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Barriers to Research on Research Ethics Review and Conflicts of Interest

Research on research ethics—regarding both the governance and practice of the ethical review of human subjects research—has a tumultuous history in North America and Europe. Much of the academic literature focuses on issues to do with regulating the conduct and quality of ethics review of research protocols by ethics committees (research ethics boards (REBs) in Canada and institutional review boards (IRBs) in the United States).[1] In addition, some of the literature attends to issues particular to the review of qualitative research,[2] and still other literature addresses the challenges posed by and the need for research on REBs/IRBs.[3] It is this third group of literature within which our article is situated.

In 2009, we initiated an empirical bioethics project to advance REBs' understanding and management of conflicts of interest in their ethics review of research projects.[4] The focus was REBs at Canadian universities, hospitals and medical research centers. Lo and Field define a conflict of interest as "existing when an individual or institution has a secondary interest (e.g., an ownership interest in a start-up biotechnology company) that creates a risk of undue influence on decisions or actions affecting a primary interest (e.g., the conduct of objective and trustworthy medical research)."[5] Our project was to involve 1) an analysis of the specific ethical challenges that conflicts of interest pose in REBs' review of health research, and 2) the development and testing of practical model ethics guidelines to assist REBs in managing conflicts of interest. We set out to create a model that could be generalized across diverse institutional settings. Yet many REBs—often lacking a clear understanding of what constitutes a conflict of interest—did not consider themselves as being faced with conflicts of interest because "we don't review clinical trials involving the pharmaceutical industry." The result was that many REBs, especially those reviewing projects primarily in the social sciences, refused to participate in our study. Thus our second objective, that of building and testing a model guideline, was transformed into developing practical teaching tools to help REBs better *identify* and *manage* conflicts of interest when they review research projects.

Because we were interested in the experience of the REB as a group—not specifically of individual members—our plan to conduct interviews meant that an REB had to review and approve the proposed project. We obtained approval from one of the REBs at our university in early 2010. However, as we also wished to interview REBs in medical centers, we were obliged to submit our project through Canada's provincial multicenter process (also known as a multisite review). This necessitated a second full application to a central REB (which was based in a hospital), as well as to the dozen REBs we hoped to recruit as "participants" in our study. We were interested in learning from the experiences of REBs that dealt mainly with clinical research, from those that reviewed psychosocial, behavioral and public health research, as well as from REBs that reviewed non–health related research. This second review process proved much more complicated and time consuming. Moreover, it involved unduly demanding and inappropriate requests due to 1) an apparent "clinical trial bias" on the part of some REBs (i.e., a bias against qualitative research based on the view that all research projects require the same level of risk analysis and protections as clinical trials), and 2) structural elements imposed by the multicenter process (e.g., substantial paperwork, requirement to have local respondents, and ethics review at all participating medical centers).

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We eventually decided not to pursue the multicenter process, and so continued our interviews with a limited number of REBs (less than five from the healthcare setting, a formal threshold under which multicenter approval is not required) that expressed an interest in participating in our study. In a detailed letter in early 2011 to the central REB that had reviewed our project, and to all the participating REBs at healthcare institutions, we explained the reasons for our decision to withdraw from the multicenter review process. Our hope was that the letter—which led to writing this article—might help to further the dialogue on ways to improve the multicenter review process. More specifically, we wished to highlight how projects considered as minimal risk according to the new *Tri–Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2)[6]—Canada's principle research ethics framework—were inappropriately treated with as much scrutiny and concern as would be projects that present a high risk to participants; the result is that the current review process is not conducive to certain types of qualitative and empirical bioethics research. Following Article 2.7 of the TCPS2, REBs "should adopt a proportionate approach to ethics review, based on the principle that as the risk to participants increases, so should the level of scrutiny in assessing the research and the level of expertise involved in the review process."[7]

As ethicists exploring issues in research ethics, this experience, while frustrating, was also a useful source of practical information. It reinforced our conviction that REBs are placed in a difficult situation, and so while they need better support and training to carry out their very important work of ensuring that research involving humans meets the highest ethical standards, they also need a more coherent and supportive governance system. This article is thus not meant as a condemnation of the REBs with whom we interacted in the ethics review process (or of REBs in general), but as a reflection on the challenges facing these committees and the need for continued training about conflicts of interest, about what constitutes risky versus minimal risk research, and about the appropriate evaluation of projects that employ qualitative research methods in a health sciences context.

Conflicts of Interest, Vulnerability and Risk

From the start of our project, we recognized that what we were proposing was rather unique. The REBs that would review our project—and thus their members—would also be the subject of research, and this was not trivial nor without consequence. As we stated in our recruitment letter *"We realize that asking you to both review and consider participating in our project places you in an awkward conflict of roles (i.e., reviewer and participant). Nonetheless, we hope that in recognising this tension—and the importance (and challenge!) of dealing with COI more generally—you will be favourably inclined to accept and agree to participate in our study."* But once we received their comments and recommendations, we quickly recognized that the REBs in the multicenter process had rarely dealt with our type of project (empirical bioethics), or the particular conflicts of interest that we had explicitly named and defined.

■ ***Whose Interests and What Risks?*** One of the primary responsibilities and interests of an REB is to evaluate the risks and benefits to participants of a given research project. But when REBs are themselves the potential participants, they may have other primary interests in participating in a study (that would be secondary interests when viewed from their role as REB members), such as being individually interested or in favor of the study or uninterested because the study would involve too much work. Equally, because we were soliciting REB participation as a whole—and not that of specific members—some REB members might have found it difficult to separate their individual (member) and collective (REB) interests.

Many REBs often lack a clear understanding of what constitutes a conflict of interest and therefore do not consider themselves as being faced with conflicts of interest when reviewing research projects.

The conflicts of interest that the REBs were likely most familiar with, and which probably shaped their review of our project, include 1) those in which an REB member has a conflict due to their involvement with a project under review, or 2) those that arise in the clinical research setting (whether involving physical or psychosocial care),[8] such as financial ties or personal relationships that can negatively effect clinician-researcher objectivity. In these cases, the selection of other evaluators (i.e., recusal from decision-making) or

research participants without any conflict of interest would be an appropriate way to ensure objectivity and to protect vulnerable populations, such as patients. A similar approach was used to evaluate our project; that is, we were told that the project must include impartial evaluators who were in no way involved or participating in our project, thereby excluding participation of the REBs.

Our view was that while the evaluators would also be research participants in the context of our research, they did not share the same vulnerability as participants in clinical trials and thus did not require a similar level of protection. REB members are invariably highly educated competent adults who are tasked with assessing the ethics of research projects; they do not demonstrate the specific vulnerabilities of patient participants or minority groups (e.g., being ill, in need of treatment, or subject to a strong power relationship with the investigator), because they are not at any grave risk of physical or psychosocial harm. Nor is the ability of REB members to give free and informed consent compromised. The questions we hoped to ask them were not in any way sensitive, because we were not interested in particular cases of conflicts of interest (or possible misconduct) that might put the REB in a difficult position with regard to their institution. Instead, we wanted to know 1) how and what they would define as a conflict of interest, 2) whether their institution had relevant/useful policies or guidelines about conflicts of interest, 3) their experience (if any) with and management of conflicts of interest, 4) their view of the role of ethics committees in a situation involving a conflict of interest, and 5) what major ethical issues or dilemmas they encountered with regard to conflicts of interest.

As a side note, the TCPS2 has specific text that makes clear that participant vulnerability alone should not be grounds for exclusion from research: "Individuals or groups whose circumstances may make them vulnerable in the context of research should not be inappropriately included or automatically excluded from participation in research on the basis of their circumstances."[9] The rationale is that if vulnerable populations (such as women, children, the elderly, minority communities) are prohibited from participating in research because of their vulnerabilities, they can then never benefit from the results of research (as do other groups), thereby reinforcing their vulnerability.

The ethics review of our proposed project overestimated the actual risk to which REBs as participants might be exposed because standards for protecting patient participants involved in clinical trials were used, and because the review did not take into consideration the existence (or not) of vulnerabilities that would legitimately preclude participation in research, and thus neglected the contextual elements of our study. The specific elements that did pose risks were mainly confidentiality and autonomy, which were managed through standard ethical research procedures to ensure anonymity and informed consent of participating REBs, and thus their members.

■ ***Which Management Procedures?*** Our proposed project raised a number of conflicts of interest, of that there was no doubt. But the problematic conflicts were primarily those to do with REBs' role in reviewing the project:

- The role conflict of the in–house respondent (a local collaborator, something imposed by the provincial multicenter process), i.e., chairs of the REBs, meant that this person would be a putative research team member, participant and reviewer;
- The role conflict of the principal investigator (PI), who is also a member of the University Committee on Research Ethics which has an oversight function with regards to affiliated health institutions' REBs;
- The conflict of roles for REB members who would be both reviewers and research participants.

The multicenter process required us to identify, up front, institutional respondents/collaborators from the contexts where we would be conducting our study, even though these individuals were not involved in the conduct of the research. We understand that this requirement may be an important safeguard in the context of clinical trials, i.e., by ensuring that there is a local research collaborator involved in any trial conducted in the institution. However, this requirement was entirely inappropriate, and even unethical in the context of our project, because it imposed a collaborator who was not a member of the research team nor in anyway active in the project. Should we include these respondents in all steps of the research (e.g., data collection, analysis, manuscript writing and editing)? Would their collaboration merit recognition through authorship on subsequent publications, even though they had little knowledge of research about conflicts of interest? How would we manage confidentiality with such collaborators? In order to complete the formal requirements imposed by the process, we had named as the key contact persons the chairs or coordinators of the REBs who we hoped

would participate. But it made no sense for them to be or to consider themselves to be collaborators on our project, which led to the inevitable confusion on the part of some REBs as to the roles of their REB chairs/coordinators.

One of the solutions proposed by the evaluating REB to *avoid* some of these conflicts involved the *withdrawal* of the PI from major aspects of the project, specifically from reviewing any of the primary interview data. This proposal seemed inspired by an analytic framework proper to the context of clinical trials, where the issues of vulnerability of participants—and therefore the risks associated with conflicts of interest, namely bias—are significantly greater than was the case in our project. Also, if a conflict of interest can be resolved in certain circumstances by withdrawal or disclosure, these strategies are not always appropriate or effective.[10] In the case of our project, transparency about our methodology coupled with a process of open discussion between the research team and REB members should have been sufficient to manage any conflicts of interest, while still protecting the integrity of research participants and the ethics review process. In fact, such an approach would have enabled the development of a relationship of mutual trust between the researchers and the REB members, while still ensuring a rigorous process of ethics review and continuous monitoring. In addition, it should have been noted by the REBs that, if at first glance, our project raised a number of conflicts of interest, they were not particularly risky or unmanageable. These conflicts of interest should have been the starting point for a dialogue between the research team and the REB members about how to appropriately identify, evaluate and manage conflicts of interest. As we have found in the other interviews conducted with REBs outside the multicenter process, the very act of participating in our study provided an opportunity—i.e., time—for this very sort of dialogue and learning about conflicts of interest, something that even the most conscientious REBs were hard pressed to do themselves given their very busy schedules and significant workloads.

Another important issue that was raised was potential bias of REBs as research participants. The evaluators of our proposed project argued that as the REB members had read the full proposal (including the letters of recruitment, methodology, and questionnaire), and since they would also be participants in our research, knowing our theoretical framework and hypothesis would bias their point of view, thereby undermining the objectivity and validity of our research findings. This issue was a particularly odd concern, and one that we were not at all expecting to be raised because of our research methodology and epistemological orientation. In our project, as in many qualitative traditions, subjectivity is a common reality, and even valorized because the intent is not to isolate the variables of a phenomenon under study (e.g., by controlling the conditions of data collection) as in many hypothetical-deductive studies in the quantitative tradition, but rather to encourage the emergence of a phenomenon's complexity through documentation of research participants' experience.[11] It is the justification of the methodology and transparency of the research process that ensures the reliability of the research data.[12] There was no question, in the context of our project, of formally testing a hypothesis; our aim was to develop an understanding of REB experience in order to support REBs in their review of research projects, and in particular, to help them identify and better manage conflicts of interest when these could not be avoided.

Ethics training for REBs should focus on managing conflicts of interest, but also more generally on differences in research methodologies and traditions.

A final suggestion from the reviewers of our project was that we submit our proposal for ethics review to the Ethics Unit at the Ministry of Health to avoid certain conflicts of interest. This clearly illustrated the impasse faced by researchers conducting research on research ethics and REBs;[13] we cannot submit proposals to an REB without generating conflicts of interest. Even asking the Ethics Unit—which oversees the research ethics review process in the province (at least for REBs in the healthcare system)—to evaluate this type of project would be a conflict of interest because they have a vested interest in how research ethics is conducted in the province. In other words, regardless of where our project or others on the ethics of research ethics are evaluated, they will be subject to diverse sorts of conflicts of interest (e.g., an interest in the practices of specific REBs). This impasse confirms that it is imperative to continue such research so that REBs can better understand, identify and manage conflicts

of interest. But how is such knowledge to be developed in the current context where REBs seem unable to fully understand the nature of conflicts of interest and how to manage them? Because they were scared of conflicts of interest and of the potential consequences of identifying them, many REBs took the safest route and refused to be participants in our ethics research study. In so doing, they undermined the possibility of conducting research for which they are the intended beneficiary, at least until better management of conflicts of interest becomes possible.

Possible Ways Forward

Unlike some pessimistic colleagues, we do not share the view that "research ethics is unnecessary and meddlesome bureaucracy that stifles research!" We are fully aware that REBs, whether in universities or in healthcare institutions, are working extremely hard with very limited financial and personnel resources, and are doing the best they can to protect research participants. There are, however, possible ways forward to improve the system currently in place. A good starting point to improve the ethics review of research projects in Canada would be for the provincial Ministries of Health, and the provincial and federal granting agencies, to be more cognizant of and responsive to the challenges encountered by some humanities and social science researchers in the process of research ethics review.[14] In particular, these entities should pay heed to the TCPS2, which has an entire chapter on the ethics of qualitative research (Chapter 10).

It is also essential that a coordinated and efficient multicenter review process be implemented. Ideally, this would entail better management of multicenter research by testing different initiatives, such as reciprocal or centralized review. Reciprocal review involves agreements between different REBs to accept each other's reviews, while centralized review involves all participating REBs sending protocols to a centralized REB with demonstrated experience in conducting a specific type of review (usually in a field of research or on a specific topic). Such initiatives are being developed in the United States and in some Canadian provinces. In building the confidence between REBs (e.g., favoring dialogue) that would be necessary for better coordinated multicenter review, there would also be an opportunity to improve and facilitate knowledge sharing[15] about best practices, especially with regard to the evaluation of qualitative research and the identification and management of diverse forms of conflicts of interest (whether in the context of REB review or as part of the project under evaluation).

The fact remains that much work still has to be done in providing robust and accessible research ethics training for REB members in both clinical and university contexts. Training should focus on managing conflicts of interest, but also more generally on differences in research methodologies and traditions.[16] While REB members come from different research contexts, they are specialists in the methodology of their own disciplines. As such, some methodological approaches may be misunderstood as being "soft" or lacking in scientific credibility. Such an ideological stance may even be a conflict of interest—because of the interest in defending one particular perspective—and consequently has the potential to introduce bias in the ethics review of proposed projects.

The online training tools (tutorials, webinars) developed by the Interagency Panel on Research Ethics to explain the TCPS2[17]— along with those developed by U.S. universities,[18] the U.S. Institute of Medicine,[19] or the University of Manitoba[20]—are excellent starting points. But these tools may still be insufficient. Even if REB members are fully versed in the TCPS2 and its guidance regarding conflicts of interest, multicenter review, minimal risk and proportional review, or the specificity and diversity of qualitative methods, their ability to implement such knowledge may be impeded by a lack of practical tools ("how, in practice do we deal with conflicts of interest?"), not to mention by structural or bureaucratic factors imposed by the provincial multicenter process (e.g., obligatory "local respondents"). What is necessary, then, is to find a way (e.g., through managing conflicts of interest and an external evaluation of them) for REBs to participate in ethics research on research ethics. By doing so, we will ensure that ethics researchers can develop the knowledge needed to create practical tools that can help REBs do their work better, something that our team is aiming to provide.

Conclusion

As researchers who conduct research on conflicts of interest and on research ethics more generally —and some of us are members of REBs—we clearly have a vested interest in seeing such research funded by the Canadian granting councils, and better understood (e.g., its particularities) and supported (e.g., educa-

tion) by universities and healthcare institutions. But as researchers whose proposed projects undergo ethics review by REBs, we also have an interest in seeing REBs better resourced—both in terms of personnel and knowledge—so that they have the time to participate in research and ongoing learning, and thus are able to continue their work of ensuring that all research involving human participants meets the highest ethical standards. We would even go so far as to argue that REBs have a responsibility to be partners in research and continuing education about ethical issues such as conflicts of interest because research and education may help them improve the quality of the ethics review process.

In recounting our experience with issues about the ethics review of conflicts of interest research involving REBs as participants, we hope to have shown that substantial effort is still needed to sensitize the research ethics community to nuances in notions of vulnerability and risk, to the fact that not all research should be treated "just like clinical research," and to the importance of identifying and appropriately managing conflicts of interest that cannot or should not be avoided. Both REBs and ethics researchers must work to build mutual trust, which is necessary for any collaboration to succeed, whether it be for continuing ethics education or the conduct of ethics research. The current impasse facing research about REBs and conflicts of interest in the ethics review of research studies can thus be seen as an opportunity to engage in a constructive dialogue between all parties involved in research ethics —REB members, researchers, policy makers—which, after all, is part of what ethics is about.

Disclaimer

This paper presents the experience of a research team submitting their project for ethics review as part of a multicenter review process, thus we have anonymized the name of this Research Ethics Board. Our study was also initially reviewed and approved (prior to engaging in the multicenter process) by the Research Ethics Board of the Faculty of Medicine (CERFM) at the University of Montreal.

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