Note on the Discipline/ Réflexion sur la discipline

Myths about Qualitative Research and the *Tri-Council Policy Statement*

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It is no secret that qualitative research and Canada's *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) has been an unhappy union. Much in the TCPS is drawn from the research ethics literature that addresses research in the medical context. Although acknowledged, the social sciences and humanities research experience has a low profile in the TCPS. The presence of qualitative research methods within the spectrum of healthcare research has an even lower profile. Some might suggest (incorrectly) that the social sciences, humanities, and qualitative research methods do not appear to influence the policies found in the TCPS at all. Accordingly, in universities and hospitals, in discussions among colleagues at conferences and research venues, and outside the closed doors of research ethics board (REB) meetings, there has been much criticism about the TCPS by those who use different theories and methods than are typical in medical research protocols.

While some criticism is justified, some of it is misguided. Despite its emphasis on research ethics in medicine, the TCPS actually allows for more flexibility than some qualitative researchers and REB members sometimes give it credit for. In this paper we address eight common criticisms related to qualitative research and the TCPS, most of which relate to supposed "requirements" surrounding the consent process. It is our contention that these criticisms are not inherent in the TCPS itself, but rather in its interpretation and application. Hence we call these criticisms "myths". By debunking these myths, our aim is to free researchers and REBs from placing undue restrictions on qualitative research. We encourage qualitative researchers and REBs to refer to

the text of the TCPS and interpret it in the context of specific research projects. We advise REBs to think beyond the medical model, and qualitative researchers to quote relevant passages from the TCPS in their protocol submissions to justify the procedures they propose.

Tri-Council Policy Statement

In August 1998, Canada's three major research funding councils — the Medical Research Council (MRC) (now Canadian Institutes of Health Research (CIHR)), the National Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC) — released their joint policy regarding research involving humans: the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS). This joint policy statement replaced previous guidelines of MRC and SSHRC and united the three major research-funding councils under one research ethics umbrella. The TCPS sets out the ethical norms and requirements for conducting research that involves human participants, as well as, requirements for structuring REBs and how they are to operate in their review of research involving human participants.

The Councils stipulate that they "will consider funding (or continued funding) only to individuals and institutions which certify compliance with this policy" (TCPS: i.1). Thus, access to funding (or the risk of loss of funding) motivates institutions receiving funding from any of the three Councils, to ensure that *all* research involving human participants conducted at these institutions or by their researchers complies with the TCPS. This motivation does not reach over privately funded institutions whose research in conducted behind their own closed doors. However, when privately funded institutions collaborate with academic researchers whose institutions receive funding from any of the three Councils, the TCPS is meant to apply to those collaborations.

The move from discrepant guidelines that apply to some to a unifying policy that applies to many was (and still is) a challenge, both for individual researchers and the institutions that receive Tri-Council funding. The concerns that we are responding to in this paper could be seen as arising in an era of transition when many institutions were/are formalizing their processes for research ethics review to be in accord with the new TCPS, and other regulations as well. We hope that the myths we address will be dispelled and left behind as qualitative researchers, REBs and the TCPS move forward under a shared goal of ensuring the highest ethical standards of research are achieved.

We acknowledge that our analysis and conclusions do not resolve all concerns in the ethics review process raised by social science and humanities researchers. For instance, there are legitimate concerns about "gaps" in the TCPS, i.e., aspects about ethical research in the social sciences and humanities

that are not addressed by the TCPS that subsequently cause great difficulty and frustration for researchers and REBs alike. We also acknowledge the *Report of the Social Sciences and Humanities Research Ethics Special Working Committee* (June 2004) to the Interagency Advisory Panel on Research Ethics (PRE), which is the panel charged with the responsibility to address issues with and update the TCPS; this report identifies several important priority areas to consider when revising the TCPS. While we agree that the TCPS is in need of revision with respect to qualitative methodologies and social sciences and humanities, we emphasize that our aim in this paper is to address "myths" of interpretation and application of the current TCPS. It is our hope that our analysis can be of immediate help to researchers and REBs, as well as alert PRE to implementation challenges of the TCPS for researchers using qualitative methodologies.

Myth #1: Anonymity Must be Guaranteed.

It is sometimes believed that the TCPS mandates that the identity of research participants must always be kept confidential, and accordingly, anonymity must be guaranteed (Piron, 2002: 6). Yet, contrary to this "requirement", qualitative researchers are aware that some research participants wish to be identified. Participants may have an additional motive in participating in research that requires their identity to be disclosed. For example, a participant may be an activist on the topic being researched and want readers of the research results to know her name so that they may be able to contact her or even be aware of her ideas and beliefs. Some participants are proud of their participation in research and want that participation acknowledged. Additionally, as Richards and Schwartz (2002: 138) note "participants may not wish to remain anonymous [because] identification with their expressed beliefs may help participants to maintain ownership of the content and meanings of their narratives." After all, many of the methodologies of qualitative research depend on the personal narratives of participants, which touch upon the participants' sense of personal identity.

Upon review of the TCPS, we find no claim that anonymity must be guaranteed. Indeed, regarding confidentiality, it advises that "a subject-centered perspective on the nature of the research, its aims and its potential to invade sensitive interests may help researchers to better design and conduct research" (TCPS: 3.1). This implies that one can consider the interests of the individual participants when planning how confidentiality should be protected. The TCPS correctly advises that: "*As a general rule*, the best protection of the confidentiality of personal information and records will be achieved through anonymity" (TCPS: 3.2, emphasis added). However, by noting that this is a "general rule" implies that some exceptions may be justified. Consistent with this interpreta-

tion, the TCPS tells us that during the consent process, researchers should indicate to participants "the *extent* of the confidentiality that can be promised" (TCPS: 3.2, emphasis added). That is, they should indicate who has access to what information and how? If some information will not be confidential (e.g., participants' names) an explanation of the limits of confidentiality must be disclosed.

The TCPS recognizes the importance of confidentiality in research. One of its guiding principles is "Respect for Privacy and Confidentiality." This principle derives from what the TCPS identifies as the overarching principle of research ethics: "Respect for Human Dignity," which "aspires to protecting the multiple and interdependent interests of the person—from bodily to psychological to cultural integrity" (TCPS: i.5). By referring to the overarching principle of Respect for Human Dignity with its emphasis on the protection of the interests of individual participants, the TCPS offers a measure to interpret how best to apply other ethical principles, in this case: Respect for Privacy and Confidentiality. We may conclude that: when the protection of the multiple and interdependent interests of the participant do not require anonymity, the TCPS does not require it either.

Myth #2: Written Consent is Always Required.

There are three objections that are commonly made by qualitative researchers in response to a "requirement" for *written* consent. First, requiring participants to sign a consent form may be culturally inappropriate because it implies distrust, or because the culture adheres to a collectivist approach. In a collectivist-oriented culture, it may be the community or the community leadership (e.g., tribal leader) who has the cultural authority (and responsibility) to consent to research participation. Second, requiring written consent is incompatible with some research methodologies, such as ethnographic research where the researcher immerses herself within the culture that is being studied as one of its members with as little intrusion as possible. Third, the presence of a signed consent form puts some research participants at undue personal risk (e.g., for political persecution).

Elaborating on the third reason given to reject the "requirement" for *written* consent, some researchers have reported "excessive rigor in implementation of the written consent policy" when there is significant risk of danger to participants if consent forms must be signed (Piron, 2002: 3). In some such cases, researchers have reported that their projects have "failed because of REB insistence on requiring signed consent statements" (van den Hoonaard, 2004: 11). In an extreme example, the Social Sciences and Humanities Research Ethics Special Working Committee reports being "told of an REB that tried to require a researcher to get signed consent statements from persons who would

be killed if their governments knew of their participation." (van den Hoonaard, 2004: 33). Less extreme, it has been noted as "unwise or tactless" to require written consent for "studies of street-corner people, poachers, hookers, fishers, drug users, professional thieves, and the homeless" and even "those who occupy positions of power and prestige" (van den Hoonaard, 2002: 10).

Qualitative researchers are correct to be worried about any policy that *always* requires *written* consent. The TCPS recognizes many of the challenges that these researchers face and allows for some exceptions to the expectation that written consent would normally be obtained: "Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented" (TCPS Article2.1b: 2.1). These two exceptions in the TCPS respond to the first two objections above. The third objection above is dealt with by an allowance made in the TCPS to waive or alter the consent procedure, provided that the REB judges and documents that the following conditions apply:

i. The research involves no more than minimal risk to the subjects;
ii. The waiver or alternation is unlikely to adversely affect the rights and welfare of the subjects;
iii. The research could not practicably be carried out without the waiver [sic.] alteration;
iv. Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and
v. The waivered or altered consent does not involve a therapeutic intervention (TCPS Article 2.1c: 2.1).

Thus the myth that written consent is always required by the TCPS is debunked. There is in fact flexibility not only for research involving non-written (e.g., verbal) consent, but also for research that uses an altered consent process (e.g., consent by tribal leader), and that waives consent completely, should certain criteria apply.

Myth #3: New Written Consent is Required for Each Encounter.

There are some who believe that a new written consent must be obtained each time the researcher meets with participants (Cooper, 2002: 9; Piron, 2002: 3). According to this myth, each time the researcher is in contact with a participant to gather data the researcher must begin the meeting by acquiring written consent anew.

Much of qualitative research involves observing or interviewing research participants on a number of different occasions. Obtaining a new written consent for each encounter would be burdensome and in some cases would pose

a practical constraint against actually conducting the research. So, it is fortunate that it is only a myth that a new written consent is required at each encounter with a research participant.

In the TCPS, as in the ethics literature more broadly, consent is understood to be a *process*. Consequently, obtaining the participant's signature at every step is not required. Even in typical clinical trials' research, participants may make many visits to the clinical research unit, but only sign a consent form once at the outset of the research. After that, their on-going consent is assessed informally (e.g., by their compliance with research procedures and absence of signs of objection). That this procedure is acceptable is implied in the TCPS notation that sometimes researchers may need to disclose to participants that they will be given new information in a timely manner whenever such information is relevant to their decision to continue or withdraw from research participation (TCPS: 2.7). Likewise, researchers must respond appropriately to participants' questions and concerns. It is only in exceptional circumstances that consent needs to be formally reassessed and re-confirmed in writing. This should hold for qualitative research as well. For example, if during the course of research, researchers learn that an employer plans to fire any employees who participate in the on-going research project, then not only should researchers inform participants of this new added risk and what (additional) protections are in place to protect participants' confidentiality, but also invite them to reconsider their decision to participate. If the participants wish to continue in the research, then they should sign an addendum to (or a revised) consent form.

Myth #4: A Consent Form Must Have a Certain Format.

Some believe that a consent form for research must have a certain format. For example, one sociologist writes: "Some committees, taking what can only be described as a fundamentalist view of ethics, require wording of letters that might be appropriate for drug trials (in which there is indeed some potential risk to participants) but not for surveys of students where there is absolutely no risk of harm" (Grayson, 2004: 40). While some committees might make this a "requirement", the TCPS does not.

Many qualitative researchers are aware that the language and format of a consent form influence potential participants' willingness to participate in research. It is important that qualitative researchers in particular, have some flexibility in the format of a consent form since many sample consent forms are designed with clinical research trials in mind. While ensuring that every "t" is crossed and "i" dotted for high-stakes clinical trials research, some REBs forget, and some researchers do not realize, that the same format is not required by the TCPS for all consent forms.

Article 2.4 of the TCPS describes information that must be disclosed to research participants, but the TCPS leaves open the format of that disclosure. Phrases such as "A comprehensible statement that ..." and "A comprehensible description of ..." imply recognition of some variation in how disclosures are made. In addition, this article also stipulates that it is "Subject to the exception in Article 2.1(c) ...", which acknowledges that alterations or waivers of consent procedures are appropriate in some cases. This includes what information is disclosed to participants. Furthermore, in the text expanding on Article 2.4, the TCPS clarifies that "researchers must clearly explain the nature and goals of the research and other essential information, *in a manner appropriate* for the prospective subjects' cultural settings"(TCPS: 2.6, emphasis added). The phrase "in a manner appropriate" also implies that the format of a consent form can vary. The TCPS adds: "With some cross-cultural research projects, it may not be possible to offer an adequate translation of the researcher's understanding to prospective subjects. REBs should proceed cautiously in such cases and require stringent protection for the interests of subjects, such as appointing an individual to act in an independent advocacy role ..."(TCPS: 2.6). What is important for researchers and REB members to keep in mind is that protection of the interests of research participants is paramount, both in what is disclosed and how that disclosure takes place.

Myth #5: Observational Research is Jeopardized by Consent Rules.

In observational research, participants are usually unwitting participants. Researchers do not usually pre-select them and their identities are not usually known or recorded. Likewise, consent is not usually obtained. Some believe that the TCPS requires consent to be obtained by individuals who are only being observed. They see this as not only being detrimental to the research itself, but also for training students. For example, one anthropologist who is also an REB member writes:

> Strictly interpreted, the current guidelines in the TCPS would make most [observational] research impossible. If for example, a student doing observational research in a coffee shop must obtain consent from every patron, the project quickly would become impossible... Similarly, a simple observational study of people in a university cafeteria would present insuperable problems. Yet such projects, in which subjects are neither identified nor recorded (e.g., on videotape), are truly minimal risk and are important for the training of students (Cooper, 2002: 9).

Indeed, obtaining consent in observational research may be difficult if not impossible in light of most observational research designs and theoretical justifications. As a result, the enterprise of observational research would be jeopardized if a requirement for obtaining consent existed. Fortunately, the

TCPS does not have such a requirement and does not jeopardize observational research.

In Article 2.3, the TCPS confirms that most naturalistic observation research requires REB review, and stipulates one exception:

> REB review is normally required for research involving naturalistic observation. However, research involving observation of participants in, for example, political rallies, demonstrations or public meetings should not require REB review since it can be expected that the participants are seeking public visibility.

When people are seeking public visibility with their actions and statements, simultaneously recording their actions or statements for research purposes does not threaten their privacy and dignity. Note that this exemption applies only to a subset of observational research. It does not apply to people who are *not* seeking public visibility with their actions and statements.

For observational research that is not included under the exemption specified, the TCPS (2.5) advices researchers and REBs to "pay close attention to the ethical implications of such factors as: the nature of the activities to be observed; the environment in which the activities are observed ...; and the means of recording the observations." The TCPS (2.5) specifically acknowledges that: "Naturalistic observation that does not allow for identification of subjects, and that is not staged, should normally be regarded as of minimal risk." Thus, observational research meeting these criteria can proceed following allowances appropriate for research involving minimal research. Importantly, to undermine this myth, Article 2.1c of the TCPS (quoted above under Myth #2) allows for waiving consent if certain criteria (regarding no more than minimal risk, maintaining rights and welfare of participants, inability to carry the research with the waiver or alternation, provision of pertinent information when practical, and absence of therapeutic component to the research) are met. One can imagine that these criteria can be met for most observational research. Thus, we conclude that observational research is not jeopardized by the consent rules of the TCPS.

Myth #6: Risks and Benefits Must be Known in Advance.

Some qualitative researchers complain that the ethics review process of research requires the impossible: that the risks and benefits of research participation must be known in advance (O'Neill, 2002:18). These risks and benefits "must" be shared with potential participants so that they can make a fully informed decision about whether to participate in the research. Yet, some risks and potential benefits may not be known, or knowable, before the research is begun or completed. For instance, many of the risks and potential benefits of qualitative research derive from human psychology and social relations, which researchers cannot fully know. Thus, stipulating that the risks and benefits be

disclosed in the informed consent process creates unattainable requirements for qualitative researchers. Fortunately, this "requirement" is also a myth.

The TCPS does not require knowledge or disclosure of all risks and potential benefits to research participants. Rather, it requires researchers to provide prospective participants with a "comprehensive description of *reasonably foreseeable* harms and benefits that may arise from research participation..." (Article 2.4c, emphasis added). Adding a caveat during the consent process that some risks and potential benefits may be unknown at the time of the research participation is both acceptable and common.

Myth #7: Minors Must Have Approval of Parents/Guardians.

Requiring the approval from parents/guardians for a minor to participate in research fails to take into account the reality of some minors' social context. Qualitative researchers rightly claim that for some qualitative research involving minors, it would be inappropriate or even disrespectful to require prior parental/guardian permission. For example, some would claim that it is inappropriate for a researcher to require permission from a minor's parent or guardian before a child/teen runaway participates in a study on the experience of child/teen runaways. To limit the study sample to runaways who have returned to their parents/guardians in order to receive their permission to participate, may result in a biased sample and fail to address all the research questions. Similarly, some would claim that it is disrespectful to ask a sixteen-year-old mother to gain permission from her parent/guardian to participate in a study about teenage motherhood. Referring to a TCPS "requirement" that *all* minors must obtain parental/guardian permission prior to research participation, one anthropologist writes, "this demand relies on a preconception of what a person of 18 and under is and is socially ideologically tainted and does not correspond to the reality of anthropological fieldwork" (Piron, 2002: 6).

One of the guiding ethical principles of the TCPS is Respect for Vulnerable Persons, including children. Thus, the protection of participants who are children, or in a situation of vulnerability, is an important aspect of conducting ethical research. Parents or guardians are called upon to fulfill the role of the decision-maker regarding a minor's participation in research because of the duty of care that they have regarding the minor. They are expected to champion the minor's welfare.

The TCPS does not directly address the issue of authority to provide consent to research participation for minors who are runaways, mothers, married or living independently. However, by placing protectionist restrictions on "individuals who are not legally competent" and qualifying those restrictions as "subject to applicable legal requirements", Article 2.5 of the TCPS acknowledges that those who have the authority to consent to research participation are

those whom the law designates. Indeed the law has precedence over the TCPS, and it is prudent that the TCPS does not assert requirements that conflict with the law. In some legal jurisdictions "mature minors" are authorized to act on their own behalf; in other legal jurisdictions they are not. For example, according to the *Civil Code of Quebec*, a minor who is a mother may consent to research participation for her child (assuming the criteria of the TCPS Articles 2.5-2.7 are met), however she may not consent to research participation for herself (C.C.Q., Article 14, par.2 and Article 21).

While this clarification will remain unsatisfactory for some researchers and some REB members, it is important to realize that the source of the authority of parents/guardians or minors to consent to minors' research participation turns on the law in Canada, not the TCPS. Thus some research designs can be approved in some jurisdictions but not others. Efforts to change this requirement must address lawmakers not the TCPS.

Myth #8: All Research Must Follow the Biomedical Model.

The "biomedical model" for research is hypothesis driven; that is, researchers generally begin with a formal hypothesis, make use of experimental designs and quantitative data, and engage in deductive reasoning with the aim of confirming the hypothesis. While some qualitative research aims to confirm a hypothesis, or is used to generate a hypothesis, qualitative research is often descriptive in nature. That is, qualitative research often is designed to answer exploratory questions that strive to understand the essence or elements of an experience or situation. Thus, much qualitative research does not conform to basic assumptions of what research should look like in the biomedical model.

Different approaches to research have implications for formulating the study design and carrying out the research. In some qualitative research, the focus of the research itself can change as the research is being conducted (e.g., in response to observations or responses to interview questions). Failing to acknowledge and accommodate these differences, for example by adopting one approach as the 'standard' in which ethical evaluations are made, can seriously compromise the scope and quality of qualitative research. Researchers report that REBs often require that researchers present them with the list of questions that are to be posed to the participant, and imply that these questions cannot change when carrying out the research (without prior REB approval). Such a demand fails to recognize the methodological approach of qualitative research; and consequently undermines the notion of "discovery during inquiry" that is "usually considered a strength" of qualitative research (O'Neill, 2002: 18). Given the above, if it were the case that all research requiring review under the TCPS must follow the biomedical model, then qualitative researchers (and REB

members) are right to criticize this restriction. It is a relief, however, that the TCPS does not require that all research follow the biomedical model.

The quotations and references cited from the TCPS throughout this paper imply distinctions made in the TCPS between methodologies in biomedical and social sciences and humanities research, and moreover that differing methodologies will entail different applications of ethical principles. In addition, note that the TCPS (Article1.3a) stipulates that REB membership must include "at least two members [who] have broad expertise in the methods or in the areas of research that are covered by the REB." The TCPS (1.4) also advices that REBs may nominate ad hoc members to review specific research projects, if specific expertise is needed but not available within the REB membership. These statements recognize that REBs can expect to receive research projects using different methodologies and areas of research, and that expertise in those methodologies and areas of research may be necessary for an appropriate ethical review. While REBs should attempt to have a membership that is representative of the methodologies and areas of research of the research community that it serves, they should accommodate research proposals received using less common methodologies and from less common research areas. Hence, an REB that reviews mainly biomedical (or hypothesis-driven research) research should have or have access to expertise to review other types of research as well. It appears then that the "biomedical model" is *not* presented in the TCPS as *the* model for all research involving humans.

Perhaps, even more obvious is the distinction noted in TCPS Article 5d that:

> Certain *types* of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on organizations. Such research should not be blocked through the use of harms/benefits analysis or because of the potentially negative nature of the findings. (Emphasis added)

In this Article, the TCPS allows for a variation in the application of harms/benefit analysis based on the type of research proposed, and specifically identifies some social science and humanities research where the participants are not patients but public figures as an example of when this variation in analysis is appropriate. With these examples, and other passages quoted throughout this paper, we can be assured that the myth that "all research must follow biomedical model" is indeed undermined.

Conclusion

We conclude that these eight "myths" about qualitative research and the TCPS are indeed myths. We advise researchers and REB members in Canada to re-read the TCPS in light of the multi-methodology, multi-disciplinary research

community to which it applies. While the TCPS does not address all the issues of concern for qualitative researchers, it does undermine the eight myths we identify in this paper. Since REBs in Canadian institutions that receive funding from the three major public research-funding agencies (CIHR, NSERC, and SSHRC) must follow the TCPS as a minimum standard for ethics review, it may be advantageous for qualitative researchers to quote the TCPS in their protocol submissions when possible to justify their procedures. Doing so may facilitate a smoother review of their research protocols by prompting REB members to review their minimum standards and consider protocols received in light of them (and also reconsider their own institutional policies that exceed the minimum standards).

We also encourage REB members, particularly those from REBs that mainly review biomedical research, to think beyond the biomedical model and its typical implications for ethics review. Returning the focus of the review to basic questions of ethical research may help to achieve this. Such questions will include:

> Are the research questions clear?
>
> Can the research questions be answered with the chosen methodology?
>
> Has the plan for recruiting participants, collecting data, and analyzing data been described and justified (Cantini, Ells, Hirtle & Letendre, 2004: 14)?

As opposed to questions that focus on commonly accepted "ethical" procedures (such as: Is there a hypothesis? Can the research method confirm or disconfirm the hypothesis? Is the anonymity of the participants protected? Etc.), considering basic research ethics questions (such as the three questions quoted above) should not predispose REB members to look for specific answers, or specific procedures.

Similarly, we encourage researchers and REB members to focus first on guiding ethics principles in research ethics (e.g., Respect for free and informed consent, Respect for privacy and confidentiality), understanding that those principles stem from an overall principle of respect for human dignity (TCPS: i.5). This should help to avoid looking mainly for typical procedures (e.g., a particular consent form format, written consent, anonymity) in an REB review. Furthermore, being guided by the ethical principles that underlie a policy (or practice) can help in interpreting the policy and what should be done in situations that the policy does not address.

More analysis addressing ethical aspects of qualitative research is needed in the scholarly literature. Such analysis would help qualitative researchers plan aspects of their research, REB members to better review that research, and

policy makers to set standards and guidelines to ensure that appropriate protections are in place for people who participate in research.

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