Research and Graduate Studies Committee

University Human Ethics Committee

Participant Information Statement and Consent Form Guidelines

The information and details to be included in the Participant Information Statement (PIS) and the Consent Form is set out in the points below. The format and content should not normally vary from what is set out in these Guidelines. If this model is inappropriate for your group of participants, alternative models will be considered by the University Human Ethics Committee (UHEC) or College Human Ethics Sub-Committee (CHESC). It is advisable to discuss alternate models with either the Secretary or a member of the UHEC or CHESC.

The Participant Information Statement (PIS) 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.

Where the PIS is presented as an introduction to an on-line survey data gathering instrument and the participant has not already received a copy, then it must contain instructions on how to save and/or print a copy of the document.

A PIS must comply with all of the instructions below and contain all of the following details:

1. La Trobe University School/Department/Centre letterhead should appear at the top of the page. When the research is conducted through an external agency, it may also be appropriate for the agency's logo to be used or letterhead to be included.

2. The title of the project written in block letters.

3. Names, affiliations and convenient contact details of all researchers (University staff and students as well as external investigators). For reasons of individual safety, the inclusion of personal telephone numbers on PIS and Consent Forms are not recommended. 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, for example, "In order to participate you must be aged 18 years or older.

5. If applicable, a declaration of any personal, professional or institutional conflicts of interest by the researcher or their institution or the name(s) of commercial companies that have provided funding or sponsorship for the project.

6. A description of the research procedures including the anticipated time commitment expected of the participant, the information you will be obtaining, how that information will be collected, and a description of 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, such as pregnant women, asthmatics, children under a particular age, etc.

8. A statement which details the use of the data. This must be explained in sufficient detail so that a participant is able to give informed consent about the actual use of their 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, for example, 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, such as hard copy and/or electronic, the data will be maintained and 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 postal surveys, a statement explaining any follow-up procedures, such as reminders to complete questionnaires, use of coded envelopes or 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 from the research. This is particularly important where participants are in a dependent relationship with the researchers or their professional associates who are providing continuing treatment or care to the participant 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, it is recommended to not provide personal telephone numbers or phone numbers of administrative staff who are not involved with the project.

14. A separate statement advising the method of complaint/concerns must be included. You are advised to copy and paste the following statement:

If you have any complaints or concerns about your participation in the study that the researcher has not been able to answer to your satisfaction, you may contact the Senior Human Ethics Officer, Ethics and Integrity, Research Office, La Trobe University, Victoria, 3086 (P: 03 9479 1443, E: humanethics@latrobe.edu.au) . Please quote the application reference number _____.

15. A withdrawal of consent declaration, explaining that the participant is free to withdraw consent and discontinue participation in the research at any point during their immediate involvement in the research and following their involvement in the research. In certain 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 this.

    When focus groups are conducted, it is important to explain that it may not be possible to withdraw an individual's data from that collected from the focus group session, depending on how the data is captured.

    When anonymous surveys are conducted, it is important to explain that it will not be possible to withdraw an individual's data from that collected.

    Following a participant's involvement in the research, a written withdrawal of consent form and request to remove a participant's data should be provided. Researchers must retain evidence of all submitted requests for withdrawal of consent and removal of a participant's data. Consent forms may include a time limit on a request for the withdrawal of data as long as the time limit specified is not less than four weeks following the completion of data collection. An example of the suggested wording for withdrawal follows:

    > *"You have the right to withdraw from active participation in this project at any time. You may also request 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 researcher by email 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. When the research is conducted through an external agency, it may also be appropriate for the agency's logo to be used or letterhead to be included.

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, and can withdraw my data 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 to occur, usually by providing a 'yes'/'no' tick box option.

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.

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