Compensation for the Moral Costs of Research-Related Injury

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Abstract. In the United States, researchers are not legally required to compensate trial participants for research-related injuries. Nevertheless, institutional review boards (IRBs) ought to require that all research proposals include broad compensation plans. However, the standard justifications for mandatory compensation cannot reconcile the need for adequate participant protections with a duty on the part of the research community to provide them. This situation can be resolved only through a deeper analysis of research-related costs. Once mere costs are distinguished from moral costs, a compelling case can be made that the principle of respect for persons, or human dignity, provides a sound moral foundation for assigning responsibility for research-related injuries. *National Catholic Bioethics Quarterly* 17.4 (Winter 2017): 633–648.

Because clinical research necessarily involves uncertainty, participants enrolling in research are unavoidably exposed to some level of risk. Thus, even in the most carefully designed and conducted research, participants can be injured. In the United States, however, there is neither a national program for compensating participants for research-related injuries nor any legal obligation for researchers to provide such compensation.[1] Instead, federal regulations require only that prospective participants be informed as to whether compensation will be made available in the case of injury. Consequently, very few US institutions guarantee medical care, and none provide

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1. For the sake of simplicity, I shall use the term "researchers" broadly to include those directly responsible for designing and conducting biomedical research, the research sponsors, and the research institutions.

financial compensation for lost wages or pain and suffering.[2] This is true despite the fact that there is a long history of calls from ethics advisory boards to institute such a policy[3] and despite the fact that most developed countries outside the United States have some such program in place.[4]

Instead, the current strategy in the United States for dealing with research-related injury relies primarily on tort law. This can create serious challenges for injured participants who seek compensation, and litigation can undermine their trust in the research. In addition, it is at odds with a moral consensus on what ethical participant protections should require.[5] Given that there is little reason to anticipate major policy change in the immediate future, the question is whether institutional review boards (IRBs), which are charged with ensuring the ethical conduct of human-subjects research, should routinely require researchers to include a compensation plan in trials that are classified as more than minimal risk.

While there are few empirical data, it seems highly unlikely that IRBs regularly if ever require clinical trials to include a compensation plan. Two reviews of informed-consent documents and guidelines strongly suggest that, at best, IRB requirements are merely consistent with the federal requirements to inform patients

2. David B. Resnik, "Compensation for Research-Related Injuries: Ethical and Legal Issues," *Journal of Legal Medicine* 27.3 (November 23, 2006): 263–287, doi: 10.1080/01947640600870866; David B. Resnik et al., "Research-Related Injury Compensation Policies of U.S. Research Institutions," *IRB: Ethics and Human Research* 36.1 (January–February 2006): 12–20; and Lewin Group, *Task Order Proposal No. 2: Care/Compensation for Injuries in Clinical Research: Draft Final Report Prepared for the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation* (Falls Church, VA: Lewin Group, 2005), ES-2.

3. Tuskegee Syphilis Study Ad Hoc Advisory Panel, *Final Report*, US Department of Health, Education, and Welfare, April 24, 1973, available at https://biotechlaw.lsu.edu/; Secretary's Task Force on the Compensation of Injured Research Subjects, *Report of the Task Force* (Bethesda, MD: National Institutes of Health, 1977), VI; President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research 42 U.S.C.A. § 300 (1982); US President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Compensating for Research Injuries: The Ethical and Legal Implications of Programs to Redress Injured Subjects*, vol. 1, *Report* (Washington, DC: Department of Commerce, 1982); Advisory Committee on Human Radiation Experiments, *Final Report* (Washington, DC: US Government Printing Office, 1995); National Bioethics Advisory Commission, *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*, vol. 1, *Report and Recommendations* (Bethesda, MD: NBAC, 2001); Presidential Commission for the Study of Bioethical Issues, *Moral Science: Protecting Participants in Human Subjects Research* (Washington, DC: PCSBI, 2011); Institute of Medicine, *Responsible Research: A Systems Approach to Protecting Research Participants* (Washington, DC: National Academies Press, 2003).

4. Efthimios Parasidis, "Compensation for Research-Related Injuries Involving Human Participants," *Harvard Journal on Medical Ethics* 2 (2001): 26–33.

5. Elizabeth R. Pike, "In Need of Remedy: US Policy for Compensating Injured Research Participants," *Journal of Medical Ethics* 40.3 (March 2014): 182–185, doi: 10.1136/medethics-2012-100771.

about the availability of such plans.[6] Yet mandatory compensation plans seem consistent with the broader responsibility of IRBs to ensure that research is conducted ethically and patients are protected, despite the fact that compensation is sometimes regarded as conceptually separate from the sort of protections that IRB review is meant to provide.[7]

Many practical obstacles that have frustrated previous attempts to implement a coherent national compensation scheme might make IRBs reluctant to require that researchers implement one on their own. I do not intend to address the familiar practical challenges of implementing such compensation programs. Instead, I will identify a theoretical problem that underlies many of the relevant ethical arguments for mandatory compensation. Identifying the problem will at the very least help us to establish (1) the justification for claiming that compensation plans should be an ethical requirement of risky human-subjects research, (2) the scope of such requirements, and (3) who is responsible for discharging these requirements. Even if this analysis does not resolve the practical difficulties, we at least will be better prepared to address them seriously in a scientific and political context in which no socially mandated policy exists. Crucially, a new justification for broad injury-compensation plans may overcome the practical challenges of implementation where existing arguments have failed. Examining the range of moral arguments also may help clarify the rationale behind compensation schemes in other countries, as there is no consensus on what is owed, to whom, and why.[8]

Because researchers have a moral responsibility to ensure research-related injury compensation, IRBs generally ought to require compensation plans as a condition of trial approval, even when there are no preexisting compensation programs in place. This should be no different from the routine requirements to inform research participants about risks, alternatives, and, plans for data management. It will be helpful to begin with a brief overview of the minimum ethical standards that are necessary although not sufficient for participant protections. These standards will inform our examination of the general principles and commonsense intuitions that motivate the calls for compensation policies and programs in the United States. I shall then attempt to show why the existing arguments based on these principles conflict with the minimum ethical standards. Drawing on the distinction between the "mere costs" and the "moral costs" of research, I argue that focusing on the principle of respect

6. Resnik, "Compensation for Research-Related Injuries"; and Parasidis, "Compensation for Research-Related Injuries."

7. For the claim that compensation for injury is "additional" to the sorts of protections aimed at by IRB review, see Presidential Commission for the Study of Bioethical Issues, *Compensation Background* (Washington, DC: PCSBI, 2015), 5.

8. See European Forum for Good Clinical Practice, *The EFGCP Report on the Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe and Beyond: Question 31*, April 2012, http://www.efgcp.eu/; and Robert Steinbrook, "Compensation for Injured Research Subjects," *New England Journal of Medicine* 354.18 (May 4, 2006): 1871–1873, doi: 10.1056/NEJMp068080.

for persons can align current opinions on researcher duties with the ethical requirements for participant protections.

The Minimum Threshold for Participant Protections

At minimum, IRBs must ensure that research plans are consistent with the guidelines set out in federal policy for the protection of human subjects, known as the Common Rule.[9] The specific requirements of the Common Rule are based on three ethical principles governing human-subjects research as identified in the *Belmont Report*: respect for persons, beneficence, and justice.[10] Without claiming that it is the only relevant general standard, we can recognize an uncontroversial, commonsense minimum threshold principle that can serve as a heuristic for judging whether research participants are *not* being provided adequate protections. The general principle, which can be called the protectionist principle, states that participants should not be worse off for participating in research than they would have been had they not participated in that research.

Because the protectionist principle is a minimum threshold, to assert that IRBs should apply it as a standard is not to deny that there may be other, higher ethical standards for research. There most certainly are. But the principle is useful because it identifies at least one point at which participants are no longer satisfactorily protected. Given that IRBs exist to protect research subjects from unethical practices, in normal circumstances they should not approve any research proposal until they are satisfied that it meets the requirements of the protectionist principle.

Most clearly, this principle involves beneficence, which the *Belmont Report* understands as a dual requirement to "(1) do not harm and (2) maximize possible benefits and minimize possible harms."[11] Although the protectionist principle may not be a sufficient condition of beneficence, it is clearly implausible to maintain that patient protections satisfy the ethical demands of beneficence when subjects are worse off than they would have been had they not enrolled.

The protectionist principle also indirectly involves aspects of respect for persons and justice. Subjects who are coerced, manipulated, discriminated against, or socially or economically disadvantaged as a result of their participation can obviously claim to be worse off than had they not participated, even if their health or overall physical well-being was not reduced.

The Standard Moral Arguments

As mentioned, despite the lack of progress in establishing research-related injury compensation protections, there is a long history of attempts to work out the ethical justification for such programs. In 1976, James Childress set out a basic framework

9. Protection of Human Subjects, 45 C.F.R. part 46, subpart A (2009).

10. National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, *The Belmont Report* (Bethesda, MD: The Commission, 1979), part B, https://www.hhs.gov/.

11. Ibid., part B(2).

that is helpful when discussing almost all subsequent treatments of the topic.[12] He identifies three general approaches: the humanitarian approach, the beneficence approach, and the compensatory justice approach. The differences between them are illustrated by their divergent interpretations of the protectionist principle.

The humanitarian approach focuses on the significant needs of injured research subjects,[13] which warrant an ethical response to compensate the injured party. According to critics like Childress, however, the main problem with the humanitarian approach is that humanitarian concerns generate, at best, only imperfect duties. These differ from perfect duties, which must be fulfilled in all circumstances, because they admit of exceptions or allow for considerable freedom in determining when or how they are to be discharged. In the words of a 1977 report from the US Department of Health, Education, and Welfare, "However laudatory, [humanitarianism] remains morally optional."[14] Since the humanitarian approach merely establishes that it is a morally good thing to address human needs, it can motivate but not obligate anyone to compensate an injured research subject—that is, the "should" in "should not be worse off" indicates only a desirable ideal rather than a moral obligation. Understood in this way, the protectionist principle no longer functions as a minimum threshold for judging the moral adequacy of participant protections, since the humanitarian can agree with the moral sentiment of the protectionist principle without expecting that any protections will ever be actually provided. Such an interpretation is inconsistent with both the principles in the *Belmont Report* and the commonsense intuition that it is not only good but morally necessary to protect research participants.

Given the inadequacy of the humanitarian approach, most discussions focus on Childress's remaining two alternatives, often attempting to assert them simultaneously. The first is the beneficence approach, which like the humanitarian approach begins with the needs of the injured research participant. Childress immediately rejects beneficence for the same reason he rejects humanitarianism. Indeed, he makes little effort to distinguish between the two because in both instances, "we have a less stringent duty to do good for others apart from special relationships such as parent–child and physician–patient."[15] Conspicuously, this criticism ignores the fact that ethicists commonly recognize a special relationship between researcher and research participant that is analogous but not identical to the relationship between physician and patient. If such a relationship exists in the research context, it could, contra Childress, generate special perfect duties to do good and avoid harm similar to those Childress recognizes in the physician–patient relationship. If the beneficence approach is understood in terms of a special or professional relationship, it is possible to identify grounds for a perfect duty to ensure that participants are not made worse off by taking part in research. Therefore, when the necessary risks involved

12. James F. Childress, "Compensating Injured Research Subjects: I. The Moral Argument," *Hastings Center Report* 6.6 (December 1976): 21–27, doi: 10.2307/3561144.

13. For this approach, Childress draws on Clark C. Havighurst, "Compensating Persons Injured in Human Experimentation," *Science* 169.3941 (July 1970): 153–157.

14. Task Force on Compensation, *Report*, VI.4.

15. Childress, "Compensating Injured Research Subjects," 22.

in research result in injury, professional beneficence can require researchers to compensate participants for those injuries.

While it seems like the beneficence approach could justify mandatory compensation plans, it does not adequately interpret "worse off for participating in research." Since the justification for a strict obligation depends on the researcher–participant relationship, the scope of this professional duty falls short of the threshold intended by a commonsense reading of the protectionist principle. First, since the perfect duty is generated by the professional relationship, it is generally limited to what the researcher owes the participant qua research participant alone. In catastrophic research injuries that result in the death of the participant, there would be no resultant duty to compensate the participant's family.[16] Yet it is simply implausible to claim that a deceased participant whose children are no longer provided for is not made relevantly worse off by that fact.

Second, the beneficence approach limits the scope of the protectionist principle by narrowly defining the kinds of compensation that may be required. Since the perfect duties are tied to the researcher–participant relationship in this view, the content of those duties is defined by the researcher's professional role. Therefore, beneficence-based compensation programs generally require only that researchers provide what is within their professional competencies—usually, immediate medical care and little or nothing else.[17] Compensation for pain and suffering, lost wages, and long-term care are generally not considered to be the sort of needs that underpin a perfect professional duty to compensate. Researchers who choose to compensate for these things can be commended for doing so on humanitarian grounds, but they cannot be required to do so on professional grounds. Consequently, IRBs would have no reason to reject proposals merely because they do not include guarantees of broad compensation.

The idea that the intuitions behind the protectionist principle imply a broad understanding of a perfect duty to compensate supports the third and most widely held view regarding the moral justification for mandatory research-related injury compensation—the compensatory justice approach.

Rather than focusing on the needs of injured parties, compensatory justice aims to fairly distribute the benefits and burdens that result from socially sanctioned risky activities that pursue some social good. According to this line of thought, participants are positively owed care and financial compensation in the event of injury because the important good of clinical research could not be achieved without exposing them to potential risks. Therefore, while the compensatory justice approach agrees with professional beneficence that the duty to provide compensation is a stringent, perfect duty, it goes further by recognizing that many ethically relevant harms may fall outside the researcher–participant relationship.

16. See, for instance, Leslie Meltzer Henry, "Moral Gridlock: Conceptual Barriers to No-Fault Compensation for Injured Research Subjects," *Journal of Law, Medicine and Ethics* 41.2 (June 2013): 411–423, doi: 10.1111/jlme.12052.

17. Ibid., 416.

In addition, the compensatory justice approach can explain why the tort system in the United States clearly does not adequately redress broadly construed research-related injuries, even if successful litigation were easier than it currently is. Because compensatory justice focuses on the duty owed to those who accept necessary risks in pursuit of important social goods, it assigns responsibility for redressing harm primarily on the basis of the distribution of burdens, risks, and their consequences rather than on the basis of who caused those burdens. This explains why care and compensation are not forgone merely because an individual has voluntarily accepted a risk.

Compare this with a libertarian conception of justice, in which a person is owed nothing morally, provided that he or she is fully informed of and freely accepts the risks involved in some activity. The libertarian, therefore, understands the responsibility for inequalities that result from individuals' choices in terms of the processes by which the inequalities emerge rather than the resulting end states or patterns of distribution that result from those processes or the history of those patterns.[18]

The grounds for the libertarian emphasis on the processes that cause inequality and the resulting account of the relationships between consent, risk, and responsibility are readily observable in the domain of financial investment. If I voluntarily and with sufficient understanding make a risky investment, I am responsible for bearing whatever injury or loss I may suffer, unless I am the victim of specific wrongdoing. Similarly, I may rightfully and exclusively enjoy whatever benefits might result from my voluntary risk-taking. The fact that I may suffer more than others as a result of accepting a risk in pursuit of my own good is not in itself morally problematic and does not justify a claim for compensation. In common law, this is known as *volenti non fit injuria* (to a willing person, no injury is done). However, since medical research is a socially sanctioned activity in pursuit of an important social good, assessments of its outcomes must differ from assessments regarding personal financial risk-taking, since the fairness of the patterns of unequal burdens that result from risk-taking is no longer bound by the participant's evaluation and acceptance of the potential benefits and risks. The fact that the socially sanctioned activity places the participant at risk for the benefit of others makes the resulting distributive patterns or end states relevant, even when the risks are voluntarily assumed. Therefore, *volenti non fit injuria* does not adequately determine responsibility in the context of activities like biomedical research.

The Paradox of Protectionism

At this point, we can see that the compensatory justice approach captures two relevant and important features of the protectionist principle that the previously discussed approaches fail to address adequately, namely, the obligation to protect participants and the broad scope of those protections. Like the beneficence approach, the compensatory justice approach captures the obligatory quality of the protectionist principle because it is justified by the justice-based demand that the burdens of

18. Robert Nozick, *Anarchy, State, and Utopia* (New York: Basic Books, 1974).

socially valuable research be fairly distributed. Because it is based on the distribution of burdens, it allows for an equally commonsense understanding of the ways in which research participation can make participants worse off. Consequently, like the humanitarian approach, it is not necessarily restricted to interpreting morally appropriate responses in terms of the narrow professional role of the researcher.

However, it is important to note that, unlike the perfect duties recognized in the beneficence approach, the subject of the broad perfect duties—the party responsible for discharging the duties—is not the researcher but society, since the value of the social good or the social sanction to pursue that good, not the professional relationship, generates the relevant moral duty. Hence, the ability to account for the stringent and wide scope of a duty to compensate is purchased by denying that the researchers are themselves subjects of that duty. Herein lies the paradox at the heart of mandatory compensation plans. The closer we get to a commonsense understanding of the minimum threshold for adequate participant protections, the less we are able to demand of the researchers engaged in that activity, whereas if we focus on what researchers themselves are professionally obligated to provide by way of protections for injured participants, we apparently must deemphasize the commonsense demand that participants are genuinely not to be made worse off. Given the broad support for the compensatory justice approach, it is little wonder then that IRBs do not routinely require a guarantee of broad compensation.

One might think that this paradox can be resolved if society discharges its duties simply by demanding that researchers guarantee compensation to injured research participants. In a society that has already established a national compensation scheme, providing that guarantee would not be problematic, because researchers would be required to do little more than inform participants of the scheme, which would already be required under current informed consent guidelines. In the current social and political reality in the United States, however, this kind of unproblematic guarantee is not available.

In the absence of a socially guaranteed compensation scheme, it appears that defenders of the compensatory justice approach can resolve the paradox only by requiring researchers themselves to provide the compensation programs. However, this requirement is difficult to justify in the context of compensatory justice. Obviously, the fact that X is owed A does not entail that some specific Y has the duty to give A to X. To say that some particular agent or institution ought to give X what is owed requires a justification for the claim that this particular agent or institution is the appropriate subject of the duty. The salient question, then, is why, when the compensatory justice approach recognizes society's obligations to research participants, should researchers, their sponsors, or their institutions be expected to bear the costs of discharging a duty that is not properly theirs alone? Without a justified answer to this question, IRBs cannot demand that research proposals include a broad compensation plan.

In defending the claim that the compensatory justice approach can justify researchers' duty to provide compensation, some have looked to the benefits derived by the research community from risky trials. For example, a 2001 report from the National Bioethics Advisory Commission argues that researchers can be expected to discharge society's duty to compensate subjects for research-related injuries: First,

researchers are "most likely to profit or derive other benefits" from the research activity. Second, the research community can serve as a type of conduit for discharging the social duty by internalizing the costs of compensation programs and passing them on to those patients and consumers who benefit from bringing the products to market.[19] Thus, according to the NBAC report, it is acceptable on compensatory grounds to hold the researchers responsible for discharging this duty when it is not ensured by society in general.

This argument, however, fails for reasons already discussed. Even if a drug company significantly benefits from research, there is no reason to think that the company is benefiting from an unjust distribution of burdens and is thus subject to a duty to compensate, so long as participants have given their informed consent to accepting the risks. When mere patterns of inequality arise from research, injured participants who have accepted the risk–benefit ratio do not have cause to seek compensation from particular parties that benefit from that inequality, except through a reparative system and only when the injury is the result of some additional wrongdoing. On the other hand, if the distribution of burdens is the important element, then claims of compensatory justice are appropriate, and compensation may be owed for injury regardless of wrongdoing. But there still is no more reason to identify the researcher as the subject of a specific duty to provide compensation than there is to hold weapons manufacturers solely responsible for compensating military veterans injured during their service simply because the manufacturers may have profited enormously and can pass on the costs of compensation through higher prices. One cannot create a moral duty, especially such a potentially burdensome one, for a particular agent merely because it is a convenient solution when those who *actually* have the duty lack the will or desire to act on it.

Moreover, passing on the costs of compensation through higher market prices merely shifts the costs of compensation from the researchers to the patients who purchase the products. But there is no reason to suppose that these individuals are any more responsible for discharging the social duty to provide compensation than is the research community, despite the fact that they, too, benefit tremendously from the research. Such a solution would be akin to expecting the owners of a house that has caught fire to compensate the fire fighters who were injured in extinguishing it, simply because the homeowners stood to benefit most directly and extensively from the risky activity that resulted in the injury. To justify shifting the cost to any particular group, whether it be researchers or patients, one must explain why that group ought to bear the costs of socially valuable but risky activity. Neither the ability to internalize cost nor the magnitude of direct benefit provides an explanation that is consistent with compensatory justice.

Consequently, recognizing this paradox provides even stronger reasons for establishing a coherent national compensation scheme. Since the demands of

19. National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants*, vol. 1, *Report and Recommendations* (Bethesda, MD: NBAC, 2001), 125–126.

compensatory justice cannot be met ethically unless society ensures that injured research participants are compensated, the compensatory justice approach provides a strong justification for policy change at the national level. However, if that is all we can say, then it would appear that IRBs cannot require compensation plans prior to a policy change, since as we have seen, we cannot specify any responsibility on the part of the researcher to ensure compensation on the basis of compensatory justice. And it would be inconsistent to insist that researchers—or patients through higher market costs—should bear this burden merely because it provides a convenient solution to the sociopolitical problem. But holding that IRBs should approve research that lacks any guarantee of compensation for research-related injuries flies in the face of the ethical protectionism that IRB review is designed to ensure. Moreover, accepting that the most we can provide is an argument supporting the call for social change would miss an important implication of this paradox.

Like all paradoxes, however, this one emerges because of a conceptual problem in how we think about the issues involved. Recognizing this possibility should motivate us to at least reconsider the typical framework of the discussion, especially when decades of standard thinking have led to little actual progress in establishing important protections.

Mere Costs and Moral Costs of Research

The paradox of requirements for research-related injury compensation results from trying to understand the commonsense minimum threshold identified by the protectionist principle in terms of humanitarianism, beneficence, or compensatory justice alone. The remaining Belmont principle, respect for persons, is commonly not considered to be a central feature of this debate, except insofar as it supports the existing Common Rule requirement that participants be informed of whether compensation schemes already exist. Occasionally, commentators will mention in passing that compensation is one way in which we might respect participants, but there is as yet no well-developed explanation of how respect for persons might function as the principal moral justification for mandatory compensation.

To see how respect for persons might provide such a moral justification while avoiding the paradox, we can begin by recalling what makes the protectionist principle necessary and significant in the first place. Were biomedical research not both important and risky, we would not need to insist on IRB review to ensure that participants are protected. If biomedical research were important but not risky, we could and should pursue it without the need for full IRB oversight. And if research were risky but unimportant, it would not be warranted and should not be conducted at all.

The fact that research is warranted, even when it could injure participants, demonstrates the uncontroversial fact that "unavoidable injury to a few is the 'cost' of engaging in research which ultimately benefits the many."[20] It is reasonable to conclude that the existence of such costs requires us to (1) minimize and mitigate those costs (beneficence) and (2) distribute them fairly (justice). But neither beneficence- nor

20. Tuskegee Syphilis Study Panel*, Final Report*, 37.

justice-based approaches say much about how we are to understand the costs themselves. The prevailing opinion seems to be that injury is, of course, a regrettable cost of pursuing the important goods of research. It is also an unavoidable cost. Those are the brute facts. How we respond morally to those brute facts is the important and the only question. However, this misses the fact that our understanding of the costs themselves matters if we are to identify how we ought to respond morally to them.

We might call some costs "simple," or "mere costs," for example, the market price of some good or service. Mere costs may also be incurred by forgoing some good to pursue a desired end, for example, opportunity costs, or by accepting some other type of harm, burden, or loss as the necessary means or by-product of pursuing an end, for example, the time and discomfort involved in a dental procedure.

Therefore, mere costs are real costs, and they may be necessary and significant costs of important goods. The essential aspect of mere costs, for the purpose of their analysis, is that we choose to accept or reject them solely on the basis of their value relative to the good for which they are the cost. For example, while we may not be happy about the high market price of living in the neighborhood of our choosing, if the value of living there exceeds the mere cost of doing so, then it would be rational to accept that cost. Moreover, doing so should not engender any regret with respect to either our evaluation of the cost or the resultant decision to act. If the opportunity costs of enjoying a movie when I have papers to grade is greater than the value I place on seeing the movie, it would be irrational or akratic to go to the movie instead of finishing my work. This is, of course, because mere costs are recognizable as acceptable losses, because they are judged in relation to the value of some greater good being pursued.

It is important to note that a course of action that involves mere costs can also generate moral requirements, especially when a third party is directly affected by those costs. When mere costs are serious, morality requires that those losses ought to be minimized to ensure the best possible ratio of benefits and harms and the fair distribution of those losses and the goods that result from them. Again, beneficence and justice are therefore relevant when considering how we think about mere costs.

But are there costs that are not mere costs? If there are, then the significance or evaluation of those losses might not be fully explicated in terms of their relation to the value of the desired good and the fair distribution of losses and gains. If some costs cannot be understood entirely in these terms, then it is possible that the moral responses to those losses might require more than just the voluntary, rational acceptance of benefits and the fair distribution of minimized burdens.

The main alternative to mere costs is what Bernard Williams calls moral costs.[21] Moral costs are the same kind of losses as mere costs, and they are justified in the same way. For Williams, I incur a moral cost because the loss involved is rationally acceptable from an all-things-considered perspective. However, the considerations that warrant this acceptance do not preclude me from experiencing justified moral

21. Bernard Williams, "Politics and Moral Character," in *Moral Luck* (Cambridge, UK: Cambridge University Press, 1981): 54–70.

regret. I may not like the fact that grading papers precludes me from seeing a movie with my friends tonight, and I may regret missing the event, but that is not a moral regret. My choice to grade papers does not involve doing some wrong, precisely because the losses involved are offset by the relevant gains. However, moral costs are not automatically offset by the gains even if they are justifiable. Therefore, I still rightfully recognize that my action involves some wrongdoing even though I had good reason to engage in it. Consequently, I can regret the costs incurred for what I regard as a justified course of action.

Moral costs are most clearly seen in tragic cases and moral dilemmas. Moral dilemmas are situations in which whatever the agent does, he or she does something which is morally wrong. Jean-Paul Sartre describes the famous example of his student who was forced to choose between caring for his mother and fighting in the resistance.[22] Whichever he chooses, he could be criticized for neglecting the other. Genuine moral dilemmas, if they exist, are significant, then, because they illustrate the controversial possibility that there are cases in which there may not be an overall morally right thing to do. Because dilemmas involve two morally equivalent but conflicting actions, we incur the moral cost of forgoing or violating the alternative requirement, regardless of which requirement we satisfy. So long as the dilemma exists, that cost cannot be fully offset by the gains made.

Moral costs, therefore, can be present whether or not there is a recognized all-things-considered right course of action. These costs are significant, because they suggest that there is something wrong with at least two predominant ways of thinking about moral deliberation. The first is the idea that the right course of action maximizes the overall best outcome. For Williams, this idea is exemplified by utilitarianism. In such a view, it may be necessary to violate an individual's rights or to injure that individual to promote the greatest utility. Although this is unfortunate, the necessity of doing so is all that counts from the moral perspective. The utilitarian recognizes that doing anything, including the right thing, involves costs. But such costs cannot be seen as moral costs. Instead, they are mere costs—simply the price we pay for what ought to be achieved or pursued. Thus, on any maximizing conception of morality, there is nothing morally disagreeable about any costs incurred in acting as one ought to act. The losses incurred in maximizing the good are the same sort as those incurred in the purchase of some good at its market price. The loss may be dear, but it would not be rational to regret it from a moral point of view. If moral costs exist, then, there is something deeply inadequate about such maximizing conceptions of morality, since they rule out the possibility of rational but morally regrettable costs.

The second view is Rossian pluralism, which has had a tremendous influence on the development of principlism.[23] According to Rossian pluralism, there are many fundamental moral values or principles that ought to guide moral deliberation. However, while these principles are fundamental, they are also prima facie—that is, in any particular case, they can be overridden by another principle or set of principles.

22. See Jean-Paul Sartre, "Existentialism Is a Humanism," in *Existentialism from Dostoevsky to Sartre*, ed. Walter Kaufman (New York: Penguin, 1975), 345–369.

23. See W. D. Ross, *The Foundations of Ethics* (Oxford: Oxford University Press, 1939).

For example, while beneficence is clearly a fundamental principle that ought to guide ethical thinking in medical practice, Rossian pluralism holds that there may be concrete cases in which another principle, such as autonomy or justice, overrides it. In such cases, features which were salient with regard to the overridden principle no longer carry decisive moral weight all things considered, so there is no conceptual room for the experience of moral regret for having done something which, all things considered, is morally obligatory.[24]

While not a maximizing conception, Rossian pluralism is challenged by the experience of genuine moral regret. For Rossian pluralists and principlists, there is no longer a good reason to regret disregarding a value once it has been superseded.[25] For example, a physician fully committed to beneficence ought to strive to do good to and avoid harming his patients. For the Rossian pluralist, however, the physician nevertheless does no wrong by withholding medically necessary treatment at the request of a competent patient with a well-informed and carefully considered wish to terminate that treatment—provided that there are no additional consideration that might in turn defeat the principle of respect for autonomy. Although this might be psychologically difficult for the physician, since autonomy supersedes the prima facie principle of beneficence in this case, it simply would be inappropriate to experience genuine moral regret. In other words, it would be wrong to accuse the physician of violating his commitment to beneficence, because strictly speaking, that principle is not operative here at all.

Therefore, moral costs are not recognizable in the utilitarian or pluralist frameworks. However, Williams acknowledges that incurring moral costs is a common feature of genuine moral experience. Virtuous agents do not and should not dismiss the harms done to innocent victims simply because a commitment to avoiding the harms conflicts with an overriding principle in the concrete context. Martha Nussbaum

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24. Ross writes, "But while we might agree that the same act may be in some respects right and in others wrong, we do not suppose that the same act can be in fact right on the whole and wrong on the whole. To think this would be to put an end to all ethical judgment." Ibid., 60. Immanuel Kant expresses a similar idea, translating principles to duties or obligations: "Since … duty and obligation are in general concepts that express the objective practical necessity of certain actions and because two mutually opposing rules cannot be necessary at the same time, then, if it is a duty to act according to one of them, then it is not only not a duty but contrary to duty to act according to the other. It follows, therefore, that a conflict of duties and obligations is inconceivable." Immanuel Kant, *Metaphysical Elements of Justice*, trans. John Ladd, 2nd ed. (Indianapolis, IN: Hackett, 1999), 17.

25. It is possible to conceive of principlism, as Beauchamp and Childress claim they do, as allowing for the possibility of moral dilemmas when incommensurable values or incompatible principles conflict. See Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 5th ed. (Oxford: Oxford University Press, 2001), 11–12. As Joseph DeMarco points out, versions of principlism that allow for genuine moral dilemmas will recognize "moral residue" and thus moral regret. J. P. DeMarco, "Principlism and Moral Dilemmas: A New Principle," *Journal of Medical Ethics* 31.2 (February 2005): 101–105, doi: 10.1136/jme.2004.007856. A principlism that does genuinely recognize the possibility of moral regret would also be consistent with the position defended below that the costs of research cannot be understood as mere costs.

observes that claiming otherwise "makes morality the handmaiden of fortune." To say that defeated obligations never incur moral costs results in an "unacceptable picture of the moral agent, as lacking principled commitments, as able to improvise his moral identity freely at any time." This leads to a view of personal responsibility "in which we boldly take credit for choices that we make, undeterred by remorse for the wrong that we thereby have done."[26] For Nussbaum, this is not just incompatible with the facts of moral experience. It is a dangerous conception of responsibility when held by those charged with the pursuit and care of important social goods. Such a conception of responsibility fosters a character that is insensitive to the morally salient features of particular circumstances and thus is untroubled by the morally regrettable cost of important decisions and activities.

What would it mean, then, to regard research-related injuries as moral costs, not mere costs? First, the social good of research may warrant risky trials. Second, the value of the social goods does not nullify the moral significance of the injury suffered by a particular individual for the benefit of others. In other words, the good of research can justify risky human-subjects trials without fully excusing the researcher's responsibility for engaging in an activity that he or she knows could injure innocent participants. This is paradoxical according to the standard approaches, because they lack the resources to separate the costs of an activity from its justification and desired outcome. And as Nussbaum's argument suggests, to think that the importance of research morally justifies its inevitable costs has potentially dangerous consequences, because the operative and internalized conception of responsibility obscures the range of salient moral considerations across the entire professional context.

Consider, for example, the following case discussed by Gerald Postema, in which a truck driver, through no fault of his own, hits and seriously injures a child. Postema agrees that, from an impartial or all-things-considered perspective, "it may be correct to say that, since he drove with care and could not have avoided hitting the child, the driver is guilty of no wrong and thus is not blameworthy."[27] Unlike the moral dilemmas that Nussbaum discusses, this case does not necessarily involve the moral opportunity cost of forgoing some obligation for the sake of another conflicting one. However, Postema points out that there still seems to be something morally problematic about this assessment of personal responsibility, even if it is morally correct. A spectator observing things from something like an impartial perspective

> may offer help, or contribute money for hospital bills, or even visit the child, but these actions would be understood (by him and by us) as expressions of pity, kindly concern, or perhaps generosity. From the driver, these same actions would be intended and understood as expressions of a special form of regret. Suppose, however, that the driver takes the attitude of the uninvolved spectator … feeling no need to make restitution. He can rightly argue that he was not to be blamed for the accident, that he had done no wrong. In doing so, he could

26. Martha C. Nussbaum, "The Costs of Tragedy: Some Moral Limits of Cost–Benefit Analysis," *Journal of Legal Studies* 29.2 (June 2000): 1010, doi: 10.1086/468103.

27. Gerald J. Postema, "Moral Responsibility in Professional Ethics," *New York University Law Review* 55.1 (April 1980): 68–69.

> perhaps be rightly said to have gotten his moral sums right. But … he would reveal a defect of character—a defect much deeper and more serious than a lack of generosity.[28]

The driver is unable to recognize the moral costs of his actions because he confuses the impartial all-things-considered perspective with the moral perspective. Certainly, the impartial perspective is a moral one, and it may often be quite appropriate when determining what ought to be done. However, as Postema concludes, "morality is not merely a matter of getting things right—as in solving a puzzle or learning to speak grammatically—but a matter of relating to people in a special and specifically human way."[29]

Forms of moral deliberation that deny moral costs undermine the ability to relate to people in this "special and specifically human way." Instead, they encourage us to think that people have claims on us only insofar as we can be held blameworthy from the all-things-considered perspective, for example, when we have not received informed consent, have failed to work hard enough to minimize the risks, do not fairly distribute the relevant benefits and burdens, or act with malice or negligence. But if one cannot be held accountable in these terms, then any harm or injury that persons suffer amounts only to a mere cost of doing what is correctly considered the right thing. We arrive, then, at the same problematic and dangerous conception of moral responsibility that is implied by the denial of moral costs in dilemmatic situations—a conception of responsibility which allows us to calculate the rightness of our actions without any regard for the ways in which they relate to and affect others. And we arrive here simply because the existing models of moral deliberation do not evaluate costs apart from their relation to the value of the ends we pursue.

Compensating individuals for the injuries or wrongs we commit while doing what is justified or reasonable overall is one way in which we recognize that other people have a special moral value for us that cannot be reduced, overridden, or defeated by any additional value or good we pursue. The commitment to compensate for any unforeseen and unavoidable injury that may follow directly from medical research is consequently an important component of the respect owed to research participants. It acknowledges that researchers are responsible for their choices that affect others, especially where they have good reasons and social sanction. Guaranteeing compensation also affirms that the value of the research participant's experience cannot be understood merely in relation to the contribution that it makes to the benefit of others. In short, respecting the personhood and dignity of the research participant entails that we cannot regard his or her negative experiences as the mere costs of doing research. Although it is necessary to receive their consent for participation because this maximizes the benefits, minimizes the risks, and fairly distributes burdens and benefits, this understanding of costs does not adequately account for the full range of costs associated with risky human-subjects research.

28. Ibid., 69.
29. Ibid., 70.

Researcher Responsibility and IRB Requirements

In short, research participants may experience injuries that cannot be avoided if important social goods are to be achieved. Researcher responsibility for these experiences cannot be morally evaluated solely on the basis of the value of the research in itself or for others without violating a requirement to respect the personhood and dignity of participants. Researchers who refuse to recognize their responsibility and consequently do not attempt to ensure that participants are compensated in the case of research-related injuries cannot claim to meet the commonsense minimum threshold, which requires that participants are never made worse off because of their participation. Given that IRBs should not approve research that fails to satisfy this minimum threshold, they are professionally and ethically obligated to require broad compensation plans as a condition for the approval of any human-subjects research that is classified as more than minimal risk, regardless of whether institutional or legally mandated compensation plans are in place.