

**La Trobe University
Research Services**

Human Research Ethics

Guidelines

Participant Information Statement and Consent Form

The information to be included in the Participant Information Statement and the Informed Consent Form is set out in the points below. The format and content should not normally vary from what is set out here. If this model is inappropriate for your group of participants, alternative models will be considered by the UHEC or FHEC. It is advisable to discuss alternate models with either the Secretary or a member of the UHEC or FHEC.

The Participant Information Statement must be a separate document from the Consent Form. Forms must be titled 'Participant Information Statement' and 'Consent Form'. A separate PIS and Consent Form should be prepared for, and retained by, each participant or his/her guardian, or organisation.

A Participant Information Statement should contain the following information:

1. La Trobe University School/Department/Centre letterhead should appear at the top of the page. Note: Where the research is conducted through an external agency, it may be appropriate for the agency's letterhead to be used.
2. Title of the project (Block Letters).
3. Names, affiliations and convenient contact details of all investigators (University staff and students as well as external investigators). The inclusion of personal home telephone numbers on the Information and Consent Forms, however, is strongly discouraged. Similarly, phone numbers for administrative staff who are not involved with the project should not be given. Where an undergraduate, honours or postgraduate student is to conduct the project, state the name of the course of study for which the research is being conducted and who is supervising the research.
4. A description in lay language of the aims of the project and how the participant has been identified and recruited and any requirements to be met by participants, e, g., "In order to participate you must be aged 18 years or older.
5. A declaration of the name(s) of any commercial companies that have provided funding or sponsorship for the project, if applicable.

6. A description of the research procedures including the anticipated time commitment expected of the participant, the information you will be obtaining, the sources of that information, and any actual physical interventions.
7. A statement of any risks, discomforts or harms which may result from participation in the project. Include an explanation of how any such risks or harms will be minimised and a statement of who would **not** be eligible to participate (e.g., pregnant women, asthmatics, etc).
8. A statement which details the use of the data. This must be explained in sufficient detail that participants will be able to give informed consent as to the actual use of the data. This statement must include:
 - (a) procedures to be followed to ensure security and confidentiality of data;
 - (b) circumstances under which the confidentiality of the participant cannot be guaranteed, if applicable (e.g., as authorised or required by law, or where the investigators believe that disclosure is necessary to lessen or prevent a serious threat to public health or public safety);
 - (c) how and in what format (e.g., hard copy and/or electronic) the data will be used for reporting and publications (including publication of interview transcripts or written narratives prepared by participants);
 - (d) that the participant may request a copy of their personal data collected in the course of the research (if applicable);
 - (e) that participants will be provided with an opportunity to review transcript(s) of their interview(s) prior to submission of a thesis or publication of reports or papers (if applicable);
 - (f) that participants will be provided with a summary of the results of the research (if applicable);
 - (g) when, how, and for what purpose the data might be preserved for possible future use in another project;
 - (h) who might be given access to data preserved for possible future use in another project;
 - (i) when and how the raw data will be disposed of
9. In the case of mail surveys, a statement explaining any follow-up procedures (e.g., reminders to complete questionnaires, use of coded envelopes/questionnaires)
10. A statement of the benefits of the project to the participant (or lack thereof) and to society in general.
11. A statement that explains that there are no disadvantages, penalties or adverse consequences for not participating or for withdrawing prematurely from the research. This is particularly important where participants are dependent on the investigators or their professional colleagues for continuing treatment or care or where the participants are students of the investigators.

12. Where deception is used, the following statement should be incorporated:

“It is sometimes essential for the validity of research results not to disclose the true purpose of the research to participants. If this occurs participants will be debriefed as soon as possible and at that time given the opportunity to withdraw from the research and have data arising from their participation not used in the research project.”

13. An offer to answer any questions the participant has regarding the project, as follows:

“Any questions regarding this project may be directed to the Investigator(s) (name(s)), of the School of (name) on telephone number (details).”

For contact numbers, please do not provide personal telephone numbers or phone numbers of administrative staff who are not involved with the project.

14. A statement advising the method of complaint/query as follows:

For UHEC applications:

“If you have any complaints or queries that the investigator has not been able to answer to your satisfaction, you may contact the Secretary, Human Ethics Committee, Research Services, La Trobe University, Victoria, 3086, (ph: 03 9479 1443, e-mail: humanethics@latrobe.edu.au).” Please quote UHEC application reference number _____.

For FHEC applications (please refer to section 1.4 for specific FHEC details):

“If you have any complaints or queries that the investigator has not been able to answer to your satisfaction, you may contact the Secretary, Faculty Human Ethics Committee, Faculty of (insert appropriate faculty title), La Trobe University, Victoria, 3086, (ph: insert appropriate FHEC phone number), e-mail: [insert appropriate e-mail address](#)”. Please quote FHEC application reference number _____.

15. A statement that explains the participant is free to withdraw consent and to discontinue participation in the research at any time. However, the ethics committees acknowledge that in a limited range of cases it is appropriate to distinguish between the right of a participant to withdraw from active participation in a project and the right to demand that no data arising from their participation is used. Participants may request data to be destroyed, in instances where a participant has a right to request withdrawal of their consent and removal of data arising from their participation. It is

important, however, to retain evidence of the withdrawal of consent and request to remove the participant's data. In such cases, UHEC / FHEC will consider the use by investigators of consent forms that include a time limit on requests for the withdrawal of data (i.e., a sunset clause), provided the time limit specified is not less than four weeks following the completion of data collection (please refer to item 3). An example of the suggested wording of sunset clauses follows:

*"You have the right to withdraw from active participation in this project at anytime and, further, to demand that data arising from your participation are not used in the research project provided that this right is exercised within four weeks of the completion of your participation in the project. **You are asked to complete the "Withdrawal of Consent Form" or to notify the investigator by e-mail or telephone that you wish to withdraw your consent for your data to be used in this research project.**"*

The Consent Form should contain the following information:

1. La Trobe University School / Department / Centre letterhead must appear at the top of the page Note: Where the research is conducted through an external agency, it may be appropriate for the agency's letterhead to be used.
2. Title of the project (Block Letters).
3. A signed statement of agreement to participate, as follows:

*"I (the participant) have read (or, where appropriate, have had read to me) and understood **the participant information statement and consent form**, and any questions I have asked have been answered to my satisfaction. I agree to participate in the project, realising that I may withdraw at any time. I agree that research data provided by me or with my permission during the project may be included in a thesis, presented at conferences and published in journals on the condition that neither my name nor any other identifying information is used."*

Or, if a sunset clause is to be used:

*"I (the participant) have read (or, where appropriate, have had read to me) and understood **the participant information statement and consent form**, and any questions I have asked have been answered to my satisfaction. I understand that even though I agree to be involved in this project, I can withdraw from the study at any time, up to four weeks following the completion of my participation in the research. Further, in withdrawing from the study, I can request that no information from my involvement be used. I agree that research data provided by me or with my permission during the project may be included in a thesis, presented at conferences and published in journals on the condition that neither my name nor any other identifying information is used."*

4. If photographs or audio or video recordings are being taken, the consent form needs to request specific permission for these, usually by providing a 'yes'/'no' tick box.

5. Provisions for signatures of the participant (or authorised representative) and the senior investigator:

Name of Participant (block letters):

Signature:

Date

***Name of Authorised Representative (block letters):**

Signature:

Date

Name of Investigator (block letters):

Signature:

Date

****Name of Student Supervisor (block letters):**

Date:

*Use this signature block only in such cases where the participant is not capable of providing his/her own informed consent. See Question 6(g) of the application form.

**To be used when the investigator is either an undergraduate or postgraduate student.