(Why) Should We Require Consent?

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N.B. The citations are radically incomplete

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“I have the innate duty . . . so to affect posterity through each member of the sequence of generations in which I live, simply as a human being, that future generations will become continually better . . . and that this duty may thus rightfully be passed on from one generation to the next.” (Kant)

- “The voluntary consent of the human subject is absolutely essential.”
  (Nuremberg Code)
- “Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.” (The Common Rule)
- “After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent.” (Declaration of Helsinki)
The principle of informed consent lies at the epicenter of research ethics. Setting many important exceptions aside (more on that to follow), current discussion of the principle of informed consent focuses on interpreting and applying the notion that valid consent must be informed, and, to a lesser extent, that valid consent must be voluntary. So, for example, it may be asked precisely what information must be disclosed to subjects and what and whether that information must be understood. But the principle of informed consent is itself regarded as so clearly correct that that it does not require an extended defense.

Interestingly, the principle that some sort of consent is required for medical treatment or research is arguably unnecessary. After all, the unauthorized invasion of a person’s body without consent constitutes the ordinary crime and tort of battery. Moreover, and as a practical matter, except in cases where a subject is unconscious or direct force is used, it is virtually impossible to gain access to a person’s body without some semblance of consent. Investigators may gain a subject’s uninformed consent by withholding information or misinformed consent via deception, but it is difficult to gain access to a person’s body against the person’s wishes.

Now despite its centrality and apparent absoluteness, informed consent is actually regarded as neither sufficient nor necessary for ethical research. It is not

- “Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them.” (Belmont Report)
regarded as sufficient because it is generally assumed, among other things, that research is ethical only if the risks to subjects are reasonable in relation to the anticipated benefits to subjects or to others. There is some dispute as to whether the “reasonable risk” criterion places any limits to the risks to subjects so long as they are exceeded by the anticipated benefits to others, but there is no dispute that IRBs must determine that the risks are reasonable before subjects are offered the opportunity to consent to participate. I have argued elsewhere that, despite appearances, the “reasonable risk” criterion does not actually supplement consent; it is a partial replacement. It is best understood as a form of soft-paternalism in which IRBs act as surrogates for subjects who are not in a position to competently evaluate the risks and benefits of participation. After all, except for cases of extreme altruism, prospective subjects would be unlikely to give informed consent to participate in research where, at a minimum, the risks to them were not exceeded by the benefits to them or others. The problem is that even reasonably well informed subjects lack the medical and scientific competence to make these determinations. And even if people can evaluate the risks and benefits to themselves, who among us is in a position to determine whether the research is scientifically valid and likely to yield important benefits to others? So the present structure of biomedical research requires that IRBs give their consent to a person’s participation before she can give the functional equivalent of a child’s “assent” to participation.

It is also commonly accepted that informed consent is not strictly necessary for ethical research. Robert Levine has written that “The use of a person as a
research subject can be justified only if that person, or one authorized to speak on
his or her behalf, consent to such use.” Strictly interpreted, this is not quite right. If
we adopt the Common Rule’s definition of research as “a systematic investigation,
including research development, testing and evaluation, designed to develop or contribute
to generalizable knowledge,” then much research proceeds without the subject’s consent.

We may think that research without any sort of consent is justifiable when it is
exclusively observational as when psychologists sought to determine whether
wealthy drivers (as indicated by their cars) behaved more unethically than less
wealthy drivers. Observers stood near an intersection, coded the status of
approaching vehicles, and recorded whether the driver cut off other vehicles by
crossing the intersection before waiting their turn. No drivers were asked for or
gave their consent. Interventional research without informed consent may be
justifiable when subjects must be deceived if research is to produce scientifically
valid data. And so like much social and behavioral research, a recent book about
people’s propensity to lie and cheat (Daniel Ariely, “The Honest Truth About
Dishonesty: How We Lie To Everyone – Especially Ourselves) relies heavily on
experiments in which subjects were deceived about its purpose -- a characteristic of
the research that the author fails to note. Indeed, Federal Regulations explicitly
allow for waivers of informed consent under these very sorts of conditions.

Consent is more likely to be required in biomedical research, but there are
exceptions there as well. Even if we set aside cases in which surrogates consent for
the subject (for example, children), there are special circumstances, such as
emergency research in which research may be justified even though no sort of
consent is possible (assuming surrogates cannot be located). Research without any kind consent may also be justifiable when it involves public health surveillance, collection of data from health records, or cluster randomized trials where it is impractical or impossible to seek everyone’s consent. Some think that research without consent may be justifiable when investigators seek to compare two established effective treatments that are regularly prescribed.

These exceptions to the Nuremberg principle deserve more attention than they receive. Given that it is generally thought that so much research is ethically permissible without consent of any kind or without valid informed consent, it is a puzzle as to why informed consent is typically regarded as a sine qua non of ethical biomedical research. It is possible, of course, that we should require explicit informed consent (without deception) in all research including social and behavioral research, even though doing so would bring much social and behavioral and biomedical research to a screeching halt. But assuming that the Common Rule’s criteria for waiving informed consent reflects a sensible moral position, it simply can’t be the case that people have a strong general right not to be used as a research subject without their consent as contrasted, say, to a right not to be put at risk of harm without their consent.

Nonetheless, despite these considerable and important exceptions to the Nuremberg Principle, the fact remains that there is a wide spectrum of cases – particularly in biomedical research -- in which it is completely uncontroversial that ethical research requires consent that is voluntary, informed, and competent. Call this the Consent Requirement (CR). In those cases, the question is not whether valid
consent is required. That is a given. The question is what is required by valid
cconsent, i.e. when we should regard a participant’s token of consent as valid or
morally transformative?

To elaborate on the previous point, we may worry as to whether members of
certain “vulnerable” groups such as prisoners can give valid consent. Some think
that one cannot give voluntary consent if one has no reasonable alternative but to
participate, say because one otherwise lacks access to medical care. Some maintain
that people can be coerced by the offer of payment. Other worries focus on
cognitive deficiencies. For example, some argue that those in the grips of the
“therapeutic misconception” are not giving valid consent or that offers of payment
may distort a prospective subject’s evaluation of the benefits and risks of
participation and therefore constitute undue influence. There is considerable
discussion as to whether informed consent requires that investigators inform the
subjects about certain matters or whether, in addition, the subjects must actually
understand that information. Does informed consent require that subjects
understand such concepts as randomization? Does excessive optimism about
benefitting from participation invalidate one’s consent?

All that said, and with considerable room for disagreement at the margins, it
is generally assumed that it is wrong to conduct biomedical research without a
subject’s informed consent. In the word of the Belmont Report, this principle is
“unquestioned.” Should it be? In an important article R.M. Hare wrote that
although he and we would all agree that slavery is wrong, “there are dangers in
taking for granted that something is wrong; for we may then assume that it is obvious that it is wrong and indeed obvious why it is wrong.

So too for research without consent. The history of the Nuremberg Code exemplifies the problem. The wrongness of the Nazi experiments was grossly over-determined. As Jay Katz has noted, the first principle of the Nuremberg Code “was irrelevant to the case before the tribunal, for the basic problem with the concentration camp experiments was not that the subjects did not agree to participate; it was the brutal and lethal ways in which they were used.” The Nazi experiments were carried out by an unjust regime in pursuit of unjust goals, the experiments often had no scientific value, the subjects were chosen from groups that were being destroyed, and there was, to say the least, no regard for the well-being of the subjects. Given all this, it would be a mistake to point to the Nazi experiments in trying to explain why research without consent is wrong.

The “unquestioned” character of CR is particularly puzzling when viewed in a larger context. It is relatively easy to justify CR if we view research as an interaction between investigators and subjects. At the most general level, we’re not entitled to harm others without their consent or put them at risk, except in ordinary activities like driving. As a general principle, A is not entitled to interfere with B’s body or property without B’s consent.

But it is arguably another matter if we were to view (some) research as an issue of political philosophy, as an interaction between the state and a citizen. After all, there is a wide range of things that the state does to people without consent or coerces them to do. Although it is theft when A takes B’s property, it
may be legitimate taxation when the state takes B’s property. The state requires that people serve on juries, appear as witnesses at trials, get vaccinations, or purchase medical insurance (now that the Supreme Court has upheld the “mandate” component of the Affordable Care Act). It may be that the state is not justified in doing these things or that it is justified in using coercion in these contexts but that participation in research is different. But if that is so, why is that so? The canonical statements do not provide an answer and bioethicists do not seem sensitive to the possibility that the question might be asked.

The purpose of this paper is to start an investigation as to whether and why we should accept CR. It’s dirty work but someone’s got to do it. As will become clear in the next paragraph, my strategy will take us only part of the way. I suspect, but will not argue that we probably should continue to accept CR as an operative policy or rule. But – and this is a crucial “but” -- I will also argue that contrary to what is commonly supposed, CR cannot easily be justified by appeal to the sorts of principles that are often cited in its defense such as respect for autonomy, respect for persons, rights, bodily integrity, not treating subjects merely as means, or the like. Rather, I will argue that the best justification for CR has to be less simple, less direct, less elegant, and less definitive. In effect, I will argue that we can’t get to CR through a front-door straightforward moral argument from basic principles, but we can get there through the back door.

In On Liberty, John Stuart Mill maintains that even if the received view on some matter is the truth, “unless it is suffered to be, and actually is, vigorously and earnestly contested, it will, by most of those who receive it, be held in the manner of
a prejudice, with little comprehension or feeling of its rational grounds.” In that spirit, and as an argumentative strategy or thought experiment, I propose to start with what might appear to be an implausible counter-proposal to CR, namely, that it is legitimate to coerce people into participating in biomedical research or serving as research subjects (I understand that “coercive participation” may be an oxymoron, but I will continue to use the phrase). Law professor Lars Noah recently wrote that while “it has become increasingly difficult to recruit sufficient numbers of subjects for trials, conscripting people for this purpose would represent a radical solution that likely no one would take seriously.” Although I do not ultimately defend such a policy, I believe that our understanding of the justification of CR will be enhanced if we do take it seriously.

My plan is this. I will first describe the sort of coercive participation I have in mind. I then ask whether the use of coercion is legitimate and distinguish that question from asking whether the use of coercion is justifiable. I consider several candidate principles for regarding coercion as illegitimate and argue that none of them is sufficient. Having established a prima facie case for the legitimacy of coercive participation, I ask whether the use of coercion is justifiable. I conclude that it probably is not. Finally, I argue that even if the use of coercion is legitimate and sometimes justifiable as a matter of “first-order” ethics, there are good moral reasons to adopt a rule that bars coercive participation. I leave open the question as to whether we can and should establish a rule such as CR that disallows research without consent or without valid consent so long as coercion is not employed. But if CR is to be justified, I think it will require a similar type of defense.
Coercive Participation. Why even consider coercing people to participate in research? Is there a problem to which coercion might be an answer? I believe so. The lack of participants is one – although not the only -- serious barrier to successful and timely biomedical research. Scott Ramsey and John Scoggins noted that more than one trial in five sponsored by the National Cancer Institute failed to enroll a single subject, and only half reached the minimum needed for a meaningful result. In addition, eighty percent of trials are delayed at least a month because of unfulfilled enrollment. It seems reasonable to assume that more and faster completed studies would prevent a non-trivial amount of avoidable morbidity and mortality or improve people’s quality of life. One study concludes that new medicines generated 40% of the gain in life expectancy over the past, and that ignores the contribution of new interventions to quality of life. It stands to reason that increasing the ease of recruitment into clinical trials would lead to even greater gains. And it is at least plausible to suppose that regarding a subject’s consent as necessary reduces the amount and pace of research even when research poses minimal risks or offers a compensating potential for clinical benefit.

The difficulty of undertaking and completing clinical trials has led some to lament the entire enterprise of the regulation of research. Whitney and Schneider argue that the regulation of research results in avoidable deaths because it delays the introduction of life-saving interventions into ordinary medical care, not to mention that the regulatory process screens out some potentially beneficial research from being undertaken and deters other potentially beneficial research from ever being proposed. They correctly note that there has not been any
systematic attempt to evaluate the costs and benefits of the regulation of research. We really don’t know whether and to what extent the present regulatory system prevents unethical research or at what cost in foregone generalizable knowledge (we can probably calculate the time and financial costs). At the same time, Whitney and Schneider are too quick to assume that regulation that “does more harm than good is itself unethical,” if their conception of a regulatory system includes component principles such as informed consent. We may have moral reason to adopt CR even if abandoning CR would do more good than harm on some sort of aggregative consequentialism. Just as we may have moral reason to weigh the interest of criminal defendants more than our social interest in convicting the guilty (“better that ten guilty persons go free than that one innocent person be punished”), we may have moral reason to weight the interests and autonomy of research subjects more heavily than the interests of those who would benefit from a less demanding regulatory system that produced more high quality biomedical research and at a faster pace.

There is a long-standing debate as to the moral importance of the benefits of biomedical research. Hans Jonas famously argued that avoidable illness and death is regrettable but not of overarching moral significance because “progress is an optional goal.” On his view, there is no ethical necessity “about seeking new knowledge or finding ‘new miracle cures.’” He writes that a “permanent death rate from heart failure or cancer does not threaten society.” It is a “human misfortune,” but not a “social misfortune.” By contrast, society would be “threatened by the erosion of those moral values . . . caused by too ruthless a pursuit of scientific
progress..." But even if violations of some of a society's moral principles are more important than practices that promise to reduce the morbidity and mortality of its members, the foregone benefits are hardly without moral significance. We do well to remember that yesterday's "miracle cure" which was the product of "optional" medical research is today's ordinary medical treatment. And the fact is that while we have made considerable progress in treating some diseases, there is virtually no treatment for some devastating and diseases such as Alzheimer's and inadequate treatment for many other diseases or conditions.

There are numerous impediments to medical research. Funding is limited. Treating physicians may think it wrong to refer their own patients to clinical trials and participation may be burdensome for them. In addition, it is often very difficult to recruit prospective subjects. This is especially so with respect to adult oncology research. Between 60%-80% of children diagnosed with cancer participate in clinical trials, in part because pediatric oncology has historically integrated research and treatment such that children enrolled in randomized controlled trials typically do better than those that do not. By contrast, among adults diagnosed with cancer, fewer than 5% participate in trials. And while those who enroll may help to generate knowledge that is beneficial to others, they do not generally have improved outcomes as compared with those who do not enroll.

Although it is rarely discussed in these terms, participation in research often constitutes a classic collective action problem. It is in the ex ante interest of most people that research be conducted, but participation in actual research can be contrary to the interests of each individual. Ex ante, we may all be better off if all of
us do our fair share of participation in research. But the knowledge generated by research is a public good, i.e. it is a good that is available to all whether or not one contributed to it. And to the extent that people are self-interesteD, they will seek to reap the benefits of research without paying the costs. Precisely for that reason, we often rely on the use of coercion to solve collective action or public good problems in many contexts. We tax citizens to pay for public goods, including funding research that generates knowledge that is available to all. We require that cars come equipped with catalytic converters. We require people to collect and perhaps sort their recyclables and then place them on the curb outside their home. We can at least ask: Why not require people to participate in research?

For present purposes, coercive participation does not mean physically overpowering and restraining people and then subjecting them to invasions of their body. Rather, I have in mind a scheme under which prospective subjects are required to participate in research on pain of some sanction for refusal. People could still voluntarily enroll in research, and thus might be immune from further demands. The scheme would be similar to “compulsory voting” schemes adopted in Australia and Belgium where people are fined if they do not vote, but where (I assume) many people vote for their own reasons and not because they are required to do so. I suspect that the possibility of coercive participation is rarely taken seriously because it conjures up images of Nazi-like experimentation on people’s ability to survive in freezing water or at very high altitudes. But that is, to say the least, not what I have in mind. The United States already requires that people participate in the census – a form of social and behavioral research – on pain of
being fined for refusal. Here I ask whether it would be legitimate to take a similar approach to biomedical research.

To render the idea of coercive participation at least minimally plausible, I will assume for the sake of argument that any research would meet several criteria and that it would be subject to review by an IRB that would certify that research met those criteria. First, the risks of participation would be reasonable in relation to their anticipated benefit to subjects or to others. (The use of coercion would be somewhat albeit less problematic if participation had net direct medical benefit for the subjects as compared with the alternatives). This implies that the research is socially valuable and scientifically valid. Second, the risks and burdens of participation would not be excessive, although subjects would have to bear the burdens of time, inconvenience, and low risk procedures necessary for research purposes such as blood draws. Those procedures might well involve some bodily intervention, but some procedures (e.g. blood pressure readings) are less invasible and, in some cases, subjects might simply be required to report on the state of their health. Third, the identification of subjects – both healthy volunteers and patient/subjects -- follows a fair procedure and is based on relevant criteria. Lotteries may be used when appropriate. Fourth, within a coercive context, subjects are treated with concern and respect and may be offered compensation for participation (as with jurors) as well as compensation for injuries caused by participation. Fifth, the use of coercion is limited to research conducted or co-sponsored by non-profit or government funded agencies. Readers are invited to add other non-consent criteria to the list. The point of this exercise is is to isolate
the moral significance of coercion by asking whether it would be legitimate for the state to require people to participate in research on pain of being penalized for refusal when all other criteria of ethical research are satisfied.

The proposal for coercive participation does not assume that all citizens have a pro tanto obligation to participate in research, although it would be easier to make the case for coercion if they do. I have argued elsewhere that people do have an obligation to do one’s fair share of participation in non-beneficial research just as they have an obligation to contribute to other public goods. And if people have a pro tanto moral obligation to participate, there may also be a pro tanto case for enforcement. As Michael Otsuka observes, we need an explanation as to why we should not be required to do that which we have a moral duty to do. Nonetheless, I will not assume that people have an obligation to participate, because positing such an obligation is neither sufficient nor necessary to justify the use of coercion.

Positing an obligation to participate is not sufficient to justify coercion because it does not follow that it is permissible to coerce B to do X or that B need not consent to do X just because B has an obligation to do X, One might think that people have an obligation to vote or to limit the size of their families or to use less carbon or that scholars have an obligation to do their fair share of manuscript reviewing, but also think that it is wrong to force people to vote or limit the size of their families or use less carbon or review manuscripts (although the latter does not seem feasible). One has a moral obligation to keep one’s promises, but it does not follow that either the state or the promise is entitled to punish promise-breakers. If B has borrowed tools from A on numerous occasions, it seems that B has an
obligation of reciprocity to loan a similar tool to A upon request. But this does not mean that it is permissible for A to take B’s tool without B’s permission. So even if people do have an obligation to participate in research, it does not follow that it would be legitimate to require them to do so or do research on them without their informed consent.

Somewhat less obviously, an obligation to participate is not a necessary condition of justifiable coercion because we can be justified in coercing people to do things that they have no obligation to do voluntarily. As Thomas Nagel observes, although there are cases “in which a person should do something although it would not be right to force him to do it . . . sometimes it is proper to force people to do something even though it is not true that they should do it without being forced.”iv Nagel suggests that while it is permissible for the state to require people to pay taxes, they may have no obligation to make such payments voluntarily, in part because they may lack assurance that others are doing their fair share and because making voluntary contributions to the state involves “excessive demands on the will.”

Given that positing an obligation to participate in biomedical research is neither sufficient nor necessary to the case for coercive participation, I will bypass this issue and ask whether the use of coercion is legitimate.

Legitimacy and Justifiability. The question on which I will focus first is whether the use of coercion is legitimate and not whether it is justifiable, all things considered. Here I follow Joel Feinberg.v In his four-volume magnum opus on the moral limits of the criminal law, Feinberg aims to identify the principles that render it legitimate for
the state to criminalize behavior or limit individual liberty. Following Mill, Feinberg argues that “harm to others” (the harm principle) and “offense to others” (the offense principle) are legitimate grounds for criminalization but that it is not legitimate for the state to criminalize behavior on the grounds that it is harmful to a competent adult himself (legal paternalism) or on the grounds that the behavior is wrongful although harmless (legal moralism).

Setting aside these particular principles, Feinberg claims that there is an important distinction between policies that are “legitimized by valid moral principles and those that are justified on balance as being both legitimate and useful, wise, economical, popular, etc.” Given this distinction, if a proposal for the use of state coercion passes a legitimacy test we can then go on to ask whether it is justifiable. But if a proposal for the use of state coercion does not pass a test of moral legitimacy, then its justifiability is not on the table.

Principles of legitimacy appear to operate as deontological constraints, whereas justifiability appears to take a consequentialist form. But this is somewhat deceiving. First, whereas principles of legitimacy do not involve direct appeal to consequences at the practical level, they may be rooted in consequentialist considerations. Second, justifiability may take note of what might be thought of as deontological values such as autonomy or respect for persons. In the final analysis, it may well turn out that the distinction between legitimacy and justifiability is not as sharp as Feinberg supposes, but I begin with the question of legitimacy because it is generally assumed that it would be beyond the moral pale to coerce people into participating in research and that the values that are served by consent should not
be regarded merely as moral desiderata to be weighed (even heavily) in determining whether research is ethical.

*Is Coercive Participation Illegitimate?* I suspect that most people think that CR is rooted in a simple and basic moral principle that commands widespread support even though the principle was enshrined in guidelines and codes without an underlying justification. The Nuremberg Code's insistence on consent seems designed to prevent harm and abuse. Faden and Beauchamp maintain that the Belmont Report reflects the view “that the underlying principle and justification of informed consent requirements . . . is a moral principle of respect for autonomy.” Because there are multiple arguments for CR, it is important to consider them separately.

*Treating People Merely as a Means.* Robert Levine argues that the requirement for consent “is grounded in . . . the universal obligation to treat persons as ends and not merely as means to another's end.” Following Van der Graaf and Van Delden, calls this the *not merely as a means principle* (*NMMP*). NMMP has achieved mantra-like status in bioethics. In those circles, to say that a practice treats someone merely as a means is generally viewed as a conversation stopper. Still we need to ask several questions: is there an account of NMMP that can actually provide moral guidance? Is the principle sound? And does it support CR?

As is often pointed out, no sensible moral principle could prohibit using people *as a means* so long as one is not using them *merely* as a means. In general, we do not treat people wrongly or *merely* as a means if they consent to the terms of an
interaction. The taxi driver uses me as a means to earn an income and I use him as a
means to get to my destination. There is nothing remotely problematic here if we
both give valid consent to the terms of the transaction -- he does not deceive me
about the fare and I do not make a false promise to pay him. It is not clear whether
valid consent is always sufficient to satisfy NMMP, but it surely goes much of the
way towards doing so.

Now depending upon what is required to satisfy NMMP, the principle is
certainly not inviolable. To use Amartya Sen’s example, if one can prevent a
heinous rape by taking B’s car without B’s consent and against B’s well-informed
objections, one arguably treats B and his property merely as means, but any
principle that would condemn such a “use” should be rejected. Samuel Kerstein
agrees. He argues that we should reject the Kantian prescription “never” to treat
people merely as a means and accept a pro tanto (Kant-inspired) version of the
principle, acknowledging that it may be morally permissible – all things considered
– to treat someone merely as a means. But to say that we should accept a pro tanto
version of the principle is not particularly helpful without knowing something about
its weight and what is required to override or outweigh it. There are pro tanto
obligations and pro tanto obligations. It might, after all, be objected that Sen’s
example shows only that there can be extreme cases which surpass the
“deontological threshold” established by NMMP. So we must first determine
whether – for a more normal range of cases -- NMMP entails that we must seek and
receive a person’s consent before using her as a means.
The problem is that there is no generally accepted account of NMMP. As Kerstein observes, there is no single ordinary way in which we think of treating others merely as means. Derek Parfit has argued that we do not treat B merely as a means just because we use B without B’s consent. Consider the scientific use of animals.

One scientist . . . does her experiments in the ways that are most effective, regardless of the pain she causes her animals. This scientist treats her animals merely as a means. Another scientist does her experiments only in ways that cause her animals no pain, though she knows these methods to be less effective.viii

Parfit claims that the second scientist is not treating the animals merely as a means because her “use of them is restricted by her concern for their well-being.”

Parfit argues that we treat a being (animal or person) merely as a means when we regard them “as a mere instrument or tool: someone whose well-being and moral claims we ignore, and whom we would treat in whatever ways would best achieve our aims.” On this view, NMMP does little work by itself. On the standard – contrary – view that dominates bioethics, doing X can be wrong because it violates NMMP. On Parfit’s view, doing X violates NMMP only when doing X is wrong. As Richard Arneson has argued, if NMMP is interpreted as the injunction not to use people “in ways that are unacceptable according to correct moral principles,” everything turns on the content of those principles, and that is a matter on which NMMP is silent.ix A person’s moral claims may include respect for her rationality or autonomy or rights or requiring consent to biomedical research, but the
specification of those claims would become the relevant task. Indeed, if morality requires that we give equal consideration to everyone’s interests, then we do not treat someone merely as a means if we use them to advance the welfare of others as long as we weigh their interests equally along with everyone else. On this account, coercive participation might be consistent with respecting NMMP.

There may, however, be a different linkage between NMMP and CR. On this Kant-inspired view, it is sometimes argued that deception and coercion are wrong because one could not possibly consent to a deceptive or coercive transaction. As Christine Korsgaard puts it:

According to Kant, you treat someone as a mere means whenever you treat him in a way to which he could not possibly consent. Kant’s criterion most obviously rules out actions which depend upon force, coercion, or deception for their nature, for it is of the essence of such actions that they make it impossible for their victims to consent. If I am forced I have no chance to consent. If I am deceived I don’t know what I am consenting to. If I am coerced my consent itself is forced by means I would reject.

Note, however, that Kant did not think that NMMP requires that people give actual consent to a particular action. After all, Kant defends a retributive theory of punishment on which we do not violate NMMP when we punish a criminal who has been judged to be guilty and who receives his just deserts. On one reconstruction of Kant’s view, just punishment does not treat criminals merely as means not because they consent to be punished for the crimes they have committed
but, importantly, because they *could* give rational consent to the laws they are
punished for violating and to the punishment system that is used to punish them.

Along these lines, Parfit proposes that we adopt a *principle of possible rational consent* as a general principle of morality. On this view, an act is wrong if we could not possibly give rational consent to be treated in that manner. Susan Wolf objects to this principle on the grounds that it “might allow us to do things to someone even if we had no reason whatsoever to suppose that the person affected by it *would* consent to it – indeed, it would allow us to do things to a person even if he explicitly refuses to consent to it under conditions of full rationality and information.” This is too quick. As Parfit argues, the fact that B could rationally consent to have sexual relations with A does not render it permissible for A to have sexual relations with B without B’s *actual consent* because whereas *we could* give rational consent to *some* types of acts without our actual consent (such as just punishment for violating laws) there are other cases – such as sexual relations – to which we could not possibly give rational consent to be acted upon without our actual consent. Some contexts require actual consent to avoid a violation of NMMP and some do not.

Is participation in biomedical research like sex (in *this* respect!)? Could we give rational consent to a system of biomedical research that coerces people to participate in research much as we could give rational consent to a system that coerces us to pay taxes or recycle our soda cans or fasten their seat belts? I say “biomedical” because – and I think this is important -- we do *not* seem to think that social and behavioral research is impermissible whenever it uses people as subjects
without their informed consent. Rather, it's that both sex and biomedical research involves invasions of a person's body, and so we will need to consider whether it is *that* feature of biomedical research that justifies requiring consent. By itself, it seems that NMMP does not establish that it would be illegitimate to coerce people into participating in research.

*Protecting Interests*

Although bioethicists typically discuss consent as if it serves and is entailed by a deontological-type principle such as NMMP or respect for autonomy, it is arguable that the Nuremberg Code's insistence on consent was interest based; it was primarily designed to protect subjects from the sorts of palpable harms imposed by the Nazis and not to protect something as ethereal as autonomy. Although this justification for CR may not seem to be as philosophically deep as appeals to deontological principles, it is no less important. As Buchanan and Brock suggest, there are several reasons why people have an interest in “making significant decisions about their lives for themselves.” First, self-determination “is instrumentally valuable in promoting a person's well-being.” Because people will typically give valid consent to transaction if but only if the transaction serves their interests, regarding a person’s valid consent as necessary and (generally) sufficient method for rendering another’s action permissible is a reasonably reliable method for protecting or promoting a person’s well-being. As Mill wisely observes, even if other people are smarter or more knowledgeable than a given individual about matters that affect that individual's welfare, that person's judgment about his
interests is likely to be better because he cares more about his interests -- “He is the person most interested in his own well-being . . .”

The tie between consent and well-being is strengthened to the extent that a person’s interests depends on “the particular aims and values of that person.” For example, given that prostate surgery may involve a trade-off between some increased in expected survival and a substantial increase in risk of impotence, we cannot say whether this will enhance a particular patient’s well-being or interests without knowing the weight that he places on these outcomes. In addition, because people want to make decisions for themselves and enjoy doing so, the simple satisfaction of this desire is also a component of their well-being.

In addition to advancing welfare or well-being, consent also serves to protect and promote a person’s autonomy. I will say more about that below. Here I want to explore the alleged tension between promoting a person’s interests and respecting their judgments. We generally believe that people have a right to make decisions in certain spheres even when the decision does not advance their well-being. Thus we may think that a Jehovah's Witness has a right to refuse a life-saving blood transfusion even though the refusal does not advance her well-being (even allowing for the value she attaches to her particular religious aims).

The tension between the value of promoting a person’s well being and the value of protecting and promoting autonomy or self-determination is sometimes overstated. Although there are no doubt some cases in which these two values conflict, it is arguable that we would not value respecting people’s autonomy or their choices if – as a general rule – they made choices that did not advance their
interests or aims. Moreover, it cannot be entirely coincidental that the very conditions that are thought to render an agent’s decisions less than fully autonomous – coercion, deception, incompetence -- are also conditions that reduce the likelihood that her decisions advance her well-being. If an infirm widow were to sign a contract to sell a $100,000 farm for $10,000, we would not say, “Ah, this doesn’t advance her interests, but we need to respect her autonomous choice.” Rather, we would say, the fact that this decision sets back her interests is (defeasible) evidence that this wasn’t an autonomous choice.

Interestingly, the tension between considerations of well-being and respect for autonomy is much greater in clinical care than in clinical research. In clinical care, there are long standing debates as to if and when physicians can justify deception or withholding information from patients when they think that full disclosure would not serve a patient’s interests. But we are here considering whether coercive participation might be justifiable even though it is contrary to a person’s interest to participate in research and she would not do so voluntarily. Here, promoting the person’s well-being and respecting her autonomy are on the same side of the street.

Still, it matters whether we adopt an autonomy or interest-based justification for CR. If the principal justification for CR is that it protects and promotes the interests of the consenter, then we must ask why those interests should dominate the interests of present and future people who would benefit from more and faster medical research if we were to reject CR. We cannot simply say that an individual’s interest should trump the interests of others without additional argument. From an
impartial perspective, a regime that required people to participate might yield greater benefits than a system that allowed individuals to avoid participation by refusing to consent.

*Rights.* It might be thought that it is wrong to coerce people to participate in research because people have a right not to participate in research without their consent. So stated, this won't take us very far. We would need to know what grounds such a right and we would need to determine the strength of that right. As Richard Arneson observes, “you have a moral right not to be tortured murdered for fun, but you also have a moral right that your extra shirt button on your least favorite shirt not be taken from you without your consent.” If rights are of variable weight, then even if there is a right not to participate in research without one’s consent, it might be easily overridden. Our practices demonstrate that if there is such a right, it cannot be very strong because we allow for many forms of research without consent or valid consent. Perhaps there is no such right at all. I do not think it much matters much so long as it does not – by itself – provide much support for CR.

Now it may be argued that there is an important distinction between being used for research *without one's valid consent* in research and being *coerced to participate in research.* It may be argued that there is an important distinction between research that involves intervention in one’s body and research that does not. And it may be argued that there is an important distinction between research that poses no or little risk of net harm and research in which the risks are at least greater than zero. All of this may be so, and we will consider such claims in what
follows. For present purposes, the principal point is that we will not get very close to establishing that it is illegitimate to coerce people into participating in research by a straightforward appeal to the claim that it violates people's right not to be used for research without their consent.

*Autonomy and Respect for Persons.*

Although a commitment to respect for persons may be thought to entail or is synonymous with assigning a high priority to individual freedom or autonomy, I think that is a mistake. I do not think that the “mandate” component of the Affordable Care Act should be rejected on the grounds that it fails to respect those who would prefer not to purchase medical insurance. Indeed, it may be argued on behalf of a full-blooded consequentialism that “the demand for equal consideration of interests embodied in the utilitarian theory (and other consequentialist theories) is precisely what it means to respect or honor individuals.” Recalling Belmont’s language, we can “give weight” to “autonomous persons’ considered opinions and choices” without treating those preferences as dispositive or even close to doing so. Treating a person disrespectfully consists in “riding roughshod over his legitimate moral claims” and so to settle what constitutes genuinely disrespectful treatment requires an account of a person’s legitimate moral claims. So if the task is to determine whether we are justified in requiring people to participate in research, “respect for persons” is not up to the task.

Respect for autonomy may fare somewhat better. As I noted above, it is generally assumed that CR is entailed by respect for autonomy. As Faden and
Beauchamp put it, the Belmont Report reflect the view "that the underlying principle and justification of informed consent requirements, at least for autonomous persons, is a moral principle of respect for autonomy, and no other." The soundness of this argument depends, of course, on how we should understand what it is to respect someone's autonomy and the weight that should be assigned to that principle.

On a Kantian view, autonomy refers not to "self-determination" in its ordinary sense, but conformity with the moral law. On a Rawlsian version of this view, "acting autonomously is acting from principles that we would consent to as free and equal rational beings . . ." This general conception of autonomy is not likely to lend much support to CR. If people have an obligation to do their fair share of participation in research, a person could agree to accept a regime that would require such participation.

Of course, this is surely not the conception of autonomy that is regarded as a core principle of bioethics. The Belmont report summarizes the standard view in this passage:

To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.
A careful reading of this passage suggests two quite distinct dimensions of respect for autonomy. First, to respect a person’s autonomy is to respect that person’s judgment. In particular, it is to treat each person as the best arbiter of her own interests aims and values. Second, to respect autonomy is to allow people to act on those judgments, either through vetoing interventions to which they do not agree or authorizing transactions or interactions with others.

The first – judgment respecting -- dimension of autonomy lends more support to requiring consent to medical treatment than to requiring consent to participate in research. In treatment, a principal reason to insist on truthfulness and disclosure of relevant information is to block “paternalistic” intervention by physicians on the ground that the physician is better able to judge what is in a patient’s interests than the patient herself. In addition, respect for the patient’s judgment precludes forcing beneficial treatment on the patient and may bar some forms of manipulation which do not rise to the level of coercion, although, interestingly, we do not seem to think it forbids denying people access to medical treatment or drugs that they seek.

In any case, such judgment respecting concerns are irrelevant to coercive participation in research. For the sort of coercive participation under discussion does not disrespect a person’s judgment about her interests or undermine a person’s capacity as a decision-maker. Rather, it says that the subject’s judgment does not rule the day. If the state requires me to pay taxes, the state is not disrespecting my judgment that I would be better off if I paid no taxes. It’s just that I have to pay them. If the state requires B to participate in research on pain of a
penalty for refusal, the state does not disrespect B’s judgment as to whether participation is consistent with her interests or aims. It’s just that the state has made the option of not participating more costly.

It’s worth noting that this judgment-respecting dimension of respecting persons is violated by deception but not by coercion, for deception undermines the target’s capacity to rationally deliberate as to whether an action serves her ends under the circumstances in which she finds herself. The deceived person may not even know she is a subject in research. The coerced subject knows he is a subject. It’s just that coercion changes the circumstances in which a person finds herself.

In addition to showing respect for the content of a person’s judgment, Belmont maintains that we fail to respect autonomy when we “deny an individual the freedom to act on those considered judgments . . “ (emphasis added). But how important is the freedom to act on one’s considered judgments? Other things being equal, it is certainly preferable that people not be forced to do things that they do (or might) not want to do. But while this may give us reason to regard consent to participate as an important desiderata, it does not justify elevating consent into a virtual requirement for ethical research or bar coercive participation given that there are many things that we can be required to do (or not do).

Belmont adopted a pluralistic approach with respect to the three core values – autonomy, beneficence, and justice. It did not claim that respect for autonomy trumps or is even more weighty than considerations of beneficence, which might support abandoning CR. As Beauchamp and Childress put it, “The principle of respect for autonomy does not by itself determine what, on balance, a person ought to be free to
know or do or what counts as a valid justification for constraining autonomy.” Although this view may run counter to a common view among bioethicists, it would hardly be a surprise among political philosophers. We ordinarily think that the state may legitimately and justifiably do a variety of things to people (or their resources) without their consent or coerce people into performing a wide range of actions. We are not disrespected just because we are forced to do something we don’t want to do and this is particularly so if good reasons can be advanced in defense of such forcings. In particular, we generally think that we can justifiably use coercion to solve collective action problems. We require that all cars come equipped with catalytic converters because it would not be in any individual’s interest to buy one. Air quality is a public good (or bad); we benefit (or do not benefit) from the quality of air whether or not we contribute to pollution. Similarly, we might be required to participate in research on some fair basis because we benefit from medical research whether or not we contribute via participation. A general commitment to respect for autonomy is not sufficient to justify adopting CR.

Of course all interventions are not created equal. It might be thought that coercive interference with our bodies compromises our autonomy or fails to show respect for people in ways that other uses of coercion do not. I will consider that argument in more detail below. But however much comes to rest on appeals to autonomy or freedom, we need to distinguish between interventions that prevent people from living an autonomous life such as slavery and interventions that constitute relatively small interferences with an individual’s freedom to do what he wishes. David Archard suggests that “... an autonomous decision is valuable insofar as it concerns a matter critical to
the leading of a . . . person’s life – what projects he can undertake, what he finds worthwhile and rewarding in life, what gives his life purpose and value.” Requiring a person to buckle his seat belt or serve on a jury for a day (or two) interferes with his freedom, but is a trivial interference with his life. To the extent that appeals to autonomy or freedom derive their moral and rhetorical power from the importance of a person’s ability to lead an *autonomous life*, we cannot appeal to respect for autonomy to block the possibility of justifying coercive participation in research.

*Bodily Integrity.* The problem with many arguments for CR is their excessive breadth. If one appeals to principles such as respect for autonomy or a right not to be treated merely as a means, then we cannot justify a large range of research that takes place without (in some cases) any sort of consent by the subject or (in much social and behavioral research) without a subject’s *informed or undeceived* consent. Arguments that appeal to NMMP or autonomy seem to apply as much to social and behavioral research as to biomedical research. After all, when researchers deceive a subject about the purpose of the research in which she enrolls, they of necessity “withhold information necessary to make a considered judgment.” If *that* were the key moral issue, we should be much less inclined to waive the requirement of informed consent just because participation poses only minimal (if any) risks or because “the research could not practicably be carried out” without a waiver of informed consent. Moreover, given that many cases of state coercion barely raise our hackles, we need to explain why the prospect of coercing people into participating in research strikes us as so abhorrent.
Enter bodily integrity. If there is something especially illegitimate about coercing people to participate in research – other than its inglorious history and the extraordinary harms that were inflicted on unwilling subjects (and that might be enough) – it is that regardless of the level of risk, it may be that interventions that trespass the boundaries of a person’s body are of special moral significance and of much greater moral significance than interventions with a person’s “external resources” or property. It is bodily integrity, not autonomy that is important.

To elaborate on the previous sentence, there is an important distinction between respecting a person’s bodily integrity and respecting her autonomous decisions. Consider sexual relations. If it is wrong to have sexual relations with a person who says “no” while extremely intoxicated, it is not because we are respecting an autonomous decision; rather, it is morally impermissible to enter another person’s body against her wishes – autonomous or not.

Or consider this variation of a case presented by Jessica Flanigan

Debbie has diabetes and her physician advises her to start insulin treatment.

Debbie . . . is unwilling to live by a schedule and monitor her medication.

Against medical advice, Debbie decides to try to manage her diabetes with diet and exercise.

It is not clear whether Debbie is making an autonomous decision, but it does not matter much. It is not permissible for Debbie’s physician to inject Debbie with insulin against her wishes even if her reasoning is seriously deficient. It is bodily integrity and not respect for autonomy that seems to be doing the most moral work here.
Following Kasper Lippert-Rasmussen, let us refer to the claim that interventions with internal resources are more ethically problematic than interventions with external resources as the “the asymmetry thesis.” Some libertarians may reject the asymmetry thesis. For example, Robert Nozick argues that since the state cannot legitimately take a person’s internal resources, such as his eyes or his kidneys or force one to engage in labor for the benefit of others, the state cannot legitimately take a person’s external resources to use for the benefit of others. As Nozick famously quipped, “Taxation of earnings from labor is on a par with forced labor.”

By contrast, “redistributionist liberals” are inclined to support the asymmetry thesis. They will argue that it is comparatively easy to justify policies under which the state takes a person’s external and generally fungible resources through taxation or eminent domain or requires one to purchase a catalytic converter or health insurance but that it is comparatively difficult to justify policies that would allow the state to take or intervene with a person’s internal resources be it through forced labor, conscripting organs for redistribution, or requiring people to serve as research subjects.

The asymmetry thesis has strong intuitive appeal. We do tend to draw a psychological boundary around our body and regard encroachments on our physical person as worse than encroachments on our external resources. As Charles Fethe remarks: “Taxation . . . represents a standard procedure for exacting social obligations; but introducing a social duty to volunteer for medical experiments presents a claim for a . . . sacrifice [that] is more personal, deeper within that sphere
which we normally like to think of as protected from social encroachment.” As stated, the comparison is not quite right. The current question is not whether one might have a “social duty to volunteer for medical experiments,” any more than whether one has a duty to donate money to the state. The question is whether society can justifiably coerce people to participate in research just as it can justifiably coerce people to pay taxes. And while I agree that “we normally like to think” that the interventions consequent to participation in research are “deeper” and deserve greater protection from state coercion, the question is whether those intuitions mark a morally significant distinction on which we should rely.

Charles Fried argues – or appears to argue – that the body has intrinsic moral significance.

The human person identifies himself with his body; he knows that he IS his body, that his knowledge of and relation to the whole of the outside world depends on his body and its capacities, and that his ability to formulate and carry out his life plan depends also on his body and its capacities. This is not quite right. As a metaphysical truth, it is questionable whether a person “is his body” as distinct from his psychological capacities. As a moral matter, although it is true that one's ability to “carry out his life plans” depends upon elements of one's body, it is not true that all parts of one's body are of equal importance to one's agency. On a closer reading of this passage, it seems that Fried implicitly endorses the view that the moral weight of one's control over one's bodily parts depends on the importance of those parts to what genuinely matters in life, that is, to one's ability to carry out “his life plan.” And the strength of that
relationship is a factual or contingent matter and does not assume that the body actually has intrinsic moral significance. If I lose a finger, I may persist as pretty much the same person. A violinist may well lose his ability “to carry out his life plans.”

In addition to its relation to one’s agency, the moral significance of one’s body – or its parts -- also depends on its psychological importance. First, it matters whether a touching is intentional or incidental. As Justice Holmes remarked, “Even a dog distinguishes between being stumbled over and being kicked.” We do not regard being bumped on the subway as a battery. In the present case, of course, the touchings are decidedly intentional. Second, not all intentional non-consensual touchings are not equally worrisome. To take the most obvious example, some parts of our bodies are sexualized whereas others are not. It makes a psychological difference if A gives B a congratulatory pat on the back or kisses B’s cheek without B’s consent as contrasted with A’s fondling B’s breast or kissing B on the lips without B’s consent (some may regard the former as morally problematic, but I suspect that they would not regard the two sets of examples as equally problematic). The differences are partly conventional and vary with the cultural or ideological sensibilities of the parties or the relationship between the parties. Some orthodox Jews regard shaking hands with a member of the opposite sex as objectionable. And persons in positions of authority may be well advised to avoid all physical contact with a subordinate.

As a general proposition, the moral significance of the body depends on its relation to agency or psychological reactions. It is a serious matter to cut a person’s
hair without her consent, not because one’s hair is part of one’s “body,” but because people legitimately care about their physical appearance. We do not think that one has ownership rights to the hair on the salon floor – although we might think differently if it were economically valuable because it was used to manufacture wigs. A similar point applies to the moral importance of privacy or information about oneself. Having control over one’s medical records or social security number or credit card or images of one’s naked body is important not because the information exists in physical form but because the information can be used in ways that deeply affect the course of one’s life. Once again, the general point is that the moral significance of a resource does not depend on its physical properties or whether it is internal or external to the body. It depends on its fact-sensitive connection to what is important.

A similar point applies to a person’s external resources. As Matt Zwolinski suggests control over external goods can be deeply connected to a person’s projects: “Our . . . projects cannot be pursued – especially not over any significant period of time – without the ability to plan and rely on the use of external goods.” It is one thing to take someone’s money via taxation, but it is quite another to take someone’s house through eminent domain, even if he receives “just compensation” as required by the Fifth Amendment. For people can develop deep personal ties to their homes. A musician’s violin is no mere fungible external resource. Dylana Jenson was a rising star violinist who was loaned a Guarnerius del Gesù. When she decided to marry, her patron took back the violin, saying she wasn’t sufficiently committed to her career. She was devastated: “It was an intimate part of my ability to express
myself as an artist."xii And surely, the theft of a scholar's only (pre-digital) copy of a manuscript is not the mere taking of a stack of paper.

But the previous point cuts two ways. If taking a person's property has greater moral significance when and because it interferes with a person's projects and lesser moral significance when it does not, it seems that an intervention with a person's body is of greater moral significance when it interferes with a person's projects and of lesser moral significance when it does not. As Cecile Fabre puts it, "the objection from bodily integrity derives much of its force from the view that in violating people's bodily integrity, one is interfering with their life to an unacceptable extent." If this is so, it seems to follow that violations of bodily integrity are of less importance if they do not interfere with one's ability to lead an autonomous or flourishing life or, perhaps, when they do not cause psychological distress. No straightforward appeal to the importance of the body is sufficient to establish that coercive participation is illegitimate.

In discussing the moral importance of bodily integrity or other similar principles, it is important to avoid what David Sobel has called "The conflation problem." We should be careful not to conflate cases that represent interventions on the "trivial end of the spectrum and on the serious end and treat them as if there were equally morally important." Consider coercive removal of B's kidney to save A. Kidney transplants can be quite safe when performed under appropriate conditions and the "donor" can generally go on with his life and pursue his life plan without great difficulty. Still, I believe that most people would regard coercive removal as seriously immoral. If we assume that this intuition is sound, we can still ask what it shows. It
does not show that any violation of bodily integrity is of great moral significance. To use James Griffin’s example, if one’s blood had some marvelous factor and a few drops painlessly extracted from one’s finger in a minute’s time could save scores of lives, then it is doubtful that we would regard one’s claim not to have one’s finger pricked as of moral significance. Once again, we should not assume that all interventions of a particular type – say, interventions with the body – are of comparable moral importance.

Two concluding points about the body. First, although the correlation between the location of a resource and its moral significance is imperfect at best, the correlation may be quite high nonetheless. The line around the body may be a good heuristic even though it is an imperfect marker of moral significance. Moreover, even when a violation of bodily integrity does not interfere with one’s life plans, it may give rise to considerable psychological or belief-mediated distress, particularly if we believe – rightly or wrongly – that the body marks an important boundary.

Consider second-hand smoke. There was a time when people did not think they had a right that others not smoke in their presence. The smoke may have bothered them, but they did not feel that their rights were violated. And so smoking in others’ presence caused less distress than is frequently the case today. Similarly, if one believes that others have no right to touch or intervene in one’s body without consent, then such touchings will cause considerable distress.

Second, the identity or role of the non-consensual “invader” may also be of moral and psychological significance. It matters whether the invader is an unauthorized private person in pursuit of his own private aims or an authorized government official pursuing important public purposes. It is one thing if a private
individual touches one’s body without one’s consent and quite another if one is subject to a random special pat down by a TSA official or a police officer conducting a “stop and frisk.” These interventions may be problematic and can certainly be abused, but we are inclined to regard them as legitimate if not always justifiable.

_Widening the lens._

I argued in the previous sections that we cannot say that that coercing people to participate in research is illegitimate by straightforward appeal to deontological notions or principles such not treating people merely as means or autonomy or respect for personhood or by reference to the special moral importance of bodily integrity. In this section I want to place the argument for the legitimacy of coercive participation in a wider context by considering a range of cases in which many think that it is legitimate for the state to coercively interfere with people’s bodies or make policies that affect their bodies or internal resources without their consent. I want to consider coercive participation not as an issue in bioethics, but as a problem for political philosophy.

There are numerous policies that affect the bodies of citizens without their consent. The state may require vaccinations as a matter of public health. We have traditionally required pre-marital testing for disease (although one could avoid the testing by avoiding marriage). The state may obtain blood samples from criminal suspects without violating Fifth Amendment protection on grounds of self-incrimination. The police may stop and frisk people. The state may involuntarily quarantine people with dangerous contagious diseases. Although the first two
examples may be justified on the paternalistic grounds that the vaccination or testing is beneficial to the parties themselves (in addition to providing public health benefits), the latter two cases involve interventions with the body for the benefit of other persons.

Now it may be argued that these examples involve compulsory bodily interventions to prevent harm to others, which are legitimate as opposed to interventions designed to generate benefits to others, which are not. Along these lines, Charles Fried notes that whereas doctors have been allowed to override the expressed wishes of their patients in order to protect the public or other persons, they are not permitted to compel a person to “confer a benefit against his will, for instance by ordering him to donate an organ or blood of a rare type.”

Consider McFall v. Shimp. McFall suffered from a rare disease. His prognosis for survival was very poor unless he received a bone marrow transplant. After considerable searching and testing, it was determined that his cousin, Shimp, was the only plausible donor. Shimp refused to donate. McFall asked the court to compel Shimp to submit to further testing and the extraction of bone marrow if the testing indicated that his bone marrow was compatible. The Court was sympathetic to the view that Shimp had a moral duty to give marrow to his cousin, but was not prepared to legally require Shimp to do so.

For our law to COMPEL the Defendant to submit to an intrusion of his body would change the very concept and principle upon which our society is founded. To do so would defeat the sanctity of the individual and would impose a rule
which would know no limits, and one could not imagine where the line would be drawn.

It is not entirely clear if the Court was primarily objecting to the use of coercion for a reasonably invasive procedure such that it might have reached a different conclusion if something like a blood draw was sufficient. It does seem, however, as if the Court was not so much concerned about requiring Shimp to submit to further testing, but, rather, that approving the use of coercion in this case would constitute a precedent and thereby place the law on a slippery slope that would raise “the spectre of the swastika and the Inquisition . . .” But its hyperbolic rhetoric aside, if the Court was right not to require Shimp to help McFall, then it’s arguable that we should not abandon CR in research because, as Fried puts it, the subject who “refuses to submit to experimentation does not by his refusal constitute a danger to others; he merely refuses to confer a benefit.”

If we expand our horizons beyond research and consider public policies that affect people’s bodies (as opposed to direct interventions with people’s bodies), the distinction between “preventing harm” and “benefitting” loses much of its salience. A wide range of public policy decisions puts people’s bodies or health at risk without their consent, although these policies do not involve the use of direct coercion on individuals or direct invasion of a person’s body. A decision to place a toxic waste dump in location X rather than location Y may place those in location X at increased risk. A decision to set the standards for air pollution at a given level (as opposed to a feasible lower level) puts people at risk, nay, leads to predictable illness and death. The designation of speed limits, the number of police on the street, the length of prison sentences for violent
criminals, the amount of road salt on winter roads, the prevalence of street lighting, the level of enforcement of food safety, the level of taxation on alcohol – all these policies affect the frequency with which people are injured or killed or get sick. Of course any speed limit or level of street lighting or level of police patrolling will affect the number of people killed or injured. And I am not arguing that good public policy will always seek to minimize deaths and injuries, or we would have a nationwide 30 mph (or lower) speed limit. There are other values at stake, including cost and convenience. But the general point remains that the state regularly makes policies that affect what happens to our bodies without our consent.

The state also conducts life-affecting research without seeking consent of those involved or affected. Some examples, such as educational research or research on welfare policy, can affect the quality of people’s lives, but perhaps not whether they live or die. In some cases, research may lead to avoidable injury and death. For example, suppose that a state highway department is concerned about the trade-off between the financial and environmental costs of various quantities of road salt and the accident rates on snow covered roads. It might conduct a three-arm trial by using its standard amount (X) on one 10 mile stretch of a highway, half that amount (.5X) on another 10 mile stretch and double that amount (2X) on a third ten mile stretch and then study the accident rates and environmental effects (it knows the cost). Such research experiments with people’s lives. Indeed, although any level of road salt does that. The present point is that the highway department is surely conducting life-affecting research without consent, unless one implausibly argues that drivers tacitly consent to such research by (as Locke put it) ‘travelling freely on the highway.’
Of course, even if these cases exemplify legitimate ways in which the state puts people’s bodies at risk without consent, it does not follow that it is legitimate for the state to require people to participate in biomedical research. It is arguable that there is a distinction between road salt research that puts the bodies of “statistical lives” at risk and research that involves direct intervention such as a blood draw with an identifiable person. Just as we are prepared to do more to save identifiable coal miners trapped in a mine than to prevent similar mining accidents to future statistical miners, we are more willing to conduct road salt research that puts unidentified drivers on slippery roads at risk than to require identifiable drivers to participate in road safety research. In addition, we may distinguish between research that evaluates the effect of behavior (such as driving) that people undertake for their own reasons under conditions that we manipulate (varying levels of road salt or different speed limits) as contrasted with research that places people in a situation in order to see what happens to them.

Perhaps most important, we intuitively distinguish between research without consent (as in purely observational research or research with medical records) or without informed consent (as when researchers deceive or withhold information) and the use of coercion. Although all three involve research without valid consent, the latter strikes us as worse, although we should bear in mind that some of the most famous American exemplar of unethical research – Tuskegee – involved deception and withholding of available medical treatment but not direct coercion. Consider two cases of psychology research.
Deception. A psychology professor asks his students to participate in a study of puzzle solving, but the study is actually designed to discover whether they are cheating.

Coercion. A psychology professor tells his students – truthfully -- that they will be penalized one grade if they do not participate in a study (where participation has no significant educational value and students are otherwise entitled to the grade they would otherwise receive).

In principle, an IRB could approve Deception under the Common Rule’s provision for a waiver of informed consent, if it were minimal risk and the data could not be obtained without deception. I assume that Coercion could not be approved even though there is minimal or no risk in both cases and the burdens of participation are comparable.

Is the asymmetry defensible? I am not sure. Coercion may generally involve a more aversive experience than deception and this is particularly so if subjects do not find out that they were deceived. The magnitude of this difference is, of course, an empirical question. The moral weight of aversive experience is a different issue. We do not think deception is unproblematic whenever people do not discover they were deceived. In any case, even if research without consent or without valid consent is less bad than coercive participation, it is another question as to whether coercive participation should be viewed as illegitimate. I suggest that when we reflect on the numerous ways that the state regularly and invisibly makes decisions that puts people’s bodies at risk without consent, it is not implausible to argue that it is legitimate to use coercion to garner sufficient subjects in a timely manner if the
various aforementioned non-consent related criteria of legitimate research are satisfied.

Now participation in biomedical research often involves “labor” in addition to interventions with the body, and this is particularly so if we bracket research with medical records or cluster randomized trials which do not require subjects to do anything but receive medical treatment. Although this dimension of participation has received much less attention than risks to one’s health, it can be much more burdensome than the bodily invasion itself. There is not much risk or pain in a blood draw, but getting to a hospital and waiting to be seen might involve a considerable burden in time and inconvenience. So bracketing questions about bodily invasions, we can ask whether it is illegitimate for the state to compel people to engage in the labor involved in serving as a research subject.

It seems not. Consider Mill’s defense of the harm principle, i.e. the principle that states that the use of state coercion to limit individual freedom is legitimate only when the behavior in question harms others. In elaborating this principle, Mill maintains that one can harm others by inaction as well as action. One may be required to perform “certain acts of individual beneficence, such as saving a fellow-creature's life,” because not doing so constitutes a harm, says Mill, whenever one has a moral duty to perform the rescue.

I’m not convinced that Mill is right to describe such omissions as harms, although Mill may think his theory requires him to do so if he is to justify requiring such acts of
beneficence. In any case, Mill actually abandons the language of harm in the following passage.

There are also many positive acts for the benefit of others, which he may rightfully be compelled to perform; such as, to give evidence in a court of justice; to bear his fair share in the common defence, or in any other joint work necessary to the interest of the society of which he enjoys the protection. (Emphasis added)

It might be said that these are cases in which not performing these activities also constitutes harming by omission, but however such acts are described, but Mill thinks that the state may legitimately require people to perform them. In particular, Mill well understood that state coercion is sometimes necessary to solve collective action problems among citizens. He noted that if we want workers to benefit from a shorter workday, we may have to make it illegal for them to work a longer day. Otherwise, every individual worker would be better off working the extra hour if most others do not and all may end up working longer for the same pay. So if we accept the basic structure of Mill’s argument, we can ask whether participation in research qualifies as an instance of the “joint work necessary to the interest of the society of which he enjoys the protection.”

Let’s start with bearing one’s fair share “in the common defence.” It might be claimed that if it is legitimate for the state to conscript people into military service, then it must be legitimate for the state to conscript people into research where the burdens and risks are lower and the time commitment is comparatively trivial. Although there is something to this line of argument, I prefer not to go that way. First, it is not clear that it is legitimate for the state to conscript people into military service. Second, using
conscription as an analogy may prove too much, for if conscription is legitimate and justifiable, then virtually all invasions of personal freedom can be justified. There are good reasons to treat the possible need for military conscription as a special case of societal survival, and so it is better to use less fraught comparisons.

So consider some examples of labor that the state may require people to perform. Some jurisdictions require that people recycle certain materials. In my home town, we once had to sort our recyclables (glass, plastic, paper, metal) and put them in a bin on the street (sorting is no longer required). If we accumulate the required labor over 52 weeks a year times many years, the total required labor is not trivial. In any case, we don’t say that it’s permissible for the state to take my fungible money via taxes to pay for the recycling service, but that it’s not permissible for the state to force me to sort my recyclables, keep them until the weekly pick-up, and then move them to the curb (and who knows how much disease or injury is caused by this activity?). This is simply not the sort of forced labor or involuntary servitude that we regard as illegitimate.

The criminal justice system coerces people to perform labor and, sometimes, to put themselves at considerable physical and emotional risk in doing so. We may require a person to testify as a witness to a crime on pain of being held in contempt of court even if the person genuinely and legitimately fears retaliation for doing so. (There is a “witness protection program” for a reason). Victims of crime may be required to testify because the state can decide to prosecute even if the victim does not want to press charges, as may happen in rape cases where the victim fears humiliation in court or in domestic violence cases where the victim has a change of heart or fears retaliation by her
abuser. We require people to serve on juries. This frequently involves minimal labor (one or two days) and little risk, but then serving as a research subject often involves minimal inconvenience and minimal risk. Moreover, jury service sometimes involves the risk of retaliation as well as considerable inconvenience and loss of income when a trial takes days or weeks and particularly if the jury is sequestered for a length of time.

I am not assuming that all the foregoing examples are legitimate exercises of state coercion. Moreover, even if they are all legitimate exercises of state coercion, it may be argued that coercive participation in research is not legitimate because it serves less weighty goals. The point remains that if we accept the general structure of Mill’s principle, we can surely ask whether participation in research constitutes a form of “joint work necessary to the interests of society.” Jonas would say that medical progress is not “necessary.” Others might disagree. But one can’t reject coercive participation simply on the grounds that it is illegitimate for the state to require us to endure personal burdens if it serves legitimate public purposes. One needs an argument as to why it might be illegitimate for the state to require people to bear the time and inconvenience burdens of participation in research that provides a public good. That is where the debate should occur.

Or consider a mandatory national service program that would be modeled around military conscription. New York Times columnist David Brooks recently wrote that in order to reduce social inequality, we need a program that would force people from various “social tribes” to live and work together “to spread out the values, practices and institutions that lead to achievement.” Subsequent letters to the editor were varied in
their response. Many were enthusiastic – “a splendid, outstanding idea.” Some disagreed. But none argued that it should be rejected out of hand on the grounds that it constitutes a form of slavery or forced labor. Setting aside whether such a program should be adopted, it seems that if it would be legitimate for the government to require that people spend months or a year or two years in service to their society, it hardly seems out of line that they might be required to undergo blood draws or a lumbar puncture to advance medical knowledge. How do we explain why Brook’s proposal does not fill people with the dread? Is compulsory intervention with the body so much worse than taking a year or two of a person’s time?

Finally, consider bad Samaritan legislation. Some nations and some jurisdictions in the United States have adopted bad Samaritan laws under which people may be punished for failing to make an easy rescue. And it is commonly thought – by philosophers if not the general public – that it such legislation is legitimate and justifiable. There are questions about the degree of risk that it is reasonable to require people to assume, but the basic principle is widely accepted. Although the duty to rescue is typically understood as the duty of one individual to aid another individual, Arthur Ripstein argues that the duty to rescue is best understood as a duty to support a fair system of providing people with the preconditions of living a self-directed life. On his view, the common law is correct not to regard the failure to rescue as a tort against the person in peril for which the latter could demand compensation, but we would be justified in making the failure to rescue a criminal offense against a society-wide practice that is required by considerations of justice.
On Ripstein’s view, a just society “holds certain misfortunes in common” and thus supports “equitable schemes of redistributive taxation, so as to pay for such essentials as health and education.” In some cases, our legally enforceable duties derive from the fact that virtually everyone benefits, as with laws prohibiting pollution. In other cases, our duties derive from an obligation to support institutions that provide for basic needs. On the plausible assumption that the need for effective and safe medical care is a basic need, it is arguable that we might be required to contribute to a system of medical research by supporting institutions such as NIH and by participation in medical research just as we may be required to contribute to a system of universal access via taxation or required to purchase medical insurance.

The point of the previous sections is not to present a compelling argument for the legitimacy of coercive participation or for the view that we should abandon the general requirement of informed consent in biomedical research. The point is to render both ideas more plausible. By considering the wide range of ways in which the state makes policies or conducts research that affects our body and indeed sometimes does so via coercion, and by looking at the ways in which the state requires us to accept burdens and inconveniences for the sake of our fellow citizens, I hope to have shown that it is not all that easy to explain why there is a significant moral distinction between the activities in which state coercion is regarded as legitimate and participation in research where it is not.

Does This Argument Apply to Both Patients and Healthy Persons? If, for the sake of argument, we assume that it is *in principle* legitimate to coerce people into participating
in research, it is relatively easy (I don’t say easy) to legitimize requiring healthy persons to serve as subjects, say in Phase I trials or in vaccination trials or in studies of diagnostic techniques if – once again – we assume the risks of participation are not too high.

Consider this example.

_Alzheimer’s Research._ Alzheimer disease constitutes an enormous burden on society and its members. To evaluate potential medications, researchers first needed to identify biological markers for its presence. This involved a lumbar puncture – the insertion of a needle into the backs of subjects – to obtain a small amount of cerebrospinal fluid. Researchers needed to have samples from Alzheimer’s patients and from both healthy volunteers who would serve as controls.

This is a particularly useful example, because it illustrates the important and yet incremental character of much bio-medical research. Suppose that few healthy persons would volunteer to undergo the procedure (I think this is doubtful if people are given incentives to do so). Here we could use a process similar to the lottery mechanisms that are used for jury service and make whatever exemptions were thought necessary if participation were particularly burdensome for some. Given the large numbers in the potential pool of participants, it is possible that one might never be asked to participate or be asked to participate infrequently in this sort of research, and so the expected amortized burden of such service over a lifetime need not be particularly great. A lumbar puncture is relatively low risk and not particularly burdensome. Nonetheless, if large numbers of persons undergo such procedures, we can expect that a few people would be injured or
die as a result of their participation just as a few people die as a result of compulsory vaccination and seat belt laws – even if vaccination and seat belt laws prevent many more deaths than they cause. If these consequences are not decisive objections to requiring seat belts and vaccinations – and they are not – then the infrequent deaths and injuries that result from requiring people to participate in medical research need not be decisive objections to that practice. It may be more difficult for people to visualize the connection between research and its benefits than with seat belts and vaccinations, and so a similar requirement might meet more resistance. But the principle seems much the same.

But what about patients? Alzheimer’s patients may not be capable of consenting to participate, although surrogates might consent on their behalf. But would it be legitimate to require them to undergo a lumbar puncture for the non-therapeutic purpose of trying to identify biological markers of the disease? There are competing moral considerations. On the one hand, those with particular diseases are in a unique position to contribute to research, for it is only on them that interventions and pathogenesis studies can be conducted. In addition, while many patients are already suffering from their disease, the additional risks and burdens consequent to participation in research may be relatively minimal, particularly if a study is comparing treatments that are in equipoise. They may have to undergo research procedures unrelated to treatment, but these may be very low risk and not particularly burdensome. On the other hand, it may be thought that the sick are already suffering and, as Jonas put it, that “the afflicted should not be called upon to bear additional burden and risk [because] . . . they are society’s special trust and the physician’s particular trust.” Moreover, whereas military conscription applies to a
“well defined segment of the population . . . disease . . . strikes randomly and indiscriminately in all people regardless of age, gender, or ethnicity.” In addition, it has been argued that if researchers need subjects with particular conditions, then an enforceable “universal duty of research participation would do little to meet their needs.”

I do not think that these objections to coerced participation of patient subjects are particularly convincing. First, it is unfortunate but true that the sick are often in unique position to contribute to the search for generalizable knowledge. It is similarly unfortunate that victims of crime are in a unique position to contribute to the pursuit of justice, but we still demand that they appear at trial if needed even if they have reason to fear the experience or its consequences. They cannot say, “I’ve already suffered; leave me alone.” Second, the unpredictability of obligations is a familiar feature of our moral lives. Although some obligations are predictable because they are a function of one’s undertakings, as when one makes a promise, other obligations are foisted upon us by the circumstances in which we find ourselves, as when we are witnesses to an accident or crime and must report what we have seen and appear in court if necessary. On this score, being able to contribute because one has a disease is no different. Third, a universal enforceable duty can supply researchers with a supply of subjects with particular conditions. It depends on the way the universal duty is specified. If all citizens have an enforceable duty to make an easy rescue or report that they witnessed a crime should the situation arise, then there is a universal duty that requires action only when such situations arise. The fact that not everyone will be called to action seems irrelevant. Similarly, if we say that all patients can be required to participate in research under “to be specified” conditions, then such a requirement can supply researchers with suitable
subjects under the specified conditions. As Arthur Ripstein has observed, there are a variety of legal duties “that select people on the basis of their availability and capacity,” be it to help build a dyke in a flood or allow the police to take a vehicle if necessary. In general, we prefer more systematic methods of insuring that everyone contributes to projects “required for the security of all.” We prefer to socialize our contributions via taxes and hire professional firefighters than to fight the fires ourselves. But when we cannot socialize the performance of some task, then we can legitimately call on those who are in a position to contribute.

So we return to the question: can we defend the view requiring people to participate in research illegitimate whereas requiring people to perform these other actions is legitimate? I have no doubt but that many feel that there is a distinction between (1) requiring victims and witnesses to testify at trials or requiring people to serve on juries or to make easy rescues and (2) requiring people to serve as research subjects. Research exceptionalism runs deep. But, once again, if we assume that the research otherwise meets a set of ethical criteria, it is difficult to see why it would be illegitimate to require people to spend the time or undergo the inconvenience and relatively small risks involved in appropriate biomedical research.

*From Legitimacy to Justifiability.* I have argued that no simple deontological-type principle -- such as autonomy or respect for personhood or not treating people merely as means or bodily integrity -- is sufficient to establish that it is illegitimate for the state to coerce people into participating in research. I have also argued that coercive participation in research bears considerable similarity with other cases in which we...
regard coercion as legitimate. It is difficult to articulate a principle that legitimates coercion in these other contexts, but not in research. It is possible that I have overlooked compelling arguments that can do the trick, but, obviously, I do not know what they are (or I would have considered them).

I suggested above, that even if it is in principle legitimate for the state to require that people participate in research, it does not follow that it would be wise, prudent, or morally justifiable to do so. The balance of moral reasons may not only support the need for consent in a specific case, but more importantly, it may support barring the use of coercion as a general rule for the conduct of at least a certain range of research contexts. Put in slightly different terms, we may decide to treat coercive participation as illegitimate because it is typically unjustifiable, not by appeal to a simple principle such as autonomy or bodily integrity, but as a decision rule for the organization of bio-medical research that is favored by the balance of moral reasons. In effect, I am arguing that although we can’t get to a ban on coercive participation through the front door, we can and probably should get there through the back door.

In considering the justifiability of coercive participation, we need to distinguish between “first-order” morality and “second-order” morality. By “first-order” morality I refer to the conclusion that would be reached by an omniscient moral reasoner who could weigh and aggregate all the relevant moral considerations. By “second-order” morality, I refer to the moral conclusion that takes into account the fact that first-order moral reasoners are not omniscient and, as a consequence, the desirability of institutional guidelines and rules for conducting our affairs. This distinction mirrors the structure of
the familiar distinction between act-utilitarianism and rule-utilitarianism, but does not assume that first-order morality is purely consequentialist. In both moral and prudential contexts, we often do and should rely on second-order principles or rules when and because doing so will yield the results favored by the first-order balance of moral reasons than deciding each case on the basis of first-order considerations.

As a matter of first-order morality, the justifiability of coercing people into participating in research in a particular case turns on at least seven factors (there are no doubt others): (1) the benefit to be gained from research; (2) the risks and burdens of participation; (3) the efficacy of plausible coercive mechanisms; (4) the weight of the “deontological” moral factors that tell in favor of CR; (5) the weight of the indirect or negative externalities that would be generated by a coercive approach; (6) the psychological and social distress that would be caused by a coercive system; (7) the availability of non-coercive means by which to obtain a sufficient number of subjects in a timely manner. Coercive participation would be justified if and only if a sensitive weighing of these factors supports it. It would be a complex and arguably calculation. I suspect such a calculation would generally not support the use of coercion, although it is hard to tell. Let us consider the factors I have identified.

a) The benefits of research. Although medical research contributes to our health and well-being, we should neither underestimate nor overestimate the extent to which that is so. It is entirely possible that most of the major advances in the reduction in morbidity and mortality are behind us in advanced industrial nations and that the greatest realizable improvements will not come from additional research but from the application of existing
knowledge and getting people to avoid unhealthy behaviors. Research on rare diseases and research that prolongs life by months or a few years will surely matter to those whose lives could be improved or extended, but it will not have major society-wide effects. Indeed, the contribution of medical care as well as medical research to declines in mortality and morbidity may have contributed relatively little to health improvements as compared with public health measures. On the other hand, even when research does not lead to significant declines in mortality or morbidity, it can enhance the quality of life. As I noted above, developments in joint replacement surgery have helped many people gain mobility. And who knows the extent to which drugs for erectile dysfunction have enhanced the quality of the lives of men or their relationships?

Estimates of the expected benefits of research is very difficult. Something like an NIH “scientific review group” could evaluate the expected benefits from a proposed study, but it is unlikely that we should or would have much confidence in their estimates. Even if the macro-level benefits of the enterprise of research are demonstrable, the link between specific studies and the benefits to other (including future) people is difficult to see, not to mention that we have difficulty taking the interests of future people seriously. There might be medical emergencies – such as a pandemic flu – in which the importance of timely research is clear. But, for the most part, the gains from more and faster research are likely to be modest and hard to demonstrate.

b) Risks and burdens. Second, the justifiability of penalizing non-participation in research would surely depend, in part, upon the risks and burdens of participation. In discussing the legitimacy of coercive participation, I have tried to bracket this concern by
assuming that the risks and burdens are not excessive. Still, and as I have noted, even when participation poses little long-term risk to one’s health, participation in research can be time-consuming, inconvenient, and may involve discomfort. At the same time, the net risks and burdens may and should be off-set by compensation. If only some people are required to serve as research subject for the sake of public purposes, we can socialize that burden by compensating them adequately for their service such that participation is reasonably perceived as a benefit by most persons. In any case, the magnitude of the net risks and burdens would have to be part of any reasonable first-order moral calculus.

c) *The coercive mechanism.* It is not clear that we could design a coercive mechanism that is both effective and politically acceptable. If the penalties for non-compliance were small and mostly symbolic, then they may be insufficient to motivate compliance behavior, although some will regard “it’s the law” as a reason to comply. If the penalties are severe enough to motivate people to comply (for example, like going to jail for contempt of court for refusing to testify as a witness), they might well be viewed as excessive unless there were a substantial cultural shift about the moral importance of participation in research.

Now the causal arrows between laws and moral beliefs may go in both direction. A change in moral beliefs will affect the perception that a law is legitimate, but enacting laws can also effect a change in moral beliefs. A law that requires participation in research may signal that society regards this as a duty and will help to give people a moral reason to participate. Still, there has to be *some* cultural support for legislation to get the ball rolling and it is doubtful that such support is now sufficient. Laws
prohibiting smoking in public places are perceived as legitimate because there had already been a societal shift against the desirability of smoking, but it’s not clear that such a shift is in the offing with respect to participation in research. In a recent small survey study, about half of the respondents agreed that “Everyone should share the responsibility and be in medical research studies to improve public health.” Although this suggests some support for requiring participation, it is worth noting that only 30% of respondents agreed with the statement “I feel it is my duty to participate in medical research.” Given the reluctance of people to think it might be wrong for them not to participate, it is not clear whether we could design a system that would be effective and would not be viewed as excessively harsh.

d) Deontological values The “deontological” factors such as autonomy, liberty, not being treated merely as a means, respect for bodily integrity and the like should bear considerable weight and would often be sufficient to outweigh the beneficial consequences of coercive participation, although considerations of fairness might favor a policy in which the burdens of participation in research are more widely shared. I place “deontological” in scare quotes for two reasons. First, it is possible that these moral reasons are themselves ultimately grounded in consequentialist considerations even if – as a practical matter – we do not apply them by direct appeal to consequences. Although Mill says that the harm principle is entitled to govern “absolutely” the use of social coercion and thus works as a side-constraint on government policy, the need for such a principle is justified on grounds of utility which he regards as the “ultimate appeal on all ethical questions.” Second, although respecting people’s freedom and their control over their bodies and labor is of considerable moral importance, I have argued that these
values are not, by themselves, sufficient to bar coercive participation in the way deontological prohibitions are sometimes thought to work.

It’s not just that they may be over-ridden or outweighed under extraordinary conditions. For most non-doctrinaire deontologists will grant that. Rather, the problem is that it not clear precisely how much weight such considerations bear for the normal range of public policy questions. We might think that it is wrong to interfere with someone’s bodily integrity or limit their freedom whenever doing so promotes greater utility than not doing so. A small gain – say amount N -- in social utility would not be sufficient. On the other hand, we might think that such interferences would be justifiable if they led to an increase in 2N (or 3N or some other multiple of N) amount of social utility. Here, as elsewhere, we need an account of the strength of these deontological considerations or the level of good that is necessary to justify violating some value.

As I have already noted, it appears that we are already committed to a pluralistic/balancing view with respect to the benefits of research and at least some of the “deontological” values secured by informed consent. The Belmont Report, which is often cited as encapsulating the basic values of research ethics, does not rank order its three values – beneficence (or non-maleficence), respect for persons (or autonomy), and justice – or claim that respect for persons trumps all other possible values that might be served by research without consent. And while few (if any) have defended coercive participation, our practices surely suggest that we do not think it impermissible to engage in research without consent or without informed consent so long as certain conditions are met. As I noted at the outset, Federal Regulations specifically allow the waiver of the
need for consent in various forms of research, and so our practices suggest that we do not regard violations of autonomy or (on some constructions of this principle) treating people merely as a means as sufficient to render research unethical.

e) Negative Externalities. If the principal argument for coercive participation is that it would generate positive utility not otherwise attainable, then we must also consider the distutilities to which it might give rise. These may take several different forms. First, whether or not coercive participation in biomedical research would constitute a genuine independent wrong, I suspect that it would be experienced by many people as a grave violation unless people underwent a significant psychological change. As an analogy, consider people’s views about incest between adult siblings. When people are given a scenario in which all of the standard objections to brother-sister incest do not apply (it is consensual; no harm occurs; no one else knows; contraception is used, etc), people still say that they believe it is wrong even though they are hard pressed to justify their response. They exhibit what Jonathan Haidt calls “moral dumbfounding.”

Many people have a greater fear of cancer than heart disease even though their chances of dying from heart disease are much greater than their chances of dying from cancer. And people may have a greater fear of being required to undergo a lumbar puncture as part of a research protocol than dying in an automobile accident because the speed limit is raised from 55 m.p.h. to 65 m.p.h.

Although I lack anything but anecdotal evidence here, I suspect that people tend to regard the risks of participation in biomedical research as especially weighty when compared, say, to the risks of employment even when participation is consensual. It is
not clear whether this sort of “research exceptionalism” can be justified although we may be able to explain it. David Wendler has argued that research related risks are regarded as particularly fraught because they are directly imposed by another person rather than being the result of activities (such as employment) that are organized by others. In addition, people may transfer some of their intuitions about medical care to medical research. We understand that employers use employees for their own purposes, even when employees benefit from the interaction. But people may think that physicians and the medical profession do and should seek to benefit those with whom they interact and thus medical research (whether conducted by physicians or non-physicians), which uses people for the benefit of others, runs directly counter to those beliefs.

Let us assume for the sake of argument that – as a matter of psychological fact – most people would have an aversive reaction to the prospect of coercive participation in research. How much moral weight should we give to that fact? I am not sure, but there are several reasons to take it seriously. First, it is possible that these views reflect a principle of some importance even if those who hold this view are unable to articulate what it is. Second, even if these feelings and beliefs are not independently defensible, their existence may exert their own moral force. As Nir Eyal puts it (in a related context) “. . . the culture of respect for autonomy is beneficial and worth preserving, from a non-consequentialist and certainly from a consequentialist standpoint. Protecting a culture of respect weighs heavily in support of cultivating opposition to coercion in spheres where coercion is likely to retain its public image as an utter violation of the respect.”
A policy of coercive participation might also undermine trust in and support for the research enterprise and the relation between patients and physicians. The history of abusive medical research (and the perceptions of that history) cast a long shadow. To take but one example, some research with healthy volunteers and a greater proportion of research with patient subjects is facilitated by physicians who identify patients as prospective subjects in research protocols. If patients do not trust their physicians to be concerned only or at least primarily with their interests, then people may avoid seeking medical care or fail to trust their physician’s recommendations for treatment.

f) Non-coercive strategies of recruitment. Although I continue to think that the timely recruitment of subjects is a sufficiently serious problem to warrant taking coercive participation seriously there may be non-coercive means by which to obtain a sufficient number of subjects in a timely manner. Just as we are able to recruit soldiers into a “volunteer army” by paying them more than when soldiers were conscripted, we may not have explored the full potential of recruiting research participants by expanding the use of financial incentives to research subjects both in terms of the proportion of trials that offer payment and the level of payment frequency and level of payment. To the extent that people avoid participation because of the burdens of research – time, inconvenience, pain – it should be relatively easy and morally unproblematic to overcome such resistance through the offer of payment. We can surely recruit healthy volunteers to serve as controls in the Alzheimer’s study by paying them to undergo a lumbar puncture, and patient-subjects might also be paid to accept the burden of research related procedures that do not involve great risk when their care is not compromised.
To the extent that people avoid participation because of the perceived risks of participation, it will be more difficult to overcome such resistance, although it will often be feasible to do so. Here I want to make two points that should lend credibility to the prospect of a more expansive approach to payment. First, much research does not in fact pose particularly high risks and this is so even with respect to Phase I research with healthy volunteers. Second, people regularly and reasonably accept the risks of employment (think lobster fishermen, coal mining, tunnel digging, structural steel workers, loggers, fire-fighters) when they are paid enough for doing so. Third, setting aside non-medical risks to our health, we already accept some medical risks for the sake of financial benefit. People will take older generic drugs if they are sufficiently cheaper than more recent and slightly superior drugs still on patent. People will avoid seeking medical care to save money. In effect, they are accepting a risk to their health for financial reasons. There is no reason to think that we could not get many people to accept the risks of participation in research if they were paid an adequate amount and if they received appropriate compensation for research related injuries.

Even if an expanded use of payment were effective in recruiting subjects, we need to consider several ethical objections to such a practice. First, it may be objected that the use of payment may yield a subject class that is biologically unrepresentative of the target population of the intervention being tested and thereby compromise the scientific validity of a study. In addition, the use of payment may compromise scientific validity if it leads prospective subjects to lie about or withhold information that would lead to exclusion from the study. When the use of payment compromises scientific validity then payment should not be used. Period. But the use of payment is often quite compatible with
scientific validity when proper controls are in place, and so I will assume that is so in what follows.

Second, it might be objected that increasing the prevalence and amount of payment might constitute coercion or undue inducement and thereby jeopardize the validity of consent. I have argued elsewhere at (excessive?) length that these concerns are generally misplaced. Simply stated, offers of payment do not coerce because they do not constitute a threat of harm for non-participation. One is not coerced to accept an offer of payment because one has no reasonable alternative to doing so any more than a patient is coerced to consent to medical treatment when she has no reasonable alternative. And contrary to what many believe, a prospective subject is not unduly induced or influenced to participate simply because an inducement gets them to participate when they would otherwise not do so. Rather, offers of payment constitute an undue inducement if and only if they distort the prospective subjects’ ability to weigh the risks and benefits (including payment) of participation, and there is little evidence that payment leads to such distortion. If a reasonable subject would value payment greater than the risks and burdens of participation, there is no reason to think that a subject’s consent is not valid.

Third, even if payment is compatible with scientific validity in a given study (say because there is no scientific necessity for a subject pool that is socio-economically diverse), it might be thought that the use of payment will unfairly burden the poor. In effect, the affluent would buy their way out of having to participate in research by (indirectly) paying the less affluent to do so in their place.
There are several different worries here. A *democratic* or *egalitarian* argument might claim that it is important that all citizens do their part in providing certain services, and so some object to the volunteer army on the grounds that it allows the affluent to buy their way out of serving in the military. There may be something to this thought, but if are prepared to allow a volunteer army despite its unrepresentativeness, I see no reason to think that this argument should disallow a system of incentivizing participation in research. Second, it may be thought that it is unseemly for the affluent to pay people to do serve as guinea pigs in their stead. But this is true for all work. We pay others to manufacture our cars and clothing, to mine coal, to provide public services such as firefighting and police protection and to provide personal services such as landscaping, massage, hair styling, garbage collection, house cleaning, waiting tables, and the like. And it is hard to see why we should regard paying people to participate in research as morally unworthy or unseemly while it is perfectly permissible to pay people to perform these other – often dirty and disagreeable – tasks, if it is beneficial to all concerned.

Third, it may be thought that an expanded use of payment will unfairly burden the poor because they would be accepting a disproportionate share of the risks and burdens of participation in research. This would be a valid concern if it were true, but I think it is actually the weakest argument against payment. Although research participants might be disproportionately poor, this argument depends on an excessively narrow conception of “burden.” From the perspective of the participants themselves, the key question is whether the value of payment is greater than the disvalue of the risks and burdens of participation. And if it is, then those who participate are not *burdened* by participation, all things considered. Rather, they *benefit* from participation.
If the less affluent are frequently or generally not capable of making a reasonable judgment as to whether the financial benefit exceeds the risks and burdens of participation, then we could object to the use of payment on the grounds that it constitutes an “undue influence” and that they have not given valid consent. But absent evidence to the contrary, I see no reason to think that less affluent people are not capable of determining whether the benefits of payment are sufficient to compensate them for the risks and burdens of participation.

Finally, it may be objected that a more expansive practice of payment would reduce the willingness of people to participate in research altruistically. As Richard Titmuss argued with respect to blood donation, people may want to contribute something that cannot be purchased and so the use of payment may deter some people from participating at the same time that it incentivizes others. If the overall effect of payment on recruitment were negative, then it should obviously not be used for that reason. But the evidence suggests that Titmuss is wrong; the overall effect on payment for blood is to increase “donations,” and there is no reason to think that research is different. And if the use of non-coercive financial incentives serves to facilitate recruitment, as seems likely, it renders the use of coercion all that much harder to justify.

There may, however, be another reason not to resort to an expanded use of payment to facilitate recruitment. Even if many of the arguments against the use of payment are mistaken, we know they are widely held among IRB members and it would be surprising if they weren’t widely held among the general population. For example, a recent survey revealed that many IRB members believe that offers of payment coerce if
they get people to consent to participate when they would otherwise not do so or when they believe they have no reasonable alternative but to participate for the money. Even if those views are mistaken – as I have argued – a proposal to expand the use of payment is likely to generate considerable resistance and undermine support for the research enterprise. And so while I think that this approach can and should be pushed further, there may be limits to how far we can go.

*Through the Back Door*

I have argued that even if coercive participation cannot be ruled out on the grounds that it violates a basic deontological principle, it may still be unjustifiable all things considered in many cases. It may be unjustifiable because a coercive system would be inefficacious or too harsh, because the benefits would not be sufficiently large to override the value of autonomy and control of one’s body, because the negative externalities are too great, because the positive benefits (if any) would not be sufficient to outweigh the disvalue of violating individual freedom, and because there are incentive based systems available that could generate an increased and faster rate of completion.

But even if an omniscient moral calculation would occasionally support the use of coercion, there may be second-order reasons to bar its use in biomedical research, although less reason not to allow research without consent in social and behavioral research or, perhaps, with stored tissues or the like. There may be second-order reasons to bar coercion because we are not omniscient reasoners. It is entirely possible that no
institution that could make those judgments reliably and with reasonable accuracy and in which people would have sufficient confidence. Given the value of clear and firm rules, it may be better to adopt a simple relatively inflexible version of CR under the actual conditions in which we live. In addition, there is a political dimension to second-order morality. It is arguable that a justifiable policy must be perceived as legitimate even if were otherwise justifiable and it must be democratically endorsed. I suspect that a decision to abandon CR would not meet either of these tests.

In a world with excellent decision makers and widespread trust in their capacities, we would not need to rely on a (relatively) hard and fast rule such as CR that unnecessarily impeded medical progress. We would allow decision-makers or IRBs to balance the various moral considerations and approve the use of coercion when it is justified and disapprove its use when it is not. We would treat the use of coercion as legitimate and ask IRBs to decide when it is justifiable. In effect, we would adopt the moral equivalent of “yield” signs for traffic. We would ask people to exercise discretion: go when it’s safe, stop when it’s not. Although there are some intersections where it is sufficiently safe to use yield signs, there are many other intersections where the advantages of allowing drivers to use yield-like discretion are outweighed by the dangers. And so we use stop signs – even though it would often be perfectly safe for drivers to proceed cautiously through the intersection and stop only if necessary (the way that many bicyclists treat stop signs and traffic lights). As Frederick Schauer puts it, “rule-based decision-making is premised in part on the belief that none of us, ordinary or not, have the mental capacity
incessantly to consider all of the things than an ‘all things’ considered decision-making model requires of us.”

There are some legal contexts in which we opt for “standards” rather than “rules.” In child custody cases, for example, courts typically use a non-constraining “best interest” standard rather than a more constraining set of rules such as “the mother” or “the primary care giver” or (as Jon Elster once suggested) “flip a coin.” Perhaps the advantages of allowing such discretion are sufficient to outweigh the inevitable bad decisions it allows and litigation that it encourages.

By contrast, there are many other decision contexts in which we forego attempting to use the theoretically optimal principles – the ethical equivalent of yield signs -- and make do with rules that are good enough and command widespread social acceptance. Even if an omniscient moral calculation could justify the use of coercion under some conditions, it is entirely possible that we would not have a reliable mechanism or institutions to determine when those conditions obtain. Given the choice between an unreliable mechanism for determining when coercion should be used and the adoption of a rule that prohibits its use, it might be preferable to draw a bright line around bio-medical research and simply bar the use of coercion. It might be better to adopt a rule that would ban all use of coercion, than to allow decision-makers to determine if and when it should be permitted. Better to treat all coercion as illegitimate than to attempt to block unjustifiable coercion.

This “rule based” argument for CR parallels an important line of argument in Mill’s On Liberty. Although Mill sometimes implies that it is always wrong for the
state to interfere with self-regarding conduct, Mill says that the “strongest of all the arguments against the interference of the public with purely personal conduct, is that when it does interfere, the odds are that it interferes wrongly, and in the wrong place.” Note that this line of argument does not deny that interference with “purely personal conduct” is sometimes justified. It actually assumes it. After all, for it to be the case that the “odds are” that the interference is wrong, it must be the case that interference is sometimes right. Mill is arguing here that because interference with “purely personal conduct” is usually wrong and because society cannot be trusted to interfere only when such interference is right, it is better to adopt “one very simple principle, as entitled to govern absolutely the dealings of society with the individual in the way of compulsion and control.”

To illustrate the case for rules over standards, consider two examples: literacy tests for voting and sexual relations between psychotherapists and patients. One can make a plausible if inconclusive case for literacy tests for voters if such tests were applied in a non-partisan and non-discriminatory manner. But given the history of using such tests to exclude potential voters for partisan and racist reasons, we are well advised to adopt a rule that bans literacy tests altogether. We treat literacy tests as illegitimate. Sexual relations between psychotherapists and patients might be morally permissible if both parties could give valid consent and if such relations are not harmful to patients. But even if those conditions sometimes obtain, there is good reason to think that neither psychotherapists nor patients are well positioned to judge when that is so. Given that the “odds are” that a patient’s consent is tainted by transference or a function of underlying mental disorders or
that the psychotherapist’s judgment is tainted by counter-transference and given that such relations are likely to be harmful to the patients or interfere with a beneficial psychotherapeutic relationship, society is well advised to adopt a hard and fast ban on such relations. It is sometimes said that psychotherapy patients can never give valid consent to sexual relations with their psychotherapists. I doubt that this is actually true. Nonetheless, it may be quite sensible to follow a rule that always treats such consent as invalid.

So, too, for the use of coercive participation in biomedical research. In the context of social and behavioral research or even medical contexts where the risks of participation are low and it is not feasible to garner individual consent, we are prepared to allow IRBs to exercise discretion and allow for research without consent, although they probably wrongly permit some research to go ahead without consent where consent could and should have been obtained. Moreover, research without informed consent – such as social and behavioral research that uses deception -- is of relatively low visibility. It does not seem to generate many of the negative externalities I have discussed. But given that the costs of allowing coercive participation in the biomedical context are likely to exceed the benefits, it is probably better to treat it as illegitimate as matter of course.

In addition, and as I suggested above, any justifiable policy must pass the test of democratic legitimacy. Even if people should allow for coercive participation, it is unlikely that they will do so. Even if coercive participation passes a Feinberg-like test of moral legitimacy, it will probably not be perceived as legitimate and that – in itself – is a moral reason to reject it. A commitment to democracy means that there is moral reason
to defer to the wishes of the majority even if the majority is wrong, at least when the policy at stake does not violate basic rights.

Although we may not have sufficiently acknowledged the extent to which informed consent is not required for social and behavioral as well as biomedical research, a generalized belief in CR is well entrenched. Consider gun control. If we could turn back the clock such that the Constitution did not include the 2nd Amendment, then we might be well served by the sort of general prohibition on (certain kinds of) guns that some societies have adopted. But there is no turning back. I once argued that there are good reasons to adopt a policy of compulsory voting in the United States, a policy that has been adopted in several other Western democracies. I also argued that “it is a good idea whose time is either past or has not yet come.” Along similar lines, Aaron Spital has argued that while a policy of conscription of cadaveric organs for transplantation would save the living and would pose no harm to the dead, most people oppose such a policy, and so he reluctantly concludes that this is a “stimulating” idea whose time has also not yet come. Much the same may be true for coercive participation in research. And this is particularly so given the fear – supported by many bioethicists and the subject protection industry -- that any weakening of CR would put us on a slippery slope to Nazi-like or at least Tuskegee-like experimentation with human subjects even if such fears are unjustified. It is true that people’s views can change. Same-sex marriage was not on the radar screen twenty years ago, but is now widely accepted. Still, I do not see a massive change in society’s views about the need for informed consent on the horizon.
Conclusion. So we return to the uncontroversial and unquestioned principle with which we started. Peter Singer has remarked that the chief task of philosophical analysis is “Thinking through crucially and carefully, what most of us take for granted.” And this is so, I believe, even if we end up confirming what we take for granted. Although bioethics seems to have assumed that it is obvious that and why it is ethical to conduct biomedical research only if subjects have given their voluntary and informed consent, I have argued that the justificatory story is more complex. It would be nice if we were able to ground CR in a simple and uncontroversial ethical principle such as respect for persons or not treating people merely as means or the sanctity of a line around “the body.” But if I am right, that is not to be.

I have argued that no straightforward argument for a ban on coercive participation can be made to work. We cannot get to such a ban through the front door. But we can get there through the back door, by seeing such a ban as justified as a second-order principle that is rooted in our inability to make reliable judgments as to when coercive participation is justified by first-order moral principles. I am eminently aware that my argument for a ban on coercive participation will prove unattractive to many, as it is decidedly inelegant, partially consequentialist, institutional, and, dare I say, political. I understand the attractions of Occam’s Razor. But if I am right, the truth about the justification for banning coercive participation is inelegant, partially consequentialist, institutional, and political. And that will have to suffice.
One final thought. Even if my argument for a ban on coercive participation is on the right track, I will not have produced an argument for CR – through the front door or the back door. And this for two reasons. First, there is a distinction between banning coercion and requiring valid consent. To show that it is illegitimate to coerce people to participate in research does not entail that it is illegitimate to use them as research subjects without any token of consent, as in cluster randomized trials, or by using deception to gain their consent. Second, and as I have noted on several occasions, we already regard it as justifiable to do research without consent or valid consent in many contexts. We do not treat CR as a general requirement for ethical research. We may be able to carve out a general class of research in which consent should be required. But that task remains to be done. I venture to guess that the argument for adopting CR for that class of research is likely to prove as inelegant as the argument I have made in this paper.


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iv Nagel


vi Ibid., p. 6. (original emphasis)


viii On What Matters, Chapter 8 (Oxford: Oxford University Press, forthcoming)


xi Fethe

Wendler, 162.
Haidt