

Reflections on My Experience in Human Research Ethics

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Published online: 21 July 2009
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Abstract This paper was delivered at the 2009 annual conference of the National Council on Ethics in Human Research. It is a reflective piece based on many years of experience with human research ethics and the role of Research Ethics Boards in human participant research.

Keywords Human research ethics · Research ethics boards · Ethical behaviour in research

Introduction

The organisers have asked me to reflect on my experience in human research ethics. Although back is not a direction in which I am accustomed to look, requests of this sort are becoming more frequent at this stage in my life. I have decided that this is simply one more symptom of the enormously interesting process that I have named ARDS: Age Related Decay Syndrome.

Before I embark on the reflection, honesty in advertising requires me to remind you of the background that I bring to the endeavour. I bring a combination of a passion for and continuing fascination with insects and the way that they work.

I also had a parallel career as an academic administrator, who I have often compared to monkeys: the higher they climb, the greater the range of unattractive features that they reveal.

As an administrator, however, I understood organisations generally, and in particular academic organisations, and I suspect it was this experience rather than my passion for bugs that led to my invitation to join the National Council on Ethics in Human Research (NCEHR). This is simply my way of reminding all of you that I have no formal background in ethics. I have always, however, had a great interest in ethics in science more broadly

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construed, and have viewed with growing concern the way that the competitive environment has eroded ethical behaviour.

Given this background, what can I possibly offer to a room full of experts by way of reflection? My back ground did prepare me for one of the principal activities of NCEHR, the educational site visits. I had conducted a number of visits for Natural Sciences and Engineering Research Council of Canada (NSERC) and the NCE, knew something of what could be accomplished, and understood how organisations operated. I have participated in several NCEHR visits to universities. I haven't kept track of the number, but it is certainly more than a dozen. These visits were of course a great learning experience for me, and for NCEHR as well as, I hope, for the Research Ethics Boards (REBs).¹ I have decided to focus on what I have learned from this experience. What was the single most important lesson that I derived—the AHA?

The lesson is best expressed by

It's not JUST the REB.

I want to spend a little time explaining this, and indicating why it's important as we move into the future.

In our site visits, there were two issues that were common to every visit. There is first and foremost the issue of workload. We saw REBs that were considering as many as 600 protocols in a year. The burden, including preparation, was very large. Moreover, many REBs felt that their efforts were not well appreciated or understood in the institution. The chair of the REB might receive an honorarium or a reduction in workload, but members were volunteers who were expected to make time in an already very demanding schedule. As a consequence, it was often difficult to find members willing or able to devote the necessary time.

Conversely, there were a few REBs in which the workload was very low raising the question of providing the members with the experience required to develop and enhance competence.

There was an additional difficulty in most of the organisations that we visited. The REBs were administered by the VP Research or her equivalent, giving rise to the perception of institutional conflict of interest (COI). This structural COI can be managed, and increasingly is managed effectively, but an external observer would not understand the difference between “reporting to” for administrative purposes and “accountable to” for substantive purposes.

Looking at these issues from my uninformed perspective raised for me the question of whether the organisations in which the research is done ought to be in the REB business at all. Surely this is an expert activity requiring expert knowledge and training and involving the commitment of a good deal of time. Does it not make more sense, I asked myself, to recognise this as a professional activity to be supplied by properly trained, adequately rewarded REBs existing outside the organisations doing the research? Protocols would be assessed to a common standard in a timely fashion.

While I kept this view to myself, it was heavily influenced by my administrative experience with academic computing. In the 80s academic computing from e-mail to sophisticated calculations was supplied by central computers located on campus. Meeting the demand further increased the demand, and we were constantly on an almost annual

¹ Research Ethics Boards (REB) are the committees in Canadian institutions (primarily universities and hospitals) that are responsible for the ethics review of research involving human subjects or participants.

basis having to upgrade. This involved selling off computers installed several months earlier and replacing them with the latest models. This led to some absurdities: at one point I was making payments for a computer that we no longer had. So, I reasoned that computing was a utility like electricity or water. We trust the supply of those utilities to outsiders, so why not computing. We simply contracted to a provider for capacity, and stopped worrying about the purchase, housing and maintenance of central computing. Of course, that problem has since evaporated with the development of distributed computing for most academic purposes.

So, as I participated in the earlier site visits, I asked myself why not regard REB services as a utility to be supplied reliably and on demand?

I am glad that I kept these early views to myself, because I have now concluded that such an action **for most purposes** would be an error. I should say, I suppose, at the outset, that there are some situations where an external or common REB makes sense. But for most organisations that are conducting research with humans, I think it is important that the REB be embedded in the organisation. There are at least two major issues that are involved.

The Web of Accountabilities

The accountability of REBs leads them in a number of directions.

They are, first and foremost accountable to the research subjects who trust them to ensure that any risk is explained to them, that the risk is essential to the research, that the research will answer useful questions, that the research will be carried out responsibly as described by persons competent to do the research, and that, where appropriate, the participants will know what the results were.

But the accountability of the REB does not end there. They are also accountable to researchers to help them to design research with humans that minimises the risk without compromising the usefulness of the research, that meets the appropriate guidelines and regulations, and to provide their services in an even-handed and timely way.

The REB is also accountable, of course to the organisation. The REB ensures that the research with humans meets all of the regulations and guidelines that apply to the research carried out by the members of the organisation, giving the organisation confidence that its agreements with sponsors such as the granting agencies are being respected. There are some who might say that, indeed, the **only** accountability of the REB is to the organisation, and that it is the organisation that is ultimately accountable to the research subjects. These are not mutually exclusive alternatives. Indeed, all of the actors share accountability to the subjects, but it is in the REB that that a particular and **independent** accountability lies.

At the same time the organisation is accountable not only to the research subjects and the sponsors but also to the REB and the researchers.

It has a responsibility to ensure that, where appropriate, the research is monitored to be certain that protocols are being followed.

It must provide adequate support to the REB and the broader ethics enterprise. This support is not simply financial, enabling the REB to do its work efficiently and properly assisted, although that is important. It must also provide an administrative and operational environment for the REB to operate independently, giving it direct access when needed to its highest level of governance.

It must develop and maintain policies that govern research with humans by members of the organisation. A wise organisation will ensure that all actors, including researchers and participants, are involved in that process, or at the least, consulted.

It must ensure that its general policies governing research include reflection on publication and conflict of interest. For example, what are the circumstances under which a sponsor can require a delay in publication of results, and for how long?

It must provide opportunities for the education of researchers, including students.

Researchers have a responsibility, where appropriate, working with the REB to inform subjects about the outcome of the research, and to inform themselves and be sensitive about the ethical issues, as well as understanding and adhering to the requirements of the process. Mentors have a particular duty by example and more directly to instil in their students respect for the subjects and the process.

In this web of accountabilities and responsibilities, the REB plays a central role, which, while it is sometimes advisory, is both essential and embedded in the organisation.

Given these realities, does it make any sense to remove the REB from the organisational environment and place it outside the organisation?

Organisations are Different

For me, a more powerful argument for having REBs embedded in the organisations that they serve lies in the fairly obvious observation that organisations are not the same. So what? Are not the values that underlie our codes, guidelines and regulations universal? Do not all organisations have to apply the same rules? Yes, that is true, but given that, what then is the importance of required community members if not to bring the values of the community to the table and thus increase the confidence that the community has in the process? Not all communities are the same.

Similarly, organisations are different. All of the organisations conducting research share the principles and values that underlie research with humans, and apply the same guidelines and regulations. But the ethics process in those organisations is situated in and informed by organisation-specific values.

Saint Michael's Hospital in downtown Toronto is located in a cluster of other hospitals, all involved in research. But St Mike's is the community hospital of the downtown, and its values and, indeed, its general atmosphere are different from those of its neighbours. Its research ethics enterprise is admirable: indeed they are leaders in some areas, but that enterprise is informed by and embedded in a commitment to serving its local community, including street people.

Similarly, there are 4 universities in the Greater Toronto Area (GTA), each of them conducting some research with humans. All, of course, subscribe to and support the principles, guidelines and regulations that apply to research with humans. But they are very different organisations in terms of their institutional values. It is perhaps dangerous to try to encapsulate my perception of those values, but let me try. The University of Toronto (U of T) is both enormously complex, with its interrelationships with the huge network of biomedical institutes and hospitals, and heavily focused on research. York University, while no less ambitious, continues its deep commitment to social justice and inclusiveness, even as that commitment sometimes erupts in noisy and unattractive confrontation. Ryerson University, only a few blocks south of the U of T, is perhaps the most firmly embedded in the city: it is to the academic enterprise what City TV is to the Canadian Broadcasting Corporation (CBC). The University of Ontario Institute of Technology (UOIT), the most recent, has a market centred approach, looking to the technological world.

While these descriptions may or may not be apt or accurate, the point on which all would agree is that they **are different**. Although they share the values of the academy,

those values are to some degree shaped by an overlay of concerns and values of the communities that they serve.

So what: what difference will this make to the assessment of protocols by an outside REB? It is, I submit, a question of confidence. Researchers, administrators and perhaps even research subjects are likely to have greater confidence in a process and REB membership that is part of and “understands” the values of their community.

An REB situated outside the organisation, no matter how efficient, well trained and appropriate for the research may not have the confidence of the research community in the organisation because they do not see that their values are represented: the peers are too distant.

Of course, there are particular circumstances for which “external” or professional REBs are necessary, provided either by the private sector or by government or Non-Governmental Organizations (NGOs).

If one accepts these views, then you will note that while the REB still plays a central role, the responsibilities of other components of the organisation have become more prominent. This realisation is reflected in the gradual broadening of the focus of the NCEHR site visits to include these other components. The accreditation process suggested by NCEHR focuses on the organisation. Organisations have begun to realise that their responsibilities are not limited to appointing and supporting one or more REBs. This is, I suppose, is simply one more step in the continuing process of maturation set in motion by the Tri-Council Policy Statement (TCPS) in Canada. Would establishing independent REBs outside the organisations further or disrupt the process?

I leave you with this question to ponder.