

AGAINST RISK-BENEFIT REVIEW OF PRISONER RESEARCH

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ABSTRACT

The 2006 Institute of Medicine (IOM) report, 'Ethical Considerations for Research Involving Prisoners', recommended five main changes to current US Common Rule regulations on prisoner research. Their third recommendation was to shift from a category-based to a risk-benefit approach to research review, similar to current guidelines on pediatric research. However, prisoners are not children, so risk-benefit constraints on prisoner research must be justified in a different way from those on pediatric research. In this paper I argue that additional risk-benefit constraints on prisoner research are unnecessary: the current Common Rule regulations, omitting category-based restrictions but conjoined with the IOM report's other four main recommendations, ensure that prisoner research is as ethical as non-prisoner research is. I explain why four problems which may be more prevalent in prisons and which risk-benefit constraints may seem to address – coercion, undue inducements, exploitation, and protection from harm – are in fact not solved by adding further risk-benefit constraints on prisoner research.

1. INTRODUCTION

The 2006 Institute of Medicine (IOM) report, 'Ethical Considerations for Research Involving Prisoners', recommended five main changes to current US regulations on prisoner research:

1. expand the definition of 'prisoner';
2. ensure universally and consistently applied standards of protection;
3. shift from a category-based to a risk-benefit approach to research review;
4. update the ethical framework to include collaborative responsibility; and
5. enhance systematic oversight of research involving prisoners.¹

Current regulations on US human subjects research are encapsulated in the Code of Federal Regulations Title 45,

Part 46, commonly called the Common Rule.² Subpart A of the Common Rule articulates two major requirements for all human subjects research: (1) universal oversight implemented via institutional review boards (IRBs) and (2) informed consent. Subparts B, C, and D articulate further requirements for research with various vulnerable populations: B for pregnant women, fetuses, and neonates, C for prisoners, and D for children.

The portion of subpart C relevant to this paper requires that prisoner research focus on either (a) incarceration or criminal behavior, (b) prisons, or (c)

² Code of Federal Regulations. 2005. Title 45: Public Welfare, Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks, Part 46 *Protection of Human Subjects*. Bethesda, MD. Available at: <http://ohsr.od.nih.gov/guidelines/45cfr46.html> [Accessed 22 Mar 2008]. The Common Rule does not bind certain forms of privately funded research; its main jurisdiction is over federally funded research. This caveat is the focus of the IOM report's second main recommendation, but nothing I say in this paper will turn on this issue, so I ignore it. Also, I obviously ignore regulations on prisoner research in other countries, on which see B.S. Elger. Research Involving Prisoners: Consensus and Controversies in International and European Regulations. *Bioethics* 2008; 22: 224–238.

¹ L.O. Gostin, C. Vanchieri & A. Pope, eds. 2006. *Ethical Considerations for Research Involving Prisoners*. Washington, DC: National Academy Press.

conditions affecting prisoners, or else must (d) benefit its subjects.³ The IOM report argues that such category-based constraints are inadequate, because they are too subject to interpretation and do not address actual prisoner vulnerabilities.⁴ For the purposes of this paper, I will assume that the IOM report is right on this score. The IOM report then suggests, as its third main recommendation, that we replace category-based constraints with risk-benefit constraints. I will argue, in contrast, that additional risk-benefit constraints on prisoner research are unnecessary: the current Common Rule regulations, omitting category-based restrictions but conjoined with the IOM report's other four main recommendations, ensure that prisoner research is as ethical as non-prisoner research is.⁵

2. PRISONERS AND CHILDREN

It is telling that the IOM report makes an explicit analogy to subpart D of the Common Rule, which regulates pediatric research on the basis of risk-benefit constraints.⁶ The reason we need extra risk-benefit constraints on pediatric research is that children are not competent to give rational consent; thus, we must protect them by determining what is in their best interest. However, prisoners are not children; they are mostly adults who can make rational decisions about whether to participate in research. Of course some prisoners are minors, and others may be mentally incompetent. Risk-benefit constraints on research with these sub-populations will make sense for the same reason that they make sense for pediatric research, namely rational incompetence.

However, this concession still leaves untouched a broad swath of prisoners – the mentally competent adults. These prisoners can make rational choices about various matters that affect them. I am not the first person to insist on this claim. Carl Cohen argued for it forcefully 30 years ago, when the historical context was much more hostile towards prisoner research, due to then-recent research scandals.⁷ Indeed, even the IOM report

acknowledges that prisoners seem capable of making rational choices about research participation:

This committee visited one prison and one prison medical facility to discuss experimentation with current prisoners and peer educators. The prisoners actively expressed the desire to have access to research. They stated that they would feel they had a choice as to whether to participate and that they know their rights when it comes to study participation. The prisoners and peer educators at those sites also echoed the sentiment that prisoners possess sufficient autonomy to make informed decisions about whether to participate in a given study.⁸

Thus, risk-benefit review is a solution in search of a problem. It solves a ready and obvious problem in the context of pediatric research (and research with the mentally incompetent), but prisoners are not children. In the remainder of this paper, I will explain why four problems which may be more prevalent in prisons and which risk-benefit constraints may seem to address – coercion, undue inducements, exploitation, and protection from harm – are in fact not solved by adding further risk-benefit constraints on prisoner research.⁹

3. COERCION

While children are obviously not yet fully rational, prisoners are obviously not fully free to pursue their own ends. Of course, autonomy requires both rationality and freedom.¹⁰ Thus risk-benefit constraints might be appropriate to protect against lack of autonomy more generally, where children lack the rational capability part of it and prisoners, by definition, lack the freedom part. Prison life is highly regulated; prisoners have much less choice in how to live their lives than the rest of us do. Perhaps in such a coercive environment, prisoners cannot

many of the same points he did – his argument incorrectly describes all concerns about prisoner research as concerns about coercion. The last thirty years has seen enormous progress in answering conceptual questions surrounding the related yet distinct areas of coercion, undue inducement, and exploitation. I draw on this recent literature in a way that Cohen could not.

⁸ Gostin et al., *op. cit.* note 1, p. 122.

⁹ It should be obvious that some problems faced especially by prisoners are not solved by risk-benefit constraints. Privacy concerns are an example. We do not say that, as long as its benefits outweigh its risks, research which runs roughshod over legitimate privacy concerns is still permissible. In the main body of the paper I will consider only problems which might seem especially amenable to risk-benefit-constraint-solutions.

¹⁰ Rebecca Kukla, for example, in a recent discussion of autonomy and its use in medical ethics, characterizes it as ‘. . . the ability to make and act upon free, informed decisions resulting from capable and uninfluenced deliberation’. R. Kukla. *Conscientious Autonomy: Displacing Decisions in Health Care. Hastings Cent Rep* 2005; 35: 34–44: 35.

³ Code of Federal Regulations, *op. cit.* note 2. Title 45: sec 46.306a2.

⁴ Gostin et al., *op. cit.* note 1. Another powerful reason to reject category-based restrictions on prisoner research is that they infringe on prisoner autonomy.

⁵ I focus my argument on the thesis that additional risk-benefit review is unnecessary. Of course, if I am right, then such constraints are also positively objectionable, because they preclude us from engaging in permissible research that respects autonomy and benefits prisoners, researchers, and society. I will touch on this point again briefly in section 6.

⁶ Gostin et al., *op. cit.* note 1. See Code of Federal Regulations, *op. cit.* note 2, for the full statement of risk-benefit restrictions on pediatric research.

⁷ C. Cohen. *Medical Experimentation on Prisoners. Perspect Biol Med* 1978; 21: 357–372. Though Cohen's argument is strong – indeed I make

freely choose whether to participate in research. This suggestion can be defended on a variety of grounds, but in the end none succeed.

One defense of the suggestion claims that people living in coercive prison environments are completely unfree. Of course, this is simply false if interpreted to mean that all their choices are made under duress. Prisoners can choose freely whether to sleep on their left or right sides, for example; they can choose which of several books in the library to read; and so on. Even though prisoners live in a very coercive context, so that many of their choices are subject to coercive interference, this does not mean that every choice they make is subject to coercive interference.

A much more plausible way to interpret the idea that prisoners are unfree is that in order for people to be free a significant range of options must be available to them. If, for example, prisoners face the same choice of the same two meals every day, then that reduces their freedom, even if they can choose between those two without interference at every meal. Prison life is so highly regulated, and prisoners have such a diminished range of daily options, that it may be accurate to say that they are completely unfree.

Unfortunately, even if this way of speaking is linguistically accurate, this sort of positive freedom – the having of a significant range of daily options rather than the mere negative absence of coercive interference – is irrelevant to our question, which is whether a prisoner's consent to participate in research is sufficiently informed and rational and free of interference to be valid. After all, a prisoner's consent to undergo a medical procedure can be valid, even if he lacks a significant range of options from which to choose in his daily life. The mere absence of significant options does not mean that we can thereby operate on prisoners without their consent (even with the consent of proxies), the way we might for mental incompetents or children. Further, if anything, giving prisoners the option to participate in research promotes their positive freedom, because it increases their range of daily options.

We must admit, then, that prisoners can make at least some free choices, and that these choices should be respected. A more plausible defense of the suggestion – that prisoners cannot freely choose to participate in research because of their coercive environment – admits that prisoners can make some uncoerced choices, but fears that the particular choice to participate in research will always be coerced. In other words, the worry is not merely that prisoners live in a coercive environment in general. Rather, the worry is that they might be coerced into research participation in particular.¹¹ After all, perhaps a hidden motive behind loosening restrictions on

¹¹ Of course there has been an enormous philosophical literature on coercion, but I will suppress reference to that literature, as none of what I say in what follows hangs on any controversial theses about the analysis of coercion. But for those who want an explicit definition, we

prisoner research is to allow researchers to coerce prisoners into participating. And, obviously, it is impermissible to coerce prisoners into participating in research.

Of course that is right. However, first, coercion is forbidden by subpart A of the Common Rule, which applies to research with all populations.¹² Indeed, it is safe to say that the Common Rule arose precisely (a) because of various research scandals, including scandals involving prisoner research,¹³ and (b) to guard against any similar such scandals in the future. Granted, it would be very bad if prisoner research returned to the immoral, coercive form it took before the end of the 1970s.¹⁴ Likewise, it would be very bad if prisoner research took a cue from more recent historical scandals involving prisoner abuse, such as the Abu Ghraib scandals circa 2004. But that is agreed on all sides – the point of the Common Rule is to ensure that this does not happen.

Second, and perhaps more importantly, risk-benefit constraints do nothing to alleviate these concerns about coercion anyway. Of course the question of whether prisoners are in fact coerced into participating in research is empirical, and it is also an empirical matter whether the government or public cares about such coercion. (Indeed, the Abu Ghraib scandal suggests that many prison officials do not, or at least did not, care about prisoner abuse.) But suppose, to make the case as difficult as possible, that prisoners are routinely coerced into research participation.¹⁵ Of course, that is unethical, even if prison

can say roughly that A coerces B to do X if and only if: A, in order to make B's doing X more attractive, credibly threatens B with some harm should B refrain from doing X, and B does X at least partly for to avoid this threatened harm. The seminal article is, of course: R. Nozick. 1969. Coercion. In *Philosophy, Science, and Method: Essays in Honor of Ernest Nagel*. S. Morgenbesser et al., eds. New York, NY: St. Martin's Press: 440–472. The most rigorous sustained book-length treatment is A. Wertheimer. 1989. *Coercion*. Princeton, NJ: Princeton U. Press. A useful recent encyclopedia article about coercion is S. Anderson. 2008. *Coercion*. The Stanford Encyclopedia of Philosophy (Fall 2008 edn). Available at: <http://plato.stanford.edu/archives/fall2008/entries/coercion/> [Accessed 21 Mar 2009].

¹² See Code of Federal Regulations, *op. cit.* note 2. Title 45: sec 46.116.

¹³ See H.K. Beecher. Ethics and Clinical Research. *N Engl J Med* 1966; 274: 1354–1360.

¹⁴ See A. Hornblum. 1999. *Acres of Skin: Human Experiments at Holmesburg Prison*. New York, NY: Routledge.

¹⁵ See, for example, National Commission for the Protection of Human Subjects and Biomedical and Behavioral Research. 1976. *Research Involving Prisoners: Report and Recommendations*. Bethesda, Maryland: DHEW Publication No. (OS) 76-13:12:

In the course of its investigations and review of evidence presented to it, the Commission did not find in prisons the conditions requisite for a sufficiently high degree of voluntariness and openness, notwithstanding that prisoners currently participating in research consider, in nearly all instances, that they do so voluntarily and want the research to continue.

Available at: http://www.bioethics.gov/reports/past_commissions/Research_involving_prisoners.pdf [Accessed 11 Sep 2009].

officials turn a blind eye. But we do not say that passing through a risk-benefit filter would thereby make it ethical to coerce prisoners into participating after all. No, if we are worried about coercion, the right response is not to ensure that at least the research passes risk-benefit review; rather, the right response is to ensure that the research is not coercive to begin with. This may require more stringent oversight for prisoner research than for typical research, which is the IOM report's fifth main recommendation, but adding a further risk-benefit constraint on prisoner research is not the same as taking more steps to ensure that the constraints we already have in place for all research are followed.

Now, perhaps my interlocutor will claim that, as a practical matter, it would be too difficult or costly to be able to discriminate with perfect specificity (conjoined with reasonable sensitivity) exactly who has consented freely; therefore, we can adopt risk-benefit review as a back-up filter.¹⁶ I have three responses to this suggestion. First, the objection I raised in the previous paragraph is still cogent: merely adding risk-benefit review should not make us feel any better about research done without free consent, even if we cannot identify which particular subjects consented under duress. In other words, a back-up risk-benefit filter merely distracts us from the ethical problem rather than solving it.

Second, this concern applies to non-prisoners as well as to prisoners. Prisoners are not the only people at risk of consenting under duress, so if we need a back-up risk-benefit filter we need it for all research. In fact, such a filter already exists. According to subpart A of the Common Rule, all studies are required to demonstrate that 'Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.'¹⁷

Of course, the IOM report recommends even more stringent risk-benefit review than is already specified in subpart A of the Common Rule, perhaps because coerced consent is more of a worry for prisoners than for non-prisoners. But this leads to the third point, which is that, in effect, the idea of using further risk-benefit review as yet another back-up filter just postpones rather than eliminates my initial criticism.¹⁸ The right response to this concern is not to design an even more stringent tertiary

risk-benefit filter just for prisoners. After all, we already have two filters in place for everyone: the primary filter of ensuring that consent is not coerced and a secondary risk-benefit filter, which also applies to everyone, as specified under subpart A of the Common Rule. Rather, the right response is to make sure that the first and second filters we already have in place, which are presumably adequate for typical research, also do their job when applied to prisoners. After all, even if prisoners incorrectly pass through the first, uncoerced consent filter more often than non-prisoners do, there is no reason to think they likewise incorrectly pass through the second risk-benefit filter more often as well. Equivalently, the concern that prisoners will incorrectly pass through the Common Rule's risk-benefit filter applies equally well to non-prisoners, and therefore is a reason to amend subpart A of the Common Rule, not a reason to add a tertiary, more stringent risk-benefit filter just for prisoners.

A slightly different yet related concern for my thesis is that even if researchers and prison officials have the best of intentions, still, the suspicion of duress can never be eliminated. Perhaps prisoners will be so suspicious of their captor's motives that they will almost always assume (wrongly yet perhaps justifiably) that they are required to participate, if only to avoid some implicit, unarticulated threat. According to this proposal, our original suggestion – that prisoners cannot freely choose to participate in research because prison environments are coercive – is strictly speaking false, but because prisoners will usually (and perhaps justifiably) harbor suspicions about the attitudes and motives of prison officials, they will typically think that they are choosing under duress even when they are not.

This is an empirical conjecture, for which we have no evidence. Indeed, the IOM report itself is skeptical about it, as evidenced in passage I quoted from that report earlier in section 2.¹⁹ Further, though the conjecture is empirical, it appears unfalsifiable. That is, someone who adamantly believes the conjecture may continue to do so no matter what evidence we attempt to present to the contrary. For example, even though prisoners might say that they recognize their rights and so forth, the conjecture can avoid refutation by insisting that the prisoners are saying that only out of fear of retribution. Given that our access to a prisoner's attitudes must be mediated through his behavior, it is always in principle possible for the prisoner to say the right things to appease regulators, yet harbor inner worries that remain unarticulated.

While we should be dubious of arguments that rely on unfalsifiable assumptions, there may be some truth to the concern that perhaps prisoners are often unreliable reporters of their own sense of security in their rights.

¹⁶ See F.G. Miller & A. Wertheimer. Facing Up to Paternalism in Research Ethics. *Hastings Cent Rep* 2007; 11: 24–34: 33.

¹⁷ Code of Federal Regulations, *op. cit.* note 2, Title 45: sec 46.111a2.

¹⁸ This third point is obviously related to my first one, but it is distinct. My first point was that risk-benefit filters do nothing to assuage concerns about coerced consent. This third point is independent because it is compatible with the falsehood of my first point. Even if risk-benefit filters assuage concerns about coerced consent, if we are worried that a given risk-benefit filter is not working, the proper response is not just to add on an additional, more stringent risk-benefit filter on top of the prior risk-benefit filter which is already in place.

¹⁹ Gostin et al., *op. cit.* note 1.

Even so, risk-benefit calculations do nothing to assuage this concern. Consider a study where the prisoner-subjects incorrectly think they will suffer some (wrongful) punishment if they decline to participate. Such a study is impermissible even if its risk-benefit ratio is acceptable. This is because in such a case the prisoner is, in an essential aspect, misinformed, and therefore his consent is invalid even on criteria applicable to non-prisoner research, as articulated in subpart A of the Common Rule.

Of course, as before, we might think that concerns about subject perceptions are especially poignant in cases where we conduct research with prisoners. But, as before, the right way to address this is with more oversight over the constraints we have already put in place, rather than in implementing further, *ad hoc* constraints such as risk-benefit review. Perhaps researchers and prison officials must make more of an effort to ensure, not only that the prisoners' decision whether to participate is not made under duress, but also that prisoners *know* that they are not under duress. This is the topic of the IOM report's fifth general recommendation, with which I have no quarrel.

4. UNDUE INDUCEMENTS

I have argued that the threat of coercion in prisoner research is not resolved by imposing additional risk-benefit review. The same is true for the threat of undue inducements. An inducement to enroll is undue when it inappropriately sways the subject to enroll. Of course, not all inducements are undue. For example, an inducement which is so tempting that no reasonable person could refuse it is not thereby undue; surely my choice for the new car as my prize on a game show over the goat can be valid – i.e. protected against interference – even though no reasonable person would take the goat over the car.

To get any traction at all, the concept of undue inducement must appeal to some independent standard of evaluating goods, and say that an inducement is undue whenever the subject is tempted incorrectly, or perhaps irrationally, to assign the inducement more value than it ought to receive.²⁰ In other words, undue inducement must involve some sort of irrationality or psychological

²⁰ There is a substantial literature on undue inducement, and my brief characterization has only scratched the surface. However, it is consistent with the standard ways of distinguishing due from undue inducements. For example, E. Emanuel. Undue Inducement: Nonsense on Stilts? *Am J Bioeth* 2005; 5: 9–13 insists that there are four elements to undue inducements, an (1) offered good, which is (2) excessive, and where there is (3) poor judgment, and (4) risk of serious harm. Alan Wertheimer and Frank G. Miller, in their Payment for Research Participation: a Coercive Offer? *J Med Ethics* 2008; 34: 389–392: 391, write, with their emphasis, 'As a general category, an inducement is

defect in the subject. Facts about the subject's objective external circumstances alone – for example, that the subject is poor – do not suffice to prove an undue inducement charge. For example, if people reliably yet irrationally discount long-term harms excessively in relation to short-term benefits, then an offer which proposes to give a few short-term benefits in return for many long-term harms might unduly induce. By contrast, if a very poor person is rationally desperate for money, then an offer that gives him money in return for research participation need not unduly induce.²¹

Now, prisoner research might seem especially susceptible to undue inducements. For example, research can have many long-term risks. If prisoners irrationally downgrade the significance of these long-term costs, in relation to the very short-term gain of, say, breaking the monotony of their daily routine for a short while, then perhaps this constitutes undue inducement. This is a legitimate concern, but it is not solved by imposing risk-benefit constraints. This is so for two reasons.

First, the concern with undue inducements is that there are too many (illegitimate) inducements, whereas the concern the IOM report intended to address is that there might not be enough (legitimate) inducements for prisoner research. Eliminating undue inducements entails reducing the level of (illegitimate) inducements; in contrast, the IOM report is concerned with risk-benefit analysis because it wants to ensure that the benefits of prisoner research are great enough to outweigh the risks: 'Ethically permissible research must offer benefits to prisoners that outweigh the risks'.²² Nowhere in its defense of risk-benefit constraints does the IOM report discuss the threat of undue inducements as a motivating factor for its proposal of risk-benefit constraints.²³

The second problem with undue inducements is that they are a potential concern for all subjects, not just for prisoners. Two points are worth making in this regard. First, prisoners are arguably no more susceptible to the irrationalities that underlie concerns about undue

undue only when it predictably triggers *irrational* decision-making given the agent's own settled (and reasonable) values and aims.' And Christine Grady, in her Vulnerability in Research: Individuals with Limited Financial and/or Social Resources. *J Law Med Ethics* 2009; 37: 19–27: 22, says, 'Attractive offers in research, sometimes referred to as "undue inducements" are thought to impair individuals' ability to make rational decisions and may be especially irresistible to those with limited resources.' Whether bribes necessarily constitute undue inducements, on this characterization, is an open and interesting question.

²¹ Such an offer might still exploit. I will define and contrast exploitation from undue inducement more explicitly in the following section.

²² Gostin et al., *op. cit.* note 1, p. 123.

²³ See *ibid.* Indeed, the two times the IOM report mentions undue inducements are in the context of its fourth main recommendation, to include prisoner input decisions about prisoner research. *Ibid.*: 130–134.

inducements than people in the general population are. As I said before, prisoners are not (necessarily) mentally incompetent. Consider, for example, the problem of irrationally discounting long-term harms in favor of short-term gains. Perhaps prisoners discount long-term costs because they realize they have, on average, shorter life expectancies than non-prisoners. But, even assuming (perhaps controversially) that this is right, such discounting would be rational. Furthermore, this shows only that we should restrict our comparison class to non-prisoners with the same life-expectancy as prisoners.

On the other hand, the risk of imprisonment is itself a long-term cost which many (guilty) prisoners perhaps did not weigh sufficiently in relation to short-term gains from their crime. If so, then perhaps one is more likely to accrue research subjects who irrationally discount long-term costs over short-term gains if one recruits prisoners rather than non-prisoners. Though this is obviously an empirical conjecture, several *a priori* points cast doubt on it.

First, to say that prisoners lost a gamble between the short-term gain of their crime and the chance of long-term costs due to imprisonment is not yet to say that their choice to make that gamble was (prudentially) irrational. The gamble could have been *ex ante* (prudentially) rational, even if it was net harmful *ex post*. Second, this irrationality, even if it is more prevalent in prisoners than in the general population, can often be easily overcome, so that resorting to risk-benefit review is still otiose. For example, many crimes are not pre-meditated, and while prisoners may have neglected to consider the long-term ramifications of their crimes of passion, this says nothing about their ability to weigh long-term costs when they are forced to deliberate, as when they are recruited into research participation. Third, there may be an overcompensation effect: because prisoners have been burned (at least) once, they may well now marginalize short-term gains in relation to overblown long-term costs. And, finally, even if prisoners incorrectly weighed short-term criminal gains against long-term risks of imprisonment, this is not yet to say that they will also incorrectly weigh short-term gains of research participation against its long-term risks. Those two activities – criminal behavior and research participation – are sufficiently different that prisoners may choose irrationally in one setting yet rationally in the other. All this suggests that the conjecture that prisoners are more prone than non-prisoners to discount long-term costs in relation to short-term gains is at best tenuous.

The second point worth making, in relation to my claim that undue inducements are no more problematic for prisoners than they are for the general population, is that, as previously mentioned, the Common Rule already contains a clause that essentially expressly forbids undue

inducement.²⁴ The Common Rule even dictates that the benefits used in calculating risk-benefit ratios cannot include ancillary benefits of healthcare or long-term benefits of knowledge to the scientific enterprise.²⁵ Now, one might suggest that these admittedly terse and oblique portions of the Common Rule are insufficiently clear to guarantee that IRBs will preclude studies from employing undue inducements. I disagree, but even if so, that is a concern for all research, not one unique to prisoner research. Thus, our response should be to amend or flesh out subpart A of the Common Rule, rather than to put further constraints only on prisoner research.

One might then respond by saying that, although undue inducements are in principle a potential problem for all research, they are much more likely to arise in prisoner research than in non-prisoner research. However, we must distinguish two ways in which this might be true. One way it might be true is inaccurate, and the other is irrelevant.

The inaccurate way is exemplified by thinking that, for example, the prospect of getting to sleep in a clean bed in a quiet room is an undue inducement to a prisoner, though perhaps not an inducement at all for non-prisoners. This is inaccurate, because the central worry is not that prisoners irrationally desire to sleep in clean beds in quiet rooms, so that they incorrectly think that getting a good night's sleep is more important than their long-term health (though this might also be the case). Rather, the concern is that in some sense, which I will clarify in the next section, we are exploiting the prisoner's unfortunate situation by offering them something which would not even count as a benefit for non-prisoners.

The irrelevant way in which undue inducement is more likely to be problematic for prisoner research than for non-prisoner research is that researchers will face less scrutiny in prisons and so will be more likely to get away with things that they cannot get away with in the general population, such as offering undue inducements. This might happen, but again, further *ad hoc* constraints such as risk-benefit review do nothing to safeguard against this possibility. Rather, we should implement stricter scrutiny

²⁴ Code of Federal Regulations, *op. cit.* note 2, Title 45: sec 46.116: '... An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.' (my emphasis).

²⁵ Code of Federal Regulations, *op. cit.* note 2, Title 45: sec 46.111a2: 'Risks to subjects are [must be] reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.'

to guarantee that the constraints already in place are followed, as suggested in the IOM report's fifth main recommendation.

5. EXPLOITATION

Exploitation is the strongest candidate problem that risk-benefit constraints on prisoner research might help solve. If, for example, prisoners are lured into research participation just by the prospect of a clean, quiet place to sleep for a few nights, perhaps researchers are inappropriately exploiting them. In this section I will argue that additional risk-benefit constraints on prisoner research do not resolve exploitation problems.

Just what counts as exploitation is contentious. However, only some accounts of exploitation are even potentially worrisome for my contention. In particular, worrisome accounts of exploitation must insist that whether one is exploited in an exchange depends in part on the level of benefits one receives in that exchange. After all, on the contrary supposition, no amount of benefits thrown at the prisoners would suffice to eliminate the stigma of exploitation, in which case constraining prisoner research with risk-benefit review will not affect whether they are being exploited.²⁶

However, several prominent accounts of exploitation are compatible with the thesis that exploitation depends at least partly on the benefits received. For example, a Marxist insists that capitalists exploit workers whenever the workers are not paid the full labor value of the products they make. Abstracting from Marxist criticisms of capitalism, the most prominent contemporary theorist on

exploitation, Alan Wertheimer, argues that exploitation in general involves taking unfair advantage, which itself depends at least in part on the level of benefits received in the exchange.²⁷ For example, if an American athletic shoe company sets up a factory in southeast Asia and pays its workers a subsistence wage far below the US minimum wage, when it could easily pay them more, we might think that it treats those workers unfairly and therefore exploits them. Finally, it seems that we have found an appropriate problem for which selective risk-benefit constraints are an adequate solution. After all, concerns about exploitation push us towards giving more benefits to prisoners, whereas concerns about undue inducements push us towards taking (undue) benefits away. Further, exploitation is especially problematic in prison contexts, whereas, for example, irrationally discounting long-term costs in favor of short-term gains is not.

Unfortunately, several problems remain. One such problem is that the IOM report tries to address concerns about exploitation in a different way, namely by imposing a 50% prisoner cap on all study populations.²⁸ Part of the thought behind this idea is that, if the researchers have to make the study attractive enough to appeal to non-prisoners, then it cannot exploit prisoners. Now, I do not wish to rely on the 50% cap proposal, because I suspect the conditional I articulated in the previous sentence is false (for example, a study might recruit only prisoners and the unincarcerated poor, thereby exploiting both), and there are potentially other, independent problems with the 50% cap as well.

However, several other problems remain. One such problem is that merely ensuring that benefits to prisoners outweigh risks to prisoners does not suffice to preclude exploitation. As Wertheimer has reminded us, exploitation can be mutually beneficial: it is possible to exploit even when both the exploiter and the exploitee gain net benefits.²⁹ To return to my earlier example, sweatshop workers might benefit from working in the athletic shoe factory (if that job opportunity was not available, their situation would be even more grim), even though the athletic shoe company is taking unfair advantage of their situation and therefore exploiting them.

How to assess the extent of exploitation is controversial. Perhaps benefits to the prisoner must be proportional to benefits to the researcher and society. Or, perhaps there is a moral threshold below which prisoner benefits cannot fall. Wertheimer argues for a version of

²⁶ For example, Alan Wood argues that exploitation is bad because 'proper respect for others is violated when we treat their vulnerabilities as opportunities to advance our own interests and projects. It is degrading to have your weaknesses taken advantage of and dishonorable to use the weaknesses of others for your ends.' See A. Wood. *Exploitation. Soc Philos Policy* 1995; 12: 136–158; 150–151. This roughly Kantian idea that wrongful exploitation is linked with inappropriately treating someone merely as a means is plausibly incompatible with the thesis that one can eliminate exploitation merely by paying the exploited person more. Similarly, Ruth Sample argues that exploitation is degradation, where degradation is again Kantian in spirit (about treating people with proper respect), not necessarily a matter of measuring benefits and harms. See R. Sample. 2003. *Exploitation*. Lanham, MD: Rowman & Littlefield Publishers: 1–2 & 12–13. One might even think that exploitation is a form of coercion, perhaps with an essential connection to abusive power relations. (I am grateful to an anonymous reviewer for this suggestion.) I think this last analysis is mistaken – exploitation is not necessarily coercive (see, for example, *ibid*: 11–12) – but even if it is right then the points I make in the coercion section of this paper suffice to refute the idea that risk-benefit review can resolve problems of exploitation. For I there argued that risk-benefit review cannot resolve coercion problems, and my arguments did not turn on whether the coercion involved was also exploitative. Therefore, if exploitation is a form of coercion then it follows that risk-benefit review also cannot resolve exploitation problems.

²⁷ A. Wertheimer. 1996. *Exploitation*. Princeton, NJ: Princeton University Press: 10–12. Of course, one might disagree with Wertheimer (and Marx), but the reason I focus on this sort of analysis, which analyzes exploitation in terms of comparative benefits, is that, again, it is the only sort of analysis which has any hope of being able to justify risk-benefit restrictions on prisoner research.

²⁸ Gostin et al., *op. cit.* note 1.

²⁹ Wertheimer, *op. cit.* note 21.

this latter sort of view, according to which the threshold is set by a hypothetical competitive market price.³⁰ Of course, a hypothetical market price itself also depends on the benefit received by the researcher (and society, if we care to eliminate positive externalities).

The point is that, in order to eliminate exploitation, we will have to determine not just whether the benefits of participation exceed the risks. Rather, we will also have to determine whether the net benefits are sufficiently high; and this may well depend on comparing those benefits to the benefits to the researcher and to society as well. From this it follows that if we are really concerned to address exploitation in prisoner research, we should require not just an assessment of risks and benefits to prisoners but also an expected benefit calculation for the research team and society. This is not in the spirit of the IOM report's third recommendation, which nowhere suggests that we have to compare prisoner benefits to researcher and societal benefits, in order to ensure that the distribution of benefits is not exploitative.

Now, perhaps we should adopt this more complex comparative net benefit calculation. It would be a significant change from the IOM report's simpler recommendation but perhaps a welcome one. However, this suggestion is still problematic. One problem with it is that the comparative calculation sometimes gets the wrong results. Following similar guidelines in pediatric research, a defender of risk-benefit review should say that, as the societal benefit of the research increases, so too does the level of acceptable subject risk. Equivalently, as societal benefit decreases, we must take extra care to ensure that subjects are not harmed. The intuitive idea here is that greater risks to subjects are worth paying only if we accrue greater societal gains as a consequence. However, the opposite conclusion follows if our motivation for risk-benefit review is exploitation avoidance. For, if society stands to gain a great deal, then subjects must also benefit to a greater degree, lest they be exploited for that societal gain. Equivalently, if there is little or no societal benefit from the research, then we need not ensure subjects benefit from it at all, in order to avoid exploitation. In other words, concerns about exploitation, like concerns about undue inducement, can be resolved in part by risk-benefit review, but not in a way that is friendly to the spirit of the IOM report's recommendation.

A second problem is that, as before, exploitation is a potential problem for all research, not just for prisoner research. If we care to eliminate exploitation from research, presumably we should care to eliminate it even when the subjects are not prisoners. In other words, if constraints against exploitation are appropriate, they should appear in subpart A of the Common Rule, not in a special section reserved for prisoners. Of course, as I

admitted earlier, prisoners are plausibly much more vulnerable to exploitation than non-prisoners are. Prisoners can be exploited by even the humble offer to sleep in a quiet, comfortable bed, for example. But what does this show? Not that we should forbid exploitation only in prisoner research. Rather, it shows that we should forbid all exploitation with general constraints for all research, and perhaps implement more rigorous safeguards to ensure that these constraints are followed in prisoner research.³¹ Again, the general theme is that we do not need additional constraints on prisoner research; what we need is better oversight to ensure that more general constraints, which apply to all research, are followed.

A final problem for the exploitation defense of risk-benefit constraints is that it is unclear when, if ever, we should forbid mutually beneficial exploitation, even if we think that it is wrong.³² Consider again the south-east Asian sweatshop laborer. As bad as this worker's conditions are, things could go even more badly for her if we forbid the American company from setting up its factories in southeast Asia, for, in that case, the worker would have to take an even worse job or be unemployed. Yes, we may decry the situation and fight for improvements for the worker's conditions, but this is compatible with permitting mutually beneficial exploitation, because forbidding it would harm the worker more than allowing it. Likewise, we do not necessarily improve conditions for prisoners by banning mutually beneficial exchanges, just because those exchanges are also exploitative.³³ Thus risk-benefit constraints, if intended to preclude mutually beneficial exploitation, may be misguided.

6. PATERNALISM

At this point my interlocutor may take a more radical approach. Perhaps I am being dialectically unfair in criticizing the IOM report for suggesting selective risk-benefit constraints only for prisoner research. After all, the

³¹ We can specify the comparison class for the 'more rigorous safeguards' in two ways, but only one follows from what I have been arguing. The way which follows is that we should implement more safeguards for prisoner research than for non-prisoner research. The way that does not follow is that we should implement more safeguards (for prisoner research) than exist right now (for prisoner research).

³² For more on the distinction between an act being wrong and it being reasonable to forbid it, see J. Waldron. *A Right to Do Wrong*. *Ethics* 1981; 92: 21–39.

³³ For more on this, see Wertheimer, *op. cit.* note 21, chapter 9, especially pp. 285–286. Wertheimer there discusses several other potential reasons to permit mutually beneficial exploitation: (1) reasonable disagreement in disputes about fairness, (2) the improbability that the state will be a better judge of standards of fairness, (3) privacy concerns, and (4) exploitation as a signal of market inefficiency, which stimulates voluntary market correction. I ignore these other reasons because the one I gave is the most powerful – a mutually beneficial transaction is Pareto-superior to no transaction.

³⁰ *Ibid*; ch. 7.

report committee was tasked only with discussing prisoner research, but perhaps they believe that more stringent risk-benefit constraints are appropriate for all research, not just prisoner research. Thus, the suggestion continues, I cannot fault the IOM report for proposing such constraints only in the context of prisoner research, because they had no authority to report their stronger belief that risk-benefit constraints should be implemented more generally. The rationale behind such a general constraint need not be the desire to avoid coercion, undue inducement, or exploitation, which are perhaps more acutely faced by prisoners. Rather, the rationale might be paternalistic, where it is acknowledged that this paternalistic rationale applies equally to prisoners and non-prisoners alike. In other words, perhaps it would benefit us all if there were more stringent risk-benefit review for all research protocols, even studies not enrolling prisoners.

Three responses are in order. First, this concession accepts the broader position I want to defend. That broader position is that we do not need additional constraints on prisoner research that do not also apply to non-prisoner research. Rather, we need more safeguards to ensure that universal constraints for all research are met even when participants are prisoners. Secondly, and relatedly, this concession is already enshrined in subpart A of the Common Rule, as I have mentioned earlier.³⁴

But perhaps even this is not enough. Perhaps we want even more explicit and stringent risk-benefit constraints on all research than even can be found in subpart A of the Common Rule. My last point is that this concession, in effect, proposes to treat us all like children. Paternalism is of course appropriate for children; they cannot choose for themselves, so we perform very stringent risk-benefit calculations on their behalf. That such stringent risk-benefit constraints preclude children from some forms of altruism is an unfortunate yet acceptable consequence of such paternalism. However, autonomous adults should not be forced into egoism; if we want to be altruistic, we should be allowed to be. Thus, even if some level of paternalism is always appropriate in research contexts,³⁵ surely the same level of paternalism that is appropriate for children is inappropriate for autonomous adults. Likewise, if additional risk-benefit constraints on prisoner research can be defended only by endorsing a much more paternalistic stance towards all research than is

currently considered reasonable for autonomous adults (but which is considered reasonable for children), then I am content to stop the dialectic, at least in the confines of this paper, by suggesting that this is a *reductio* of such constraints.

Let me be clear in my form of argument. I am not insisting that paternalism against autonomous adults is impermissible. Rather, I am insisting that the same level of paternalism that is appropriate for children is inappropriate for adults. This comparative claim acknowledges that the current Common Rule already treats autonomous adults somewhat paternalistically, but the Common Rule also treats children more paternalistically than it treats adults, and I merely insist that this distinction in the degree of paternalism between children and adults should be preserved.

7. CONCLUSION

In this paper I have argued that, in order to ensure ethical prisoner research, we do not need more constraints on it than on non-prisoner research, though this is of course compatible with needing more constraints on both than we have right now. In particular, risk-benefit constraints do nothing to address problems prisoners face more acutely than non-prisoners do: problems such as coercion, undue inducement, and exploitation. Further, it is inappropriate to treat adults as paternalistically as we treat children. We do not need additional risk-benefit constraints on prisoner research; rather, we need better oversight to ensure that the appropriate constraints on all research are followed even when the subjects are prisoners.

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³⁴ Code of Federal Regulations, *op. cit.* note 2.

³⁵ See Miller & Wertheimer, *op. cit.* note 11.

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