Assessing the social value of research involving minimal risks

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ETHICS IN ETHICS COMMITTEES

Assessing the social value of research involving "minimal risks": who is accountable?

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Over time the debate has matured regarding the governance of research ethics boards (REBs), their roles and their mandates, and how their services can be audited for quality control. With the fast changing character of research in every field involving human research participants, today's REBs can be expected to encounter newer challenges. The last decade of health research has witnessed unprecedentedly large budget initiatives with a global sweep. It is also marked by its growing trans-disciplinary nature. Accordingly, the terrain of research ethics is also changing, and posing new problems. For example, in the absence of a harmonised global research ethics framework and regulatory arrangements, how will the various stakeholders in a research enterprise respond to issues of data sharing, bio-banking, benefit sharing with study communities and research participants and credit sharing in the ever-increasing quantum of international collaborative research in the life sciences that leads to healthcare innovations? Indeed, there is enough to challenge our brains to address these issues in coming times.

Can we assume, then, that the very "primordial" research ethics issues have been addressed fully so that we may move on to look at newer challenges in the field? It seems not. While the old challenges may be less visible and viewed almost as "trivial", they have not necessarily been resolved.

This essay refers to discussions among a group of friends and colleagues called A7, currently located in Toronto, Canada. We belong to different nationalities and come from diverse socio-cultural contexts. We come from different disciplines and professional backgrounds although all of us are connected to the health field in one way or the other. In hindsight, the unstructured, informal and, above all, non-judgmental ambience of this forum allows us to talk about several issues fearlessly and without much awkwardness.

In a recent discussion, one of the group members talked about the issues she confronted during her work in the late 1990s. The concerns expressed regarding REBs' role in determining the "social value" of research, and the serious implications it could have, continue to be very relevant today.

The "social value" of research

It is still fresh in my mind how passionately I had argued during my bioethics programme that the principle of "social value" should take precedence over that of "scientific validity" alone. To date, I continue to hold this stand. It has been further strengthened based on the opportunities that I have had to witness the research enterprise in an ever growing globalised context. The "social value" of any proposed research continues to be one of the core principles of research ethics (1). Although it is most basic, it appears that it is the least attended to, particularly in empirical social science research including empirical bioethics. REBs are no exception to the disregard of this principle. Such disregard may be due to pragmatic constraints, the unhealthy academic culture of "publish or perish", or the ever increasing pressure to be innovative, novel and unique.

Let me share the story that my friend discussed with us. In the late 1990s, Rosanna was associated with a mega project that appeared to be unique and perhaps exemplary in several ways: its global scope, its multidisciplinary nature, its being in the limelight and its being almost a flagship project for the funder. It played a key and strategic role in a large global health initiative conceptualised and sponsored by the funding agency and consisting of about 25 projects meant to address international health issues and located all around the world. Rosanna's team's mandate was to offer solutions to ethical concerns encountered by the scientists working on these 25 projects during their scientific endeavours. Her own project, therefore, was evolutionary in nature. It played the role of advisor and support of all these projects on ethical, social, cultural and regulatory challenges as and when these project teams confronted them. Rosanna's team, therefore, was an assured resource made available by the Sponsor agency to ensure the quality of this global health initiative including its ethical content, socio-cultural sensitivity and regulatory soundness. Indeed, it appeared to be a pathbreaking model bringing bioethics, social sciences and life sciences together from the outset of this large global health initiative. The initiative seemed to be crafted with ingenuity, creativity and a sense of commitment to the developing world's health concerns. Overall, it was a collective commitment – of scientists from around the world, sponsors, and Rosanna's Team members – to people's health and well-being.

Rosanna was also involved in a sub-project concerning empirical bioethics. Its mandate was to conduct primary research to better understand how research ethics norms and principles get translated in real-life situations. It did this while interacting with research participants, their families and people in their neighbourhoods. It also looked at how these

principles played out in different socio-cultural settings and in different health research contexts including biomedical research and public health interventions. Again, this looked like an interesting, relevant topic of enquiry. However, as we discussed what Rosanna narrated to us, one of us asked if the topic warranted such a large investment at that point. However, others felt differently. Clearly, a thorough review of the contemporary literature on the theme was necessary to ensure that it warranted systematic empirical research in international settings. Interestingly enough, the relevance of the topic seemed obvious to several other sectors outside health. To us, this implied that it would be a very demanding task to review the literature on the topic across several sectors to state confidently whether or not it needed further exploration.

Rosanna traced the genesis of the sub-project to the needs articulated by some projects in the initiative. Their expectations were in line with the strategic position that the project held in this initiative. One could imagine how the "pressure to respond" might be exerted on the team just by virtue of its being a "problem solving" team in this global health initiative. The "pressure to respond" seemed due to the fact that Rosanna's project was handsomely funded to address other teams' concerns and challenges in meeting goals of the respective projects without compromising on their quality as described earlier. The creation of such resource in the form a Rosanna's project was also a thoughtful strategy of sponsors to optimise on the huge research resources in the initiative to ensure either tangible gains or the creation of knowledge to form foundation for further enquiry into the respective research areas Against this backdrop, Rosanna said that her team took the position that the topic was "insufficiently explored" and therefore needed further enquiry based on its informed guesses. Consequently, it occupied a prime spot in the project and claimed substantial allocation of project funds. To her, it was less justified at least at that point in time. We all stopped to ponder over the question: In a multi-million dollar international health project, what weight should the question of its social value have? And who should be responsible to ensure this social value? Could research ethics boards be safety nets to prevent redundant research?

Can Research Ethics Boards be safety nets?

In any case, Rosanna said, her sub-project proposal was developed and submitted to the designated REB at the academic institution where her project was located in North America. REBs in this part of the world are quite sophisticated when it comes to infrastructure, human resources allocation and overall resource allocation at an institutional level to run them. Nonetheless, there is no reason to believe that they are without constraints. Rosanna's frustration at this stage was at two levels. First, the research protocol that the team had prepared was not to her satisfaction for a number of reasons, the most important being that the team did not adequately develop the justification for focusing attention on an in-depth, multi-centric, international research study. Second, she therefore anticipated that the REB would raise questions on this seminal aspect of the research. However, to her surprise other than asking for some minor clarifications, the REB approved it at one sitting. So her expectation that REB could work as safety net did not materialise in reality.

On further discussion, one of the group members asked whether the REB was appropriately chosen to review this research proposal. In the larger academic setting with numerous disciplines and numerous REBs, each REB is assigned to conduct ethics review for particular departments. This seemed to be a pretty robust system within a huge, centralised bureaucracy in an academic setting. However, it turned out that her institute was categorised under a life sciences stream. It was therefore assigned to an REB that is primarily equipped to look into hardcore biomedical research protocols, especially clinical trials, with a minimum of the focus and orientation that social science research demands. Rosanna also noted that the REB checklist, for researchers to respond to as part of the REB submission, was not geared to capture the nuances of empirical bioethics and social science health research. This is because such research is usually put the category of "minimal harm". Once researchers classify their protocols as doing "minimal harm", REB scrutiny is nominal.

Our sustained discussion within A7 about Rosanna's project left us with the following questions that we thought could be educative for the peer community of researchers, REB members and bioethicists alike:-

- What if the team did not take up the literature search and did not produce quality work of relevance to international health research?
- How important would it be to have an REB equipped to review research that involved only "minimal risks" to study communities and/or participants?
- In large academic settings where REB functioning and operations are systematised, super-standardised, and are constituents of the academic administrative system, who should take responsibility to point out mismatches between designated REBs and the departments assigned to these REBs?
- What other fool-proof mechanisms could be set up at the REB level to help discourage "me too" research, especially on projects which are uniquely situated, such as the one described above?
- The specific context and nature of the project that Rosanna discussed with us seemed to be a situation with potential conflicts of interest. Should there be better mechanisms for REBs to capture such potential threats?
- Should REBs have additional, special mandates to scrutinise big projects involving large research funds for their social value? What could those mechanisms be?
- Would tighter and closer scrutiny only confirm the skepticism and criticism of those who believe REBs are policing structures that obstruct research more than they facilitate better research ethics compliance?

Some of us in the group came from low-resource settings

where we strived to obtain scarce research dollars to pursue research of relevance. Often, the topics of our enquiry stemmed from our work on the ground. Also, research findings got fed back to advocacy campaigns and policy and legal reforms. They had on occasion helped shape healthcare and related services at the grassroots level. Rosanna herself came from a country in Latin America where she was involved in health activism and trained in the critical theory tradition. As a consequence she found it challenging to be in an academic setting which appeared to be so far removed from the ground realities that people are confronted with. It was heart wrenching to learn that research supported with millions of dollars was not necessarily socially relevant, nor did it generate much new knowledge.

The debate around the social value of research is not new (2) and it is not easy to resolve. It is harder to lay down general guiding principles to arrive at fair decisions on the social value of a particular research project. This leaves all stakeholders in the research enterprise with much more accountability for the quality of their own research and the use of scarce research funds.

Postscript: *Rosanna told us that eventually the team undertook a systematic, structured review of literature, spanning several sectors beyond health. Some of us in the group are acquainted with the products of her project. Indeed, these are outstanding and made original contributions to the field in the early 2000s. On the other count, efforts to explore other appropriate REBs from within the academic setting were not encouraged at her institute. To her, this was because REB approval came by quickly through the current arrangement with the current, designated REB.*

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Process, pitfalls and probity: sharing experiences on setting up and running ethics committees in India

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Jesani recently (1) pointed out in his editorial that even after 30 years of having ethics committees (ECs), we still do not have empirical and factual knowledge about how ethics committees function in the country. He rues that information on how "ECs function, the problems and dilemmas faced and experiential sharing is not available in the public domain." Brahme and Mehendale (2) provide one of the few accounts in the literature of characteristics of ECs, focusing on institutions in Pune.

In this article, we describe the framework of a workshop that we organised at the Second National Bioethics Conference in Bangalore in December 2008; we also highlight the challenges in establishing and administering ECs in India identified during the discussion among workshop participants. We believe that our experience will help researchers and institutions better understand how to start and sustain an EC, efficiently and effectively.

Concept and structure of the workshop

The workshop was organised with three objectives: to learn about the requirements for setting up an EC; to identify the potential obstacles to setting up an EC, and to find ways to conduct the day-to-day activities of an EC effectively

The workshop was also conceived as a venue for participants to discuss the problems, pitfalls and processes involved in setting up an EC. This was done through a structured discussion which was initiated during the second half of the workshop. The 35 participants and five facilitators had varying levels of experience in the field of EC functioning.

The workshop began with an introduction to the rationale of the workshop, followed by a presentation on the guidelines for setting up an EC and the challenges in building it from scratch. A discussion with the participants was then started with a focus on the challenges faced in setting up and running ECs, and the responses to these challenges. These were finally distilled and presented as a summary at the end of the workshop.

Highlighting regulatory guidance on ECs and practical tips in running an EC

Following the introduction, one of the facilitators (S Swarnalakshmi) presented guidelines for setting up of an EC. Universally, ECs resemble each other in concept as their focus remains the safety and dignity of human participants in research studies. However, they may be differentiated by regional variations and cultural nuances.