

AGAINST THE INALIENABLE RIGHT TO WITHDRAW FROM RESEARCH

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ABSTRACT

In this paper I argue, against the current consensus, that the right to withdraw from research is sometimes alienable. In other words, research subjects are sometimes morally permitted to waive their right to withdraw. The argument proceeds in three major steps. In the first step, I argue that rights typically should be presumed alienable, both because that is not illegitimately coercive and because the general paternalistic motivation for keeping them inalienable is untenable. In the second step of the argument, I consider three special characteristics of the right to withdraw, first that its waiver might be exploitative, second that research involves intimate bodily access, and third that it is irreversible. I argue that none of these characteristics justify an inalienable right to withdraw. In the third step, I examine four considerations often taken to justify various other allegedly inalienable rights: concerns about treating yourself merely as a means as might be the case in suicide, concerns about revoking all your future freedoms in slavery contracts, the resolution of coordination problems, and public interest. I argue that the motivations involved in these four types of situations do not apply to the right to withdraw from research.

INTRODUCTION

Suppose a researcher wants to test a new drug that increases hemoglobin oxygen saturation. The drug is known to be safe, and the researcher just wants to test its efficacy. The proposed test is also safe: subjects take the drug, and then their pulse oximetry is measured via finger-clip for the next five minutes. However, suppose that the drug is so expensive that the researcher cannot afford to have any subjects remove the clip from their finger within this five-minute window, if statistical power is to be preserved. Thus, without a guarantee that subjects will not withdraw, the researcher will not be able to perform the study. In such a situation, I think that researchers and subjects are morally permitted to come to an (informed) agreement whereby the subjects autonomously choose to waive their right to withdraw. That

example illustrates the thesis I intend to defend in this paper: the subject's right to withdraw from research is sometimes alienable, where a right is *alienable* just in case its holder is permitted to waive or rescind it, and it is *inalienable* just in case it is not alienable.¹

Three points deserve immediate mention. First, I said *sometimes*, not *always*. The case with which this paper began is a purported example, but I do not claim that it would still be legitimate if enough of its details were changed.

Second, I will argue merely that subjects are sometimes morally permitted to waive their right to withdraw from

¹ For the purposes of this paper I take *alienating* a right to be synonymous with *waiving* that right. The reason I did not make use of this synonymy in the above definition is that 'a right is alienable just in case its holder is allowed to alienate it' is less cognitively helpful than the definition given in the text.

research, but my arguments also apply to the claim that subjects are sometimes morally permitted to *condition* that right, which is to agree to satisfy a condition or pay a penalty if it is exercised. Thus, if the right to withdraw is alienable, then it is also 'condition-able'.² (A *condition-able* right is one the bearer is permitted to condition, whereas a *conditional* right is one that has been conditioned.) One reason for this is that the easiest way to enforce a waiver is often by conditioning. In legal terms, the point is that requiring *specific performance* is sometimes impractical. It will be easier merely to collect a fine from me than to force me to show up at the clinic for a blood draw, for example. But, besides that practical reason, there is also a good theoretical reason to infer from alienable to condition-able, for everyone involved might prefer merely to condition rather than to alienate. In any case, henceforth I will suppress reference to condition-ability, but all my arguments will go through even for the conjoined concept of alienability plus condition-ability, and the reader is invited to make that mental substitution freely within any of my arguments: the subject's right to withdraw from research is sometimes alienable (*and also condition-able*).

Third, my focus is on whether the *moral* right to withdraw is alienable, not whether the *legal* right *should* be. The difference is subtle yet important.³ Essentially every major code and guideline for the conduct of medical research insists that we should have the legal right to withdraw from research. (The Nuremberg Code is the

major exception.)⁴ Thus, for example, the Helsinki Declaration states in its 22nd principle, 'The subject should be informed of . . . the right to withdraw consent to participate at any time without reprisal'.⁵ The council of Europe declares in Chapter II article 5 of its Convention on Human Rights and Biomedicine, 'The person concerned may freely withdraw consent at any time'.⁶ The US Code of Federal Regulations, which governs all research funded by the US government, requires in section 46.116a8 on the protection of human subjects that ' . . . the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled'.⁷ Finally, the Council for International Organizations of Medical Sciences claims in its International Ethical Guidelines for Biomedical Research on Human Subjects (which is based on the US Code of Federal Regulations): 'that the individual . . . will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled'.⁸ Andrew Herxheimer conveniently summarizes this growing consensus by making it the fourth of his six rights of the patient in clinical research:

⁴ The Nuremberg Code's clause on subject withdrawal is:

During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him impossible.

(Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law, No. 10, Vol. 2, 1949. *Nuremberg Code*. Washington, DC: US Government Printing Office: 181–182.) This is an exception to the general consensus of the inalienable right to withdraw, but not one friendly to my argument, for if I am right then it is sometimes permissible for a subject to waive the right to withdraw *even when* he has reached the physical or mental state where continuation seems to him impossible.

⁵ World Medical Association (WMA). 2004. *Declaration of Helsinki, Ethical Principles for Medical Research involving Human Subjects*. Tokyo, Japan. Available at: <http://www.wma.net/e/policy/b3.htm> [Accessed 18 Mar 2008].

⁶ Council of Europe. 1997. *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*. Oviedo, Spain. Available at: <http://conventions.coe.int/Treaty/EN/Treaties/Html/164.htm> [Accessed 18 Mar 2008].

⁷ Code of Federal Regulations. 2005. Title 45, Public Welfare, Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks, Part 46 *Protection of Human Subjects*. Bethesda, MD. Available at: <http://ohsr.od.nih.gov/guidelines/45cfr46.html#46.116> [Accessed 18 Mar 2008].

⁸ Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization. 2002. *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Geneva, Switzerland. Available at: http://www.cioms.ch/frame_guidelines_nov_2002.htm [Accessed 17 Apr 2007].

² Sarah Edwards has recently argued that the right to withdraw is condition-able (to use my terminology), but my argument for alienability both assumes less and proves more. I don't rely on Kantian considerations, as she does; I argue for the stronger claim of alienability rather than the weaker claim of mere condition-ability; and I explicitly consider and reject a myriad of different reasons why one might believe to the contrary, which she does not acknowledge. My argument provides a nice complement to hers. See S.J.L. Edwards. Research Participation and the Right to Withdraw. *Bioethics* 2005; 19: 112–130. Monique Spillman and Robert M. Sade have also recently published a piece urging that participants in xenotransplantation trials not be allowed to withdraw from life-long surveillance, on analogy with making a Ulysses-contract. This is not the place to assess their complex argument, but it can be interpreted as arguing in a particular case that the right to withdraw from research is alienable. See M.A. Spillman & R.M. Sade. Clinical Trials of Xenotransplantation: Waiver of the Right to Withdraw from a Clinical Trial Should Be Required. *J Law Med Ethics* 2007; 35: 265–272.

³ Judith Jarvis Thomson argues that the distinction between moral and legal rights rests on a confusion, that 'moral right' and 'legal right' do not name distinct species of rights. (See Judith Jarvis Thomson. 1990. *The Realm of Rights*. Cambridge, MA: Harvard University Press: chapter 2, section 5.) My point here can be stated in a way consistent with her thesis: I intend to argue that the right to withdraw from research is alienable, not that we should implement legal policy to allow such alienation.

Even after the patient has agreed to take part he has the right to withdraw from the study at any time, without having to give a reason, and without this in any way prejudicing his treatment. For example, he may decline to answer particular questions in a questionnaire, or may withdraw from a trial because he dislikes one of the investigators.⁹

Now, although these codes and guidelines are perhaps best interpreted as suggesting what our legal rights should be, I intend to argue that the most plausible rationale for that legal position, namely the rationale according to which the legal right to withdraw follows from a more fundamental moral right, is mistaken. Thus, this paper consists of the broad consideration of various possible arguments that might be given in defense of an inalienable moral right to withdraw from research, and then laying out the reasons to reject each of them. I take the argument against the inalienable moral right to withdraw to be the central, most important step in changing our legal system to reflect the moral facts, but the relation between moral rights and legal rights is too intricate for sustained treatment here.¹⁰

This topic is important because the inalienable right to withdraw is costly.¹¹ It is costly for subjects because they might in some situations rationally prefer to rescind their right to withdraw, as for example in the pulse oximetry study with which I began this paper. It is costly to researchers because it means that they are always at risk of losing statistical power for ongoing studies, which may have already incurred a heavy investment of resources. It is costly to bystanders in situations where partial treatment is worse than none at all, due for example to drug

resistance. And finally, it is costly to society in general, because we are losing out on the fruits of otherwise permissible research.

Now, some philosophers have argued that almost all rights are alienable.¹² Indeed, on a popular view of how rights are justified, namely as protected choice, it might follow rather quickly that (almost) all rights are alienable.¹³ For, if the point of rights is to protect choice, then surely we should also have the (protected) choice of waiving those rights. I am sympathetic to these arguments, but I anticipate my interlocutor will not be. Thus, I will not appeal to them. Rather, I will proceed by laying out reasons to think that there should be a *presumption* that any particular right is alienable, and then I will go on to consider whether possible exceptions to that presumption might apply to the right to withdraw from research.

In slightly more detail, my argument proceeds in three major steps. In the first step, I argue that rights are typically alienable, both because that is not illegitimately coercive and because the general paternalistic motivation for keeping them inalienable is untenable. In the second step of the argument, I consider three special characteristics of the right to withdraw, first that its waiver might be exploitative, second that research involves intimate bodily access, and third that it is irreversible. I argue that none of these characteristics justify an inalienable right to withdraw. In the third step, I examine unique considerations often taken to justify various other alleged inalienable rights, the right to life, the right against slavery, the right to a 40-hour work week, and the right to whistle-blow. I argue for each of these cases that the reasoning involved does not apply to the right to withdraw from research.

STEP 1: RIGHTS SHOULD BE PRESUMED ALIENABLE

Illegitimate Coercion

Given an arbitrarily chosen right, why presume that it is alienable? Perhaps the best way to answer this question is to dispel some confusions about what alienability does (not) entail. And perhaps the most important potential confusion to dispel is the idea that making the right to withdraw alienable is illegitimately coercive. It is not; it is

⁹ A. Herxheimer. The Rights of the Patient in Clinical Research. *Lancet* 1988; 12: 1128–1130.

¹⁰ One very important issue which I will not consider is whether, even granting that the moral right to withdraw is sometimes alienable, it might be too costly or open to abuse to figure out when exactly subjects should be allowed to waive it. I suspect that many of the costs of figuring out when subjects are competent enough to decide to waive their right to withdraw will be borne by the research team itself, on a par with how a clinical care team is responsible for determining when their patients are competent to consent to medical treatment. However, there will surely be extra burdens on oversight committees and the legislative system to accommodate this moral right. The important point is that these sorts of questions fall under the heading of whether we should allow the legal waiver of the right to withdraw, not whether it is in fact morally permissible to allow subjects to waive that right.

¹¹ Of course, this is not to say that (a) whether rights are alienable depends on considerations of cost. Rather, it is to say merely that (b) the reason it is important to examine whether rights are alienable is that the wrong answer may be costly. And, of course, neither (a) nor (b) above presupposes that *rights* are grounded in cost or utility, though the affirmative answer to (a) claims that *whether rights are alienable* is grounded in costs or utility.

¹² See, for example, Stuart Brown, Jr. Inalienable Rights. *Philos Rev* 1955; 64: 192–211. (The only exceptions, for Brown, are the quite abstract ‘rights of a man to the protection of his moral interests, his person, and estate’, which cannot be specified in more detail.)

¹³ For a recent defense of the choice theory of rights, see Hillel Steiner. 1994. *An Essay on Rights*. Oxford: Blackwell Publishers.

merely an instance of the enforcement of a prior agreement, which, depending on how best to carve up the conceptual terrain, either need not be coercive or else if coercive then need not be illegitimately so. Let me explain. We can conveniently distinguish between three different kinds of cases, depending on what the research team articulates to prospective subjects about withdrawal. In the first kind of case, the research team informs the prospective subject that once enrolled she will be permitted to withdraw. In the second kind of case, the research team fails to mention at all whether enrolled subject will be permitted to withdraw. In the third kind of case, the research team informs the prospective subject that once enrolled she will *not* be permitted to withdraw.

The first kind of case is the easiest, because we all agree that if the transacting parties come to the explicit agreement that the subjects are permitted to withdraw then they are so permitted. To say that the subject is permitted to withdraw even in the second kind of case is just to insist on the simple (potentially alienable) right to withdraw, which for the purposes of argument we will assume the subjects to have. Thus this second kind of case is also not our interest. Rather, our focus will be on the third type of case, and we can now see the conceptual confusion in the idea that alienating the right to withdraw counts as illegitimate coercion. That charge would be legitimate if we were considering cases of the first or second type. But our concern is with cases where the researchers explicitly articulate that subjects will not be permitted to withdraw. In such cases, forbidding withdrawal counts as coercion in a sense, but only if we focus myopically on the segment in time after the experiment has begun, where a subject wants to withdraw but cannot, and ignore the fact that the real question at hand is the legitimacy of a prior (attempted) agreement, before the experiment had even begun.

Of course, we cannot be so myopic in our focus, for to do so would be to classify essentially all sequential transactions as illegitimately coercive. For example, it would count as illegitimately coercive all rental contracts where the renter is allowed to back out of the contract only on condition of paying out the entirety of the rent for the remainder of the agreed-upon rental period. Such contracts are ubiquitous, and their permissibility makes intuitive sense more generally. Suppose that you and I agree that I will give you a widget today in exchange for you giving me a doodad tomorrow. Now, if we focus myopically only on what transpires tomorrow, it might seem that this agreement is illegitimately coercive, for, assuming that I have given you the widget today, I am requiring that you give me the doodad tomorrow. And what if you change your mind tomorrow? You have my

widget, but you no longer want to give me the doodad. Would it be illegitimately coercive for me, or perhaps the civil government acting on my behalf, to take your doodad (or its equivalent as compensation, if specific performance is impractical) forcibly? Of course not; that would eliminate the possibility of engaging in non-instantaneous transactions.

That the examples considered so far are mutually advantageous is not relevant. Consider: I propose to give you a doodad today, altruistically, in return for nothing. Surely you're still within your rights to insist that if you accept my doodad today, then I must also give you a widget tomorrow, else you refuse the entire transaction, perhaps because accepting a doodad without its widget complement incurs some cost to you. (Compare this to the pulse oximetry case that began this paper. There, the researcher incurs a great cost by enrolling a subject who then withdraws, namely the cost that she has failed to achieve statistical significance with her limited supply of drug.) In such a case, if I agree to this proposal, and if I altruistically give you the doodad today, then I am obligated to give you the widget tomorrow as well.

Paternalism

A second very important confusion to dispel is the idea that inalienable rights better protect our interests than merely alienable ones do. This form of reasoning is typically mistaken, for three reasons.¹⁴ First, making a right alienable does not diminish or take away from that right. Nor does it take away from our rights more generally. Indeed, in arguing against the inalienable right to withdraw, I am in fact *defending* another right, namely a *second order* right to determine whether one can give up a first order right. In other words, there is a fallacy in the following sort of reasoning: 'It's good for people to have a right to something; therefore it's even better for them to make that right inalienable.' One thing we can do with our rights is to exercise them, but another thing we can do with them is to trade them away in return for other things we want. For example, I have the right to sleep in on Saturday mornings, but I might trade that right away by agreeing to volunteer at the soup kitchen.

Thus, the paternalistic reasoning that it's better for me if my rights are inalienable also infringes on autonomy, and this is the second reason to reject that form of

¹⁴ I say 'typically' to postpone discussion of possible exceptions, such as slavery contracts, which I will address shortly. At the moment, my concern is merely a general presumption in favor of alienability.

reasoning.¹⁵ Even if things go better for me if my right to something is inalienable, still, I should be free to waive that right. (It may be in my self-interest to sleep in on Saturday, but I should still be free to feed the hungry instead.) Indeed, in the case of the right to withdraw, which is usually motivated out of respect for autonomy, a dilemma arises. If autonomy is *not* important then perhaps people shouldn't even have the (simple) right to withdraw, let alone inalienably. On the other hand, if autonomy *is* important, then autonomous people should be allowed to rescind their right to withdraw, because forbidding that infringes on their (second order) autonomy.¹⁶

The third fatal flaw in the paternalistic motivation is that, just as it might be in my best interest to receive mild electric shocks if it's within the confines of a well-controlled psychology experiment where I'm handsomely compensated, so also it might sometimes be in my best interest to waive my right to withdraw from research. In the pulse oximetry case, for example, the researcher cannot conduct the study without a guarantee that her subjects will not withdraw. If participation in that particular study improves my overall well-being, then it will be in my best interest to be allowed to waive the right to withdraw, because otherwise there will be no study at all. Thus, a paternalistic prohibition of alienation can fail on its own grounds: it sometimes precludes us from acting in our own best interest.¹⁷

Rights, then, should presumptively be considered alienable, because the best reasons for thinking that they are all inalienable – coercion and paternalism – are mistaken. I will now consider some unique features of the right to withdraw from research. After dismissing these features as insufficient to warrant making that right inalienable, I will move on to consider whether unique features of other allegedly inalienable rights apply also to the right to withdraw from research.

¹⁵ This second reason may be just a restatement of the first, but if so the restatement still looks at the issue from a different-enough angle to be worth articulating and distinguishing.

¹⁶ Note that this dilemma does not take a stand on the contentious issue of whether considerations of autonomy are distinct from and should trump consequentialist concerns. The dilemma still arises even if autonomy is merely one among many goods to be thrown into the consequentialist hopper, for in that case there is still no good reason to throw only first-order autonomy into the hopper, excluding second-order autonomy.

¹⁷ Note that I need not take a stand on whether rights are grounded in respect for autonomy, as opposed to grounded in consequentialist concerns. That is because *either way* rights should be presumed to be alienable: inalienable rights can infringe on autonomy and also lead to worse consequences.

STEP 2: UNIQUE FEATURES OF THE RIGHT TO WITHDRAW DON'T HELP

Exploitation

Is forbidding a subject from withdrawing from research exploitative and therefore bad? The answer to this question depends on what counts as exploitative, and there is a massive literature on this topic. Fortunately, we can simplify the terrain by appealing to Alan Wertheimer's insight that exploitation is a form of unfairness.¹⁸ Thus, our question now becomes whether it is unfair to allow subjects to waive their right to withdraw from research. Unfortunately, waiving the right to withdraw does not necessarily make a research agreement unfair, for the same reason that agreeing to work long hours or in dangerous conditions does not necessarily make those agreements unfair – it depends on the work's compensation. Granted, all else being equal, it is less fair to ask workers to work for long hours in dangerous conditions than it is to ask them to work for short hours in safe conditions, but all else is not equal. Fairness depends both on what is being asked and on what is being given, and to focus only on what is being asked while ignoring what is being given is as myopic a mistake as that discussed earlier, of assessing coercion by focusing only on part of a mutually consensual transaction instead of on the entire agreement.

Likewise, whether it is fair to ask subjects to waive their right to withdraw depends on how they are compensated. Granted, all else being equal, it is less fair to ask subjects to rescind their right to withdraw than it would be to make that right inalienable, but all else is not equal. To return to the original pulse oximetry example, it may be that a beneficial study cannot be conducted without the waiver. Thus, to assess fairness fairly we need to consider not only what is being asked of subjects but also what they will receive.¹⁹

¹⁸ A. Wertheimer. 1996. *Exploitation*. Princeton, NJ: Princeton University Press.

¹⁹ Again, to simplify discussion on a very complex topic I have formulated my discussion of exploitation in terms of fairness. However, similar remarks apply if we treat exploitation as extracting surplus value (Karl Marx), as taking advantage of vulnerability (Robert Goodin), or as degradation (Ruth Sample), for example. In all cases, whether research without the right to withdraw is exploitative depends not only on what is asked of the subjects but also on what they are given (and perhaps on other things as well). See K. Marx. 1993. *Capital: A Critique of Political Economy*, vol. 3. Translated by D. Fernbach. Introduction by E. Mandel. London, England: Penguin Classics; R.E. Goodin. 1998. *Reasons for Welfare: the Political Theory of the Welfare State*.

Intimate Access

Research involves intimate bodily access, and perhaps the right to withdraw from such intimacy should always be protected as inalienable. As an analogy, sex requires intimate bodily access, so one might argue that the right to withdraw from sex is never alienable. Three responses to this suggestion are in order.

First, quite a bit of research does not require intimate bodily access, on any plausible account of intimacy. For example, social science research doesn't require intimate access. Neither do surveys and epidemiological studies. Measuring my weight does not require it; even drawing blood does not require intimate access. Thus, even if this suggestion is right, it leaves unscathed a large body of cases for which the right to withdraw is potentially alienable.

Second, even the most intimate bodily access in research is still not nearly as intimate as sex. This is true partly for the obvious reason that research is not sex, but it is also partly because good research is minimally intrusive. Thus, ethical research will minimize the number of *additional* prostate and cervical exams performed, say, and instead just piggyback the research onto clinically indicated exams. Another reason this is true is that good clinical care, and therefore good research as well, makes every effort to make patients (subjects) comfortable. Good gynecologists have chaperones and mirrors, for example, and they explain what they are doing, so that stress and anxiety are minimized. If a cervical examination ever feels like sex, that's clearly wrong, but the major problem with such cases lies not with the inability to waive the right to withdraw from an otherwise permissible study (examination) but rather with whether such a study (examination) is even ethical in the first place.

Third, the intimate access objection assumes that we care more about intimate bodily access than we do about other things. That is, it assumes that we should always be more protected when there is intimate access than when there is not. This is wrong, because we should let subjects decide what is important to them. Many may care a great deal about intimate bodily access, but some may not. Suppose, for example, that a prostate study requires intimate bodily access but (directly) benefits prospective subjects. Suppose further that, like the original pulse oximetry example, for financial reasons the study cannot go forward unless the

researchers have a guarantee that their subjects will not withdraw. If I do not care about intimate access to my body, then I should be allowed to make this agreement and enrol, even if that enrolment requires the waiver of my right to withdraw. We should be able to support this decision, but the overly blunt insistence that intimate bodily access *always* requires the inalienable right to withdraw cannot.

Irreversibility

Once a subject waives her right to withdraw she cannot ever get it back; that decision is irreversible. Unfortunately, irreversible decisions shouldn't necessarily thereby be prohibited. Indeed, irreversible decisions are ubiquitous and still presumably permissible: surgical resection, amputation, and blood transfusion are all irreversible, yet we (rightly) allow them. What irreversibility demands from us is not the prohibition of doing anything irreversible, but rather an increase in standards for going through with something irreversible: are you really *sure* you want this resection/amputation/blood transfusion? Likewise, what the irreversibility of the waiver of the right to withdraw demands from us is not the prohibition of that waiver but rather a higher burden of proof that this is what the subject (and researcher) genuinely, autonomously wants to do.

Further, that the irreversibility of surgical resection, amputation, and blood transfusion are due to facts about nature and not to conventional decisions is irrelevant, because we also allow irreversible conventional contracts. Ordinary contracts of payment for performance can be interpreted in this way. I agree to pay you some amount of money tomorrow if you give me a doodad today. After you give me the doodad, I can no longer get out of – or reverse – the contract. And this is so for reasons of convention, not natural impossibility: we have decided that our contract will be binding and irreversible. Indeed, courts recognize the legitimacy of enforcing specific performance in some cases, most typically in the sale of land.²⁰

In the last three sections we considered three potentially unique features of the right to withdraw from research, and I argued that none of them justify making that right inalienable. In the next four sections I'll argue that reasons for making four other rights inalienable do not apply to the right to withdraw from research.

Princeton, NJ: Princeton University Press; and R. Sample. 2003. *Exploitation: What It Is and Why It's Wrong*. Lanham, MD: Rowman and Littlefield Publishers.

²⁰ See, for example, *Mohrlag v. Draper*. 219 Neb. 630, 633 (Neb. 1985).

STEP 3: UNIQUE FEATURES OF OTHER INALIENABLE RIGHTS DON'T APPLY

Kant on Suicide

Immanuel Kant argued that there were certain things no one should ever do. For example, no one should commit suicide, which can be interpreted as another way of asserting an inalienable right to life. Kant's reason, roughly, is that committing suicide treats you merely as a means to maintain a tolerable life, rather than also treating you as an end in yourself.²¹ I think that Kant was simply mistaken on the standing of many of his categorical imperatives, such as the imperative never to kill yourself. For the purposes of this paper, however, I will point out only that precluding yourself from withdrawing from research doesn't treat you or anyone else merely as a means. This follows from the uncontroversial assumption that homelier non-instantaneous contracts also don't treat anyone merely as means. For example, I might agree with a prospective landlord that I will pay out the remainder of my rental contract should I choose to move out, and yet this doesn't treat me or him or humanity merely as a means.

I mention Kant on suicide and means/ends first, not because I think his theory is the best hope for a theoretical defense of the inalienable right to withdraw from research but, rather, because the form of an argument is often clearer when the content is simple and uncontroversial. The form of this final step of my argument is that while various unique rights may generate legitimate exceptions to the general presumption in favor of alienable rights, the right to withdraw from research doesn't share the relevant features of those exceptional rights. I now move on to more difficult cases.

Mill on Slavery

J.S. Mill argued that the right against slavery is inalienable: no one should be allowed to sell him/herself into slavery. His reason, roughly, is that rescinding all my future freedom, as would occur if I chose to be a slave, defeats the entire purpose of protecting my freedom.²² Fortunately, we needn't examine the intricacies of Mill's argument, because the decision to forgo the right to withdraw from research is not like slavery. When a subject waives the right to withdraw from research, she doesn't

thereby rescind all of her freedoms in the future forever more; she doesn't even thereby rescind *most* of her future freedoms. Rather, she rescinds only some very small proper subset of her future freedoms – such as the freedom to sleep in tomorrow morning rather than show up at the clinic for a blood draw – and even then only for a limited time (until the study ends). Compare: contracting to work for a salary entails giving up a significant yet in the relevant sense still small subset of future freedoms, such as the freedom of where to be during weekday business hours.

Granted, in an extreme, limiting case, some particular study might be designed so that waiving the right to withdraw from it is essentially to become a slave: such an experiment would have to endure for the entirety of its subjects' lives, and it would have to restrict severely what its subjects were able to do with their lives. In that unusual situation, perhaps the right to withdraw is as inalienable as is the right against slavery, but two points can be made in response. First, such research is objectionable on other (more important) grounds – the most important thing to say about slavery-like research is that it is impermissible, not that the right to withdraw from it is inalienable. Second, even if slavery-like research were allowed, my contention is only that people would *sometimes* be permitted to waive their right to withdraw, not *always*.

Coordination Problems and the Nine-Hour Workday

Russell Hardin suggests that one reason to treat certain rights as inalienable is that by doing so, a group of people can achieve something as a collective that would be nearly impossible for each member to achieve individually.²³ Thus, consider Hardin's example, taken from Mill, where workers want the possibility of a ten-hour workday at the same *hourly* wage as the nine-hour day, yet they know that if this possibility is open they are more likely to get something they don't want instead, namely a ubiquitous ten-hour workday at the same *daily* wage as the nine-hour day. In order to prevent the possibility of the ten-hour workday at the same daily wage as the nine-hour day, perhaps the workers should collectively preclude all ten-hour workdays, no matter their wage rate. Hardin equates this with making the right to a nine-hour workday inalienable.

Let's assume for the sake of argument that this contentious equation is warranted. Let's further assume for the

²¹ I. Kant. 1997. *Groundwork of the Metaphysics of Morals*. Cambridge Texts in the History of Philosophy. Edited by M. Gregor. Introduction by C.M. Korsgaard. Cambridge: Cambridge University Press.

²² J.S. Mill. 1989. *On Liberty' and Other Writings*. Edited by S. Collini. Cambridge: Cambridge University Press: 102–103.

²³ R. Hardin. The Utilitarian Logic of Liberalism. *Ethics* 1986; 97: 47–74.

sake of argument the correctness of Hardin's speculation that the possibility of ten-hour work days would devolve into a situation where the workers work longer hours for the same (daily) wage. I want to show only that Hardin's reasoning cannot motivate an inalienable right to withdraw from research. Hardin's reasoning is multiply problematic,²⁴ but the important problem for us begins by pointing out that it is unclear how to restrain its scope. Consider a purported right for people always to get \$50 for their participation in research. Such a right would be nonsense, of course. Yet, it seems we can use Hardin's reasoning to conclude that if there is such a right then it is inalienable – nonsense on stilts. For while subjects might prefer to have the option of participating in research without the \$50 incentive, say if other non-monetary benefits swamp the benefit of the \$50 incentive, it will probably turn out that allowing this option also opens up the possibility that they participate in research without the swamping non-monetary benefit and where they still don't get the \$50.

Perhaps what's gone wrong is that Hardin's reasoning is meant to apply only to genuine rights that we antecedently find legitimate. In that case, the reason there is no inalienable right to \$50 for research participation is because there is no (mere) right to it, whereas we assume that there is a (mere) right to withdraw. Still, the important question is what blocks that collapse of every legitimate (mere) right into an inalienable right. After all, for each particular (mere) right it's logically possible that making that right inalienable resolves a coordination problem.²⁵

The key to answering this question is empirical: will allowing for the possibility of the most desired option thereby result in everyone being forced into their least desired option? Even if that empirical question is settled in favor of the inalienable nine-hour workday, it is at best unclear whether it would also be settled in favor of an inalienable right to withdraw. That is because the empirical question rests on the relative strength of the bargaining positions occupied by employer versus prospective employee, researcher versus prospective subject. Here the analogy is implausible, for even if employers are in a strong bargaining position relative to their workers, the

same cannot be said for research. This is so for two reasons.

First, and most obviously, with very few exceptions people work because they need to in order to (buy things they consider necessary to) live. That is not the case for research participants: typically research participants could get along comfortably without participating in research, even when they benefit from enrolling.²⁶ Thus, in contrast to researchers, whose careers may be significantly affected by whether they can enrol enough subjects in their trial, prospective subjects often can afford to take a 'take it or leave it' attitude towards research participation. That is, of course, not true for the employer/employee: a prospective employee may have no other feasible means for putting food on the table.

Second, study recruitment, often enough, is already difficult and costly.²⁷ Indeed, conscientious experts often worry in the opposite direction, that certain incentives to enrol can count as *undue inducements*.²⁸ That the threat of undue inducements is even a worry is strong evidence that, at least in some areas of research, the demand for participants far outstrips the available supply. In other words, the fact that researchers often have to resort to adding extra incentives, indeed enough extra incentives to spur a worry that there may be too many (illegitimate ones), suggests that participants have a stronger bargaining position in relation to researchers than employees have in relation to employers. Again, in contrast, the worry that employers might offer too many undue inducements to their employees is much less threatening, if not downright unheard of.

Thus, although there is as yet no direct data examining the particular empirical question of relative bargaining power of researcher and subject, we have good indirect reason to believe that the relationship between researcher and subject is in important respects not analogous to the that between employer and employee: if research subjects are allowed sometimes to rescind their right to withdraw we will not end up in a situation where, because everyone is so desperate to participate in research and therefore

²⁴ See A. Kuflik. The Utilitarian Logic of Inalienable Rights. *Ethics* 1986; 97: 75–87.

²⁵ Another potential disanalogy is that the right to \$50 is trivial, in the sense that agents are not missing out on much if they fail to get it. Thus, perhaps Hardin's reasoning is intended to apply only to *significant* rights. However, this worry can be accommodated easily enough: just change the monetary amount in question from \$50 to whatever amount is sufficient to generate a significant right.

²⁶ Exceptions include those for whom the research protocol is the last hope for therapy and those for whom research participation is a full-time job. For professional research subjects, see Carl Elliott. 2008. Guinea-Pigging. *The New Yorker* 7 January: 36–41.

²⁷ K.B. Dreenan. Patient Recruitment: the Costly and Growing Bottleneck in Drug Development. *Drug Discov Today* 2002; 7: 167–170; J. Sullivan. Subject Recruitment and Retention: Barriers to Success: Study Findings Identify Various Factors Affecting Subject Enrollment in Today's Clinical Trial World. *Applied Clinical Trials* 2004; 4: 50–54.

²⁸ J.P. Bentley & P.G. Thacker. The Influence of Risk and Monetary Payment on the Research Participation Decision Making Process. *J Med Ethics* 2004; 30: 293–298; but see also E.J. Emanuel. Undue Inducement: Nonsense on Stilts? *Am J Bioeth* 2005; 5: 9–13.

willing to trade away some of their alienable rights to do so, no one is ever allowed to withdraw from research.

Public Interest and Whistle-Blowers

One final reason to make certain rights inalienable is that doing so is in the public interest. One way to think about whistle-blower protections, for example, is as creating an inalienable right to whistle-blow: employees should always be allowed to whistle-blow, even if they want to rescind that right when negotiating their employment contracts. Why should we allow this? Because it is in the public interest to know when employers are engaged in wrongdoing. For example, it is in the public interest to know that tobacco companies intentionally tried to make cigarettes more addictive, so we protect their employees' right to inform the public of that, as Jeffrey Wigand did in a famous whistle-blower case in 1993.

As before, let us assume for the sake of argument the contentious point that it is appropriate to construe whistle-blower protections as inalienable rights. The relevant point for us is that similar reasoning cannot be used to justify an inalienable right to withdraw from research. That is because there is no similar public good to be protected by making the right to withdraw inalienable. Indeed, if there are any externalities at all in a research case, they are usually *positive*: we have a public interest in the knowledge gained by research, which tugs us in the direction of forbidding withdrawal all together! (Of course, I do not advocate that.)

But what about the reputation of the research enterprise? Even if all my arguments above are correct, so that permitting subjects to waive their right to withdraw is ethical, still, people will continue to think – incorrectly – that doing so is unethical. In that case, even if nothing else is wrong with permitting alienation, it still might severely damage the reputation of the research enterprise if a subject rescinded her right to withdraw and then later tried to withdraw, was refused, and subsequently suffered serious harm.

Now, if my arguments above are right, then that response is irrational. That is, such a 'scandal' would not really be *legitimate*, any more than it would be a legitimate scandal for you if I agreed to paint your house in exchange for money, received the money, then tried to break the agreement, was refused, and subsequently suffered serious harm while painting your house. Now, in some cases we might want to kowtow to irrational fears and prejudices, but it is typically better to try to eliminate

irrationality. In other words, rather than simply allowing irrational fears to dictate people's rights – including the second order right to alienate the first order right to withdraw from research – I favor a two-prong approach: give people the rights they deserve and correct irrational fears and prejudices. In general that seems the better approach to adopt (for example, towards irrational prejudices against homosexuality), and I see no reason to stray from it in this particular case.

This leads to a second response to the worry about scandal. The contention – that allowing the waiver of the right to withdraw will damage the research enterprise more than it will benefit everyone – is clearly empirical. But there is no evidence for it, and it strikes me as quite implausible. Thus, I think it is appropriate to endorse an alienable right to withdraw for now, leaving open the possibility of revisiting the issue in the unlikely event that irrational scandal arises in an uneducable public.

CONCLUSION

I've argued that we should sometimes allow people to waive their right to withdraw. The reason we should sometimes allow this is that it respects our autonomy and allows us to make beneficial agreements, together with the important fact that the right to withdraw doesn't deserve special exemption to the general principle that rights are typically alienable. I've tried to make my argument as exhaustive as possible; however, it may be incomplete, because, while it's easy to find assertions of the contrary position, defenses of it are as yet non-existent. Perhaps this paper will encourage others to formulate such defenses, defenses better than the ones I consider and reject here.

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