Government of Canada
Gouvernement du Canada

Interagency Advisory Panel on Research Ethics
Groupe consultatif interagences en éthique de la recherche

Ottawa, Canada
K1A 1H5

Subject:	Retention of Research Data
Keywords:	data, data retention, length of data retention, considerations thereto, local institutional policy, exceptions thereto, field and purpose of research, archiving
TCPS Articles:	3.2, Section 2, Section 3
Date:	April 2005

1. This is in response to your request for interpretation in which you inquire if the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) addresses the archiving of research findings and data. You ask about a policy that would permit the retention of research data indefinitely. Your inquiry has been referred to the Interagency Advisory Panel on Research Ethics (PRE) for their advice.[1]

2. In providing our response, we consider "data" to refer to recorded information, regardless of form or the media on which it may be recorded. However, the context in which we provide this response does not extend the definition of data to biological samples and specimens.

Data Retention under the TCPS

3. The TCPS underscores the importance of considering data retention by research ethics boards (REBs) in their reviews of studies that collect identifiable personal information about research participants: "Researchers shall secure REB approval for obtaining identifiable personal information about subjects. Approval for such research shall include such considerations as… (c) Limits on the use, disclosure and retention of the data…" (TCPS article 3.2 [c]). This is to ensure that the appropriate safeguards for security and confidentiality of the collected information are in place.

4. The TCPS does not specify a required length of time for retention of research data. Data retention periods tend to vary depending on the research discipline, research purpose and kind of data involved. These are further explained below.

5. Under the TCPS, REBs typically apply guiding principles and/or address issues relevant to data retention, such as respect for free and informed consent (Section 2); respect for privacy and confidentiality, and principles for the secondary use of data (Section 3); and respect for applicable laws and regulations. The "legal context for research involving human subjects is constantly evolving, and varies from jurisdiction to jurisdiction,"[2] and therefore an "understanding of relevant legal issues and contexts is advisable for all REBs..."[3] For example, Canadian clinical trials law outlines duties to preserve data for up to 25 years.[4]

6. To put TCPS principles into effective practice, the policy sensitizes its users to the need for flexibility and accommodation of the variety of research disciplines that it covers:

> Ethical principles are sometimes criticized as being applied in formulaic ways. To avoid this, they should be applied in the context of the nature of the research and of the ethical norms and practices of the relevant research discipline…. Thus, because principles are designed to guide ethical reflection and conduct, they admit flexibility and exceptions. To preserve the values, purpose and protection that they attempt to advance, the onus for demonstrating a reasonable exception to a principle should fall on those claiming the exception.[5]

Considerations Concerning Length of Retention

7. Throughout the TCPS, a number of factors are relevant to defining periods of data retention. These include the following:

- *Purpose of retaining data:* What is the purpose and use of retention? For example, is the retention necessary to achieve the specific purpose for which the data were gathered and used? Is its retention for, and necessary to, secondary uses?
- *Type of data collected:* Is it sensitive data? Are participants identifiable? What is the effect on the participants, etc., of conservation of data?
- *Nature of research under review:* Does the field require retention of data for the continuity of scientific research, such as in the case of historical or statistical research? What are the professional standards for the relevant discipline?
- *Informing participants:* Have the participants provided informed consent to the purposes, uses and retention of the data collected? Have they been informed of any potential for secondary use of such data?
- *Access to data:* Who is authorized to have access to the data? How will access be managed?
- *Data storage, security, and protection:* Will the data obtained be stored securely and protected with all the precautions appropriate to the sensitivity of the data?
- *Confidentiality and anonymity of data:* Have the researchers taken appropriate measures to preserve anonymity, consistent with the presumption that anonymity accords with the privacy preference of participants?[6]
- *Legal and other requirements:* Do applicable regulatory or statutory requirements, including relevant federal or provincial Privacy Legislation, affect the retention period? Does the institution itself have policies on record retention?

8. It seems prudent to incorporate such factors into local data retention policies that institutions have been encouraged to develop.[7] Exceptions to retention of data beyond institutional policy requirements should be legitimate and justifiable. The onus is on researchers to justify their case and address all consent, confidentiality and security issues to the satisfaction of their local REB.

Considerations Related to the Field of Research

9. With the range of disciplines that might be covered by an institutional data retention policy, researchers' plans for preserving and destroying participants' data should be appropriate to the field of research, in light of its best practices and its professional, ethical and legal norms. For example, professional practice in oral history may be to archive the information collected (with the participants' consent) for future generations to use. This spectrum is also reflected in the retention and disposal standards for personal information banks collected under the authority of Federal Government Agencies such as Statistics Canada[8] and Public Health Agency of Canada[9] . This varies from two years (e.g., Inventory of Requests Made Under the Access to Information and Privacy Acts), to 100 years (e.g., Canadian Hospitals Injury Reporting and Prevention Program), to indefinitely (e.g., Longitudinal Administrative Data).

10. Internationally accepted principles of data retention suggest that data should be generally retained for the length of period necessary to achieve the purposes for which they were collected. Some international data protection laws have created specific conditions for indefinite retention of data for research purposes.[10] "Research purpose" as used here includes statistical or historical purposes.

We hope that you find this information helpful to your human research ethics deliberations on the TCPS.

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 TCPS page. i.8: Ethics and Law.
3. See TCPS, page 1.3: Membership of the REB.
4. Health Canada. "Regulations Amending the Food and Drug Regulations:" 1024 (2001) http://www.hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/reg/1024_tc-tm_e.html.
5. See TCPS, page i.9: Putting Principles into Practice.
6. Some instances, such as a case in which a community or individual declines anonymity, may require appropriate information-sharing procedures that may be part of ethics review of the research design.
7. See, e.g., *Tri-council Policy Statement: Integrity in Research and Scholarships*: "Institutions are encouraged to develop policies on such areas as requirements for authorship for publications or applications, on copyrights and patents, and on the responsibilities for retention of data appropriate to the range of disciplines that they offer. (http://www.nserc.gc.ca/professors_e.asp?nav=profnav&lbi=p9)
8. http://www.infosource.gc.ca/inst/stc/fed07_e.asp
9. http://www.infosource.gc.ca/inst/ahs/fed06_e.asp
10. See, e.g., United Kingdom. *Data Protection Act 1998*, c. 29, section 33, superseding the *Data Protection Act* of 1984. (http://www.hmso.gov.uk/acts/acts1998/19980029.htm#aofs).