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Observers, Community and Legal Members on REBs: Examining the Ethics of the Regulators of Ethical Conduct in Research Involving Humans

Forthcoming

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Research involving humans, research ethics, research governance, regulatory ethics, research ethics boards (REBs), knowledge production, participant observation

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Abbreviations

PRE, the Panel – Interagency Advisory Panel on Research Ethics

REB, the Board – Research Ethics Board

RIH – Research Involving Humans

TCPS, the Policy – *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. TCPS-1 and TCPS-2 refer to 1998 and 2010 editions respectively.

Introduction

Understanding the ethical dimension of the regulatory space in research involving humans (RIH) is a necessary prerequisite for examining the processes of centralization, standardization and professionalization in research ethics. In this paper I concentrate on the ethics of the regulators of ethical conduct rather than on the ethics of researchers and research participants engaged in RIH. The ethical dimension in RIH is created by multiple actors who have a broad range of diverse interests and ethical standards, which makes the governance of RIH and its study a complex task. Although our knowledge of the institution of ethics review has significantly increased in recent years thanks to an emerging interest of researchers and regulators,¹ we still know very little about this institution's ethical principles and everyday ethics. The task of this paper is to contribute to an understanding of the ethics of the immediate regulators of ethical conduct in

¹ See especially *IRB: Ethics & Human Research, Journal of Empirical Research on Human Research Ethics, HEC Forum, Qualitative Inquiry*; and specialized issues of *Northwestern University Law Review*, 101(2) (2007), *Health Law Review*, 13(2 & 3) (2005), and 17 (2 & 3) (2009), *The Journal of Law, Medicine & Ethics*, 40(4) (2012), *Law & Society Review*, 41(4) (2007), *PolAR: Political and Legal Anthropology Review*, 30(2) (2007)

RIH – Research Ethics Boards (REBs), their members and administrators, by focusing on the processes of fragmentation and specialization affecting REB membership.

I begin by discussing the challenges of participant observation and covert research as preferred methods in studying the institution of ethics review and its culture. Then I proceed to examining the roles of observers, community, and legal members on research ethics boards, and the contribution of these groups of experts to the institution of ethics review.

In late 1960s REBs consisted for the most part of researchers, and functioned as an additional institutionally-based peer-review mechanism. By the present time, REB membership accommodates several groups of experts and it is subject to a number of regulatory requirements. Now it includes experts in research methodology, ethics, and law, and also community representatives, REB professionals, observers, and researchers whose studies are reviewed. The division of labor is now a part and parcel of the present-day ethics review, but is not known how the demands for a particular expertise influence its institutional culture and the governance of RIH in general. This knowledge is crucial for understanding the processes of (1) *centralization* in the governance of RIH, when a hybrid “new governance”² model gives way to a more centralized approach; and (2) *standardization*, and in particular – the challenges that the expansion of ethics oversight has caused to the social sciences and humanities, where it has become known as “ethics creep,” “methodological colonialism,” and “ethical imperialism”.³

Institution of ethics review as an object of study: An experience of unsolicited “ethics”

A few years ago I was working on a research project at the Department of Philosophy at York University which involved a conceptual analysis of Martin Heidegger’s work and phenomenological interpretation of published autobiographies of psychiatric patients. At that time I learned that my research had to “pass ethics”, to get an approval from an ethics committee that determines if proposed research projects pose more than a minimum risk to human subjects. It was not clear why a whole department, most members of which are engaged in a conceptual and textual analysis, has to apply for ethics approval. But what was most concerning is the attitude of my colleagues and supervisors. The attitude was – “just submit the form”, “don’t think about it”, “promise whatever the REB wants you to do”, “it is just a bureaucratic requirement”... So I submitted the form. Subsequently I found out that my research did not even qualify as research, not meeting the definition provided in the Policy⁴ governing RIH, and hence, it was “exempt” from ethics review. However, it was not up to “researchers” (whom the Policy would not even recognize as researchers) to determine whether their “research” was exempt or not. This was an interesting research situation – I was engaged in an academic activity, which was denied the status of “research”, yet I had to fill out ethics forms indicating that my research

² for a discussion of ethics review from the perspective of “new governance” see S. Burris, "Regulatory innovation in the governance of human subjects research: A cautionary tale and some modest proposals," *Regulation & Governance* 2, no. 1 (2008).

³ Kevin D. Haggerty, "Ethics Creep: Governing Social Science Research in the Name of Ethics," *Qualitative Sociology* 27, no. 4 (2004); Zachary Schrag, *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009* (Johns Hopkins University Press, 2010).

⁴ Canadian Institute of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (1998 (with 2000, 2002, 2005 amendments)), <http://www.pre.ethics.gc.ca>.

did not involve human subjects and to submit them for ethics review, thus participating and promoting a paradoxical ethics review regime.

While the initial experience of dealing with institutionalized ethics review raised multiple ethical questions, I did not try to examine them *systematically*⁵ at that time. I returned to them when developing my LL.M proposal at Osgoode Hall Law School and preparing it for ethics review in 2009. My initial idea for an LL.M. research focused on the governance of unsolicited electronic communication, otherwise known as “junk email”. While preparing the documents for ethics review, I had a *déjà vu*, an experience similar to that of submitting my philosophy proposal three years earlier. This experience of unsolicited ethics raised much of the same questions, which I could now engage with systematically. Accordingly, I refocused my research project on the governance of RIH.

Throughout the past three years I have been involved in the work of the institution of ethics review as an observer and REB member at an interdisciplinary research institute in Toronto. This REB has recently merged with a broader network of REBs, becoming one of this network’s specialized boards. This event was characteristic of the processes of centralization and standardization in the governance of RIH. In addition to being an REB member, I have also had an opportunity to study several other REBs in Toronto, communicate with many REB professionals and researchers, and collaborate on several educational and research initiatives in the research ethics community. One of the notable outcomes of these initiatives included the “Ethics Rupture” Summit⁶ in November 2012 in Fredericton,⁷ *The New Brunswick Declaration* (February 2013),⁸ and the forthcoming volume edited by Will van den Hoonaard, and Ann Hamilton.⁹

Methodology overview: The meaning of “ethics”

For the purposes of this paper, “ethics” is understood in terms of *habitual* practices, i.e. following the etymology of a Greek word “ethos”, i.e. habit, custom or disposition. “Ethos” refers to an action that is done habitually, customarily, and which is expected to occur in the form in which it usually takes place. It is in this sense that an action done habitually is “good” –

⁵ A number of concepts related to research ethics, including “research”, “systematic”, “harm”, “risk”, have been appropriated by the biomedically-centered ethics review, which after the expansion of ethics oversight to the social sciences and humanities serves as a basis for questioning their status as research disciplines. See esp. Haggerty, “Ethics Creep: Governing Social Science Research in the Name of Ethics.”

⁶ Will C. van den Hoonaard, “The “Ethics Rupture” Summit, Fredericton, New Brunswick, Canada, October 25–28, 2012,” *Journal of Empirical Research on Human Research Ethics: An International Journal* 8, no. 1 (2013). The “Ethics Rupture” Summit Website: <http://wp.stu.ca/ethicsrupture/>.

⁷ the follow-up “Ethics Rupture Down Under” will be taking place January 30 – February 1, 2015 at the University of Otago, Dunedin, New Zealand.

⁸ The Declaration is available online at the United Kingdom Social Research Association website, http://the-sra.org.uk/sra_resources/research-ethics/the-new-brunswick-declaration. For background information see Will C van den Hoonaard, “The Social and Policy Contexts of the New Brunswick Declaration on Research Ethics, Integrity, and Governance: A commentary,” *Journal of Empirical Research on Human Research Ethics: An International Journal* 8, no. 2 (2013).

⁹ W.C. van den Hoonaard and Ann Hamilton, eds., *Ethics Rupture* (University of Toronto Press., 2014 (forthcoming)).

it takes place repetitively, again and again, as an inherent constituent of everydayness; it does not stand out in everyday experience; it is a standard practice that maintains the standard. When actions deviate from the established standard, their non-conformity becomes perspicuous, and their ethics is brought to the front. From this perspective, there is nothing intrinsically good or bad about actions themselves. “Ethics” emerges when there is a challenge to the everyday routine. We speak in the same way about things we deal with in everyday situations. A “good” tire supports the car. We rely on it without thinking about it. It remains hidden in the process of driving. A tire is “bad” when it becomes flat, it can no longer iterate continuously and render support to the vehicle. Good and bad, right and wrong generally correspond to the character everyday practices; they characterize regular and irregular practices from the viewpoint of everydayness.¹⁰

Studying the “ethics” of ethics review

In studying the ethics of ethics review, it is important to pay attention to similar kinds of interruptions in the otherwise routinely reproduced practices. Such interruptions can be caused artificially through the interventions of social scientists, as it is done in ethnomethodology and dramaturgy.¹¹ When a regular process is disrupted, the standard – “good” or “ethical” practice – emerges as a phenomenon accessible to close investigation. However, similar interruptions may and often do occur spontaneously without any planned interventions, when novices and outsiders, who may not be entirely familiar with standard, “good” practices, introduce spontaneous alterations or modifications in the regular process. In such situations, the standard practice is usually quickly re-established as soon as the novice learns the way things are done (and thus should be done) on a regular basis, as part of the everyday routine. This process may be facilitated by establishing and maintaining a process that allows for a quicker integration of new REB members and personnel through orientations, trainings, workshops, peer support and mentorship programmes, team- and community-building initiatives.

The study of REB ethics considers the procedural components of ethics review, such as REB meetings, but goes further to include a broad spectrum of conceptual phenomena that influence and define ethics review, such as local modes of thinking and communicating. Additionally, as in any dynamic environment, one has to consider both positive and negative practices/standards, i.e. when something *is* and *is not* done. For example, a “positive” practice would be adhering to a paper-based process of ethics review, when researchers submit a dozen or so copies of their research project for board review. A “negative” practice in this example would be an absence of an electronic system of research data management, when such a system is a standard practice in other similar situations.

Participant Observation of REBs and its challenges

¹⁰ In this approach to everyday practices I rely on Heidegger’s phenomenology. Martin Heidegger, *Being and Time* (Harper, 1962). See also Maurice Merleau-Ponty, *Phenomenology of Perception* (Routledge, 2002).

¹¹ Harold Garfinkel, *Studies in Ethnomethodology* (Prentice-Hall Inc., 1967).
; Erving Goffman, *Behavior in public places: Notes on the social organization of gatherings* (The Free Press, 1963).
; Augusto Boal, *Theatre of the oppressed*: (Urizen Books, 1979).

Policy research in the governance of RIH, which relies on participant observation of REBs as one of its methods, poses an ethical dilemma for REBs.¹² First of all, it exposes an underlying conflict of interest, since REBs have to review a study the goal of which is to critically interrogate its own ethical standards. Secondly, participant observation is a deeply problematic method for REBs. It contradicts their approach to risk management, which is based on a specific understanding of research, the context for which is provided by ethical challenges in biomedical disciplines. Hence the TCPS speaks of vulnerable “human subjects”, expresses concerns with free and informed consent, privacy and confidentiality, dignity, justice and inclusiveness, and sets the tasks to minimize harm and maximize benefit. These are the “guiding ethical principles” of the TCPS-1.¹³ Meanwhile participant observation is a research method that is generally informed, developed, and applied within a context that poses different ethical challenges. Accordingly, participant observation can be seen as insufficiently objective, lacking in systematic character, and purposefully contaminating research data through researcher’s participation. Hence, it can be perceived by REBs as methodologically weak and “risky”. Indeed, participant observation does not fit the standard biomedical understanding of research, when researchers and research subjects are two distinct categories, with the former enjoying more power and opportunities to abuse it. In participant observation the distinction between researchers and researched is blurred. Research participants (who are not necessarily reducible to individual humans, e.g. organizations or institutions) are often more powerful. Besides, it may be meaningless to create a “protocol” for participant observation, since the method is designed to be flexible and responsive, interactive and adaptive.

Insiders and Outsiders

The insider/outsider distinction has always been important in the social sciences. There are at least two reasons for this. *First*, the status of an insider presumably gives access to some concealed information, which is not accessible for interview or other pooling techniques and non-participatory observation. In other words, an insider-researcher is an expert who may be otherwise interested in non-disclosing internal information to outsiders. Expert knowledge has its own challenges as scientific data. Expert knowledge is not easily verifiable, if verifiable at all – it is often unique, contextual and irreducible to a set of indicators. *Second*, being an insider may be considered a factor that negatively affects the objectivity of research. Although interpretative disciplines question the Cartesian distinction between subject and object, emphasizing the

¹² Although the ethnography of ethics review is a relatively new field, there have been already a few notable contributions that complement multiple reports of researchers’ experiences with ethics review in the journals discussing ethical issues in research involving humans. See especially, Charles L. Bosk, “The New Bureaucracies of Virtue or When Form Fails to Follow Function,” *PoLAR: Political and Legal Anthropology Review* 30, no. 2 (2007); R. Lederman, “The perils of working at home: IRB “mission creep” as context and content for an ethnography of disciplinary knowledges,” *American Ethnologist* 33, no. 4 (2006); R. Lederman, “The ethical is political,” *American Ethnologist* 33, no. 4 (2006); M. Tolich and M. H. Fitzgerald, “If ethics committees were designed for ethnography,” *Journal of Empirical Research on Human Research Ethics* 1, no. 2 (2006); Laura Stark, “Morality in Science: How Research Is Evaluated in the Age of Human Subjects Regulation.” (Ph.D. Dissertation, Department of Sociology, Princeton University, 2006); L. Stark, *Behind closed doors: IRBs and the making of ethical research* (The University of Chicago Press, 2012).

; W.C. Van Den Hoonaard, *The seduction of ethics: transforming the social sciences* (University of Toronto Press, 2011).

¹³ pp. i5-i6.

impossibility of stepping outside of the studied phenomenon, and proposing instead other strategies for doing good science from within, a number of social science techniques take data-contamination seriously, trying to limit/control for the impact of the researcher. This concern is not without merit for interpretative sciences, since it presents a possibility for the second order knowledge about the studied phenomenon through awareness of one's own contribution.

One of the main objectives of my study was to get a better understanding of the institutional culture of REBs. Interviews, surveys, or focus groups with researchers, REB administrators, chairs and members, may all facilitate the study of the institution of ethics review. However, given the criticisms¹⁴ of REB oversight, which include secrecy, lack of transparency in decision-making, censorship, risk aversion, conflict of interest, among others, there was a possibility for a disconnect between what REB members and researchers do and what they say they do. Participant observation enables researchers to experience ethics review first-hand in various settings – not only through participation in REB meetings, but also in educational and social events for REB professionals and researchers. Importantly, participant observation does not preclude from using other methods of collecting information. On the contrary, it facilitates them, in particular, informal free interview. Participant observation is a research method that provides multiple opportunities to engage in various conversations that directly and indirectly relate to the review process. Such opportunities are not planned and arise spontaneously before and after REB meetings, in formal and informal settings beyond the review process, such as casual conversations on the subway or conference breaks.

Participant observation also presents an opportunity for covert research. In fact, two methods overlap, but are different from the viewpoint of ethics review, since covert research remains largely unregulated. According to the Secretariat on Responsible Conduct of Research, covert research is exempt as long as it is consistent with other principles outlined above.¹⁵ Therefore, in a situation when a research project based on participant observation encounters difficulties in getting REB approval, covert research may be a good substitute. This example illustrates how ethics review affects research ethics in the social sciences and how social researchers resist REB ethics. It also reflects my situation with passing ethics review for this project.

I had to resubmit my ethics application two times to get an approval for this study. My initial proposal was based on participant observation in studying the ethics review process, but I had to modify it to proceed with my study.

Ethics approval can take a considerable amount of time, which is a scarce resource for a doctoral researcher. Furthermore, for a graduate student ethics review involves an extra step – a review by the members of the supervisory committee. After which the ethics application is submitted to the graduate program to be reviewed and signed by the graduate program director and then forwarded to the REB for its review. In my case it took four months to receive a response letter

¹⁴ A good overview in Carol A. Heimer and JuLeigh Petty, "Bureaucratic Ethics: IRBs and the Legal Regulation of Human Subjects Research," *Annual Review of Law and Social Science* 6, no. 1 (2010).

¹⁵ Susan Zimmerman's (Executive Director, Secretariat on Responsible Conduct of Research) contribution to the "Great debate: *Be it resolved that the Tri-Council Policy Statement is a good standard for which to review research in the social sciences and humanities*" at the CAREB 2013 National Conference and Annual General Meeting in Calgary, April 25-27.

from the REB after submitting my ethics application to the graduate program. After that I was able to communicate with the REB directly, and it took only three days to get a response to the modified proposal, which also contained a request for more changes, and the final third version of the proposed research project received an approval within three days as well. Contrary to the initial proposal which I used as an opportunity to probe how REBs review studies based on oral consent, my third proposal was designed to be approved and it was.

Requesting modifications is how REBs say “no” to the project, since REBs rarely reject proposed studies. In my case the REB was not satisfied with my justification for the use of oral consent and insisted on getting written consent from everyone present at REB meetings, which would make my research impossible for a number of reasons, and was superfluous as I discuss further. The memo I received from my REB stated:

“The committee has reviewed your protocol and found that the rationale you have provided to obtain verbal consent from the participants is insufficient. Verbal Informed Consent is only to be used in ‘in extenuating circumstances where written communication is not feasible’. The committee kindly asks that you provide a written consent form for the participants and researcher to sign and date.”¹⁶

It is important to notice that the REB quoted a local institutional policy, which is more restrictive than the TCPS itself, and is a reflection of the TCPS-1 position that local boards can set even “higher” ethical standards.

Becoming an insider: Observers on the REB

Studying REB ethics by observing the work of this institution is facilitated by the fact that many REBs have a process regarding observers who fulfill a number of important functions: (a) observers form a pool of potential candidates for REBs, and (b) in some institutions, observer is a required step for becoming an REB member. In the latter case a candidate has to attend two or more REB meetings as an observer.

There are various motives for becoming an observer and learning the ethics review process first-hand – educational, research, exchange of best practices, employment and others. For example, the observer experience can be useful if one pursues a research ethics career, such as that of a bioethicist, REB coordinator or administrator. Regardless of the reasons that engage people in observing the ethics review process, REBs have their own motives for bringing observers on the Board. One of them is a continuous search for qualified members. Since REBs rely on volunteers, they develop strategies to ensure they have enough REB members to meet the regulatory requirements regarding the quorum and composition of the Board and ensure a seamless process of ethics review. This applies to both recruiting new and retaining current members. Ensuring that the Board continuously meets the TCPS quorum and expertise requirements is the main reason for opening up REB meetings to observers. Meanwhile the openness of ethics review is instrumental in many other ways, such as informing the public about this institution, and thus contributing to its legitimacy as an institution that protects research participants and promotes public safety.

¹⁶ On file with the author.

To illustrate, the TCPS-2 identifies two types of ethics review – *delegated review* for minimal risk studies and *full board review* for studies posing greater than minimal risk. Depending on the amount of reviewed projects, and the ratio of delegated reviews to full board reviews, REBs may be interested in maintaining a broader membership. Full board reviews should satisfy the quorum and expertise requirements. A broader membership allows for more flexibility since REBs do not have to rely on the presence of few unique experts. If the number of members exceeds the TCPS minimum, then REBs can reduce the quantity of reviews a member is assigned to do over a period of time. It is important for REBs that members are motivated in continuing their service on the Board. A moderate amount of work, i.e. an amount that would not outweigh the benefits provided by REB membership, contributes to a low turnover rate of REB members. The benefits of REB membership vary from individual to individual and from REB to REB, and generally include: advanced access to cutting edge scholarship and research, networking, professional development, or credited as administrative duties. Low turnover rate may also help to reduce administrative costs for REBs and ensure institutional memory related to the review process. However, if the mobility is low and the process of ethics review is not open for observation, then researchers may perceive their REB as being “privatized” by a small group of people. This gives rise to such widespread criticisms and generalizations of the REB as a lack of transparency in decision-making, secrecy, hostility and attempts to rationalize REB members as unsuccessful researchers, or those who enjoy power. Admitting observers to REB meetings helps to transform existing and emerging stereotypes, and ease tensions between researchers and reviewers.

Becoming an Observer

Gaining access to REB meetings as an observer is a fairly simple process, but this statement does not apply to participant observers – ethnographers of ethics review. Nevertheless I did not encounter any difficulties, thought I did not aim at studying any particular REB, but began where an opportunity presented itself. Access to other REBs was greatly facilitated by the snowball technique, inter-REB networks and facilitated by the fact that ethics review relies on qualified volunteers and therefore welcomes observers to REB deliberations.

While attending a Regional Workshop for Ontario on the Second Edition of the Tri-Council Policy Statement conducted by the Panel on Research Ethics in March 30-31, 2011, I met one of the regional organizers of the Workshop, an REB administrator. I introduced my research project and explained my interest in learning more about the governance of RIH in Canada. I encountered the same person again at the talk “The Problem with REBs” by Giles Scofield at the Joint Centre for Bioethics, University of Toronto on April 6, 2011. Two days later I received a message, inquiring if I am interested in learning more about my interlocutor’s REB, to which I replied positively and scheduled a visit for May 12, 2011. At the meeting we were joined by another REB officer from the same institution. During an hour-long casual conversation about research ethics I inquired about a possibility to attend an REB meeting as an observer and was invited to join the upcoming monthly meeting in May 2011.

This evidence can be interpreted as an indicator of openness of the REB as a social institution; as well as its integration in existing research ethics networks. Although I should stress that my characteristics as a potential observer – such as being a graduate law student interested in

research governance – could have contributed to a positive disposition of REB professionals, since law is a sought after expertise on the REB. Inviting me to the meeting was in a way a screening of my qualifications, collegiality and interest in joining the REB. However, in van den Hoonard's study some REBs were reluctant to open their meetings for observation.¹⁷ But again, the status of van den Hoonard in the research ethics community, such as being a founding member of the PRE and the Chair of the Social Sciences Working Group on Ethics in 2003-5, could have played its role.

Conditions of observing: Confidentiality agreements and informed consent forms

Since observers are an important part of the REB process, some REBs have a standard (two-page in my case) confidentiality agreement applicable to both REB members and observers. REB members and observers (potential or future REB members) are treated equally with respect to accessing REB materials – agendas, research projects, expert opinions and other internal information. Confidentiality agreements center on the non-disclosure of REB confidential property, including submissions to the REB and the confidential details of the ethics approval process. Given that ethics review involves a substantial amount of confidential information, it is not surprising that the confidentiality agreement is fairly restrictive. The researcher who is studying the institution of ethics review by observing REB meetings is limited by the confidentiality agreement with the REB. Meanwhile the researcher's relationships with REB members and personnel are also regulated by the researcher's home REB, if it prescribes to seek written or other forms of consent for participation, as it probably will. This situation gives rise to a number of issues regarding consent and the status of observer/ethnographer of ethics review (vs. observer/community person, or observer/scientist/future member).

On the one hand, the existence of a standard confidentiality agreement may render the free and informed consent requirement superfluous for researchers who study the institution of ethics review. Indeed, the whole idea of admitting observers to REB meetings is to let them observe – they are present at the meetings for the purpose of observing the process of ethics review, regardless of the purposes of their observation. Observers are usually identified and introduced by the Chair and their status is noted in the minutes. Accordingly, other present members are well informed about the presence of observers, know that they are subject to observation, and they are aware that their presence is regulated by the confidentiality agreement, which stipulates the limits and conditions of observation. Since the status of observer is not limited to specific categories of the population, there are no reasons to think that researchers are excluded. Hence, those who study the institution of ethics review can also be observers.

However, the TCPS generally requires free, informed, and standing/revocable consent from all research participants, including participants in observational research beyond publicly accessible situations, and involves a reasonable expectation of privacy. Thus the requirement of free, informed, and standing consent implies that (a) participants are informed about research objectives and the risks involved, (b) they are not pressured to participate in research and are able to opt out from taking part in it at any point, including retroactively. Importantly, the Policy requires that free and informed consent is given individually by everyone involved in the research. Neither REB chair, nor REB administrator, or anyone else from the Research Office

¹⁷ Van Den Hoonard, *The seduction of ethics: transforming the social sciences*.

can decide on behalf of every individual participant. Accordingly, the confidentiality agreement can hardly be a substitute for the TCPS-(generally)-required and REB-(typically)-enforced consent form.

It should be noted about the free and informed consent requirement that it was introduced in the TCPS-1 to address ethical concerns in biomedical research, and although they may be not at home in critical policy research, the TCPS-2 sets them as a standard for all RIH. Since researchers routinely study situations, access to which is regulated by confidentiality agreements, the situation with observing the work of REBs is just one example where a set of issues related to privacy, confidential information, intangible property is regulated through the instruments of consent for participation in research and confidentiality agreements. These instruments can overlap, conflict, and influence each other in a number of ways. One instrument can be more restrictive than the other. Both types of instruments are contracts that seek to regulate researcher's conduct. Consent forms set limits to researchers' conduct in relation to individual participants, whereas confidentiality agreements in relation to organizations, which may also protect REB members' interests as REBs understands them.

Observers as community members

The presence of observers at REB meetings, or general *accessibility* of REB meetings can serve as an indicator of how well the institution of ethics review reflects such principles of administrative law and "good governance," as openness, accountability, participation, and others. Administrative principles, i.e. a particular set of them, are subject to interpretation and political priorities. They often include in various combinations the principles of legality, legitimacy, effectiveness, efficiency, economy, consistency (coherence), due process, rationality, proportionality, fairness (impartiality, and more generally, justice), and others.¹⁸ In a broader research project it would be important to interrogate how these principles of "good governance" are implemented in RIH. In this regard "accessibility" to REB meetings can be understood as one of the principles of "good governance," as well as a condition of possibility for the principle of participation.

Observers are important for the institution of ethics review in a number of ways – they may act as external auditors and experts. They may provide feedback, and contribute an external perspective at its operations. Furthermore, observers can be understood as representatives of the public. In this sense observers are close to community representatives, whose presence on the REB is required by the TCPS, but who may not be fully enabled to contribute in a meaningful way to REB meetings and more broadly in the governance of RIH, due to the ambiguities of their status as either representatives of the public or experts. The same limitations apply to observers. Accordingly, the accessibility and openness of REBs may not necessarily translate into greater legitimacy, accountability, or democracy of the institution of ethics review. Nevertheless, observers and community representatives do contribute to these processes, even if they are not able to do so effectively.

¹⁸ See e.g. Carol Harlow for a discussion of an (im)possible list of global governance principles: Carol Harlow, "Global Administrative Law: The Quest for Principles and Values," *European Journal of International Law* 17, no. 1 (2006).

Policy profile of community members

The TCPS-2 defines “community members” and their “primary role” on REBs in the following way:

“The community member shall not be affiliated with the institution. The community member requirement (Article 6.4[d]) is essential to help broaden the perspective and value base of the REB, and thus advances dialogue with, and accountability to, relevant communities. In addition to a broad-based representation from the community, it is highly desirable that institutions seek to appoint former participants on REBs. Their experience as participants provides the REB with a vital perspective and an important contribution to the research ethics review process. ... Their primary role is to reflect the perspective of the participant. This is particularly important when participants are vulnerable and/or risks to participants are high.”

In other words, the TCPS-2 has significant expectations in relation to the role of community members in the governance of RIH. It is expected that community members will be independent, thus contributing to the independence of the REB, as an autonomous institution responsible for ethics review within research institutions. Community members are also expected to represent a broad spectrum of community interests and act as a link between the research community and the community in which research is conducted. Moreover, community members are expected to have an experience of research participants.

These characteristics are thought to contribute to an impartial and multifaceted ethics review and the legitimacy of RIH. From the institutional and REB perspectives – the task of community members is to make researchers/institutions/REBs accountable for their work, since community members are understood as reflecting community interests and serving as a link with the community. From the viewpoint of ethics review, they contribute their unique expertise – that of research participants.

Community members as experts: What community?

Undoubtedly, it is challenging for community members to play the role assigned to them by the TCPS. Other experts on the REB may not be willing to recognize community members’ expertise – neither as research participants nor community members.¹⁹ “Non-community” REB members may dismiss the expertise of community members as not unique and inessential. Some of “non-community” members may be coming from the same geographic community. Furthermore, the concept of community is not limited to geographic localities. Depending on research context, territorial community may be secondary, if important at all. Researchers engage with various kinds of communities and collectivities, such as “internet community” or “lifestyle

¹⁹ Stark expresses a similar concern: “This ambiguity over the meaning of *community* is inherent in the role of “community members” on the board. All IRB members could interject their opinions and warrants for the views through their claims to knowledge about participants by thinking of their friends, family members, students, neighbours, colleagues, and acquaintances.” Stark, *Behind closed doors: IRBs and the making of ethical research*: 15.

community,” when “community” refers to an “imagined community”²⁰ to use Benedict Anderson’s term or even simply to a category of the population, where social ties are loose or speculative and interests are plural and antagonistic. The TCPS does not explicitly clarify how “community” is to be understood; hence this task is left to individual REBs. Nevertheless, the TCPS emphasizes the value of research participant’s experience, and accordingly REBs may also interpret this as an indication that the community in question is a “community” of research participants. To represent such communities is a challenge in itself and requires answering a number of questions regarding which interests to represent and how to best represent them. This may pose a political problem given the multiplicity of interests and limited available resources.

Who do REB-appointed community representatives represent?

In addition to the questions regarding *community*, the status of community representatives as *representatives* of a given community is no less acute. Community representatives are neither delegated by the community to represent its interests, nor are they acting as trustees in any sense. Given the diversity of communities, it is hard to see how community representatives can legitimately represent them. It does not help that community members are appointed by REBs themselves – and in this sense they can effectively represent the REB community only. It is important to note that other terms used to articulate the same idea of non-institutional REB members – “lay members” and “non-scientist members” – run into similar problems.

The expertise of community members as research participants is also not unquestionable. Research participant’s experience is not necessarily generalizable or relevant to the reviewed studies. *Firstly*, it is hard to speak of some universal experience of research participants that community members as former research participants can contribute to the process of ethics review. Even the stereotypical “guinea pig” experience of research participants is not universal. For example, for some research participants being a guinea pig is a career choice and thus their understanding of risks and benefits can differ drastically.²¹ Which interests should the community representative stand after in this case? *Secondly*, it is probably the case that most non-community members have participated in research studies as research participants. Hence, they should be able to represent the participants’ perspective no less effectively than community members. “Non-community” members who are active researchers are also research participants in the broader sense of research participants that includes everyone involved in research, although the TCPS does not see it this way.

Accordingly, community members, despite (a) their designation that emphasizes community ties and (b) TCPS-2 recommendations to recruit from former research participants, may experience a deficit of social and expert capital. Both non-community members on the REB and members of the studied communities may be reluctant to accept community members’ credentials as community representatives. It can be argued that their expertise as community members and research participants is inherently limited, private and only marginally valuable to ethics review. Community representatives’ experience as research participants is hardly generalizable for

²⁰ Benedict Anderson, "Imagined communities: Reflections on the growth and spread of nationalism," (New York and London: Verso. Reprinted, 1991).

²¹ Roberto Abadie, *The Professional Guinea Pig: Big Pharma and the Risky World of Human Subjects* (Duke University Press, 2010).

various proposed research initiatives. To the degree in which it may be generalizable, it is likely to be covered by other REB members. It is hard to expect that community representatives will be able to represent a significantly relevant spectrum of communities. Moreover, the communities which community members are able to represent may be irrelevant and even antagonistic to the reviewed study designs and their research contexts. Community representatives are neither delegated, nor reporting back to “their” communities, which are unaware that they have a representative on the REB. Due to these reasons it is difficult to expect that community representatives will be able to carry out the functions envisioned by the TCPS successfully.

Can a wider community representation make a difference?

Due to inherent problems with community representation as such, REB personnel and other members may rationalize the presence of community members on REBs merely as a regulatory requirement, without expecting from them any substantial contribution, and consequently, not encouraging and even suppressing their participation. It is probably the case that community REB members themselves also realize the paucity of necessary social capital and refrain from active participation in REB deliberations. In the literature discussing community/lay/non-scientist members on REBs, it is common to hear proposals to increase the number of community representatives in order to empower them, to create a support group. However, taking into account the above-mentioned problems with their social status as representatives of communities and research participants, it is hard to avoid a skepticism that an increase in number will translate into a better ethics review, or lead to an improvement in the governance of RIH. If the above-mentioned problems with community representation are not addressed then it would be more realistic to expect more of the same.

Community presence on the PRE

In the beginning of 2012 the Secretariat on Responsible Conduct of Research (the Secretariat) issued a “Targeted Call for Nominations for Panel²² Members”, indicating that “[c]andidates should have experience in research ethics as a research participant, and/or a community/lay member of a research ethics board.”²³ Accordingly, the Secretariat was looking for a PRE member that would have an REB experience in the capacity of a community member, in addition to research participant’s experience. Candidates had to be nominated²⁴ by their respective REBs. In the framework of my research this was an opportunity to learn more about the governance body that develops the policy in RIH. My application, submitted April 25, 2012, pursued two objectives: *First*, to learn more about the structure and composition of the Interagency Advisory Panel on Research Ethics, and the specific roles of the Secretariat and the PRE in the governance of RIH. *Second*, to get a better understanding of how PRE manages tensions in setting common standards for ethics oversight in RIH; in particular how it negotiates the differences between the biomedical model of ethics review, adopted as a common standard, and the plurality of ethico-methodological approaches in the social sciences. My task here was to probe if the Secretariat

²² Interagency Advisory Panel on Research Ethics (PRE).

²³ *Targeted Call for Nominations for Panel Members: Panel on Research Ethics*. Available at <http://www.pre.ethics.gc.ca/eng/resources-ressources/news-nouvelles/nr-cp/2012-04-04/>.

²⁴ *Nomination form* is available at [http://www.pre.ethics.gc.ca/archives/participation/docs/Nomination%20Form%20\(EN\).pdf](http://www.pre.ethics.gc.ca/archives/participation/docs/Nomination%20Form%20(EN).pdf)

was interested in diversifying the spectrum of research participants' perspectives and learning from non-biomedical research participants.

As indicated in the *Terms of Reference*, the PRE is composed of 12 members, all of whom are volunteers “in addition to the Executive Director of the Secretariat, who is an ex officio member (without voting rights). Observers may also be invited to participate in the meetings.”²⁵ In light of the discussion above, it is important to highlight that the *Terms of Reference* specifically mention that PRE is open to observers. The criteria for membership are rather complex, given the limited number of PRE members.

In addition to geographical and gender representation, PRE membership provides:

- a balanced representation of researchers in biomedical and health sciences, social sciences and humanities, and those in the natural science and engineering fields undertaking research involving humans;
- expertise or experience in ethics, law, REB operations and research administration at an institutional level;
- representation from the Aboriginal community and research participants.²⁶

The geographical requirement is rather weak since it is not specific and there is no reference to Canada's political (or any other) geography. Gender and other representation criteria are not designated in terms of numbers or ratios. This allows for a more flexible approach to PRE membership. Given the Tri-council nature of the PRE, there must be members representing all three branches of RIH – health and social sciences, and engineering, in addition to representing technical expertise in ethics, law, and research governance at an institutional level. Final set of criteria requires representation from the Aboriginal community and research participants. The three groupings in the *Terms of Reference* generally cover three perspectives – that of (1) researchers conducting RIH, (2) technical experts and research administrators, and (3) researched communities, with a special place given to the Aboriginal community. Together with the geographical and gender perspectives, (4) and (5) respectively, this constitutes the five basic requirements to PRE membership.

Following the adoption of “human participants” in place of “human subjects” in the TCPS-2, it was necessary to find out whether this terminological change reflected an attempt to better integrate social science perspectives on the governance of RIH. Previously, the normative human subject was a research subject in biomedical research. The TCPS-1 extrapolated this vision to all RIH, including the social sciences and humanities. The experience of research participants in these disciplines was seen as hardly different from biomedical research and thus not requiring separate representation. This is reflected in the composition of the PRE as it did not have a representative who would voice a social science perspective.²⁷ My application featured a nonbiomedical perspective, thus providing an alternative to an expected/standard nominee for the position of a community/lay PRE member. In light of the multiple criteria for PRE membership,

²⁵ *Panel on Research Ethics: Terms of Reference*. Available at <http://www.ethics.gc.ca/eng/panel-group/tor-cdr/>.

²⁶ *ibid.*

²⁷ See past and current PRE Members profiles at: <http://www.pre.ethics.gc.ca/eng/panel-group/about-apropos/members-membres/>

there could be multiple reasons for preferring one nominee over another. While my nomination was not supported by the Councils,²⁸ it is important to indicate that the newly appointed community PRE member once again represents the experiential field of biomedical research. Accordingly, in this respect the social sciences remain unrepresented. This can be seen as a further testimony that the adoption of the concept of human participants in the TCPS-2 was done without challenging the normativity of the biomedical human subject.²⁹

REB-Ls (“rebels”): Lawyers on the REB

There are multiple motives in becoming an REB member – some are interested in learning more about research ethics as part of their academic or professional career; others join their institutional REBs after attending a session at which their research project is discussed; still others may want to make a genuine contribution to institutional research culture and ethics, to share their vision and expertise. Some research institutions ask faculties and departments to delegate representatives. It is also not uncommon for REB members to “migrate” from one board to another, especially if a member has a sought-after expertise, such as in privacy law. When there is an ongoing centralization and professionalization in research ethics governance, as well as the emergence of external and commercial REBs, there may be other incentives and motives for taking part in the review process, including financial remuneration. Similar to peer-review in academic journals, REB membership provides advanced access to cutting-edge scholarship and can be a good way to stay on top of the ongoing and innovative research, in addition to learning local review ethics and using this knowledge to facilitate the review of proposed projects.

After two months as an observer, in September 2011, I continued as an REB member, since REB membership offered even broader opportunities for learning about ethics review and the processes of fragmentation/specialization in REB membership, centralization and standardization. I was appointed as a member knowledgeable in the law, commonly referred to as “legal member”. A decisive factor for me was that this particular REB was a prominent player in the governance of RIH, negotiating and navigating these processes. Moreover, this REB generally reviewed only one or two studies during full board meetings, with other studies reviewed through a delegated process. A small number of studies allowed not only for an in-depth discussion of study designs and a variety of emerging and pressing issues in research ethics, but also gave an opportunity for researchers themselves to introduce their studies and address any question of the Board.

Thirty years ago REBs were largely homogenous in terms of their composition. At that time REB review was essentially an additional layer of peer review. But from the very start there began a differentiation in the roles of REB members. At first – a lay/non-scientist/public/community member requirement was added; then a gender requirement was introduced. After that, with the rise of bioethics, bioethicists were included; and with the growing sophistication of the normative framework – legal members. This process is still ongoing. For example, a number of REBs in Toronto include an additional member who

²⁸ Letter on file with the author.

²⁹ Igor Gontcharov, "The Eclipse of 'Human Subjects' and the Rise of 'Human Participants' in Research Involving Humans," in *Ethics Rupture*, ed. Will C. van Den Hoonaard and Ann Hamilton (University of Toronto Press, 2014 (forthcoming)).

specializes in privacy law, although there is no corresponding requirement in the TCPS. Nevertheless, REBs find it necessary to have an expert in this area. Market pressures and high cost of multicenter studies, demands for consistency in ethics review among various REBs, as well as the questions of mutual trust and recognition of the results of ethics review of other Boards have led to the development of certification³⁰ and qualification³¹ programs. Accordingly, REB professionals will further diversify the spectrum of expert knowledge. Although REB professionals – administrators and coordinators – are not voting REB members, their contribution in terms of ethics review and Board discussions is often decisive. While the division of labour is necessitated by the changes in the regulatory and research environment, the process of specialization has another dimension – fragmentation of REB membership. From a peer review ethics review has evolved into a multi-expert review, which changes the dynamics of ethics review since there emerge different expectations in respect to various experts on the Board. The question that was central for me is how fragmentation affects institutional culture? What is the contribution of each expert group into research ethics?

I will give one ethnographic example here. TCPS requires that the Board should include “at least one member knowledgeable in the relevant law (but that member should not be the institution’s legal counsel or risk manager). This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research.”³² These members are usually called “REB lawyers”. In 2012 I had an opportunity to be on the working committee and attend an educational event for a group of REB lawyers working in Toronto.³³ There were thirty “REB lawyers” present. The event was important in terms of thinking about the roles and expectations of different REB members, experts in ethics, research methodology, law, and community, and representing both genders. (Speaking to the last point – on my REB about 80% of members are women, which may highlight a certain gender dynamics of ethics review in interdisciplinary health research, but also raises concerns about the reasons for such an imbalance.)

REB-Lawyers call themselves “REB-Ls” – “rebels”! This designation has probably emerged with the founding of *The Research Ethics Board Legal Society* (REB-LS)³⁴. The abbreviation is a truly performative one, to use John Austin’s expression.³⁵ Thus it was voiced a few times during the event that REB-Ls offer a distinct voice, rebel against other members’ views. Nevertheless, no one of those expressing this view attempted to elaborate what the rebellion is about, which would help to understand the role of REB-Ls in ethics review and their disposition to other members. It is important to notice that according to the TCPS, there should be no “rebels” on the REB at all. The Policy speaks of members “knowledgeable-in-law”, M-KiLs, to

³⁰ Canadian Association of Research Ethics Boards has a Professional Development Committee that is “working on an initiative to develop a Canadian certification program for REB professionals” <https://www.careb-accr.org/content/professional-development>.

³¹ Clinical Trials Ontario is currently working on implementing the Ontario Qualification Program that will also introduce a Delegated Board of Record model. See “Report: Working Group on Research Ethics Board Streamlining,” (Clinical Trials Ontario, 2013). Available at <http://www.ctontario.ca/wp-content/uploads/2013/04/Full-Report-Working-Group-on-REB-Streamlining-April-2013.pdf>

³² TCPS2, Article 6.4(c).

³³ “An educational workshop for TAHSN REB lawyers: Problems and solutions in Canadian research ethics oversight: Interpreting the Tri-Council Policy Statement (TCPS-2).” March 26, 2012. Toronto.

³⁴ See REB-LS webpage at <http://rebels.pbworks.com/w/page/9110752/FrontPage>

³⁵ J. L. Austin, *How to do things with words* (Clarendon Press, 1962).

use Suzan Zimmerman's term³⁶ that carries similar rebellious undertones. In reality almost all legal members are lawyers – this is supported by the fact that there was only one non-lawyer in attendance at the event for “REB lawyers”.

What are the consequences of having REB-Ls instead of M-KiLs for the governance of RIH? They are significant. For example, lawyers may shift the emphasis from the risk of harm to *human participants* to the issues of institutional liability; from consent as a process to consent forms; from human interaction to contractual obligations; from general normative and ethical questions to legalistic ways of risk management; litigation maybe favoured over negotiation, mediation and arbitration, as a way of dispute resolution; expanded guidelines favoured over local interpretations and principle-based decision-making. These consequences are reflected in REBs' insistence on the use (as well as in the content and size) of the consent forms that are structured as multi-page disclaimers. For example, the second edition of the TCPS has doubled in size. Meanwhile REBs are losing their interpretative authority with PRE assuming a more active role in this process.³⁷ These phenomena highlight the kind of rebellion that REB lawyers represent, their role in the ethics review process. For a participant observer of REB ethics, rebellious practices, and self-identification as rebels are important in clarifying the obvious that remains hidden in everyday life – institutional ethics of ethics review. In this sense REB lawyers as rebels or otherwise, as well as other groups of experts, challenge the norm thus making it perspicuous to the researcher.

Conclusion

The study of the roles of observers, community, and legal members is important for understanding the processes transforming ethics review as an institution that seeks to transcend peer-review. It helps to understand how various groups of experts contribute to its accountability, legitimacy, and normativity. This study is a step to understanding the ethos of REBs and its contribution to the ethical dimension in RIH. Contrary to how REBs approach “ethics” in their everyday practice, the ethical dimension in RIH extends beyond the interactions between researchers and human participants. It includes the very institution of ethics review and covers interrelations between researchers and REBs.

Since its emergence in biomedical and behavioral government-sponsored research in late 60s the institution of ethics review experienced difficulties in identifying and defining its mission vis-à-vis other peer-review mechanisms, a mission that would be also reflective of a continuously broadening scope. The initial task of REBs was to manage risks in specific research situations when human subjects had a limited ability to give free and informed consent, e.g. army personnel, psychiatric patients, and prisoners. When a common policy in RIH was adopted in 1998 it was based on the biomedical understanding of research and was speaking to ethical

³⁶ Zimmerman, Susan. Keynote Address: Problems and Solutions in Canadian Research Ethics Oversight: Interpreting the Tri-Council Policy Statement (TCPS 2). “An educational workshop for TAHSN REB lawyers: Problems and solutions in Canadian research ethics oversight: Interpreting the Tri-Council Policy Statement (TCPS-2).” March 26, 2012. Toronto.

³⁷ See a new section on the interpretation of the TCPS-2 on the PRE website at <http://www.pre.ethics.gc.ca/eng/policy-politique/interpretations/Default/>

challenges in this field of knowledge. By late 90s ethics review expanded to the social sciences and humanities, and started to cover all research, including self-funded and unfunded and all categories of the population. However, the approach to risk management implemented in the institution of ethics review had not undergone any significant changes – neither in the practices of ethics review, nor in the composition of the panel of experts. While REBs now accommodate a broader range of expertise – including such areas as community, privacy, and health law – these experts generally contribute to the biomedical perspective at research ethics – prospective ethics review as the model of ethical governance in RIH. It is not surprising then that social scientists characterize the process of expansion in terms of “ethics creep”, “ethical imperialism”, and “methodological colonialism” that are reflective of the tensions between social scientists and REBs in understanding research ethics.

Although on the surface the TCPS subscribes to “methodological pluralism”, it gives preference to a one-size-fits-all approach. Therefore the processes of specialization and professionalization happening in ethics review further marginalize the social sciences and humanities with their approaches to research ethics, while continuing to inscribe them in the biomedical model of prospective ethics review, which fuels the homogenization and pauperization³⁸ of the social sciences. It has taken a while to recognize that there must be an expert in the relevant methodology while reviewing social science research, but the effect of this innovation has been limited in promoting a methodologically pluralist approach to ethical governance in RIH. One of the reasons is the impact of non-scientific REB members, such as community and legal experts, who continue to promote the biomedical perspective. The institution of ethics review *prima facie* transcends the limits of peer-review by bringing on board observers, community, and legal members, yet in practice these experts are not particularly helpful in promoting either disciplinary pluralism, or a non-scientific viewpoint.

³⁸ Van Den Hoonaard, *The seduction of ethics: transforming the social sciences*.