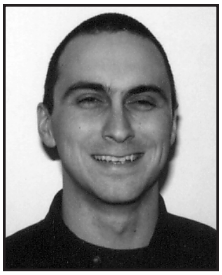
Higher Standards for Privately Funded Health Research



It has been widely suggested that, despite the evident difficulties involved in establishing appropriate systems of governance, privately funded health research should be held to the same standards of ethical conduct as publicly funded research. The purpose of this paper is to argue that that claim is false: instead, privately funded health research should be held to a *higher* standard of ethical conduct than publicly funded research.

Background: scrutiny of the private sector

It has often been noted that a large and growing proportion of health research in North America receives funding from private – that is to say, corporate – sources. The fact that companies invest in research is undoubtedly a good thing, all things considered. But privately funded health research has recently received considerable, and increasing, public and scholarly scrutiny. Concerns raised have included the potential for corporate secrecy to frustrate the openness upon which scientific progress depends, the potential for corporate money to skew the direction of university-based research, and the potential for research to be turned prematurely into clinical interventions (Caulfield, 1998). Further, questions have been raised about the possibility of bias in privately funded research. For example, an impressive meta-analysis, published in *JAMA*, of analyses of privately funded research has concluded that "strong and consistent evidence shows that industry-sponsored research tends to draw pro-industry conclusions" (Bekelman et al, 2003).

More general concerns have arisen over the fact that privately funded health research is subject to more lax ethical standards than publicly funded health research. In Canada, for example, research done at institutions funded by the Federal government's three granting councils is subject to the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans; privately funded research, on the other hand, is not generally subject to the TCPS's relatively stringent standards. And in the U.S., while privately funded research is subject to ethical review standards imposed by the Food and Drug Administration, such research is not subject to the more stringent standards imposed by the Department of Health and Human Services (Resnik, 1999). As was pointed out in a 2002 *CMAJ* editorial, Canada's regulatory environment currently features a "double standard by which privately funded research is effectively exempt from ethical scrutiny and regulatory safeguards" (CMAJ, 2002). It has been noted that, indeed, some researchers go so far as to move their work into the private sector in search of more "streamlined" ethics review processes, or to avoid falling under the jurisdiction of specific governmental ethics regulations (e.g., American restrictions on stem cell research) altogether (Resnik, 1999).

But note that, to date, scrutiny of privately funded health research has been limited to an almost exclusive focus upon the possibility of conflict of interest, and upon the effects of such funding relationships on academic freedom and on academic integrity. Such worries suggest a need for better governance, but not, it seems, a need for reconsidering the standard to which privately funded research ought to be held.

An argument: higher standards

While much has been said about the relative lack of oversight for privately funded health research, little has been said about the standards to which such research *should* be subject. The general assumption seems to be that the source of funding has implications for how funding is handled, and for the lengths to which researchers must go to avoid conflict of interest; but beyond that, the general assumption seems to be that as far as research goes, standards are standards, and sources of funding just don't matter, ethically speaking. I here take issue with that unstated assumption.

It is of course not hard to argue for the ethically trivial point that those who conduct privately funded health research should be held to the same basic standards of honesty, integrity, and methodological rigour as publicly funded research. To that extent, it is true that "standards are standards." What I propose here is a more radical thesis: the specific standards of ethical behaviour – what is to *count* as honesty, integrity, and methodological rigour – should be understood differently in the context of privately funded research.

Rationale: political legitimacy

The over-arching aim of research ethics is to protect research subjects, while at the same time permitting socially important research to get done. Unfortunately, the implementation of this goal is not straightforward. In practice, much of the work of protecting research subjects requires considerable judgment. For example, it is generally thought that researchers and REB's should seek to ensure that the consent given by research subjects is free, informed, and voluntary "enough." The risks to which research subjects are

subjected ought to be "reasonable," and "proportionate to" the value of the information to be gained from the research. The making of such value judgments on behalf of others (in this case, research subjects) places researchers and REBs into an agency relationship with research subjects and the public. That is, due to the complexity of human-subjects research, researchers and REBs must make some decisions *on behalf of* research subjects.

Given that the goal of research ethics is to balance the good of the research subject and the social value of the research being done, those making decisions must be able to estimate, at least roughly, what is in the interests of (or at least not contrary to the interests of) research subjects (either individually or as a group), as well as to decide what research is socially valuable. I argue that the validity of these agency relationships is grounded in two factors: the professionalism of the researcher, and the intentions of those who fund the research. I will leave aside the question of the professionalism of the researcher, and focus here exclusively on the intentions of funding organizations.

Governments in democratic societies have political legitimacy that gives them the authority to make decisions on behalf of citizens (under at least some circumstances). Indeed, they have the public good as their raison d'être. So, it may be reasonable for researchers to assume that *most* citizens will most often have some willingness to go along with the goals of government-sponsored research, because it will be reasonable for citizens to assume that government funded research has, as its goal, some version of the public good. For-profit corporations, on the other hand, lack political legitimacy. They can't assume that individuals (i.e., would-be research subjects) endorse their corporate goals, because individuals can't (and shouldn't) assume that corporations have their eye on the public good. Now, this is not to say that corporations don't serve an important function, or even that they don't generally *serve* the public good. Indeed, we (through government) allow businesses to incorporate precisely because we value what they contribute: we want the things that corporations can produce. But it is important to note that the *way* corporations serve the public good is by seeking profit; and the route to profit is to produce a valuable commodity (i.e., something individuals, *qua* consumers, want). This insight of Adam Smith's is an important one, and it works as a generalization about the nature of a market economy (Smith 1776). But the significance of this insight, for our purposes here, is to be found in the fact that for corporations, the public good is only a contingent effect, not a first-order goal. For them, contributing to the public good is an aspiration (perhaps) and also a (hopefully frequent) side-effect of their profit-seeking behaviour. But it's not guaranteed. So, we as citizens are right to be wary of corporations; hence we as potential research subjects are right to want to hold corporately funded research to higher standards. Less trust means stricter standards, and perhaps stricter regulation.

Clearly, this difference between governments and corporations is one of degree. There are more and less legitimate governments, just as there are more and less well-intentioned corporations. The point here is simply that the less reasonable it is, in any circumstance, to rely upon the goodwill of the organization involved, the more we should demand in terms of mechanisms of control and accountability.

What standards should shift?

Let me be very specific in my claim. I am arguing not about different kinds or styles of research, and not about the integrity of different kinds of researchers, but about different sources of funding. I am arguing that if two researchers, equally qualified and of unimpeachable integrity, were to conduct two parallel studies on the same topic, and if their respective research protocols were identical in every way except for the fact that one was funded by a federal granting agency and one was funded by a private corporation, then the researcher whose study was privately funded should be held to a different, higher standard of research ethics. (The fact that I am advocating higher, or stricter, standards for privately funded research should under no circumstances be mistaken for advocating lower, or more lax, standards for publicly funded research. Publicly funded research should continue to be held to very high standards. What I am in effect advocating, here, is the development of *higher standards still* for privately funded research.)

What differences would that mean, in practice? I describe here, very briefly, just three illustrative examples.

Informed consent. The argument presented here applies perhaps most readily to standards for informed consent. It is generally understood that the consent process is never perfect; thus we can argue for demanding either a more or a less complete and exhaustive process. This implies that, given that corporations (and their agents) are less-qualified as proxy decision-makers for citizens / research subjects, we should expect research funded by corporations (and carried out by their agents) to be extremely diligent in ensuring that consent is free, informed, and voluntary.

Confidentiality. Researchers generally have an obligation to keep confidential any information gathered from research subjects as part of their studies. Once information has been gathered and stored for the purposes of a particular study, it may at some later date become attractive to use that same information for some novel, perhaps unanticipated, purpose. The question that arises is whether the consent already given by the research subjects should be considered sufficient to permit further use of their information, or whether researchers must engage in the sometimes difficult process of re-contacting subjects in order to

seek further consent. Donald Willison has suggested that, as concerns such secondary use of data, standards for the protection of the privacy of research subjects should depend upon the source of funding (Willison 2003).[1] That is, while publicly funded researchers might contact research subjects and offer them the opportunity to opt *out* (where having one's data *included* is the default), privately funded researchers ought to be required to contact research subjects and offer them the opportunity to opt *in* (where having one's data *excluded* is the default).

Minimal risk. According to the Tri-Council Policy Statement (Article 1.6), research that falls below the threshold of "minimal risk" may be eligible for expedited review. What counts as a "minimal" risk?

> The standard of minimal risk is commonly defined as follows: if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk. Above the threshold of minimal risk, the research warrants a higher degree of scrutiny… (TCPS, preamble to Article 1.5)

Clearly, applying such a standard requires the exercise of judgment. The argument presented in this paper suggests that privately funded researchers should be even more wary than publicly funded researchers in assuming that a given study, or particular intervention, falls below the threshold for minimal risk.

Conclusion

I am at pains to note, here, that nothing in the argument I have presented depends upon cynicism about corporate ethics. Nor should my argument be taken as an insult to corporations that invest in health research. I have no data to support a claim that corporate funded research is more risky than publicly funded research or that the goals of such research are less likely to be endorsed by research subjects. Given that an argument is stronger if it relies upon fewer unsupported empirical claims, the grounding of my conclusion in a theoretical argument from political philosophy, rather than in unfounded speculation about corporate motives, is a virtue.

Finally, a word about practicalities. I have argued here that privately funded health research should be held to higher ethical standards than publicly funded research. Yet I have said little about implementation. As readers of Michael McDonald's report to the Law Commission will know, our efforts at implementing ethical standards for health research lag far behind our theoretical understanding of the topic (see McDonald 2000). At this point, I have no particular suggestions about how to implement higher standards for privately funded research. I will leave that question to those who understand better the policy arena. But I take it as uncontroversial that in seeking the best policy arrangements, we ought at least to be aiming at the right target.

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NOTES:

1. Indeed, the present article was inspired by Willison's comments during his excellent presentation to the 2003 joint meeting of the CBS and ASBH.

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Canadian Council on Animal Care

The Canadian Bioethics Society has been asked to nominate someone to represent us on this committee for a term from April 1, 2004 to March 31, 2007.

If anyone has an interest please indicate that the Dr. Mitchell, who can provide more information on the commitment.

CBS Representative on Outside Bodies

Christine Harrison President 2000-02 and myself have been asked by a number of organizations to nominate a "successor" as the CBS representative on their Board. The CBS does not have a systematic list of organizations that have CBS representation. If any members sit on Boards and as a representative of CBS please be in touch with me so that we can compile a list for the Executive. It would be helpful to know the terms, and the expiry date.

Yours sincerely,
Ian Mitchell, MA, MB, FRCPC
Professor, Department of Paediatrics
Director, Office of Medical Bioethics