ETHICS, INTEGRITY & BIOSAFETY
RESEARCH OFFICE

Guide to Creating a Participant Information & Consent Form

All research projects that involve people and sometimes their data, require a detailed statement, written in plain language, that meets the information needs of potential participants.

The purpose of the Participant Information and Consent Form (PICF) is to explain the research project, identify what will be asked of research participants, and outline the risks and safeguards that are in place so that true voluntary and informed consent for participation can be obtained.

The form should be succinct (2-3 pages), written in language that is 'in tune' with participants and provide enough detail to enable them to make an informed decision about whether they want to contribute to the research or not.

The material below provides a guide only. It outlines what is required, however, researchers should tailor or add information to suit their project. Where the research is being conducted in partnership with another agency, the guidelines of that agency relating to participant information should be combined with these guidelines.

A single PICF is usually enough for most projects. However, more complex projects may involve groups of participants, for example, school students and teachers, service providers and clients, where differing inputs are sought. In such circumstances, more than one PICF may be needed. If several types of data are collected from the same group of participants, then only one PICF is required; it just needs to mention all the modes (e.g. interview, observation, survey).

The PICF should be on LETTERHEAD and appropriately branded. The full contact details of the researcher and La Trobe University should appear clearly as a header or footer and in the text, towards the end.

The Participant Information Sheet:

Elements of the Participant Information Sheet:

- **Header:** Participant Information & Consent Form: inserted at the top left of the page with the words 'This is yours to keep.'
- **Project title**: The formal title of the research should appear prominently, centred at the top of the page in large bold type. An additional participant-friendly and welcoming subtitle can be added that appears larger and brighter (if colour is used) to engage participants.
- **Personnel**: Add the full details of the Principal Investigator including professional title, name, academic qualification, and School / Department / Centre. If there are co-investigators actively involved in participant engagement, include the same details for each of the co-investigators. This includes students and HDR candidates listed as student investigators. Include the student's supervisor and any co-supervisors. Often, this is most easily presented as a table.
- **Introduction:** The researchers, including students, should introduce themselves, the purpose and justification of the research. Where the project is student research this should be clearly stated, and the nature of the program and degree being sought named.
- **Research aim(s)**: Clearly state the aim or aims of the research in plain language, without scientific jargon or acronyms.
- **Benefits and risks of the project:** Briefly describe the benefits of the research to the participants and/or to the field of research. The benefits should be realistic and reflect the level and complexity of the proposed research. Mention all the possible risks that might be experienced in course of the research and address how they will be minimised, mitigated, or managed throughout the research.
- **General outline of the project**: Provide a brief overview of the research methods, indicate from whom the data will be collected; explain how the data will be collected, analysed, and presented, and if / how the results will be shared with participants and the community.
- **Inclusion and exclusion criteria**: Mention why they have been asked to participate in the research and detail the reasons that would exclude potential participants if relevant.
- **Participant involvement**: Describe what the participants will be asked to do, for example, complete a survey questionnaire, undertake an interview, participate in a focus group and/or permit access to personal records.
- **Time commitment**: The place of data collection, the number of occasions that participants will be required, and the approximate time commitment involved needs to be indicated clearly.
- **Confidentiality**: Indicate who will have access to the data provided by the participants e.g. members of

the research team, transcriber, research supervisor.

- **Anonymity**: Indicate whether the anonymity of the participants is to be preserved, and if so, how this will be done in dissertations, publications, reports, presentations or teaching as is relevant.
- **Voluntary engagement and right to withdraw**: Be sure to include a strong recognition of the voluntary nature of the project and a clear statement that participants are free decline to answer a question or to withdraw at any time without explanation or penalty.
- **Financial Matters**: You must provide a statement on who is funding the research (where there is funding) and provide information on any participant remuneration. Where relevant, identify what this is, how it will be provided and repeat the information in the consent form. Information on payments to participants is available from the NHMRC Payments of Participants in Research.
- **Data Management**: Data management should be addressed on several levels:
    - Identify how the data will be recorded as it is collected. Indicate where the data will be stored and how security of personal information will be maintained during collection, analysis and writing up of results. This should be succinct but enough detail for participants to understand.
    - If data are recorded by note taking or by video/tape recorder and then transcribed for analysis, indicate what will happen to a participant's data should that participant decide to withdraw from the project.
    - Participants should also be informed where the data will be stored once the project is complete. Normally this will be at the host institution that accepts responsibility for the research for a period of five years. Different locations and longer periods may apply if the research is conducted with other agencies. Identify what will happen to the data at the end of the storage period.
- **Human research ethics clearance**: Include a statement that the project has been approved by the La Trobe University Human Research Ethics Committee / La Trobe University Low-risk Ethics Advisory Panel including the relevant HREC number. If the project has gained approval from another ethics committee, include a statement to that effect that identifies the relevant body.
- **For more information about the research**: Requests for further information or queries about the research should be directed to the Principal Investigator. Provide name and contact details.
- **Concerns and complaints:** The following statement is required:
    - If you have any questions or concerns regarding the research or a member of the research team, you are invited to contact the Senior Manager, Ethics, Integrity & Biosafety on (03) 9479 1443, or by email, eib@latrobe.edu.au or you may complete the La Trobe University Ethics Complaint Form.

The Informed Consent Form

The guiding principle for consent is that any agreement to participate is voluntary and based on information that is sufficient, clear, and unambiguous and provided in the PICF for Participants.

The Informed Consent Form provides evidence of an agreement between the researcher and the participant on the conditions, rights, and obligations of both parties to conduct the research according to the project plan approved by the human research ethics committee.

Substantiation of informed consent can take several forms. It is most often given by signing a consent form but under certain circumstances, consent may be given verbally. Consent may also be given implicitly, for example by completion of a survey.

The Informed Consent form should reflect accurately each proposed intervention for which participant permission is sought, e.g., the proposed level of confidentiality, the right to say no or to withdraw without explanation. Any payment or that no payment will be provided should be made clear.

When permission to take photographs or record videos is sought or when seeking to use the data for future research, a 'tick all that apply' or Yes/No option may be helpful, as it enables participation while respecting individual preferences i.e. participants can opt out of photographs but still be interviewed.

Further essential information includes the research institution, research title and name of the researcher(s), including any additional partners or agencies involved, as well as a statement of acknowledgement by participants that they have read the participant information sheet, and understand the nature of their involvement and have had an opportunity to ask questions.

For more information, please refer to National Statement Chapter 2.2.

Templates available:

La Trobe University

- Health/Social Science Research
  - PICF
  - PIS (Online/verbal)

NHMRC Templates:

- Genetic studies:
  - PICF Genetic for Self
  - PICF Genetic for Parent and Guardian
  - PICF Genetic for Person Responsible
- Interventional study
  - PICF Interventional for Self
  - PICF Interventional for Parent and Guardian
  - PICF Interventional for Person Responsible
- Non-Interventional study
  - PICF Non-Interventional for Self
  - PICF Non-Interventional for Parent and Guardian
  - PICF Non-Interventional for Person Responsible
- Health/Social Science Research
  - PICF Health and Social Science for Self
  - PICF Health and Social Science for Parent and Guardian
  - PICF Health and Social Science for Person Responsible