A Briefing Note to PRE Regarding Statute-Based Protections for Research Participant Privacy and Confidentiality

Social Sciences and Humanities Research Ethics Special Working Committee (SSHWC)

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An Ethical Commitment to Protecting Research Participant Privacy Through Research Confidentiality

A recent article by Wolf, Zandecki and Lo (2004) regarding federal standards with respect to privacy and confidentiality issues affirms that,

> When investigators collect highly sensitive and private information from research subjects such as data on sexual behaviours and drug use, they have an ethical obligation to protect the confidentiality of that data.

On the same topic, the TCPS states,

> Information that is disclosed in the context of a professional or research relationship must be held confidential. Thus, when a research subject confides personal information to a researcher, the researcher has a duty not to share the information with others without the subject's free and informed consent. (MRC *et al* 1998, p.3-1)

Both statements, the first from a U.S. source, the second from a Canadian one, are clear and assertive in expressing the fundamental ethical obligation that researchers have to protect the privacy of research subjects/participants[1] through the provision and maintenance of confidentiality. And yet there is a difference in the context in which the two operate that makes the first promise authoritative and the second an ethical challenge that still requires satisfactory resolution.

Statute-Based *A Priori* Protections in the United States

Wolf *et al*'s article outlines the process that researchers in the United States can follow to acquire the information they seek under a cloak of legal protection for their research participants' confidentiality. The protections, called "Certificates of Confidentiality," are available to all researchers who engage in "health" research in which the data will be gathered in identifiable

[1] Hereafter "research participants" or simply "participants."

form and there would be serious repercussions to the participant if they were disclosed. As explained at NIH's "information kiosk,"

> [Certificates of Confidentiality] allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants.[2]

The protection offered to research participants by Certificates of Confidentiality was called "absolute" by the court in the one case (*People* v *Newman*, 1973) in which it was challenged.

A Broad Range of Disciplines and Areas of Research Would Benefit

Certificates of confidentiality were created in 1970 to enable research projects on drug use among returning Vietnam War veterans at a time when grand juries, Congressional Committees and the FBI were challenging research confidentiality through subpoenas and direct harassment. In this political climate, the Drug Enforcement Administration realized that it would not be possible to conduct valid and reliable research on drug use and abuse. Granted by the Secretary of what was then known as the Department of Health, Education and Welfare (HEW),[3] the first certificates protected research participants by bestowing immunity to drug researchers from compelled production of confidential research information. A 1974 amendment expanded confidentiality certificate coverage to mental health research in general, including research on the use and effect of alcohol and other psychoactive drugs. A further expansion of coverage occurred in 1988 to include any "health" research falling within NIH's mandate, although the protections are available independent of whether a project is actually funded by NIH.

The range of research projects for which Confidentiality Certificates are available is reasonably broad, notwithstanding that it is constrained by NIH's "health" mandate. The protection is provided whenever the research data are identifiable to particular individuals and confidentiality is essential for gathering valid information. Examples of such areas cited by NIH include research regarding sexual attitudes, preferences, or practices; the use of alcohol, drugs, or other addictive products; illegal conduct; information that, if released, could reasonably be damaging to an individual's financial standing, employability, or reputation within the community; information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination; information pertaining to an individual's psychological well being or mental health; genetic information.

According to a recent study by Wolf, Zandecki and Lo (2004) that examined the actual practices by which Certificates of Confidentiality are administered, the certificates are most commonly distributed within the confines of NIH's mandate for research involving genetics, substance abuse and other illegal behaviours, clinical trials, elder abuse, biodefense, Alzheimer's disease, "a range

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[2] See http://grants.nih.gov/grants/policy/coc/background.htm

[3] With departmental reorganization, the authority later passed to the Secretary of the Department of Health and Human Services (DHHS), who in turn delegated authority for the administration of Certificates of Confidentiality to the National Institutes of Health (NIH).

of behavioural studies," various "psychological projects," epidemiological studies, and tissue repositories.

The range of research projects that can end up in subpoena is broad.[4] Although virtually any discipline in which researchers gather sensitive information that a legal authority or other third party might find useful can be affected, reviews of these cases by Cecil and Wetherington (1996) and Israel (2004) list examples in sociology, criminology, various areas of health and medical studies, anthropology, political science, computer science, business administration, and sexology. This suggests the need for confidentiality protection transcends disciplines and research approaches, and that their development would benefit research participants and society across a wide range of areas and social policy issues. Indeed, the main "problem" with Certificates of Confidentiality cited in the literature is that because they are tied to the "health" domain by their location within NIH, other researchers in other areas who also conduct research on sensitive topics cannot acquire the same protection even though they have exactly the same ethical obligation to protect their research participants from harm (e.g., see Levine & Kennedy, 1999).[5]

In Canada the Only Existing Protections Are After-the-Fact and Uncertain

Certificates of Confidentiality have no counterpart in Canada, where only researchers from Statistics Canada and their research participants have a statute-based privilege, via the *Statistics Act*. Others must seek after-the-fact common law protection by claiming privilege on a case-by-case basis using the Wigmore criteria.[6] This was indeed done with success in the one case in Canada – involving Russel Ogden and the Vancouver Coroner -- where a researcher was subpoenaed and the matter actually went as far as requiring a defence.[7] Further, there is good reason to believe that the Ogden decision would have withstood appellate review,[8] and that any future claims of a research participant privilege will receive a respectful hearing as long as the Wigmore requirements are met.[9] At the same time, this particular subpoena was a national wake-

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[4] Subpoenas are not the only situation in which ethics and law may collide, but they are among the most visible. Other situations are discussed in SSHWC's accompanying discussion paper, "*Reconsidering Privacy and Confidentiality in the TCPS*."

[5] Another statute-based protection, known as a "Privacy Certificate," is available in the United States for participants in criminological research. The degree of protection they offer is equivalent to that of Certificates of Confidentiality, but they are only available for research funded by the U.S. National Institute of Justice. Considering them more extensively here would not add significantly to the current discussion, so we acknowledge but do not discuss them further. However, if PRE advises the Presidents of the granting councils to promote the development of statute-based protections, and the Presidents concur, then it will be appropriate to consider the form they might take and how they would be administered, at which point the Privacy Certificate model of administration (beyond their limitation to funded research) should be part of the consideration, as there are many ways they are arguably superior to Certificates of Confidentiality. For information regarding Privacy Certificates, see http://www.ojp.usdoj.gov/nij/humansubjects/hs_11.html

[6] The Wigmore criteria are more fully explained in SSHWC's companion discussion paper entitled "*Reconsidering Privacy and Confidentiality in the TCPS*."

[7] In two other known instances the matter was never tried as Crown subpoenas were withdrawn when it was made clear that the subpoenas would be challenged through an assertion of privilege.

[8] In a 145-page legal opinion on researcher-participant privilege prepared for Simon Fraser University (see the opinion online at http://www.sfu.ca/~palys/JackMacOpinion.pdf), Michael Jackson, QC, and Marilyn MacCrimmon concluded: "In our opinion in Russel Ogden's case there was a legally sufficient evidentiary basis upon which to ground the application of the Wigmore principles and Coroner Campbell's decision would have withstood appellate review." (pp. 86-87)

[9] An extensive review of U.S. cases shows the consistency with which U.S. courts have respected research *participant* privilege (but not necessarily a privilege for *researchers* per se). Although in no way binding on

up call signifying that the possibility of subpoena is real; that existing mechanisms for the protection of research participant privacy can only arise in Canada after the fact; and, notwithstanding the successful resolution of this case, that recognition of researcher-participant privilege is not a given. The fact is that, in the current state of Canadian law, ethics and law "may lead to different conclusions" (TCPS, p.i-8).

"Law-first" and "Ethics-first" Approaches

The legacy of the Ogden case goes beyond the successful assertion of privilege in Coroner's Court, however. The realization that case brought regarding the possibility of subpoena and the attendant possibility of orders for disclosure stimulated a vigorous and productive debate regarding the "proper" relations of ethics and law with regards to research confidentiality. Researchers, university and REB administrators, and the three granting councils all played a significant role.

It eventually became clear in the literature and was affirmed in an interpretive memorandum from the three granting councils,[10] that while all researchers must do their utmost to try and ensure law and ethics coincide, conflicts between law and ethics can be dealt with given the current state of law in two ways. One approach – an "ethics first" position – involves researchers committing themselves to protecting the research participant to the point of potentially defying a court order for disclosure and facing the consequences of doing so. A second approach – a "law first" position – involves researchers doing their utmost to protect research confidentiality while also acknowledging that they would follow the terms of a legal order for disclosure if they were to receive one. Each of these approaches has responsibilities associated with it that are considered at greater length in SSHWC's accompanying discussion paper, entitled "*Reconsidering Privacy and Confidentiality in the TCPS*." If done appropriately, both approaches meet the ethical requirements of researchers doing everything possible to protect participants and taking appropriate precautions to ensure that, even if in the last instant an order for disclosure were to arise, participants would not be harmed.

The primary danger with the "law-first" position is to ensure that it does not devolve into a form of "*caveat emptor*" – when a researcher dismisses true research confidentiality as unattainable; replaces it with a complete reliance on informed consent; and asserts that violations of confidentiality are acceptable as long as researchers warn participants ahead of time this might occur. Such an approach is ethically unacceptable for four main reasons:

- The TCPS recognizes that "Breaches of confidentiality may cause harm: to the trust relationship between the researcher and the research subject; to other individuals or groups; and/or to the reputation of the research community" (p.3-1). The *caveat emptor* approach fails to meet the TCPS principle that information that could cause harm must be kept confidential (TCPS, p.3-1).
- The *caveat emptor* approach downloads responsibility for the management of information to research participants. Most research participants are likely to be unaware of how legal

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Canadian courts, these decisions are indicative of judicial respect for research participants and the academic enterprise and, in the absence of Canadian jurisprudence on the subject, are likely to be scrutinized by Canadian judges in the course of their decision-making.

[10] Letter on behalf of the three granting councils from Anne-Marie Monteith, NSERC Research Ethics Officer, dated 27 April 2000, regarding ethics and law. The letter is available online at http://www.sfu.ca/~palys/TCPSFAQ.pdf

principles and procedures interact with research confidentiality; investigators cannot abdicate the ethical responsibility and fiduciary obligation they have for managing sensitive information and protecting participant interests.

- Depending on how their warning about the possibility of disclosure is constructed, the warning may constitute a "waiver of privilege."[11] Investigators cannot make the waiving of rights, including the right to claim privilege, a condition of participation. Doing so is a violation of the TCPS principle that researchers as a minimal standard are "honour-bound" to protect research participants "to the extent possible within the law." (TCPS, p.3-2)
- Continuing to acquire information that benefits the researcher (through publications, fame, merit increases and so on) and society (in the form of greater understanding) while divesting oneself of the responsibility for ensuring no harm comes to the participant is exploitative, and violates what the TCPS identifies as a fundamental moral imperative: "Part of our core moral objection would concern using another human solely as a means toward even legitimate ends" (p.i-4).

Confidentiality Certificates Reconcile the Prospective Gap Between Ethics and Law and Provide Other Benefits as Well

The TCPS affirms that while, "… ethical approaches cannot pre-empt the application of the law, they may well affect its future development" (p.i-8). One legacy of the Ogden case and the dialogue that followed was in how it made us aware that law and ethics could lead to very different conclusions, with "ethics-first" and "law-first" positions emerging. That distinction is made redundant and the disjunction resolved with development of a made-in-Canada version of "Confidentiality Certificates" that articulate conditions by which research confidentiality will be guaranteed *a priori* legal protection, and a set of processes through which researchers can apply.

Many benefits are achieved through the development of Confidentiality Certificates:

- The current state of statutory law creates the situation where researchers who want to put *ethics* first and safeguard their participants' confidentiality must be prepared to defy the law in order to gather sensitive information and be ethical. Confidentiality Certificates bring ethical obligations and legal protections into harmony, thereby allowing the ethics-first researcher to have their ethical commitments protected by law.
- The current state of statutory law creates the situation where researchers who would put *law* first should be prepared to refrain from asking potentially important questions or restricting themselves to techniques that produce anonymized data to avoid a *caveat emptor* approach that exposes research participants to harm. Confidentiality Certificates would enable law-first researchers to gather data of interest and fulfill both their ethical and legal obligations.
- The current state of law creates a conflict of interest for REBs to the extent their interest in creating paper records to allow research oversight may be contrary to participants' interests in remaining anonymous to anyone but the researcher. Certificates of Confidentiality would make the preservation of confidentiality both "legal" and certain,

[11] As discussed in SSHWC's accompanying discussion paper, *Reconsidering Privacy and Confidentiality in the TCPS* (see footnote 24), just what might constitute a "waiver of privilege" in a research context has yet to be determined. Legal advice on that issue is needed.

giving REBs more freedom to provide oversight to ensure all requirements for the preservation of confidentiality are met.

- Confidentiality Certificates also would make it easier for researchers to assist the courts because a prospective adversarial relation will have been averted, and the limits of researchers' assistance – up to the point where identifiable data are involved – would be more clearly defined.

- Confidentiality Certificates would help reaffirm the autonomy of the research enterprise by allowing for a more fully diverse debate out of which rational social policy might be formulated. At present, researchers employed by the State (at Statistics Canada, through the *Statistics Act*) have a privilege, but those who may be critical of its policies do not. Full and effective social debate is best accomplished by hearing a diversity of perspectives, including those most critical and most vulnerable -- and least likely -- to otherwise have their voice represented. Confidentiality Certificates would help ensure that critical empirical research can be done in a way that protects vulnerable participants from more powerful interests, including the State itself.

Conclusion

When SSHWC submitted its preliminary draft proposals for revising the TCPS section that pertains to Privacy and Confidentiality (Section 3), it recommended, "That PRE advise the Presidents of the granting agencies of the desirability of enhancing legal protections for research participant confidentiality by establishing a statute-based research participant privilege for sensitive research where a guarantee of confidentiality is required for the gathering of valid data." In its comments on that draft, PRE requested that we isolate any material pertaining to Certificates of Confidentiality for consideration in a separate briefing note, and cited two main reasons for that request. The first concerned

1. PRE's desire to give confidentiality certificates separate and full consideration (which we understand it will do at its June meetings).

SSHWC appreciates that commitment by PRE, and hopes this brief document addresses PRE's information requirements. If there is any further information that we can provide that might be of use, we are happy to assist. The second reason PRE cited was that

2. "PRE's mandate is limited to the further evolution of the TCPS and going forward with the current document may create expectations that PRE would not be able to deliver."

Although we understand and appreciate that rationale, we hope that PRE does not underestimate the moral authority that accompanies its position in Canada's ethics administration or the weight that its opinion on this matter would carry. Our recommendation is that PRE advise the Presidents of the granting agencies to do what they can to facilitate the creation of a made-in-Canada version of "Certificates of Confidentiality" that would close the gap that now exists between our ethical obligations to research participants and statutory law. The TCPS holds that while, "… ethical approaches cannot pre-empt the application of the law, they may well affect its future development" (p.i-8). If PRE and the Presidents of the three granting councils do not lead the initiative to develop law so that it reflects the highest ethical standards of research, then who will?

If PRE decides to recommend to the Presidents of the Granting Councils that they pursue and promote the development of made-in-Canada Confidentiality Certificates, there will be much work required to make them a reality. Certainly an examination and discussion awaits regarding

how they will be constructed, who will administer them, and how they will fit into Canada's existing evidentiary framework. In the interim, PRE's in-principle recognition of their appropriateness and importance is a necessary first step to their development and thereby to ensure that the ethical standards outlined in the TCPS are uniformly met, that research participant privacy is protected, and the gap between ethics and law resolved.

Selected Bibliography

Information regarding Confidentiality Certificates administered by the United States National Institutes of Health is available at http://grants.nih.gov/grants/policy/coc/index.htm .

Information regarding the Privacy Certificates administered by the United States National Institute of Justice is available at http://www.ojp.usdoj.gov/nij/humansubjects/ .

Levine, F., & Kennedy, J.M. (1999). Promoting a scholar's privilege: Accelerating the pace. *Law and Social Inquiry*, *24*: 967-976.

"Certificates of Confidentiality" (through NIH) and "Privacy Certificates" (through NIJ) offer excellent legal protection for research participants, but are limited in the range of research covered. This article, by the then-Executive Director of the American Sociological Association (ASA) and then-Chair of ASA's Committee on Professional Ethics, argues for a broadening of those legal protections to other areas of research where confidentiality is just as essential to the acquisition of valid data.

People v. *Newman* (1973). [32 N.Y. 2d 379, 298 N.E. 2d 651, 345 N.Y.S. 2d 502].

"Certificates of Confidentiality" were originally put in place in 1970 but limited at that time only to research involving drug or alcohol abuse. The first legal challenge to the legal privilege they offered came in *People* v *Newman*, where the protection they provided to research participants was affirmed by the court, which referred to it as "absolute." The U.S. Supreme Court refused to hear the case on appeal, and neither "Certificates of Confidentiality," nor "Privacy Certificates" (a parallel protection available through the National Institute of Justice) has ever been challenged since.

Palys, T.S., and Lowman, J. (2004). *Reconciling the Law and Ethics of Research Confidentiality.* Invited paper presented at the Annual National Conference of the National Council on Ethics in Human Research (NCEHR): Privacy Issues in Human Research. Aylmer, Québec: March 6-7. [Summary available online at http://www.sfu.ca/~palys/NCEHR2004.pdf]

Discussion of some of the challenges to research confidentiality that have arisen in the United States and Canada; a consideration of U.S. statute-based privileges that were formulated to meet those challenges; and a discussion of the principles that might guide the formulation of similar statute-based protections for research participants in Canada.

Wolf, L.E., Zandecki, J., and Lo, B. (2004). The Certificate of Confidentiality application: A view from the NIH Institutes. *IRB: Ethics & Human Research*, *26*(1): 14-18.

The paper explains what the "Certificates of Confidentiality" obtainable through the U.S. National Institutes of Health are, what protections to research participants they provide, and the application procedures researchers should follow in obtaining them.