Methodological Crisis in the Social Sciences: The New Brunswick Declaration as a New Paradigm in Research Ethics Governance?

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Ethics codification has been a burgeoning activity in the past two decades. Codes of ethical conduct1 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 formalisation 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 licenses2 ethical conduct. Ethics oversight first emerged in biomedical and behavioural 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 Humans3 (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

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1 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, http://ethics.iit.edu/research/codes-ethics-collection.


Councils’). The first edition of the common Policy was adopted in 1998 and the current (second) edition in 2010. The TCPS 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 Boards4 (REBs) to review research involving humans.

Research involving humans is understood by the TCPS 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, stimuli or questions by the researcher, are relevant to answering the research question’.5 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 TCPS 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.6 In practice, however, such research also requires REB review, since ‘REB[s] make[] the final decision on exemption from research ethics review’7 and not researchers. Thus, from a regulatory viewpoint, REBs 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

The TCPS emphasises that research is a ‘complex’ endeavour 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’.8 ‘Risk’ here is ‘a function of the magnitude or seriousness of the harm, and the probability that it will occur’.9 The TCPS offers three core ethical principles that would promote research, while protecting and

4 They are known as Institutional Review Boards (IRBs) and Research Ethics Committees (RECs) in the USA and the UK respectively.
6 Ibid.
7 Ibid.
8 Ibid.
9 Ibid.
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 TCPS, while respect for persons, concern for welfare and justice are the ways to operationalise it. The TCPS emphasises that core ethical principles have to be understood within the context of their application.

Although the TCPS suggests that the core principles are interdependent, the order in which they are listed is important for understanding its 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 REBs. 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-maximising, yet inherently vulnerable individuals who require comprehensive protection. This understanding is decisive for conceptualising research situations and elaborating measures for protecting human participants.

### REB COMPOSITION AND ETHICS REVIEW PROCESS

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

10 The requirement to include members knowledgeable in the relevant law is mandatory for biomedical research only.
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 TCPS is deontological, since it is based on the
concept of human dignity and articulates researchers’ duties to human participants, the
way REBs are required to review research projects is utilitarian, since it relies on balanc-
ing the risks and potential benefits of the research. A conflicting set of ethical principles
unavoidably affects the decision-making of REBs. For 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 popula-
tions’, REBs 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 TCPS 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 10 basic
principles of permissible medical experiments introduced by the US military court, bet-
ter known as the ‘Nuremberg Code’.11 These principles formed part of the judgment in
the Doctors’ Trial in Nuremberg, in 1946–7.12 The Nuremberg Code was followed by
the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human
Subjects (1964)13 of the World Medical Association, the International Ethical Guidelines
for Biomedical Research Involving Human Subjects (1982)14 of the Council for Inter-
national Organizations of Medical Sciences, Guidelines of the International Conference
on Harmonization of Technical Requirements for Registration of Pharmaceuticals for
Human Use,15 and the UNESCO Universal Declaration on Bioethics and Human Rights

11 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.
12 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.
In addition to this list, one of the most important influences in developing Canadian policy in research involving humans was the *Belmont Report*, which served as a basis for the 1981 US Federal Human Subjects Protection Policy, known as the ‘Common Rule’ since it has been adopted by 17 federal agencies and offices.

Ethical codes that inspired the development of Canada’s harmonised 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 TCPS are such as they are—no harm principle, focus on individuals rather than collectivities, anonymity, privacy, free and informed consent. Their presence in the TCPS 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 TCPS 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 essentialising ‘vulnerable populations’, preferring the concept of human participants in ‘vulnerable circumstances’.

Ethics review is a dynamic and fast-growing industry which has given rise to a new profession. 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. Ethics review was initially introduced as a way of protecting research participants in federally funded medical and behavioural research. It subsequently expanded to cover all research involving humans, regardless of the source of funding, and including the social sciences and the humanities.

19 *Tri-Council Policy Statement* (n 5).
20 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.
21 *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.
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 behavioural scholarship, social scientists have long been critical of imposing it on the whole spectrum of research. Nevertheless, ethics review expanded beyond biomedical research in 1998, when the three Canadian Research Councils adopted a ‘harmonised’ 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’, 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 (e.g. policy or criminological) research, introspective research and biographical research, due to unfitting requirements of anonymity, free and informed consent, and generalisability of data. REBs appeared to be poorly suited to research based on ‘qualitative’ methodologies (ethnographic, participatory research), research on risk-taking populations, innovative methodologies, such as community-based research, which blurs the border between researchers and research participants, research on vulnerable populations, and educational research. 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.


Despite the challenges of a harmonised approach\textsuperscript{27} 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 TCPS, 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 TCPS 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, since the social sciences proceed from voicing concerns and producing evidence of the TCPS’s questionable moral guidance, to actively discussing alternatives to ethics review.\textsuperscript{28}

\textbf{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.\textsuperscript{29} The new study under review here, Will van den Hoonard’s \textit{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 Hoonard 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 homogenisation and pauperisation of the social sciences, a methodology and knowledge crisis manufactured by the system of ethics oversight.

\textit{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

\textsuperscript{27} For an overview of the challenges, see eg Katharina Pistor, ‘The Standardization of Law and its Effect on Developing Economies’ (2002) 50 \textit{American Journal of Comparative Law} 97.

\textsuperscript{28} 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.

study as it comes from one of the architects of this system. Van den Hoonaaard, 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 Hoonaaard’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 harmonised approach adopted in the TCPS, 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 REBs. 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 Hoonaaard 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. 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 Hoonaaard. 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.

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30 Schrag (n 29).
31 Will van den Hoonaaard (ed), *Walking the Tightrope: Ethical Issues for Qualitative Researchers* (University of Toronto Press, 2002).
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 Alternatives to Research-Ethics Review’,\(^{32}\) 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 REBs 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.\(^{33}\)

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 highlights the role of professional associations and valid research standards. It shifts the focus from individuals exclusively to individuals and collectivities. It emphasises 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 externalisation 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) archaeology of ethics review, (2) ethics review process, and (3) researchers vis-à-vis formalised and externalised ethics.


The scope of *The Seduction of Ethics* makes it necessary to deal with a broad array of practical issues—from institutionalisation of ethics review, to the specifics of the review process, and to social scientists’ encounters with formalised 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 Hoonaa’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 problematising such phenomena as ethics creep or ethical imperialism. The regulatory capture has already occurred, and it is time to identify effective strategies to decolonise social scholarship. Since it has proven difficult to challenge the regulatory capture of the social sciences by offering historical and conceptual arguments, it is necessary to redraw the line of critique and let the data showing how ethics review affects the production of new 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 ethics have been received by the regulators.

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

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34 See especially Dingwall (n 12); Hamburger (n 2); Schrag (n 29).
35 Michael McDonald and Susan Cox, ‘Moving toward Evidence-Based Human Participant Protection’ (2009) *7 Journal of Academic Ethics* 1.
nascent trend of ‘outsourcing’ critical scholarship to the private sector, namely to jour-
nalists, 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 plu-
ralist platform as a possibility for restarting the conversation on the principles of ethical
governance in academic research.