Research ethics review emerged in biomedical and behavioral research following WWII, and became a mainstream practice in these areas of knowledge throughout the late 1970s to mid-1990s in both Canada and the United States. It was initially introduced as an instrument of ‘risk management’ following the disclosure (esp. Beecher 1966) of, and a growing public concern over, existing ethical problems in government-sponsored biomedical research. The current model of prospective ethics review can be traced back to particular institutional settings, and in this sense it can be understood 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” (Stark 2006). The focus of new regulations, such as the Belmont Report (1979) in the United States, and The Medical Research Council of Canada Guidelines on Research Involving Human Subjects (1987) and earlier institutional guidelines (Dickens 1979), fell largely on the risks of physical and lasting psychological harm posed to prisoners, military personnel, and psychiatric patients, who all had a limited ability to give free and informed consent for their participation in research.

Following the introduction of research ethics review in a narrow segment of government-sponsored research, the focus of ethics review started to broaden rapidly. By the late 1990s the mandate of research ethics boards (REBs) expanded to all research, including self-funded and
unfunded, and to all disciplines including the social sciences and humanities (SSH), and became applicable to all populations. Importantly, research ethics regulation has taken a global character as national research ethics regimes are borrowing from each other, uncritically transplanting the biomedical approach to the governance of all research involving humans.

The expansion of REB oversight (institutional review boards, IRBs in the USA) 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 research settings. Neither was there an open forum with either social scientists or research participants regarding their perspectives on the principles and approaches to the governance of research involving humans. It has to be noted that prior to “harmonization” in the disciplinary approaches to ethical governance in research involving humans in 1998, the social sciences and humanities had their own set of ethics guidelines, the 1979 Social Sciences and Humanities Research Council Ethics Guidelines for Research with Human Subjects (1980), which was first developed by the Canada Council for the Arts in 1976 and was largely unknown with limited regulatory effects (McDonald 2009).

The goal of this chapter is to examine how social science in general and qualitative research in particular has weathered this policy development. A case study concerning the development of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans in 1998 is featured along with its revision in 2010 and 2014. The overall thesis offered here is that research governance 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, as has also been argued by van den Hoonoord in The Seduction of Ethics (2011).
The expansion of research ethics review to SSH research has been rationalized in such terms as *ethics creep* (Haggerty 2004), *mission creep* (Gunsalus, Bruner et al. 2007), and *ethical imperialism* (Schrag 2010), which all imply a regulatory and methodological colonization of the social sciences and humanities by the growing ethics industry. The first edition of the *Tri-Council Policy Statement* (TCPS 1) was adopted in 1998. The second edition (TCPS 2) was adopted in December 2010 and updated in 2014, reaffirming 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 outcome has been an expansion of the procedural basis of research oversight.

Burris (2008) notes that the governance model behind the *Common Rule* (the phrase used since 1981 for the baseline standard of ethics for human subjects research in the USA) is in its basic design consistent with reflexive 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 regulations. In practice, however, the model functioned differently than one would predict. This observation is also valid in respect to the TCPS. For example, the character of ethical guidance by such diverse research ethics boards, existing in different research settings, 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. Accordingly, research ethics boards restricted themselves in exercising their autonomy. They demanded more guidance from the *Interdisciplinary Panel on Research Ethics*, more rules rather than principles, and thus gravitated 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
standardization, centralization, professionalization, and specialization in ethics review, which has been a characteristic of the ethical landscape in the governance of research involving humans since 1998. Importantly, and 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.

Indeed, *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 within SSH, 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 for example – anonymity may not be desirable or achievable; in critical policy research – an obligation to disclose research objectives and seek informed consent could compromise its objectives; in survey-based research consent is
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. At times the requirement of free and informed consent was seen as 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. On other occasions, the requirement 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 other cases 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 the insistence of anonymity and generalizability of data, and the 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 standards (e.g. Pistor 2002).

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 TCPS. 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 TCPS, and their counterparts in other countries, such as the Belmont Report are in any sense harmonized policies. Rather, they argued that the process of standardization in research involving humans is an example of regulatory 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” (Klitzman 2015), rather than a friendly collegial space for discussing ethical challenges and dilemmas. Tolich and Smith offer to correct this trajectory by proposing the adoption of an optional consultative model of ethics review (2015).

It is important to emphasize that the first TCPS 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 TCPS
(2010) the regime of non-working exemptions was dropped altogether. Furthermore, the second TCPS 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 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 TCPS, 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 (Gontcharov 2016).

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 consistent. Nevertheless there is still a question of whether or not prospective ethics review is an adequate measure to the character of risks arising in SSH research, and if such risk justifies a system of research oversight based on prospective ethics review.

Accordingly, some social researchers would not necessarily oppose prospective ethics review from a methodological perspective, though they might still disagree on ethical grounds (Dingwall 2008). This might explain the position of the Social Sciences and Humanities Research Council to collaborate with two other major Canadian Research 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 that did not seem to fit the framework well enough, such as qualitative, critical, public policy, educational and aboriginal/indigenous people’s research.

The minority hoped that through collaboration with their biomedically-minded colleagues it would be possible to develop a truly common ethics framework that could embrace the non-positivist modalities of knowledge production. However, as van den Hooaard, one of the founding members of the Interagency Advisory Panel on Research Ethics, writes in the Seduction of Ethics (2011), 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 initiatives to design a consensus model of research ethics.

The Ethics Rupture expert symposium was one instance of this widening rift in the ethics of the social sciences. The Ethics Rupture: Exploring Alternatives to Formal Research-Ethics Review Summit was held in Fredericton in 2012 (van den Hooaard 2013a; van den Hooaard 2013b). 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 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 (van den Hoonnaard 2012).

It is important to note that the Social Sciences and Humanities Research Council funded the Ethics Rapture Summit with members of the Secretariat on Responsible Conduct of Research attending the event. According to the Terms of Reference, 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 TCPS. The Social Sciences and Humanities Research Council’s support is indicative of its interest in learning more about the role of the TCPS 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 social sciences and humanities has not been one of the funding priorities for the Council. Even if this question is formulated more narrowly in terms of risk, safety and protection of human participants in SSH research and thus reflecting the approach of the TCPS, there is still 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 is seen to be its adoption on a moral panic (van den Hoonaard 2001; Cohen 2002) wave – that is, without a proper justification of its need and effectiveness in maintaining required ethical standards in SSH research. Another major issue is the limited interest of regulators in learning whether or not the TCPS was able to enhance the ethical dimension in research involving humans. It is necessary to find out why an event such as the Ethics Rupture Summit has not triggered a review of the conceptual and regulatory framework in research involving humans.

Now to the question of 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 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 TCPS 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 would 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 TCPS, for example, avoiding such biomedical irritants as “research subject” and “protocols”, would facilitate the development of the Policy towards multidisciplinarity, yet social scientists were excluded from the core policymaking groups. For example, Zachary Schrag’s monograph details how social researchers were excluded from the governance of research involving humans in the USA (Schrag 2010; Schrag 2011). Canada followed a similar trajectory, being influenced by the emerging ethics oversight regime in the USA, and borrowing heavily from the Belmont Report (1979), subsequently incorporated in the Code of Federal Regulations (2005).
The work on the second TCPS, updated again in 2014, presented an opportunity to respond to the recommendations and criticisms of the Law Commission of Canada Report, 2000 (McDonald 2000; McDonald 2001), Giving Voice to the Spectrum Report (2004), as well as the feedback from criminologists (Palys and Lowman 2016; Palys October 16, 2015), critical submissions received during several rounds of consultations (December 2009), and contributions 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 participants (Gontcharov 2016) have not been sufficiently empowered as policy actors and invited to the table.

Somewhat paradoxically, despite promoting a positivist perspective of 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 ethics (Beagan and McDonald 2005) has yet to become a criterion of its effectiveness in the governance of research involving humans. Since the performance of the Panel on Research Ethics is part of its accountability to the public as a research ethics regulator, it should not exclude itself when developing ethical standards. Meanwhile, 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 mainstream biomedical approach to critical public health research and health research based non-positivist methodologies (Bell, Whiton et al. 1998; McDonald 2000).

In developing the TCPS, the regulators, following the unified science model, assumed that SSH research is subject to the same problems as documented 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 TCPS, there were strong ethical and structural arguments against ethics oversight in the social sciences and humanities (Dingwall 2008; Hammersley 2009; Schrag 2011), which the *Panel on Research Ethics* could have considered. The fact that they did not challenge the overall approach can be possibly attributed to the composition of the Panel, which is tailored to the needs of biomedical research (Gontcharov and MacDonald 2016).

The promise of reflexive regulation has not been fulfilled since the overall positivist framework prevented the Panel 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 idiosyncratic decision-making could result in restricting particular research areas and methodologies in a uniform way (Stark 2012; Meyer 2013; Meyer 2014). Since 1998 the development of the TCPS 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 of research involving humans generally supports 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.

Since the formation of “moral regulation” and institutionalization of IRBs from 1953 to 1974 (Stark 2006; Stark 2012) the mandate of ethics committees has expanded beyond its original task of protecting human subjects in biomedical research. New responsibilities include the consideration of scientific merit, soundness of research methodology, institutional liability, conflict of interest, and even criminal checks of researchers. 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 such critical issues in the system of research oversight as: (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) prospective ethics review promotes how to appear ethical, and (4) management of legal risks (Gunsalus, Bruner et al. 2007). These are some of the issues behind IRB mission creep, which is also characteristic of ethics review in Canada.

The first issue, which Gunsalus et al. call “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 policy understands the production of new knowledge and the role of researcher in this process. On one hand, researchers cannot be trusted, so every single initiative required research ethics review. On the other, research ethics committees have to trust researchers anyways, since they are largely 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 protocols. But can the protocol serve as an 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, there is no comprehensive system of research ethics oversight, but rather a system of research protocol/project oversight. Nevertheless the TCPS 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. Hence the situation is such that (a) all individual research projects require review and approval and (b) research ethics boards can only hope that researchers conduct approved research ethically, since they do not entirely trust them. In part, this is a result of the TCPS’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 the “modern” trust-risk (Luhmann 2000). Understanding research in terms of 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 averts some of the dangers. This would explain 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 REBs, a research designs that corresponds to the ideal form is all that matters. This is a consequence of the TCPS’s reductionist understanding of research. This understanding is consistent with positivism, according to which research is divided into stages – rigid and sequential – in which one 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 (Kuhn 1962; Feyerabend 1993), subject to socio-political, and economic pressures and challenges. The role of research ethics boards then
becomes to identify and correct any 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. Brunger and Burgess (2005) 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. 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 with risk-taking populations.

Since the TCPS 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 experience challenges in passing ethics review. Since the format of ethics review is tailored to positivist research, “qualitative” researchers try to fit in the framework – even if it is hardly relevant – when/thus filling out REB forms, 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 Hoonaaard’s The Seduction of Ethics (2011) documents the ongoing methodological pauperization of the social sciences. 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 TCPS, as protection of human participants, sustaining trust in science, advancing research, or ensuring highest ethical standards?

When the TCPS was updated in 2010 and 2014, the overall biomedical framework had 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 important and innovative, 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 the focus on 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 than immediately after adopting the first TCPS 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 borrow from Veblen’s concept of conspicuous consumption (1979), rather than having contributed to the stated objectives of ethics review. This is why the bureaucratic process and paperwork remain the indicators of research ethics boards’ effectiveness in ensuring ethical standards in research involving humans.
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 (Gunsalus, Bruner et al. 2007). For example, “research” comes 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 (Schrag 2009). *Don’t Talk to the Humans* is a title of a popular article that captures how research ethics oversight transformed social science research (Shea 2000). For researchers whose methods include “talking” in a form of casual conversation or even more structured interviews, ethics oversight poses significant challenges since *talking* is research for which ethical clearance is required. Research ethics boards use biomedical context and definitions in reviewing social science research. Accordingly, talking can be understood as potentially dangerous to human participants. For example, it may cause an emotional 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, may be a harmless nuisance, wasting 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 SSH, 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. Others 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 (Nonet and Selznick 1978; Ayres and Braithwaite 1992; Burris 2008). 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 the social sciences. For example, see my analysis of “The Great debate: Be it resolved the TCPS 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 and MacDonald 2016). Policymakers and REB professionals tend to explain existing issues in terms of the 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 appear generally not to be 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 TCPS 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), and better training in procedural research ethics by offering REB 101 and “best practices” workshops (Mueller 2007).

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. In terms of qualitative ethics, the purpose of the course is rather to impute a complex of shared guilt, thus legitimating the system of oversight in general. A good example of this approach is an instructional film “Evolving Concern: Protection for Human Subjects” accompanying the IRB Guidebook (1993; 1993).
The culture of mutual distrust is one characteristic of the institution of ethics review. Ethics regulation in its current form is a product of a low trust environment. Many of the phenomena, such as (procedural) ethics avoidance by SSH researchers, as well as pseudo-educational TCPS 101 workshops, are a direct result of this low trust environment. Mutual distrust can generate a deviancy amplification spiral, producing more ethics regulation. Ethics regulation in its turn can further undermine ethical research practice, leading to more regulation, and also leading to greater efforts at avoidance. This issue is critical for the institutions of ethics review and was emphasized in the *New Brunswick Declaration*, as well as in *The 2016 New Brunswick-Otago Declaration on Research Ethics*, “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” (Gontcharov and MacDonald 2016).

While the first TCPS 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, an ethical pluralist approach to research ethics has not been sufficiently enabled at the level of policymakers and individual research ethics boards, either structurally or procedurally. 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 and who represent various perspective of research ethics. Instead, they act 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 and participants and 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 following 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 conceptualize research situations dissimilarly 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 (2007). 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 may distort the ethico-methodological dimension of the research situation. This may also force researchers to act unethically (in a procedural understanding of ethics), in order to ensure their research integrity within 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 their use is a condition of approval, but refrain from using them in actual research situations.

Researchers realize that consent forms may undermine 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 ground”. The flow of information is funneled (McDonald 2000) 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.

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 TCPS (Haggerty 2004). For example, the concept of research first narrowly formulated as a systematic way of data collection with the intent of contributing to generalizable knowledge in a medical context, gradually expands to embrace any kind of knowledge production, such as Augusto Boal’s dramaturgy, as a way of learning and releasing social traumas (Boal 1979), or any variant of community-based research. 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 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 committees reflect this conceptual framework, thus making it difficult to propose and pursue anything that deviates from the standard.

Many 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 may be considered as “research requiring approval,” rather than “audit” or “performance review;” or student research, none of which are conducted with intent to broaden epistemic horizons (Haggerty 2004). 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 TCPS 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 possibility, while the benefits of individual projects may not be immediately possible to assess at all.
The Illinois White Paper also makes an observation that research institutions are driven by “the desire not simply to be ethical, but to appear ethical” (Gunsalus, Bruner et al. 2007). In other words, research institutions willingly extended the Common Rule to non-federally funded research. The extension 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 standard helped to elevate the Common Rule approach to ethics oversight to its current universal and cross-disciplinary status.

Equally, the necessity to be ethical in the procedural meaning of the term, i.e., in the eyes of REBs, motivates individual researchers to adopt the standard positivist understanding of research ethics, abandoning the methodologies and themes that deviate from it, or attempting to inscribe them into the existing templates. This is one of the key reasons for the ongoing erosion of ethics in research involving humans. From a procedural standpoint of prospective review, REBs deal for the most part with the project’s ethical appearance rather than actual research ethics. Therefore, 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 (Haggerty 2004; Koro-Ljungberg, Gemignani et al. 2007). Rule following and self-censorship to satisfy procedural criteria and to appear ethical have become the new standard of ethical conduct in research involving humans. The constitutive elements of 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.

The monitoring of research ethics extends beyond REB oversight. Many other policy actors 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 (Burris, Drahos et al. 2005).

Since the TCPS introduces prospective 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 largely limited to the biomedical field, it has already begun to expand to the SSH disciplines. 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. Otherwise, the trouble with journals’ ethics ‘review’ is that it necessarily occurs after the event – all they can do is ‘reject’ the publication on ethical grounds – not advise, warn and/or guide. 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.

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 humans. 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 regulators can further use the “appropriated” contribution of other nodes as a justification for an expansive regulatory regime. In fact, it may turn out that the contribution of the TCPS to ethics education, and other stated objectives, such as the reduction of the risk of harm to human participants is negligible or even negative (Hyman 2007).

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.

Most of the regulatory initiatives 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. At the same time, there is a shortage of independent empirical data about the institution of ethics review. The regulators themselves have yet to adopt an evidence-based approach themselves. Our knowledge of 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 (Murray 2016), and document those aspects of research ethics review that might be lost when knowledge is reduced to systematically collected and generalizable data. “IRB horror stories” (Kleiman May 02, 2009) and similar first-hand encounters (Rambo 2007) 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 remains exclusively procedural, it is particularly important to identify the fault lines in the research ethics terrain. Such criteria as the length of review or number of approved projects, does 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 (2004). 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 TCPS. 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” (2004). 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.

In sum, although the first TCPS expanded the biomedical approach to SSH research, there remained a possibility that subsequent editions of the Policy will address theoretical inconsistencies and growing tensions between procedural ethics and ethics in practice. However, the elements of ethico-methodological pluralism have not received further development in the TCPS 2, despite embracing the language of research participants instead of human subjects, and projects instead of protocols. Indeed, the TCPS 2 may have a chapter devoted to qualitative research and research on collectivities, but these regulations are (1) still framed within a wider positivist approach, and (2) research project’s ethics are not reviewed by codes, but human
beings who themselves embody the positivist frame that research is linear and therefore predictable as procedural ethics. Finally, (3) policymaking in the governance of research involving humans is currently driven by biomedical experts, thus suggesting that any future updates of the Policy are unlikely to resolve the tensions in REB review of qualitative and critical research.

References


