PPE at the level of policy could easily be replicated at the level of individual behavior via the application of employer incentives, market forces, and social norms.

Even if regarding PPE as a principle for regulating the conduct of researchers as private individuals can avoid violating the harm proviso, this way of “saving” the principle comes at a steep price. Namely, it renders PPE

largely irrelevant to the fundamental questions in research ethics concerning the policies and norms that should regulate the institutional design of research and govern the conduct of the myriad stakeholders that contribute to its proper functioning.

I have been arguing that PPE offers important insight into a fault line running through the foundations of orthodox research ethics. PPE shows that when the requirements of responsiveness, the standard of care, and post-trial access are viewed as constraints on the discrete interactions of private individuals, they look like gargantuan protectionist fences intended to protect vulnerable individuals that wind up subverting that goal by “protecting” those very individuals from the only interactions that might enable them to improve their desperate condition.

### **3.8 Taking Stock: Testing the Health of Conceptual Foundations**

Environmentalists are sometimes chided for caring a great deal about little things—the health of streams in a watershed, the plight of this or that species of toad—that seem inconsequential to outsiders. PPE might seem like an inconsequential anomaly not worth the attention that I have paid to it here. But one reason that environmentalists care about streams and toads is that they are indicators of the health of watersheds and ecosystems, larger interconnected systems that create the niche for a diversity of life. So, too, my claim has been that PPE reveals something about the health of orthodox research ethics, the state of its conceptual foundations.

PPE exploits the myopic focus of orthodox research ethics on the narrow interactions of researchers and participants. The irrelevance of PPE to the large-scale questions of institutional design in research ethics reveals the importance of stepping back from the myopic focus of orthodox research ethics and considering questions of fairness and justice from the standpoint of research as a larger social system in which the activities of diverse parties are knit together in a web of cooperation. In part, PPE founders because it misconstrues the extent to which the system of medical research and its oversight and regulation involves the design and regulation of institutions and practices involving the cooperation of different parties over an extended period of time. But this shortcoming is not unique to PPE. It is a shortcoming of the system of research ethics that PPE uses and repurposes for its own ends.

Similarly, PPE is likely to be dismissed for its willingness to permit the exploitation of the vulnerable. But PPE is a reaction to the willingness of orthodox research ethics to uphold strong moral prohibitions against disrespectful treatment while treating research that would advance the interests of those who suffer from the most significant burdens of sickness and disease as morally optional. Repugnance at the way PPE strives to solve this problem does not ameliorate the underlying dilemma. It still leaves some populations trapped between the anvil of neglect and the hammer of exploitation.

The view of research as a morally optional undertaking was motivated, in part, by a fear of what would happen if research ethics embraced a more demanding duty to advance the common good. In the next chapter I revisit the question of whether there is a social imperative to carry out research. I argue that Jonas (1969) was correct to reject such an imperative as grounded in a certain conception of the common good, but mistaken in thinking that the view of the common good that he rejects is the only or the best way of thinking about that concept. Equipped with a better conception of the common good, I argue that there is a social imperative to carry out a certain kind of research but that this imperative, contrary to the assertion of McDermott (1967), requires extending the rule of law into the realm of research with humans.