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Target Article

Research Exceptionalism

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Research involving human subjects is much more stringently regulated than many other nonresearch activities that appear to be at least as risky. A number of prominent figures now argue that research is overregulated. We argue that the reasons typically offered to justify the present system of research regulation fail to show that research should be subject to more stringent regulation than other equally risky activities. However, there are three often overlooked reasons for thinking that research should be treated as a special case. First, research typically involves the imposition of risk on people who do not benefit from this risk imposition. Second, research depends on public trust. Third, the complexity of the moral decision making required favors ethics committees as a regulative solution for research.

Keywords: ethics committees, human subjects research, professional ethics, regulatory issues, research ethics, risk/benefit analysis

The past 40 years have seen a massive expansion in the ethical scrutiny of medical research. All medical research in many countries now has to be reviewed and approved by a research ethics committee (REC) or institutional review board (IRB) before any contact with human subjects is allowed to commence.[1] A great deal of emphasis is placed on the informed consent of participants, and there are also requirements for ethics approval before a study can be published—so even if for some reason there was no prior requirement to seek approval from an ethics committee, it will typically be impossible to publish a piece of medical research without it having been approved by an ethics committee. In many countries this system has recently been expanded into other university-based human participant research, either formally via legislation such as in Australia or informally via self-regulation by universities and funding bodies, making approval from a university ethics committee a precondition of starting work on any project involving human subjects.[2]

This system of regulation for research is rather more stringent than the systems of regulation we have in place for many other activities that seem to involve the imposition of similar or greater risks. In both the United States and the United Kingdom we currently see a backlash against this apparent overregulation of research (see, for example, Warlow 2005; Stewart et al. 2008; Sullivan 2008; Dyer and Demeritt 2008).

There are three responses we could make to this "overregulation" charge. First, we could argue that we are too lax in the way we regulate various other activities and that we should regulate them more stringently to bring them into line with the way we regulate research. Second, we could argue that we are too stringent in the way we currently regulate research, and we should relax our research regulations to bring them into line with the way we regulate other activities. Third, we could argue that there are sound ethical reasons why research merits stringent regulation *despite* the fact that it is no riskier than many other activities which we do not regulate stringently. We call this third approach research exceptionalism.

This article provides a qualified defense of research exceptionalism. The first and second sections provide the necessary background. The first section contextualizes research ethics within the broader field of risk regulation, while the second section makes the case that our current system of research regulation seems to be anomalous when compared to the way we regulate other types of risk. The third section examines six arguments commonly given in favour of current

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1. In the United Kingdom, Australia, and New Zealand these committees are referred to as research ethics committees, while in the United States they are referred to as institutional review boards. We here use the terms interchangeably and primarily use either research ethics committee or REC to refer to whichever committee is responsible for the ethical review of research.
2. What specifically is legally required in terms of approval for research depends on jurisdiction. In almost all jurisdictions some or much of medical research is legally required to seek ethical approval. In some jurisdictions, such as the United States and Australia, university-based nonmedical research is legally required to seek ethical approval. In others, such as the United Kingdom and New Zealand, there is no formal legal requirement to seek ethical approval for university-based research unless it is medical research or research in an area that is covered by legislation (human tissue and research involving people lacking the mental capacity to consent). A relatively complete listing of legislation governing research can be found in Office for Human Research Protection (OHRP) (2009).

systems of research regulation and concludes that none justifies us in thinking that research is exceptional. In the fourth section we advance three arguments that seem to us to be more promising in justifying research exceptionalism.

REGULATING RISK

In this article, we use the term "risk" in a nontechnical sense, to refer to "situations in which it is possible, but not certain that some undesirable event will occur"[3] (Hansson 2007). The nature of research as an activity makes talking about "the risks involved in research" potentially ambiguous. In many cases, doing research involves performing actions that are indistinguishable from other actions which are performed in a nonresearch context. For example, suppose there are currently two different treatments, A and B, for a given condition, and a research team wants to discover which is the more effective. At the moment, some doctors favor A over B, and others favor B over A. The research protocol involves cluster randomization, so that half the hospitals in the trial area will, for the period of the research, offer treatment B, while the other half will offer treatment A. Patients will not be made aware that they are part of a research study.

In a case like this, it may be that both A and B are quite risky procedures; it may be, for instance, that A and B are different methods of operating on large gunshot wounds. But it would not follow from this that the *research* was in and of itself was risky: If the patients who are participants in the research would otherwise have received either treatment A or B, depending on the subjective judgment of the doctor, then we cannot plausibly claim that the risks involved in being subjected to either treatment A or treatment B are risks *of the research*, given that these risks would have been present even if the research project had not been undertaken. Insofar as research is ethically problematic it must be because it introduces new risks that would not otherwise be present.[4]

The Idea of Regulation

Regulation, as we use it in this article, is a normative activity that aims to steer the behavior of human beings, in order that a desired goal is either achieved or approached more closely. Regulation in this sense covers a broad range of activities. Here is a small sample of common ways in which we regulate:

A. *Prospective regulation:* Regulation that requires a check to ensure it is being followed before the activity is undertaken.
B. *Reactive regulation:* In contrast to prospective regulation, reactive regulation only takes effect if the appropriate standard is breached.
C. *Licensing:* Regulation by testing operators and then trusting them to carry out the activity appropriately.
D. *Dipsticking:* Regulation that randomly tests a sample of those carrying out the activity to ensure it is being done in accordance with the appropriate standards.
E. *Financial incentives*: Indirect regulation by making the desired choice more financially attractive (for instance, raising the tax on gasoline to encourage the use of fuel-efficient cars).
F. *Architectural nudges*: Changing the environment in which choices are made in such a way as to load the dice in favor of the desired result—for instance, a school cafeteria places the healthier items at the front so people are more likely to choose them (Sunstein and Thaler 2008).

The regulation of a particular activity might well involve a mix of different forms of regulation, so, for example, driving and road safety are regulated both via standard setting with testing of drivers but also with the reactive forces of the courts if someone is found to not be maintaining the appropriate level (which itself is often determined by a form of dipsticking, namely, a limited number of police observing some, but not all, motorist activity). Architectural and financial considerations also sometimes play a role: For instance, there will typically be fines to discourage undesired driving behavior, and some cars are built to make an annoying sound if they are moving without the driver wearing his seatbelt.

Regulating Risk Versus the Risks of Regulation

Where there are undesirable events that are possible but not certain to happen, and it is within our power to prevent or

3. Hence our usage of the term is to be distinguished from that deployed in technical writing in risk, which distinguishes risk from hazard. In this literature, risk refers to cases where we can assign known probabilities to a given event—for example, a coin toss—whereas hazard refers to cases where we are unable to assign probabilities. Given that a good part of what makes research research is the fact that we lack knowledge about what the effects of our intervention will be, the regulation of research will tend to be focused more on hazard than risk. However, we have decided (as in common in philosophical discussions) nonetheless to prefer the term risk, but with the proviso that we shall use it in a broad way that also encompasses hazard. There is a further complication here that we shall largely ignore: We have not specified *to whom* the event needs to be undesirable. For instance, no doubt tobacco executives all across the United States and Europe are currently working to avoid what they perceive as an undesirable event, namely, losses to their long-term profitability caused by the greater focus on tobacco as a public health issue. We would consider this to be a risk management problem, despite the fact that the measures to reduce smoking, which are undesirable from the tobacco executive's perspective, are presumably desirable from a more objective perspective. However, in this article we are interested in which risks we should be aiming to regulate *as a society*, so we focus only on events that would be undesirable from the perspective of a just society.

4. In the case of this study we might argue, for instance, that the quality of the care the patients receive would in some sense be compromised by the research process, or that the fact of their treatment being randomized without their consent wrongs them even if it does not harm them.

mitigate these events, then there is an intuitive obviousness to the idea that we should aim to regulate in some way to ensure that we either prevent these events from occurring or mitigate them if they do.

However, it is important to note that the act of regulating a particular risk will typically introduce further risks. Among the downsides of regulation we need to consider are first its financial costs: If we choose to regulate a domain, we typically need to set up relevant regulatory standards and monitor compliance with them, train people to comply with these standards, and punish noncompliers.[5] Second, regulation will often have specifically moral costs—for example, curtailing liberty.

Regulation can also have more subtle downsides: Regulating a system with a particular standard can create perverse incentives and will often have the side effect of making it more difficult to meet other desirable goals.[6] Different types of regulation will have different types of moral and financial costs; for example, banning an activity outright is a much greater imposition on liberty than attempting to nudge people toward a desirable goal.

A particular piece of regulation R is morally justified only where it meets three criteria. The first and most obvious criterion is that the goal toward which we are trying to steer people must be desirable (or at least not undesirable). Second, the likely effects of regulating the activity in question with R (with its attendant moral costs) must be morally better than adopting a laissez-faire attitude toward the activity in question. Third, given that the goal is worth obtaining, and that R would be morally superior to a *laissez faire* approach, we need also to be convinced that R is morally superior to (or at least not inferior to) any rival ways of regulating $R_1, \ldots, R_n$.

The third criterion is the most ethically complex to apply. There will be some easy cases where two methods of regulating differ only in one way (perhaps R_1 and R_2 are identical in every way but for the fact that R_2 is 10 times as expensive as R_1). But we are likely to find that there are cases where things are less clear. For instance, R_1 might be more effective in obtaining the desired state of affairs than R_2, but be accompanied by rather higher moral costs.

In order to work out whether a given mode of regulation for a particular risk is superior to all others, we would need an account of what makes one risk worse than another. Ideally, such an account would have two features: First, it would be fully alive to all the ethical features which make one risk worse than another (call this the *accuracy requirement*), and second, it would enable us to make useful comparative judgments about which of two risks is worse from an ethical point of view (call this the *indexing requirement*). However, the accuracy and the indexing requirements conflict. The indexing requirement will tend to push us toward an account of risk where everything about risk is commensurable.[7] However, the accuracy requirement will tend to push us toward an account in which some elements of relevance to the ethical regulation of risk are partially or fully incommensurable.

At least three factors threaten the ethical commensurability of risk. First, it is unclear whether it is always appropriate to treat a small risk of a very undesirable event occurring as commensurable with a rather larger risk of a much less undesirable event occurring—and even if it is, how we should commensurate.[8] Second, it is unclear to what extent it is legitimate to commensurate risks across separate people. Is it legitimate to compare a low risk of a mildly bad event happening to a large number of people, with a high risk of something very bad happening to a single person, and if so, how do we perform these calculations? Third, it is unclear how we should account for consent to risk. Intuitively, there is a moral difference between the same level of risk of death, as assumed by a mountaineer, as compared to the same level of risk of death caused by contamination in the water supply, but it is far from clear how we should factor consent into our overall judgment about how bad a particular risk is.[9]

In light of these difficulties, it is extremely difficult to provide a full and convincing account of what makes one risk ethically worse than another. Certainly those who argue that research is currently overregulated have not done so. Presumably they think that just as we do not need a fully worked out account of justice before we can point out manifest injustices, so we do not need a fully worked out account of the ethics of risk to notice that the way we currently regulate research is grossly disproportional. The next section examines the case for thinking research is overregulated.

5. For example it has been estimated that it costs £800 for a research ethics committee to consider an application and £850 for a researcher to prepare it (Arshad and Arkwright 2008).

6. For instance, if we regulate to reduce speed in built up areas by installing a large number of road humps, this is likely to increase the risk that people being rushed to hospital for emergency treatment will die on the way.

7. This is because, as Wolff and de Shalit put it in a slightly different context, "If two goods, or two forms of advantage and disadvantage, cannot be compared, then they cannot be placed on a common scale, and so it will become impossible, in many cases, to say whether one person is worse off or better off than another" (2007, 23).

8. One obvious way is to do an expected utility calculation, by multiplying the probability of the bad event occurring, by the disutility of its occurrence, to give an expected utility score. However, it is far from clear that this is the best way to treat risk. As Wolff points out, it does not seem irrational for someone to be willing to suffer a 1 in 2 million chance of death for £1, but not to be willing to suffer a one in two chance of death for £1,000,000, let alone £2,000,000 for their certain death (2006, 61).

9. In addition, in real-world contexts we will typically be acting in the face of hazard, rather than risk, and so will not be in a position to judge accurately the probability either that the possible undesirable effects will obtain unless we act, or the likely effectiveness of our attempts to prevent the undesirable events. Hence even if we do think that we can provide an accurate index that will rank risks, given their probabilities, we may not be in a position to rank them on the basis of the information available to us.

WHY THE REGULATION OF RESEARCH MAY APPEAR TO BE DISPROPORTIONAL

Research ethics committee review requires the researchers to formalize their project in an often lengthy application form.[10] Researchers then have to wait until the committee meets and makes a decision and must then revise their project in line with the recommendations of the committee before they are allowed to start their research proper. Depending on the system, they may also have obligations to report back to the committee on a regular basis. Hence regulation by research ethics committee is a very unusual and burdensome form of regulation.

It is usually assumed that research in the relevant sense is defined by its aim: namely, to extend "a body of knowledge by means of a scientifically respectable methodology" (Bortolotti and Heinrichs 2007, 157). Acting with the aim of extending a body of knowledge is not, in general, ethically undesirable.[11] Hence it is unclear why the attempt to extend a body of knowledge ought to be taken as a marker of special moral qualms.

This complaint of the overregulation of research is at its most powerful when it is pointed out that it will often be the case that precisely the same activity could be carried out by the same people but would not require (at least according to most systems of research regulation) the same level of intrusive regulation as long as no attempt was being made to derive new generalizable knowledge from the activity. So, for example, audit activities (which are often hard to distinguish from research) are frequently excluded from research ethics regulation despite involving almost identical activities.[12] Likewise, experimental last-hope treatments are also often excluded from being considered research because they are typically on a small scale (single patient) and thus not generalizable.[13]

One possible reply to these cases is that they play on the ambiguity of the concept of research, and one response (which we would be sympathetic to) would be to argue that audit and innovative treatments really are a form of research and so should be regulated in the same way as research. However, there are plenty of less ambiguous cases—where we have activities that are clearly not research, but that nonetheless impose risks similar to or greater than much research, but that are typically not nearly so stringently regulated. We could have chosen any number of such examples, but we here choose four for indicative purposes:

1. Journalism: Journalists routinely seek out and interview members of the public, without seeking any ethical approval from anyone either before starting their article or before publication. Researchers, whether in universities or in a medical environment, typically do require ethical approval before they are allowed to interview subjects.
2. Reality TV shows: Makers of reality TV shows routinely place contestants in environments that are much more stressful than ones that would be allowed by most university ethics committees, and such shows are not typically subject to stringent ethical regulation.[14]
3. Dangerous sports: Ethics committees will frequently prevent a research project from going ahead on the grounds that it is too risky. However, the risks that ethics committees consider to be too great are often rather small in comparison with other types of activities—such as mountaineering, or skydiving—that are either not regulated at all, or regulated much less stringently than research.
4. Government action: Governments frequently impose risks on their citizens (for instance, by privatizing nationalized industries, or by cutting welfare payments). Those on whom these risks are imposed very rarely have the opportunity to opt out of the risks on an individual basis; certainly no attempt is made to ensure that the informed consent of all those affected is obtained. Conversely, ethics committees are very wary about allowing research to go ahead without the informed consent of all participants.

We agree with the proponents of the overregulation thesis that such examples create a powerful prima facie case that we currently treat research as an exceptional case. Overregulation is a morally significant problem, because of the financial and moral costs associated with regulation. We could reply in one of three ways: We could concede that our principles for the regulation of research should be of the same type as those we use to regulate other kinds of activities and then seek to either (a) "level down" our regulation of research to the level of other activities or to (b) "level up" our regulation of other activities to that of research. The third option—which we explore in this article—is to argue

10. In the United Kingdom the present National Health Service's Research Ethics Committee approval form is 34 pages long and must be accompanied by an information sheet, consent form, and a research protocol.

11. There are cases where a body of knowledge (such as body of knowledge that constitutes the science of torture) is so ethically problematic that it is wrong in itself to attempt to extend it. But very little, if any, of the research examined by ethics committees falls into this category.

12. Presumably because the information generated by an audit is not generalizable new knowledge but rather assessment of a local situation and whether it is meeting some preset standard. For further on the audit/research distinction, see Cave and Nichols (2008), Holm (2007), and Holm and Bortolotti (2007).

13. A further peculiarity of the current systems of research scrutiny is that projects may get described as research even if they do not fall under the definition just given; for example, student research projects even if they are effectively audits are often assessed by research ethics systems precisely because they are described as research projects. Likewise, the work of academics such as those in the visual or performing arts sometimes are scrutinized by research ethics committees despite there being no attempt to create generalizable knowledge as part of the process.

14. For instance, TV shows routinely reenact problematic pieces of research, such as Milgram's obedience to authority experiments, without seeking approval from an ethics committee before doing so. Note that these experiments would probably not be approved by any ethics committee now.

that despite initial appearances there are good reasons to treat research as exceptional.

SIX UNSUCCESSFUL ARGUMENTS FOR RESEARCH EXCEPTIONALISM

In order to justify research exceptionalism, we would need to demonstrate that there is some feature of research that makes stringent regulation appropriate. If this feature is only sometimes true of research, then it is unclear that it could justify regulating all research everywhere stringently. In particular, if the feature cited is shared with other contexts that we do not want to regulate as stringently, then we will not have justified research exceptionalism. It should be noted, however, that even if research exceptionalism *is* justified, it will not necessarily follow that we should have research ethics committees.[15] So while an argument for the regulation of research via research ethics committees will be dependent on the success of a justification of research exceptionalism, it does not at least straightforwardly follow from that justification.

We next examine a number of arguments that have been (or could plausibly be) put forward to justify research exceptionalism. The first type of argument commonly offered for research ethics review can be disposed rapidly since it will not serve for these purposes. These are pragmatic arguments based around present regulations and requirements. So, for example, the 1975 revision of the Declaration of Helsinki introduced the notion of a formal independent committee review of research:

> The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance. (World Medical Association 1975, I. 2)

In response to this requirement, two groups, journals and research funders, often now require research ethics review before they will publish or fund research, respectively (see, for example, Committee on Publication Ethics 2006; Economic and Social Research Council 2005). However, this pragmatic explanation of the need for the regulation of research is clearly insufficient to justify research exceptionalism. This is because the drafters of the Declaration of Helsinki could have been mistaken, and if research exceptionalism is not justified then these requirements are not justified. In other words, these pragmatic arguments are parasitic on the success of a substantive argument for research exceptionalism.

The History of Research Ethics Abuses

Research, in particular medical research, has something of a checkered past, with several significant cases of highly unethical research having been carried out, such as the medical experimentation in Nazi Germany, the Tuskegee Syphilis Study, and the Willowbrook State School Hepatitis Studies.[16] Among the social sciences, the Stanford Prison study and the *Tearoom Trade* study deserve mention as well (Zimbardo 2007; Humphreys 1975).

Behind these prominent historical abuses lie a whole further world of less famous ones. In the United Kingdom, Maurice Pappworth (1962; 1967) published his concerns about the ethics of several pieces of research being carried out at the time, and followed this 5 years later with a book. In the United States, Henry Beecher (1966) drew attention to 22 cases of seriously unethical studies that had been published in top medical journals. These cases were not necessarily as unethical as Nazi experimentation but were perhaps more troublesome in some ways because they were so ubiquitous. For example, Jenny Hazelgrove relays in an excellent historical paper the following story told by a British medical student in the 1950s:

> When I was a student at St Thomas's we had a professor of medicine who used to ask patients before they went under the anaesthetic "would you mind if while you are asleep we took a few blood samples?" What he didn't mention was that those samples were going to come from inside the heart and that he was going to push a cardiac catheter up the vein into the heart and this had a certain mortality rate. (Hazelgrove 2002, 123)

These cases do provide prima facie evidence that unregulated research can be abused. However, they fall short of demonstrating the case for research exceptionalism because of two factors. First, they do not show that these risks are specific to research: Abuses can and have occurred in many other areas of human existence. Second, they do not show that regulation will prevent these abuses. To justify research exceptionalism, we need to demonstrate that there are risks that are either specific to research or are more likely in research.

Risks of Harm to Participants

Another argument for research exceptionalism appeals to the risks of harm to research participants. Research can be extremely risky: Research participants have died or been seriously injured by participating in research (Savulescu 2001; Suntharalingam et al. 2006). But there are many other activities that also involve risk of harm. Many everyday activities involve some risks of harm, and while some of these are regulated (such as driving), others are unregulated. It is not clear that research per se is specifically risky, even if some instances of research are particularly risky. Much research—in particular, a considerable amount of survey-based research—seems, barring the risk of a paper cut, almost entirely risk free.

Difficulty in Understanding Research Protocols

However, it might be pointed out not only that are there risks in research but also that people frequently have

15. Presumably driving ought to be regulated fairly stringently, but there is no need for driving ethics committees.

16. For a concise overview of the history of research ethics, see Schüklenk (2005).

difficulty understanding research protocols. There is now substantial evidence that people confuse research with other activities such as therapy (known as the therapeutic misconception) and that people are at least some of the time unaware they are participating in research. (Appelbaum et al. 1987; Snowdon et al. 1997; Dawson 2004) This evidence ought not to be surprising, given that research is often complex and involves concepts such as randomization and double-blind trials that are not familiar in everyday life.[17] The implication of this is that people may take those risks without truly comprehending them. It might be argued that we should not allow people to make significant life choices without fully understanding the potential consequences for their lives.

However, while research protocols may be difficult to understand, they are no more difficult and often considerably less difficult to understand than many official documents such as the fine print on mortgage documentation. As such, the brute fact of difficulty does not on its own justify research exceptionalism.

A subsidiary concern of the difficulty in understanding research protocols is that people may engage in research for the wrong reasons. There are two versions of this concern; the first focused on undue inducement, and the second on exploitation.

Undue Inducement

One risk that is sometimes thought to be present in research is the risk of undue inducement (Martin 2005). Undue inducement is said to occur when an offer of money overpowers a person's faculty of rational choice in such a way that they fail to consider the risks appropriately, and instead perform the activity because of the inducement. There have been several papers questioning whether this ought to be considered ethically problematic, since it is unclear what precisely is wrong about inducements in research (Wilkinson and Moore 1997; 1999; Emanuel 2004). In any case, for our purposes, given that inducement is a common element of human life, it seems difficult to see what would be uniquely worrisome about inducement in research. Working life often involves inducements and in particular sometimes involves inducements for engaging in risky working behavior (so-called "danger money"). Though not all risky jobs attract an absolute high wage, they do in general attract a relatively high wage compared to work that is equivalent but without the risk. If we are to complain about inducement in research, it seems apt to consider it elsewhere as well.

Risk of Exploitation

Related to the risk of inducement is the risk of exploitation in research (Ashcroft 2001). Exploitation occurs when one party to an interaction relies on a weakness—whether cognitive or in power relations—of the other to create an unfair bargain, in which the distribution of the benefits from the interaction disproportionately favors the exploiter.

However, as in the other cases we have examined, the possibility of exploitation is in no way unique to research; exploitation is endemic wherever we find people who are powerless.

None of the arguments for research exceptionalism we have examined so far are compelling. This is not because they have failed to identify ethically worrisome characteristics of some research, but instead because it has not been established that these characteristics are either unique to research or more common or significant in research than in other less regulated arenas. The next three arguments, however, are more promising as they identify specific elements of research that are distinct from other areas.

THREE BETTER ARGUMENTS FOR RESEARCH EXCEPTIONALISM

The aim of research is different from other contexts with similar risks, such as health care.[18] This is because research does not (in general) aim specifically to benefit the participants; instead, the aim is to generate knowledge. This is of course not always the case with research; sometimes the research is intended to benefit the participants. Nonetheless, it is generally true that the benefits of research mostly accrue to others than those taking the risks of research.

This is ethically significant, as Hermansson and Hansson (2007) argue plausibly that whether the person who is subjected to a risk also benefits from that risk is an important factor in the ethics of risk management. On their account, in any risk management problem there are three parties. First, there are those on whom the risk is imposed; second, there are those who control the risk; and third, there are those who benefit from the risk. Risks are least problematic where the same person fills all three roles: where one and the same person benefits from the risk, and can control the risk that they are exposing themselves to. Most ethically problematic are those cases where the risk-exposed neither benefit from their risk exposure nor can control their exposure to the risk. Research participants typically do not benefit from being in research; while informed consent procedures and the ability to withdraw from research give them some control over the risk they are running, the difficulty of understanding research protocols means that they have less control over the risk than would be ideal.[19]

While the combination of risk imposition with no expected benefit and little control over the risk is by no means unique to research, it is a feature that does seem to us to be sufficiently characteristic of research to at least partially justify more stringent regulation in the case of research, in particular in regard to ensuring that the level of risk is communicated clearly to potential research participants.

17. For some of the empirical evidence, see Featherstone and Donovan (2002). For philosophical reflection on what this should mean for our attempts to gain informed consent, see Dawson (2009).

18. See Hunter (2007).

19. See Anthanassoulis and Wilson (2009).

Research Is Dependent on Public Trust

To be carried out successfully, research relies on public trust. Public trust is important both in terms of the public support for the funding of research and in terms of members of the public choosing to participate in research. Even just one scandal can significantly decrease the willingness of a population to participate in research, as has been shown in America with the damage the Tuskegee study has done to the willingness of African-Americans to participate in research (Corbie-Smith et al. 1999).

It could be argued that regulation helps support public trust in research in two ways. First, it is hoped that research ethics committees might prevent at least some of the more flagrant and newsworthy ethical abuses by researchers. Thus, regulation may have a protective effect on public trust, preventing it from being eroded in the first place. Second, the regulation of research might have a restorative effect, especially if it comes in response to a breach of public trust (van den Hoonaard 2001; Fitzgerald 2005).

While this does seem to give some reason for research exceptionalism, it will only be a compelling reason if either there is strong evidence that research ethics committees prevented research ethics scandals or that members of the public are both generally aware of the existence of research ethics committees and find the notion reassuring. There is little present evidence that this is the case, however; most people outside of research have never heard of them. Nonetheless, it does seem to support a partial justification of research exceptionalism.

Professional Ethics for Researchers

Professionals have specific ethical obligations related to their professional roles, and researchers are no exception. Obviously, those obligations include ethical duties toward their research participants. However, we next argue that determining the extent and scope of these duties is complex and cannot with a satisfactory degree of confidence be carried out by an individual researcher or nonexpert research team and would better be carried out by a research ethics committee.

There are two steps to this argument. The first appeals to the complexity and difficulties of making ethical decisions in situations of fundamental uncertainty, such as those faced in research. The second adds further complexity and difficulty by acknowledging the existence of different competing ethical norms and theories and the need for some acceptable resolution between these norms. In the face of these two factors, we argue that researchers will often be in a poor position to assess the ethical implications of their own research, and given the stringent nature of their duties toward research participants, and the likelihood of research ethics committees making both better and more democratically legitimate decisions than individual researchers, this gives a reason to support this form of regulation for research.

Uncertainty and Research

Uncertainty is a fundamental characteristic of research. We literally do not know what the outcome of research will be; that is why the research is being carried out. This uncertainty makes the research unpredictable in two important ways. First, it makes the potential benefits of the research difficult to weigh; second, it makes the potential harms to the research participant difficult to weigh. This is important because the risks of the research need to be weighed against the benefits, and given that both the risks and the benefits are often uncertain, this is very difficult.

Milgram's obedience to authority experiments,[20] which were designed to test the subjects' willingness to obey authority, provide a good example. Milgram was interested in discovering how far a research subject would go in carrying out a series of increasingly callous orders, delivering what the subject believed to be electric shocks to someone the subject took to be a recalcitrant learner. Before carrying out this research, Milgram asked various psychologist and psychiatrist colleagues (and some of his psychology majors) how many people would continue to obey the authority figure's commands right to the end, by which time they would be administering what they took to be a shock of 450 volts (Milgram 1963). They thought that only a tiny percentage would be willing to go this far; in actuality, about 65% of people were willing to go all the way. In terms of predicting the potential or likely harms, that is a big gap. And that is the point—the results of research are unknown at the outset, which makes assessing its ethical acceptability much more difficult.

Ethical Regulation in Pluralistic Societies

Weighing and specifying the different ethical values in play is also rather complex. While there are some well-known and agreed-upon standards in research ethics, there are many issues in research ethics where there is not one settled, agreed-upon answer. Further, even where there is agreement on principles, there will often be considerable disagreement at an underlying theoretical level, and these disagreements may surface when principles come to be put into practice. Nonetheless, answers, at least for the moment, must be provided. While it is possible that researchers will have been provided some training in ethics and the ethics of research, as well as acquired knowledge of this on the job, they are unlikely to have a significant expertise in ethical issues. This means that they ought to be skeptical on whether they are sufficiently aware of the ethical issues that a particular research project raises. This is particularly the case since there is evidence that even experienced members of research ethics committees miss what they consider to be significant ethical issues with research projects on occasion.[21]

20. A fuller explanation of the experiments can be found in Milgram (1974).

21. See Elliott and Hunter (2008). It might be questioned whether research ethics committees are more likely to make ethically

Even if the individual researchers feel confident in making their own ethical judgment about the project, there is a further problem of the acceptability of their decision for others in society.

This problem is characterized by the existence of multiple different defensible ethical positions. This leaves us with a decision problem in public decision making: Which ethical view ought we base our decisions on, given that no position has universal appeal? In political philosophy the typical response to this problem has been to insist on neutrality by the state toward questions where there is genuine ethical disagreement. Regardless of how viable this strategy might be at the level of choosing political principles, at the level of ethical review to choose neutrality toward contested ethical principles would rather miss the point (Ashcroft 2008; Mulgan 1999). An individual researcher will be hard pressed to represent a compromised position between these different viewpoints. However, democratically set regulations can represent a compromise position, particularly if, as in the current regulation of research, each project is looked at individually.[22]

Thus, a relatively strong case for research exceptionalism can be derived. Given the professional obligations of researchers toward the appropriate treatment of research participants, the fundamental uncertainty involved in research, and the complexity of ethical decision making in terms of both establishing reliable judgments and democratically defensible judgments, it seems that the research ethics committee might be seen as a vehicle to allow researchers to fulfill their ethical obligations to research participants.

CONCLUSION

Among the several factors we have considered, three stood out as providing a better justification for thinking that research should be subject to exceptional regulation of the kind ethics committees provide. First, research typically involves the imposition of risk on people who do not benefit from this risk imposition. In an ideal case, this would be mitigated by the fact that systems of informed consent (and the ability to exit research without sanction) give research participants a form of control over their risk exposure. But two factors about the risks in research should give us pause here: the inherent difficulty of understanding some elements of research enough to give an informed consent (Dawson 2009), and the inherent uncertainty of what the research will turn up.

Second, the dependence of research on public trust gives some support for research exceptionalism. Insofar as regulation builds or maintains public trust, this gives a reason to treat research differently than other areas.

Finally, we have seen that there may be reasons of democratic legitimacy for favoring ethics committees as a regulative solution for research, even if research is not typically more dangerous than other activities which are less stringently regulated. So while many of the reasons that have been put forward for thinking that research is exceptional fail, we think that it is too early to presume that research exceptionalism is false.[23] ■

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defensible judgments. However, it seems likely that they will be more reliable, given the plurality of different views represented on an ethics committee, the variety of experience and expertise in considering and identifying ethical issues in research, and general arguments from political philosophy such as the Condorcet Jury Theorem supporting the notion that groups will generally be more reliable decision makers than individuals (Hunter 2007).

22. It might be argued that professional bodies have codes of ethics that are a form of compromise position that may (if the profession knows what is good for it) represent the public's view. To some degree this is true; however, codes of ethics are blunt tools that require interpretation. The more complex the situation, the less use these will be in providing either reassurance or guidance. Given the complexity and variety of research, professional code of ethics will only go so far in terms of removing the need for regulation, and ethical review by committee will be needed.

23. One question we shall leave for further work is whether such arguments could justify the claim that research as such should be treated as exceptional. It might seem tempting to say that only certain categories of research (for instance, clinical trials) should be treated as exceptional, while other categories of research (such as questionnaires or interview studies) may legitimately be regulated in a less stringent fashion. However, there may be some quite sophisticated reasons for regulating all research stringently even though only some research raises sufficient moral problems to be worthy of stringent regulation. For instance, it might be the case that it is difficult to distinguish ethically problematic research from ethically unproblematic research, and that it is better, all things considered, to send all research protocols to a research ethics committee for scrutiny even though only some research protocols will be sufficiently ethically problematic to justify scrutiny by a full ethics committee. For an argument along these lines, see Hunter (2007).

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