The most plausible pro-coercion view: requiring informed agreement while penalizing non-participation in research

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ABSTRACT

In ‘(Why) should we require consent to research?’ Alan Wertheimer probes whether it is legitimate for the government to ‘coerce’ people into participating in biomedical research, including interventional biomedical research. In debating the rules that ought to govern participation in interventional biomedical research, we should distinguish two separate moral claims. First, interventional research should proceed only when the subject has given her informed agreement. Second, it is legitimate for the state to set a requirement that people participate in interventional biomedical research, and to penalize or punish those who refuse to participate. The most plausible ‘pro-coercion’ view accepts both of these claims. Though I stop short of endorsing this view, it captures important ‘pro-coercion’ and ‘anti-coercion’ intuitions.

KEYWORDS: research ethics, informed consent, coercion

The title to Alan Wertheimer’s paper asks, ‘(Why) should we require consent to participation in research?’ This title might be a little misleading. The central issue of his paper is not whether research may ethically proceed without participants’ informed agreement, but whether the state may legitimately penalize or punish people who do not

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participate in research (including interventional biomedical research)—what Wertheimer refers to as the state coercing people into participating in research.

Wertheimer dwells on the fact that currently some research may proceed without consent (‘waiver of consent’ cases permitted by the Common Rule) or with not-fully-informed consent (cases in which subjects are deceived about the study), and takes this to show that the consent requirement is not as categorical as we might've thought. But Wertheimer’s main goal is not to argue that a broader class of research should similarly be allowed to proceed without the subject’s informed agreement; Wertheimer’s main argumentative goal, rather, is to argue that it is legitimate for the government to require that individuals participate in research (including interventional biomedical research) and to penalize or punish individuals who refuse. Although Wertheimer ultimately concludes that it is probably not justifiable, all things considered, for the government to coerce research participation, he first argues that there’s no good reason to conclude that such coercion is morally illegitimate.

We should distinguish two distinct moral issues: first, whether it’s morally acceptable to proceed with research without obtaining informed agreement from research subjects in those cases in which informed consent currently is required; second, whether it’s morally legitimate for the state to penalize or punish individuals who refuse to participate in this research. The most plausible ‘pro-coercion’ view is one according to which subjects’ informed agreement to research participation is required (except for those ‘waiver of consent’ cases in which consent currently isn’t required and those cases of deceptive research in which fully informed consent isn’t required), but non-participation in research may legitimately be penalized. According to this ‘most plausible pro-coercion view’, it is legitimate for the state to set an expectation that individuals will participate in interventional biomedical research for the common benefit, and to penalize individuals who do not participate; but the boundaries of the individual’s body should never be breached for research purposes without her informed agreement.

Throughout his paper, Wertheimer presents what he calls the consent requirement (CR)—the view that a subject’s informed consent is a requirement of ethical biomedical research—as conflicting with the pro-coercion position he’s exploring. If a subject’s informed consent is a requirement of ethical biomedical research, then it is not legitimate for the state to coerce her into participating, or so Wertheimer’s paper implies. That informed consent and coercion are incompatible is a coherent claim, and may even be analytically true: if ‘informed consent’ is understood as informed and voluntary consent, and ‘voluntariness’ of consent is analyzed as being undercut by coercion, then it is analytically true that the requirement to obtain informed consent to research is incompatible with the legitimacy of coercing subjects into participating in research.¹

Nonetheless, this way of framing the issues—informed consent requirement vs. legitimate state coercion—may make it harder to see some of the underlying moral issues.

¹ However, in a departure from his typical framing of the issues (informed consent requirement vs. legitimate state coercion), in the following sentence Wertheimer implicitly acknowledges a distinction between (a) requiring people to participate in research on pain of penalty and (b) using people as research subjects without their informed consent: ‘So even if people have a moral obligation to participate in research, it does not follow that it would be legitimate to require them to do so or do on pain of penalty or, for that matter, to use them as subjects without their informed consent.’ (p. 146).
In debating the rules that ought to govern participation in interventional biomedical research, we should clearly distinguish two separate moral claims which are as follows.

(i) Interventional research should proceed only when the subject has given her informed agreement. (Contrary views are that subjects may be deceived or left uninformed about interventional research, and that subjects may be forced to participate in interventional research.)

(ii) It is legitimate for the state to set a requirement that people participate in interventional biomedical research and to penalize or punish those who refuse to participate. [A contrary view is that research participation is ‘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 Charles Fethe puts it (as quoted by Wertheimer on p. 157).]

As I interpret him, Wertheimer argues that there is no good argument against (ii) (though he ultimately argues that it would not be justifiable for states to require people to participate in research). What is Wertheimer’s position on (i)? Some of his paper could be interpreted as arguing against (i) and arguing for the legitimacy of including people in research without their agreement and even forcing them to participate. For example, in the section ‘Widening the Lens’, Wertheimer discusses numerous ways in which the state affects what happens to our bodies without our consent (and, I’d add, without our agreement):

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, and 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. But the point remains that the state regularly makes policies that affect what happens to our bodies without our consent.

Wertheimer also mentions instances of state coercion, such as obtaining blood samples from criminals or involuntary quarantine, that are backed up by the use of physical force (or at least the threat of physical force). Why is Werheimer discussing cases in which individuals don’t give their agreement and cases in which the state uses force (or the threat of force)? It would be reasonable to conclude that Wertheimer invokes these cases in order to shed light on cases of research participation in which individuals don’t give their agreement and their participation is forced. So there is some textual evidence that Wertheimer is questioning whether (i) is true.

On the other hand, the following passage suggests that the view under consideration in Wertheimer’s paper is whether the state may penalize or punish non-participation in research not whether the state may physically force people to participate in research:

I suspect that coercive participation is rarely taken seriously because it conjures up images of Nazi-like experimentation on people’s ability to survive in freezing water. But that is, to say the least, not what I have in mind. Rather, I have in mind a scheme under which prospective subjects are required to participate in research on pain of some sanction for refusal. It might be objected that to subject someone to a penalty that they could easily
accept rather than participate is not really coercive. I don’t think much turns on words here, so I will just stipulate that this is the type of coercion that I have in mind. (p. 144)

Thus, the best interpretation of Wertheimer is that the view he’s entertaining is the combination of (i) and (ii): interventional research should proceed only when the subject has given her informed agreement, and so it is morally impermissible to force people to participate in interventional research or involve them without their informed agreement, but it is morally legitimate to penalize or punish people for refusing to participate. This strikes me as the most plausible version of a ‘pro-coercion’ view. While I stop short of endorsing this view, it is a compelling view that captures some of the important intuitions that Wertheimer discusses in his paper.

The view that it is legitimate for the state to penalize or punish non-participation captures the ‘pro-coercion’ view that the state may legitimately require individuals to participate in valuable collective endeavors. Wertheimer gives the examples of jury duty and recycling our cans and bottles as examples of behavior that the state requires of us and penalizes us for not engaging in. If it is legitimate to require people to serve on juries (which can take days or weeks of their time), and it is legitimate to require people to recycle (which takes time on a daily or weekly basis), doesn’t it seem legitimate to require people to participate in medical research, so long as this research poses very little risk of injury? Medical research is unlikely to be as burdensome as jury duty is for those citizens who get impaneled on juries and spend days or weeks engaged in a task they might find unpleasant.

The view that the state may not force people to participate in interventional research captures ‘anti-coercion’ intuitions about the importance of bodily integrity and intuitions supporting ‘body exceptionalism’—that is, the view that ‘interventions that trespass the boundaries of a person’s body or personal resources are of much greater moral significance than interventions with a person’s “external resources”’ (p. 156). There’s a strong intuition that the state (or individuals, or institutions) may not breach the boundaries of adults’ bodies without their permission, except in very limited circumstances. If someone requires medical care and he is incapable of giving consent, then it may be legitimate to breach the boundaries of his body without this agreement. But there is a strong intuition that we may not breach the boundaries of individuals’ bodies, without their agreement, in order to help others or to promote the common good. Wertheimer probes and problematizes intuitions in favor of ‘body exceptionalism’. I interpret Wertheimer as rejecting the view that interfering with someone’s body is intrinsically of greater moral significance than taking her external resources, though Wertheimer would allow that interfering with the body may have greater moral significance in many contexts given contingent facts about how people experience interference with the body.

But Wertheimer doesn’t need to argue against ‘body exceptionalism’, or reject intuitions about the inviolability of the body, in order to argue for the view I’m attributing to him (the ‘most plausible pro-coercion view’). We may preserve the intuition that trespassing the boundaries of someone’s body is of greater moral significance than taking her ‘external resources’, and still argue that it is legitimate for the state to penalize people who do not participate in interventional medical research. And even if citizens’ bodies are inviolable—in the sense that it is not morally legitimate for the state to trespass the
boundaries of their bodies and physically force citizens to participate in interventional research—it may still be morally legitimate for the state to set the expectation that citizens will participate in interventional biomedical research, and to punish or penalize those who refuse.

According to the ‘most plausible pro-coercion view’, the individual citizen has the moral power to determine when others may perform interventional biomedical research on her (that is, the individual’s agreement or refusal is what makes it morally permissible or morally impermissible to perform the research), and yet it is legitimate for the government to penalize or punish certain ways of exercising this moral power (that is, the government may legitimately penalize or punish the refusal to participate in the biomedical research). This is a coherent moral view, but it may, intuitively, seem a little odd. Whether your body gets used in biomedical research is your prerogative in one sense (if you refuse, then it’s morally impermissible for the state to force you), but it’s not your prerogative in another sense (the state may ‘require’ you to use your body in this way, and penalize or punish you if you refuse). The body is protected from trespass, but the individual’s use of her body is not fully free from ‘social encroachment’, to use Charles Fethe’s phrase.

This view may seem odd, I venture, because these two moral prerogatives often go together: when the individual has the moral power to determine whether it’s morally permissible for others to touch or use her body in some way, often she is morally entitled not to be legally required to let her body be touched or used in this way. For example, individuals have the moral power to determine when others may have sex with them, and it is not morally legitimate for the state to require them to exercise this power in one way on the threat of penalty, for example by fining people who refuse to have sex with their spouses. Perhaps the most intuitive understanding of a right to bodily autonomy is that it includes both kinds of prerogatives. Nonetheless, it is coherent that these two moral prerogatives could come apart. For example, we may think that the government may not force adults to get vaccinated, but that it is legitimate for the government to penalize adults who do not get vaccinated.

In conclusion: the best interpretation of Wertheimer’s paper is that he’s entertaining the ‘pro-coercion’ view that a subject’s informed agreement is an ethical requirement on interventional biomedical research but the state may legitimately require individuals to participate in research and penalize or punish those who refuse. Whether this requirement counts as ‘coercion’ and whether informed agreement given in these conditions counts as ‘informed consent’ are interesting theoretical questions. But the spirit of this view is that legitimate state coercion and the consent requirement—that is, the view that a subject’s informed consent is an ethical requirement on research—are compatible, in contrast to Wertheimer’s opposition of them.