
Tri Council Policy Statement 2

INFORMED CONSENT SUMMARY¹

The head of the research team, also known as the principal investigator, is responsible for ensuring that the consent process is followed. This person is also responsible for the actions of any member of the research team involved in the consent process.

This process is meant to emphasize Respect for Persons. Equally, Respect for Persons implies that those who lack the capacity to decide for themselves should nevertheless have the opportunity to participate in research that may be of benefit to themselves or others.

TCPS 2 Chapter 3 The Consent Process

Article 3.1

Consent shall be given voluntarily

(a) Consent shall be given voluntarily

Undue influence and manipulation may arise when prospective participants are recruited by individuals in a position of authority. The influence of power relationships (e.g., employers and employees, **teachers and students**, commanding officers, and members of the military or correctional officers and prisoners) on the voluntariness of consent should be judged.

REBs and researchers should also pay particular attention to elements of trust and dependency in relationships (e.g., between physician and patient or between **professor and student**).

Where students do not wish to participate in research studies for course credits, they should be offered a comparable alternative.

Incentives

Incentives are anything offered to participants, monetary or otherwise, for participation in research. Where incentives are offered to participants, they should not be so large or attractive as to encourage reckless disregard of risks.

(b) Consent can be withdrawn at any time

To maintain the element of voluntariness, participants shall be free to withdraw their consent to participate in the research at any time and need not offer any reason for doing so.

The participant should not suffer any disadvantage or reprisal for withdrawing nor should any payment due prior to the point of withdrawal be withheld. If the research project used a lumpsum incentive for participation, the participant is entitled to the entire amount. If a payment schedule is used, participants shall be paid in proportion to their participation.

¹ Tri Council Policy Statement 2 (TCPS2) Chapter 3 and 5. The Consent Process and Privacy. 2010

- (c) If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials

Consent shall be informed

Article 3.2

Researchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project.

The information generally required for informed consent includes:

- (a) information that the individual is being invited to participate in a research project;
- (b) a statement of the **research purpose** in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;
- (c) a plain language description of all reasonably **foreseeable risks and potential benefits**, both to the participants and in general, that may arise from research participation;
- (d) an assurance that prospective participants:
 - are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements;
 - will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation; and
 - will be given information on the participant's right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;
- (e) information concerning the possibility of commercialization of research findings, and the presence of any real, potential, or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;
- (f) the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;
- (g) the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;
- (h) the identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research;
- (i) an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants, a description of how confidentiality will be protected (see Article 5.2), a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;

- (j) information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;
- (k) a statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm; and
- (l) in clinical trials, information on stopping rules and when researchers may remove participants from trial.

Consent Shall Be an Ongoing Process

Article 3.3

Consent shall be maintained throughout the research project. Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research.

Incidental Findings

Article 3.4

Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research

Material incidental findings are findings that have been interpreted as having significant welfare implications for the participant, whether health-related, psychological, or social.

TCPS2 Chapter 5 Privacy

Article 5.2

Researchers shall describe measures for meeting confidentiality obligations and explain any reasonably foreseeable disclosure requirements: (a) in application materials they submit to the REB; and

(b) during the consent process with prospective participants

D. Consent and Secondary Use of Identifiable Information for Research Purposes

Secondary use refers to the use in research of information originally collected for a purpose other than the current research purpose. Common examples are social science or health survey datasets that are collected for specific research or statistical purposes, but then re-used to answer other research questions.

Article 5.5

Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if the REB is satisfied that:

- (a) identifiable information is essential to the research;
- (b) the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;

- (c) the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;
- (d) the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
- (e) it is impossible or impracticable to seek consent from individuals to whom the information relates; and
- (f) the researchers have obtained any other necessary permission for secondary use of information for research purposes.

Article 5.6

When secondary use of identifiable information without the requirement to seek consent has been approved under Article 5.5 researchers who propose to contact individuals for additional information shall, prior to contact, seek REB approval of the plan for making contact.

E. Data Linkage

Article 5.7

Researchers who propose to engage in data linkage shall obtain REB approval prior to carrying out the data linkage, unless the research relies exclusively on publicly available information as discussed in Article 2.2. The application for approval shall describe the data that will be linked and the likelihood that identifiable information will be created through the data linkage.

Where data linkage involves or is likely to produce identifiable information, researchers shall satisfy the REB that:

- (a) the data linkage is essential to the research; and
- appropriate security measures will be implemented to safeguard information.