

Informed Consent

Giving Consent

In research, informed consent refers to the dialogue, information sharing and general process through which prospective subjects choose to participate in research. Consent needs to be **voluntary**, **informed**, and **ongoing**.

Voluntary Consent

According to the TCPS, part of informed consent involves the principle of 'Respect for Persons'. This implies that individuals who participate in research should do so voluntarily, understanding the purpose of the research, and its risks and potential benefits, as fully as reasonably possible (TCPS 2, 2014, Article 3.1).

Consent should be given voluntarily and as such, participants should be able to withdraw their consent during the research process. If participants do withdraw their consent, they should also be able to request the withdrawal of their data (TCPS 2, 2014, Article 3.1).

In order to make sure that consent is given freely, no undue influence should exist on the participant to participate. For example, the power dynamic between an instructor and a learner may sway the learner to participate in research involving the instructor because they fear that it may affect the instructor's perception of them if they decline to participate.

As well, the consent process should be free of coercion. **Coercion** is a "more extreme form of undue influence, involving a threat of harm or punishment for failure to participate" (TCPS 2, 2014, p. 27). **Incentives** may be used as a form of remuneration for the participant's time and effort in participating in the study, but they should not be so attractive that they encourage disregard of the risks of participating in the study (TCPS 2, 2014, Article 3.1).

Informed Consent

It is the responsibility of the researcher to provide participants with all of the information necessary to make an informed decision to participate in a research study (TCPS 2, 2014, Article 3.2).

In order to ensure that the participants are truly informed, the following areas must be addressed (TCPS 2, 2014, Article 3.2):

- 1) Information that invites the individual to participate in the research project;
- 2) A statement of the research purpose, information about the researcher(s) and any funder(s), expected duration and nature of participation in the study, a description of research procedures, and an explanation of the responsibilities of the participant;



- 3) Description of the risks and benefits of research participation;
- 4) The assurance that participation is voluntary and they are free to withdraw at any time and that they will be informed of their ability to continue or withdraw their participation throughout the research process, and their right to request withdrawal of data;
- 5) Information concerning the possibility of the 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;
- 6) The plans for research result dissemination and how the participants will be identified (i.e., directly or indirectly);
- 7) Contact information for a qualified, designated representatives who can explain scientific or scholarly aspects of the research to the participants and who the participant may contact regarding possible ethical issues;
- 8) What information will be collected about participants and for what purposes, who will have access to this information, how this information will be protected, a description of the anticipated uses of the data, and information about disclosure of information;
- 9) Information about any payments (e.g., incentives, reimbursements, compensation);
- 10) A statement that notes that consenting to participate does not waive any legal rights that the participant may have.

Participants should have adequate time for review of the information and should be able to pose any questions that they have before they decide whether they would like to participate or not. The information given should be in plain language and at the level of the participant (e.g., adjust the reading level if necessary).

Ongoing Consent

Researchers have an ongoing responsibility to provide participants with relevant information for their ongoing consent to participate in the research. Consent is a process that begins with initial contact with the potential participants (e.g., recruitment) and carries through to the end of the participants' involvement in the project (TCPS 2, 2014, Article 3.3). This becomes relevant with any changes to the research project, especially changes to the potential risks or benefits of the research.

For more information on the consent process, please see:

TCPS 2 (2014)- Chapter 3:
http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf