INTERFACE OF LAW & ETHICS IN CANADIAN RESEARCH ETHICS STANDARDS: AN ADVISORY OPINION ON CONFIDENTIALITY, ITS LIMITS, & DUTIES TO OTHERS

Derek J. Jones[*]
& Interagency Advisory Panel on Research Ethics (PRE)[**]

In special relationships clothed with duties of professional secrecy, what instances—if any—justify an infringement of confidentiality? The question is an old one. But new contexts and considerations keep the issues alive. Thirty years after the California Supreme Court recognized a limited duty-to-warn exception to strict confidentiality standards in mental health treatment, the principles of the Tarasoff *case continue to exert influence beyond the U.S. health law milieu from which they arose. For instance, to help secure participation in research involving humans, researchers will typically assure human subject/participants, as part of the informed consent process, of the general confidentiality of participants' information. Sometimes, however, those conducting research on prostitution, drug use, illegal behaviour, family abuse, infectious diseases, etc., will discover legally or socially sensitive information from participants that implicates risks to third parties. In such circumstances, do Canadian human research ethics standards impose a "*Tarasoff*-like duty" on researchers to infringe confidentiality when necessary to warn identified at-risk individuals? To answer the question as part of its mandate to provide independent, multidisciplinary advice on the interpretation, use, and evolution of the federal* Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans *(TCPS), the Interagency Advisory Panel on Research Ethics has developed an advisory opinion, "Researchers and the Duty to Warn: Limits on the Continuum of Confidentiality?" The opinion elaborates the TCPS approach for balancing respect of confidentiality with other public interests, like human safety, in this conflict of societal values and sometimes competing duties.*

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[*] Executive Director, Interagency Advisory Panel & Secretariat on Research Ethics, Government of Canada. Lecturer in Health Law & Bioethics, McGill University; Member of the Advisory Board of the McGill Health Law Publication. The views expressed in the prologue to the following advisory opinion are his alone; they do not necessarily reflect those of the Interagency Advisory Panel or Secretariat on Research Ethics.

[**] The views expressed in the following advisory opinion are those of the Interagency Advisory Panel on Research Ethics; they do not necessarily reflect those of the federal granting agencies or the Government of Canada. PRE members who participated in this opinion are: Marlene Brant-Castellano, Trent University, Aboriginal Studies; Norman Frohlich, University of Manitoba School of Business; Anne Dooley, Community Member, Saskatchewan; Pierre Deschamps, McGill University Faculty of Law & Canadian Human Rights Tribunal; Paul Johnson, PreCarn Incorporated; Derek J. Jones (*ex officio*), Interagency Secretariat on Research Ethics; Ian Mitchell, University of Calgary, Bioethics & Faculty of Medicine; Sam Ludwin, Queen's University Faculty of Health Sciences; Florence Piron, University of Laval Department of Information and Communications; and Susan Sykes, University of Waterloo Office of Research Ethics, and Department of Psychology. In cases of real, perceived, or potential conflict of interest regarding a TCPS interpretation question and a PRE member, the concerned member is recused from participating in developing PRE's response.

I
PROLOGUE

And the seasons they go round and round...
We're captive on the carousel of time.
We can't return, we can only look
Behind from where we came...[1]

A. A Duty to Warn: From *Tarasoff* to Research Ethics?

As with the retro-trends in pop culture, some legal themes from the 1970s continue to offer their insights, and those insights sometimes infuse ethics. In this sense, a recent advisory opinion on confidentiality from the Government of Canada's Interagency Advisory Panel on Research Ethics (PRE) should be of interest to scholars, lawyers, researchers, ethicists, universities, policy analysts, and committees that conduct ethical review of research involving human participants. As background to PRE's advisory opinion, below, this prologue (i) summarizes the 1970s court decision that has prompted research ethics issues, and (ii) outlines PRE's role in developing advisory opinions on such issues.

Thirty years ago, the California Supreme Court decided *Tarasoff v. Regents of University of California*.[2] The landmark case arose at the campus of the University of California at Berkeley in the late 1960s, after a patient confided to his university psychotherapist his intention to kill his girlfriend. Unfortunately, he then proceeded to do so. Neither the girlfriend nor her family was warned of the intention. The family sued the psychotherapist for negligence.

The facts presented a question: does a professional, cloaked with obligations of confidentiality, nevertheless owe a duty to an identified third party at imminent risk of serious harm? In theory, such a duty might flow from various sources—for example, ethico-legal responsibilities for preventing harms, moral conduct becoming the professional, a vision of public responsibilities in civic society. If the court were to respond yes to the question, then the omission or the failure to act on a legal duty may ground liability. Indeed, the court found that affirmative legal duties of care to third parties may arise from special relationships, like that shared by a patient and her or his physician or psychotherapist. The court concluded that when necessary to avert serious and foreseeable danger to third parties, a legal duty to exercise reasonable care to protect them may include a limited duty to warn.

An important dimension of *Tarasoff* was its recourse to professional ethics norms to inform the legal analysis. Professional ethics norms serve many purposes. They provide principled guidance for situational ethics, are thought to further professional integrity, and provide formal accountability to one's peers, clients, and the public. Since the 1950s, the code of ethics of the American Medical Association had provided that physicians keep the confidences entrusted to them "unless ... required to do so by law or unless it becomes necessary in order to protect the welfare of the individual or of the community".[3] The exception recognizes that legal duties or moral necessity may shape the precise contours and paramount obligations in commitments of professional secrecy.

B. Making, Breaking, & Telling Secrets: Amid the Duties

Following the decision, the case was remanded for trial, before which the parties agreed to settle the lawsuit. The *Tarasoff* decision thus entered the annals of law. Over three decades, it has proved to be a touchstone for evolving thought on legal and ethical duties in the making, breaking, and telling of secrets. The issues have arisen in varied contexts of health law, professional practice, public policy, and the ethics[4] of conflicting obligations. *Tarasoff* duties to warn have thus been incorporated into ethical codes and statutory standards of care for mental health professionals in many jurisdictions in the United States.[5]

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[1] Joni Mitchell, "The Circle Game," *Ladies of the Canyon LP* (1970).

[2] 17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14 (Cal. 1976) [*Tarasoff*].

[3] *Ibid*., at 347. See American Medical Association, *Code of Medical Ethics: Opinions with Annotations* (Chicago: American Medical Association, 2006-2007) at 136, art. 5.05.

[4] See e.g. David B. Resnick & Richard R. Sharp, "Protecting Third Parties in Human Subjects Research" (2006) 28:4 IRB: Ethics & Human Research 1.

[5] Paul B. Herbert & Kathryn A. Young, "*Tarasoff* at Twenty-Five" (2002) 30 Journal of the American Academy of Psychiatry and the Law 275.

U.S. courts have also applied *Tarasoff* to questions of whether health professionals have a duty to warn family members about avertable genetic risk from transmissible diseases diagnosed in their patients.[6] Analysts have asked whether health professionals have a duty to warn third parties at risk of infection from sexually transmitted diseases or from public health contagion.[7]

Tarasoff has also influenced international analyses.[8] Indeed, shortly after the California Supreme Court decision, *Tarasoff* was considered in Canadian mental health law jurisprudence.[9] The duty to warn has since been debated in the Canadian literature.[10] More recently, *Tarasoff* has been drawn upon in a case that asked whether in the exercise of reasonable ethical discretion the concerned professional may, in exceptional circumstances, breach confidences. Though the case did not directly concern an affirmative duty to warn, the Supreme Court of Canada positively noted the reasoning of the *Tarasoff* court, and outlined a public safety exception to the high confidentiality requirements of the solicitor-client relationship.[11]

Such developments have prompted questions on whether a duty to warn applies to the responsibilities of researchers who collect confidential, and sometimes legally sensitive, data from research participants. The advisory opinion below addresses such issues from the perspective of Canada's *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.[12]

C. The Tri-Council Policy Statement

PRE was created by the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada to provide multidisciplinary and independent advice on the evolution, use, and interpretation of their joint research ethics policy, the TCPS.

Since its release in 1998, the TCPS has been formally adopted by most universities and many colleges in Canada. Institutions do so as a condition for the receipt of funding from the above agencies, meaning that they agree to develop and apply TCPS norms to research conducted under their auspices.[13] This contractual approach contrasts with a federal or central regulatory model of human research statutes in countries like the United States[14] or France.[15] Canada has no equivalent national human research law. Instead, it relies on a mosaic of relevant federal[16] or provincial research,[17] privacy, and consent[18] laws, policy norms, and ethical[19] and professional[20] standards. In this mosaic of Canadian norms, the breadth of

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[6] *Safer v. Estate of Pack*, 677 A.2d 1188 (N.J. Super. Ct. App. Div. 1996). See generally Martin Letendre, "Le devoir du médecin de prévenir les membres de la famille d'un patient atteint d'une maladie génétique" (2004) 49 McGill L.J. 555.

[7] See William J. Curran & Larry Gostin, "AIDS Screening, Confidentiality, and the Duty to Warn" (1987) 77:3 American Journal of Public Health 361.

[8] Danuta Mendelson & George Mendelson, "*Tarasoff* Down Under: The Psychiatrist's Duty to Warn in Australia" (1991) 19:1-2 J. Psychiatry & Law 33.

[9] See *Tanner v. Norys*, [1980] 4 W.W.R. 33 (Alta. C.A.).

[10] H. E. Emson, "The Duty to Warn in the Canadian Context" (1993) 149 Canadian Medical Association Journal 1781.

[11] *Smith v. Jones*, [1999] 1 S.C.R. 455 [*Smith*]. See a description of this case in PRE's opinion, *infra*, at paras. 21 and 28.

[12] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (1998 with 2000, 2002 and 2005 amendments), online: CIHR <http://www.pre.ethics.gc.ca/english/pdf/TCPS%20October%202005_E.pdf> [TCPS].

[13] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Memorandum of Understanding on the Roles and Responsibilities in the Management of Federal Grants and Awards* (2002), Sch. 2.

[14] Federal Policy (Common Rule) for the Protection of Human Subjects, 56 Fed. Reg. 28003 (1991) (codified in part at 45 C.F.R. § 46).

[15] See e.g. *Loi n° 88-1138 du 20 décembre 1988*, J.O., 22 December 1988, as amended.

[16] See e.g. Correctional Services Canada, *Commissioner's Directive 009—Research Guidelines 009* (2004); Health Canada, *Regulations Amending the Food and Drug Regulations (1024 – Clinical Trials)*, S.O.R./2001-1042, especially ss. C.05.001, C.05.006, C.05.010(d), C.05.012 (Drugs for Clinical Trials Involving Human Subjects); *Assisted Human Reproduction Act*, S.C. 2004, c. 2, ss. 3, 5, 8–10, 40; Law Reform Commission of Canada, *Biomedical Experimentation Involving Human Subjects* (Ottawa: Law Reform Commission of Canada, 1988).

[17] Compare Bill 23, *An Act to Establish a Health Research Ethics Authority for the Province*, 3rd Sess., 45th Leg., Newfoundland, 2006, and *Scientists Act*, R.S.N.W.T. 1988, c. S-4.

[18] See e.g. *Civil Code of Québec*, S.Q. 1991, c. 64, arts. 10–11, 20–24 [C.C.Q.].

[19] See e.g. *Code of Ethics of Social Workers*, R.R.Q., c. C-26, r. 180, ss. 3.06.01, 4.05.01.

[20] Compare *Labrie c. Roy*, [2003] R.J.Q. 18063 (Qc. C.A.) and *Gomez c. Michaud*, [2001] R.J.Q. 2788 (Qc. C.A.) at paras. 84–

the TCPS across diverse research disciplines, its adoption in research institutions throughout the country, and its use by federal and provincial entities as operative guidance, indicate its functions as part of national standards.

A significant innovation of the TCPS flows from one of its founding premises: fundamental research ethics principles transcend disciplinary boundaries to guide and unite health, social and natural sciences, humanities, and engineering research. Some of the transcendent, guiding ethical principles of the TCPS include free and informed consent, minimizing harm and maximizing benefits, respect for privacy and confidentiality, justice, and human dignity.

TCPS principles and standards come into practice at important junctures in the research process. They are intended to help researchers foresee, identify, and address the ethical design and planning of research projects. They should guide prospective review of projects by the interdisciplinary research ethics committees found in most universities. They should also help address ethics issues that arise during research projects. Of course, the principles and standards of the TCPS convey their particular impact in the specifics of a research project. A commitment to the principle of free and informed consent, for instance, may raise conceptual or implementation issues in clinical trials that differ from those raised in participant observation research, or those in research involving communities. For such reasons, the TCPS encourages its users to take a context-centred approach to applying ethical principles.[21] The research discipline and its methods, applicable laws, professional or scholarly norms, and new developments then come into play for the research in question. This interplay is not static. Out of it may arise specific questions about the TCPS.

D. PRE's Role in Interpreting the TCPS: Interdisciplinary Advisory Opinions

As part of its mandate, PRE provides advisory opinions on TCPS issues in response to written queries from researchers, research ethics committees, administrators, etc. The diversity and complexity of the questions vary. But they typically concern issues like textual ambiguities, silences or definitions, research ethics procedure, substantive issues like confidentiality, waivers of consent or children in research, legal issues, and even disputes over the decisions of research ethics committees or institutions. The latter two matters lie beyond the mandate of the PRE. Since it is not designed to be an ethics dispute resolution entity, PRE does not serve as an appeal body for TCPS-related decisions made by institutions or their ethics committees.[22] Nor does it provide legal advice or opinions, though its "analyses may address ethical dimensions of legal issues in research ethics".[23]

PRE's role in interpreting the TCPS thus serves important purposes. It furthers institutional ethical deliberation through the provision of outside interdisciplinary advice on often complex human research ethics questions. External deliberation may help to problem-solve concrete issues, dilemmas, or policy options. Such reflection and problem-solving may, in turn, prompt policy reform. For example, by bringing conceptual, practical, and experiential quandaries of the TCPS to national attention, the interpretation dialogue may identify a need to clarify, address voids in, or otherwise amend the TCPS.

In this context, questions on the applicability of *Tarasoff* in research ethics have been put to PRE. In response, it has developed the following advisory opinion on confidentiality, its limits, and the duty to warn under the TCPS. Because the advisory opinion is based on the existing TCPS, it does not discuss whether the TCPS ought to be amended to address more directly a duty to warn in research ethics. Any such amendments or reforms remain for another day.

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85 (applying physician's professional code of ethics to research).

[21] TCPS, *supra* note 12 at i.9.

[22] See PRE's mandate, online: PRE <http://www.pre.ethics.gc.ca/english/aboutus/mandate.cfm> [Mandate].

[23] PRE, *Interpreting the TCPS* (Ottawa: PRE, 2004) at 6.

II

ADVISORY OPINION: RESEARCHERS & THE DUTY TO WARN: LIMITS ON THE "CONTINUUM OF CONFIDENTIALITY?"[24]

Dear Madam/Sir:

1 Thank you for your query concerning the standards and limits of confidentiality under the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS).[25]

You have raised three questions, namely:

- whether the TCPS bestows on researchers a "*Tarasoff* duty" to infringe research participants confidentiality when necessary to warn identified at-risk third party individuals or communities;
- whether any such "*Tarasoff* duty" is triggered by a standard of preventing "significant harms" or by a higher standard of preventing "serious physical injury or death";[26] and
- whether the TCPS requires researchers immediately to inform participants of a researcher's infringement of confidentiality, when done to protect life and limb.

A. Response Summarized

2 Your inquiry has been referred to the Interagency Advisory Panel on Research Ethics (PRE) for advice.[27] As elaborated below, the TCPS acknowledges a dynamic, intricate interface between ethics and law in human research that implicates informational privacy. The TCPS thus deems respect of research participants' privacy and confidentiality a fundamental principle of modern research ethics. It also recognizes that in collecting sometimes sensitive information for research, however, value conflicts may arise between preserving confidentiality and acting on competing ethical or legal duties that advance other societal values.

3 As also noted below, the TCPS does not impose on researchers a so-called *Tarasoff* duty to warn. The TCPS acknowledges that such disclosure duties may arise from other sources (from the law, for example), and recognizes the potential conflict of duties and values. Accordingly, it accommodates ethical deliberations thereon by specifying criteria for evaluating and balancing competing duties: confidentiality should be respected save in narrow and exceptional circumstances that may justify limited infringements, such as disclosure or reporting to protect human "health, life and safety" or to advance other "compelling and specifically identifiable public interests."[28] Some have reasoned that disclosures to avert a "clear, serious and imminent" risk of bodily harm or death to identifiable persons may be justified as a compelling public interest. The reasoning is congruent with the principles of the TCPS. Any such disclosures should be minimized to what is necessary and proportionate to address the compelling public interest in question. Researchers and research ethics boards (REBs) should anticipate and address foreseeable limits on confidentiality early in the design of the research, to enable informed choices of participants, and to help to minimize unanticipated urgencies about the methods, duties, scope, and timing of any necessary disclosures. Doing so requires concerted multidisciplinary analyses throughout the ethics review process.

B. Introduction: Confidentiality & Value Conflicts

4 As a general matter, we note that an important value conflict underlies your questions. Scholars conducting research on prostitution, drug use, illegal or threatening behaviour, family abuse, infectious diseases, etc., may discover legally or socially sensitive information from participants involved in the

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[24] The phrase is adopted from a U.S. case involving confidential research data: *In re Cusamano v. Microsoft Corporation*, 162 F.3d 708 (1st Cir. 1998).

[25] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (1998 with 2000, 2002 and 2005 amendments), online: CIHR <http://www.pre.ethics.gc.ca/english/pdf/TCPS%20October%202005_E.pdf> [TCPS].

[26] *Smith v. Jones*, [1999] 1 S.C.R. 455 [*Smith*]. See a description of this case in PRE's opinion, *infra*, at paras. 21 and 28.

[27] See PRE's mandate, online: PRE <http://www.pre.ethics.gc.ca/english/aboutus/mandate.cfm> [Mandate].

[28] TCPS, *supra* note 25 at 3.1.

research. To help secure participation, researchers will have typically assured participants, as part of the informed consent process, of the general confidentiality of participants' information. When it turns out that the collected information implicates high responsibilities to, or risk regarding, third parties, what are the researcher's obligations? On the one hand, society respects and values privacy and confidentiality. On the other hand, society cherishes and values other interests, like the protection of health, safety, and human life.

5 When these two values conflict in the research ethics context, how is the conflict to be addressed? Do privacy and confidentiality prevail? Or, do other societal interests like the protection of safety or life prevail? If neither clearly nor uniformly prevails, how do researchers strike a reasonable balance? Precise guiding criteria for evaluating and weighing the interests or values thus become important.

6 The value conflict and balancing challenge are embedded in both your inquiry and the privacy and confidentiality norms of the TCPS. Accordingly, we begin our response to your query by summarizing the privacy and confidentiality norms of the TCPS from an historic perspective. Then we apply them to your questions.

C. TCPS Privacy & Confidentiality Norms

7 Privacy and confidentiality had already become valued norms of the modern information society by the turn of the last decade, when the TCPS was adopted. As privacy and confidentiality issues prove important to society, they prove important to the research ethics community. Their importance is reflected in at least two sections of the TCPS—the TCPS Ethics Framework and a chapter devoted to their workings in research ethics review.

1. TCPS Ethics Framework

8 Respect of privacy and confidentiality is one of the foundational principles of the Ethics Framework that informs the entire TCPS. As a foundational principle in the Ethics Framework, respect for confidentiality and privacy is important in at least three respects.

9 First, the Ethics Framework explains the source and importance of respect for privacy and confidentiality:

> Respect for human dignity also implies the principles of respect for privacy and confidentiality. In many cultures, privacy and confidentiality are considered fundamental to human dignity. Thus, standards of privacy and confidentiality protect the access, control and dissemination of personal information.[29]

10 Secondly, the Ethics Framework recognizes that even with fundamental ethical principles like respect for confidentiality, the ethics review process may reveal value conflicts: "If the application of principles yields conflicts, then such conflicts properly demand probing ethical reflection and difficult value choices. Such choices and conflicts are inherent in the ethics review process."[30] In other words, putting ethical principles like respect for privacy and confidentiality into the practice of ethics review requires some deliberative weighing and balancing.

11 Thirdly, the Ethics Framework notes a dynamic relationship between ethics and law. It acknowledges, for instance, that the law "affects and regulates" privacy and confidentiality standards for research involving humans.[31] Reasonable and responsible research should respect the law,[32] meaning that research projects that raise privacy or confidentiality issues generally need to adhere to applicable legal and ethics norms. Research professionals, institutions, participants, and ethics committees play vital roles in respecting, testing, and changing legal norms on research ethics, as part of evolving civil society in a democracy. Testing or questioning a legal norm is not synonymous with violating it,[33] and "it is only in

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[29] *Ibid.* at i.5.

[30] *Ibid.* at i.9.

[31] *Ibid.* at i.8.

[32] Interagency Advisory Panel on Research Ethics, *Reasonably Designed Inclusion and Exclusion Criteria and Applicable Human Rights Legislation* (2003), online: <http://www.pre.ethics.gc.ca/english/pdf/interpretations/Reasonably%20Designed%20Inclusion%20and%20Exclusion%20Criteria%20and%20Applicable%20Human%20Rights%20Legislation_Jan%202003.pdf>.

[33] See Ted Palys & John Lowman, "Anticipating Law: Research Methods, Ethics, and the Law of Privilege" (2002) 32:1 Sociological Methodology 1; Geoffrey R. Stone, "Discussion: Above the Law: Research Methods, Ethics, and the Law of Privilege"

very exceptional cases that it might be ethically acceptable for a researcher to violate a current rule of law", as the Norwegian National Committee for Research Ethics in the Social Science and the Humanities has observed.[34] For such reasons, respect for legal norms is often an important principle of the ethical guidelines of professionals involved in research.[35] At the same time, the Ethics Framework of the TCPS recognizes that "legal and ethical approaches to issues may lead to different conclusions" in research ethics, and that such differences may further ethical and legal reflection and reform.[36]

12 The TCPS does not intend that researchers or participants ponder alone the dynamic and intricate interface of law and ethics. Article 1.3 of the TCPS outlines relevant norms for including in the membership of REBs those with ethical and legal knowledge. The multidisciplinary expertise of a duly composed REB is intended to help identify and address the thicket of professional, ethical, and legal issues and requirements that may arise from the application of confidentiality and privacy laws to research. Sometimes, the identification of legal issues by the REB will necessitate scrutiny or formal legal advice by competent local legal counsel to the institution.

2. TCPS Section 3—Privacy & Confidentiality

13 The privacy and confidentiality chapter of the TCPS, section 3, builds on the principles of the TCPS Ethics Framework to outline the standards for the access, control, and dissemination of participants' identifiable personal information in human research. The section indicates that privacy and confidentiality must generally be preserved, unless particular exceptions apply.[37]

3. Privacy & Confidentiality—General Principles

14 Privacy is "a fundamental value, perceived by many as essential for the protection and promotion of human dignity."[38] Privacy standards protect individuals' reasonable expectation of privacy, which may range from spatial privacy to informational privacy interests. Themselves a dimension of privacy, confidentiality standards govern information secrecy norms in professional relationships. When a research participant thus confides personal information to a researcher, the researcher has a general duty not to share the information with others: "Information that is disclosed in the context of a professional or research relationship must be held confidential."[39] The duty is grounded on respect for the person and her or his expectations, autonomy, and privacy rights. The unauthorized use or breach of confidential information may cause harms ranging from reputational to psychological, socio-economic, legal, or dignatory harms.[40] Participants, understandably, have a reasonable expectation that personal information and confidences disclosed for research generally will be kept confidential. Participants are more likely to share such confidences with research professionals who have formal duties of confidentiality. The duty helps further the "trust relationship"[41] between researchers and participants, thus enabling the relationship to benefit society through a methodical processing of information.

4. Privacy & Confidentiality—Exceptions

15 Mindful of the ethical conflicts that may arise over access to, or the use of, personal information, section 3 of the TCPS also outlines exceptions to general confidentiality duties. The use of publicly available or anonymized information, consent of the participant, disclosures required or authorized by

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(2002) 32:1 Sociological Methodology 19; James Lindgren, "Discussion: Anticipating Problems: Doing Social Science Research in the Shadow of the Law" (2002) 32:1 Sociological Methodology 29.

[34] Norway, National Committee for Research Ethics in the Social Sciences and the Humanities, *Guidelines for Research Ethics in the Social Sciences, Law and the Humanities* (2001) at Introduction [Norway Guidelines].

[35] See e.g. Australian & New Zealand Society of Criminology, *Code of Ethics* (2000) at art. 5 [ANZOC Code]; RESPECT Project, *RESPECT Code of Practice for Socio-Economic Research in the EU* (2004), online: <http://www.respectproject.org/code/respect_code.pdf>.

[36] TCPS, *supra* note 25 at i.8.

[37] *Ibid.* at 3.1ff.

[38] *Ibid.* at 3.1.

[39] *Ibid.*

[40] See *Ibid.* at 3.1–3.2; National Research Council of the National Academies, *Protecting Participants and Facilitating Social and Behavioral Sciences Research* (Washington, DC: National Academies Press, 2003) at 26–30.

[41] *Ibid.* at 3.1.

law, or overriding duties to others, are amongst the recognized exceptions. For instance, the reporting of anonymized information for statistical or disease tracking purposes, under mandatory reporting laws, might pose minor infringements of confidentiality or privacy for important public policy purposes. As well, it is respectful of the autonomy and privacy rights of participants to share identifiable personal information, when a participant consents to the disclosure. Participants may thus waive confidentiality protections, and such waiver of rights and consent to disclosure may limit the researcher's duty of secrecy.

16 The TCPS also recognizes that confidentiality duties may sometimes be limited by responsibilities to third parties:

> The values underlying the respect and protection of privacy and confidentiality are not absolute, however. Compelling and specifically identified public interests—for example, the protection of health, life and safety, may justify infringement of privacy and confidentiality. Laws compelling mandatory reporting of child abuse, sexually transmitted diseases or intent to murder are grounded on such reasoning.[42]

17 Hence, while the TCPS defines respect for privacy and confidentiality as a fundamental ethical principle and societal value, it also indicates that confidentiality duties are neither absolute nor unlimited. This view may distinguish the TCPS from some in the academic literature and from language in some professional codes of conduct.[43] Still, as will be seen, it harmonizes it with many academic analyses, professional codes, recent ethical norms, and leading trends in the law. Under the TCPS, research ethics review helps to put confidentiality and privacy principles and their exceptions into research practice.

D. Post-1998 Developments

18 Since the TCPS functions in an evolving research ethics context, researchers, REBs, research participants, and institutional practices and policy are constantly being shaped by laws, ethics, policy, and professional developments. We note that many relevant professional, policy, and legal developments implicating privacy that have unfolded since the adoption of the TCPS, in 1998, have tended to parallel major elements of the TCPS privacy and confidentiality norms.

1. *Flourishing Privacy & Confidentiality Norms*

19 For instance, amid evolving debates in the scholarly literature, professional groups and government entities in and beyond Canada have, over the last few years, developed and refined ethical guidelines, policy, and laws pertinent to privacy and confidentiality principles in human research ethics. Some of the newer professional standards offer specific ethical guidance to social science researchers. The British and Australian societies of criminology, for example, have adopted revised or new codes of ethics that outline privacy as a fundamental ethical obligation, subject to limited exceptions.[44] So do revised ethical principles for American psychologists, social workers, and epidemiologists, Norwegian researchers in the social sciences and humanities, and social anthropologists in the United Kingdom.[45] The approach of affording high protections to privacy and confidentiality subject to narrow, limited exceptions has also been integrated into privacy legislation adopted since 1998 in Canada,[46] the United States,[47] and the

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[42] Ibid. at 3.1.

[43] Compare e.g. American Sociological Association, *Code of Ethics* (1997) at art. 11.02, online: <http://www.asanet.org/galleries/default-file/Code%20of%20Ethics.pdf> [ASA Code] (referring to absolute confidentiality); Rik Scarce, "(No) Trial (But) Tribulations: When Courts and Ethnography Conflict" (1994) 23 Journal of Contemporary Ethnography 123 (absolute confidentiality); Michael Traynor, "Countering the Excessive Subpoena for Scholarly Research" (1996) 9:3 Law & Contemp. Probs. 119 at 119: "To date, neither legislatures nor courts have granted researchers an absolute privilege to protect the confidentiality of their research data."; Sissela Bok, *Secrets: On the Ethics of Concealment and Revelation* (New York: Vintage Books, 1989) at 116–125 (limits of confidentiality).

[44] ANZOC Code, *supra* note 35; British Society of Criminology, *Code of Ethics for Researchers in the Field of Criminology* (2003) [BSC Code].

[45] American Psychological Association, *Ethical Principles of Psychologists and Code of Conduct* (2002) at art. 4, online: <http://www.apa.org/ethics/code2002.pdf> [APA Code]; U.S., National Association of Social Workers, *Code of Ethics* (1999) (ethical standards are set out at s. 5.02(l)); American College of Epidemiology, *Ethics Guidelines* (2000) at s. 3.5, online: <http://www.acepidemiology2.org/policystmts/EthicsGuide.pdf> [ACE Guidelines]; Quebec, *Code of Ethics of Physicians*, O.C. 1213–2002, 23 October 2002, G.O.Q. 2002.II.5574, arts. 20(5), 28, 30; Norway Guidelines, *supra* note 34; Association of Social Anthropologists of the United Kingdom and the Commonwealth, *Ethical Guidelines for Good Research Practice* (1999) at paras. 5(c), 5(d), online: <http://www.theasa.org/downloads/Ethical_guidelines.pdf> [ASAUKC Guidelines]; BSC Code, *ibid.*, at art. 4.

[46] See e.g. *Personal Information Protection and Electronic Documents Act*, S.C. 2000, c. 5, s. 7(4) [*PIPEDA*] (privacy principles and exceptions).

European Union.[48] The developments provide a resource base for understanding and applying the TCPS in an evolving national and international policy context, consistent with the PRE's mandate[49] to do so.

2. Ethical & Legal Parallels

20 These trends and developments further underscore the evolving and dynamic relationship between ethics and law envisaged by the TCPS. In this regard, it is instructive to note that since the initial publication of the TCPS, the Supreme Court of Canada has further developed its analysis of privacy and confidentiality principles, and has done so in a manner consistent with the standards of the TCPS. Under the approach, privacy is treasured as a fundamental democratic value that is integral to human dignity and "essential to maintaining relationships of trust".[50] The view is consistent with the TCPS approach to privacy as integral to the trust relationship between participants and researchers.[51]

21 The view also helps explain why a duty to maintain confidences functions critically between health care workers and patients, solicitors and clients, researchers and participants, and like professional relations grounded on trust. The confidential information that individuals entrust to such professionals enables the relationship to serve an important public good—like the provision of health care, legal advice in the justice system, or research data that advances the frontiers of knowledge and public policy. However, even with such highly valued relationships, the interests and values protected by privacy and confidentiality may sometimes be reasonably limited or infringed by other competing democratic values.[52] In short, as within the TCPS, the Supreme Court has indicated that "even the fundamentally important right to confidentiality is not absolute" and sometimes must be "balanced against other compelling public needs."[53] As elaborated below, this standard is substantively identical to the TCPS standard for justifying limited infringements of confidentiality and privacy.

22 Against the background of the TCPS privacy norms and some of the leading post-1998 developments that parallel them, we turn to your questions.

E. Researchers' Duties: Participants & At-Risk Third Parties

1. The Dilemma: A TCPS Duty to Warn?

> [T]he therapist's obligations to his patient require that he not disclose a confidence unless such disclosure is necessary to avert danger to others, and even then that he do so discreetly, and in a fashion that would preserve the privacy of his patient to the fullest extent compatible with the prevention of the threatened danger.... We conclude that the public policy favoring protection of the confidential character of patient-psychotherapist communications must yield to the extent to which disclosure is essential to avert danger to others. The protective privilege ends where the public peril begins.[54]

23 You ask whether the TCPS bestows a "*Tarasoff* duty" on researchers, and if so what are the contours of the duty? By a "*Tarasoff* duty" we understand the phrase to refer generally to a professional's overriding duty of care to share information that an individual has confided to the professional; the professional's disclosure of confidential information aims to avert serious and imminent harm to identified third parties. As the excerpt above suggests, such a duty to third parties was outlined decades ago in a famous U.S. legal case. It involved a health professional who was alleged to have a duty to warn or alert third parties about an imminent risk of serious harm, revealed in confidential information, that one of his dangerous patients shared with him.[55] The court resolved the value conflict between respecting confidentiality of the patient and protecting the safety of another by finding that a health professional so situated may owe an at-risk third party a duty of reasonable care, which may include a limited duty to

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[47] See e.g. *Standards for Privacy of Individually Identifiable Health Information*, 45 C.F.R. § 164.510 (2002).

[48] European Community, *Commission Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data*, [1995] O.J. L 281/31 at arts. 8, 13 [*Privacy Directive*].

[49] See Mandate, *supra* note 27.

[50] *R. v. Mills*, [1999] 3 S.C.R. 668 at paras. 82, 89 (right of privacy of crime victim's counselling records).

[51] TCPS, *supra* note 25 at 3.1.

[52] See *Smith*, *supra* note 26 at para. 51.

[53] *Ibid.* at 74 (public safety exception to the solicitor-client confidentiality). See also *A.M. v. Ryan*, [1997] 1 S.C.R. 157 at para. 24 [*Ryan*] (confidential psychiatrist-patient communications).

[54] 17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14 (Cal. 1976) at 347 [*Tarasoff*].

[55] *Ibid.*

warn. Such limited duties to warn have since been recognized in Canadian professional codes of practice,[56] and discussed in the literature on research ethics.[57]

24 In this context, the TCPS recognizes and accommodates ethical and legal duties to warn, rather than imposing them. Section 3 recognizes that duties to third parties may arise from legal or professional obligations. The TCPS thus acknowledges that other high societal values and duties may sometimes intersect with privacy and confidentiality principles to require limited infringements of privacy or confidentiality, so as to advance "compelling and specifically identifiable public interests"—like the protection of health or safety.[58]

25 In other words, the TCPS foresees that research professionals may sometimes face difficult ethical choices: strictly respect a participant's confidentiality or share some confidential information with appropriate individuals or entities, to avoid a serious and imminent risk of harm to others. By implication, the TCPS leaves to the researcher and the REB—guided by professional guidelines, the particular facts, and relevant ethical and legal[59] duties—the important ethical deliberations that will define any precise duties of disclosure under the circumstances.

2. *A Threshold of Harm to Infringe Confidentiality?*

26 With respect to the kind of harm that triggers a duty to warn, you ask whether the TCPS permits infringements of confidentiality either to prevent "significant harms" to others or to prevent "serious threats of serious physical injury or death" to identifiable individuals, communities, and the like. The TCPS does not use or rely on such language to specify a threshold for justifying infringements of confidentiality or privacy.

27 Rather, in explaining why "the values underlying the respect of privacy and confidentiality are not absolute," the commentary to section 3 of the TCPS indicates that "[c]ompelling and specifically identifiable public interests, for example the protection of health, life, and safety, may justify infringement of privacy and confidentiality."[60] This suggests that in value contests or conflicts the cherished principle of privacy will often win, but not always because it may not in all circumstances be considered paramount or predominant in the hierarchy of public values. The TCPS observes that laws "compelling mandatory reporting of child abuse, sexually transmitted diseases or intent to murder are grounded on such reasoning."[61] The TCPS language in this context is consistent with the broader TCPS approach to exceptions to fundamental ethical principles—that is, to "preserve the values, purpose and protection that they attempt to advance",[62] exceptions to the principles should be narrow, specific, and limited. Here, the language used to indicate that infringements of privacy should be narrow and limited is that they must be justified for "compelling and specifically identified public interests".[63] The examples of "identified public

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[56] See Canadian Psychological Association, *Canadian Code of Ethics for Psychologists* (2000) at arts. I.45, IV.17, IV.18, online: <http://www.pre.ethics.gc.ca/english/pdf/links/Canadian%20Code%20of%20Ethics%20for%20Psychologists%20_2000.pdf> [CPA Code].

[57] See e.g. Paul S. Appelbaum & Alan Rosenbaum, "*Tarasoff* and the Researcher: Does the Duty to Protect Apply in the Research Setting?" (1989) 44 American Psychologist 885; Daryl Pullman & Kathy Hodgkinson, "Genetic Knowledge and Moral Responsibility: Ambiguity at the Interface of Genetic Research and Clinical Practice" (2006) 69:3 Clinical Genetics 199.

[58] TCPS, *supra* note 25 at 3.1.

[59] Such legal duties may arise from diverse sources, including relevant national, international, or provincial legal obligations. On the one hand, for instance, article 2 of the Quebec *Charter of human rights and freedoms* imposes on citizens a duty to aid those whose life is in peril, unless doing so places one in danger or unless there is another legitimate reason for not doing so. On the other hand, researchers bound by the federal *Statistics Act* or relevant provincial data collection laws that generally exclude secondary use of information collected for research purposes need to understand and respect the precise privacy standards, including any applicable exceptions. See *Charter of human rights and freedoms*, R.S.Q. c. C-12; *Statistics Act*, R.S.C. 1985, c. S-19, ss. 17–18 [*Statistics Act*]. See also *Personal Health Information Protection Act*, S.O. 2004, c. 3, Sch. A, ss. 6, 12, 18.

[60] TCPS, *supra* note 25 at 3.1.

[61] *Ibid*. On the research ethics challenges involving child neglect or abuse reporting laws, compare Camil Bouchard, "Recherche épidémiologique sur la violence envers les enfants: enjeux éthiques" (1998) 17:2 Canadian Journal of Community Mental Health 79; Joan E. Seiber, "Issues Presented by Mandatory Reporting Requirements to Researchers of Child Abuse and Neglect" (1994) 4:1 Ethics and Behavior 1; and *Child and Family Services Act*, R.S.O 1990, c. C-11, s. 72(1)ff.

[62] *Ibid*. at i.9.

[63] *Ibid*. at 3.1. Other national and international privacy and ethics standards have identified similar "public interests" that may justify limited infringements of privacy protections, such as national security, public safety, prevention of crime, protection of public health, etc. See e.g. *PIPEDA*, *supra* note 46, s. 7(4) and *Privacy Directive*, *supra* note 48 at art. 8.

interests" given in the TCPS indicate that they are illustrative, not exhaustive. The scope of any disclosure should be guided by a proportionality principle recognized in the TCPS: it should be limited in scope to what is reasonably proportionate to respond to the "compelling" interest at hand, thus "minimizing any necessary invasions"[64] of privacy.

28 The word "compelling" thus limits the range of "public interests" to beyond those which may be regarded as minimal; to be "compelling" they should be objectively serious or significant and not remote. For instance, a serious or significant physical or safety risk, or public peril is more likely to be considered compelling the more it is impending, imminent, or proximate, as opposed to remote and distant. As such, identified public interests need to be evaluated in the context of the particular circumstances and facts to determine whether they objectively qualify as "compelling." As noted above, it is instructive that important decisions in privacy law since the adoption of the TCPS have similarly interpreted the word "compelling" to justify limited infringements of confidentiality. Such decisions have reasoned that a "clear, serious and imminent risk" of bodily harm or death to an identifiable group or person constitutes a "compelling public interest" that may justify a limited public safety exception to the normal duty of confidentiality.[65] The reasoning is congruent with the logic, principles, and standards in the balancing approach outlined under the TCPS for infringements of privacy or confidentiality. Moreover, the principle of respect of law logically gives substantial weight to such standards for research ethics, and facilitates the growth and harmonization of ethical and legal norms.

3. Informing Participants About the Limits of Confidentiality

29 You also ask whether the TCPS requires researchers "immediately to inform participants" when a researcher breaches or infringes confidentiality "to protect life and limb". While the TCPS does not require such conduct, it does oblige researchers to respect reasonable privacy pledges, consistent with the process and principle of free and informed consent, unless there are important reasons for not doing so. Indeed, the TCPS outlines specific informed consent duties regarding the limits of confidentiality.

30 ***Free & Informed Consent:*** Article 2.4 of the TCPS indicates that researchers should provide to prospective participants "full and frank disclosure of all information relevant to free and informed consent".[66] Amongst other things, this includes the purpose of the research, research procedures, reasonably foreseeable benefits, harms, and risks of the proposed research. Informed consent is a continuing "process that begins with the initial contact and carries through the end of the involvement of research subjects in the project".[67] The scope and elements of informed consent should be regarded from the perspective of the precise information that a reasonable research participant would likely find relevant and helpful to making an informed decision to participate.[68] For projects in which participants are likely to find confidentiality issues relevant, researchers need to explain such matters as who will have access to identifiable data, how the data will be used, and "how confidentiality will be protected".[69]

31 From a participant's perspective, the possibility that the researcher may be obligated by legal, professional, or ethical duties to disclose normally confidential information is a foreseeable risk directly relevant to participation. Potential participants need to be able to weigh how high the risk is and to evaluate how likely are the associated harms. They may begin to do so with meaningful conversation on the relevant issues, such as the sensitivity of the information, the precise reporting or disclosure duties, the researcher's practice and procedures under such circumstances, the consequences of such disclosure, etc. On grounds of transparency, honesty, respect for informed consent and privacy, and confidentiality rights, it is reasonable to conclude that a prospective participant would wish to know the limits on confidentiality protections.

32 ***Foreseeing Limits:*** Accordingly, the TCPS specifies that researchers should indicate to participants "the extent of the confidentiality that can be promised, and hence should be aware of the relevant law".[70]

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[64] *Ibid.* at 3.2.

[65] *Smith*, *supra* note 26. See the discussion of the Supreme Court of Canada's analysis in this advisory opinion, *supra*, at para. 21.

[66] TCPS, *supra* note 25 at 2.5.

[67] *Ibid.* at 2.1.

[68] *Ibid.* at 3.1, 2.1ff.

[69] *Ibid.* at 2.7, 3.3, A.6.

[70] *Ibid.* at 3.2. See also *ibid.* at 2.5, A.6. Article 3.2 indicates that appropriate protections of privacy and anticipated secondary

As some have urged, participants "should be informed about the nature of the law and the researchers' position regarding it".[71] Responding in part to leading Canadian legal decisions[72] that confidentiality seldom is unlimited or protected absolutely, many researchers and REBs customarily indicate in the informed consent process with participants that confidentiality will be protected "within the limits of the law". The approach is standard and is noted in professional codes beyond Canada.[73] Some researchers go further to specify the particular lengths to which researchers intend to go to protect confidentiality in particular circumstances.[74] Both approaches are inspired by a research professional's ethical duty to anticipate the limits of confidentiality,[75] as an integral part of the design of, and informed consent process for, a research project that may involve ethical and/or legal duties to share legally or socially sensitive information with third parties.[76] For example, beyond its 1997 *Code of Ethics*, the American Sociological Association has more recently addressed informed consent and some limits on confidentiality:

> In some instances, confidentiality cannot be maintained (e.g., mandatory reporting of child abuse), and IRBs [Institutional Review Boards] and investigators need to take this into consideration when evaluating confidentiality protections. It is important to understand and resolve existing conflicts between any confidentiality protections and promises and the reporting statute *before* the research progresses. In such situations, it is also important that all consent forms and processes, and research protocols be designed and administered to describe clearly the limits on confidentiality so that the subjects fully comprehend these limits in determining their participation.[77]

33 ***Research Design:*** Research design and appropriate confidentiality protections and data management procedures—based on scrutiny of confidentiality and its limits in the particular project—should thus shape the methods of research, a researcher's confidentiality pledges,[78] and details of the informed consent process. These issues are key, because under the TCPS a researcher generally "is honour-bound to protect the confidentiality ... undertaken in the free and informed consent process, to the extent possible within the law."[79] Such research design methods should reduce the instances when researchers, REBs, or participants find themselves in an unanticipated conundrum or urgency about the duties, contours, and timing of disclosure of identifying sensitive information to third parties.

34 As a further part of the design of research and continuing consent process, the TCPS suggests that participants should be provided with information that may affect their continuing participation in "a timely manner".[80] Timeliness does not necessarily mean immediately. The timing should be objectively reasonable under the circumstances, taking into account relevant ethical, legal, and professional standards applied to the specific facts. For instance, if informing participants about any necessary disclosure were to defeat the purpose of warning a third party or would be prohibited by law, such disclosure would generally seem unreasonable. If reasonably foreseeable, the timing of potential disclosures should also be anticipated and included in the design of the project and the informed consent process.

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uses of data should be considered as part of the REB review process of research involving identifiable information.

[71] John Lowman & Ted Palys, "Subject to the Law: Civil Disobedience, Research Ethics, and the Law of Privilege" (2003) 33 Sociological Methodology 391 at 387 [Lowman & Palys].

[72] See e.g. *Smith*, *supra* note 26; *Ryan*, *supra* note 53.

[73] See e.g. American Educational Research Association, *Ethical Standards of the American Educational Research Association* (2000) at para. II.B.2; APA Code, *supra* note 45 at art. 4; ACE Guidelines, *supra* note 45 at s. 3.2.

[74] Lowman & Palys, *supra* note 71.

[75] The duty is outlined in such codes as the ASA Code, *supra* note 43 at arts. 11.03, 11.04;
American Academy of Criminal Justice, *Code of Ethics* (2000) at para. III.B.18; ASAUKC Guidelines, *supra* note 45 at paras. 5(b), 5(c); India, National Committee for Ethics in Social Science Research in Health, *Ethical Guidelines for Social Science Research in Health*, (2002) at s. IV.3.2; Norway Guidelines, *supra* note 34 at para. 19.

[76] See e.g. ASA Code, *ibid.* at art. 11; CPA Code, *supra* note 56 at art. I.45.

[77] American Sociological Association, *Issues in Confidentiality and Research Data Protections: A Report and Draft Recommendations to NHRPAC Social and Behavioral Sciences Working Group*, in National Human Research Protections Advisory Committee, *Recommendations on Confidentiality and Research Data Protections* (Rockville, Maryland: National Human Research Protections Advisory Committee, 2002) at 4 [emphasis added].

[78] The TCPS specification that researchers need to be aware of "relevant law" may raise ethical quandaries: if legal standards in the relevant jurisdiction provide no absolute or unlimited confidentiality, then what should a reasonable pledge of privacy say of absolute confidentiality? TCPS principles indicate that, as a minimum, the limits on confidentiality should be discussed as part of the informed consent process. See TCPS, *supra* note 25 at 1.3.

[79] *Ibid.* at 3.2.

[80] *Ibid.* at 2.6.

F. Conclusion

35 We close by noting that the questions and issues raised above are among the more challenging value conflicts and vexing dilemmas in human research ethics. As such, they merit continued study, interdisciplinary reflection and analysis, and policy development for participants, researchers, legislatures,[81] professional or learned societies, and institutions. In the meantime, we hope the foregoing proves helpful to your TCPS research ethics deliberations.

G. Appendix: Selected Readings

(* = available via the PRE's website: www.pre.ethics.gc.ca/)

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*American Educational Research Association, *Ethical Standards of the American Educational Research Association* (2000) at para. II.B.2.

*American Psychological Association, *Ethical Principles of Psychologists and Code of Conduct* (2002) at sec. 4.

*American Sociological Association, *Code of Ethics* (1997) at sec. 35.

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*Association of Canadian Universities for Northern Studies, *Ethical Principles for the Conduct of Research in the North* (2003) at principle 4.

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*Canada, Interagency Advisory Panel on Research Ethics, *Interpreting the TCPS* (2004).

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[81] Compare Australian, Canadian and the U.S. legislation protecting identifiable research data from compelled third-party access: Australia, *Commonwealth Epidemiological Studies (Confidentiality) Act 1981* (Cth.); Canada, *Statistics Act*, *supra* note 59 at arts. 17–18; United States, 28 C.F.R. § 22.1ff. (confidentiality of statistical or identifiable information in government-funded or conducted criminological research). U.S., *Education Sciences Reform Act of 2002*; *Public Health Service Act*, 42 C.F.R. § 2a (statutory certificates of confidentiality against involuntary disclosure of sensitive research data).

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