1. Informed consent

The process of providing information to and obtaining informed consent from prospective research participants is a crucial factor in assessing the ethical acceptability of a research proposal. Researchers must provide the potential participants with information that would enable an average lay person to make a voluntary and un-coerced decision to participate. Informed consent is important because it recognises patient autonomy and ensures communication of risks relevant to the patient. The principle of informed consent has its roots in the Nuremberg Code and the Declaration of Helsinki. It is now a legal and ethical requirement of conducting human research.

Provision of a Participant Information Statement and Consent form is part of the informed consent process.

2. What should Participant Information Statements look like?

Participant Information Statements should be written in clear, objective, non-technical lay language. They must be on the official letterhead of the organisation that is conducting the research and include the Chief Investigator's name and contact details. Potential participants must be properly informed regarding what they are being asked to do and what potential consequences for participating may be. They must also be told that there are no disadvantages/penalties/adverse consequences for not participating or for withdrawing from the research. This is particularly important where the potential participant is dependent on the researcher or their close colleagues for continued treatment or is a student of the researcher.

Please refer to the checklist for more detailed information about the content

3. Who requires a Participant Information Statement?

An appropriate Participant Information Statement should be prepared for:

- Each participant involved (and/or his/her guardian)
- The institution the participant is in (where applicable)
- Other involved professional workers (where applicable)

Each 'category' of participant involved – e.g. if research is being conducted in a school, it may be appropriate to prepare separate Statements for teachers, students, parents, etc.

4. More information

This document is based on the information provided by the University of Sydney Human Research Ethics Committee on the university's website.

http://sydney.edu.au/research_support/ethics/human/attachments.shtml

These pages contain more information about the informed consent process and give example templates for participant information documentation. While some instructions are Sydney University-specific, the principles remain the same. You can also visit the NHMRC website and review the consent sections of the National Statement on Ethical Conduct in Human Research (2007)

http://www.nhmrc.gov.au/book/chapter-2-2-general-requirements-consent

5. Content check list for Participant Information Statements

Item	Present
The title of the research project is on each page. The title should be easily understood.	
The names and faculty/department of the researchers and appropriate contact telephone numbers and/or other contact details are included.	
Details of the student researcher's degree if the project is being conducted as part of a degree requirement.	
The aim/purpose of the research in explained in lay terms	
Clear explanation of what is involved and expected of each participant. This should include ▪ procedures, their frequency, time commitment and the information to be obtained ▪ an indication of where each component of research will occur ▪ other requirements e.g. eligibility, abstaining from meals, special clothing/equipment, etc.	
Participants are informed if they will be recorded using audio or video tapes or photography.	
Detail any payment or incentive provided to participants. The conditions of receiving remuneration must be clearly stated.	
Participants are informed how confidentiality of data will be maintained, who will have access to the data, and if others not directly involved in the study will be granted access. No information that will identify participants should be released without explicit consent of the participants concerned.	
A statement regarding what the research will be used for and the possibility of publication. There should be assurance that publications will not include any information identifying individual participants unless specific consent has been obtained to do so.	
Advise participants if they will be given the opportunity to preview results or interview transcripts before they are used. Interview participants must be advised if they will have the opportunity to withdraw or amend information any time during or after the interview. Focus group participants must be informed that, should they withdraw, it will not be possible to destroy information they have provided due to the interdependent nature of focus groups.	
Statement on secure storage of data, how long the data will be retained, and how it will ultimately be destroyed; or materials may be archived and how.	
Participant's right to withdraw at any time without having to provide a reason. The Statement should indicate that participants will have the option of having any data already collected destroyed should they withdraw. Where data is collected completely anonymously participants cannot be guaranteed the right to withdraw at any time because their data, once submitted, cannot be linked to them. Participants cannot withdraw material from a focus group once it has commenced, nor can audiotapes be erased.	
Emphasis that refusal to participate or withdrawal will not prejudice the participant's future relationship with the researcher in any way or incur any consequences.	
Complaints clause with appropriate organisational contact details is included	