

Requirements of the Plain Language Statement

In the plain language statement the project should be described so that potential participants, after reading the description, will be able to choose freely whether or not to participate in the project. The written description should contain the following information:

Researcher Details

Clear identification of the:

1. University (statement to be printed on University letterhead);
2. Department or departments involved;
3. Project title;
4. Principal (and other) investigator(s) (including contact numbers for these);
5. Supervisor, if it is a student research project;
6. Degree for which the research is being undertaken, if it is a student research project.

Procedures/Risks

- An explanation, in language that the participants will understand, of the aim of the project and the procedures to be followed (e.g., surveys, interviews, video-taping, audio-taping, blood testing, etc). This should include a description of what participants are expected to do if participating in the project, the anticipated time involved, and any possible risks, discomfort or inconvenience resulting from these procedures. If children are the participants in research a statement should be provided for them in language they can understand as well as a statement suitable for their parents/guardian.

No Prejudice

- If provision of services, benefits, medical treatment, education or other care is involved, a clear statement that involvement or non-involvement in the project will not affect ongoing management, treatment, assessment/results or employment situation.

Right to Withdraw

1. A clear indication that participation in the project is voluntary, and that participants may withdraw consent to participate and discontinue participation at any time until data become processed. Participants should also be advised that they may, if they wish, withdraw any unprocessed data previously supplied;
2. Participants must be informed that withdrawing from the research will not jeopardise their relationship with the researchers in any way (e.g., teacher/student relationship; medical treatment);
3. A participant must be free at any time to withdraw consent to further involvement in the research. If any consequences may arise from such withdrawal, advice must be given to participants about these before consent to involvement in the research is obtained.

Confidentiality Procedures/Data use and Storage

1. Details of the anticipated use of the data (e.g., thesis, publication, whether or not copies of reports will be given to participants, sponsors etc.);
2. An explanation of procedures adopted to ensure confidentiality of data. Participants should also be advised of limits to confidentiality -i.e. subject to legal requirements, requirement to report by some professions (mandatory reporting requirements), duty of care to third party etc. Information about how the data will be used should also be included and, where necessary, the steps to be taken to ensure that participants will not be identified. (For example, if case histories are to be written up in a report of the research, a statement will

need to be included to indicate that information will be disguised by use of pseudonyms or other devices so that identification of the participant will not be possible).

Funding

- Identification of funding bodies and sponsors of the research needs to be included.

Further Assistance

Outlining:

1. An offer to answer any questions and a contact name and telephone number if any further explanation is required;
2. Arrangements for debriefing or follow-up where this is necessary to secure the well-being of participants;
3. A statement that if participants have any concerns regarding the conduct of the research project that they can contact the Executive Officer, Human Research Ethics, the University of Melbourne , Vic 3010, ph: (03) 8344 2073; fax: (03) 9347 6739

Plain Language Statement Checklist

Confirm that the Plain Language Statement:	YES	NOT APPLICABLE
1. is printed on University of Melbourne letterhead	<input type="checkbox"/>	
2. includes clear identification of the University, the Department(s) involved, the project title, the Principal and Other Researchers (including contact details), and the study level if it is a student research project.	<input type="checkbox"/>	
3. provides details of the purpose of the research project	<input type="checkbox"/>	
4. provides details of what involvement in the project will require (e.g., involvement in interviews, completion of questionnaire, audio/video-taping of events), and estimated time commitment	<input type="checkbox"/>	
5. provides details of any risks involved and the procedures in place to minimise these.	<input type="checkbox"/>	<input type="checkbox"/>
6. advises that the project has received clearance by the HREC	<input type="checkbox"/>	
7. (if the sample size is small), states that this may have implications for protecting the identity of the participants	<input type="checkbox"/>	<input type="checkbox"/>
8. includes a clear statement that if participants are in a dependent relationship with any of the researchers that involvement in the project will not affect ongoing assessment/grades/management or treatment of health (if relevant)	<input type="checkbox"/>	<input type="checkbox"/>
9. states that involvement in the project is voluntary and that participants are free to withdraw consent at any time, and to withdraw any unprocessed data previously supplied	<input type="checkbox"/>	
10. provides advice as to arrangements to be made to protect confidentiality of data, including that confidentiality of information provided is subject to legal limitations (see ** below)	<input type="checkbox"/>	
11. provides advice as to whether or not data is to be destroyed after a minimum period (if relevant)	<input type="checkbox"/>	<input type="checkbox"/>
12. provides in the footer, the project HREC number, date and version of the PLS	<input type="checkbox"/>	
13. provides advice that if participants have any concerns about the conduct of this research project that they can contact the Executive Officer, Human Research Ethics, The University of Melbourne, ph: 8344 2073; fax 9347 6739	<input type="checkbox"/>	