A Cultural Understanding of Research Ethics Governance

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Introduction

Analyses of research ethics tend to characterize ethical review and its components as a linear process of submission, review, revision, research conduct and reporting. Recommendations to improve research ethics usually seek to provide a way to better support this linear process through improved guidance, training, regulation, institutional power or legal authority. We refer to this as a linear model of research ethics governance. Recommendations on this model implicitly recognize that research is influenced by a complex web of relations. Recent discussion about conflicts of interest and research ethics also recognizes that research review and standards are subject to a web of influences. We suggest a cultural model of research ethics governance or stewardship that explicitly acknowledges that research and research ethics are subject to complex social influences that are simultaneously antagonistic and supportive of the goals of research ethics. These influences inevitably shape even the standards, practices and structures of research ethics. Recognizing this embeddedness is more than a clever social analysis—it locates research ethics as one of many activities in an arena of social action and makes it possible to identify and evaluate the presumptions that have shaped the goals of research ethics as well as a wider range of means for achieving them.

The Linear Model of Research Ethics

Discussions of research ethics are rooted in the linear characterization of a process that begins with a research proposal and passes step-wise through stages of review and revision to be approved, implemented and reported. Research ethics scholarship has generally utilized the linear model in an attempt to directly influence research activities to promote high quality and ethical research. Recommendations to improve research ethics usually seek to provide a way to better support this linear process through improved guidance, training, regulation, institutional power or legal authority. As a result, the field of research ethics has been dominated by discussions of ethics review, ethical regulations and guidelines, and forms such as informed consent.

In *The Governance of Health Research Involving Human Subjects,*[1] Michael McDonald characterizes the practice of human subject ethics review in Canada as the funnel-like reduction of complexity into an inappropriately narrow review process:

> In short, ethics is funnelled into a bureaucratic process, and the process itself is reduced to a bare minimum. That bare minimum consists of the tangible parts – consent forms and other items, like adverse incident reports. . . . An important general result of this funnelling and narrowing down of ethical concerns is that important issues are missed at all levels and at all stages. . . . More generally in terms of governance processes and structures designed to promote ethical RIHS, the REB is seen as the focal institutional tool and in turn its role is defined in terms of front-end research protocol approval. This ignores other possible tools or structures for promoting ethical research. It also ties too much of ethics in research to a particular stage –

> a very preliminary one at that – taken in isolation from the rest of the research process. The big picture is missed – concerning the larger cultural environment of research.

The funnel example demonstrates the bureaucratization of research ethics—how a broad range of research ethics issues, when channelled through the administrative mechanisms of review and consent, end up neglecting the original complexity.

Discussions of conflicts of interest in relation to research ethics also make explicit concerns about how diverse influences on research shape the research agenda .[2] Some of the most oft- cited influences on research and the ethics of research in practice include: industry influence;; directed calls for research proposals by funding agencies; private funding of research; matched funding requirements; influence of disease-based and community-based groups; and patterns of health care funding.

Research that has critiqued explicit power, such as that of industry, for its negative influence on ethical research has vastly expanded the notion of how research gets shaped, and pointing to the potential harms for research subjects and the advancement of "good" research.[3] However, this critical gaze, the questioning of industry and other powers on ethical research, has also led to an oversimplified, unambiguous picture of the role of industry (and other powerful forces) in shaping the culture of research and research ethics.[4]

Our concern is that this literature responds to influences shaping research by attracting attention to revising the "funnel" to meet the failures. It emphasizes the intentional use of power by outside forces such as the market or patient advocacy groups and describes the negative influences that these broader forces have on research. By contrast, the literature leaves unexamined the ways that research ethics is itself shaped by broader forces. Research ethics is treated as a culturally disconnected entity that is unique for its ability to stand clear of cultural influence on its practices. Stated this baldly, the notion of a culturally independent research ethics is obviously nonsense. Research ethics is as multidirectional and culturally contingent as other influences on research, although it has as a focus the attempt to clarify what forms of research are both good research and respectful of human participants.

A Cultural Model of Research Ethics

We suggest a cultural model of research ethics governance or stewardship that explicitly acknowledges that: (1) research is subject to complex social influences that are simultaneously antagonistic and supportive of the goals of research ethics; and (2) these influences inevitably shape even the standards, practices and structures of research ethics. The assessment of the influence of various forces using this cultural model will necessarily be a messy collection of complex systems with shifting and reconfiguring components and agents with multiple directions of influence on research and research ethics.

Culture and Power: Influences on Research

There are numerous strong influences on the structuring and direction of research by groups and trends that are not assigned responsibility for the ethics of research. We typically think of these other influences for their negative effects—how they direct research in ways that are potentially harmful to subjects and therefore require particularly rigorous scrutiny in the ethics review process. Indeed, these broader forces shaping research are usually identified *because* they are seen as negative influences that require regulation or review in order to resist their influence. One example is the requirement by researchers to disclose their relationship with industry, to make transparent the conflicts of interest caused when, for instance, the pharmaceutical industry offers financial incentives to physicians to recruit patients for clinical trials. However, research is subject to complex social influences that are never merely negative and never unidirectional. Indeed, these forces may be simultaneously or sequentially both antagonistic and supportive of goals of research ethics.

For example, research ethics boards (REBs) must ensure that researcher dedication to the science does not override reasonable concern for subjects; but at the same time REBs must insist on scientific rigour. To establish scientific rigour, REBs are dependent on the peer review and training of researchers; but peer review and teaching draw their understanding of what is "rigorous" research from the state of the art of similar research. As demonstrated by debates about the proper use of placebos in research,[5] while REBs may be able to enforce peer review, the actual standards and prac-

tices of peer review are influenced by multiple forces shaping multiple perspectives. Peer review and training may exert antagonistic and complementary pressures on the extent to which research practices are deemed ethical. Competitive funding, peer review of articles, and advancement based on research achievement combine to introduce pressure to compete that could lead to pressure on subjects to participate in research. But the same influence is likely to insist on rigour in research that will lead to cautious evaluations and reduced harm as a result of the research.

In other words, the standards and practices of ethics review are intertwined in a culture influenced by various factors, including peer review and teaching. This complexity means that while overt, negative uses of industry's power to shape research (such as industry offering financial incentives for researchers to recruit subjects) are obvious and open to critical inquiry, there are also subtle, "hidden" ways in which broader forces such as industry can shape the research agenda. In the example above, it is through a complex and convoluted relationship with research and researchers that industry sets the scientific standards by which research is assessed in terms of rigour. This, no less than financial incentives, shapes research ethics, but it is so subtle or "hidden" in its power and persuasiveness that it easily escapes the gaze of those concerned with conflicts of interest.

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The influence of other powerful groups and attitudes share this multi-directional and indirect relation to research ethics. For example, patient advocacy groups may improve the representation of their constituencies' concerns about the conduct of research, perhaps improving levels of knowledge or recruitment. But this same influence may also direct disproportionate attention and resources to one type of research over another, whether in response to a groundswell of support based on cultural preferences for one type of intervention over another, a strategic marketing plan, or charismatic researchers promoting their research.[6] Unlike the overt power of industry, patient advocacy groups are acting in resistance to a relatively more powerful group (industry leaders and researchers who set the research agenda); but in doing so, they too are shaping research, and research ethics, by setting the boundaries on what types of scientific knowledge should be produced.

Equally important to consider, we lose the opportunity to use the power of industry to *support* research ethics if we treat industry influence as unambiguously negative. The positive influences on research practices of other forces (such as industry-based innovations in privacy) are worth assessment. An obvious example is that both research ethics and industry have a reason to protect individual subjects from the harms of research. For industry, that is where their greatest liability is. Both research ethics and industry focus on protecting patients from the specific actions of research (drugs, access to test information, loss of privacy). This focus sustains distance between the corporation and research review and the responsibility for broader social concerns such as where best to allocate resources. But of course industry has a great deal to do with how research resources are allocated. Although research ethics committees do not have the role or expertise to evaluate allocation, it is clearly an important ethical issue that is made less visible by the lack of explicit mechanism to address it. Any serious effort on the allocation of research funding will need to engage, not ignore or villainize industry. The extent to which these influences can be part of a web of positive influence must include assessment of sustainability of the practices when they are not directly enforced by systematic incentives such as profit or cost-reduction.[7]

Culture and Power: Influences on Governance of Research Ethics

Research ethics has as an objective the promotion of ethical research through the use of regulatory and review activities. However, wider sources of power also influence the governance and oversight of ethical research in ways that complement, oppose or are neutral to the goals of research ethics.

When industry or government shapes the research ethics agenda (for instance by directing available funding to ethics and genomics at the expense of research into ethics and poverty), this use of power is relatively explicit, in that it can be questioned and critiqued. The negative effects of broader influences shaping the research ethics endeavour itself have been discussed in the ethics literature primarily in terms of conflicts of interest when ethicists support uncritically or fail to critique the blatant influence of industry on science and ethics.[8] Such power is obvious because it is perceived as inherently antithetical to the assumptions and goals of research ethics.

Power also operates through the naturalized assumptions that are *implicit*, so taken-for- granted or normalized that they are "hidden" from scrutiny and thus rarely subjected to inquiry. For example, research ethics often focuses on the linear process of consent, placing little emphasis on public involvement in order to increase demand for democratic involvement in setting research priorities. The result is that the agenda is shaped by research ethics – not by explicit regulations or rules, but by the "culture" of research ethics that pays attention to how particular research is conducted rather than how the research enterprise is directed. Similarly, calls to improve governance of research ethics that focus on improving the linear consent process reinforce the image of ethics as being natural and neutral, able to stand apart from, and safeguard against, the negative influence of powerful forces like industry, and not subject to scrutiny. This, too, is the power of research ethics, not through regulations, but through perpetuating and promoting a way of doing things; in short, through culture.

An even more subtle use of culture as power within research ethics itself can be seen in the literature speaking out in resistance against the explicitly powerful. Critiques of the power of industry have been formulated and discussed as if industry is an unequivocally negative force acting in opposition to research ethics, while research ethics itself is conceived as a "watchdog" that must retain its integrity in order to not succumb to the pressures of industry. These critical voices reshape the endeavour of research ethics in ways that are well intentioned and without doubt beneficial to the promotion of ethical research. But by emphasizing the image of research ethics as standing apart from and protecting research ethics from the negative influences of broader forces, they reify the linear model of research ethics and the "funnelling" of ethics into more stringent review and consent mechanisms. In contrast, a critique that challenges the linear model would begin by acknowledging that research ethics itself is value-laden and culture bound and would turn the critical gaze inward to notions of "governance" itself.

And, finally, the power of the previously "voiceless" in the domain of research ethics –disciplines, communities, and methodologies that have not been part of mainstream research ethics – to reframe the gazes and intentions of research ethics must also be situated within its wider context, and not simply taken as neutral. As the field of research ethics becomes increasingly interdisciplinary, as anthropologists and other social scientists begin to engage *within* ethics in a meta-analysis of the enterprise itself; when ethnic, and disease-based communities call for decision-making in the design of research previously "on" them; and when voices of critical social studies of science articulate the need to have an expanded gaze of research ethics, these forces, though small, do reshape the field of research ethics. The increasing role of critical voices within research ethics emerges from a complex series of historical, economic, and social events in the Canadian research context (the creation of the Canadian Institutes of Health Research, the Canadian Foundation for Innovation, and Canada Research Chairs, the rise of funding in genomics and genetics, and reaction against medical models of health research, to name a few). The broader contexts shaping changes within research ethics must be carefully examined in order for the nature and impact of those changes on the "culture" of governance of research ethics to be understood.

Research Ethics Boards and the Tri-Council Policy Statement (TCPS) have effect because they have explicit power—institutions and funding agencies require approval of REBs based on the TCPS for funding. That power pushes against, or works in concert with, other types and sources of power, but it is itself a form of power which, no less than industry's effect on research, is shaped in part by wider social, economic and cultural influences. Research ethics as an endeavour, and other forces shaping ethical research, cannot unambiguously be separated out as different entities. Any powerful force shaping research and research ethics (such as industry) derives and sustains its power from some of the assumptions that it shares with research ethics. Industrial forces and the standards and mechanisms of research ethics are rooted in cultural systems, and cultural systems are shared practices, values and beliefs. Indeed, a reason why broader forces such as industry involvement in research are successful – why they are powerful and persuasive – is precisely because the influence is "hidden" and implicit, because it shares a cultural, economic, and political context with research ethics.

Unless attention is paid to the influence of diverse influences on the research ethics endeavour, the question of why certain research behaviours or values come to be recognized as unethical while others go unchallenged by the regulatory framework and its enforcers will be left unanswered. A cultural framework enables us to distinguish between forces that are obviously powerful and have a negative influence on research (e.g. industry and conflict of interest) and those that are powerful and persuasive because they are hidden (e.g., the notion that research ethics is a neutral "watchdog" that can be untainted by and safeguarded against the negative influences of industry).

Understanding this complex web of multidirectional influences as the cultural context for research *as well as* research ethics is a more realistic depiction of how research and related ethics standards and practices are shaped. It suggests that the notion of research regulation or governance must not be limited to notions of self-governance based on some rational structure to achieve the goal of ethical research. Instead, research and research ethics are located in a complex social context where many factors have unintentionally ethically relevant influences.

Strategic Advantages of the Cultural Model of Research Ethics

This cultural model of research and research ethics supports a broader notion of governance articulated by a leading UK governance scholar and consultant as "the intentional use of power to structure and direct economic, political and social activities."[9] It moves beyond that understanding of governance in its relation to power to include the ways in which culture shapes, and is reshaped by, that relationship.

Research ethics will benefit from a cultural analysis for two reasons. One is that these forces might require resistance by policies or ethics reviews where they operate against the interests of research participants or researchers. The other is that some of these influences might actually be consistent with the goals of research ethics. Finding common ground that can serve the purpose of ethical research and other goals is likely to increase the sustainability and efficiency of approaches to research ethics.

Further, explicitly identifying these cultural influences makes it possible to evaluate the extent to which our ethical standards and practices themselves are shaped by other powerful interests. The cultural model explicitly seeks to examine the research ethics endeavor, including governance of research ethics, as part of and not separate from, the forces shaping ethical (and unethical) research. Explicit description of the range of influences on research and its assessment as ethical may reveal that there were alternative standards or practices that were not considered because the ethical concerns were themselves shaped by these influences.

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All uses of power in relation to research constitute the field of governance of research ethics. All parties who influence research through their various forms of power (legal, bureaucratic, financial, rhetorical, etc) will have inevitable influence on the standards and practices of research and research ethics. Explicitly powerful forces such as industry can be negative or positive in terms of how they promote, or are antithetical to, the goals of research ethics. Research ethics itself – its definition, its purpose, its process – is also shaped by cultural, political and economic forces. A cultural model emphasizes the need to understand these broader influences in their entirety in order to evaluate the ways in which they work to support, oppose, *or themselves influence or are influenced by*, the goals of research ethics.

Policies, rules, guidelines and principles are all ways of articulating and debating appropriate explicit norms for structuring and directing research involving humans. But the simple fact that sometimes those rules are intended to push back against other norms that operate in research indicates that there are less explicit norms and social forces that structure research. This will always be so, and rules are often ineffective or irrelevant if they ignore these forces. Understanding the diverse elements in a cultural model of governing research will also identify convergences of goals of

different interests and agents, as well as where they operate at cross-purposes, deepening our understanding of how research is shaped and how norms operate and can be reconsidered or influenced.

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