13 The Eclipse of "Human Subjects" and the Rise of "Human Participants" in Research Involving Humans

IGOR GONTCHAROV

Until recently the concept of human research subjects[1] was central to the conceptual framework of the system of research ethics review in Canada.[2] The purpose of 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 Sciences and Humanities Research Council (the Agencies) – adopted the second edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (*TCPS 2*) (CIHR et al., 2010). The first *Tri-Council Policy Statement* (*TCPS 1*) was adopted in 1998 and established the biomedical model of ethics review as a standard of ethical governance in all research involving humans (CIHR et al., 1998).

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 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"[3] 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 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. (CIHR et al., 1998: i.3, n2)

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. (CIHR et al., 2010: 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 2*, 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).[4] 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?

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 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 behavioural 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" (Boser, 2007) 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 ethics review, it mandated the mechanism of risk management for all research involving humans.

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" (White, 2007) 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 in the past decades. This included the problems that emerged in the process of adopting a common standard of 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: Ethical Conduct for Research Involving*

Humans should be considered in the context of the ongoing efforts to standardize 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 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 framework (Moore, 1973; Griffiths, 1986; Galanter, 1981; Merry, 1988) and welcomes social disciplines individually, rather than treating social research as a homogeneous entity.

Research *Participants* as a Way of Responsive Regulation?

The regulatory framework of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* conforms in its basic design to the principles advocated by reflexive law, responsive regulation, and new governance scholars (Burris, 2008). "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.[5]

   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, 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.[6] However, the system of ethics oversight features a strong central element – "common" and "shared" fundamental ethical principles.[7] 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?

   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 towards 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.

REBs 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 (van den Hoonaard, 2011). 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,[8] ethnographers (Bosk, 2007; Tolich and Fitzgerald, 2006; Lederman, 2007), 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.[9]

   The first *Tri-Council Policy Statement* also postulates a principle of "respect for vulnerable persons" that introduces a category of "vulnerable 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" (CIHR et al., 1998: i.5).

It is unsettling to see policymakers who view research through the lenses of "abuse, exploitation or discrimination." It is one of the perspectives that reinscribes *vulnerable persons* in the new regulatory framework and imposes double standards through the language of special protection. The second edition of the *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 multisite studies – not only is it often necessary to get 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.[10]

REBs 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 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,[11] *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 (see Onyemelukwe & Downie, 2011; Downie, 2009), it received written comments from over 123 institutions, Research Ethics Boards, and individuals.[12] 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 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 Board 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 Board 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 Board invest resources in educating researchers about the ethics review process. It is common to offer REB 101 sessions and "Best-Practices" workshops (Mueller, 2006). 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 ethics review is done by Institutional Review Boards (IRBs):

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

- 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]
- The IRB review process.[13]

"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 consensus around more contentious ethical issues" (CIHR et al., 1998). 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 edition of the *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 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.[14] 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.

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 (Austin, 1962). 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 "rottenness" (De Certeau, 1988). 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.

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: Ethical Conduct for Research Involving Humans* 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 edition of the *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 behavioural 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 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 crisis (Gontcharov, 2013) 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,[15] 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.

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.

NOTES

An earlier version of this chapter was published in the Osgoode CLPE Research Paper Series (Gontcharov, 2012).

1 I use "human subjects," "research subjects," and "subjects" interchangeably throughout the chapter.
2 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 research ethics approach in the United States remains loyal to the term *human subjects*. It is important to note that US federal regulations have been and continue to be more consistent in following the language of human subjects, while the *TCPS 1* was speaking already in 1998 in terms of humans rather than human subjects. Consider, e.g., the full title of the *Belmont Report*: *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (National Commission, 1979), and its successor, the *Federal Policy for the Protection of Human Research Subjects* (1991), whereas the subtitle of the *TCPS* (CIHR et al., 1998, 2010) is *Ethical Conduct for Research Involving Humans*. The omission of "subjects" in the *TCPS 1* can be understood as a transition point to the new language, and a point of conceptual divergence from the perspective in the United States.
3 *TCPS 1* 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" (CIHR et al., 1998: i.2)
4 E.g., http://www.etymonline.com/index.php?term=optimal
5 See Lobel (2004), Teubner (1983, 1992), Ayres and Braithwaite (1992), and Trubek and Trubek (2005).
6 After the adoption of the *TCPS 2*, 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 *TCPS*, in part also responding to the demand of REBs for such interpretations. The PRE website has a new dedicated section on the interpretation of the policy. See http://www.pre.ethics.gc.ca/eng/policy-politique/interpretations/ Default/

7 The *TCPS 1* also speaks in the same way about values and interests in research involving humans.

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

9 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.

10 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).

11 See http://www.ethics.gc.ca/eng/archives/policy-politique/ reports-rapports/reports-rapports/

12 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/

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

14 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.

15 On "ethics creep" see Kevin D. Haggerty (2004), Ronald F. White (2007), and C.K. Gunsalus et al. (2007).

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