

Hints and tips

Informed consent

- Keep in mind the autonomy of volunteers/participants/patients participating in research projects or clinical trials. Participation is voluntary and the person may withdraw at any stage without giving a reason.
- Invite the person to participate, do not issue an order or use an aggressive tone.
- Explain technical terms and avoid assumptions; use simple language. You are the expert in the field, not the participant.
- If children are under 18 years of age they should give their own consent, in addition to the consent of the parent or guardian.
- When studying records: if the records will not be used unlinked and anonymous, written consent will be required.
- Participants should be told explicitly why they or their community may benefit from the study/treatment.
- Tape recording of discussions - separate consent has to be given for tape recording. Mention explicitly how participants will be identified on the recording or how confidentiality will be maintained. Also mention for how long the recordings will be stored and when it will be destroyed.
- Obtaining consent from participants with different levels of literacy is difficult. Complete forms are necessary to be legally sound, but they could have executive summaries in peoples' home languages. If a participant cannot read, the researcher must make sure he/she understands the issues at hand - the burden is with the researcher to make consent clear.
- Confidentiality of files: it is crucial that patients should give consent for their files to be used; there can be no presumption of confidentiality.

Research question

- State clearly why the study will be done, i.e. what scientific value will be added by this study. Also mention the outcomes of the study and how long it will take.

Methodology

- State clearly how the research findings will be analysed and disseminated. Make sure that the information supplied on the statistical analysis is complete, including for example how the sample size was determined.

Questionnaires

- Always state how long it will take to complete the questionnaire. Use simple language to make it accessible to people of different education levels.

Translations

- Budget for translations: The translation of questionnaires, information sheets and consent forms should be included in budgets. Translations should be technically correct and done properly and professionally. The translator's certification should be submitted.

Budgets

- All protocols should include a justified budget. An inadequate budget may lead to mistakes that are ethical, not budgetary. If it is not indicated how the money for the project will be used, it is impossible to judge whether the budget will be adequate, and it is probable that ethical mistakes will be made. Informed consent usually suffers when there is not enough money for a project. Where there is an inadequate budget the ethics may suffer as well as the science.
- The study should warrant the money spent on it, however small the amount is.

Abuse

- When any instances or suspected instance of abuse are identified in the course of a project, it is the researcher's duty to report it. In terms of the Prevention of Family Violence Act and the Children's Act it is a criminal offence not to report abuse.