

MANDATED ETHICS: REGULATORY INNOVATION AND ITS LIMITS IN THE
GOVERNANCE OF RESEARCH INVOLVING HUMANS

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Abstract

Harmonization of risk policy in research involving humans, following the adoption of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) in 1998, which extended the biomedical model of research ethics review to the social sciences and humanities, constitutes the focus of this portfolio dissertation. The articles in the portfolio examine the challenges that prospective ethics review poses to those research disciplines, the methods and ethics of which may differ from, or even be antagonistic to the biomedical model.

The regulatory space of research involving humans is a highly dynamic field, and a place of significant tensions caused by the challenging political economy of the globalizing – postcolonial and postindustrial – world, progress in biomedical technologies, interdisciplinary structure of science, corporate interests, and the changing character of risks. These factors continuously influence the institution of research ethics review, supporting such processes as centralization and professionalization that are very prominent in the governance of research involving humans. Responding to the needs of research ethics committees, biomedical disciplines, and market pressures, these processes continue to constrain the reflexive and pluralistic elements of the policy framework, thus impoverishing the ethico-methodological foundation of the social sciences and humanities.

This portfolio dissertation includes five articles that (1) provide an overview of the key elements of the *Tri-Council Policy Statement*'s ethical and regulatory framework, as well as the institution of prospective ethics review; (2) critically examine the processes of standardization, centralization, professionalization in research ethics review as impacting the initiatives at regulatory innovation, and (3) contribute in the development of the alternative models of ethical governance in research involving humans.

Keywords

research involving humans, research ethics, research governance, regulatory ethics, research ethics boards (REBs), *Tri-Council Policy Statement*, knowledge production

Acknowledgements

“Black box” is a popular metaphor for research ethics boards in publications examining the phenomenon of bureaucratic mission creep. This metaphor highlights the fact that the process of research ethics review is generally not transparent for researchers who submit their project for ethics review. Does it also mean that it is challenging for researchers of ethics review to study this institution? Possibly, however, in my research project I have not encountered any significant obstacles in gaining access inside the “black box” beyond the ethics review stage.

Chapter Four: Observers, Community, and Legal Members on REBs argues that some research ethics committees might be interested in opening up their meetings for observers since it is one of the ways for them to attract new members, thus ensuring that the minimum requirements regarding membership and expertise are met or exceeded. By increasing the number of members it is also possible to decrease the workload. This may further contribute to establishing a rewarding environment in which REB members are motivated to stay on ethics committees, since membership may offer an advanced knowledge of research initiatives, keep committee members up-to-date with current regulatory requirements and scholarship, inform them about funding opportunities, and facilitate research ethics review of their own projects.

Regardless of the reasons, this paradoxical openness of REBs generally reflects my experience of engaging with this institution, which may not be generalizable, given the heterogeneity and idiosyncratic character of research ethics committees.

REB Chairs and Administrators, who I have had an opportunity to work with, take pride in their work, investing constantly in creating a hospitable environment, conducive to rigorous ethics and scientific review, by inviting researchers to introduce their projects, ensuring broad range of expertise, encouraging participation of all members, organizing educational and social events, and acknowledging the contribution of REB members and observers.

On a personal level – my interaction and collaboration with REB professionals and members was a truly enjoyable and rewarding experience. I wish to extend my gratitude to all REB professionals and members for welcoming me into their space and sharing their knowledge, observations and concerns about various aspects of ethics review in formal and informal settings, and inviting me to share my views and report back on the conferences and professional events that I attended in the past five years.

During the course of this study, I have had many opportunities to present my research project and discuss various aspects of research governance at a number of academic events. I have received rich feedback and benefitted tremendously from

the criticism, suggestions, and observations offered by their participants. These events included:

Ethics in Practice: Tensions Around Ethics Review and Maori Consultation. University of Otago, NZ, May 22-24, 2015.

Association of Transnational Law Schools (ATLAS) Agora, Melbourne, June 13-27, 2014, Singapore, June 16-25, 2013, Bilbao, June 20-30, 2011.

Works in Progress (WiP!) Workshop Series, Osgoode Hall Law School (OHLS), February 10, 2014.

Conflicts and Contradictions: A Forum on Studying Power as Embodied Research(ers) York University, November 7, 2012).

Ethics Rupture: An Invitational Summit about Alternatives to Research-Ethics Review, Fredericton, October 25-28, 2012.

81st Congress of the Humanities and Social Sciences: Crossroads: Scholarship for an Uncertain World, Waterloo, May 27-29, 2012.

Emerging Scholars Workshop, Critical Research Laboratory in Law & Society, OHLS, May 9, 2012.

2012 Osgoode Forum: Legal Practice and Legal Theory Discourse – Critical Views of Education and Research, Toronto, May 25-26, 2012.

8th Cornell Law School Inter-University Graduate Conference: Changing Faces in Legal Thinking: Revisiting Legal Methodologies, Ithaca, April 13-14, 2012.

The Fifth Annual Conference of the Toronto Group for the Study of International, Transnational, and Comparative Law: Contests in Security and Risk: Releasing the Legal Imagination, Toronto, January 27-28, 2012.

2011 Osgoode Forum: No Boundaries: Transnational Law and a New Order of Global Governance, Toronto, May 9-10, 2011.

The Fourth Annual Toronto Group Conference for the Study of International, Transnational and Comparative Law: Praxis of Resistance: Communities of Inclusion and Exclusion, Toronto, January 28-29, 2011.

Osgoode Hall Graduate Law Students' Association Conference: Beyond Law: At the Edges of Law's Ambit, Toronto, May 20-21, 2010.

Excellent academic, administrative and financial support, available to graduate researchers at Osgoode Hall Law School, was crucial for the completion of this project in a timely fashion. In addition to the *Graduate Seminar*, several thematic study groups, and cutting edge courses, offered by the *Graduate and Osgoode Professional Development Programs*, as well as the intensive courses by leading international scholars through the *Genest Global Faculty Program*, the *ATLAS (Association of Transnational Law Schools) Agora Program* was an excellent platform for sharing works-in-progress and discussing methodological issues and learning

from fellow graduate researchers and faculty members of the participating law schools. I had a pleasure of and benefitted greatly from attending three of the *Agoras* with its exceptional doctoral workshops, methodology sessions, and transnational courses at *Deusto University* in Bilbao, *National University of Singapore*, and *University of Melbourne*, where I received detailed feedback to my written work from Jola Gjuzi, Jean-Sébastien Sauvé, and Vivian Mak, respectively.

The original scope of my research was broader than the articles in this portfolio aim to cover, since it also included some aspects of the governance of biomedical research involving humans. Given the transnational character of biomedical research, the project required a robust international and transnational approach that would be capable of navigating complex human rights regimes and illuminating the processes of standard setting in research involving humans on a global scale. Therefore, the theme and expertise of the *ATLAS Agora* were thus important to a broader conceived project. Although this research material is not included in this portfolio, I plan to include it in subsequent publications on the institution of ethics review.

I am also grateful to the *Graduate Program in Law* for allowing me to take an academic leave in the very beginning of this project. In the 2010-2011 academic year, I was a Research Fellow at the *School of Law at Columbia University* in New York City, where I concentrated on the issues of globalization and governance, international law, and socio-political philosophy. It was an exceptional environment

for examining the problematic of human rights in research involving humans, and I am particularly thankful to my international colleagues, Christophe Germann and Koji Teraya for multiple occasions to discuss the topics at the intersection of international law and knowledge production.

While being a Research Fellow I had also a pleasure of participating in the world-famous *Colloquium in Legal, Political and Social Philosophy*, convened by Professors Ronald Dworkin and Thomas Nagel, and the *Hauser Colloquium on Globalization and Its Discontents*, convened by Professors Ryan Goodman and Robert Keohane, at the New York University School of Law.

In 2011-2014, I was a Fellow at the *Critical Research Laboratory in Law & Society* (CRL) at Osgoode Hall Law School. The CRL, directed by Peer Zumbansen, provided an outstanding collaborative environment and hosted a number of academic and research initiatives, of which I have to highlight the monthly *Toronto Circle Reading Group*, which complemented the Department's Graduate Study Groups, allowing for an in-depth discussion of the landmark contributions in regulation and governance in an informal setting. Together with Sujith Xavier and Shanthi Senthe, CRL Fellows, I convened the *Challenging Conventions!* International Speaker Series,¹ the *Emerging*

¹ The *Challenging Conventions!* Speaker Series webpage:
<http://criticalresearchlab.org/crl/project/challenging-conventions-speaker-series-ccss>

Scholars Workshop,² and a conference on critical legal studies: *Re-Igniting Critical Race: A Symposium on Contemporary Accounts of Racialization in Canada*,³ which celebrated the work of Patricia Williams and created a forum for alternative narratives of law and governance, an approach which I used in the current study of the institution of ethics review and the dominant narratives of researchers and participants, which are produced and maintained by the regulators of ethical conduct in research involving humans.

The governance of educational research is a significant part of my project and I am thankful to many of my fellow graduate researchers and professors who informally shared their narratives of “passing ethics” and dealing with actual ethical challenges emerging in research and those that arise as a result of research ethics requirements. In this regard, the following events were equally important: in 2012 I had a pleasure of participating in the *Global Legal Education Forum* at Harvard University and was a panellist on the *Global Legal Education Roundtable* at the 2012 *Osgoode Forum*, in addition to contributing to a graduate student-led discussion group *Legal Teaching and Learning Methodologies for the 21 century* at Osgoode Hall Law School.

² The Emerging Scholars Workshop webpage: <http://criticalresearchlab.org/crl/project/ESW>

³ *Re-Igniting Critical Race: A symposium on Contemporary Accounts of Racialization in Canada*. Program and Details: <http://criticalresearchlab.org/critical-race-symposium>

I am very grateful to my PhD dissertation committee – Susan Drummond, Joan Gilmour, and my supervisor Liora Salter – for always being a source of inspiration, continuing guidance and encouragement. A number of faculty members at Osgoode, as well as other departments of York University, have also shared their perspectives at this project, and I would like to thank Daniel Priel, one of the original members of my PhD dissertation committee, and Faisal Bhabha, for commenting on my written work.

This acknowledgement would not be complete without the words of love and gratitude to my spouse and children for all their patience and support, and sharing the joys and challenges of this journey.

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List of Abbreviations

CIHR – Canadian Institutes of Health Research

The Councils – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC)

IRB – Institutional Review Board

NSERC – Natural Sciences and Engineering Research Council of Canada

PRE – Interagency Advisory Panel on Research Ethics

REB – Research Ethics Board

RIH – Research Involving Humans

SSH – Social Sciences and Humanities

SSHRC – Social Sciences and Humanities Research Council

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

Introduction

RESEARCH QUESTION

This dissertation includes five articles that focus on the governance of research involving humans in the social sciences and humanities in Canada, and specifically on role of the institution of prospective ethics review. The discussion is guided by conceptual, regulatory and ethico-methodological questions and is informed by the author's research of and participatory experience in the processes of ethical governance in research involving humans. These questions inquire about the context, institutions and policy actors in the regulatory space of research involving humans. The task of this inquiry is to make explicit the modes of thinking and ethics of the regulators by examining the processes of standard setting in research involving humans.

A continuing thread that unites all articles is a question why a decentralized, "new governance" model of the first *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 1, 1998) engendered the processes of centralization, specialization, and professionalization in the governance of research involving humans? These processes emerged and proceeded contrary to the expectations of "new governance" scholars that institutional *research ethics boards*

(REBs) can function effectively and responsively in a decentralized mode, benefitting from a limited principle-based normative framework, and building on the institutionally available expertise, resources and proximity to the sites of research.

The dissertation speaks to a wide audience – from ethics professionals, regulators, and ethnographers of ethics review, to everyone who is involved in the production of new knowledge within and beyond academic institutions – in the field of community-based and independent research. Accordingly, the questions raised in this dissertation will be familiar to most researchers. They range from applied to critical. From “What is ethics review? How is it done, where, and by whom? Does my research need to pass ethics?” To “Who are these people reviewing my research? Who appointed and authorized them? Who monitors their work? What ethics do they review? What is the ethics of the reviewers themselves? Why do ethics committees have the power to reject and delay research projects? Who are they really trying to protect? Why do ethics committees use the criteria that are irrelevant to my research field and methodology?”

Although Canada’s approach to research governance constitutes this work’s primary focus, it is impossible to isolate it from a broader international and transnational dimension, since research and research governance are subject to multiple parallel

and overlapping domestic and international approaches and ethics regimes that continuously influence each other. Global markets, international and global actors, advancements in information and communication technologies, global flows of information and standards, emergent research methods and broadening public participation continuously change and challenge the way research is conducted. This aspect of the dissertation is highlighted by examining a number of aspects of research governance in the United States and New Zealand, which facilitates the discussion of regulatory and ethics transplants across these jurisdictions and globally.

This dissertation contributes to an understanding of prospective ethics review as an institution that is central to the governance of research involving humans by critically examining the ongoing changes within its conceptual framework, such as an adoption of “human participants” instead of “human research subjects”. More broadly, the articles in the portfolio address normative, methodological, and applied aspects of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* in its transition from the first (1998) to the second (2010) edition by discussing significant challenges that emerged when the biomedical regulatory framework expanded to the social sciences and humanities.

Among the challenges, captured in the rich phenomenology corresponding the expansion, which is itself described in politically-laden terms of “ethics creep”,⁴ “ethical imperialism”,⁵ and “methodological colonialism”,⁶ are the tensions and gaps corresponding the standardization and unification in approaches to research governance in various disciplines, and emerging between various policy actors and institutions, such as academic associations and existing mechanisms of peer-review.

For example, in the governance of research ethics, academic associations play an increasingly limited role, since many functions of professional governance have been claimed by the institution of prospective ethics review, which introduces hierarchies and power imbalances, such as elevating research ethics boards over researchers and participants, and their initiatives at self-governance, and thus changing and challenging research and regulatory landscape.

⁴ Kevin D. Haggerty, "Ethics Creep: Governing Social Science Research in the Name of Ethics," *Qualitative Sociology* 27, no. 4 (2004); C.K Gunsalus, "The Illinois White Paper - Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep"," in *Law and Economics Research Paper #LE06-016* (The Center for Advanced Study, University of Illinois, 2005). Martyn Hammersley, "Creeping Ethical Regulation and the Strangling of Research," *Sociological Research Online* 15, no. 4 (2010); Ronald F. White, "Institutional Review Board Mission Creep: The Common Rule, Social Science, and the Nanny State," *The Independent Review* XI, no. 4 (2007).

⁵ Zachary Schrag, *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009* (Johns Hopkins University Press, 2010).

⁶ Will C van den Hoonaard, *The seduction of ethics: transforming the social sciences* (University of Toronto Press, 2011).

The institution of prospective ethics review by research ethics boards has itself become a source of risk to researchers and participants, meanwhile policymakers and REB professions still lack the capacity to critically engage in self-reflexive analysis of its contribution to the governance of research involving humans.

The articles in this portfolio engage with and build on the phenomenology corresponding standardization in research involving humans, seeking to identify why the elements of “responsive regulation”⁷ in the first *Tri-Council Policy Statement* remained dormant.

MAJOR CONTRIBUTIONS TO SCHOLARSHIP ON ETHICS REVIEW AND THE PLACE OF THIS STUDY

The articles in this portfolio dissertation contribute to the ongoing conversation on the approaches to regulatory innovation in research involving humans, by articulating the constraints of the current regulatory framework, and by discussing emerging issues and alternatives to prospective ethics review as a central mechanism of ethical governance in research involving humans in the social sciences and humanities.

⁷ Ian Ayres and John Braithwaite, *Responsive regulation : transcending the deregulation debate* (Oxford University Press, 1992), <http://www.loc.gov/catdir/enhancements/fy0605/91017131-d.html>.

Governance of research involving humans is a dynamic field with hundreds of contributions over the past fifteen years, which examine various aspects of ethics review from a wide range of social disciplines, methodologies and perspectives. Several conferences and symposia resulted in special issues of academic journals, including the “Symposium: Censorship and Institutional Review Boards” of *the Northwestern University Law Review*.⁸ This issue included a landmark article “Getting Permission” by Philip Hamburger, which questions the constitutionality of ethics review of academic research by institutional review boards in the United States context. The core of his argument is this:

Institutional Review Boards are the instruments of a system of licensing—a system under which scholars, students, and other researchers must get permission to do research on human subjects. Although the system was established as a means of regulating research, it regulates research by licensing speech and the press. It is, in fact, so sweeping a system of licensing speech and the press that it is reminiscent of the seventeenth century, when Galileo Galilei had to submit to licensing and John Milton protested against it.⁹

⁸ "Symposium: Censorship and Institutional Review Boards," *Northwestern University Law Review* 101, no. 2 (2007).

⁹ Philip Hamburger, "Getting Permission," *Northwestern University Law Review* 101, no. 2 (2007).

Indeed, research ethics boards generally interfere with researchers' words by licensing what researchers can ask, document, disclose, and publish thus "censor[ing] the entire range of observation, inquiry, recording, talking, writing, and publishing protected by the First Amendment, and far from making a single outrageous assault on this Amendment, IRBs modify or censor well over 100,000 research proposals every year in the United States and stifle countless others that get abandoned or never get started."¹⁰

This dissertation (and *Chapter One: A New Wave of Positivism in the Social Sciences* specifically) deals with various aspects of methodological censorship. Methodological censorship issues from the conceptual framework of the *Tri-Council Policy Statement* that is tailored to a particular way of understanding and conducting research, thus forcing researchers to engage in self-censorship – abandoning or never even starting research projects on methodological grounds, or giving preference to the methods that are "sanctioned" by research ethics boards. The phenomenon of methodological pauperisation is documented by Will van Den Hooonaards in the *Seduction of Ethics*¹¹ which I discuss in detail in *Chapter Three: Methodological Crisis in the Social Sciences*.

¹⁰ Ibid.

¹¹ van den Hooonaard, *The seduction of ethics: transforming the social sciences*.

Another “Symposium: The New Bureaucracies of Virtue” appeared in *PoLAR: Political and Legal Anthropology Review* in 2007. This specialized issue is important in at least two respects: (1) methodological – in terms of thinking about the ethnography of ethics review, and (2) administrative – rasing questions about research ethics regulation in a bureaucratic setting. Three articles in this issue are particularly relevant to this dissertation: the “Introduction” by Marie Andrée Jacob and Annelise Riles,¹² Charles Bosk’s “The New Bureaucracies of Virtue or When Form Fails to Follow Function”¹³ and Rena Lederman’s “Comparative “Research”: A Modest Proposal concerning the Object of Ethics Regulation.”¹⁴

Charles Bosk’s idea of the divide between form and function in research ethics review is also well introduced by Marie Andrée Jacob and Annelise Riles in their description of modern practical ethics:

Once a soft humanitarian twist to professional, commercial, or academic ventures, relegated to the margins of knowledge, practical ethics—from business ethics to military ethics—is an increasingly mainstream, high-profile, well-funded, and bureaucratically complex discipline. What it has

¹² Annelise Riles Marie Andrée Jacob, "The New Bureaucracies of Virtue: Introduction," *PoLAR: Political and Legal Anthropology Review* 30, no. 2 (2007).

¹³ 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).

¹⁴ Lederman Rena, "Comparative "Research": A Modest Proposal concerning the Object of Ethics Regulation," *PoLAR: Political and Legal Anthropology Review* 30, no. 2 (2007).

kept from its early years is its catchy wording and a self-assured sense that it is engaged in making things better.¹⁵

What emerges in the process of bureaucratization of research ethics is a new definition of ethics, which is often far removed from the idea of actual ethical challenges arising in ethnographic work, as well as academic knowledge production in general. The antagonistic understandings of ethics are the source of “ethics rupture”,¹⁶ of growing tensions between *ethics on the books* and *ethics in action*, REB ethics and ethics of the studied situations, the conceptual and regulatory bases of which I examine in this dissertation.

Indeed, “[o]ne of the interesting features of modern ethics is that it must continually be demonstrated – it must be bureaucratically evidenced, revealed, documented, enacted, performed.”¹⁷ This is why the *new research ethics* is less and less about what happens in the field – it is now more about relations between research ethics boards and researchers. It is not sufficient to be ethical in the field, it is also necessary to appear ethical – by engaging in conspicuous ethical consumption of consent forms and supporting discourses, by adhering to the norms of procedural

¹⁵ Marie Andrée Jacob, "The New Bureaucracies of Virtue: Introduction."

¹⁶ Will C Van den Hoonaard and Ann Hamilton, eds., *Ethics Rupture: Exploring Alternatives to Formal Research-Ethics Review* (University of Toronto Press, 2016).

¹⁷ Marie Andrée Jacob, "The New Bureaucracies of Virtue: Introduction."

ethics, and demonstrating enthusiasm about certification and and “best practices” workshops offered by the research ethics professionals.

Rena Lederman has made a significant contribution in ethnography of ethics review. Her article in the *Symposium: New Bureaucracies of Virtue* issue of PoLAR: Political and Legal Anthropology Review criticises federal regulations for “presum[ing] an idealized scientific method with predetermined spaces, times, personnel, and procedures.”¹⁸ She argues, that “[a]lthough such clarity is difficult for many kinds of human subjects research, it is impossible for ethnographic fieldwork.”¹⁹ I develop this argument further in *Chapter One: A New Wave of Positivism in the Social Sciences*, which explains how a positivist understanding of research inhibits alternative modalities of knowledge production and regulatory initiatives in the governance of research involving humans.

It is equally important to also acknowledge the blogs that provide a timely overview of regulatory initiatives and critical scholarship on research ethics committees. Zachary Schrag’s *Institutional Review Blog*,²⁰ Simon N. Whitney’s *Suffocated Science*,

¹⁸ Rena, "Comparative "Research": A Modest Proposal concerning the Object of Ethics Regulation."

¹⁹ Ibid.

²⁰ Zachary Schrag's *Institutional Review Blog*, <http://www.institutionalreviewblog.com>

currently known as *Science, Scholarship, and the Challenge of Ethics Review*,²¹ and the Canadian Association of Research Ethics Boards (CAREB) listserv and LinkedIn group²² were among the most relevant sources of up-to-date information on REB ethics.

Ethnography of ethics review is a relatively new field with less than a dozen of monograph-size publications, only three of which focus predominantly on the Canadian experience with prospective ethics review of social science research: *Walking the Tightrope: Ethical Issues for Qualitative Researchers* (2002), edited by Will van den Hoonaard, who subsequently published a monograph *The Seduction of Ethics: Transforming the Social Sciences* (2011). The third publication, edited by Will van den Hoonaard and Ann Hamilton *Ethics Rupture: Exploring Alternatives to Formal Research-Ethics Review* was released in 2016.²³ I contributed Chapter 13, entitled *The Eclipse of "Human Subjects" and the Rise of "Human Participants" in Research Involving Humans* to this volume, which is a collection of works presented at the *Ethics Rupture: Alternatives to Research Ethics Review* Summit in 2012. Another legacy of this Summit is the *New Brunswick Declaration: A Declaration on*

²¹ Simon N. Whitney's *Suffocated Science*, currently known as *Science, Scholarship, and the Challenge of Ethics Review*, <http://suffocatedscience.com>.

²² Canadian Association of Research Ethics Boards (CAREB) LinkedIn Group, <https://www.linkedin.com/groups/4320630>; CAREB Listserv, <https://www.careb-accer.org/contact>

²³ Van den Hoonaard and Hamilton, *Ethics Rupture: Exploring Alternatives to Formal Research-Ethics Review*.

Research Ethics, Integrity and Governance (2013).²⁴ This declaration has a special status in the governance of research involving humans as an articulation of ethical principles from the bottom up – by researchers themselves – in a situation when research involving humans experienced a growing gap between formal research ethics review and actual ethical challenges in research practice.

These three publications represent the three stages in the evolution of social researchers' perspectives at the biomedical approach to the governance of research involving humans in the social sciences and humanities. If *Walking the Tightrope* was searching for a way to introduce and represent the ethical dimension of social research within the *Tri-Council Policy Statement*,²⁵ then the *Seduction of Ethics* becomes increasing skeptical that the voice of social researchers will ever be heard by the regulators. This skepticism is an outcome of documenting (1) the ongoing methodological pauperization of the social sciences, and (2) privatization of the research ethics infrastructure by positivist researchers.²⁶ Accordingly, the perspective changes radically – what is now required is an urgent methodological decolonization rather than further collaboration in developing a common policy.

The *Ethics Rupture: Exploring Alternatives to Formal Research-Ethics Review*

²⁴ The New Brunswick Declaration on Research Ethics is available online at <http://www.sfu.ca/~palys/NewBrunswickDeclaration-Feb2013.pdf>

²⁵ W van den Hoonaard, ed. *Walking the tightrope: Ethical issues for qualitative researchers* (Toronto: University of Toronto Press, 2002).

²⁶ van den Hoonaard, *The seduction of ethics: transforming the social sciences*.

proceeds to a discussion of practical solutions to methodological decolonization, including *The New Brunswick Declaration on Research Ethics*, a statement of alternative ethical principles by social researchers themselves, which questions the top-down approach to ethics regulation and the moral authority of the Research Councils to govern research involving humans responsively.²⁷

In the United States, the total number of similar publications is not much greater than in Canada, and two of the books are only several months old, which also indicates a growing interest in research ethics review by institutional review boards (IRBs). These books include Zachary Schrag's *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009* (published in 2010). "Ethical imperialism" is a conceptual device for understanding the expansion of the biomedical model of ethics review which has been successful in marginalizing the social sciences from any meaningful participation in the governance of social science and humanities research, thus effectively colonizing their ethical dimension. In *Chapter Five: Alternative Models of Ethical Governance in Research Involving Humans*, I examine whether the perspective of research participants at the level of the *Interagency Advisory Panel on Research Ethics* and individual *research ethics boards*

²⁷ Van den Hoonaard and Hamilton, *Ethics Rupture: Exploring Alternatives to Formal Research-Ethics Review*.

covers the interests and experiences of research participants in the social sciences and humanities.

Laura Stark's *Behind Closed Doors: IRBs and the Making of Ethical Research* (2012), as well as her doctoral dissertation *Morality in Science: How Research Is Evaluated in the Age of Human Subjects Regulation* (2006), are the only book-size publications that are based on an ethnographic study of Institutional Review Boards (IRBs). Her work explores the concept of moral regulation in science and its institutionalization in the form of institutional review boards, as well as the role of this institution in further renegotiation of the moral limits of science. She argues that "the IRB system was a solution to the contradictions and problems created by the new, munificent state-sponsorship of research in the human sciences during this period. The design of IRBs, the virtue of which is often taken for granted today, should be seen as an outgrowth of the particular organization and shifting power dynamics of the National Institutes of Health, and its parent organization, the Department of Health, Education and Welfare, in the mid-twentieth century."²⁸ This design has been used a basis for research ethics regulation in most English-speaking countries throughout the world. It is in this sense that I refer to the IRB system as an ethics and regulatory

²⁸ 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).

transplant in the governance of research involving humans throughout this dissertation.

Laura Stark's work shows how "sound decisions about human subjects came to be represented in the characteristics of decision-makers rather than in the actual substance of decisions."²⁹ This approach has been institutionalized in the form of multi-expert panels engaged in prospective ethics review, and has become the source of key issues related to the inconsistency of ethical decision-making by institutional review boards that are guided by procedural norms rather than adhere to any particular principle-based ethics code. In Canada and globally, the idiosyncratic character of research ethics committees has been one of the key factors determining the development of ethics regulation in the direction of centralization, professionalization, and specialization, the processes that I discuss in *Chapter Five: Alternative Models of Ethical Governance in Research Involving Humans*.

In the subsequent section on standard setting I introduce another doctoral dissertation by Ann Hamilton's *Institutional Review Boards: Politics, Power, Purpose and Process in a Regulatory Organization* (2002). Despite being completed 14 years ago, it remains one of the most current contributions on the subject of ethics review, approaching it from a number of complementary theoretical perspectives.

²⁹ Ibid.

Carl E. Schneider's *The Censor's Hand: The Misregulation of Human-Subjects Research* (2015) and Robert Klitzman's *The Ethics Police? The Struggle to Make Human Research Safe* (2015) are the most recent contributions examining the systems of ethics review in the United States. Robert Klitzman's *The Ethics Police* provides an excellent profile of the institution of research ethics review from within the biomedical field. It is an interview-based study that documents the ethos and language of IRB professionals. Although this is not central to the study, *The Ethics Police* also questions the suitability of a one-size-fits-all approach in the governance of research involving humans.

Carl E. Schneider's approach and the one presented in this dissertation have a lot in common – from the conceptual questions of research and its risks, to operational/procedural cost and effectiveness, to understanding the IRB system in regulatory terms, and examining its impact on academic freedom.

Carl E. Schneider refers to the driving force behind the expansion of ethics review as “regulationism”, suggesting that regulationists “know little about risks but treat them as dangerous” and “instead of evidence and argument, [] use “justification by

scandal””.³⁰ This parallels my discussion of the *Tri-Council Policy Statement’s* operational conceptual framework in terms of a “medieval” coupling of danger/hope rather than “modern” risk/trust, while the “justification by scandal” is a way of advancing certain approaches to governance on a moral panic wave.

Carl E. Schneider is equally critical of the broad jurisdiction and slight constraints of the IRB systems, and uses the same concept of “IRB ethical imperialism” that gave title to Zachary Schrag’s work. The author of *The Censor’s Hand* describes this phenomenon in the following way:

[The IRB system] has colonized new lands and occupied them in battalions. A system born primarily to keep government from conducting another Tuskegee irrepressibly finds more research to regulate, more duties to enforce, and harsher standards to impose.³¹

Importantly, Carl E. Schneider discusses the limits of regulatory innovation that are caused by what he calls “Big Ethics – the strategically situated people who and institutions that believe in and benefit from the IRB system.” The proposed solution is twofold – allow disciplinary self-regulation and continue examining the role of the

³⁰ Carl E. Schneider, *The Censor’s Hand: The Misregulation of Human-Subject Research* (The MIT Press, 2015).

³¹ Ibid.

IRB system in knowledge production, thus eventually making it obvious for everyone involved that it is a poor instrument of ethical governance in research involving humans. Carl E. Schneider uses an example of blood-letting, the medical standing of which was reduced to zero with the increase in our general understanding of health and various methods of treatment.³²

In addition to the works originating from Canada and the United States, Martin Tolich and Barry Smith's *The Politicisation of Ethics Review in New Zealand* (2015) is part of the same conversation on the ethics of ethics review and regulatory innovation in the governance of research involving humans.

Indeed, many researchers, whose works have been cited above, participated in the *Ethics Rupture Invitational Summit about Alternatives to Research-Ethics Review* in Fredericton in 2012, Canada³³ and the *Ethics in Practice: Tensions around Ethics Review and Maori Consultation* Conference in Dunedin in 2015, New Zealand³⁴ and contributed to the New Brunswick Declaration on Research Ethics.

³² Ibid.

³³ The program and podcast of the presentations and discussions have been archived at <http://web.archive.org/web/20130507065940/http://wp.stu.ca/ethicsrupture/>

³⁴ The program is available at: <http://www.otago.ac.nz/ethicsreviewproject/conference/index.html>

A number of other researchers have also made a significant contribution to this field of knowledge, thus influencing the understanding and analysis of the institution of ethics review in this dissertation. In particular, Kevin Haggerty, Ted Palys,³⁵ Mark Israel,³⁶ and John Mueller's³⁷ works were helpful in terms of thinking about bureaucratic mission creep in research ethics review, as well as its impact on various disciplines, such as criminology, and critical assessment of "best practices" in research ethics. Rena Lederman,³⁸ Robert Dingwall,³⁹ and Martyn Hammersley's⁴⁰ work provided a methodological reference point for the ethnography of ethics review in other jurisdictions; Scott Burris made an important observation regarding the underlying regulatory design of the institutions of ethics review, which were on paper congruent with new governance approaches, but functioned otherwise.⁴¹

³⁵ Thematically organized articles on various aspects of ethical governance by Ted Palys are available at <http://www.sfu.ca/~palys/articles.htm>

³⁶ Mark Israel, *Ethics and the governance of criminological research in Australia* (NSW Bureau of Crime Statistics and Research, 2004).

³⁷ John H Mueller, "Best Practices: What Perspective, What Evidence?," *Journal of Social Distress and the Homeless* 15, no. 1 (2006); John H Mueller, "Ignorance is Neither Bliss Nor Ethical," *Northwestern University Law Review* 101, no. 2 (2007).

³⁸ 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); Rena, "Comparative "Research": A Modest Proposal concerning the Object of Ethics Regulation."

³⁹ R. Dingwall, "The ethical case against ethical regulation in humanities and social science research," *Twenty-First Century Society* 3, no. 1 (2008).

⁴⁰ Martyn Hammersley, "Against the ethicists: on the evils of ethical regulation," *International Journal of Social Research Methodology* 12, no. 3 (2009); Hammersley, "Creeping Ethical Regulation and the Strangling of Research."

⁴¹ S. Burris, "Regulatory innovation in the governance of human subjects research: A cautionary tale and some modest proposals," *Regulation & Governance* 2, no. 1 (2008).

Multiple works on the governance of health research have been equally valuable to this project, even if less referenced in the articles in this portfolio due to its focus on the social sciences and humanities. Michael McDonald, Trudo Lemmens, Susan Cox, Raphael Saginur, Jocelyn Downie and a number of other health law, ethics and governance scholars contributed to understanding the processes in the governance of health research involving humans.⁴² Their scholarship is especially relevant to this dissertation when it addresses such issues as qualitative health research, critical public health research, market and political pressures in research involving humans, conflict of interest, ghost writing, and professional governance, to name a few.

Understanding the driving force(s) behind the expansion of prospective ethics review is important in mapping the regulatory landscape in research involving humans. If this question is posed in terms of interest groups, then there is no singular interest group responsible for the introduction, development and

⁴² Michael McDonald, *The Governance of Health Research Involving Human Subjects (HRIHS)* (Law Commission of Canada, 2000).

; Jocelyn Downie and Fiona McDonald, "Revisioning the Oversight of Research Involving Humans in Canada," *Health Law Journal* 12(2004); Michael McDonald, "Canadian governance of health research involving human subjects: is anybody minding the store?," *Health Law Journal* 9(2001); Brenda Beagan and Michael McDonald, "Evidence-based practice of research ethics review?," *Health Law Review*, 2005 Spring-Fall 2005; Michael McDonald, "Special Issue: Canadian Governance for Ethical Research Involving Humans, Introduction," *Health Law Review* 13, no. 2 & 3 (2005); Michael McDonald, "From Code to Policy Statement: Creating Canadian Policy for Ethical Research Involving Humans," *Health Law Review* 17, no. 2 & 3 (2009); Michael McDonald and Susan Cox, "Moving Toward Evidence-Based Human Participant Protection," *Journal of Academic Ethics* 7, no. 1 (2009); S. M. Cox and M. McDonald, "Ethics is for human subjects too: Participant perspectives on responsibility in health research," *Social Science & Medicine* 98(2013).

proliferation of the ethics review model. The deployment of the new standard took place on a moral panic wave,⁴³ when policymakers received the mandate to implement an additional layer of protection, building on existing elements of peer review, yet aspiring to transcend them through the elements of public audit via community participation in the processes of ethics review. Nevertheless, the origins of this particular model were rather circumstantial, being “an outgrowth of the particular organization and shifting power dynamics of the National Institutes of Health.”⁴⁴

Although ethics oversight was originally designed for biomedical and behavioral state-sponsored research, it rapidly entered the stage of “ethical imperialism”,⁴⁵ colonizing the social sciences and humanities, and extending its influence beyond academic institutions. At this stage, research ethics boards began to play a more active role in facilitating the transition from a compact principle-based regulatory model to a more expansive rule-based regulatory approach. Nevertheless, these processes were enabled by the Policy’s contradictory set of ethical principles, which translated into a particular design of ethics oversight on the basis of prospective ethics review.

⁴³ W van den Hoonaard, "Is research ethics review a moral panic?", *Canadian Review of Sociology and Anthropology*, no. 38 (2001).

⁴⁴ Stark, "Morality in Science: How Research Is Evaluated in the Age of Human Subjects Regulation.."

⁴⁵ Schrag, *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009*.

As I indicate in *Chapter One: A New Wave of Positivism in the Social Sciences*, the divide is not between biomedical and social researchers, since both of them use research methods consistent with positivist and non-positivist understanding of research. Mixed-method, experimental and critical methodologies also have their protagonists and practitioners in both fields of research, and thus no attempt is made to identify biomedical researchers and/or their sponsors as a sole driving force behind the ethics review model.

Indeed, the regulatory and funding structure of academic research is for the most part attuned to the positivist paradigm of knowledge production. In this sense, it is helpful to think about “ethics creep” in terms of paradigms rather than interest groups.

Nevertheless, particular groups of experts are becoming more and more prominent in advancing the ethics review agenda without necessarily subscribing to any particular scientific paradigm. They are the core of what Carl E. Schneider calls “Big Ethics” or those who believe in and benefit from research ethics oversight. In a similar vein, Will van den Hoonaard addressed the participants of a special panel about ethics review of social science research at the Canadian Association of Research Ethics Boards Conference in Calgary as “believers” in the one-size-fits-all

model, which I discuss in *Chapter Five: Alternative Models of Ethical Governance*. It is necessary to emphasize that the system of beliefs is supported by the regulatory design that is generally indifferent to a critical evaluation of its actual contribution in research ethics.

RESEARCH METHODOLOGY

The scope of the articles in this portfolio consists in the conceptual analysis of the institution of prospective ethics review as it was undergoing a substantial revision from the first, 1998, *Tri-Council Policy Statement*, to the second edition, adopted in 2010. It was important to understand how policymakers, as well as other groups of stakeholders, approach and address the tensions around research ethics review in the social science and humanities, which resulted in “ethics rupture” between the policy in research involving humans, or *mandated ethics*, and *ethics in actual research practice*. While the focus of the included articles falls on the governance of academic research, the impact of ethics review extends to other areas of knowledge production, such as independent and community-based research. Therefore, it is important to examine how the institution of prospective ethics review affects the ethical dimension of research outside of the academic community. This research constitutes an important next step in understanding the limits of regulatory innovation in research involving humans. Similarly, a deeper analysis is necessary in relation to a number of other key concepts and issues, including “vulnerability”,

“risk” and “trust”, group and individual consent, which I could only touch upon in the included articles, and the analysis of which thus constitutes the future stage of this research.

Although conceptual analysis is the principal method of this project, this study should also be understood in terms of community-based participatory research. Throughout the project the methodology has evolved from conceptual analysis and phenomenology to community-based participatory research, i.e., a community of social researchers raising questions and collecting data about the governance of research involving humans, and aiming at social/regulatory changes by expanding their knowledge base about their community and the institution of ethics review.

Conceptual analysis in this project has been also informed by participant observation of research ethics boards, as well as numerous informal conversations with fellow graduate and academic researchers, ethics professionals and regulators, and, of course, research participants. Much of the material collected with ethnographic methods remains beyond the methodological scope of the included articles and has yet to be presented in subsequent publications. Nevertheless, Chapters *Four* and *Five: Observers, Community, and Legal Members* and *Alternative Models of Ethical Governance*, respectively, include some elements of auto-ethnography, *directly* – when I discuss my experience of interaction with the

Interagency Advisory Panel on Research Ethics, local ethics committees, and the community of researchers who are studying the institution of ethics review. And more generally – when I engage in conceptual analysis from the position of researcher/REB member.

Chapter Four discusses the challenges of doing ethnography of ethics review. It introduces the methodology, as well as a number of possible perspectives, thus also reflecting on my itinerary as an *observer*, *community member*, and *member-knowledgeable-in-law* on a research ethics board. I have been involved in ethics review since 2011 and had an opportunity to informally observe the work of several ethics committees, participate in and organize educational and professional events for REB members, share my perspective with researchers of ethics review at academic conferences, as well as with other REB members and professionals. Most importantly I had an opportunity to experience first-hand some of the tensions existing in the regulatory space of research involving humans. My experience of ethics review from multiple perspectives has contributed to the analytic work presented in this portfolio.

Research ethics boards are idiosyncratic in their decision-making⁴⁶ and vary widely in their approaches to research ethics review in its procedural and substantive aspects. I refer to these approaches or ways of ethics review in terms of unique REB cultures, the study of which is important for understanding the processes of standardization in ethics review, which was a regulatory response to the idiosyncratic character of decision-making by institutional research ethics boards vis-à-vis universalistic claims of biomedical science. In *Chapter Four* I discuss a number of features that are characteristic and constitutive of local REB cultures, such as group dynamics, research and ethics expertise, horizontal and vertical knowledge transfer, training and continuing education, networking and communication, use of technology, openness for observers and researchers whose projects are reviewed, local discourse and interpretations of the Policy, and risk management strategies, to name a few.

The past five years have been very dynamic in terms of the processes affecting the research ethics landscape – major updates of the Policy, specialization and professionalization in ethics review, market pressures, transition to electronic record-keeping, expansion of ethics review and growing tensions in various fields of

⁴⁶ On this point see especially Stark, "Morality in Science: How Research Is Evaluated in the Age of Human Subjects Regulation.." And Michelle N. Meyer, "Regulating the Production of Knowledge: Research Risk-Benefit Analysis and the Heterogeneity Problem," *Administrative Law Review* 65, no. 2 (2013).

research involving humans where the biomedical ethical framework encountered certain limits, such as indigenous research, or more generally research on collectivities, where group consent is just as important as individual consent; or non-linear social science research which does not map on the prospective ethics review model used by research ethics boards; or community-based and independent research for which no access to the review infrastructure has been envisioned by policymakers; or critical policy research which does not go well with the “free and informed consent” requirement, among many others. In other words, research ethics boards themselves have become a source of ethical challenges and dilemmas, a source of the risk of harm to human participants, to use their language. Thus, it became necessary to understand the ethics of the immediate regulators of ethical conduct in research involving humans, which constituted the focus of my observations and analytic work.

Conceptual analysis presented in this dissertation has been informed by my direct involvement in the processes of ethical decision making in research involving humans. Thus, I attended over thirty full board meetings since 2011. A small number of projects at full board discussions make it possible to invite researchers to present their projects to the board and facilitate a deeper discussion on a wide range of ethical and methodological issues, often incorporating educational sessions on various aspects of ethics review. A low number of projects, inclusion of

researchers who introduce their projects, in-depth discussion of projects and regulations, frequent educational sessions, among other features, differentiate this research ethics boards from others that I had an opportunity to study directly or indirectly. The features that differentiated this board from others made it possible to experience in practice a number of regulatory and procedural initiatives that are often discussed in the literature on ethics review, and which have been already adopted by some research ethics boards.

Furthermore, this board has recently integrated into a larger network of research ethics boards. It has become a specialized board that reviews projects in a particular area of interdisciplinary health research, thus offering its expertise to other research institutes as well. After the integration I was able to observe the work of two other research ethics boards in the network. This integration was itself an excellent example of the ongoing specialization and centralization (as well as standardization and harmonization) in the governance of research involving humans at the municipal and provincial levels. Similarly, the *Clinical Trials Ontario* and the *Ontario Cancer Research Ethics Board* are two other initiatives that were helpful in understanding the processes of specialization and centralization in the governance of research involving humans.

Also, I volunteered as a researcher at the *Mount Sinai Hospital Research Ethics Board* to examine its institutional and reporting structure in light of the new edition of the *Tri-Council Policy Statement* and the new *Tri-Agency Framework* in October 2011 – January 2012.

I benefitted from the review of my research projects by York University's Research Ethics Board. I was particularly interested in the communication part of the ethics review process, and was also able to experience how institutional policies contribute to and challenge the regulatory and conceptual framework of the *Tri-Council Policy Statement*, as well as how research ethics boards review critical policy research about prospective ethics review.

I have to indicate yet another research ethics board, to which I had a special access, since my spouse became affiliated, midway my research project on the institution of ethics review, with a research ethics board of a psychiatric hospital in Ontario. The presence of a special informant during the course of this study enriched my understanding of the human relations aspect of ethics review, and facilitated the study of procedural and conceptual challenges arising in daily operations of research ethics boards.

I collaborated with a number of social researchers who study how the institutions of ethics review affect social science research and research safety. The most important outcome of this collaboration was the *Ethics Rupture* Summit in November 2012 in Fredericton,⁴⁷ the *New Brunswick Declaration*, adopted in February 2013, the *Ethics in Practice* Conference in Dunedin, as well as the ongoing work on the updated version of the *New Brunswick Declaration*, which has an unofficial name *New Brunswick-Otago Declaration*. While taking part in these initiatives, I focused on understanding existing tensions between research ethics boards, researchers and participants, and alternative approaches to the governance of research involving humans.

I attended more than a dozen of workshops and conferences for REB members, researchers, and REB administrators, including the Canadian Association of REBs (CAREB) 2013 National Conference “Fifty Shades of Research Ethics”, Calgary, April 25th, 2013, which focused specifically on harmonization in ethics review; annual educational *REB Retreats* (November 2, 2011, November 12, 2012, November 12, 2013, November 20, 2014), *TCPS 2 Workshop: Resolving Research Ethics Issues*, May 29, 2015.

⁴⁷ <http://wp.stu.ca/ethicsrupture/>

I also participated in planning and organizing a specialized educational workshop for REB lawyers in Toronto, “Problems and Solutions in Canadian Research Ethics Oversight: Interpreting the Tri-Council Policy Statement (TCPS 2)”, Toronto, March 26, 2012, Documenting such events is important not only in light of the ongoing specialization, but also potential fragmentation of REB membership.

Since the beginning of the projects I attended more than a dozen of academic events on research ethics, health law and ethics, business ethics, which are well attended by REB professionals. Specifically, I would like to mention, events at the Joint Centre for Bioethics at the University of Toronto. A casual conversation with an REB administrator at the beginning of this project at one of such events, “The Problem with REBs” by Giles Scofield on April 6, 2011, facilitated a quick integration into the field of ethics review, and opened access to a number of other research ethics boards – a research methodology known as the *snow ball technique*. Importantly, various materials that were distributed at these academic and professional events and/or shared by presenters and participants, including programs, summaries, slides, audio-visual information, and web links contributed to my understanding of the institution of prospective ethics review.

During the course of my research project I was able to talk informally with the Executive Director and Policy Analysts of the *Secretariat on Responsible Conduct of*

Research, which provides substantive and administrative support to the *Interagency Advisory Panel on Research Ethics* and the *Advisory Panel on Responsible Conduct of Research*,⁴⁸ about reflexivity in the governance of research involving humans. This took place at the *Regional Workshop for Ontario on the Second Edition of the Tri-Council Policy Statement*, Toronto, March 30-31, 2011; 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; The *Ethics Rupture: Alternatives to Research Ethics Review* Summit, Fredericton, New Brunswick, October 25-28, 2012.

The website of *Interagency Advisory Panel on Research Ethics* archives multiple submissions received during public consultations over proposed modification to the *Tri-Council Policy Statement*, which I examined in terms of content and social and disciplinary representation, along with contributions of the *Social Sciences and Humanities Research Ethics Special Working Committee*, which produced the *Giving Voice to the Spectrum Report to the Interagency Advisory Panel on Research Ethics* in 2004.

⁴⁸ Organizational Structure: http://www.pre.ethics.gc.ca/eng/panel-group/organizational_structure-structure_organisationnelle/

I monitored major listservs in the field of ethics review, including CAREB listserv, linkedin groups, and blogs, most importantly, the *Institutional Review Blog*,⁴⁹ maintained by Zachary Schrag.

Key initiatives in ethics review, such as the *TEAR – The Ethics Applications Repository*, an open access, online repository of ethics application forms and consent documents at the University of Otago, constituted another focus of my study.⁵⁰

Last but not least, I have had also hours of informal conversation with fellow graduate researchers, friends and colleagues who shared their experiences of passing ethics review and reflecting on the tensions between the prescriptive ethics of research ethics boards and the actual ethical challenges posed by their research projects.

LIST OF ARTICLES IN THE PORTFOLIO

- (2016) A New Wave of Positivism in the Social Sciences: Regulatory Capture and Conceptual Constraints in the Governance of Research Involving
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⁴⁹ “Institutional review blog: News and commentary about institutional review board oversight of the humanities and social sciences,” <http://www.institutionalreviewblog.com/>

⁵⁰ “The Ethics Application Repository,” <http://tear.otago.ac.nz/>

Humans. Osgoode Legal Studies Research Paper No. 10/2017. Available at

SSRN: <https://ssrn.com/abstract=2861908> or

<http://dx.doi.org/10.2139/ssrn.2861908>

- (2013). *Methodological Crisis in the Social Sciences: The New Brunswick Declaration as a New Paradigm in Research Ethics Governance?* Transnational Legal Theory, 4(1), 146-156. <http://dx.doi.org/10.5235/20414005.4.1.146>
- (2015) *The Eclipse of "Human Subjects" and the Rise of "Human Participants" in Research Involving Humans.* In W. C. van Den Hoonaard & A. Hamilton (Eds.), *Ethics Rupture: Exploring Alternatives to Formal Research-Ethics Review.* University of Toronto Press. [Forthcoming in May 2016
<http://www.amazon.com/The-Ethics-Rupture-Alternatives-Research-Ethics/dp/1442648325>]
- (2014) *Observers, Community and Legal Members on REBs: Examining the Ethics of the Regulators of Ethical Conduct in Research Involving Humans.* Osgoode Legal Studies Research Paper No. 36. Available at SSRN: <http://ssrn.com/abstract=2451059>
- (2016 forthcoming) *Alternative Models of Ethical Governance in Research Involving Humans: Towards the 2015 New Brunswick-Otago Declaration on Research Ethics?* (A slightly revised shorted version is published as Igor Gontcharov, Lindsey MacDonald. *Alternative Models of Ethical Governance:*

The 2016 New Brunswick-Otago Declaration on Research Ethics. New Zealand
Journal Sociology 31(4), 2016.)

STANDARD SETTING IN RESEARCH INVOLVING HUMANS

The term “mandated science”, introduced in *Mandated Science : Science and Scientists in the Making of Standards*, describes a “concern[] with the way in which the policy “mandate” affects the kind of scientific assessment that is done”.⁵¹ In the same vein, “mandated ethics” is used in this portfolio to describe a concern with the way in which the policy “mandate” (of key market players and/or particular interest groups) affects the kind of ethics assessment that is done.

Standards and standard setting in research involving humans are a general thread in this portfolio. When I discuss the subjects of codification, unification, harmonization, regulatory capture, ethics creep, or ethics transplants, I essentially deal with the processes of standard setting in the regulatory space of research involving humans. These processes are complex and even more so since they unfold within a field of politics. As Salter argues in *The Housework of Capitalism*, “standardization provides the opportunity for critical interaction” among public and private policy actors. In

⁵¹ Liora Salter, *Mandated science : science and scientists in the making of standards* (Dordrecht, Holland ; Boston [Mass.] : Kluwer Academic Publishers, 1988).

this sense, “standards are a proxy for conflicts” – “conflicts for dominance ... [that] are often acted out as if they were merely conflicts about technical standards.”⁵²

In research involving humans, these conflicts for dominance occur between distinct paradigms in approaches to scientific knowledge production, as well as between academic approaches and other – alternative – ways of knowing. These conflicts and tensions cut across the whole field of disciplinary knowledge, and are present at various locations and stages in understanding the unknown – in university education and methodological training, in peer and ethics review, in governance and funding structure, in fieldwork and communication of results, in relations between the university and the public.

Standards are *ubiquitous, malleable, variable* in character, content, and, as indicated above, they are also a *proxy* for conflicting group interests.⁵³ Accordingly, it is important to determine “*for whom* is a standard an agreed-upon technical specification – *for what purposes*, and *to what effect* in each particular instance.”⁵⁴ On the surface, definitions of “ethics”, “research”, “researcher”, “human” and “human involvement,” and others may be seen as conventions among the parties that seek to

⁵² Liora Salter, "The Housework of Capitalism: Standardization in the Communications and Information Technology Sectors," *International Journal of Political Economy* 23, no. 4 (1993-1994).

⁵³ Ibid.

⁵⁴ Ibid.

promote knowledge production while making it safe and beneficial for all involved in the process. On a deeper level, it is often about unilateral decisions that exclude certain stakeholders and suppress particular modes of knowing.⁵⁵

Prospective ethics review is one of the main standards in the governance of research involving humans, but it is supported by the “agreed upon” conceptual framework and “established” historical accounts. Conventional understandings of research and researchers, risk, harm, context, as well as standard historical narratives give shape to and legitimate the institution of prospective ethics review. They are part of the origin story of the institution of ethics review, its standard mythology. It is customary, that is, standard, to begin an introduction into research ethics by recounting the notorious events in biomedical and behavioral research. The list of names and events is standard and the interpretations are uniform – this material is cloned from one book on research ethics to another. The online tutorial on the *Tri-*

⁵⁵ Tim Büthe and Wallter Mattli’s publications provide an excellent overview of literature on standard setting, and are important in understanding the roles of public and private authority in standard setting. In my work the focus is not so much on the public and private distinction, and possible hybrid approaches to governance, but rather on how particular paradigms of knowledge production use standard setting institution to further their objectives. See Tim Büthe and Walter Mattli, *The New Global Rulers: The Privatization of Regulation in the World Economy* (Princeton University Press, 2011).

; Tim Büthe, "Governance through Private Authority? Non-State Actors in World Politics," *Journal of International Affairs* 58, no. 1 (2004); Tim Büthe, "The Globalization of Health and Safety Standards: Delegation of Regulatory Authority in the SPS-Agreement of the 1994 Agreement Establishing the World Trade Organization," *Law and Contemporary Problems* 71, no. 1 (2008); Walter Mattli and Tim Büthe, "Setting International Standards: Technological Rationality or Primacy of Power?," *World Politics* 56, no. 1 (2003).

Council Policy Statement is a mandatory certification mechanism for all researchers in Canada, which ensures that everyone is familiar with the standard narrative.⁵⁶

Meanwhile, standardization in research involving humans has not been understood uniformly by various stakeholders. The expansion of prospective ethics review as a risk management approach from the biomedical field to social science research has been introduced as “harmonization” in the first *Tri-Council Policy Statement*. However, harmonization presupposes integration of existing standards, or an elaboration of a new standard with the input of stakeholders, whereas the social sciences and humanities had no equivalent to prospective ethics review and were not invited to the table in a representative manner.⁵⁷

Accordingly, some social scientists have argued that standard setting in their field of knowledge is better expressed in terms of “ethical imperialism” and “methodological colonialism,” rather than harmonization, since we deal with the extrapolation of the biomedical standard of risk management and the corresponding worldview on other fields of knowledge production.⁵⁸ The politics of standard setting in research involving humans is a crucial part of this study. The questions for

⁵⁶ TCPS 2: CORE (Course on Research Ethics), <https://tcps2core.ca/welcome>

⁵⁷ Schrag, *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009*.

⁵⁸ van den Hoonaard, *The seduction of ethics: transforming the social sciences*; Schrag, *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009*.

whom, for what purposes and to what effect are important for understanding the political dimension of standard setting, and thus facilitate the analysis of standardization in research ethics.

These questions can be informed by a wide range of theoretical perspectives. For example, Van den Hoonaard's analysis of the deployment of the research ethics review standard, using Cohen's idea of "moral panic," allows not only for identifying interest groups, but also understanding the "mechanics" and projecting a probable lifecycle of the new standard.⁵⁹ Similarly, Ann Hamilton's *Institutional Review Boards: Politics, Power, Purpose and Process in a Regulatory Organization* utilizes an analytic device of "SINS" (structures, institutionalization, naturalizations, and simulations), in tracing how new standards (structures/regulations) are institutionalized and naturalized, and subsequently manifested in the simulations of the increased detachment of regulations from the lifeworld – the research environment.⁶⁰

Using conceptual analysis, I examine how the regulators of academic knowledge production relied exclusively on positivism as a distinctive paradigm in advancing

⁵⁹ Stanley Cohen, *Folk devils and moral panics: The creation of the mods and rockers* (Psychology Press, 2002).

; van den Hoonaard, "Is research ethics review a moral panic?."

⁶⁰ Ann Hamilton, "Institutional review boards: Politics, power, purpose and process in a regulatory organization." (Ph.D. Dissertation, The University of Oklahoma, 2002).

the frontiers of the known, when introducing the prospective ethics review standard in non-biomedical fields. Importantly, positivism was a *de facto* scientific standard in policymaking, promoting the “applied,” administrative, and quantitatively expressed dimension of disciplinary knowledge, such as *administrative criminology*.

Furthermore, policymakers largely overlooked an opportunity to learn from previous attempts to standardize the field of knowledge production and deflected the criticisms of positivism as a scientific ideology, which was offered by phenomenology, psychoanalysis, critical theory, and feminism, to name a few streams of thought, which were able to carve out spaces in academia for non-positivist – unique, non-generalizable, non-systematic, performative, intuitive and critical approaches to knowledge production, even if remaining largely unrepresented at the funding level, and thus remaining largely self-funded and unfunded.⁶¹

These streams of thought repeatedly questioned mainstream definitions of research and knowledge, as well the usefulness of the distinction between academic research

⁶¹ The purpose of standard setting in research involving humans was to ensure that all government-funded research satisfies minimum standards. *Section A* of the 1998 Tri-Council Policy Statement states, “As a condition of funding, we require, as a minimum, that researchers and their institutions apply the ethical principles and the articles of this Policy.” Nevertheless, the standard was introduced for all academic and non-academic research, regardless of the sources of funding or its absence, and despite the lack of data supporting the claim that these categories of research required and would benefit from regulatory intervention.

and alternative approaches to understanding the unknown, such as intuition, inspiration, or improvisation. The first *Tri-Council Policy Statement*, article 1.1., defines research as “involve[ing] a systematic investigation to establish facts, principles or generalizable knowledge” that excludes a wide range of research methodologies, and assigns them the status of non-standard academic practices, that is, not research. Although, this initially suggested a separate regulatory regime for non-research projects through the mechanisms of exemptions, it has been never realized in practice, since research ethics boards claimed the authority to determine whether a certain way of inquiry qualifies as research or not. The first *Tri-Council Policy Statement*, which “describes standards and procedures for governing research involving humans,” was effectively generalizing positivist standards, rather than *describing* best ethical practices in research involving humans.

Importantly, non-positivist streams of thought challenged the monodisciplinary standard of knowledge production, bringing forward the arguments for the transgression and even transcendence of disciplinary boundaries in *multi-, cross-, inter-, counter-,* and *transdisciplinary* initiatives. They have also argued that the concept of researchers should be expanded to include non-academic researchers, in order to engage and empower the community, thus enabling *community-based, participatory, independent* and *alternative* research.

The distinction between “voluntary” and “mandatory” standards is of great interest to the ethnographers of ethics review. I deal with the processes of codification in research ethics specifically in the *Methodological Crisis* and *A New Wave of Positivism in the Social Sciences*. Here I would like to highlight that the governance of research involving humans presents a fascinating case of rapid transition from voluntary to mandatory standards and capturing the whole regulatory space of research involving humans. The language of voluntary standards, soft law – of ethical guidelines and codes of ethics – was instrumental in promoting a positivist paradigm by first monopolizing the idea of ethics in research involving humans and subsequently homogenizing knowledge production by introducing a common standard of prospective ethics review, which non-positivist and non-established researchers simply could not meet.

Another aspect of standard setting in research ethics relates to the concept of minimum standards, allowing research institutes to raise them higher – a practice which was promoted by the overall conceptual framework. Meanwhile the minimum standard was introduced to ensure the “highest ethical standards” in research involving humans. This has led to the rich phenomenology of high and highest standards as minimum standards, with research institutions trying to appear even more ethical than minimally required, and thus raising the highest standards even higher, which in procedural terms of ethics review often translates

in further exaggeration of irrelevant ethical requirements for proposed research, such as longer consent forms, and more emphasis on the harm side in the application of the harm/benefit analysis by research ethics boards.

THE MEANING OF ETHICS IN THE GOVERNANCE OF RESEARCH ETHICS

Ethics has been a prominent topic in academic scholarship, fiction and mass media from the mid-1980s, when social movements and the progress in information, communication and bio-technologies started to produce a synergetic effect in challenging the *status quo* in many fields of human activity, thus leading to a destabilization and reconsideration of standard and established, that is, *ethical* practices across the whole field of human activity. In this sense the socio-political discourse of conservative and liberal argumentation is linked to the question of what is ethical, unethical and not so-ethical, as well as the breadth of what is acceptable as ethical and marginal, of old and new standards.

Academic scholarship, including philosophy, where ethics traditionally constitutes one of the branches along with aesthetics, logic, and metaphysics, has dedicated itself to the study of various applied aspects in their respective specialized fields. In the 1990s and early 2000s we could also see how the university curriculum at the departments of philosophy shifted towards ethics, responding to the demand from

other disciplines for ethics education. During this period the codes of ethics emerge everywhere – either by designing a new code of ethics, producing a code based on unwritten rules, or simply borrowing/cloning a suitable code of “best practices,” which illustrates that it was fashionable, that is, *ethically important* to have a code of ethics. In this manner, most academic associations and professions adopted a code of ethics.

The questions of ethics are the questions of governance and self-governance, which transcend disciplinary and jurisdictional borders. For example, in business ethics the discussion about corporate social responsibility challenges a narrow focus on domestic markets, engaging various aspects of the local and global in terms of manufacturing and living standards, work safety and child labour, quality of life and sustainability, self-governance and dependence.

Similar processes occur in other fields adjacent to the governance of human research ethics. For example, in animal ethics the scope of questions is equally vast – from the treatment of animals in terms of animal care and nutrition to personhood and quality of life. In an even closer field of animal research ethics, there is an ongoing shift from considering animals as disposable – previously seen as animal automata, pain-exhibiting, but lacking a conscious experience of pain, creatures – to equals, whose personhood needs to be recognized. Importantly, the government is

not necessarily a prominent actor engaged in standard setting in these fields – many initiatives, such as labelling products “not tested on animals” in hygiene products, or “free range,” “free run,” “organic” in farming, are a result of grassroots initiatives, local movements with a global reach, of multiple actors who participate in the process of standard setting, deliberating and determining new ethical standards.

Multiple aspects of academic, research, and teaching ethics are important to the governance of human research ethics. The *Tri-Council Policy Statement*, given its origin and approach to risk management, addresses only some of them. For example, it pays attention to researchers’ conflict of interest, but generally bypasses such phenomena as ghost-writing, which may be no less important for the governance of research involving humans. Its conceptual framework is a combination of what can be seen as conflicting ethical principles drawn from deontology and utilitarianism. Accordingly, the implementation of the Policy by research ethics boards is not devoid of tension and conflicts that are already present at the conceptual level. Importantly, virtue ethics plays a limited role in the Policy and, accordingly, The *Tri-Council Policy Statement* offers no mechanisms of cooperation with the existing communities of practice at the institutional and departmental levels, generally focusing on the command and control approach to

research ethics, although not without certain elements of responsive regulation and new governance.⁶²

The institution of prospective ethics review is embedded in and is a reflection of the overall socio-political discourse, thus negotiating some of its ideas at the Policy level. The most important of them was a transition from the language of human experimentation to research involving humans, from “human subjects” to “human participants,” the analysis of which is offered in this portfolio.

The articles in this portfolio challenge the *Tri-Council Policy Statement’s* understanding of research ethics predominantly in terms of the ethics of researchers, by arguing that the ethical dimension is necessarily wider, including the regulators of ethical conduct in research involving humans, research participants, and is not confined to academic institutions, since communities are always engaged in the processes on knowledge-production about themselves. The emergence of REB professionals has introduced a new dimension in the governance of research involving humans, making it necessary to factor in their professional and daily ethics, as well as contribution to research ethics, in addition to considering the ethics of the national sponsors of research involving humans.

⁶² Burris, "Regulatory innovation in the governance of human subjects research: A cautionary tale and some modest proposals."

In addition to regulatory and community ethics, I argue that it is necessary to consider disciplinary ethics – methodologies of particular approaches to knowledge production. In this sense, these articles bring forth an argument for ethical pluralism in the governance of research involving humans.⁶³ Furthermore, research ethics education and experiential ethics point in the direction of virtue ethics as a possible source for development of the *Tri-Council Policy Statement*, which could produce a creative blending of various theoretical approaches rather than continuing to build on the deontological understanding of autonomous individuals and utilitarian risk/benefit analysis that have met their limitations as an ethics platform for governing research in the social sciences and humanities.

Throughout the articles in this portfolio I draw attention to the tensions in the conceptual framework of the *Tri-Council Policy Statement*. These tensions issue from a particular interpretation of the concept of human dignity that is leaning towards the concept human rights in its theoretical understanding, yet translates in a particular way of ethics oversight, based on the harm-benefit analysis. Accordingly,

⁶³ There have been a number of contributions recently on the subject of disciplinary and ethical pluralism in the governance of research involving humans. See Rena Lederman, "Fieldwork Double-Bound in Human Research Ethics Reviews: Disciplinary Competence, or Regulatory Compliance and the Muting of Disciplinary Values," in *The Ethics Rupture:Exploring Alternatives to Formal Research Ethics Review* ed. Will C. van den Hoonaard and Ann Hamilton (University of Toronto Press, 2016); Z. M. Schrag, "Ethical Pluralism: Scholarly Societies and the Regulation of Research Ethics" in *The Ethics Rupture:Exploring Alternatives to Formal Research Ethics Review* ed. Will C. van den Hoonaard and Ann Hamilton (The University of Toronto Press, 2016).

the Policy builds upon deontological and utilitarian principles, which produce a regulatory design, in which the application of the harm/benefit analysis is a challenging task, since the analysis of benefits is generally dropped in prospective ethics review and the whole process is reduced to the analysis of the risk of harm.

The 1998 *Tri-Council Policy Statement* introduces the concept of human dignity as the cardinal principle of research ethics and translates it into eight “correlative” “guiding principles”: respect for human dignity, respect for free and informed consent, respect for vulnerable persons, respect for privacy and confidentiality, respect for justice and inclusiveness, balancing harms and benefits, minimizing harm, and maximizing benefit.

The 1998 *Tri-Council Policy Statement* uses a protectionist interpretation of human dignity and associated individual interests, which is consistent with a particular understanding of the research situation involving human subjects:

The cardinal principle of modern research ethics ... is respect for human dignity. This principle aspires to *protect* the multiple and interdependent *interests of the person* – from bodily to psychological to cultural integrity.⁶⁴

⁶⁴ TCPS 1, my emphasis.

Human dignity is a concept that generally lacks an established definition and is thus open to multiple interpretations. It is often interpreted as involving the ideas of autonomy, privacy, equality, and protection of agency. It can also be understood in terms of human rights and international law. This approach was important in the development of bioethics. The 1998 *Tri-Council Policy Statement* generally avoids the language of human rights directly, but addresses the first generation of rights through the ideas of privacy, free and informed consent, justice and inclusiveness. Social rights and the ideas of agency associated with it remain largely outside of its scope.

Many of the challenges in the governance of research involving humans in the social sciences and humanities are an outcome of this particular interpretation of the concept of human dignity.

The 2010 *Tri-Council Policy Statement* recognizes the vagueness of the concept and radically reduces the number of guiding ethical principles:

Respect for human dignity has been an underlying value of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS or the Policy) since its inception. Despite clear recognition of its centrality in research ethics, the term lends itself to a variety of definitions and

interpretations that make it challenging to apply. Respect for human dignity requires that research involving humans be conducted in a manner that is sensitive to the inherent worth of all human beings and the respect and consideration that they are due. In this Policy, respect for human dignity is expressed through three core principles – Respect for Persons, Concern for Welfare, and Justice. These core principles transcend disciplinary boundaries and, therefore, are relevant to the full range of research covered by this Policy.⁶⁵

In the 2010 *Tri-Council Policy Statement* the utilitarian approach is removed from the list of guiding principles, yet it is still retained as a methodology of risk assessment. Meanwhile the 2010 *Tri-Council Policy Statement* receives a stronger grounding in international law and thus the concept of human dignity receives a stronger interpretation in terms of human rights. Importantly, the second edition of the Policy now embraces the group rights problematic, thus effectively multiplying the challenges of harm-benefit analysis, since ethics review has to now accommodate the perspective of collectivities, including such issues as group consent.

⁶⁵ TCPS 2

When the 1998 *Tri-Council Policy Statement* was still current, various aspects of individual free and informed consent were challenging for researchers and research ethics boards alike. The second edition introduces the problematic of (free, informed, and standing) group consent that has to be accommodated and resolved on its own and vis-à-vis individual consent. The 2010 *Tri-Council Policy Statement* introduces the issue of group rights and collectivities in a chapter on aboriginal research, suggesting that it can serve as a template for research on collectivities in general.

OVERVIEW OF THE DISSERTATION

The titles are abbreviated in further discussion as “Methodological Crisis”, “Eclipse of Human Subjects”, “A New Wave of Positivism”, “Observers, Community, and Legal Members on REBs”, and “Alternative Models of Ethical Governance”.

All of the included articles offer a necessary background for the discussion of the conceptual and applied issues relevant to their objectives, relying on the author's experience within, as well as the ethnography of, the institutions of prospective ethics review.

Chapter One: A New Wave of Positivism in the Social Sciences? Conceptual Constraints in the Governance of Research Involving Humans identifies key conceptual limitations of prospective research ethics review in the social sciences and humanities and discusses some of the implications of employing a positivist methodological toolkit in designing a governance framework for all research involving humans. This discussion is necessary for facilitating a revision of the *Tri-Council Policy Statement* in a way that would build upon and enhance the pluralistic ethico-methodological nature of the social sciences and humanities. The article consists of two parts, examining procedural and conceptual aspects in the governance of research involving humans respectively. First it analyses procedural reasons contributing to the emergence of a one-size-fits-all regulatory model on the basis of the biomedical standard in 1998 (first edition of the *Tri-Council Policy Statement*) and the limited ability to respond to the criticisms of social researchers in the subsequent iterations of the Policy in 2010 and 2014 (*TCPS 2* and *TCPS 2 2014*). Secondly, it offers a detailed analysis of the positivist conceptual framework, including methodological reductionism, objectivism, and universalism, and its impact on policy making in research involving humans.

Chapter Two: Methodological Crisis in the Social Sciences: The New Brunswick Declaration as a New Paradigm in Research Ethics Governance? consists of two parts. *Part One* discusses the processes of codification in academic research and

introduces the current policy framework, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, adopted in 1998. Specifically, it examines the principles, articulated in the Policy, which are, presumably, shared by all research disciplines, the limitations of the utilitarian harm-benefit analysis for the prospective ethics review of all research as a strategy of risk management in research involving humans, which also conflicts with such deontological principles in the Policy as human dignity. It discusses further the implementation of the policy framework by research ethics boards, also detailing their composition and the processes of prospective ethics review. It situates research ethics review within a broader regulatory landscape and provides a historical background for the emergence of the institution of ethics review and its subsequent expansion to the social sciences and humanities. Although the expansion is generally understood by policymakers as *harmonization*, it was in fact *standardization* on the basis of the biomedical approach to risk management, which created multiple points of tension in social science and humanities research.

Part Two offers a review of a major and still unique book-length monograph documenting the impact of ethics review on the social sciences in Canada. It is the *Seduction of Ethics: Transforming the Social Sciences* by Will van den Hoonaard, which offers evidence of the ongoing methodological pauperization in the social sciences and the widening rupture between the formal procedural mechanisms of

prospective ethics review and the actual ethical challenges of social research in context. It also discusses the *New Brunswick Declaration* as a first collective attempt to articulate alternative ways of research governance in the social sciences and humanities at the *Ethics Rupture: Alternatives to Research-Ethics Review* Summit, an approach which would be able to re-establish the principle of methodological pluralism.

This chapter serves as a background for other articles in the portfolio since it introduces the conceptual framework that needs to be discussed in order to understand how the language of the *Tri-Council Policy Statement* defines the ethical dimension in the social sciences and humanities research. The conceptual framework, along with the institutional design of ethics review, embodies the experience and perspectives of the biomedical sciences traumas, moral panics, corporate interests, vulnerability, and failure of peer review mechanisms, among others. Accordingly, the ethical principles of the *Tri-Council Policy Statement* and its conceptual apparatus mirrors this particular universe of vulnerable subjects, lack of free and informed consent, lack of privacy, self-interested researchers and institutions, conflict of interests, and hierarchical power relationships between researchers and research subjects. Importantly it also “overlooks” or avoids some other issues – corporate research, ghostwriting, dubious moral standards of the government and corporate sponsors of academic research, the existence of

“professional guinea pigs” who rely on the employment within the clinical trials system, effectively faking participation and thus manipulating research outcomes. The *Tri-Council Policy Statement*’s framework presupposes a certain understanding of research and research participants, or all those who take part in research in their various roles and capacities; it uses a particular set of lenses to look at what it conceptualizes as the central ethical issue in research involving humans – risk of harm to individual participants posed by separate research projects; and it offers a strategy of addressing this issue by instituting a mechanism of reviewing individual research projects prospectively by multi-expert panels.

I discuss the elements of this conceptual framework and their influence on social science research in all chapters included in this portfolio. A general discussion of the conceptual framework takes place in *A New Wave of Positivism*. The *Eclipse of Human Subjects* provides an in-depth analysis of the concepts of *human subjects* and *participants*, which are central for understanding the nature of the tensions within the *Tri-Council Policy Statement* following the expansion to the social sciences and humanities in 1998. In *Observers, Community, and Legal Members on REBs*, I discuss the concepts of *ethics* and *expertise* in research and research ethics review, which is also the focus of the *Alternative Models of Ethical Governance*, which otherwise looks at the transformation of ethics review as a social institution in recent years.

Chapter Three: The Eclipse of “Human Subjects” and the Rise of “Human Participants” in Research Involving Humans. The 2010 edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* adopted a new language of human participants, leaving the previous central concept of “human subjects” behind. This chapter seeks to identify the reasons for this important change and stimulate a debate over the main subject of the policy, and approaches to regulatory innovation in research involving humans. In particular, it considers whether the transition to human participants was necessitated by harmonization and unification in approaches to ethics oversight on the basis of the biomedical standard, or whether it was an outcome of a given regulatory approach, which is *prima facie* congruent with “new governance”.

This chapter also examines negative performativity of “human subjects” in relation to researchers and research subjects. Finally, it calls for a critical assessment of the current universalist framework, arguing that superficial, albeit important conceptual changes, if unsupported by deeper structural modifications, will likely create a new euphemism, rather than successfully integrate the social sciences and humanities in the TCPS policy framework.

From a theoretical perspective this chapter makes a trifold contribution. *First*, it critically discusses the structure and ethics of the human subjects approach to

research governance, which underlies the *Tri-Council Policy Statement*. *Second*, it questions the regulatory framework implemented in the Policy and daily practices of research ethics boards. In particular, it discusses whether the *Tri-Council Policy Statement* is indeed an example of *responsive regulation*, which matches and performs as a *new governance* model. *Third*, it argues that the effects of regulatory innovation in the second edition of the *Tri-Council Policy Statement* will be limited, since these significant terminological changes are not supported by equally profound changes in the general philosophical foundation underpinning the Policy. On the contrary, some of the elements of ethico-methodological pluralism vanish in the second edition, while the processes of centralization and professionalization (which can also be understood as privatization by certain interest groups as discussed in *Observers, Community and Legal Members*) of research ethics review accelerate.

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

discusses the challenges of non-scientific members on research ethics boards – *observers, community, and legal members* – in establishing ethics review as an institution that seeks to go beyond peer review in research involving humans. By focusing on the processes of fragmentation and specialization in REB membership, it contributes to an understanding of the ethics of the regulators of ethical conduct in

research involving humans. A special emphasis is put on the role of expert knowledge and community representation in research ethics review.

Since the study of research ethics boards poses a number of ethical and research challenges, this article discusses participant observation as a methodology for examining the governance of knowledge production in research involving humans. It details some of my challenges in doing ethnography of ethics review in the processes of being as an observer and REB member at an interdisciplinary research institute in Toronto during the past four years, and an observer at several other research ethics boards in Toronto, and through collaboration with various groups and actors in event planning and organization, as well as, participation in the mainstream and alternative conferences and events dealing with a broad spectrum of issues in the governance of research involving human in Canada and internationally.

This chapter introduces the institution of ethics review as an “object” of study and discuss the meaning of “ethics” in research ethics review, i.e. the ethics of the regulators of ethical conduct versus the ethics of other research participants in research involving humans. It further discusses advantages and disadvantages of studying ethics review as an insider, a participant observer involved in the work of

research ethics committees and active participant in the processes that shape the governance of research involving humans internationally.

From a theoretical perspective this study relies on phenomenology and hermeneutics as a methodology which challenges the positivist research toolset – objectivity, linearity, neutrality, observation without impact on what is observed, and others as discussed in *A New Wave of Positivism*. The works of Martin Heidegger, Jacques Derrida, Michael Foucault, Sigmund Freud, Gilles Deleuze and Felix Guattari, and Jurgen Habermas are the main sources for my understanding of phenomenology as a critical methodology. Harold Garfinkel's ethnomethodology and Erving Hoffman's dramaturgy are the closest interpretations of phenomenology in terms of a sociological method of study. Similar to the Critical Legal Studies movement that questioned the neutrality of law, this research questioned the neutrality of ethics of the *Tri-Council Policy Statement* and its interpretation and application by research ethics boards as the immediate regulators of research involving humans. This chapter, as well as others in this portfolio call for developing a multi-perspective pluralistic approach to research governance and ethics. Accordingly, legal and ethico-methodological pluralism constitute an important theoretical and methodological part of this research project.

The chapter proceeds by critically examining the roles of observers, community and legal members as reflective of the general processes of specialization and professionalization in ethics review, by posing such questions as: *Whose interests do community members represent? How do lawyers contribute to ethics review?* and *What is the ethics of REB professionals?* Similarly in the *Eclipse of Human Subjects* chapter, I inquire: *What is the meaning of the missing perspective of human participants and the social sciences and humanities researchers on the governance of research involving humans?* The *Alternative Models* chapter in its turn offers an example of a critical community-based research into the governance of research involving humans who seek social and regulatory changes by offering their perspective on prospective ethics review.

Chapter Five: Alternative Models of Ethical Governance in Research Involving Humans: Towards the 2015 New Brunswick-Otago Declaration on Research Ethics? first critically discusses the current model of ethical governance in research involving humans in the social sciences and humanities, which relies on prospective ethics review in ensuring that research is conducted ethically. One of its key features is to distrust researchers and their initiatives regardless of the subject matter, discipline, research methodology or settings, sources of funding, or researcher's experience. As a possible alternative to the current model, this article discusses the *New Brunswick Declaration on Research Ethics*, which was adopted by

the participants of the *Ethics Rupture: Alternatives to Research-Ethics Review* Summit in 2013.

In particular, it provides background for the regulatory capture of the social sciences by the biomedical institutions of ethics review, and explains why this resulted in the tensions between “ethics on the books” and “ethics in practice”, and why the processes of centralization, bureaucratization, professionalization, and specialization in the governance of research involving humans have not resolved them. Further, it summarizes the *New Brunswick Declaration’s* approach in addressing existing tensions and concludes by examining the limitations of the Declaration, and offers a set of principles for the development of the *New Brunswick Declaration* following its discussion at the *Ethics in Practice: Tensions around Ethics Review and Maori Consultation* Conference at the University of Otago in Dunedin in May 2015. This is an example of a community-based research that not only inquires why the perspectives of social science and humanities researchers, individual and collective research participants, and independent researchers are not reflected at the level of policymakers, but also seeks to initiate a regulatory change by offering an alternative set of ethical principles.

CHAPTER ONE: A NEW WAVE OF POSITIVISM IN THE SOCIAL SCIENCES: REGULATORY CAPTURE AND CONCEPTUAL CONSTRAINS IN THE GOVERNANCE OF RESEARCH INVOLVING HUMANS

The task of this chapter is to identify key conceptual limitations of prospective ethics review in the social sciences and humanities and discuss the implications of employing a positivist methodological toolkit in designing a governance framework for all research involving humans. This is necessary to facilitate a revision of the *Tri-Council Policy Statement* in a way that would built upon and enhance the pluralistic ethico-methodological nature of the social sciences and humanities.

The chapter consists of two parts, examining procedural and conceptual aspects in the governance of research involving humans, respectively. First, it focuses on the procedural reasons that contributed to the adoption of a one-size-fits-all regulatory model in 1998 and the limited ability of the regulators to respond to the criticisms of social researchers in the subsequent iterations of the *Tri-Council Policy Statement* in 2010 and 2014. Second, it offers an analysis of the positivist conceptual framework, including methodological reductionism, objectivism, and universalism, and its impact on policy making in research involving humans.

WAVES OF POSITIVISM IN THE SOCIAL SCIENCES AND HUMANITIES

The adoption of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* in 1998 demarcates a turning point in the governance of research in the social sciences and humanities (SSH). It is a turning point since the preference was given to a positivist framework with its peculiar understanding of knowledge production as a linear process that poses risks to individual human research subjects. With the *Tri-Council Policy Statement* the biomedical approach to risk management in research involving humans became standard for all research disciplines and types of research. From a governance perspective, such standardization can be understood as a regulatory capture of academic research by the biomedical institutions of prospective ethics review.

The *Tri-Council Policy Statement* is a joint policy of the three major Canadian Research Councils – the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada – which articulates common ethical principles for the governance of research involving humans, and establishes a mechanism of compliance by reviewing all proposed research prospectively at the institutional level. Prospective ethics review is generally conducted by the panels of experts, known as *research ethics boards* (REBs) in Canada, and *research ethics committees* and *institutional review boards* abroad.

Research ethics review emerged in biomedical and behavioral research following WWII, and became a mainstream practice in these areas of knowledge throughout

late 1970s through mid-1990s in Canada and the United States. It was initially introduced as an instrument of risk management following the disclosure of and a growing public concern over existing ethical problems in *government-sponsored biomedical* research.⁶⁶ The focus of new regulations, such as the *Belmont Report* in the United States,⁶⁷ fell largely on the risks of physical and lasting psychological harm posed to such categories of human research subjects as prisoners, military personnel, and psychiatric patients, who had a limited ability to give free and informed consent for their participation. Almost immediately, the focus of research ethics review started to broaden. By late 1990s the mandate of research ethics boards expanded to all research, including self-funded and unfunded, and all disciplines, including the social sciences and humanities, and all categories of the population.

The expansion of REB oversight progressed with little respect to the principles, standards, and contexts of SSH research, and was not supported by relevant data substantiating its need and effectiveness in non-biomedical environment. Neither was there an open forum with either social scientists or research participants

⁶⁶ See esp. Henry K. Beecher, "Ethics and Clinical Research," *The New England Journal of Medicine* 274, no. 24 (1966).

⁶⁷ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "The Belmont Report: Ethical Principles and Guidelines for the protection of human subjects of research," (1979).

regarding *their* perspectives on the principles and approaches to the governance of research involving humans.

Governing research on the basis of the biomedical model of prospective ethics review has negatively affected the ethics and methodologies of knowledge production in the social sciences and humanities.⁶⁸ Accordingly, the expansion of research ethics review to SSH research has been rationalized in such terms as *ethics creep*,⁶⁹ *mission creep*,⁷⁰ and *ethical imperialism*,⁷¹ which imply a regulatory and methodological colonization of the social sciences and humanities by the growing ethics industry. The second edition of *Tri-Council Policy Statement*, adopted in December 2010 and updated in 2014, reaffirmed the biomedical model of research ethics review as a standard of ethical governance, thus further tightening the regulatory capture of the social sciences and humanities by the institutions of prospective ethics review.

The next section takes a closer look at the procedural basis for the expansion of the system of research oversight.

It has been noted that governance models behind the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* is generally consistent with reflexive

⁶⁸ van den Hoonaard, *The seduction of ethics: transforming the social sciences*.

⁶⁹ Haggerty, "Ethics Creep: Governing Social Science Research in the Name of Ethics."

⁷⁰ C. K. Gunsalus et al., "The Illinois White Paper: Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep"," *Qualitative Inquiry* 13, no. 5 (2007).

⁷¹ Schrag, *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009*.

regulation and new governance models, presumably allowing research ethics committees to take advantage of their proximity to the sites of research, local experts and broad autonomy in interpreting and applying the Policy.⁷² Expectedly, the character of ethical guidance by such diverse research ethics boards was idiosyncratic – their review and decisions regarding the same projects, such as in multicenter studies which had to pass review at every participating site, were inconsistent and often contradictory. Thus, research ethics boards restricted themselves in exercising their autonomy, demanded more guidance from the *Interdisciplinary Panel on Research Ethics*, more rules rather than principles, gravitating towards a decontextualized ethics review model to ensure consistency, and other ways to ensure the uniformity of expert knowledge contributing to ethics review. This has led to the processes of centralization, professionalization, and specialization in ethics review which were characteristic of the ethical landscape in the governance of research involving humans since 1998. Importantly, although these processes were generally triggered by the requirements of biomedical research, they unavoidably affected knowledge production in the social sciences and humanities. These processes prompted further integration of non-biomedical research in the biomedical framework of ethics review.

⁷² Burris, "Regulatory innovation in the governance of human subjects research: A cautionary tale and some modest proposals." on the Common Rule, or the set of Federal Regulations in the US governing human subjects research

“HARMONIZATION” IN RESEARCH INVOLVING HUMANS OR AN ADOPTION OF THE BIOMEDICAL STANDARD OF RISK MANAGEMENT VIA PROSPECTIVE ETHICS REVIEW?

Standardization may bring with it a number of advantages. In terms of the cost-benefit analysis, which is often used as a rationale for standardization, such advantages include lower expenditures on implementation, management, learning, adaptation, and further development. Meanwhile, standardization has its own costs related to the transition and subsequent performance of the common standard, which may be distributed unequally among the standardized fields. Thus, the adoption of the common standard in the governance of research involving humans was accompanied by an unavoidable extinction of many established practices and disciplinary research standards, especially in the social sciences and humanities, which policymakers could not, or preferred not to accommodate.

For example, there are significant differences with respect to *free and informed (documented) consent* for participation in research. While it is an important standard in the biomedical sciences, this requirement may contradict certain research methodologies, and if implemented and followed, may serve as a source of harm to researchers and participants. Similarly, a number of “default settings” in SSH research are different, and even opposite to those of biomedical research. In biographic research – anonymity may not be desirable; in critical policy research – an obligation to disclose research objectives and seek informed consent could

compromise its objectives; in survey-based research the consent was implied, unless revoked by the participant. The extension of the biomedical standard to these research environments introduced a different standard – often antagonistic to the context and applied research methodology. In some cases the requirement of free and informed consent was merely a nuisance, contributing an element of awkwardness, such as insisting on written consent forms in a basic survey, which only wasted time and resources of all parties, in others – it could put researchers and participants in danger when studying such sensitive issues as corruption, use of regulated substances, or euthanasia.

Meanwhile, biomedical ethics has influenced the standard of care in the social sciences, changing their research landscape. For example, research participants may now expect and request written consent forms. Accordingly, the defaults have been reversed. Such influence has significant consequences for a number of research fields and methodologies. In some cases written consent forms may be understood by researchers and participants as annoying legalistic requirements/interventions, a kind of disclaimer limiting institutional liability, rather than informing about research objectives, risks of harm, or communications of gratitude for participation. In others – potential research participants may insist on written consent forms to restrict researchers' access, thus protecting organizational and personal interests. Even if an understanding of research participants as vulnerable may generally reflect the situation in biomedical research, in the social sciences and humanities the

context may be different: individuals and organizations are often more powerful and may pose risks to researchers.

Similar observations can be made about other biomedical requirements, such as insistence of anonymity and generalizability of data, and understanding of risks and benefits in terms of individuals rather than collectivities.

It is common to identify three general approaches to standardization: (1) developing a new standard from “scratch”; (2) proceeding from a common denominator; and (3) generalizing existing standard.⁷³

Standardization of the mid to late 1990s in the governance of research involving humans, was generally rendered by policymakers in terms of *harmonization*. This is the language used in the first *Tri-Council Policy Statement*. In practice, the biomedical approach of prospective ethics review was adopted as a common standard, since the social sciences and humanities lacked the mechanism of prospective ethics review altogether, even if some research was peer reviewed at the funding stage. This is why a number of academic researchers disagreed that the first *Tri-Council Policy Statement*, and their counterparts in other countries, such as the *Belmont Report*, is in any sense a *harmonized* policy. Rather, they argued that the process of standardization in research involving humans is an example of regulatory

⁷³ See, for example, Katharina Pistor, "The standardization of law and its effect on developing economies," *American Journal of Comparative Law* 50, no. 97 (2002).

capture, describing what was happening in terms of biomedical “ethics creep”, “ethical imperialism”, “methodological colonialism”, using politically-loaded language to emphasize the disempowerment of social disciplines and the worsening of their ethical landscape. This is when “ethics” acquired a derogatory meaning for many social researchers, and research ethics boards acquired an aura of “the ethics police”,⁷⁴ rather than a friendly collegial space for discussing ethical challenges and dilemmas.⁷⁵

It is important to emphasize that the first *Tri-Council Policy Statement* formally endorsed *ethical pluralism* and even allowed for alternative regulatory regimes (via a mechanism of exemptions) for certain research methodologies, but these regimes were immediately suppressed by the overall framework requiring determination of the exemption status by research ethics boards. In the second *Tri-Council Policy Statement* the regime of non-working exemptions was dropped altogether. Furthermore, the second *Tri-Council Policy Statement* adopts the language that is, presumably, more familiar to the social sciences, such as “*human participant*” instead of “*research subject*”, or “*project*” instead of “*protocol*”. These changes can be better understood as formal gestures to SSH researchers, since the universality of

⁷⁴ Robert L. Klitzman, *The Ethics Police? The Struggle to Make Human Research Safe* (Oxford University Press, 2015).

⁷⁵ This is noted by Martin Tolich and Barry Smith who propose an optional consultative model of ethics review. See M. Tolich and B. Smith, *The Politicisation of Ethics Review in New Zealand* (Dunmore Publishing Ltd, 2015).

prospective review has not been challenged in any way in the new edition of the Policy. For example, the concept of *human participants* is not necessarily representative of the whole spectrum of relationships among humans involved in knowledge production in the social sciences and humanities. Furthermore, when transplanted into a positivist framework of the *Tri-Council Policy Statement*, they may not be able to “patch up” such problems of human subjects as power imbalances or lack of free and informed consent in biomedical research, but they will introduce more challenges for critical research, as I argue elsewhere.⁷⁶

WHY THE SOCIAL SCIENCES AND HUMANITIES RESEARCH COUNCIL COLLABORATED IN METHODOLOGICAL “COLONIZATION”?

The “colonization” of the social sciences and humanities was facilitated by the heterogeneity of their ethico-methodological landscape. A number of social disciplines use a methodological toolset that they share with biomedical disciplines, especially in research projects that unfold sequentially and adhere to an earlier established study design or protocol. In this case, the application of prospective ethics review as an instrument of risk management is at least methodologically

⁷⁶ Igor Gontcharov, "The Eclipse of 'Human Subjects' and the Rise of 'Human Participants' in Research Involving Humans," in *Ethics Rupture: Exploring Alternatives to Formal Research-Ethics Review*, ed. Will C. van den Hoonaard and Ann Hamilton (University of Toronto Press, 2016).

consistent. Nevertheless there is still a question if prospective ethics review is an adequate measure to the character of risks arising in SSH research, and if such risks justify a system of research oversight based on prospective ethics review.

Accordingly, some social researchers would not oppose prospective ethics review from a methodological perspective, though they might still disagree on ethical grounds.⁷⁷ This might explain the position of the *Social Sciences and Humanities Research Council* to collaborate with other two Councils in developing common ethical standards in research involving humans. The social sciences reflect a broader spectrum of research methodologies, but not all of them are equal at the governance level, where preference is given to quantitative data rather than views/narratives from a unique perspective.

The majority of social researchers, who participated in developing a new “harmonized” approach of prospective ethics review, generally represented a perspective consistent with positivist methodology. For them the integration of the social sciences and humanities in the existing biomedical framework would not be a methodologically incoherent step. Accordingly, the *Social Sciences and Humanities Research Council* generally adopted the biomedical approach, while making reservations and exceptions for disciplines, methodologies, or populations which

⁷⁷ Dingwall, "The ethical case against ethical regulation in humanities and social science research."

did not seem to fit this framework well enough, such as qualitative, critical, public policy, educational and aboriginal research.

The minority hoped that through collaboration with their biomedically-minded colleagues it will be possible to develop a truly *common* ethics framework that would embrace the non-positivist modalities of knowledge production. However, as van den Hoonaard, one of the founding members of the *Interagency Advisory Panel on Research Ethics*, writes in the *Seduction of Ethics*, it had become obvious very soon that the underlying conceptual and regulatory structure was tailored to the needs of biomedical sciences, which effectively suppressed any initiates to design a consensus model of research ethics.⁷⁸

ALTERNATIVE VOICES IN THE GOVERNANCE OF RESEARCH INVOLVING HUMANS IN THE SOCIAL SCIENCES AND HUMANITIES

Since the “common” standard was not based on “shared” ethical principles as the first *Tri-Council Policy Statement* argued, those areas of knowledge and knowledge production, which deviated from the positivist standard, but were nonetheless

⁷⁸ van den Hoonaard, *The seduction of ethics: transforming the social sciences*.

inscribed into it, started to experience an ethics rupture due to a widening distance between *ethics on the books* and *ethics in action*.

This widening rift in the ethics of the social sciences was the topic of the *Ethics Rupture: Exploring Alternatives to Formal Research-Ethics Review* Summit in Fredericton in 2012.⁷⁹ This was the first conference – 14 years after adopting the biomedical standard – which focused on the impact of prospective ethics review on the social sciences in Canada and discussed the alternatives to prospective ethics review. In the words of its organizers:

Many scholars in the social sciences and humanities have noted the inadequacy of the current formal system of research-ethics review to fairly offer ethical consideration in light of their research needs. The formal system of ethics review has placed the social sciences (and some humanities research) in a precarious situation. The bio-medical conceptions of research on which the system relies are not up to the task to give discipline-appropriate advice to other fields.

The time has come to convene an international summit to find alternative means to underscore the ethical approaches in social-science and humanities

⁷⁹ 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); 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).

research. Alternative means would also stem the tide of the homogenization of the social sciences and the humanities and the pauperization of their methodologies brought on today by research-ethics regimes.

... Because supporters of the prevailing formal research-ethics regimes are already given much air-time on official agendas, listservs, and policy conferences, the Summit provides a unique opportunity for scholars to freely exchange ideas about alternative ideas about research-ethics review. The Summit is open to all who wish to follow and learn more about these ideas.⁸⁰

It is important to note that the *Ethics Rapture* Summit was funded by the *Social Sciences and Humanities Research Council* with members of the *Secretariat on Responsible Conduct of Research* attending the event. The mandate of the Secretariat on Responsible Conduct of Research is to provide substantive and administrative support to the *Interagency Advisory Panel on Research Ethics* with respect to the *Tri-Council Policy Statement*.⁸¹ The *Social Sciences and Humanities Research Council's* support is indicative of its interest in learning more about the role of the Policy in the governance of social science and humanities research. However, in the preceding seventeen years the study of the impact of prospective review on the

⁸⁰ *Ethics Rupture: An Invitational Summit about Alternatives to Research-Ethics Review* in Fredericton, New Brunswick in October 25-28, 2012.

<https://web.archive.org/web/20130507065940/http://wp.stu.ca/ethicsrupture/>

⁸¹ Terms of Reference of the Secretariat on Responsible Conduct of Research.
<http://www.ethics.gc.ca/eng/secretariat/tor-cdr/>

social sciences and humanities has not been among the funding priorities of the Council. Even if this question is formulated more narrowly – in terms of risk, safety and protection of human participants in SSH research, thus reflecting the approach of the *Tri-Council Policy Statement*, still there was no systematic approach to measuring the effectiveness of prospective ethics review. In this sense the process of policy development in research involving humans has not been empirically grounded and validated.

A major issue with prospective ethics review was its adoption on a *moral panic*⁸² wave – that is, without a proper justification of its need and effectiveness in maintaining required ethical standards in SSH research. Another major issue is a limited interest of the regulators in learning whether the *Tri-Council Policy Statement* was able to enhance the ethical dimension in research involving humans. It is necessary to find out why such an event as the *Ethics Rupture Summit* has not triggered a review of the conceptual and regulatory framework in research involving humans.

Now to the question why “non-positivist” researchers, that is, those who represent the disciplines and methodologies inconsistent with the biomedical model of risk management, did not or could not offer a strong and persuasive alternative to

⁸² van den Hoonaard, "Is research ethics review a moral panic?" Cohen, *Folk devils and moral panics: The creation of the mods and rockers*.

prospective ethics review. A number of reasons contributed to this outcome – methodological heterogeneity, disciplinary fragmentation, and existing methodological hierarchy at the level of funding and governance.

As indicated above, some researchers counted on the evolution of the *Tri-Council Policy Statement* into a policy that will eventually embrace ethico-methodological pluralism, since the 1998 edition was still relatively open to non-positivist research. It also emphasized its flexibility and consultative character, positioning itself as a living document and soft law – flexible ethical guidelines rather than administrative law. Thus, there was a hope that the policy will build upon and learn from the existing communities of research practice, rather than reshaping them from above.

Others counted on the exemptions mechanism and separate regulatory regimes for their disciplines, methodologies and areas of research. Still others thought that the issue is not so much in the underlying ethical principles and prospective ethics review as a mechanism ensuring compliance, but in the composition of research ethics boards – their methodological expertise. They argued that the presence of experts in “qualitative” methodologies on ethics committees would be necessary when considering non-positivist research. Similarly, there were suggestions that a linguistic overhaul of the *Tri-Council Policy Statement*, for example, avoiding such biomedical irritants as “research subject” and “protocols”, would facilitate the development of the Policy in direction of multidisciplinarity.

MANDATED ETHICS AS AN ARGUMENT IN THE OLD DEBATE OVER UNIFIED SCIENCE

The reason why many SSH researchers would not object the biomedical framework as a whole, searching for solutions to existing problems from within, is reflective of the overall methodological structure of the social sciences. This structure features a positivist core and antipositivist periphery. From this perspective – the expansion of the positivist framework can be seen as an attempt to colonize the periphery by the social sciences' methodological core. Accordingly, methodological colonialism is an inner business of the social sciences, rather than an effort of the biomedical sciences to bring them into their orbit. The *Tri-Council Policy Statement* was an opportunity for the center to reassert its dominance over the margins of social research, by introducing a licensing mechanism⁸³ favoring positivist research.

The *Tri-Council Policy Statement* can be better understood in light of the ongoing debate within the social sciences about its methodology, such as the *positivism dispute* in the 1960s, when Habermas offered a critique of the positivist thesis of unified science, where unification follows a natural-scientific model. Habermas argued that social reality is historically contextualized and thus symbolically prestructured – it cannot be accessed by observation alone and requires a

⁸³ On the subject of REBs as a licensing body see Hamburger, "Getting Permission."; Philip Hamburger, "The New Censorship: Institutional Review Boards," *The Supreme Court Review* (2004).

hermeneutical situation-specific understanding of meaning.⁸⁴ Nevertheless, despite the critique of positivism and scientism from the side of hermeneutics, phenomenology, psychoanalysis, Marxism, feminism, critical legal studies, to name a few perspectives, the governance mechanisms and the funding structure remained largely under control of the protagonists of unified science.

Zachary Schrag's monograph details how social researchers were excluded from the governance of research involving humans in the USA.⁸⁵ Canada followed a similar trajectory, being influenced by the emerging ethics oversight regime in the USA, and borrowing heavily from the *Belmont Report*⁸⁶ and later from the *Code of Federal Regulations*.⁸⁷ The work on the second *Tri-Council Policy Statement*, which has been recently updated again in 2014, presented an opportunity to respond to the recommendations and criticisms of the *Law Commission of Canada Report, 2000*,⁸⁸

⁸⁴ J. Habermas, *On the Logic of the Social Sciences* (Polity, 1990 (1967)).

⁸⁵ Schrag, *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009*. See also Zachary M. Schrag, "The Case against Ethics Review in the Social Sciences," *Research Ethics* 7, no. 4 (2011).

⁸⁶ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "The Belmont Report: Ethical Principles and Guidelines for the protection of human subjects of research."

⁸⁷ Department of Health and Human Service, "45 Code of Federal Regulations, Part 46: Protection of Human Subjects," (2005).

⁸⁸ McDonald, "Canadian governance of health research involving human subjects: is anybody minding the store?"; McDonald, *The Governance of Health Research Involving Human Subjects (HRIHS)*.

Giving Voice to the Spectrum Report, 2004,⁸⁹ separate disciplines, such as criminology,⁹⁰ rich feedback received during several rounds of consultations,⁹¹ and those of the *Ethics Rupture* Summit participants. However, by and large the *Panel on Research Ethics* has not taken advantage of these critical contributions, since SSH researchers, non-biomedical research participants⁹² have not been sufficiently empowered as policy actors and invited to the table.

Somewhat paradoxically, despite promoting a positivist perspective at research ethics, the *Interagency Advisory Panel on Research Ethics*, including the Secretariat on Responsible Conduct of Research, has not adopted an empirical standard for evaluating its own performance. Evidence-based regulation of research ethics⁹³ has yet to become a criterion of its effectiveness in the governance of research involving humans.⁹⁴ Since the performance of the *Panel on Research Ethics* is part of its

⁸⁹ "Giving Voice to the Spectrum: Report of the Social Sciences and Humanities Research Ethics Special Working Committee to the Interagency Advisory Panel on Research Ethics," in *Ottawa* (2004).

⁹⁰ I would highlight multiple contributions by Ted Palys and John Lowman. An extensive bibliography is available at <http://www.sfu.ca/~palys/articles.htm>. See Ted Palys's video recording of a presentation "Research Confidentiality: Researcher & Institutional Responsibilities" at Langara College on October 16, 2015, available at <https://youtu.be/xB21-3jWMQk>, for an example of existing tensions between *ethics on the books* and *ethics in practice* from a criminological perspective.

⁹¹ PRE's website has an archive of submitted comments on the revised draft of TCPS 2 at <http://www.ethics.gc.ca/eng/archives/events-actualites/tour-tournee/>.

⁹² Gontcharov, "The Eclipse of 'Human Subjects' and the Rise of 'Human Participants' in Research Involving Humans."

⁹³ Beagan and McDonald, "Evidence-based practice of research ethics review?."

⁹⁴ Although empirical studies of research ethics boards were rare by the time when ethics review expanded to the social sciences, they already expressed concerns about the suitability of the current approach to critical public health research and health research based non-positivist methodologies. See, esp. James Bell, John Whiton, and Sharon Connelly, "FINAL REPORT: Evaluation of NIH

accountability to the public as a research ethics regulator, it should not exclude itself when developing ethical standards.

In developing the *Tri-Council Policy Statement*, the regulators, following the unified science model, assumed that SSH research is subject to the same problems as in other branches of positivist research, and therefore no justification for the expansion of ethics oversight was required and provided. Although SSH researchers could not immediately produce sufficient evidence regarding the impact of the first *Tri-Council Policy Statement*, there were strong ethical and structural arguments against ethics oversight in the social sciences and humanities,⁹⁵ which the *Panel on Research Ethics* could have considered. The fact that it did not challenge the overall approach can be possibly attributed to its composition, which is tailored to the needs of biomedical research. Moreover, the *Panel on Research Ethics* itself is also exposed to the conflict of interest, as I argue in the *Alternative Models of Ethical Governance in Research Involving Humans*.⁹⁶

Implementation of Section 491 of the Public Health Service Act, Mandating a Program of Protection for Research Subjects June 15, 1998. Prepared for The Office of Extramural Research, National Institutes of Health," (1998); McDonald, *The Governance of Health Research Involving Human Subjects (HRIHS)*.

⁹⁵ Dingwall, "The ethical case against ethical regulation in humanities and social science research."; Hammersley, "Against the ethicists: on the evils of ethical regulation." See also Schrag, "The Case against Ethics Review in the Social Sciences."

⁹⁶ Igor Gontcharov, "Alternative Models of Ethical Governance in Research Involving Humans: Towards the 2015 New Brunswick-Otago Declaration on Research Ethics?," *New Zealand Journal of Sociology* (2016 (forthcoming)).

According to the *Terms of Reference*, the *Panel on Research Ethics* is “an interdisciplinary and pluralistic advisory body, providing the Agencies with independent reflection and advice on human research ethics, consistent with the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans*, 2nd edition.”⁹⁷ There are significant limits to *Panel on Research Ethics’* interdisciplinary status and pluralism. Additionally, the *Panel on Research Ethics* is a subsidiary to the three major Research Councils of Canada and not an independent agency, which leads to a potential conflict of interest, since the mandate of the Councils is to promote research, whereas the original purpose of ethical regulations was to ensure that there is an effective oversight mechanism over state-sponsored research. In practice, the *Tri-Council Policy Statement* has evolved into a policy that covers all research involving humans (broadly understood) regardless of the source of funding, and extending beyond academic boundaries into community-based and independent research. Similarly to academic non-positivist and critical research, community-based and independent research currently experience significant challenges. These challenges are even broader since the regulators have not even envisioned or designed an adequate ethics review infrastructure for them.

⁹⁷ Terms of Reference of the Interagency Advisory Panel on Research Ethics.
<http://www.ethics.gc.ca/eng/panel-group/tor-cdr/>

REB POSITIVISM AS A BARRIER TO REGULATORY INNOVATION IN RESEARCH INVOLVING HUMANS

How does the *Tri-Council Policy Statement*'s conceptual framework affect regulatory innovation in research involving humans?

As noted above, idiosyncratic decision-making of research ethics boards is not evidence of the functioning reflexive regulation at the level of research ethics boards. The promise of reflexive regulation has not been fulfilled since the overall positivist framework prevented them from becoming a learning regulator, capable of transfiguring their approaches in response to the needs and values of *all* researchers and participants whose conduct it regulates, rather than responding to the needs of biomedical researchers exclusively. This explains how idiosyncratic⁹⁸ decision-making could result in restricting particular research areas and methodologies in a uniform way. Since 1998 the development of the *Tri-Council Policy Statement* proceeded in the direction of enabling positivist research and suppressing research initiatives and methodologies that deviate from it. The processes of centralization, specialization and professionalization in the governance

⁹⁸ See esp. Meyer, "Regulating the Production of Knowledge: Research Risk-Benefit Analysis and the Heterogeneity Problem.;" Michelle N. Meyer, "Three Challenges for Risk-Based (Research) Regulation: Heterogeneity Among Regulated Activities, Regulator Bias, and Stakeholder Heterogeneity," in *The Future of Human Subjects Research Regulation*, ed. Glenn Cohen and Holly Fernandez Lynch (MIT Press, 2014). And L. Stark, *Behind closed doors: IRBs and the making of ethical research* (The University of Chicago Press, 2012).

of research involving humans generally support the biomedical framework, thus making it more and more difficult for research ethics boards to attune themselves to the actual ethical requirements of SSH research.

This section considers two questions: (1) in what way the overall positivist conceptual framework limits the expertise and autonomy of research ethics boards, sustaining the phenomenon of REB positivism, which is characterized by methodological reductionism, solipsism, individual understanding of harm, and "medieval" understanding of risk; (2) how *REB positivism* influences regulatory innovation in the governance of research involving humans.

Contrary to the claims to be free from all metaphysics,⁹⁹ *positivism*¹⁰⁰ can be described as the metaphysics of the scientific method, which is based on a number of assumptions regarding knowledge production. It is assumed that reality is

⁹⁹ Auguste Comte, *A General View of Positivism* (Truebner and Co., 1865), <http://books.google.com/books?id=SgaHpaEAewC&ots=iubuk2ztrh&dq=%22A%20General%20View%20of%20Positivism%22&pg=PR2>.

¹⁰⁰ Scientific positivism has to be distinguished from legal positivism (Lon Fuller, "Positivism and Fidelity to Law - A Reply to Professor Hart," *Harvard Law Review* 71(1957); H.L.A. Hart, *The Concept of Law*, Second ed. (OUP, 1994)., see also Leslie Green, "Legal Positivism," <<http://plato.stanford.edu/archives/fall2009/entries/legal-positivism/>>.). However, the two positivisms – despite different origins – both convey the idea of positive sciences, as they study what is posited whether by king's decree, the legislature, or by convention – in this sense all social sciences study what is posited, and not only the social sciences. The reason why positive sciences are positive is that they study what is in front of us, as objects of study (as posited by nature, god). In difference to negative science – philosophy – which has an "object" that is not there in front of us. They are also close in other respects – methodological reductionism is not uncommon to legal positivism (evident in Hart-Fuller exchange, for example. See Fuller, "Positivism and Fidelity to Law - A Reply to Professor Hart.;" H.L.A. Hart, "Positivism and the Separation of Law and Morals," *Harvard Law Review* 71, no. 4 (1958).), as well as universalism. Nevertheless, in this paper the term positivism does not refer to legal positivism.

objective, consistent and accessible to our sense experience. Our sense experience, uncorrupted by prior theorizations, is able to register reality correctly, and by reasoning we can identify regularities in sense data, thus producing a truthful picture of reality. Meanwhile, it is also assumed that researchers are able to step outside of the object of their study, and therefore avoid contaminating data by their presence.

The goal of science is the discovery of truth that is understood as a correspondence between the picture of reality and the actual state of affairs. Importantly, the analytic core of the scientific method contains a reductionist presupposition that the whole consists of the sum of its parts and relationships among them. This position, also known as *methodological reductionism*, breaks the homogeneity of science, introducing a hierarchy of sciences based on the underlying reductionism and materialism – e.g., sociology can be reduced to psychology, psychology to biology, biology to chemistry, chemistry to particle physics.

Positivism is preoccupied with general laws, with what is stable and recurrent. Knowledge in the social sciences is more qualitative in character – it is perspectival, contextual, tentative, observer-dependent, and narrative. Accordingly, positivism questions the relevance and scientific status of such knowledge, preferring reductionist approaches in the dealing with social phenomena, selectively focusing on such knowledge production techniques that are more congruent with the disciplines occupying upper positions in the hierarchy of sciences.

Objectivism, universalism, and reductionism have been widely criticized by the philosophers of science.¹⁰¹ For example, the presumable objectivism of science rests on a questionable subject/object distinction and an assumption that it is possible and desirable to isolate the impact of the observer; universalism – on the suppression of other knowledge, such as in the social sciences and humanities; and reductionist explanations are not necessarily superior or even possible for understanding the phenomena.

Despite a profound critique of positivism in the 20th century, the *Tri-Council Policy Statement* adopted the biomedical understanding of research as a standard for all research involving humans, thus creating a system of research oversight that is based on an ideology of positivist research, rather than on a plurality of actual practices of knowledge production and ethical challenges in understanding the unknown.

¹⁰¹ Thomas Kuhn, *The Structure of Scientific Revolutions* (University of Chicago Press, 1962). ; Paul K. Feyerabend, *Against Method*, 3d ed. ed. (Verso, 1993). ; T. Adorno and et al., *The Positivist Dispute in German Sociology*, trans. Glyn Adey and David Frisby (Heinemann, 1976).

IS RESEARCH PROTOCOL AS A GOOD INDICATOR OF RESEARCH ETHICS?

Research ethics committees have assumed a number of functions beyond their original task of protecting human subjects in biomedical research. New functions include considerations of scientific merit, soundness of research methodology, institutional liability, conflict of interest, and even criminal checks. C.K. Gunsalus and co-authors in a landmark policy paper *The Illinois White Paper: Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep"* identify a number of critical issues in the system of research oversight: (1) the system of reward and punishment does not correspond to the stated objectives of ethics oversight, (2) vague definitions lead to expansive interpretation, (3) appearing ethical is given priority in ethics review (4) management of legal risks.¹⁰²

The first cause, which Gunsalus calls “rewarding the wrong behaviors”, is a result of an “inherent contradiction” in the mission of research ethics committees. This contradiction is a consequence of how the *Tri-Council Policy Statement* and the *Code of Federal Regulations* understand the production of new knowledge and the role of researcher in this process. On one hand, researchers cannot be trusted. Therefore, every single initiative required research ethics review. On the other, research ethics

¹⁰² Gunsalus et al., "The Illinois White Paper: Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep"."

committees have to trust them anyways, since they are unable to oversee the actual run of research, beyond the initial ethics review and periodic review based on self-reporting. Accordingly, research ethics boards can only assess the ethics of the submitted research project. But is it a good indicator of the actual research? Since the review procedure does not engage with the research itself, research ethics boards can only *hope* that research is conducted ethically.

Currently, we do not have a system of research ethics oversight, but rather a system of research protocol/project oversight. Nevertheless the *Tri-Council Policy Statement* understands the mission of research ethics boards as extending beyond the oversight of research projects, but can hardly engage in the oversight of the actual research projects due to financial and logistical limitations. Accordingly we have a situation when individual research projects require review and approval and research ethics boards *hope* that researchers will conduct approved research ethically, since they do not entirely trust them. In part, this is a result of the *Tri-Council Policy Statement's* understanding of research in terms of danger, rather than risk, despite using the language of *risk* management, such as, *risk of harm* to human participants. Its general operative framework is built on the “medieval” coupling danger-hope, rather than “modern” trust-risk.¹⁰³ Understanding research in terms of

¹⁰³ Niklas Luhmann, "Familiarity, Confidence, Trust: Problems and Alternatives," in *Trust: Making and Breaking Cooperative Relations*, ed. Diego Gambetta (Oxford: Department of Sociology, University of Oxford, 2000).

uncertain dangers forces research ethics boards to address a wide spectrum of possible dangers associated with research activity, rather than focus on the specific risks that research poses to its participants. In this sense, research ethics boards can only hope that ethics review avert some of the dangers. This would explains why neither the *Interagency Advisory Panel on Research Ethics*, nor individual research ethics engaged in developing the substantive indicators of their contribution in protecting human participants on national and institutional levels, which would go beyond the procedural ones, such as the duration of ethics review or the number of projects reviewed.

Although the focus on research projects rather than research itself can be explained in terms of limited resources, the preoccupation with research protocols can be also seen as an outcome of the adopted conceptual framework, which gives priority to the scheme of research. From the procedural point of research ethics review, as in Platonism, the protocol is truer and more real than research itself. For research ethics boards, research designs that corresponds to the ideal form is all what matters. This is a consequence of the *Tri-Council Policy Statement's* reductionist understanding of research. This understanding is consistent with positivism, according to which research is divided into stages, rigid and sequential, in which a stage of research design always precedes other stages, such as data collection, analysis, interpretation, and dissemination of results. It is assumed that researchers will follow the approved design until research is completed. Indeed, the actual

picture of science is more nuanced, paradigmatic,¹⁰⁴ subject to socio-political, and economic pressures and challenges. The role of research ethics boards is to identify and correct undesirable deviations from the prescribed standard at the stage of research design.

A linear understanding of the research process maps poorly on other methodologies of knowledge production.¹⁰⁵ For example, in “qualitative” methodologies the stage of research design does not necessarily precede data collection. In fact, various stages, if we use this language, may coincide. Research design may change in the process of “data collection”. It has to be flexible and adaptive, capable of responding seamlessly to the changes in the research situation, as required, for example, in participant observation of risk taking populations.

Since the *Tri-Council Policy Statement* adopted the positivist understanding of research as a universal standard for all research disciplines, it is unavoidable that some research initiatives based on alternative or mixed methods started to experience challenges in passing ethics review. Since the format of ethics review is tailored to positivist research, “qualitative” researchers try to fit in the required framework – even if it is hardly relevant – when/thus filling out REB forms,

¹⁰⁴ Kuhn, *The Structure of Scientific Revolutions*; Feyerabend, *Against Method*.

¹⁰⁵ Brunger and Burgess use the term “linear model of research ethics” to articulate a similar idea. They suggest that governance on the basis of the linear model should give way to an analysis that would consider research ethics as an embedded phenomenon, thus explicitly recognizing that it is subject to complex social influences. See Ferm Brunger and Michael Burgess, “A Cultural Understanding of Research Ethics Governance,” *Health Law Review* 13, no. 2 & 3 (2005).

identifying risks of harm, answering questions about anonymity and generalizability of data, or designing written consent forms. If they anticipate significant challenges in passing ethics review, they will probably decide against pursuing the project. Van den Hoonaard's *The Seduction of Ethics* documents the ongoing methodological pauperization of the social sciences.¹⁰⁶ If the projects are designed to appear consistent with the positivist standard, then how can ethics review have any favorable effect on achieving such goals of the *Tri-Council Policy Statement*, as protection of human participants, sustaining trust in science, advancing research, or ensuring highest ethical standards?

When the *Tri-Council Policy Statement* was updated in 2010 and 2014, the overall biomedical framework has not been critically and systematically reassessed. Instead, the *Interagency Advisory Panel on Research Ethics* preferred to better accommodate the social sciences and humanities within the deficient conceptual framework through terminological changes and expanded guidance to REB members and professionals. Although some elements of the updated Policy Statement are undoubtedly progressive, such as the idea of group consent in aboriginal research, these elements had not resulted in questioning the universality of the biomedical approach with its focus on individuals – risk management via the assessment of the risk of harm to individuals, written individual consent, or focus on

¹⁰⁶ van den Hoonaard, *The seduction of ethics: transforming the social sciences*.

privacy and anonymity. The concept of collectivities remained exclusive to aboriginal communities. Most of the tensions between prospective research ethics review and the actual practices of knowledge production are even more acute now when immediately after adopting the first *Tri-Council Policy Statement* in 1998, when it still had the status of ethical *guidelines*.

Since the biomedical conceptual framework remains largely intact, all initiatives at knowledge production that do not fit the required protocol format continue to be censored or modified by researchers themselves in order to resemble the standard. In this sense, prospective ethics review engendered a practice of *conspicuous compliance* (to contextualize Veblen's concept of *conspicuous consumption*)¹⁰⁷ rather than contributed to the stated objectives of ethics review. This is the reason why the bureaucratic process and paperwork remain the indicators of research ethics boards' effectiveness in ensuring ethical standards in research involving humans, while the boards continue to "reward the wrong behaviors".

¹⁰⁷ Thorstein Veblen, *The Theory of the Leisure Class* (Penguin Books, 1979).

THE POSITIVISM OF LOCAL KNOWLEDGE: REGULATORY EXPANSION AND CONCEPTUAL REDUCTION

According to *The Illinois White Paper*, vague definitions of such central concepts as *risk*, *harm*, *research*, *research subject*, and distinctions, such as *practice/research*, *confidentiality/anonymity* in the *Common Rule* constitute another cause of REB mission creep.¹⁰⁸ For example, “research” becomes to be understood expansively as including any kind of verbal interaction between researchers and human participants.

Zachary Schrag’s *How Talking Became Human Subject Research* traces how the mission of ethics committees expanded to the social sciences and humanities.¹⁰⁹ *Don’t Talk to the Humans* is a title of a popular article that captures how research ethics oversight transformed social science research.¹¹⁰ For researchers whose methods includes “talking” in a form of casual conversations or even more structured interviews, ethics oversight poses significant challenges since *talking* is research involving humans for which ethical clearance is required. Research ethics boards use biomedical context and definitions in reviewing social science research.

¹⁰⁸ Gunsalus et al., "The Illinois White Paper: Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep"."

¹⁰⁹ Zachary M. Schrag, "How Talking Became Human Subjects Research: The Federal Regulation of the Social Sciences, 1965-1991," *Journal of Policy History* (forthcoming).

¹¹⁰ Christopher Shea, "Don't talk to the Humans: The Crackdown on Social Science Research," *Lingua Franca* 10, no. 6 (2000).

Accordingly, talking becomes potentially dangerous to human participants. For example, it may cause psychological distress. These dangers, if research ethics boards find them acceptable, together with research objectives, have to be communicated to research participants, who are expected to document their consent in a tangible form, such as by signing a written consent form.

In most situations the review procedure and REB-required interventions in research situations, such as consent forms, are usually harmless – a nuisance, wasted time and resources, but they may also impede research, go against ethical practices in certain disciplines, and even introduce risks to researchers and participants, such as in critical policy research. It is worth noting, that after ethics review expanded to the social sciences and humanities, some researchers could not see any reflection of their practices of knowledge production in the adopted definitions of research. They argued that talking to people is not research in this sense since the context is different. Other sought exemptions, or other strategies of escape from the regulated sphere, arguing that talking to people is closer to “unregulated” creative practices than to biomedical research.

Where does the problem of vague concepts and unclear distinctions come from? When national systems of research oversight were introduced in North America in 1970s, the idea was to articulate a set of general ethical principles, leaving research

institutions the task of their interpretation. This initiative can be seen as congruent with responsive law and regulation, new governance, and soft law approaches.¹¹¹ Research institutions, by establishing research ethics committees within their limits and by delegating them the authority of deciding on ethical matters, would create a local and contextual approach to ensuring the safety of research involving humans. It was expected that institutional ethics committees will be flexible in interpreting and applying general ethical principles to individual research projects, building on and benefitting from their expert knowledge of available resources and researched populations in their various dimensions.

A priori, this may look like a good approach, but in practice this resulted in an opaque, expensive and expansive regulatory regime with a reductionist understanding of research ethics, insensitive to the specifics of research situations and methodologies, lacking consistency in decision making, and not capable of assessing its contribution to the protection of human participants beyond procedural indicators, to name some of the critical issues with prospective ethics review.

Policymakers and REB professionals generally respond to the criticisms of ethics review by insisting that the overall conceptual and regulatory framework is good for

¹¹¹ Burris, "Regulatory innovation in the governance of human subjects research: A cautionary tale and some modest proposals."; Philippe Nonet and Philip Selznick, *Law and society in transition: toward responsive law* (Octagon Books, 1978).
; Ayres and Braithwaite, *Responsive regulation : transcending the deregulation debate*.

the social sciences.¹¹² They tend to explain existing issues in terms of limited resources available to research ethics boards and poor understanding of their mission by researchers. Thus, what needs to be done is to allocate more financial and human resources to research ethics boards, and to *educate* researchers about the risks of research, goals of research ethics oversight, and constitutive elements of a successful ethics application.

In other words, policymakers deflect the criticisms of the conceptual framework and its implementation and consider further expansion of ethics oversight as a solution to current problems. Since SSH researchers are generally not trusted, their feedback regarding the governance of research involving humans does not receive proper consideration. Instead, policymakers assume that SSH researchers lack adequate understanding of the mission of the *Tri-Council Policy Statement* and research ethics boards; and hence the situation can be addressed through online certification programs, such as the *TCPS 2: CORE (Course on Research Ethics)*,¹¹³ and better training in procedural research ethics by offering *REB 101* and “best practices” workshops.¹¹⁴

¹¹² See for example, my analysis of “The Great debate: Be it resolved the Tri-Council Policy Statement is a good standard for which to review research in the social sciences and humanities” at CAREB National Conference in Calgary in April 2013. Gontcharov, “Alternative Models of Ethical Governance in Research Involving Humans: Towards the 2015 New Brunswick-Otago Declaration on Research Ethics?”

¹¹³ *TCPS 2: CORE (Course on Research Ethics)*. <https://tcps2core.ca/welcome>

¹¹⁴ Mueller, “Ignorance is Neither Bliss Nor Ethical.”

Again, the context of the online course is largely biomedical, and it omits mentioning that prospective ethics review emerged as a way of ensuring the safety of government-initiated and sponsored studies. The purpose of the course is to impute a complex of shared guilt,¹¹⁵ thus legitimating the system of oversight in general.

With each update of the *Tri-Council Policy Statement*, the *Interagency Advisory Panel on Research Ethics* and the supporting *Secretariat on Responsible Conduct of Research* act less and less as an agency that initially planned to draft a consensus-based set of guidelines, representing various perspective of research ethics, as it is stated in the first edition, but as an agency that has a superior understanding of research ethics, and thus has to assume the task of ethics education, rather than listening and learning from researchers, building on the existing communities of practice, sponsoring the transfer of knowledge, creating platforms for sharing of best research practices and discussing actual ethical challenges that are relevant to particular disciplines and communities. The first *Tri-Council Policy Statement* acknowledges different approaches to research ethics, and expresses a wish to become an arena for ethical deliberation, by promoting consensus on the most challenging issues. However, an ethical pluralist approach to research ethics has not

¹¹⁵ A good example of this approach is an instructional film accompanying the IRB Guidebook, "Evolving Concern: Protection for Human Subjects, Part 1, and The Belmont Report: Basic Ethical Principles and Their Application, Part 2," National Institute of Health and the Food and Drug Administration, National Institute of Health and the Food and Drug Administration. <http://videocast.nih.gov/ram/evolving.ram>; "IRB Guidebook," ed. OHRP (1993).

been sufficiently enabled at the level of policymakers and individual research ethics boards either structurally or procedurally.

Another feature of the biomedical conceptual framework helps to understand why the regulators of research involving humans are conservative in revising their own assumptions. Research disciplines may conceptualize research situations differently in respect to power relationships. For example, Boser, who uses a Foucauldian approach, argues that tensions between participatory researchers and research ethics boards are caused by different operative understandings of power.¹¹⁶ REB professionals rely on a hierarchically-structured concept of power, *power as dominance*, assuming that researchers have *power over* their human participants. On the other hand, participatory researchers do not operate from within this “power over” perspective, since the context presupposes a more nuanced, multidimensional understanding of power, in which even the very distinction between researchers and participants may be blurred or even irrelevant.

When research ethics boards insist on the universality of the *power as dominance* perspective, they distort the ethico-methodological dimension of many research situations. This may also force researchers to act unethically (in a procedural understanding of ethics), in order to ensure their research integrity within a

¹¹⁶ S. Boser, "Power, ethics, and the IRB - Dissonance over human participant review of participatory research," *Qualitative Inquiry* 13, no. 8 (2007).

particular fields of knowledge or research methodology. For example, researchers may promise to hand out consent forms to the participants (i.e., to seek free and informed consent), since the form is a precondition of approval, but never use it. Researchers realize that (free and informed) consent forms may ruin their research situation, since research participants may experience an ethics rupture, questioning the existing relationships of trust between them and researchers, and thus refusing to participate. In critical policy and criminological research, where it may be desirable to conceal the very fact of research, seeking free and informed consent is not even a viable option.

There are known challenges concerning knowledge transfer between expert systems and people on the spot.¹¹⁷ It takes time for the information about a particular situation to reach the panel of experts, who then take time to process it and transmit their decisions back. By the time it reaches people on the spot, its value may be significantly diminished. The flow of information is *funneled*¹¹⁸ and stripped of many details constitutive to situational research ethics. This challenge becomes more acute, if the information has to undergo conceptual conversion, such as when travelling between the frameworks with different understandings of power.

¹¹⁷ F.A. Hayek, "The Use of Knowledge in Society," *The American Economic Review* 35, no. 4 (1945).

¹¹⁸ McDonald, *The Governance of Health Research Involving Human Subjects (HRIHS)*.

Research ethics boards as a governance node in the system of research oversight based on prior approval of research initiatives receive limited feedback from researchers *doing* research, rather than *planning* it. When researchers need to modify something in their research, the change has to be approved. Research ethics boards do not allow making changes “on the fly”, which would imply delegating ethical authority to researchers themselves. In other words, any change in research is considered to be a change in research design (protocol/scheme/form) and, hence, requires ethics approval.

Haggerty suggests that “ethics creep” is an outcome of the expanding semantics of the key concepts of the *Tri-Council Policy Statement*.¹¹⁹ For example, the concept of research first narrowly formulated as a systematic way of data collection with intent of contributing to generalizable knowledge in a medical context gradually expands to embrace any kind of knowledge production, such as Augusto Boal’s dramaturgy¹²⁰ as a way of learning and releasing social traumas, or community-based research, generally speaking. Once the new fields of knowledge production have been captured by the system of ethics oversight, research ethics boards apply a reductionist positivist understanding of research. Accordingly, conceptual expansion and reduction go hand in hand in “colonizing” and inscribing knowledge production in other fields in a traditional biomedical positivist framework, insisting

¹¹⁹ Haggerty, "Ethics Creep: Governing Social Science Research in the Name of Ethics."

¹²⁰ Augusto Boal, *Theatre of the oppressed*: (Urizen Books, 1979).

on privacy, anonymity, generalizability, free and informed individual paper-based consent, vulnerability, personal data, or risk of harm to participants. Research ethics forms, used by research ethics boards reflect this conceptual framework, thus making it difficult to propose and pursue anything that deviates from the standard.

Research ethics boards understand research not just in terms of academic research, that is in terms of practices intended to advance scholarship, but all research on campus and beyond, for example, exit surveys of graduates, or student research, none of which are conducted with intent to broaden epistemic horizons.¹²¹ In the concept of “research involving humans,” the human involvement component is treated very broadly and the prerogative of determining the non-involvement of humans rests with REB professionals, who also determine whether proposed research is minimal risk of harm or above.

Originally, “risk of harm” was understood in terms of physical or lasting psychological harm, but the principles of human dignity in the first *Tri-Council Policy Statement* suggested an emphasis on privacy thus expanding the understanding of harm in terms of social, professional, and economic standing. Since the likelihood of physical and lasting psychological harm in SSH research is remote, the emphasis shifts to possible reputational harms and/or challenges to participants’ worldview and system of beliefs. In critical policy research, for example, this is a definite

¹²¹ Haggerty, "Ethics Creep: Governing Social Science Research in the Name of Ethics."

possibility, while the benefits of individual projects may not be immediately possible to assess at all. Furthermore, as I argue in the *Methodological Crisis* chapter, the harm-benefit analysis is generally reduced to the analysis of harm, since in the *Tri-Council Policy Statement* the utilitarian risk management approach contradicts a broader deontological framework.

ON BEING AND APPEARING ETHICAL

Another reason for the expansion of ethics oversight, identified by Gunsalus, consists in “the desire not simply to be ethical, but to appear ethical,” which prompted research institutions to give preference to general assurance over limited assurance.¹²² In other words, research institutions were willingly extending the *Common Rule* to non-federally funded research. The extension of ethics oversight to non-government funded research by research institutions themselves was prompted by such consideration as demonstrating loyalty to federal sponsors, saving resources on developing new ethics codes, or through realization that the *Common Rule* is becoming a new standard of care. The adoption of the external

¹²² Gunsalus et al., "The Illinois White Paper: Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep"," 628.

standard helped to elevate the *Common Rule* approach to ethics oversight to its current universal and cross-disciplinary status.

The need to “appear ethical” in the eyes of research ethics boards motivates individual researchers to adopt the standard positivist understanding of research ethics on the procedural level, abandoning any methodologies and themes that deviate from it, or attempting to inscribe them into the existing templates. This is the main reason for the ongoing erosion of ethics in research involving humans. From a procedural standpoint of research ethics boards, *appearing ethical* is more important than *being ethical*, since prospective review can only deal with appearances. But if the look of things is more important than things themselves, then it is important to interrogate the operative concept of ethics in the governance of research involving humans.

Regarding the impact of prospective ethics review on research ethics it has been noted that researchers’ intrinsic ethics gives way to rule following and bureaucratic compliance, thus depleting the ethical dimension of researchers, at least in their interaction with research ethics boards.¹²³ Rule following and self-censorship to satisfy procedural criteria and appear ethical have become the new standard of ethical conduct in research involving humans. The constitutive elements of

¹²³ Haggerty, "Ethics Creep: Governing Social Science Research in the Name of Ethics."; M. Koro-Ljungberg et al., "The technologies of normalization and self - Thinking about IRBs and extrinsic research ethics with Foucault," *Qualitative Inquiry* 13, no. 8 (2007).

externalized ethics include filling out prescribed ethics forms and adopting recommended language and consent forms, patiently awaiting ethics approval, and introducing recommended changes, even if they pose new risk of harm to human participants. An ethical researcher acknowledges the ethical authority and superiority of research ethics boards, completes the online certification program and attends “best practices” workshops.

A reductionist understanding of research leads to a reductionist understanding of research ethics as expressed in the documents submitted for ethics approval by REB members and professionals. When research ethics boards consider research prospectively, they can only review the ethics of stated research intentions. Deviation from the required procedural standard serves as a proxy for the risk of harm to human participants. Accordingly, a missing comma, an “incorrect” font, or “none” in the field “risks to human participants”, which REB professionals take as a personal insult, “because there are so many things that could go wrong in research”, may be taken as evidence of poor research ethics.

MANAGING LEGAL RISKS

The final reason of ethics creep that will be discussed here is that ethics committees were seen as a convenient instrument for managing legal risks.¹²⁴ I discuss the processes of professionalization in ethics review, and the emergence of REB lawyers (health law and privacy, in particular) as a new group of experts in research ethics in *Observers, Community and Legal Members on REBs*. This process was triggered by the growing normative complexity of ethics review, but was also supported by the operative biomedical framework that included the human rights language. The growing prominence of lawyers on research ethics boards and in the *Secretariat on Responsible Conduct of Research* of the *Interagency Advisory Panel on Research Ethics* has affected the way ethics is understood in research involving humans. This influence can be seen in the emphasis on contractual understanding of research participation, reinterpretation of the “balancing harms and benefits” objective in terms of risk management, and prioritization of legal risks. While the lawyerization of ethics review is itself an example of ethics creep, this process has been especially challenging for research in the social sciences and humanities.

¹²⁴ Gunsalus et al., "The Illinois White Paper: Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep"."

The concept of human rights played an important role in understanding the limits of human subjects research in biomedical sciences. It questioned the dominant understanding of power relationships between researchers and human subjects. It triggered paradigmatic changes that accompanied the adoption of the concept of human participants, thus beginning to redefine research involving humans in terms of active participation, awareness, initiative, and equality, presumably bringing it closer to how researchers in the social sciences and humanities understand the human dimension of knowledge production. I discuss the reasons and implications of these changes in *The Eclipse of "Human Subjects" and the Rise of "Human Participants" in Research Involving Humans*, noticing that the underlying conceptual framework of the *Tri-Council Policy Statement* has not been challenged and thus the concept of human participants will have a limited role in bringing research ethics review closer to the actual ethical challenges in the social sciences and humanities.

POOR COORDINATION BETWEEN GOVERNANCE NODES IN THE REGULATORY SPACE OF RESEARCH INVOLVING HUMANS

The *Tri-Council Policy Statement's* understanding of the regulatory space in research involving humans is largely limited to research institutions and research ethics boards. Meanwhile there are many other policy actors which operate in the same

regulatory space, including academic journals, funding agencies, academic and professional associations, university departments, centers and other communities of research practice, paradigmatic circles, various territorial and virtual communities, and of course, researchers and participants, all of whom influence the processes of knowledge production. These policy actors can be understood as governance nodes, which have their own resources, modes of thinking, and technologies.¹²⁵

Since the Policy introduces ethics review as a singular mechanism ensuring ethical standards in research involving humans without any need for coordination with other nodes, this may willingly or not undermine the work of other nodes. For example, it is becoming standard for academic journals to request evidence of ethics approval when accepting research articles for publication. Although this practice is still limited to the biomedical field, it may expand to the social disciplines in the near future. The downside of this process is that academic journals may start withdrawing from the regulatory space, transferring ethical issues to research ethics boards, despite being in a better position to review the ethics of the actual research, beyond the proposal stage that is accessible to research ethics boards. Similarly, ethics workshops, offered by REB professionals, may undermine local communities of practice, serving as an argument for administrators for limiting the place of research ethics training in the curriculum.

¹²⁵ Scott Burris, Peter Drahos, and Clifford Shearing, "Nodal governance," *Australian Journal of Legal Philosophy* 30(2005).

Since ethics review was extended to SSH research without justifying its need and effectiveness, without mapping the regulatory space and understanding the role of various nodes in research ethics, it becomes rather difficult to isolate the contribution of prospective ethics review in maintaining ethical standards in research involving human. Accordingly, the *Panel on Research Ethics* can claim the contribution of other nodes, while ascribing the failures to other peer review mechanisms, individual researchers and research teams, since it does not oversee the actual research. The “appropriated” contribution of other nodes can be further used by the regulators as a justification for an expansive regulatory regime. In fact, it may turn out that the contribution of the *Tri-Council Policy Statement* to ethics education, and other stated objectives, such as the reduction of the risk of harm to human participants is negligible or even negative.¹²⁶

A view that prospective ethics review by research ethics boards is the only necessary and sufficient instrument ensuring proper research standards, which requires no coordination with other governance nodes, is an obstacle to regulatory innovation in the governance of research involving humans.

¹²⁶ David A. Hyman, "Institutional Review Boards: Is This the Least Worst We Can Do?", *Northwestern University Law Review* 101, no. 2 (2007).

ONE-SIDED REGULATORY INITIATIVES

The literature on REB oversight discusses numerous regulatory initiatives. Most of them, however, deal with the procedural aspects of ethics review, such as proposals related to centralization, standardization and coordination between institutional ethics committees, or to required expertise, duration of review, quorum and voting procedures, criteria for expedited and full board review, presence of researchers, certification of REB professionals and accreditation of individual boards, recognition of other boards' ethical decisions via introduction of the board of record model or similar mechanisms, among others. The number of initiative that challenge the conceptual basis of ethics review, its suitability and effectiveness for all research disciplines, or offering alternatives to prospective research ethics review is significantly smaller. These initiatives are most often raised by SSH researchers. *The Ethics Rupture: Exploring Alternatives to Formal Research Ethics Review*, 2016, edited by Will van den Hoonaard and Ann Hamilton is the latest and most comprehensive collection of papers on this subject, to which I contributed Chapter 13, *The Eclipse of "Human Subjects" and the Rise of "Human Participants" in Research Involving Humans*. Also, in the forthcoming article *Alternative Models of Ethical Governance in Research Involving Humans* I discuss the *New Brunswick Declaration* as a ground up

approach to articulating a set of ethical principles that would better reflect the position of SSH researchers and participants.¹²⁷

These regulatory proposals commonly emphasize a shortage of independent empirical data on the institution of ethics review, as well as the need for the regulators themselves to adopt an evidence-based approach. Our knowledge on the impact of ethics review on SSH research, its ethics and methodology is limited. There is also no data that could shed light on the contribution of research ethics boards *vis-à-vis* other actors in the regulatory space of research involving humans. It is necessary to highlight the importance of (auto)ethnographic narratives of research ethics review,¹²⁸ and documenting those aspects of research ethics review that might be lost when knowledge is reduced to systematically collected and generalizable data. "IRB horror stories"¹²⁹ and similar first-hand encounters¹³⁰ are very important for understanding the phenomenon of ethics review in the social sciences and humanities. Since the criteria for evaluating research ethics boards' performance remain exclusively procedural, it is particularly important to identify the fault lines in the research ethics terrain. Such criteria as the length of review or

¹²⁷ Gontcharov, "Alternative Models of Ethical Governance in Research Involving Humans: Towards the 2015 New Brunswick-Otago Declaration on Research Ethics?."

¹²⁸ Lee Murray, "Research Ethics Boards: Are They Ready for Autoethnography?," in *The Ethics Rupture: Exploring Alternatives to Formal Research-Ethics Review*, ed. Will C. van den Hoonaard and Ann Hamilton (University of Toronto Press, 2016).

¹²⁹ Michael Kleiman, "The IRB Horror Show,"

http://www.samefacts.com/archives/science_and_its_methods_/2009/05/the_irb_horror_show.php.

¹³⁰ Carol Rambo, "Handing IRB an Unloaded Gun," *Qualitative Inquiry* 13, no. 3 (2007).

number of approved projects, do not give a comprehensive understanding of the boards' contribution to research ethics.

Haggerty notes that it takes an insider to expose the expansion of REB oversight. The reason for this is a deficit of transparency of the institution of ethics review.¹³¹ Research ethics boards communicate their decisions to researchers, but the "ethics kitchen" remains generally inaccessible. It is hard to observe directly how research ethics boards interpret and apply the *Tri-Council Policy Statement*. Furthermore, research ethics boards have a conflict of interest in reviewing critical policy studies on ethics review. It is hard to expect that they would be interested in facilitating research initiatives that could potentially challenge or undermine the institution of prospective ethics review. For example, Haggerty refers to a study, rejected by his research ethics board, which intended "to measure the participation rates of research subjects when different styles of informed consent forms were used."¹³² This example shows that research ethics boards may, perhaps inadvertently, but nonetheless effectively, filter off research initiatives that could shed light on the effectiveness of the instruments they use. In this case, consent forms for individuals are generally taken by research ethics boards as a standard way of documenting free and informed consent, suppressing other methods of consenting to participation and documenting consent. I had a similar experience in getting ethics

¹³¹ Haggerty, "Ethics Creep: Governing Social Science Research in the Name of Ethics."

¹³² Ibid., 406.

approval for this study, which I documented in *Observers, Community and Legal Members on REBs*. Not only the board reviewing my ethics application did not raise a concern about potential conflict of interest in reviewing a study on ethics review that could potentially involve them, but it also applied an institutional policy that is more restrictive than the *Tri-Council Policy Statement*, thus insisting on the use of a written consent form that was inappropriate for the studied situation.

It has to be noted that written consent forms tend to erode trust between researchers and research participants. The signature does not guarantee free and informed consent; it is a trail that can be used to identify the participant, thus going against the requirement of anonymity. Written consent forms are a feature of REB oversight, which has a demoralizing effect on researchers, since they realize that they can only pass ethics by accommodating the elements that are native to research ethics boards, but potentially foreign to their projects. Accordingly, they indicate that they will use the REB approved consent form, but in reality never use them.

CHAPTER TWO: METHODOLOGICAL CRISIS IN THE SOCIAL SCIENCES:
THE NEW BRUNSWICK DECLARATION AS A NEW PARADIGM IN
*RESEARCH ETHICS GOVERNANCE?*¹³³

Ethics codification has been a burgeoning activity in the past two decades. Codes of ethical conduct¹³⁴ became an important domain of regulatory activity among governments, professions and corporations on a global scale. As a categorical imperative, codified ethics cuts across all sectors of society—from the strict ethics codes of the Mafia to that of ISS astronauts. The ongoing formalization and increasing codification of the respective rules of conduct have left their imprint on research governance and the academic and professional debate about ethical conduct. But in academia the process has taken a peculiar twist. Codes of ethics are for the most part “soft law” – guidelines, recommendations, or collections of best practices. However, in the governance of research ethics, and more specifically in research involving humans, codification has led to the emergence of a system of ethics oversight, which places a prior restraint on research activity and licenses¹³⁵

¹³³ Published in 4 (1) *Transnational Legal Theory* 146-156, DOI: <http://dx.doi.org/10.5235/20414005.4.1.146>

¹³⁴ See, for example, a collection of over 850 Ethics Codes at the Center for the Study of Ethics in the Professions at the Illinois Institute of Technology, available at <http://ethics.iit.edu/research/codes-ethics-collection>.

¹³⁵ Philip Hamburger, ‘Getting Permission’ (2007) 101 *Northwestern University Law Review* 405.

ethical conduct. Ethics oversight first emerged in biomedical and behavioral research, but expanded by late 1990s to the social sciences and the humanities, reshaping these disciplines' scholarship and ethics.

In Canada, research involving humans is governed by the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*¹³⁶ (TCPS, or “the Policy”), adopted by the major federal funders of research involving humans—the Natural Sciences and Engineering Research Council of Canada, the Social Sciences and Humanities Research Council (SSHRC), and the Canadian Institutes of Health Research (hereinafter “the Councils”). The first edition of the common Policy was adopted in 1998 and the current (second) edition in 2010. The *Tri-Council Policy Statement* is interpreted and developed by the Interagency Advisory Panel on Research Ethics (PRE). The Policy requires that institutions receiving federal funding establish or appoint research ethics boards¹³⁷ to review research involving humans.

Research involving humans is understood by the *Tri-Council Policy Statement* very expansively. “Research” is defined as “as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation” and “human participants” as “those individuals whose data, or responses to interventions,

¹³⁶ Available at www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default.

¹³⁷ They are known as Institutional Review Boards (IRBs) and Research Ethics Committees (RECs) in the USA and the UK respectively.

stimuli or questions by the researcher, are relevant to answering the research question.”¹³⁸ As a cross-disciplinary universal definition, it seeks to cover all research involving humans, spanning biomedical disciplines and the social sciences and humanities, research involving physical intervention and archival research. All research that satisfies the definition has to pass REB review.

The *Tri-Council Policy Statement* has a category of exempt research, which includes research based on publicly available information and anonymous data, observational research in public places, quality assurance and improvement studies, and creative practices.¹³⁹ In practice, however, such research also requires REB review, since “REB[s] make[] the final decision on exemption from research ethics review”¹⁴⁰ and not researchers. Thus, from a regulatory viewpoint, research ethics boards review all research involving humans, including exempt research. However, it should be noted that this does not mean that all researchers in the social sciences and the humanities, apply for REB review for every research project they conduct.

ETHICAL PRINCIPLES GOVERNING RESEARCH INVOLVING HUMANS

¹³⁸ 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* (2010), www.pre.ethics.gc.ca.

¹³⁹ *Ibid.*

¹⁴⁰ *Ibid.*

The *Tri-Council Policy Statement* emphasizes that research is a “complex” endeavor and “a step into the unknown,” which entails *risks of harm* to participants. It defines “harm” as “anything that has a negative effect on the welfare of participants, and the nature of the harm may be social, behavioral, psychological, physical or economic.”¹⁴¹ “Risk” here is “a function of the magnitude or seriousness of the harm, and the probability that it will occur.”¹⁴² The *Tri-Council Policy Statement* offers three core ethical principles that would promote research, while protecting and respecting its participants. The principles focus on *protecting* participants, rather than *promoting* research. Academic freedom and the corresponding responsibilities serve as a justification for the application of the three core (protectionist) principles. These core principles comprise *respect for persons*, *concern for welfare* and *justice*. The policy understands them as three “complementary and interdependent” ways of expressing what can be called a meta-principle—*respect for human dignity*. Accordingly, *respect for human dignity* is the ethical basis of the *Tri-Council Policy Statement*, while *respect for persons*, *concern for welfare* and *justice* are the ways to operationalize it. The *Tri-Council Policy Statement* emphasizes that core ethical principles have to be understood within the context of their application.

Although the *Tri-Council Policy Statement* suggests that the core principles are interdependent, the order in which they are listed is important for understanding its

¹⁴¹ *Ibid.*

¹⁴² *Ibid.*

ethical framework. The principle of respect for persons is a direct reflection of the meta-principle of respect for human dignity. Concern for welfare introduces and provides justification for the harm-benefit analysis as the primary analytic technique of research ethics boards. The principle of justice introduces the basic approach to risk management through the concept of vulnerability. The three core principles articulate a vision of human beings as autonomous, rational, self-interested, utility-maximizing, yet inherently vulnerable individuals who require comprehensive protection. This understanding is decisive for conceptualizing research situations and elaborating measures for protecting human participants.

REB COMPOSITION AND ETHICS REVIEW PROCESS

When research institutions establish or appoint research ethics boards, they delegate to them the authority to approve, recommend changes to, reject or terminate research on ethical grounds. Research institutions have to ensure that research ethics boards are independent in their decision-making. Striving for diversity, balanced disciplinary expertise, representation and social accountability, research ethics boards include men and women, and consist of experts in research

methodology, ethics and law,¹⁴³ as well as community members. Their review method is twofold: one focusing on future research projects—*prospective review*, and the other as a process that accompanies ongoing research undertakings—*ongoing review*. Prospective review relies on the analysis of submitted research projects, whereas ongoing review generally takes the form of periodic review, and relies on researchers' reporting, rather than engaging in actual monitoring of the ongoing research.

Ethics review is a means of risk management in research involving humans and as such adopts a proportionate approach, adjusting the level of scrutiny to the nature of the risk involved. Research that is assessed by REB professionals as not exceeding minimal risk can be delegated for review to REB member(s)—*delegated review*. All other research is reviewed by a full board—*full board review*. In reviewing research, REB members are guided by the core principles—*respect for persons, concern for welfare and justice*. Despite the fact that the ethical framework of the *Tri-Council Policy Statement* is deontological, since it is based on the concept of human dignity and articulates researchers' duties to human participants, the way research ethics boards are required to review research projects is utilitarian, since it relies on balancing the risks and potential benefits of the research. A conflicting set of ethical principles unavoidably affects the decision-making of research ethics boards. For

¹⁴³ The requirement to include members knowledgeable in the relevant law is mandatory for biomedical research only.

example, the balancing of risk and benefits may be understood to be inconsistent with the principle of human dignity. Accordingly, the deontological framework would be given precedence and require an application of a more narrow risk management approach, rather than the one involving balancing of harms and benefits. For example, if research involves “vulnerable populations,” research ethics boards may use this concept as a proxy for identifying research exceeding minimal risk, and inadvertently limiting it. Such an outcome would be contrary to the intention of the *Tri-Council Policy Statement* not to exclude humans in vulnerable circumstances from the benefits of research.

BROADER REGULATORY LANDSCAPE IN RESEARCH INVOLVING HUMANS

Research involving humans is not confined to national boundaries and is subject to multiple overlapping private and public ethics codes and regulatory regimes. National approaches to research ethics are elaborated in dialogue with existing international and transnational regulations and guidelines. The most influential on the list are the ten basic principles of permissible medical experiments introduced

by the US military court, better known as the “Nuremberg Code.”¹⁴⁴ These principles formed part of the judgment in the Doctors’ Trial in Nuremberg, in 1946–7.¹⁴⁵ The Nuremberg Code was followed by the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (1964)¹⁴⁶ of the World Medical Association, the International Ethical Guidelines for Biomedical Research Involving Human Subjects (1982)¹⁴⁷ of the Council for International Organizations of Medical Sciences, Guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use,¹⁴⁸ and the UNESCO Universal Declaration on Bioethics and Human Rights (2005).¹⁴⁹ In addition to this list, one of the most important influences in developing Canadian policy in research involving humans was the *Belmont Report*,¹⁵⁰ which served as a basis for the 1981 US Federal Human Subjects Protection Policy,¹⁵¹ known as the “Common Rule” since it has been adopted by 17 federal agencies and offices.

¹⁴⁴ *Trials of War Criminals Before the Nuernberg Military Tribunals under Control Council Law No 10*, vols 1 and 2 (Nuernberg Military Tribunals October 1946–April 1949), www.loc.gov/rr/frd/Military_Law/NTs_war-criminals.html.

¹⁴⁵ For a discussion of the place of the Nuremberg Code in the institutional history of ethics review, see R. Dingwall, ‘The Ethical Case against Ethical Regulation in Humanities and Social Science Research’ (2008) 3 *Twenty-First Century Society* 1.

¹⁴⁶ [www.who.int/bulletin/archives/79\(4\)373.pdf](http://www.who.int/bulletin/archives/79(4)373.pdf).

¹⁴⁷ www.cioms.ch/publications/layout_guide2002.pdf.

¹⁴⁸ www.ich.org/products/guidelines.html.

¹⁴⁹ www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights.

¹⁵⁰ www.hhs.gov/ohrp/humansubjects/guidance/belmont.html.

¹⁵¹ 45 Code of Federal Regulations, Part 46: Protection of Human Subjects (Department of Health and Human Service June 23, 2005), www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

Ethical codes that inspired the development of Canada's harmonized policy in research involving humans have a distinguishing feature—they represent a vision of ethical conduct in the field of biomedical research. This explains why the virtues of the *Tri-Council Policy Statement* are such as they are—no harm principle, focus on individuals rather than collectivities, anonymity, privacy, free and informed consent. Their presence in the *Tri-Council Policy Statement* is informed and necessitated by the past and present ethical challenges in biomedical research, and reflects a particular understanding of research, the types of human involvement, and the status of human participants. According to this understanding, also known as positivist, research unfolds sequentially, following research protocols. There is a clear distinction between researcher and researched. Hence research participants are research subjects, vulnerable and engaged in vertical power relationships. It has to be noted that the 2010 *Tri-Council Policy Statement* introduced a number of changes to make its language more familiar to the social sciences and humanities. For example, the Policy now refers to “human participants” instead of “human subjects,” “research projects” instead of “research protocols,” and refrains from essentializing “vulnerable populations,” preferring the concept of human participants in “vulnerable circumstances.”¹⁵²

¹⁵² *Tri-Council Policy Statement* (n 6).

Ethics review is a dynamic and fast-growing industry which has given rise to a new profession.¹⁵³ It is also an industry that directly influences how and what research is conducted domestically, affecting the competitiveness of national research markets, such as clinical trials. For example, REB review is considered to be a factor behind a dramatic decline in Canada's share of the global market of clinical trials.¹⁵⁴ Ethics review was initially introduced as a way of protecting research participants in federally funded medical and behavioral research. It subsequently expanded to cover all research involving humans, regardless of the source of funding, and including the social sciences and the humanities.

EXPANSION OF ETHICS REVIEW TO THE SOCIAL SCIENCES AND THE HUMANITIES

Although an understanding of research as an undertaking that unfolds sequentially according to a research protocol maps sufficiently well onto biomedical and behavioral scholarship, social scientists have long been critical of imposing it on the

¹⁵³ Also reflected in the existing certification programs, eg the Certification Program for Institutional Review Board professionals in the USA, www.primr.org/Certification.aspx?id=206. The development of a Canadian certification program for REB professionals is also underway. See www.careb-accer.org/content/professional-development.

¹⁵⁴ *Canada's Clinical Trial Infrastructure: A Prescription for Improved Access to New Medicines* (Standing Senate Committee on Social Affairs, Science and Technology, November 2012), www.parl.gc.ca/Content/SEN/Committee/411/soci/rep/rep14nov12-e.pdf.

whole spectrum of research. Nevertheless, ethics review expanded beyond biomedical research in 1998, when the three Canadian Research Councils adopted a “harmonized” approach to ethics review based on the biomedical model. The expansion of ethics review to the social sciences and the humanities has become widely known as “ethics creep,”¹⁵⁵ since it proceeded without evidence of its need and effectiveness, and without regard to valid practices of ethical governance in non-biomedical sciences. It is hardly surprising, then, that ethics review engendered multiple conceptual and practical challenges in social science research.

These challenges include the suppression of several streams of research, such as critical (eg policy or criminological) research,¹⁵⁶ introspective research and biographical research, due to unfitting requirements of anonymity, free and informed consent, and generalizability of data. Research ethics boards appeared to be poorly suited to research based on “qualitative” methodologies (ethnographic, participatory research),¹⁵⁷ research on risk-taking populations, innovative

¹⁵⁵ Kevin D Haggerty, ‘Ethics Creep: Governing Social Science Research in the Name of Ethics’ (2004) 27 *Qualitative Sociology* 391. See also Ronald F White, ‘Institutional Review Board Mission Creep: The Common Rule, Social Science, and the Nanny State’ (2007) XI *Independent Review* 547.

¹⁵⁶ See eg Ted S Palys and John Lowman, “Moving Ahead” or ‘More of the Same’? Comments on Moving Ahead: The Draft Report of the Experts Committee for Human Research Protection in Canada’ (2007), www.sfu.ca/~palys/CommentOnMovingAhead-TSP-JL.pdf. Other papers on research ethics by Ted Palys and John Lowman are available at www.sfu.ca/~palys/articles.htm.

¹⁵⁷ M Tolich and MH Fitzgerald, ‘If Ethics Committees were Designed for Ethnography’ (2006) 1 *Journal of Empirical Research on Human Research Ethics* 71; Rena Lederman, ‘Comparative ‘Research’: A Modest Proposal concerning the Object of Ethics Regulation’ (2007) 30 *PoLAR: Political and Legal Anthropology Review* 305; S Boser, ‘Power, Ethics, and the IRB: Dissonance over Human Participant Review of Participatory Research’ (2007) 13 *Qualitative Inquiry* 1060; Charles L Bosk, ‘The New

methodologies, such as community-based research, which blurs the border between researchers and research participants, research on vulnerable populations, and educational research.¹⁵⁸ Most importantly, ethics review in the social sciences was adopted without sufficient evidence of its need and effectiveness. While there is data on the costs of ethics oversight, there is no evidence of a positive contribution to public safety or better research ethics.¹⁵⁹

Despite the challenges of a harmonized approach¹⁶⁰ to research governance, the SSHRC continues to support the development of a common cross-disciplinary research policy that would speak to the tasks and methods of the social sciences. This is evident in the new edition of the *Tri-Council Policy Statement*, which speaks in a fresh language of human participants and research projects and avoids “human subjects” and “protocols.” But on the whole, the 2010 edition of the *Tri-Council Policy Statement* still relies on the biomedical standard of prospective ethics review as a universal approach to ethical governance in research involving humans. Meanwhile, the regulatory context is currently undergoing a major transformation,

Bureaucracies of Virtue, or When Form Fails to Follow Function’ (2007) 30 *PoLAR: Political and Legal Anthropology Review* 192.

¹⁵⁸ Will C van den Hoonaard, ‘Trends in Canadian Sociology Master’s Theses in Relation to Research Ethics Review, 1995–2004’ (2006) 1 *Journal of Empirical Research on Human Research Ethics: An International Journal* 77.

¹⁵⁹ John H Mueller, ‘Ignorance is Neither Bliss Nor Ethical’ (2007) 101 *Northwestern University Law Review* 809; David A Hyman, ‘Institutional Review Boards: Is This the Least Worst We Can Do?’ (2007) 101 *Northwestern University Law Review* 749.

¹⁶⁰ For an overview of the challenges, see eg Katharina Pistor, ‘The Standardization of Law and its Effect on Developing Economies’ (2002) 50 *American Journal of Comparative Law* 97.

since the social sciences proceed from voicing concerns and producing evidence of the *Tri-Council Policy Statement's* questionable moral guidance, to actively discussing alternatives to ethics review.¹⁶¹

FROM THE SEDUCTION OF ETHICS TO ETHICS RUPTURE

Although the scholarship that exposes how ethics review affects research practices in the humanities and the social sciences, as well as everyone involved in the research process, has been growing steadily, there are few book-length studies devoted specifically to this subject. Furthermore, the existing scholarship has a predominantly US focus.¹⁶² The new study under review here, Will van den Hoonaard's *The Seduction of Ethics*, is the first monograph that focuses on the Canadian experience. It is written by someone with wide experience and expertise in the field of research ethics governance. Professor emeritus Dr Will van den

¹⁶¹ Alternatives to ethics review was a theme of a recent academic event, 'Ethics Rupture: An Invitational Summit about Alternatives to Research-Ethics Review', Fredericton, New Brunswick, 25–28 October 2012.

¹⁶² See Ann Hamilton, 'Institutional Review Boards: Politics, Power, Purpose and Process in a Regulatory Organization' (PhD thesis, University of Oklahoma, 2002); Laura Stark, 'Morality in Science: How Research is Evaluated in the Age of Human Subjects Regulation' (PhD thesis, Department of Sociology, Princeton University, 2006); Zachary Schrag, *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965–2009* (Johns Hopkins University Press, 2010).

Hoonaard is a founding member of the Interagency Advisory Panel on Research Ethics.

By studying the world of research ethics boards and examining the process of ethics review and its impact on the social sciences, the book offers evidence of the ongoing methodological and substantive transformation of social science scholarship. Methodological diversity and richness of the social sciences is declining under the pressure of ethics review. The monograph's central theme and concern is the ongoing homogenization and pauperization of the social sciences, a methodology and knowledge crisis manufactured by the system of ethics oversight.

The Seduction of Ethics is a critical study of the current system of ethics review, the system that is based on the biomedical understanding of research. It is also a self-critical study as it comes from one of the architects of this system. Van den Hoonaard, a sociologist and professor emeritus at the University of New Brunswick, opens *The Seduction of Ethics* with a personal narrative, in which he admits that he initially adhered to the possibility of developing a common, universal approach to research ethics through collaborative work with experts in bioethics. However, under the weight of the growing evidence, which suggests that the current system of ethics review is neither owned by the social sciences nor able to enhance its ethical dimension, his initial enthusiasm for a common, all-disciplinary approach to research ethics gave way to "pessimism." This pessimism is a result of the current methodological, ethical and regulatory impasse in the social sciences. *The Seduction*

of Ethics does not show an immediate way out of the impasse. Rather, it offers an evidence-based account of ethics review and the problems it creates in the social sciences. This account contributes to the conceptual emancipation of the social sciences, but aims at changes in the governance of research involving humans.

van den Hoonaard's present study is, by his own assessment, a "radical departure" from the biomedical approach to ethical governance and its core principles. It bids farewell to attempts to articulate a social science perspective within it, to the search for common ethical principles, and to efforts to develop an all-in-one regulatory solution that will serve the purposes of all disciplines conducting human research. As a departure from the harmonized approach adopted in the *Tri-Council Policy Statement*, the monograph is a new beginning. Nevertheless, *The Seduction of Ethics* is not a manifesto with a ready-to-implement alternative and agenda.

Instead, the book concludes with recommendations for implementation by universities, researchers and research ethics boards. Accordingly, the audience of the study is not limited to social researchers, but extends to PRE members, university administrators, REB members and professionals. Van den Hoonaard pragmatically seeks to engage multiple stakeholders in the search for an alternative "ethics". There are a number of reasons why social scientists alone can hardly be the sole agents of regulatory changes. They have not been particularly effective in

translating their concerns into policy decisions.¹⁶³ Nor are they a homogenous interest group since their understanding of science and risk involved in the production of new knowledge may vary significantly.

The Seduction of Ethics is a successor to *Walking the Tightrope: Ethical Issues for Qualitative Researchers*, a volume edited by van den Hoonaard.¹⁶⁴ As is to be expected of any perspective study, both volumes end by posing a new question. While the earlier publication asks whether it is time to proceed “towards a separate structure of ethics review”, the later work restates the question in a more radical way: “Will the social sciences wither away or is there an alternative?” Thus the question is no longer that of an alternative *ethics review* for the social sciences, but that of possible alternatives to ethics review.

THE NEW BRUNSWICK DECLARATION AS A NEW PARADIGM IN RESEARCH ETHICS GOVERNANCE

In order to explore the conceptual and regulatory alternatives to prospective ethics review, van den Hoonaard convened “Ethics Rupture: An Invitational Summit about

¹⁶³ Schrag (n 30).

¹⁶⁴ Will van den Hoonaard (ed), *Walking the Tightrope: Ethical Issues for Qualitative Researchers* (University of Toronto Press, 2002).

Alternatives to Research-Ethics Review”,¹⁶⁵ which ran from 25 to 28 October 2012 in Fredericton, NB. This unique event brought together ethical governance scholars from Australia, Brazil, Canada, Italy, New Zealand, the United Kingdom and the United States, who were given a rare opportunity to voice social science perspectives at ethics review and disrupt the bioethical monopoly on defining the principles of research ethics. Taking their cue from *The Seduction of Ethics*, the participants focused on examining the impact of ethics regimes, relations between research ethics boards and researchers, the role of knowledge in risk regulation, and existing and perspective approaches to regulatory innovation. The main outcome of the summit is *The New Brunswick Declaration: A Declaration on Research Ethics, Integrity and Governance resulting from the 1st Ethics Rupture Summit, Fredericton, New Brunswick, Canada*, dated 4 February 2013.¹⁶⁶

The *New Brunswick Declaration* addresses the concerns of *The Seduction of Ethics* and the contributors to the *Ethics Rupture* summit. It envisions an alternative approach to research governance based on ethical and methodological pluralism, which would encourage research initiative while promoting the interests of research participants. The Declaration proposes a multilateral approach, and

¹⁶⁵ Further details and podcasts of presentation are available at <http://wp.stu.ca/ethicsrupture>. See also a report on the event: Will van den Hooonaard, ‘The ‘Ethics Rupture’ Summit, Fredericton, New Brunswick, Canada, October 25–28, 2012’ (2013) 8 *Journal of Empirical Research on Human Research Ethics: An International Journal* 3.

¹⁶⁶ Available on the website of the United Kingdom Social Research Association at: http://thesra.org.uk/sra_resources/research-ethics/the-new-brunswick-declaration and on Ted Palys’ webpage at Simon Fraser University: www.sfu.ca/~palys/NewBrunswickDeclaration-Feb2013.pdf.

highlights the role of professional associations and valid research standards. It shifts the focus from individuals exclusively to individuals and collectivities. It emphasizes the necessity of promoting existing ethical communities of practice and of supporting socially embedded contextual ethics education. Importantly, it calls for continued critical examination of the system of ethics review, and collaborative elaboration of the alternatives to the current regulatory culture.

The Seduction of Ethics is a crucial source for the *New Brunswick Declaration*, and both engage critically with the biomedical monopoly on articulating the principles of ethical governance, the problems with ethics review process, and the erosion of intrinsic ethics—the process that accompanies the externalization of research ethics and the establishment of the formal system of ethics review. The book consists of 15 chapters that can be grouped into three parts: (1) archeology of ethics review, (2) ethics review process, and (3) researchers vis-à-vis formalized and externalized ethics.

The scope of *The Seduction of Ethics* makes it necessary to deal with a broad array of practical issues—from institutionalization of ethics review, to the specifics of the review process, and to social scientists' encounters with formalized ethics. The first part examines the normative ethics framework of social science researchers and explains how biomedical oversight restricts and censors the application of ethical social science methods that deviate from the prescribed ideals of positivist research, such as consent, autonomy, confidentiality and vulnerability. The second brings the

REB perspective and deals with bureaucracy, secrecy, undemocratic governance, and power imbalances in REB decision-making. The third introduces the researchers' perspective. It focuses on researchers' practices of coping with prospective ethics review, and their impact on social science scholarship.

Will van den Hoonaard offers a remarkable study from the methodological point of view: it builds on participant observation of research ethics boards; interviews with researchers, REB chairs and administrators; a focus group; and broad textual analysis (from reports to LISTSERVs). It also makes use of survey data, and unavoidably relies on the author's rich first-hand experience of participating in the Canadian research ethics regime as a PRE member (2001–5), and the first chair of the Social Sciences and Humanities Working Group on Ethics (2003–5).

Van den Hoonaard's contribution to the debate on approaches to ethical governance in the social sciences demarcates a new stage. The problem no longer lies in the necessity of substantiating the claims of and problematizing such phenomena as ethics creep or ethical imperialism. The regulatory capture has already occurred, and it is time to identify effective strategies to decolonize social scholarship. Since it has proven difficult to challenge the regulatory capture of the social sciences by offering historical and conceptual arguments,¹⁶⁷ it is necessary to redraw the line of critique and let the data showing how ethics review affects the production of new

¹⁶⁷ See especially Dingwall (n 13); Hamburger (n 3); Schrag (n 30).

knowledge speak for itself. Impact studies of ethics review are especially important, since there have been no unequivocal signs indicating that the calls for evidence-based regulation of ethics¹⁶⁸ have been received by the regulators.¹⁶⁹

The data collected by van den Hoonaard indeed speaks of the profound methodological crisis in the social sciences—at least in the academy, since the market for critical scholarship has not disappeared entirely. As van den Hoonaard suggests, there may be a nascent trend of “outsourcing” critical scholarship to the private sector, namely to journalists, which hardly serves as a plausible alternative to academic scholarship. This is especially true when the Agencies, to whom the task of knowledge promotion is given, are engaged in suppressing research initiative and maintaining an ethics regime that makes an ambiguous contribution to the social science research ethics. In this light, the *New Brunswick Declaration* offers a way out of the impasse, by embracing an ethical pluralist platform as a possibility for restarting the conversation on the principles of ethical governance in academic research.

¹⁶⁸ Michael McDonald and Susan Cox, ‘Moving toward Evidence-Based Human Participant Protection’ (2009) 7 *Journal of Academic Ethics* 1.

¹⁶⁹ The latest commissioned studies date back to the time of the 1998 *Tri-Council Policy Statement* and thus do not account for the impact of ethics review on the social sciences and the humanities. Still, they remain an important source of knowledge on the institution of ethics review. See James Bell, John Whiton and Sharon Connolly, *FINAL REPORT: Evaluation of NIH Implementation of Section 491 of the Public Health Service Act, Mandating a Program of Protection for Research Subjects June 15, 1998. Prepared for The Office of Extramural Research, National Institutes of Health* (1998); Michael McDonald, *The Governance of Health Research involving Human Subjects (HRIHS)* (Law Commission of Canada, 2000).

CHAPTER THREE: THE ECLIPSE OF “HUMAN SUBJECTS” AND THE RISE OF “HUMAN PARTICIPANTS” IN RESEARCH INVOLVING HUMANS¹⁷⁰

Until recently the concept of human research subjects¹⁷¹ was central to the conceptual framework of the system of research ethics review in Canada.¹⁷² The purpose of research ethics review was to protect human subjects from the risks of harm associated with their involvement in research. In December 2010 the three major research agencies in Canada – the Canadian Institutes for Health Research, the Natural Sciences and Engineering Research Council, and the Social Science and Humanities Research Council (the Agencies) – adopted the second edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)*. The first *Tri-Council Policy Statement (TCPS 1)* was adopted in 1998 and established

¹⁷⁰ An earlier version of this paper was published in the Osgoode CLPE Research Paper Series; Gontcharov (2012).

¹⁷¹ I use “human subjects,” “research subjects,” and “subjects” interchangeably throughout the chapter.

¹⁷² While I focus on the Canadian approach to ethics oversight, the discussion is relevant to other jurisdictions, and, in particular, to the United States. The system of oversight in the United States also exhibits similar tensions that emerged after the expansion of the system of ethics review beyond the field of biomedical research, but at the moment the United States research ethics approach remains loyal to the term *human subjects*. It is important to note that United States Federal Regulations have been and continue to be more consistent in following the language of human subjects, while the first *Tri-Council Policy Statement* was speaking already in 1998 in terms of humans rather than human subjects. Consider, e.g. the title of the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects of Research” (National Commission, 1978), and its successor, the “Federal Policy for the Protection of Human Research Subjects” (1991), whereas the subtitle of the *Tri-Council Policy Statement* (both editions) is “Ethical Conduct for Research Involving Humans.” The omission of “subjects” in the first *Tri-Council Policy Statement* can be understood as a transition point to the new language, and a point of conceptual divergence from the perspective in the United States.

the biomedical model of research ethics review as a standard of ethical governance in all research involving humans.

In agreement with the accepted biomedical terminology, the first *Tri-Council Policy Statement* used the concept of human *subjects* to refer to those humans who bear the risks of the research. The second *Tri-Council Policy Statement* features human *participants* as its new central concept. Given the potential impact of this subtle terminological change, which can be viewed as necessitating a profound revision of research ethics review and the entire approach to the governance in research involving humans, this chapter identifies reasons for the change in terminology, and proceeds as follows: After considering policy definitions and providing background on the human subjects approach to research governance, I discuss possible reasons for adopting the new language. In particular, I consider whether the new language (1) is a result of an attempt to better accommodate the social sciences and the humanities; (2) is an outcome of the responsive elements in the current regulatory framework; or (3) is a response to the performativity of *subjects* and *participants*, when the use of the concepts comes along with a corresponding philosophy and approaches to governance that are reflected in the name itself; or (4) is a combination of these options.

POLICY DEFINITIONS OF SUBJECTS AND PARTICIPANTS

The first *Tri-Council Policy Statement* preserved in an endnote an interesting fragment of the conceptual history of human *subjects*. It provides in it a rationale for preferring *subjects* to *participants*. This endnote is evidence that the development of a “harmonized”¹⁷³ approach to research governance posed a specific set of regulatory challenges that policymakers tried to address by locating an “optimal term:”

During preparation of this Policy Statement, there was extensive discussion of the optimal term to describe those on, or about whom, the research is carried out. This discussion focused on the terms “participant” and “subject.” Though research subjects may participate actively in research, so also do many others, including the researchers and their staff, administrators in the institutions, and funding sponsors and members of research ethics boards (REBs). Research subjects are unique among the many participants because it is they who bear the risks of the research. The Agencies have therefore chosen to retain the

¹⁷³ The first *Tri-Council Policy Statement* uses the term *harmonization* rather than *integration*. *Harmonization* implies that the perspectives of the social sciences will be reflected in developing a common approach to research ethics. “The Policy seeks to harmonize the ethics review process. The Agencies expect that REBs will benefit from common procedures within a shared ethical framework. This will also benefit those projects involving researchers from different disciplines or institutions. The Agencies hope that the Policy will serve as an educational resource” (TCPS 1).

word “subject” because of its relative unambiguity in this context, and because the prime focus of the Policy Statement is on those who bear the risks of research.¹⁷⁴

Twelve years later the revised *Tri-Council Policy Statement* introduces the shift from *subjects* to *participants*:

Human participants are unique among the many parties involved in research, because they bear the primary risks of the research. These individuals are often referred to as “research subjects.” This Policy prefers the term “participant” because it better reflects the spirit behind the core principles: that individuals who choose to participate in research play a more active role than the term “subject” conveys. As well, it reflects the range of research covered by this Policy, and the varied degree of involvement by participants – including the use of their data or human biological materials – that different types of research offer. The core principles of this Policy – Respect for Persons, Concern for Welfare, and Justice – help to shape the relationship between researchers and participants.¹⁷⁵

¹⁷⁴ TCPS 2: i.3, endnote 2.

¹⁷⁵ TCPS 2: 16.

In 1998 (the year *TCPS 1* was published) *research subjects* was considered a relatively unambiguous term that described those individuals who bear the risk of research. Research subjects belonged to a broader category of research participants. In the 2010 *Tri-Council Policy Statement*, the term *subjects* disappears in the body of the document, being only present in the references and in the quotation above. In place of *subjects* the policy uses *participants*, who are seen as those who bear the “primary risks” of the research. If previously research subjects were unique among research participants, now research participants are considered to be unique among “the many parties involved in research.” Importantly and a bit ironically, the second *Tri-Council Policy Statement* indicates that we are still speaking about the same individuals, only using juxtaposed labels.

The second *Tri-Council Policy Statement* offers human *participants* as a term that “better reflects the *spirit* behind the core principles” (emphasis added). While the first *Tri-Council Policy Statement* justified the choice of human *subjects* by referring to the context, the second *Tri-Council Policy Statement* refers to the *spirit* behind the core principles. The context of the first *Tri-Council Policy Statement* was largely biomedical, and it became normative for all research involving humans, thus introducing tensions in the system of ethical governance of the social sciences and humanities. A question arises: Is the “spirit” of the second *Tri-Council Policy Statement* not of the same biomedical quality? Does the concept of *participants* change and challenge in any way the vision of the second *Tri-Council Policy*

Statement in relation to the actual governance of research involving humans? Or is it merely a linguistic transplant, likely to be subsumed by the unshaken normative underpinnings of the first *Tri-Council Policy Statement* so that nothing changes except the term?

The first *Tri-Council Policy Statement* puts forth human *subjects* as the “optimal term” (and we might notice that *optimal* is originally a word in biology).¹⁷⁶ Language in the second *Tri-Council Policy Statement* is less optimistic about locating an optimal term, demonstrating a preference for human *participants* as described above. The rationale for replacing *subjects* with *participants* is not clearly spelled out in the Policy and not directly intelligible. Instead, authors of the second *Tri-Council Policy Statement* invoke the *spirit* of the core principles provoking the need for a séance to clarify the meaning of human *participants*. Irony aside, the absence of a meaningful explanation for the transition to *participants* does not mean that there is a lack of explanations for the ongoing conceptual overhaul of the *Tri-Council Policy Statement*. Was the replacement of *subjects* with *participants* motivated by the participatory mindset of policymakers? Was the change an outcome of the tensions produced by the subsuming of social research into an ethical governance framework designed for biomedical research?

¹⁷⁶ E.g., <http://www.etymonline.com/index.php?term=optimal>

THE HUMAN SUBJECTS APPROACH TO RESEARCH GOVERNANCE

From the viewpoint of governance, the adoption of *participants* may serve as a focus for profound changes in the regulatory approach. In order to understand how this shift in terminology may transform research ethics review, it is necessary to clarify why this change is taking place at all. Consider three aspects of this question – factual, comparative, and programmatic. First, it is important to determine what happened that made the term *human subjects* problematic. Did the concept itself become a conceptual and practical hurdle to be overcome? Second, why is the concept of *participants* used to replace *subjects*? Were alternatives considered? Finally, what are the limitations and implications of the old and new language for the ethics of human research? What has *happened* as a result of this change? What might happen?

Prior to the second *Tri-Council Policy Statement*, the very experience of being a research subject was a problem for policymakers. This problem emerged as a result of a growing awareness that some biomedical and behavioral experiments in Canada are conducted unethically – under pressure, without consent and without disclosing information about foreseeable risks, and involving vulnerable populations including prisoners and psychiatric patients. Accordingly, the task was to develop a regulatory approach that would effectively limit such activities; the result was the protectionist mindset of the first *Tri-Council Policy Statement*,

incorporating a risk-management approach based on free and informed consent and concerned with special protections for vulnerable populations.

In human subjects research, researchers are viewed as possessing certain “power over”¹⁷⁷ their research subjects, who are seen as vulnerable and defenceless. The relationship between the two parties is hierarchical, and accordingly, there is a possibility for abuse, given the fact that biomedical researchers are prone to conflicts of interest. In this situation the state is expected to intervene and protect vulnerable subjects by developing, implementing, and maintaining a system to oversee research institutions and researchers. Importantly, the first *Tri-Council Policy Statement* implied that the experience of research subjects is a universal trans-disciplinary phenomenon, requiring an omni-disciplinary (i.e., to include all academic disciplines, research methodologies, or research situations) application of protectionist measures. Because the biomedical approach was used as a normative basis for the integrated system of research ethics review, it mandated the mechanism of risk management for all research involving humans.

¹⁷⁷ Boser, "Power, ethics, and the IRB - Dissonance over human participant review of participatory research."

THE CHALLENGE OF PARTICIPANTS

The adoption of human *participants* demarcates a conceptual end of the human *subjects* approach to risk management. The new approach corresponds to the participatory philosophy of the concept of *participants*. While overcoming the *subjects* in human *participants* remains a problem, the focus now falls on ensuring that human *participants* are indeed participants and not merely humans involved in research.

The task can no longer be reduced to protectionism, to acting on behalf of human *subjects*. It must go beyond determining the degree of risk to participants, checking for conflicts of interest among researchers, and ensuring that researchers seek free and informed consent. The task now is to empower human *participants*, to awaken their agency, and to engage them in the research process as partners. In other words, the new concept emerges as a direct challenge to the “nanny state”¹⁷⁸ and the patriarchal modes of conceptualizing the research process.

Such items in the regulatory agenda emerge if we deal primarily with the semantics of the concept of participants, which is not sufficient, given the complexity of the context and specific trajectory of ethical governance in research involving humans

¹⁷⁸ White, "Institutional Review Board Mission Creep: The Common Rule, Social Science, and the Nanny State."

in the past decades. This included the problems that emerged in the process of adopting a common standard of research ethics review as a universal approach to the governance of research involving humans. Accordingly, the semantics of *participants* and the participatory philosophy rendered by the concept and embedded within the overall conceptual framework of the second *Tri-Council Policy Statement* should be considered in the context of the ongoing efforts to standardize research ethics review.

If we focus on the semantics alone, the change in language may appear as a progressive step, an institutional achievement, but in practice, the new language has encountered the limitations similar to those that prompted the dismissal of its predecessor. When research ethics review expanded to the social sciences, human *subjects* was used as a universal cross-disciplinary concept, but it did not fare well in this capacity; it poorly reflected how research is approached in the social sciences and the ways of human involvement in it. The concept of *participants* is no more likely to succeed as a universal concept. Indeed, it may be able to relieve some of the tensions (including those stemming from the weak integration of the social science perspectives), but unavoidably, it will engender new ones. The concept of *participants* is not applicable in some biomedical research situations. For example, a person in a coma can hardly give consent. Moreover, a universal application of human *participants* may harm a number of research fields and methodologies in the social sciences, including critical policy and public health research, or criminological

research, for example, in observational studies or research on corruption in public offices, when it is crucial that “participants” do not act as co-researchers, but continue to engage in their routine activities.

As long as the problem of integrating the social sciences into the existing model of ethics oversight is approached superficially, rather than through a substantial revision of the foundation of the system, it will be challenging to locate a single satisfactory term. In a revised approach to research governance, the task of locating a suitable universal term may no longer be on the agenda. Further, any presumably universal social science research concept, such as human *participants*, or *research projects*, changes meaning when transplanted to the biomedical conceptual framework of the *Tri-Council Policy Statement*. Accordingly, the problem of the “optimal term” can hardly be addressed until the *Tri-Council Policy Statement* embraces an ethical/legal pluralist framework¹⁷⁹ and welcomes social disciplines individually, rather than treating social research as a homogenous entity.

¹⁷⁹ Sally Falk Moore, "Law and Social Change: The Semi-Autonomous Social Field as an Appropriate Subject of Study," *Law & Society Review* 7, no. 4 (1973); John Griffiths, "What Is Legal Pluralism?," *Journal of Legal Pluralism and Unofficial Law* 24, no. 1 (1986); Marc Galanter, "Justice in Many Rooms: Courts, Private Ordering and Indigenous Law," *Journal of Legal Pluralism* 19, no. 1 (1981); Sally Engle Merry, "Legal Pluralism," *Law & Society Review* 22, no. 5 (1988).

RESEARCH PARTICIPANTS AS A WAY OF RESPONSIVE REGULATION?

The regulatory framework of the *Tri-Council Policy Statement* conforms in its basic design to the principles advocated by reflexive law, responsive regulation, and new governance scholars.¹⁸⁰ “New governance” puts an emphasis on gaining input of the regulated, broad participation in decision-making, and mobilization of situated knowledge and capacity, thus engaging in the process of governance the expertise, technologies, and resources of those who work on the ground and calls for the use of hybrid forms of governance designed to be responsive, to transcend the limitations of regulatory and deregulatory approaches.¹⁸¹

Indeed, the regulatory framework of the *Tri-Council Policy Statement*, both its first and second versions, has a number of elements consistent with new governance. For example, research ethics review is decentralized – local boards review research projects in close proximity to the sites of everyday decision-making in human research, interpreting general ethical guidelines to applying them to specific research situations.¹⁸² However, the system of ethics oversight features a strong

¹⁸⁰ Burris, "Regulatory innovation in the governance of human subjects research: A cautionary tale and some modest proposals."

¹⁸¹ See Lobel (2004), Teubner (1983, 1992), Ayres and Braithwaite (1992), Trubek and Trubek (2005).

¹⁸² After the adoption of the second *Tri-Council Policy Statement*, the Interagency Advisory Panel on Research Ethics is taking a more active role in interpreting the policy, thus limiting the deregulatory elements of the original *Tri-Council Policy Statement*, in part also responding to the demand of REBs

central element – “common” and “shared” fundamental ethical principles.¹⁸³ These principles are articulated by the three major Canadian Research Councils, without input from a representative spectrum of research participants and researchers. It should be noted, though, that contrary to the position expressed in the *Tri-Council Policy Statement*, universal ethical principles are universal in a declarative sense only—they are not shared by all research disciplines and they reflect the values of a particular research paradigm. Because the articulation of ethical principles in research involving humans is centralized, the governance model implemented in the *Tri-Council Policy Statement* can be best understood as a hybrid. It does incorporate a number of responsive regulatory mechanisms, such as self-governance, or use of situated knowledge and capacity, since research ethics boards (unless research institutions appoint an external REB) generally consist of local researchers and community members who review the projects of their peers. But, again, a deeper discussion is necessary to determine whether and how a localized ethics review benefits from situated knowledge and capacity. Does it allow, for example, the engagement of various research disciplines and systems of knowledge in the governance of research involving humans?

for such interpretations. The Interagency Advisory Panel on Research Ethics website has a new dedicated section on the interpretation of the policy. See <http://www.pre.ethics.gc.ca/eng/policy-politique/interpretations/Default/>.

¹⁸³ The first *Tri-Council Policy Statement* also speaks in the same way about values and interests in research involving humans.

If the *Tri-Council Policy Statement* is an example of responsive governance, then the adoption of the concept of *participants* can be considered a step toward further responsiveness, an example of a responsive governance framework in action. However, this explanation presents at least two problems: (1) research ethics boards are, in fact, constrained in their reflexive capacity and unable to take advantage of their regulatory autonomy; and (2) the *Tri-Council Policy Statement* has not been sufficiently attuned to the diverse interests of various actors involved in research and its governance.

RESEARCH ETHICS BOARDS AND THE CHALLENGES OF DECENTRALIZED GOVERNANCE

Presumably, the degree of freedom given to research ethics boards, as well as their advantageous position in close proximity to many research sites, should promote flexibility, adaptability, and promptness in REB decision-making. In practice, however, this has not happened. The benefits of regulatory decentralization are restrained by a number of factors, including challenges in creating an ethics review environment that acknowledges and accommodates diverse methods of research. For example, a disproportionate number of REB chairs represent clinical

psychology, which generally follows the biomedical model.¹⁸⁴ However, this is not just a problem of expertise on the board and/or adequate representation of the disciplinary spectrum in the board membership. The dominance of positivism at the REB level stems from the fact that the presumably existent “common” and “shared” ethical principles are not as common and shared as assumed in the *Tri-Council Policy Statement*. Thus, the principles of “free and informed consent” and “respect for privacy and confidentiality” are not universally shared, for example, by criminologists,¹⁸⁵ ethnographers,¹⁸⁶ policy researchers, biographers, journalists, and others. Some of the principles in the first *Tri-Council Policy Statement* can be understood as being antagonistic, for example, “respect for human dignity” and “balancing harms and benefits,” which belong to deontology and utilitarianism, respectively, and policymakers do not offer an effective strategy of reconciling them.¹⁸⁷

The first *Tri-Council Policy Statement* also postulates a principle of “respect for vulnerable persons” that introduces a category of “vulnerable

¹⁸⁴ van den Hoonaard, *The seduction of ethics: transforming the social sciences*.

¹⁸⁵ See e.g. multiple contributions by Ted Palys and John Lowman, available at <http://www.sfu.ca/~palys/articles.htm>.

¹⁸⁶ Bosk, "The New Bureaucracies of Virtue or When Form Fails to Follow Function."; 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); Rena, "Comparative "Research": A Modest Proposal concerning the Object of Ethics Regulation."

¹⁸⁷ Hence, in actual REB deliberations, a utilitarian approach is often dropped, and the harm-benefit analysis, which is offered as a main decision-making mechanism, is reduced to an often nonsensical analysis of harm.

persons/populations": "Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination."¹⁸⁸

It is unsettling to see policymakers who view research through the lenses of "abuse, exploitation or discrimination." It is one of the perspectives that re-inscribes *vulnerable persons* in the new regulatory framework and imposes double standards through the language of special protection. The second *Tri-Council Policy Statement* makes an effort to resolve some of these tensions – it offers a simplified ethical framework, based on the concept of human dignity, expressed through three core principles – *respect for persons, concern for welfare, and justice*. Thus, the priority is now clearly given to the deontological approach. However the second *Tri-Council Policy Statement* retains the harm-benefit analysis and the two major categories of human participants, even if revising its language – human participants and human participants in vulnerable circumstances. Accordingly, the lack of an updated conceptual framework for the second edition of the *Tri-Council Policy Statement* continues to be a source of significant tension, affecting the decision-making of research ethics boards, reducing the methodological options for researchers, and ignoring the autonomy of competent adults. The decentralized governance model also poses challenges to multi-site studies – not only is it often necessary to get

¹⁸⁸ TCPS 1.

permission from multiple research ethics boards that may require numerous incompatible changes, it also puts additional logistical and financial burdens on researchers that delay the production of new knowledge (potentially useful to people in general). This situation sometimes forces research sponsors to transfer research to countries with a more favourable research environment.¹⁸⁹

RESEARCH ETHICS BOARDS AND THE CHALLENGES OF RESPONSIVE GOVERNANCE

The regulatory design implemented in the *Tri-Council Policy Statement* suggests that policymakers and regulators at the institutional level must be interested in collaborating with the interest groups who are subject to the Policy. With respect to researchers, REB members are recruited from among the researchers of a particular institution, and these research ethics boards are situated in the same institution, thus allowing for unmediated communication between REB members and researchers. With the degree of freedom in interpreting and applying the *TCPS* principles, this may appear from afar as a model of self-governance. However, this has not been the case in practice, because research ethics boards remain cautious in

¹⁸⁹ It has been suggested that decentralized ethics review is behind Canada's dwindling share of the global market of clinical trials. See, e.g., Senate of Canada (2012).

exercising their liberty of interpreting the *Tri-Council Policy Statement*, preferring to act conservatively and redirect the questions to the Interagency Advisory Panel on Research Ethics (PRE).

Speaking in terms of policymaking, the drafting of the second *Tri-Council Policy Statement* was also a fairly open multistage process, involving working groups,¹⁹⁰ *TCPS* consultations, and written comments. Thus, it is stated on the *TCPS* website that following the release of the first draft of the second edition of the *Tri-Council Policy Statement*, in December 2008, “Panel members participated in 58 events attended by approximately 1,800 people in 17 cities.” The second draft was released in December 2009, and written comments were accepted until March 2010. In this very short period of time, for which the Panel was justly criticized,¹⁹¹ it received written comments from over 123 institutions, research ethics boards and individuals.¹⁹² This reflects a high degree of interest and (academic) public participation in developing the policy, and allows characterizing the process of drafting the second *Tri-Council Policy Statement* as an open one. However, taking into account that the *Tri-Council Policy Statement* is envisioned as a “living

¹⁹⁰ <http://www.ethics.gc.ca/eng/archives/policy-politique/reports-rapports/reports-rapports/>

¹⁹¹ see Cheluchi Onyemelukwe and Jocelyn Downie, "The Tunnel at the End of the Light? A Critical Analysis of the Development of the Tri-Council Policy Statement," *Canadian Journal of Law and Society* 26, no. 1 (2011).

¹⁹² The number is probably higher. I included only those individuals and institutions whose comments were published on the *TCPS* website.

<http://www.ethics.gc.ca/eng/archives/participation/comments-commentaires2009/>

document” and gets its first major update in 12 years, it is difficult to explain such a limited consultation period and the rush to adopt a new edition.

Nevertheless, one should note that while the Panel takes initiative in engaging researchers in developing the Policy, research ethics boards remain passive in this regard. For example, research ethics boards could not establish themselves as institutions that seek dialogue on ethical issues with researchers—by far the social group most affected by the *Tri-Council Policy Statement*. By and large, research ethics boards do not demonstrate interest in researchers’ feedback, and even less in how they conduct research or understand research ethics. Instead of engaging researchers in the governance process, research ethics boards invest resources in educating researchers about the ethics review process. It is common to offer REB 101 sessions and “Best-Practices” workshops.¹⁹³ These workshops are designed to provide researchers with useful tips about gaining ethics approval. Below is a typical workshop agenda, this one from a leading US research university in 2012. Notice the language of human *subjects* is still current in the United States, where research ethics review is done by institutional review boards (IRBs):

- A history of human subjects protection and the ethical principles that guide human subjects research;

¹⁹³ Mueller, "Best Practices: What Perspective, What Evidence?."

- An overview of the federal regulations for the protection of human subjects in research;
- Criteria for IRB review;
- Tips for submitting complete and understandable new protocols, modifications, renewals and adverse event reports;
- Tips for obtaining IRB approval more quickly;
- The RASCAL system [a web-based research management and compliance tool]; and
- The IRB review process.¹⁹⁴

“Best-Practices” workshops are hardly a reflexive moment in the system of research ethics oversight. The goal is not to learn from researchers, but rather to ensure compliance through REB indoctrination, the imposition of a biomedical understanding of research, and a process of prospective review as the only way of ensuring research safety. Contrary to its own expectations, the first *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* has not been particularly effective in “encourag[ing] continued reflection and thoughtful

¹⁹⁴ Agenda for July 24, 2012 IRB 101 Seminar, offered by the Columbia University IRB.

consensus around more contentious ethical issues".¹⁹⁵ Consensus is *sought*, not imposed: If the *Tri-Council Policy Statement* is to be seen as a platform conducive to a multilateral dialogue about research governance, then it is important to make progress by embracing a pluralist framework in acts rather than only in words.

Meanwhile, the input of those the first *Tri-Council Policy Statement* refers to as research *subjects*, as yet another interested group, has also been rather limited. A community representative on the REB panel may speak for some research subjects but it is a question of whether this person is able to represent the interests of a wide range of research subjects. In practice, community representatives represent the REB community—they are appointed by REB administrators. They are neither delegates, nor trustees. They are not elected nor selected by participants. Community representatives do not report back to any community. Moreover, if *community* refers to a geographic community, rather than a community of research participants, as it is implied in the second *Tri-Council Policy Statement*, then for many research projects geography is not an important factor. It is also questionable if community representatives can represent the diversity of communities and perspectives within them.

Furthermore, it is not even clear whether all research subjects require representation. In critical research, representation may lead to censorship and may

¹⁹⁵ TCPS 1.

even pose harm to researchers, for example, in critical policy research when the studied community may perceive the researchers as a threat to its cultural practices. None of this, of course, explains a general lack of interest in incorporating the views of research subjects. Members of the Interagency Advisory Panel on Research Ethics assume, as they did in relation to researchers, that research subjects are a homogeneous group, and therefore do not need broad interdisciplinary representation.¹⁹⁶ The paternalistic mentality of the institutions of ethical governance prescribes them to speak for research subjects, determining, without consultation, their vulnerability status, questions of proper compensation, and informed consent issues. The first *Tri-Council Policy Statement* did not accept research subjects as autonomous agents capable of contributing to the governance of research involving humans, and accordingly the change to research *participants* at the end of the life cycle of the first *Tri-Council Policy Statement* has also occurred without the input of research subjects. Accordingly, the regulatory emancipation of research *subjects* who have acquired the label of *participants*, if not the rights of participants, in the second edition of the *Tri-Council Policy Statement* was neither a revolution nor a gift.

¹⁹⁶ Community representatives on REBs for the most part are retired scientists or biomedical participants and patients. Among PRE Members currently there is no community member who would represent participants in social research.

It is difficult to maintain the initial presupposition that the adoption of human *participants* is an outcome of the reflexive governance framework; there is limited evidence that the elements of new governance have yielded an institution interested in engaging researchers and research subjects in the governance process. Accordingly, it is difficult to see the adoption of *participants* as a response to the criticisms of research ethics oversight from the side of social scientists.

WHAT IS IN A NAME?

If there is little evidence that the transition to the new term was prompted by the new governance framework, then one might assume that policymakers were motivated by an aspiration to eschew the factual or potential performativity of the term *subject*, just as they hoped to engage the performativity of *participants*. This assumption involves the following two points: (1) The language of the Policy is indeed performative enough (or at least potentially performative) to produce passive, disinterested, and defenceless research subjects, and (2) the Interagency Advisory Panel on Research Ethics takes this performativity seriously. This is something more than merely omitting research subjects from the list of policy actors in whose feedback research ethics boards should be interested as a site of responsive ethical governance.

This explanation is not easy to rule out altogether. Names and/or labels are performative and things can be made with words.¹⁹⁷ It has also been suggested that powerful institutions rely on the acceptance of a submissive designation by their subjects, for example, religious followers accept the authority of their churches, when they accept their “rotteness”.¹⁹⁸ In a similar fashion, humans involved in research accept that they are merely subjects of research interests, a datum for scientists. Indeed, with 40 years of using the language of *subjects* in the system of research oversight, it may have taken root in public consciousness. Especially when the public has learned that it was the subject of harmful government-sponsored experiments, such as the infamous Tuskegee syphilis study, radiation studies, and LSD experiments in the military. The main message was that various population groups (some more than others) were used as guinea pigs for government experiments, or in other words, as research *subjects*. The concept of research *subjects* has never been neutral. It has never been divorced from the institutional history of state-sponsored (and highly unethical) research and remains integral in maintaining the hierarchical structures of modern social and political institutions. In light of this institutional history, one can explain the adoption of the concept of *participants* as an attempt to disrupt the political economy of *subjects*-based state-sponsored research disasters.

¹⁹⁷ J. L. Austin, *How to do things with words* (Clarendon Press, 1962).

¹⁹⁸ M. De Certeau, "The Institution of Rot," in *Psychosis and Sexual Identity: Toward a Post-Analytic View of the Schreber Case*, ed. D.B. Allison (Albany: SUNY Press, 1988).

Some objections to this explanation have emerged. First, human subjects themselves may not be universally aware that they are research *subjects* and that this is how the first *Tri-Council Policy Statement* identified them in their relationship to research and researchers. Second, researchers may not use this designation either, and therefore, if research *subjects* accept the designation it is not because they are referred to in this way. If they accept it at all, then this is because for them the distinction between research *subjects* and research *participants* (or any other possible label) is a difference that does not *make* a difference.

When I fill out a questionnaire I do not necessarily think of myself as a research *subject*, even if I am addressed in this way on a consent form, which is unlikely. Neither do I think the research benefits me directly. And, if I am a *subject* of an observational study I may not even be aware of the research or my place in it. The concept of *subjects* is not meaningful in all research situations. Being a *subject* implies obedience or compliance; neither is present in observational research. Only in a very limited sense one could say that a person who unknowingly participates in an observational study somehow complies. An individual being observed is likely conforming to numerous situational norms, and the researcher is likely doing the same thing when observing, and when characterizing the observations and writing about them. How is it the case that these people, researchers and the people observed, need protections from going about their daily lives?

If the problem that the second *Tri-Council Policy Statement* tried to address is not the autonomy of research subjects, then it is likely the case that it wishes to somehow *correct* the mindset of researchers. Namely, researchers are set up as masters, as royalty, because they have subjects. The testimony to this is the very language of human *subjects*, which is widely used in biomedical and behavioral sciences, but not common in the social sciences. The mindset of royalty/subjects, masters/slaves is not universal in scientific research. In policy research, for example, a researcher may be under the influence of (i.e., subjugated to) a more powerful organization or person. Therefore, by adopting the concept of human *participants*, authors of the second edition of the *Tri-Council Policy Statement* are addressing a problem that rarely if ever exists in social science.

CONCLUSION

The search for “optimal” language can be productive for the system of ethics oversight in research involving humans, but only if policymakers are successful in adopting a more nuanced understanding of the ethical concerns present in social science research. Such understanding can best be achieved by engaging a large number of interested parties in all stages of the governance process. At present, however, significant barriers hamper research ethics boards from becoming sites of

responsive governance. It is not possible to resolve the continuing methodological crisis¹⁹⁹ in the social sciences through conceptual means alone, without also challenging the biomedical standard underpinning research ethics review.

The adoption of research *participant* speaks to the following phenomena. First, it is the continuing expansion of ethics oversight and the corresponding erosion of its original biomedical conceptual framework. Ethics creep continues,²⁰⁰ and the concept of human *subjects* is no longer adequate to address this ever-broadening field of research involving humans. In an attempt to embrace social science scholarship, policymakers have adopted a new major concept. Research *participants* may relieve some tensions in the current conceptual framework, but it will be a source of new ones, because the concept is not at home in either social or biomedical research. Moreover, in the social sciences the concept of human *participants* continues to impose the biomedical understanding of research ethics by insisting on informed consent forms, especially standardized ones, and thus obstructing social science scholarship, especially participant observation, covert research, and the use of confederates, for example.

¹⁹⁹ Igor Gontcharov, "Methodological Crisis in the Social Sciences: The New Brunswick Declaration as a New Paradigm in Research Ethics Governance?," *Transnational Legal Theory* 4, no. 1 (2013).

²⁰⁰ On "ethics creep" see Haggerty, "Ethics Creep: Governing Social Science Research in the Name of Ethics.;" White, "Institutional Review Board Mission Creep: The Common Rule, Social Science, and the Nanny State.;" Gunsalus et al., "The Illinois White Paper: Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep"".

Second, the term research *subject* is politically obsolete. The concept is historically conditioned and possesses negative connotations. In this respect, the task of the word *participant* is to change the mindset of both researchers and the researched, and to empower humans involved in research. It is questionable, however, that such a task can be accomplished through locating a new term. Moreover, there is no guarantee that the participatory aspect will make its way into the actual practice of research involving humans. For this reason the adoption of *participant* may be seen as an attempt to evade existing problems, to serve as a distraction (much like the near endless editing of consent documents) rather than resolving problems in an open process involving all stakeholders. This situation can be described as a euphemistic spiral: when a word becomes offensive, a taboo, it is necessary to substitute it with a new one in order to be able to continue referring to the same thing. And of central importance here, no data exist that demonstrate the *Tri-Council Policy Statement* makes any positive contribution to research safety. The term human *subject* has become an obscene term and policymakers are happy to introduce *participant* to continue the business of regulating research and research *subjects*. This situation cannot last very long; the new term will soon meet the same fate because the change changes nothing.

In psychoanalysis, *patient* is no longer deemed an acceptable term because it speaks of illness, and *client* is not acceptable – it speaks of money. So, the (same) person on the couch is referred to as *analysand*. Nevertheless, this *analysand* neither annuls

nor subsumes the patient and the client. This parallel may sound ironic, but the way researchers and participants see each other is necessarily plural. Researchers may (or may not) see research participants as participants, colleagues, interviewees, patients, clients, nameless individuals, and someone known or unknown, and even as *subjects*. Social researchers study social situations, whereas the *Tri-Council Policy Statement* requires them to reduce the richness of a research situation to consenting individuals involved in research. To become myopic about specific terms is to continue missing the point of research ethics.

CHAPTER FOUR: OBSERVERS, COMMUNITY AND LEGAL MEMBERS ON REBS: EXAMINING THE ETHICS OF THE REGULATORS OF ETHICAL CONDUCT IN RESEARCH INVOLVING HUMANS

This chapter discusses the challenges of non-scientific members of research ethics boards – observers, community, and legal members – in establishing research ethics review as an institution that seeks to go beyond peer review in research involving humans. By focusing on the processes of fragmentation and specialization in REB membership, it contributes to an understanding of the ethics of the regulators of ethical conduct in research involving humans. Since the study of research ethics boards poses a number of ethical and research challenges, the paper also discusses participant observation as a methodology for examining the governance of knowledge production in research involving humans.

INTRODUCTION

Understanding the ethical dimension of the regulatory space in research involving humans 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 research involving humans. The ethical dimension in research involving humans is created by multiple actors who have a broad range of diverse interests and ethical standards, which makes the governance of research involving humans and its study a complex task. Although our knowledge of the institution of research ethics review has significantly increased in recent years thanks to an emerging interest of researchers and regulators,²⁰¹ we still know very little about this institution's ethical principles and everyday ethics. The task of this chapter is to contribute to an understanding of the ethics of the immediate regulators of ethical conduct in research involving humans – research ethics boards, 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 research 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 research ethics review.

²⁰¹ 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)

In the late 1960s, research ethics boards 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 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 part and parcel of the present-day research ethics review, but it is not known how the demands for a particular expertise influence its institutional culture and the governance of research involving humans in general. This knowledge is crucial for understanding the processes of (1) *centralization* in the governance of research involving humans, when a hybrid “new governance”²⁰² 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”.²⁰³

²⁰² for a discussion of ethics review from the perspective of “new governance” see Burris, “Regulatory innovation in the governance of human subjects research: A cautionary tale and some modest proposals.”

²⁰³ Haggerty, “Ethics Creep: Governing Social Science Research in the Name of Ethics.”; Schrag, *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009*.

INSTITUTION OF RESEARCH 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 Policy²⁰⁴ governing research involving humans, and hence, it was “exempt” from research 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

²⁰⁴ 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>.

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

While the initial experience of dealing with institutionalized research ethics review raised multiple ethical questions, I did not try to examine them *systematically*²⁰⁵ 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 research 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 research involving humans.

²⁰⁵ 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.”

Throughout the past three years I have been involved in the work of the institution of research 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 research ethics boards, becoming one of this network's specialized boards. This event was characteristic of the processes of centralization and standardization in the governance of research involving humans. In addition to being an REB member, I have also had an opportunity to study several other research ethics boards 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: Alternatives to Research-Ethics Review* Summit²⁰⁶ in Fredericton in November 2012, *The New Brunswick Declaration: on Research Ethics, Integrity and Governance*, adopted in February 2013,²⁰⁷ *Ethics in Practice: Tensions around Ethics Review and Maori Consultation* Conference in Dunedin in May 2015,²⁰⁸ and the forthcoming volume edited by Will van den Hoonaard and Ann Hamilton.²⁰⁹

²⁰⁶ Hoonaard, "The "Ethics Rupture" Summit, Fredericton, New Brunswick, Canada, October 25–28, 2012." The *Ethics Rupture* Summit webpage, including podcast, has been archived at: <http://web.archive.org/web/20130507065940/http://wp.stu.ca/ethicsrupture/>.

²⁰⁷ 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 van den Hoonaard, "The Social and Policy Contexts of the New Brunswick Declaration on Research Ethics, Integrity, and Governance: A commentary."

²⁰⁸ It was known as *Ethics Rupture Down Under* Conference during the planning stage. Conference website: <http://www.otago.ac.nz/ethicsreviewproject/conference/index.html>

²⁰⁹ Van den Hoonaard and Hamilton, *Ethics Rupture: Exploring Alternatives to Formal Research-Ethics Review*.

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” – 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 the 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.²¹⁰

STUDYING THE “ETHICS” OF RESEARCH ETHICS REVIEW

In studying the ethics of research 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.²¹¹ 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,

²¹⁰ 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).

²¹¹ 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).
; Boal, *Theatre of the oppressed*:

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 research ethics review, such as REB meetings, but goes further to include a broad spectrum of conceptual phenomena that influence and define research 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 research 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 RESEARCH ETHICS BOARDS AND ITS CHALLENGES

Policy research in the governance of research involving humans, which relies on participant observation of research ethics boards as one of its methods, poses an ethical dilemma for research ethics boards.²¹² *First*, it exposes an underlying conflict of interest, since research ethics boards have to review a study the goal of which is to critically interrogate its own ethical standards. *Second*, participant observation is a deeply problematic method for research ethics boards. 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 *Tri-Council Policy Statement* 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 first

²¹² 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, Bosk, "The New Bureaucracies of Virtue or When Form Fails to Follow Function."; Lederman, "The perils of working at home: IRB "mission creep" as context and content for an ethnography of disciplinary knowledges."; R. Lederman, "The ethical is political," *American Ethnologist* 33, no. 4 (2006); Tolich and Fitzgerald, "If ethics committees were designed for ethnography."; Stark, "Morality in Science: How Research Is Evaluated in the Age of Human Subjects Regulation.."; Stark, *Behind closed doors: IRBs and the making of ethical research*; van den Hoonaard, *The seduction of ethics: transforming the social sciences*.

*Tri-Council Policy Statement.*²¹³ 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 research ethics boards as methodologically weak and "risky". Indeed, participant observation does not fit the standard biomedical understanding of research, according to which researchers and research subjects are two distinct categories, with the former generally enjoying more power over the later. In participant observation the distinction between those doing the research and those being 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.

²¹³ pp. i5-i6.

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 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 research ethics boards. Interviews, surveys, or focus groups with researchers, REB administrators, chairs and members, may all facilitate the study of the institution of prospective ethics review. However, given the criticisms²¹⁴ 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 research 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.

²¹⁴ 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).

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.²¹⁵ 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 research ethics review for this project.

I had to resubmit my ethics application twice to get an approval for this study. My initial proposal was based on participant observation in studying the research 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, research ethics review involves an extra step – a review by the members of the supervisory

²¹⁵ Susan Zimmerman's (Executive Director, the 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.

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 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 research ethics boards review studies based on oral consent, my third proposal was designed to be approved and it was.

Requesting modifications is how research ethics boards say “no” to the project, since research ethics boards 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 will discuss further. The memo I received from my research ethics board 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."²¹⁶

It is important to notice that the REB quoted a local institutional policy, which is more restrictive than the *Tri-Council Policy Statement* 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 research ethics boards have a process regarding observers who fulfill a number of important functions: (a) observers form a pool of potential candidates for research ethics boards, and (b) in some institutions, being an 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 research ethics review process first-hand. Among them – educational, research and career-related interests, exchange of administrative practices in research ethics review, and

²¹⁶ On file with the author.

others, which I discuss in the final section in more detail. 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 research ethics review process, research ethics boards have their own motives for bringing observers on the Board. One of them is a continuous search for qualified members. Since research ethics boards 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 research 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 research 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.

To illustrate, the second *Tri-Council Policy Statement* identifies two types of research ethics review – *delegated review* for minimal risk studies and *full board review* for studies posing greater than minimal risk. Depending on the number of reviewed projects, and the ratio of delegated reviews to full board reviews, research ethics boards 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 research ethics boards do not have to rely on the presence of few unique experts. If the number of members exceeds the *TCPS* minimum, then research ethics boards can reduce the number of reviews a member is assigned to do over a period of time. It is important for research ethics boards 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, also some researchers may prefer REB review to other administrative duties, if it is credited as such by the institution. Low turnover rate may also help to reduce administrative costs for research ethics boards and ensure institutional memory related to the review process. However, if the mobility is low and the process of research 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 research 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 research ethics boards was greatly facilitated by the snowball technique, inter-REB networks and facilitated by the fact that research 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 research involving humans in Canada. I encountered the same person again at the talk “The Problem with Research Ethics Boards” 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. However, 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 Hoonaard's study, some research ethics boards were reluctant to open their meetings for observation.²¹⁷ But again, the status of van den Hoonaard in the research ethics community, such as being a founding member of the Panel on Research Ethics and the Chair of the Social Sciences Working Group on Ethics in 2003-5, could have played its role.

²¹⁷ van den Hoonaard, *The seduction of ethics: transforming the social sciences*.

CONDITIONS OF OBSERVING: CONFIDENTIALITY AGREEMENTS AND INFORMED CONSENT FORMS

Since observers are an important part of the REB process, some research ethics boards 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 research 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 research 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 research 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 research 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 research 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 research ethics review can also be observers.

However, the *Tri-Council Policy Statement* 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, and (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 the REB chair, nor REB administrator, or anyone else from the Research Office can decide on behalf of any 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 first *Tri-Council Policy Statement* to address ethical concerns in biomedical research, and although it may be not at home in critical policy research, the second *Tri-Council Policy Statement* sets it as a standard for all research involving humans. Since researchers routinely study situations, access to which is regulated by confidentiality agreements, the situation with observing the work of research ethics boards 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 research ethics boards understand 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.²¹⁸ In a broader research project it would be important to interrogate how these principles of "good governance" are implemented in research involving humans. 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.

²¹⁸ 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).

Observers are important for the institution of research 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 *Tri-Council Policy Statement*, but who may not be fully enabled to contribute in a meaningful way to REB meetings and more broadly in the governance of research involving humans, 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 research ethics boards may not necessarily translate into greater legitimacy, accountability, or democracy of the institution of research ethics review. Nevertheless, observers and community representatives do contribute to these processes, even if they are not able to do so effectively.

POLICY PROFILE OF COMMUNITY MEMBERS

The second *Tri-Council Policy Statement* defines “community members” and their “primary role” on research ethics boards 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 research ethics boards. 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 second *Tri-Council Policy Statement* has significant expectations in relation to the role of community members in the governance of research involving humans. 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 experience as research participants.

These characteristics are thought to contribute to an impartial and multifaceted ethics review and the legitimacy of research involving humans. 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 *Tri-Council Policy Statement*. Other experts on the REB may not be willing to recognize community members' expertise – neither as research participants nor community members.²¹⁹ “Non-community” REB members may dismiss the expertise of community members as not unique and inessential. Some of the “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

²¹⁹ 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.

collectivities, such as “internet community” or “lifestyle community” when “community” refers to an “imagined community”,²²⁰ to use Benedict Anderson’s term or even simply to refer to a category of the population where social ties are loose or speculative and interests are plural and antagonistic. The *Tri-Council Policy Statement* does not explicitly clarify how “community” is to be understood; hence this task is left to individual research ethics boards. Nevertheless, the *Tri-Council Policy Statement* emphasizes the value of research participant’s experience and, accordingly, research ethics boards 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

²²⁰ Benedict Anderson, “Imagined communities: Reflections on the growth and spread of nationalism,” (New York and London: Verso. Reprinted, 1991).

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 research ethics boards 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. *First*, 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.²²¹ Which interests should the community representative stand for in this case? *Second*, it is probably the case that most non-community members have participated in research studies as

²²¹ Roberto Abadie, *The Professional Guinea Pig: Big Pharma and the Risky World of Human Subjects* (Duke University Press, 2010).

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 *Tri-Council Policy Statement* 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 the 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 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 *Tri-Council Policy Statement*, 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 substantive contribution, and consequently, not encouraging and thus possibly 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 research ethics boards, 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 research involving humans. 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 INTERAGENCY ADVISORY PANEL ON RESEARCH ETHICS

In the beginning of 2012 the Secretariat on Responsible Conduct of Research (the Secretariat) issued a “Targeted Call for Nominations for Panel²²² 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.”²²³ Accordingly, the Secretariat on Responsible Conduct of Research 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 nominated²²⁴ by their respective research ethics boards. In the framework of my research, this was an opportunity to learn more about the governance body that develops the policy in research involving humans. 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

²²² Interagency Advisory Panel on Research Ethics (PRE).

²²³ *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//>.

²²⁴ 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)

roles of the Secretariat on Responsible Conduct of Research and the Panel in the governance of research involving humans. *Second*, to get a better understanding of how the Panel on Research Ethics manages tensions in setting common standards for research ethics oversight in research involving humans; 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 on Responsible Conduct of Research 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 Panel on Research Ethics 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."²²⁵ In light of the discussion above, it is important to highlight that the *Terms of Reference* specifically mention that the Panel on Research Ethics 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:

²²⁵ *Panel on Research Ethics: Terms of Reference*. Available at <http://www.ethics.gc.ca/eng/panel-group/tor-cdr/>.

- 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.²²⁶

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 research involving humans – 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 research involving humans,

²²⁶ ibid.

(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 second *Tri-Council Policy Statement*, it was necessary to find out whether this terminological change reflected an attempt to better integrate social science perspectives on the governance of research involving humans. Previously, the normative human subject was a research subject in biomedical research. The first *Tri-Council Policy Statement* extrapolated this vision to all research involving humans, 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 Panel on Research Ethics as it did not have a representative who would voice a social science perspective.²²⁷ My application featured a non-biomedical 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, there could be multiple reasons for preferring one

²²⁷ See past and current PRE Members profiles at: <http://www.pre.ethics.gc.ca/eng/panel-group/about-apropos/members-membres/>

nominee over another. While my nomination was not supported by the Councils,²²⁸ 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 second *Tri-Council Policy Statement* was done without challenging the normativity of the biomedical human subject.²²⁹

REB-LS (ALSO KNOWN AS “REBELS”): LAWYERS ON RESEARCH ETHICS BOARDS

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 research ethics boards 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

²²⁸ Letter on file with the author.

²²⁹ Gontcharov, "The Eclipse of 'Human Subjects' and the Rise of 'Human Participants' in Research Involving Humans."

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 research ethics boards, 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 research ethics board was a prominent player in the governance of research involving humans, negotiating and navigating these processes. Moreover, this Board 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, research ethics boards were largely homogenous in terms of their professional and social 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 research ethics boards in Toronto include an additional member who specializes in privacy law, although there is no corresponding requirement in the *Tri-Council Policy Statement*. Nevertheless, research ethics boards 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 research ethics boards, 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 certification²³⁰ and qualification²³¹ programs. Accordingly, REB

²³⁰ 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-accer.org/content/professional-development>.

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 being a form of 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. The *Tri-Council Policy Statement* 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.”²³¹ These members are usually called *REB lawyers*. In 2012 I had an opportunity to be on the working committee and attend an educational event

²³¹ 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>

²³² TCPS 2, Article 6.4(c).

for a group of REB lawyers working in Toronto.²³³ 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 – about 80% of members were women on my REB in 2012, 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”, pronounced as “rebels”! This designation has probably emerged with the founding of *The Research Ethics Board Legal Society* (REB-LS)²³⁴. The abbreviation is a truly performative one, to use John Austin’s expression.²³⁵ Thus, it was voiced a few times during the event that REB-Ls offer a distinct voice, rebelling against other members’ views. Nevertheless, not 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 *Tri-Council Policy Statement*, there should be no “rebels” on the REB at all. The Policy speaks of members “knowledgeable-in-law” – M-KiLs, to use Suzan Zimmerman’s

²³³ “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.

²³⁴ See REB-LS webpage at <http://rebls.pbworks.com/w/page/9110752/FrontPage>

²³⁵ Austin, *How to do things with words*.

abbreviation²³⁶ 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 research involving humans? 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 research ethics boards’ 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 *Tri-Council Policy Statement* has doubled in size. Meanwhile research ethics boards are losing their interpretative authority with the Interagency Advisory Panel on Research Ethics assuming a more

²³⁶ 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.

active role in this process.²³⁷ 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 research ethics boards and its contribution to the ethical dimension in research involving humans. Contrary to how research ethics boards approach “ethics” in their everyday practice, the ethical dimension in research involving humans extends beyond the interactions between researchers and human

²³⁷ See a new section on the interpretation of the second *Tri-Council Policy Statement* on the Interagency Advisory Panel on Research Ethics website at <http://www.pre.ethics.gc.ca/eng/policy-politique/interpretations/Default/>

participants. It includes the very institution of ethics review and covers interrelations between researchers and research ethics boards.

Since its emergence in biomedical and behavioral government-sponsored research in late 1960s 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 research ethics boards 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 research involving humans was adopted in 1998 it was based on the biomedical understanding of research and was speaking to ethical 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 research ethics boards 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 research involving

humans. 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 research ethics boards in understanding research ethics.

Although on the surface the *Tri-Council Policy Statement* 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 pauperization²³⁸ 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 research involving humans. 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

²³⁸ van den Hoonaard, *The seduction of ethics: transforming the social sciences*.

experts are not particularly helpful in promoting either disciplinary pluralism, or a non-scientific viewpoint.

CHAPTER FIVE: ALTERNATIVE MODELS OF ETHICAL GOVERNANCE IN RESEARCH INVOLVING HUMANS: TOWARDS THE 2016 NEW BRUNSWICK-OTAGO DECLARATION ON RESEARCH ETHICS²³⁹

The current model of ethical governance in research involving humans in the social sciences and humanities relies on prospective ethics review in ensuring that research is conducted ethically. One of its key features is to distrust researchers and their initiatives regardless of the subject matter, discipline, research methodology or settings, sources of funding, or researcher's experience. This paper discusses the *New Brunswick Declaration on Research Ethics* adopted by the participants of the *Ethics Rupture: Alternatives to Research-Ethics Review* Summit in 2013. In particular, it provides background for the regulatory capture of the social sciences by the biomedical institutions of ethics review, and explains why this resulted in the tensions between "ethics on the books" and "ethics in practice", and why the processes of centralization, bureaucratization, professionalization, and specialization in the governance of research involving humans have not resolved them. Further, it summarizes the Declaration's approach in addressing existing tensions. It concludes by examining the limitations of the Declaration, and offers a

²³⁹ An earlier version of this paper was presented at the *Ethics in Practice: Tensions around Ethics Review and Maori Consultation* Conference, which took place on May 22-24, 2015 at the University of Otago, Dunedin, New Zealand. Prof. Mark Israel and I were discussants of Prof. Will van den Hoonaard's keynote presentation "The New Brunswick Declaration". I am grateful to anonymous reviewers of this journal for constructive suggestions and Lindsey MacDonald for his input on New Zealand's regulatory framework in research involving humans.

set of principles for the development of the New Brunswick Declaration following its discussion at the *Ethics in Practice: Tensions around Ethics Review and Maori* Consultation Conference at the University of Otago in Dunedin in May 2015.

ETHICS RUPTURE: BACKGROUND OF THE NEW BRUNSWICK DECLARATION

The *Ethics Rupture: An Invitational Summit about Alternatives to Research-Ethics Review* took place in October 25-28, 2012 in Fredericton, New Brunswick, Canada. I had a pleasure to participate in this international event and contribute my comments on the draft of *A Declaration on Research Ethics, Integrity and Governance resulting from the 1st Ethics Rupture Summit, Fredericton, New Brunswick, Canada* (also known as *The New Brunswick Declaration*).²⁴⁰ The Declaration was finalized in February 2013 and served as a demarcation point in the formation of an alternative perspective at the governance of research involving humans. If previously there were only fragmentary voices of criticism and discontent with the expanding system of ethics review, then with the adoption of the New Brunswick Declaration there

²⁴⁰ The Declaration is accessible online at Prof. Ted Palys's webpage: <http://www.sfu.ca/~palys/NewBrunswickDeclaration-Feb2013.pdf> or in van den Hoonaard, "The Social and Policy Contexts of the New Brunswick Declaration on Research Ethics, Integrity, and Governance: A commentary."

emerged a clear point of reference, a policy reform platform. At that time I was conducting my doctoral research on the ethics of standard setting in research involving humans, and thus the Summit was a unique opportunity to experience first-hand the challenges of doing critical policy research while engaging in the research governance process in Canada and beyond.

The Summit was a follow up to Will van den Hoonaards's 2011 monograph – "The Seduction of Ethics", a review of which I offered in *Transnational Legal Theory*.²⁴¹ The monograph documented the ongoing methodological erosion in the social sciences and a knowledge crisis manufactured by the system of ethics oversight. Van den Hoonaard's position was echoed by the majority of the participants²⁴² of the Invitational Summit, the purpose of which was thus to discuss the alternatives to the biomedical model of prospective ethics review in the social sciences and humanities. The Declaration emerged as an effort to identify a set of principles that would further research in these disciplines, while enhancing their ethical dimension.

The New Brunswick Declaration is an important element in the governance of research involving humans – **directly** as a grassroots initiative, a code of ethics, or even a counter-code, designed by social researchers themselves; and **symbolically** – as a representation of a network of social researchers who seek to address the

²⁴¹ Gontcharov, "Methodological Crisis in the Social Sciences: The New Brunswick Declaration as a New Paradigm in Research Ethics Governance?."

²⁴² <http://web.archive.org/web/20130507065940/http://wp.stu.ca/ethicsrupture/>

tensions between the institution of ethics review and ethical challenges that social researchers face in their day-to-day practice, by (a) articulating relevant to their disciplines – “indigenous” approaches to research ethics, and (b) documenting the limitations of regulatory transplants from the biomedical field.

The value of the New Brunswick Declaration is also as a barometer of the changes in the ethics governance in various jurisdictions. This paper provides a Canadian and New Zealand context to the elaboration of the New Brunswick Declaration. In Canada the focus is on the ongoing development and implementation of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)*, a joint policy of the three major Research Councils governing all research involving humans in Canada. The Policy has been developing steadily since its initial adoption in 1998 (*TCPS 1*). In 2010 the second edition was adopted (*TCPS 2*), and updated again in December 2014 (*TCPS 2 2014*). New Zealand research ethics governance has been less regulated in social science and overall has had a more stable regulatory environment than Canada in the last 10 years. For instance, New Zealand has no overarching regulatory regime for prospective and ongoing ethics review of research involving humans, except in the Health and Disability sector. The Health and Disability Committees (HDEC) are creatures of the Minister of Health who appoints the committee members, sets their operating procedure and ambit. Any other human subject research is reviewed only if the researcher’s institution (e.g. university) has a review board. However, the autonomy of the most social science

research in New Zealand ethics review does not mean that research involving humans in New Zealand is closer to the aspirations of the New Brunswick Declaration. Recent research by Tolich and Barry has confirmed that the current New Zealand ethics regime is adapting global biomedical norms inhibiting social science research, and the quality of the ethics review of health research has been severely curtailed by political interference.²⁴³ At the same time, New Zealand researchers note that they can learn from and build upon the centralized approaches, such as the *Tri-Council Policy Statement*, especially in regard of the governance of indigenous research.²⁴⁴

The latest opportunity for international scholars to consider the New Brunswick Declaration in the context of global challenges in the governance of research involving humans occurred at the *Ethics in Practice: Tensions around Ethics Review and Maori Consultation* Conference at the University of Otago in Dunedin in May 2015. Several panel discussions, seminars and a keynote were held focussed on the New Brunswick Declaration, with talks by many of the original scholars who

²⁴³ Tolich and Smith, *The Politicisation of Ethics Review in New Zealand*.

²⁴⁴ M. Tolich and B. P. Smith, "Evolving ethics envy—New Zealand sociologists reading the Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans," *Kōtuitui: New Zealand Journal of Social Sciences Online* 9, no. 1 (2014).

contributed to the New Brunswick Declaration, including van den Hoonaard, Tolich, and Israel.²⁴⁵

²⁴⁵ Conference webpage: <http://www.otago.ac.nz/ethicsreviewproject/conference/index.html>

CODIFICATION OF ETHICS: ADOPTION OF ETHICS REVIEW AS A REGULATORY MODEL BASED ON DISTRUST

The background of the Ethics Rupture Summit in New Brunswick was a growing scholarly concern with the global expansion of prospective ethics review as a way of governance in research involving humans. The “signing” of the New Brunswick Declaration took place in early 2013 –fifteen years after the “harmonized” policy extended the institution of ethics review to all research involving humans in Canada, and close to twenty years after a similar initiative was considered in New Zealand, following the Cartwright Inquiry.²⁴⁶ During 1990s codes of ethics were emerging in every field as part of the global ethics movement. In general, the creation of the codes of ethical conduct was a copy/paste activity reflecting an expectation to produce a code of ethics, but occasionally they were based on the existing unwritten set of ethical rules. For the most part these codes are soft law, general guidelines, and collections of best practices. However, in academia the codification of ethical principles resulted in a system of licensing,²⁴⁷ based on the prospective ethics review of individual research projects by multi-expert panels. The adoption of prospective ethics review as a central element of research governance introduced a totally different governance model – a model based on distrust to researchers,

²⁴⁶ On the Cartwright Inquiry and its legacy in the governance of RIH New Zealand see Ch.1 of Tolich and Smith, *The Politicisation of Ethics Review in New Zealand*.

²⁴⁷ Hamburger, "Getting Permission."

which was also introduced in a paternalistic manner – without a public discussion and necessary justification of its basic principles, relevance and effectiveness in the social sciences and humanities.

This model has effectively disempowered researchers individually and as a social group, undermining their ability to self-governance via professional associations, and professional socialization through existing academic institutions. It has put under question the ethico-methodological expertise and professional integrity of academic researchers. Meanwhile, it has given rise to a new profession, members of which are known as REB professionals or experts in the procedural aspects of ethics review.²⁴⁸ Since the task of REB professionals is to interpret and apply the Policy which continues to be poorly adapted to the ethical landscape of the social sciences, tensions started to emerge between ethics committees and researchers. *Article 5* of the New Brunswick Declaration, “[we] encourage regulators and administrators to nurture a regulatory culture that grants researchers the same level of respect that researchers should offer research participants”, emphasizes the existing imbalances of power and proposes that the culture of mutual respect should be a feature of research governance in general, including relationships between researchers on the

²⁴⁸ Thus The Canadian Association of Research Ethics Boards (CAREB) Professional Development Committee is currently “working on an initiative to develop a Canadian certification program for REB professionals, based on Canadian policy and legislation” as it is indicated on its website at <https://www.careb-accer.org/content/professional-development>.

one hand and research ethics boards and the Interdisciplinary Advisory Panel on Research Ethics on the other.

The system of prospective ethics review emerged as an attempt to manage the social trauma of being used as “guinea pigs” in the government-sponsored biomedical research. In this sense the institution of ethics review is a reflection of a “moral panic”.²⁴⁹ Meanwhile this event can be also understood as a moment of self-reflexivity on the side of the government which realized that federally-funded research has not always been conducted in accordance with the “highest” ethical standards. However, instead of introducing additional scrutiny for government-sponsored research – an effective model of public oversight over governmental research initiatives, it established a quickly expanding institution which currently covers all research involving humans regardless of the source of funding, research discipline and methodology. Although there were several reasons triggering the expansion of the new institution, it is important to notice that the language of “highest standards” was and remains problematic for Canada, since the first *Tri-*

²⁴⁹ van den Hoonaard, "Is research ethics review a moral panic?." The 'unfortunate experiment' is an example of a moral panic in New Zealand, which reverberates beyond biomedical research creating an atmosphere of risk avoidance in the ethics review of social science research involving humans. See Martin Tolich, "Beyond an unfortunate experiment: ethics for small-town New Zealand," *Research Ethics in Aotearoa New Zealand*, Longman, Auckland (2001).

Council Policy Statement was, in fact, introducing minimally-acceptable standards, yet giving the power to research ethics boards to raise them “higher” thus promoting risk-aversive and speculative approach by reviewing social research prospectively.

OVERVIEW OF THE PROCESSES OF BUREAUCRATIZATION, CENTRALIZATION, PROFESSIONALIZATION, AND SPECIALIZATION IN THE GOVERNANCE OF RESEARCH INVOLVING HUMANS

BUREAUCRATIZATION

From a regulatory viewpoint it is worth emphasizing that both the Canadian and New Zealand systems of ethic review appear rather progressive on paper – both governance regimes’ overall design was consistent with responsive regulation and the “new governance” approaches.²⁵⁰ The objective of the 1998 *Tri-Council Policy Statement* was to establish a decentralized infrastructure for ethical governance in research involving humans relying on expert review of proposed research by fellow researchers, bioethicists and community members. In this governance model the task of the center was to articulate “common and shared” ethical principles, while delegating their interpretation and application to the level of individual academic institutions. Institutional research ethics boards were envisioned as independent panels of local experts, yet including community representation to ensure direct

²⁵⁰ Burris, "Regulatory innovation in the governance of human subjects research: A cautionary tale and some modest proposals."

public accountability. In New Zealand, outside the review of health and disability research involving humans, institutions are free to set their own ethics review policies, and even the Health and Disability committees were initially meant to be representative of their local communities. From looking at these designs, which were, essentially, an enhanced version of peer-review, one might expect ethics committees to be inexpensive, autonomous, prompt and efficient in reviewing research projects.

In reality the institutionalization of ethics review has followed a more bureaucratic approach – moving away from the general principles and contextual flexibility and towards procedural bureaucratic forms of governance.²⁵¹ *Bureaucratization* of research ethics proceeded alongside other processes in the governance of research involving humans, such as *centralization, professionalization, and specialization*.

CENTRALIZATION

With regard to centralization, in Canada, research ethics boards were constantly demanding more guidance from the Interagency Advisory Panel on Research Ethics (PRE, the Panel) via the Secretariat on Responsible Conduct of Research,²⁵² as a

²⁵¹ Bosk, "The New Bureaucracies of Virtue or When Form Fails to Follow Function."

²⁵² Organizational Structure: http://www.pre.ethics.gc.ca/eng/panel-group/organizational_structure-structure_organisationnelle/

result of conceptual limitations and contradictions²⁵³ in the Policy, rapid changes in the field biotechnologies, and limited institutional jurisdiction which hampered multisite research and clinical trials.

Expectedly, the *2010 Tri-Council Policy Statement* doubled in size from the first edition, and became part of the *2011 Tri-Agency Framework: Responsible Conduct of Research*.²⁵⁴ Furthermore, the Panel opened a rapidly expanding *TCPS 2 Interpretations*²⁵⁵ section on its website in 2010. Some of the interpretations are unavoidably candidates for subsequent codification and thus further expansion of the normative framework.

In New Zealand, a 2012 review of the standard operating procedures of the ethics committees in the Health and Disability sector empowered a secretariat based in the Ministry of Health to act as a clearing house for all applications to the Health and Disability committees, including the power to decide which applications needed HDEC approval, and which did not.²⁵⁶ In the University sector, the health research regulations and funding streams created an impetus to adopt the Health Research Council standards of ethics review. Thus, like in Canada, normative standards were

²⁵³ The contradictions, to name to a few, included a confusing set of ethical principles, such as a deontological framework along with a harm/benefit approach to risk assessment, positivist and over-expansive definition of 'research' and biomedical understanding of 'research subjects' not comparable with certain research methodologies, absence of group interests and group consent, the status of critical policy research and academic freedom.

²⁵⁴ <http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/>

²⁵⁵ <http://www.pre.ethics.gc.ca/eng/policy-politique/interpretations/Default/>

²⁵⁶ <http://ethics.health.govt.nz/operating-procedures>

rapidly promulgated amongst all New Zealand ethics committees, undermining the original attempt to devolve ethics decisions to local institutions and communities.

PROFESSIONALIZATION

The emergence of REB professionals as a social group is only one aspect of the ongoing professionalization in ethics review across many jurisdictions. Indeed, day-to-day functioning of research ethics boards requires a good grasp of the conceptual framework of the Policy and procedural aspects of ethics review. However, in addition to the *Tri-Council Policy Statement*, the *Tri-Agency Framework*, multiple institutional guidelines, Health Canada and FDA Regulations, knowledge of accreditation procedures, it is also necessary to be familiar with the legal framework, most importantly, given the focus of the Policy on privacy and anonymity, with The Personal Health Information Protection Act²⁵⁷ and The Personal Information Protection and Electronic Documents Act.²⁵⁸ Accordingly, an emergence of REB professionals as a group of experts able to navigate the procedural space of research ethics was only a matter of time. Currently we see the consolidation of the profession through the implementation of the certification programs.

²⁵⁷ <http://www.ontario.ca/laws/statute/04p03>

²⁵⁸ <http://laws-lois.justice.gc.ca/eng/acts/P-8.6/index.html>

Other aspects of professionalization are related to bioethicists and lawyers. If a requirement for a bioethicist on the panel of experts was a reflection of the advances in biotechnologies, then the presence of lawyers is a reflection of the growing normative complexity in the field of health research. Importantly lawyers on research ethics boards are also a sign of the ongoing lawyerization of ethics review, since there is an emergent trend to have an additional privacy lawyer, which may shift the perspective of the reviewer into a more traditional adversarial mode of thinking, issues of liability, written forms of consent, among others. It is important to note that although the policy requires for a presence of a member knowledgeable in the relevant law, this is commonly interpreted as a requirement for the presence of a lawyer.²⁵⁹

SPECIALIZATION

In Canada, although specialized ethics boards were not envisioned in the first *Tri-Council Policy Statement*, the need for particular expert knowledge in ethics review was recognized through such requirements as presence of community members, experts in relevant research methodologies and health law. Furthermore, after the adoption of the first *Tri-Council Policy Statement*, it became obvious that a decentralized model of research ethics governance and the institutional character of

²⁵⁹ Igor Gontcharov, "Observers, Community and Legal Members on REBs: Examining the Ethics of the Regulators of Ethical Conduct in Research Involving Humans," *Osgoode Legal Studies Research Paper No.36* 10, no. 9 (June 16, 2014). See also my footnote re gradual change from soft to hard law, from memorandums and guidelines to agreements and administrative law.

ethics review is an obstacle to multicenter clinical trials. The need to obtain approval at all research sites not only delays the onset of research and increases its costs, but also creates additional ethical challenges for researchers due to an idiosyncratic character of research ethics boards' decision-making, resulting in differences in the assessment of research projects. Local circumstances, including differences in available ethico-methodological expertise, in knowledge, interpretation and application of regulations, in understanding of risk and risk management, in addition to a number of psycho-social factors influencing group dynamics, influence how research ethics boards consider proposed research projects.

Consequently, a number of initiatives emerged to address this situation, which can be understood in terms of increasing specialization of ethics committees, but they are also part of the processes of centralization. Clinical Trials Ontario is one of the examples of an agency, the task of which is to streamline clinical trials via standardization through accreditation of research ethics boards and development of the institution of the Board of Record, thus creating a mechanism for research institutes to recognize and accept the results of ethics review by a designated Boards of Record.

The Ontario Cancer Research REB is an example of a specialized board that reviews cancer clinical trials. It currently serves 26 of the 27 hospitals conducting such

research. This is how OCREF reflects on the advantages it offers to participating institutions:

OCREF's centralized model means that once a study has been approved by OCREF, additional study sites can receive OCREF approval within days. This minimizes redundancy and saves the time and cost of having the study reviewed by an REB at every participating institution. ... In annual surveys, stakeholders have noted many advantages of OCREF over the single centre REB model, for example: high quality reviews; efficiency in the submission and review processes; ease of use and transparency of the online system; consistency in consent forms across all sites in the province; rapid approval times; clear communication; consistency in processes; and professional and knowledgeable staff.²⁶⁰

In other words, a decentralized model has significant limitations in reviewing complex, multicenter studies.²⁶¹ This shortcoming was a consequence of a parochial understanding of research as an activity, limited to a particular institutional jurisdiction, and initiated by researchers affiliated with it, and working within its

²⁶⁰ See The Ontario Cancer Research REB Website: <http://oicr.on.ca/oicr-programs-and-platforms/ontario-cancer-research-ethics-board>.

²⁶¹ For a comprehensive examination of the issues associated with New Zealand's reforms in this area, and the reasons why The Multi-region Health and Disability Ethics Committee was dismantled see Tolich and Smith, *The Politicisation of Ethics Review in New Zealand*.

walls. These assumptions, of course, map poorly on collaborative, multi-institutional, and transnational research initiatives.

It is worth noting that research ethics boards themselves recognize these limitations and are actively engaged – directly and via professional associations – in (a) creating networks and “evolving” from institutional research ethics boards reviewing all institutional research to specialized research ethics boards, (b) developing common standards, harmonizing ethics forms and standard operating procedures. Knowledge transfer occurs at various levels – municipal, provincial and national. For example, The Toronto Academic Health Science Network (TAHSN), comprised of the University of Toronto and 13 affiliated academic hospitals, has been using a standardized ethics review form.²⁶² Similarly, OCREFB, the National Cancer Institute of Canada Clinical Trials Group (NCIC CTG), and the British Columbia Cancer Agency REB have been engaged in harmonizing their approaches to free and informed consent.²⁶³ Similar initiatives have taken place in other provinces.

Community-based research ethics boards can be seen as yet another example of specialization. They emerged to fill the gap in non-institutional and non-academic research. The *Tri-Council Policy Statement* and its counterparts in other countries influence the “standard of care” for all researchers, even if they are not affiliated

²⁶² <http://www.tahsn.ca>

²⁶³ <https://ocrefbonline.ca> See “what’s new” and “memos and SOPs”.

with academic institutions. Thus “consent forms” may now be expected from community researchers, even if they are self-funded or unfunded. An increasing number of academic journals require a proof of ethics review and approval as a condition for publication. Neither in New Zealand, nor in Canada has any government or other policy articulated how the emerging institutional infrastructure for ethics review could be extended to non-academic and independent researchers. Yet there was a clear need as government and private researchers had no access to research review. In New Zealand, former chairs of the dissolved Multi-region Health and Disability Ethics Committee acknowledged the shortcoming of the existing ethics review infrastructure by creating the New Zealand Ethics Committee to review research proposals from any researcher unable to access an institutional ethics committee. This initiative was motivated by the necessity to “move beyond a gatekeeping research governance function to that of bridge-building”.²⁶⁴

The New Zealand Ethics Committee is a national ethics advisory committee, based in Dunedin, serving any researcher not eligible for ethics review from the standing institutional or health and disability ethics committees. Many

²⁶⁴ Jay Marlowe and Martin Tolich, "Shifting from research governance to research ethics: A novel paradigm for ethical review in community-based research," *Research Ethics* (2015).

research projects from professional, community and government researchers fall outside this narrow realm of health or university based research.²⁶⁵

In Canada, one response, among others, has been the creation of *The Community Research Ethics Office*, an REB, serving Waterloo region and located in Kitchener, Ontario, is one of the ethics committees that emerged to facilitate community-based research.²⁶⁶ It sees its mission in terms of maintaining ethical standards in community based research, and has to speak the language of harm prevention used in the second *Tri-Council Policy Statement*:

Research is increasingly being conducted by not-for-profit organizations, governments, independent consultants, community organizations, community researchers, and others. Unlike those institutions which have a Memorandum of Agreement²⁶⁷ with any of the three federal research agencies, community based researchers may not have access to institutional Research Ethics Boards. They are, however, still concerned with maintaining

²⁶⁵ From the “welcome message” on The New Zealand Ethics Committee website:
<http://www.nzethics.com/>

²⁶⁶ <http://www.communityresearchethics.com/>

²⁶⁷ “Agreement on the Administration of Agency Grants and Awards by Research Institutions”. The latest version available at <http://science.gc.ca/default.asp?lang=En&n=56B87BE5-1>. It is important to note that the Agreement had previously a ‘softer’ status and was called the “Memorandum of Understanding (MOU) on the Roles and Responsibilities in the Management of Federal Grants and Awards”. Similarly, the *Tri-Council Policy Statement* had a status of ethical guidelines before becoming a Policy.

ethical research standards which help to ensure that no harm comes to those who choose to participate in their research.²⁶⁸

CHALLENGES IN TRANSCENDING THE BIOMEDICAL FRAMEWORK AND THE PEER-REVIEW MODEL

Another important feature that characterizes the development of the system of ethics oversight is a continuous effort to transcend the existing peer review model, to engage non-scientific members in the ethics review of prospective research. Presumably this introduces an element of direct public audit, thus increasing transparency and social responsibility. This process has been rather challenging given a number of conceptual constraints, such as a positivist understanding of research as an activity done by scientific experts through disciplined inquiry and with intent of contributing to generalizable knowledge.

First editions of the Common Rule and the *Tri-Council Policy Statement* make little emphasis on research as a social institution, on its role and function in society and its relations to the people in various capacities, including that of a primary stakeholder and collaborator. Within such a conceptual framework non-scientific

²⁶⁸ <http://www.communityresearchethics.com/background/>

members could hardly fulfill the function of independent (public) auditors, increase the transparency and accountability of research involving humans, or contribute in a meaningful way to the development of ethical guidelines.

Earlier policy initiatives did not have a clear understanding of the role of non-scientific members on ethics committees. This is reflected in how these roles were rendered in policies and guidelines – *lay* and *non-scientific* members, *former research subjects/participants, non-institutional* and *community* members. Moreover, often there was an expectation that “external” members will be able to act in several capacities. For example, the requirements for “community” members on the Interagency Advisory Panel on Research Ethics highlight the research participant perspective, which they understand in biomedical terms.²⁶⁹ According to my observations *community* members are generally recruited from the research community (e.g. retired academics) and are, in this sense, *internal* members.

Other groups of experts which could help to augment, if not transcend the scientific peer review model include bioethicists, experts in relevant methodologies, experts in health law and privacy, in addition to REB administrators as experts in the procedural aspects of ethics review. I take a more detailed look at these experts

²⁶⁹ Gontcharov, "Observers, Community and Legal Members on REBs: Examining the Ethics of the Regulators of Ethical Conduct in Research Involving Humans."

elsewhere.²⁷⁰ Again, similar to community members, these expert groups have not been empowered enough to facilitate the opening up of the institution of ethics review (for example, experts in “qualitative” methodologies), or in some cases promoted the biomedical perspective (bioethicists, health and privacy law experts).

REGULATORY CAPTURE OF THE SOCIAL SCIENCES

In the past two decades there was a rapid expansion of the system of ethics oversight, which was capturing more and more disciplines, more and more types of research, including unfunded and self-funded, academic and community-based. The biomedical model of prospective ethics review was used as a standard. The social sciences and humanities became subject to the new ethics regime which gave rise to multiple points of tension between prescribed and valid ethical practices in research involving humans. The question is why the Canadian social sciences did not resist the “harmonized” ethics of the first *Tri-Council Policy Statement*? Or in New Zealand, why social scientists did not protest the entrenchment of the Health Research Council’s biomedical standards in universities?²⁷¹ And why did not social

²⁷⁰ Ibid.

²⁷¹ Though there has been a few constructively critical publication in various social disciplines, political science, criminology, or ethnography, to mention a few, e.g., Anthony J. Langlois, "Political

researchers protest as a group when the consequences of “ethics creep” (to use Haggerty’s expression) or “ethical imperialism” (Zachary Schrag’s) became apparent? One of the reasons is heterogeneity of the social disciplines – they represent a methodological spectrum thus embracing structured experimental methods and more flexible contextual “qualitative” research techniques. Another reason for the lack of resistance to the new ethics regime is a desire to appear more scientific, even at the cost of sustaining a new ethics bureaucracy.

As Will van den Hoonaard writes in the *Seduction of Ethics* – initially some social researchers thought that it will be possible to collaborate with their biomedical colleagues in designing a common set of rules which would speak to all disciplines, but it soon became obvious that the design stage is over, that the regulatory capture of the social sciences has already occurred. The hope for an independent regime, or real exemptions for certain methodologies or research subjects, were also rapidly disappearing. It was a moment of a growing rupture between ethics on the books (procedural ethics) and ethics in practice. Thus, it became necessary to explore the alternatives to prospective ethics review. This is also reflected in Will van den Hoonaard’s work: in 2002 in the edited volume “Walking the Tightrope” the key question was whether we should proceed “towards a separate structure of ethics

Research and Human Research Ethics Committees,” *Australian Journal of Political Science* 46, no. 1 (2011). Israel, *Ethics and the governance of criminological research in Australia*; Martin Tolich and Maureen H. Fitzgerald, “If Ethics Committees were Designed for Ethnography,” *Journal of Empirical Research on Human Research Ethics: An International Journal* 1, no. 2 (2006).

review".²⁷² "The Seduction of Ethics" raises a more assertive question: "What are the possible alternatives to ethics review"?²⁷³

NEW BRUNSWICK DECLARATION AS A WAY OF ADDRESSING GROWING TENSIONS AND REGULATORY GAPS

The New Brunswick Declaration²⁷⁴ is very carefully worded to avoid any antagonism with the defenders of the current model. Rather, it sought to emphasize the common ground and leave room for ethics committees, but not necessarily for the prospective ethics review. Indeed, the only "radical" element is a suggestion that research ethics boards use different standards in respect to researchers and participants (*Article 5*). Further is an overview of the remaining articles.

Article 1 emphasizes that freedom of expression is essential to research. It is an issue of great importance these days, when the institution of tenure is rapidly eroding and academic researchers join the precariat, when "mandated science" and corporate interests dominate research agendas.

Article 2 introduces "collectivities". Accordingly, it questions the current approach of risk management in research involving humans on the basis of individual harm and

²⁷² van den Hoonaard, *Walking the tightrope: Ethical issues for qualitative researchers*.

²⁷³ van den Hoonaard, *The seduction of ethics: transforming the social sciences*.

²⁷⁴ Online reference: <http://www.sfu.ca/~palys/NewBrunswickDeclaration-Feb2013.pdf>

invites us to think about *group* interests and *group* consent. Although the present edition of the *Tri-Council Policy Statement* introduced the concept of collectivities in context of the aboriginal research, and even suggests that this model might be applicable and used for guidance in other research situations, the concept of harm is still largely understood in terms of the individual.

Article 3 speaks of the role of professional associations and methodologically-relevant standards. In essence, *Articles 2* and *3* call for capacity-building. The task is to empower researchers and participants by articulating the importance of both – professional self-governance and community engagement, thus encouraging research associations and various groups of the population to play a more active role in research governance.

Article 4 acknowledges the actual contribution of multiple actors in the governance of research involving humans. It would be unreasonable not to take advantage of existing peer-review mechanisms, in particular, given the problems that research ethics boards experience in transcending or enhancing the peer-review model by engaging non-scientific members. A multi-actor model of ethical governance would decenter research ethics boards, disrupt their hegemony on determining what is ethical.

Article 6 emphasizes contextual, experiential learning of ethical research practices. Developing good research habits through collaborative research, mentorship,

apprenticeship, and student involvement in the projects of experienced researchers has clear advantages over formal and speculative approaches to research ethics education. Passing ethics quizzes (tailored to biomedical research), filling out ethics forms, and dealing with procedural aspects of ethics review are unlikely to prepare students for actual ethical dilemmas arising in day-to-day research situations.

Article 7 calls for evidence-based ethics, for more constructive critical scholarship about the system of research governance. Currently research ethics boards may effectively censor critical policy research on them, without even noticing their own conflict of interest.²⁷⁵ Meanwhile, the internal and independent audit of the REB system by the Interagency Advisory Panel on Research Ethics or the Councils has to be made a priority for policymakers. How do regulators know about the effectiveness of ethics review and its impact on various disciplines, directions of research, and quality of research involving humans, if they do not conduct any research in this area? When I asked Suzan Zimmerman, the executive director of the Secretariat on Responsible Conduct of Research, if they monitor the effectiveness of the *Tri-Council Policy Statement*, I received a negative response.²⁷⁶ Indeed, policymakers take notice of the facts that are hard to miss, such as Canada's

²⁷⁵ For example, in reviewing my policy research project on the system of ethics review, the REB did not comment about any potential conflict of interests involved in its review of such projects. I discuss this further in Gontcharov, "Observers, Community and Legal Members on REBs: Examining the Ethics of the Regulators of Ethical Conduct in Research Involving Humans."

²⁷⁶ Ontario Regional Workshop on the second *Tri-Council Policy Statement*, Toronto, March 30-31, 2011.

shrinking share in the global clinical trials market. For example, Clinical Trials Ontario, “an independent not-for-profit organization established with support from the Government of Ontario”, is one of the initiatives established to streamline multicenter biomedical research and remedy the situation with clinical trials.²⁷⁷

A similar market situation pressured New Zealand’s Government to redesign the structure and operating procedures of the Health and Disability Ethics Committees in 2012 to ensure that its ethics review is competitive internationally. While the attractiveness of conducting biomedical research in New Zealand may have increased, the ethics community is concerned regarding their impact on the value and quality of ethics review. Regarding the streamlined, “assembly-line ethics review”, Tolich and Smith note that “these changes were detrimental to the Health and Disability Ethics Committees’ ability to robustly review applications.”²⁷⁸

While New Zealand and Canada’s share of social research may also be shrinking, as well as their attractiveness for social researchers from other jurisdictions, no similar initiatives to speed up ethics review for the social sciences have taken place, since financial indicators are not readily available and social research itself is not easily quantifiable. It is important to note that although the *Tri-Council Policy Statement* and New Zealand statutes postulate various principles governing research involving

²⁷⁷ <http://www.ctontario.ca>

²⁷⁸ Tolich and Smith, *The Politicisation of Ethics Review in New Zealand*.

humans, in reality the market may often take precedence. Therefore it is necessary to examine how the governance of research involving humans actually occurs, and not how policymakers think it should. The term “mandated science” describes a “concern[] with the way in which the policy “mandate” affects the kind of scientific assessment that is done”²⁷⁹. In the field of research ethics, “mandated ethics” would similarly describe a concern with the way ethics review is done, when the market or any particular policy actor sets policy priorities.

Article 8 speaks of the Declaration as a necessary step in creating an environment that would bolster social research while enhancing its ethico-methodological dimension. It is necessary to enhance our empirical knowledge base and understanding of the impact of various regulatory approaches in the governance of research involving humans. Academic conferences, and in particular *The Ethics in Practice* conference as a successor of the *Ethics Rupture* Symposium has a special role in this process, since one of the key objectives was to revisit the Declaration and further refine its principles.

²⁷⁹ Salter, *Mandated science : science and scientists in the making of standards*.

NEW BRUNSWICK DECLARATION'S IMPACT

Has the Declaration been noticed in the discursive field of the research ethics community? The answer is positive²⁸⁰ – for example, the Canadian Association of Research Ethics Boards had a special session at the CAREB National Conference in Calgary in April 2013, entitled the “Great debate: Be it resolved the Tri-Council Policy Statement is a good standard for which to review research in the social sciences and humanities”. Although the title reflects the position of the Association that the current “one-size-fits-all” model is good enough for all research involving humans, it is commendable that those who oppose it are invited to the table to share their views and concerns.

In the Great Debate the pro-TCPS side was represented by Lisa Given and Laura-Lee Balkwill (of the Secretariat on Responsible Conduct of Research) and the opposite side by Will van den Hoonaard and Kirsten Bell. It is worth highlighting the modes of argumentation since they help to understand how and why the regulators deflect the criticisms of social researchers. The debate focused on the past ten years and

²⁸⁰ See also M. Tolich and K. Fergusson, "Measuring the Impact of the New Brunswick Declaration," *Cross-Cultural Communication* 10, no. 5 (2014).

inquired whether policymakers succeeded in accommodating the recommendations of the “Giving Voice to the Spectrum” Report.²⁸¹

According to the supporters of the current Canadian model – the *Tri-Council Policy Statement* is effective in enabling ethical social research. Thus, Lisa Given suggested that there has been significant progress in relation to most of the Report’s policy recommendations. For example, the second *Tri-Council Policy Statement* speaks in a new language of human participants instead of subjects, and projects instead of protocols. Kirsten Bell agreed that there has been some progress in respect to policy recommendations, but emphasized that this does not address the question of the debate is the *Tri-Council Policy Statement* is a good standard of ethical governance in the social sciences. Will van den Hoonaard offered the content analysis of the Policy which elevates the status of REB members and professionals, while conceptualizing researchers as the only responsible party for the success of the Policy of which researchers may have limited control and which may not even speak to the actual ethical challenges of social research.

What this debate brought to surface is that there emerged a large group of professionals who are content with the one-size-fits-all model and their new status above “ethics”, and who may not be interested in studying the substantive issues,

²⁸¹ "Giving Voice to the Spectrum: Report of the Social Sciences and Humanities Research Ethics Special Working Committee to the Interagency Advisory Panel on Research Ethics."

including those engendered by the system of research ethics review itself. I have argued elsewhere that the ongoing re-articulation of the *Tri-Council Policy Statement* in what sounds like the language of the social sciences may not be a sufficient and adequate response to address the governance of social research. For example, the transition from the concept of human subjects to participants, without addressing the underlying issues, will merely create a new euphemism.²⁸² Moreover to the questions of relevance and implementation, we can now add an acute problem consisting in methodological pauperization of the social sciences, since researchers gravitate towards the methods “sanctioned” by research ethics boards.

Although the Declaration has indeed been noticed, its message has yet to translate into policy decisions in Canada. As we have seen in an earlier given example, regulatory innovation proceeds quickly when it is market-driven. Academic papers and independent declarations have limited efficiency when there is no immediate and documented threat to domestic and global economic markets. Accordingly, one of the approaches to triggering regulatory activism would be to render the ongoing methodological erosion of social scholarship in market. However, to render “methodological pauperization” in the social sciences in economic terms may not be suitable and/or welcomed by social researchers as a strategy of promoting social research. Nevertheless, it is possible to emphasize the impact of the Policy. What can

²⁸² Gontcharov, "The Eclipse of 'Human Subjects' and the Rise of 'Human Participants' in Research Involving Humans."

be done now is to rearticulate the articles of the Declaration in terms of policy recommendations, while continuing to build capacity by including a plan for action.

CONCLUSION: PROPOSED DEVELOPMENT OF THE NEW BRUNSWICK DECLARATION

One of the central themes of the Ethics-in-Practice Conference in Dunedin was the New Brunswick Declaration, including Prof. van den Hoonaard's keynote, two subsequent workgroup discussions, and a number of papers focusing on the problematic of the Ethics Rupture Summit – a widening gap between mandated ethics and ethics in research practice.

Indeed, the conference itself was designed to showcase an approach to ethics inspired by the New Brunswick Declaration. First, in contrast to numerous conferences for ethics professionals as venues for sharing administrative and management practices, or, the so-called, “research ethics 101” workshops by REB professionals for researchers on how to pass ethics review successfully by tailoring your application to procedural requirements, the Ethics-in-Practice Conference was envisioned as a platform for discussing (a) actual ethical challenges, faced by researchers on the ground, including the presence of embedded and alternative

ethical systems, such those of indigenous populations, (b) scholarly research about the institution of ethics review and governance in research involving humans.

Second, the conference was preceded by an indigenous welcome by mana whenua (people of the area) to appropriately locate the conference on their geography, under their Mana (power, authority), and within their kawa & tikanga (rules and customs). Moreover, kawa and tikanga were discussed within by the spokesperson for mana whenua within the context of the contribution by mana whenua to the governance of research involving humans, within Otago, and their concerns and criticisms of the local process were raised.

Third, the opening plenary took place at the Otago Museum, allowing the participants to appreciate the richness of the cultural traditions of the area. In this plenary, Barry Smith, a prominent Maori scholar of ethics review, argued, on the basis of the a new book that he co-authored with Martin Tolich, for improved dialogue about the governance of research involving humans in New Zealand, which would be evidence-based rather than driven by policymakers and REB professionals' considerations. As discussed above, these considerations are often dictated by the market, or are reflective of moral panics, and methodological preferences, rather than genuine interests in creating a safe environment conducive to the advancement of knowledge. This was a theme repeated and placed in a global perspective by both the second and third plenary speakers, Julie Bull and Martin Tolich respectively.

Following discussions during the conference and workshops, and extensive email correspondence, participants agreed that the New Brunswick Declaration would benefit from further elaboration and refining of its principles and should set an immediate priority of improving relations between ethics committees and researchers. Endorsing this priority, I suggest below one of the possible ways to restructuring the articles of the Declaration to highlight this objective of cultivating trust in ethics review, thus supporting multiple actors, contexts and research methodologies, enhancing the ethical dimension in research involving humans, and promoting critical scholarship and a broad discussion of regulatory innovation in the governance of research involving humans.

Article 1 (*Culture of Trust*) – emphasizes trust and mutual respect as a basis of research governance. Researchers and participants should be treated equally by ethics committees and policymakers.

Article 2 (*Collectivities and Individuals*) – the importance of collectivities, group interests and group consent in the governance of research involving humans, and the limitedness of risk management on the basis on individual harm.

Article 3 (*Professional Self-governance*) – the role of professional associations, professional self-governance and methodologically-relevant standards in the governance of research involving humans.

Article 4 (*Ethical Pluralism and Broad Governance*) – ethical and methodological pluralism, the role of existing institutions of peer-review, and the contribution of multiple actors, including the public, in the governance of research involving humans.

Article 5 (*Experiential Learning*) – the importance of experiential ethics, contextual ethical education and academic apprenticeship.

Article 6 (*Bridges between Ethics Committees and Researchers*) – acknowledges the existing rupture between procedural ethics and ethics in practice.

Article 7 (*Freedom of Expression*) would emphasize the connection between academic research and freedom of expression, the importance of which is particularly important now when the institution of tenure is rapidly eroding.

Article 8 (*Evidence-Based Ethics*) – the need for evidence-based ethics and support of critical scholarship on the current models of ethics review and research governance.

Article 9 (*Consultative Governance*) – the benefits of consultative models over prospective ethics review.

Article 10 (*Research Beyond Academia*) – the interconnectedness of academic, independent and journalistic research.

Article 11 (*Declaration: Today and Tomorrow*) – the need for further development of the principles outlined in this Declaration.

CONCLUSION: FURTHER DIRECTIONS OF RESEARCH – SCIENCE, ETHICS AND THE GOVERNANCE OF RESEARCH INVOLVING HUMANS

When the three major Canadian Research Councils, following a global trend, designed a joint policy governing research involving humans, the *Tri-Council Policy Statement*, a biomedical approach was adopted as a common standard for all research disciplines. As a result, the biomedical perspective – its context and ethical issues, its understanding of power imbalances between researchers and participants, as well as the methods of risk assessment and management, were extrapolated to the social sciences and humanities, and even beyond academic institutions – to independent and community-based research. All research involving humans thus became subject to licensing by institutional research ethics boards, which remained biomedical in their approach to research, despite a number of initiatives to broaden their methodological expertise and representativeness. Such expansion has undermined the pluralistic ethico-methodological environment in non-biomedical and non-academic fields of knowledge production, since licensing and common standards, despite their possible advantages, are also known for their ability to exclude and suppress alternative knowledge and practices.

When the Interagency Advisory Panel on Research Ethics Developing was revising the *Tri-Council Policy Statement*, it chose to reaffirm the “harmonized” approach

(TCPS 2, December 2010), despite the mounting criticism of the adopted regulatory model and the missing evidence of its effectiveness. The ethical bases of the *Tri-Council Policy Statement* preserved the tensions between deontological principles and utilitarian approaches to risk management. The biomedical understanding of harm and consent in terms of individuals was also retained, although a requirement for group consent was introduced for aboriginal research. Basic conceptual framework continued to be grounded in positivist understanding of research and its socio-political problematics. The role and place of research ethics review vis-à-vis other forms of peer review and public accountability were not critically examined. Accordingly, the role of community members remained obscure. The processes of professionalization and lawyerization received additional support.

In light of the rising costs of research oversight and the lack of understanding of its contribution to (1) the objective of protecting human participants from research risks, and (2) more generally, to research and society, the articles in this portfolio take a critical look at the principles and current practices of regulating and governing research involving humans. The task of the project was to determine how the expansion of the biomedical model of ethics review, (critically described in terms of “ethics creep” and “ethical imperialism”) interrupts critical scholarship and depletes the ethical dimension in the social sciences and humanities. This dissertation identifies and discusses conceptual and institutional barriers to regulatory innovation in research involving humans, and contributes to the

emergence of viable alternatives to research ethics review in the social sciences and humanities.

Chapter One: A New Wave of Positivism in the Social Sciences introduces the ethics creep issue from the perspective of standardization, while *Chapter Two: Methodological Crisis in the Social Sciences* puts this disciplinary debate in a broader historical context of “ethics” as a new regulatory paradigm that has infiltrated and colonized human activity, including the social sciences and humanities, while avoiding a rigorous debate over the ethics of the new “ethics paradigm” in the governance of research involving human – a necessary analysis of its socio-political dimension.

Chapter Three: The Eclipse of “Human Subjects” and the Rise of Human Participants provides an illustration that the overhaul of the *Tri-Council Policy Statement*, which aimed mitigating the tensions in the conceptual framework and better integration of the social science and humanities, generally failed to address the critiques offered by the sociologists and ethnographers of ethics review. *Chapter Four: Observers, Community, and Legal Members on Research Ethics Boards* discusses the status of expert knowledge, as well as the processes of professionalization and the role of communities in ethics review

Chapter Five: Alternative Models of Ethical Governance acknowledges the limits of transforming the system of governance from above, which could not take advantage

of the elements of responsive regulation. As a viable alternative it offers community-based research as a methodology to regulatory innovation in the governance of research involving humans, which was able to develop a set of ethical principles from below (The New Brunswick Declaration), while engaging in critical evidence-based “ethics”. The regulatory space of research involving humans is a host of multiple actors.

Most scholarship on research governance offers a segmented and/or one-sided analysis, which cannot provide a strong foundation for elaborating and evaluating approaches to regulatory initiatives, since they generally avoid the study of the sociopolitical dimension of standard setting in research involving humans. This dissertation project, based on conceptual analysis of the regulatory and conceptual frameworks, and informed by the author’s participation in the governance of research involving humans, contributes to further understanding of this complex regulatory space, and to developing a methodological foundation for elaborating and evaluating innovative regulatory proposals.

In conclusion, I would like to identify a number of directions that would further enhance the value of this project. These issues in the governance of research involving humans are crucial to research governance and knowledge production, and their understanding would facilitate the closing of the rupture between procedural and fieldwork ethics. The study of these directions could also facilitate further conceptual and empirical understanding of “mandated ethics”.

1. Science Policy and “Vulnerable Populations”: Ethics Review and the Production of Vulnerability

Following the adoption of the common policy in research involving humans in Canada in 1998, research ethics boards have developed a number of strategies for identifying “risky” research. One of such strategies is based on determining whether the study involves “vulnerable populations”. The implications of this strategy can be dramatic for designated vulnerable populations and knowledge production in general, since research ethics boards tend to ‘raise the standard’ of ethics review, which in practical terms usually translates into a slower review process, elaborate consent forms, and requests for modifications – a way of rejecting proposals by research ethics boards. This strategy is an outcome of contradictory ethical principles on which the ethics regime is based. These principles include a deontological core and the corresponding language of human rights, but rely on the utilitarian harm-benefit analysis, using “vulnerable populations” as a proxy in the assessment of harm.

My objective in this field is to examine the concept of vulnerable populations and its counterparts in other national contexts, while reflecting on its place and influence on the conceptual and ethical frameworks in the governance of research involving humans.

2. Fragmentation and Professionalization in Research Ethics

Fragmentation of REB membership and the emergence of REB professionals is yet another area that requires thorough examination. Initially research ethics boards were homogenous in terms of membership. Subsequently, a number of differentiating criteria have been introduced. REB membership is now subject to several requirements – gender balance, presence of lay/non-scientist/public members, ethicists, lawyers, and in the near future – REB professionals. While the division of labor and expert knowledge may be important in reviewing research proposals, there have been no studies on the impact of fragmentation on research, research safety, and the governance of knowledge production in general.

3. Risk Management in a Risk Society

The concept of risk is central to the current system of ethics review. Along with various other initiatives at risk regulation, such as occupational health and safety, consumer products, environmental protection, the institution of ethics review features a prospective approach to risk management. For research ethics boards, risk is something undesirable, something to be avoided. In contrast to this, “risk” can also function as a critical methodology for the analysis of governance, when it is understood as an inherent feature of our social life. Such an understanding was suggested by Luhmann, Giddens, and Beck within the theoretical frameworks of systems analysis, structuration theory, and risk society, respectively, as a way of conceiving the nature of modernity. The issue that needs be clarified is twofold. The first concerns the concept of risk within the current system of research governance,

and second – the effectiveness of risk aversion in promoting research safety in a society where risk is a given.

4. Legal Transplants in Science Policy

The expansion of the biomedical model of ethics review to social science research is known as “ethics creep”, “ethical imperialism”, and "methodological colonialism". The choice of epithets is not accidental since the consequences of the “harmonized” approach are dramatic for the social sciences and humanities. Prospective ethics review undermines methodological diversity and creativity of social researchers, promotes bureaucratic and erodes intrinsic ethics. In addition to a disciplinary “ethics creep”, the system of prospective ethics review is also expanding geographically, crossing national boundaries, thus contributing to the emergence of a new global research ethics regime. It is important to investigate and document this process if we wish to understand (a) how ethical and regulatory transplants transform the institutional culture of research involving humans, and (b) what role legal transplants play in ensuring the safety of research participants in domestic and international contexts.

5. Regulatory Challenges to Independent Research

This project is an off-shoot of my research in the field of history and philosophy of science, and my collaboration with independent and alternative researchers in the study of ethnographic evidence and artifacts that challenge the accepted historical

and anthropological narratives.²⁸³ It is crucial to document the challenges (of the regulatory character, in particular) that are experienced by independent researchers, since the *Tri-Council Policy Statement* and similar policies in other countries do not envision a mechanism allowing non-academic researchers to access the ethics review infrastructure, while making them subject to the same requirements as academic researchers. Accordingly, the task of this initiative is to contribute to the development of such policies that would facilitate independent and alternative research, and more broadly – public participation in knowledge production.

²⁸³ Igor Gontcharov, "Elongated Skulls in utero: A Farewell to the Artificial Cranial Deformation Paradigm?," *Ancient Origins* (2015); Igor Gontcharov, "The Story Of Elongated Skulls And The Denied History Of Ancient People: An Interview With Mark Laplume," *Ancient Origins* (2014).

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