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| Date | September 2003 |

1. Thank you for your correspondence on issues regarding institutional research ethics review and naturalistic observation under the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) of 1998 (with 2000, 2002 amendments).

2. You seek clarification of the TCPS's standards on (A) whether a researcher needs to reapply for Research Ethics Board (REB) approval of a research project that was approved by the REB of one university with which the researcher was previously affiliated, while the university REB with which the researcher is now affiliated does not approve the project; and (B) whether a researcher needs permission to conduct naturalistic observation research on adults and children, including videotaping of hockey games and selected crowds in public arenas.

3. Your inquiry has been referred to the Interagency Advisory Panel on Research Ethics (PRE) for advice¹. In passing, we wish to underscore the fact that the PRE does not serve as an appeal mechanism for REB decisions. While we elaborate below on important issues, we emphasize throughout that REB review of these issues is the precise role the TCPS envisions for REBs, to ensure research consistent with the highest of ethical standards.

A. Institutional Research Ethics Review Processes: Authority of the REB

4. With regard to your first question, article [1.2](#) of the TCPS indicates that the TCPS is the *minimum standard* by which an REB has the mandate to approve, reject or modify proposed human research conducted within, or by members of, the institution. Each university is responsible for research conducted under its auspices. *Each university may adopt and implement policies or procedures that establish additional requirements beyond the TCPS to govern research.* In our view, such supplemental procedures should be reasonable; they should also meet the spirit of the principles and standards of the TCPS, which is the baseline from which the PRE provides guidance.

5. Within this framework, a university that requires a researcher to submit to the local REB review of a research project previously approved by another REB is not acting contrary to the standards of the TCPS². The request does impose additional administrative requirements on the researcher. To minimize this effect, we suggest that you provide the REB at your current institution with contacts so the new REB might communicate with the original REB, and consider whether previous REB review justifies expedited review, etc.

B. Naturalistic Observation

6. Your second question concerns the conduct of naturalistic observation research in "public" places. You seek clarification on (i) the need to obtain permission to access public places or consent to conduct naturalistic observation of the crowd and of adults and children playing hockey; (ii) restrictions for videotaping; and (iii) the potential use of video footage in public presentations.

7. In the context of the TCPS and naturalistic observation, these questions raise several related issues: (a) REB review; (b) the working and functions of the general informed consent requirements and exceptions thereto; and (c) issues of privacy and confidentiality related to records of data and the public use thereof.

(i) REB review

8. The TCPS states in article [1.1 \(a\)](#) that "All research that involves living human subjects requires review and approval by an REB in accordance with this Policy Statement, before the research is started, except as stipulated below." The basic principle applied is that research that involves direct interaction with a living individual should be reviewed and approved by the REB prior to the research, to ensure conformity with free and informed consent procedures, privacy and confidentiality issues.

9. Article [2.3](#) of the TCPS specifically addresses naturalistic observation:

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.

10. As a general rule, researchers claiming an exception to a general TCPS standard bear the onus of demonstrating that the exception reasonably applies to the proposed research³.

11. Does naturalistic observation of users of public hockey arenas fall under the specific or analogous exceptions? On the one hand, hockey players might reasonably be presumed to seek such publicity. On the other hand, one would expect that users of public recreational spaces in a community setting -- e.g., adult and child players or spectators - generally do not seek public visibility. It would therefore not fall under the exception in article [2.3](#). Accordingly, the proposed research should be reviewed by the REB. The nature of the research, as well as the professional ethical norms and practices of the relevant discipline, should be considered by the REB when reviewing a research proposal.

12. Article [3.1](#) of the TCPS indicates that REB review is not required for "access to publicly available information or materials, including ... records of public interviews or performances." For the reasons noted above, we do not regard the data that you intend to record as necessarily being within the public arena or publicly available. We also find that the nature of the issues involved warrant REB review. Some of those issues concern the collection of identifiable personal information, the purpose and kind of information collected, its use and storage, the varied recording means, anticipated secondary use, provisions for confidentiality, etc. (TCPS article [3.2](#)). When recording data by such means as videotaping, we note that while some individuals may not be the focus, they may still involuntarily and indirectly participate in it, as in your proposed research that involves children who are not targeted for naturalistic observation. Indirect participants may thus become inadvertent bearers of the risk of the research (TCPS page [i.3](#)), especially if measures for anonymizing data are not taken.

(ii) Proportionate Review and Minimal Risk

13. When conducting ethical review of research, the TCPS encourages REBs to apply a proportionate approach: the more invasive or risky the research procedures, the more care and procedural protections that would generally be due. The TCPS states, "Naturalistic observation that does not allow for the identification of the subjects, and that is not staged, should normally be regarded as of minimal risk" (TCPS page [2.5](#)). If the proposed research qualifies as minimal risk, then the review process for such research could be expedited under the TCPS. (See commentary to article [1.6](#)).

(iii) Research Information, Informed Consent and its Exceptions

14. Your question regarding permission to access public arenas to undertake naturalistic observation invokes one of the guiding ethical principles of the TCPS: free and informed consent. It translates into how researchers interact with the research participants in research.

15. Section [2](#) outlines the standards, rationales for, and exceptions to the general requirement for free and informed consent for participation in human research. The general requirement serves many purposes, such as (a) respecting the dignity of potential research participants; (b) protecting their physical, mental and cultural integrity; (c) furthering informed decision-making about the risks and benefits of research via a continuing dialogue over the research process; (d) promoting a partnered approach between researchers and participants; and (e) advancing the ethical integrity of those undertaking human research. For such reasons, it is the general task of the REB and researcher to ensure that, prior to the start of the research, individuals or groups who will be participating in research be given the kind of information outlined in article [2.4](#) of the TCPS, to enable them to give free and informed consent.

Exceptions and Waivers

16. The purposes, functions and underlying values of free and informed consent are not absolute, however. They sometimes compete with other implicated societal needs and values, which is why the TCPS recognizes limited exceptions to the general requirement. PRE would emphasize that such exceptions tend to be well-defined and narrowly construed, so as to effect the basic purposes of the general requirement of informed consent. Alterations to the consent process or waivers of consent are some of the recognized, narrow exceptions.

17. Thus, under article [2.1\(c\)](#) of the TCPS, an REB may consider approving an altered consent procedure, or may waive the requirement of informed consent:

The REB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the REB finds and documents that:

- i. The research involves no more than minimal risk to the subjects;
- ii. The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects;
- iii. The research could not practicably be carried out without the waiver alteration;
- iv. Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and
- v. The waived or altered consent does not involve a therapeutic intervention.

18. All of these conditions have to be respected for the REB to waive or modify a consent procedure.

19. Whether a research proposal actually qualifies for a waiver depends on the facts, considerations and contexts, applied to the criteria of article [2.1](#): e.g., the nature, the methodology, and objectives of research; the specific kind and levels of risk, the net risk-benefit calculus; and considerations that would make individual consent "impracticable," and thus likely to render the research nearly impossible to do. The TCPS has thus far followed a general international tendency of not offering detailed definitions or guidance on what qualifies as objective "impracticability." This depends on the case. For instance, some public health research proposals involve so many participants that individual consent imposes a severe burden. Public health researchers have persuaded some REBs to waive or alter the general consent requirement as objectively impracticable.

20. Whether, in this particular instance, prospective consent from adults/parents and children is objectively "impracticable" will depend on the number of participants involved, the options, the risks to individual participants, and a variety of other factors, including:

- Will those observed be identifiable or anonymized?

- Does the setting involve a small community with a public hockey arena where public activities are held?
- If individual consent will defeat or undermine the purpose of the research, is general notice to, or consultation with, the participating groups and permission to access the premises feasible?
- Would conventional consent defeat the purpose of naturalistic observation research that involves minimal risk?

21. While we do not have before us the full facts on the proposed study, we emphasize that mere inconvenience or administrative annoyance alone does not justify a waiver. The REB should thus weigh a range of considerations to determine whether a narrowly constructed waiver or modification of the elements or procedures of free and informed consent is justified.

(iv) Confidentiality, Privacy and Anonymity: Videotaping and Use of Data

22. You also request clarification on the use of videotaping to record data that may be subsequently used in public presentations. You indicate that the identities of those involved will be anonymized.

23. Your concerns are addressed by Section 3 of the TCPS, which outlines the basic norms on privacy, confidentiality and anonymity of participants in research. To further respect for human dignity, these norms protect the access, control and dissemination of identifiable personal information. The section indicates that, in general, the privacy and confidentiality of participants' identifiable personal information must be respected, unless particular exceptions apply. Consent of the participants, disclosures required by law, authorized waivers, and the use of publicly available information are among the recognized exceptions.

24. Your proposal to de-identify or anonymize those in the video recording should help to minimize the risks of invasions of privacy. It should also affect the nature of REB review: "As a general rule, the best protection of the confidentiality of personal information and records will be achieved through anonymity. If the data being stored are truly anonymous, the research project will need only minimal REB scrutiny" (TCPS page 3.2).

25. If the identifiable information is anonymized, it reduces the risk of harm from secondary use of personal information, in that the information is no longer identifying, nor intrinsically personal. (See TCPS, articles 3.2.e and f.) The more that the data contained in video recording are "truly anonymous," the more that the privacy interests of participants are protected.

26. We recognize within the privacy and confidentiality provisions of the TCPS a general ethical duty of researchers in such circumstances to anonymize personally identifying recorded data, as one means of minimizing risks to targeted and inadvertent participants. The researcher should demonstrate to the REB that necessary precautions have been taken to ensure the confidentiality of the records and anonymity of the data used publicly. The various means of recording data by videotaping, audio-recording, or written notes pose ethical and sometimes even legal issues.

27. Three points illustrate some of the related concerns. First, the TCPS encourages researchers to be sensitive to the interests of those who might suffer loss of dignity or confidentiality, stigmatization, loss of reputation, etc., depending on the environment in which naturalistic observation takes place, the subsequent dissemination of the results, and the impact on members of that community or studied population. Again, the size and nature of the community may increase or decrease these concerns. Second, the TCPS encourages REBs and researchers to take a subject-centred approach to identify and address ethical issues. A subject-centred perspective on the nature of the research, its aims and whether it contains identifying or residually sensitive data means that researchers may face situations where what is public and anonymized in the researcher's culture may not be so in the prospective subject's culture. Finally, the commentary to article 2.3 of the TCPS notes that in some jurisdictions, publication of identifying information may be considered an unlawful invasion of privacy. Such issues are more easily identified by the multidisciplinary membership and expertise of a duly constituted REB.

We hope that you will find these thoughts helpful to your human research ethics deliberations.

Sincerely,

Secretariat on Research Ethics,
on behalf of
The Interagency Advisory Panel on Research Ethics
www.pre.ethics.gc.ca

1. PRE provides advice on such interpretation questions to assist the research ethics community in applying the TCPS to the ethical issues it faces. While responses to TCPS interpretation questions may address ethical dimensions of legal issues in research ethics, PRE does not provide legal advice. Nor does it act as an appeal body on REB or institutional decisions.

² See also CIHR, NSERC and SSHRC, *Memorandum of Understanding: Roles and Responsibilities in the Management of Federal Grants and Awards* under schedule 2: Ethics Review of Research Involving Humans (2002) (http://www.nserc.ca/institution/mou_e.htm).

³ TCPS, page 1.9.