

## Interdisciplinary Committee on Ethics in Human Research [ICEHR]

### Free and Informed Consent

Informed consent provides participants with enough information about the study to allow them to make informed decisions about whether to participate, and whether to continue to participate. It is an on-going process that starts with the researcher's first contact with the individual and continues through study completion/participant withdrawal, and beyond. It includes any verbal exchange about the study, the written informed consent form and any other written documentation given to participants.

#### **Consent must be documented.**

- If written consent is possible, the consent form should be dated, signed and the participant should receive a copy of the consent form for his or her own reference.
- If consent has been obtained orally, the consent form must be dated and signed by the researcher(s) indicating that "I have read and explained this consent form to the participant before receiving the participant's consent, and the participant had knowledge of its contents and appeared to understand it."
- When a consent form is not used, then some other means must be available for participants to indicate their consent. For example, in a survey, participants should be informed that completion and return of the survey will constitute consent to participate and permission for the researcher to use the data gathered in the manner described.
- When written consent is culturally unacceptable, or where there are other good reasons for not recording consent in writing, the procedures used to seek free and informed consent must be approved by ICEHR before data are collected and must be documented.

Participants make a vital contribution to research. They must be treated at all times with the highest respect and consideration. All communications, whether written or oral, should be professional, as well as socially and culturally appropriate. Specifically:

- Information letters and consent forms should be presented on the institutional or departmental letterhead of the Principal Investigator.
- Use the second person (i.e., "you") in the informed consent process.
- The level of language used should be appropriate to participants' age and comprehension level. Avoid or explain technical terms and jargon. (For people in the general population, a grade 6 to 8 reading level is appropriate. In Microsoft Word the Flesch-Kincaid Grade Level Score can be determined by accessing Tools/Options/Spelling&Grammar and by selecting "Show readability statistics.")
- Avoid the use of legalistic phrases.
- Use headings, small paragraphs, and spaces between paragraphs to make information easier to read.
- Ensure that spelling, grammar, and punctuation are correct.