THE UNIVERSITY OF NOTRE DAME AUSTRALIA

Guideline:

Participant Information Sheet and Consent Form for Research Involving Human Participants

Effective: 21 March 2019

Audience: Staff and Students

Policy Category: Academic
Policy Sub-category: Research

Key words:	Participant Information Sheet, Consent Form, Research, Human Participants
Guideline Owner:	Pro Vice Chancellor, Research
Responsible Officer:	Director, Research Office
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1 PURPOSE

1.1 This Guideline sets out the requirements for information to be included in the University's Participant Information Sheet and the Consent Form used for research projects in accordance with the *National Statement on Ethical Conduct in Human Research,* (2007, updated 2018) ('**National Statement**').

1.2 According to the National Statement, respect for human beings involves giving due scope to people's capacity to make their own decisions. In the research context, this normally requires that participation be the result of a choice made by participants, commonly known as 'the requirement for consent'. This requirement has the following conditions: consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.

1.2.1 The Participant Information Sheet ('**PIS**') is the explanatory information provided to potential research project participants.

1.2.2 The Consent Form ('**CF**') is a document that research participants sign to indicate informed consent for research project participation.

1.2.3 Notre Dame templates for PISs and CFs are available to use and are located on the Human Research Ethics Committee ('**HREC**') webpage. It is recommended that these be used for Notre Dame Research projects. (https://www.notredame.edu.au/research/research-at-notre-dame/ethics-and-integrity/hre/application-forms).

2 RELATED DOCUMENTS

This Guideline should be read in conjunction with the following:

2.1 *National Statement on Ethical Conduct in Human Research* (2007, updated 2018)

2.2 *Australian Code for the Responsible Conduct of Research* (2018)

2.3 *Policy: Ethics Approval for Research Involving Human Participants*

2.4 *Policy: Conduct of Conduct: Research*

2.5 *Procedure: Applying for Ethics Approval (Full Ethics Review)*

2.6 *Procedure: Applying for Ethics Approval (Low Risk Review)*

3 PARTICIPANT INFORMATION SHEET

3.1 The following should be included in the Participant Information Sheet:

3.1.1 The University of Notre Dame Australia logo or letterhead.

3.1.2 Information written in plain, 'everyday' language at the comprehension level of the target participation group.

3.1.3 A short project title and brief explanation of the research aims.

3.1.4 Names, contact details and school affiliation for all researchers involved (Notre Dame email addresses should be used only for Notre Dame researchers).

3.1.5 Study level/ degree if it is a student research project. An explanation of what each participant is expected to do and an estimate of the time commitment involved.

3.1.6 An acknowledgement of any audio-recording, video-recording or photographs and how this material will be used.

3.1.7 Objective description of any risks involved in participating and the procedures/plans in place to minimise and manage these.

3.1.8 An explanation for any payment, reimbursement or incentives to participants.

3.1.9 An explanation of any costs to participants.

3.1.10 A statement regarding expected benefits to participants and/or the wider community.

3.1.11 An explanation of arrangements for the protection of confidentiality of data and who will have access to the data.

3.1.12 A statement that confidentiality of information provided is subject to legal limitations (that is, it is possible for data to be subject to subpoena, freedom of information request or legal reporting obligations).

3.1.13 A clear statement that if participants are in a dependent or unequal relationship with any of the researchers, involvement in the project will not affect ongoing assessment, grades, management, or treatment of health.

3.1.14 A clear statement that participation in the project is voluntary and that participants are free to withdraw consent at any time, and to withdraw any unprocessed data previously supplied (explain any limitations to data withdrawal).

3.1.15 A clear plan for data management when the research project is completed.

3.1.16 Any plans to make the data available (in non-identifiable form) to other researchers for future research.

3.1.17 Plans for dissemination of research outcomes, including publication.

3.1.18 An acknowledgement of any sources of funding for the research.

3.1.19 An acknowledgement of any potential or perceived conflict of interest of researchers, sponsors or institutions.

3.1.20 State that the project has received ethical clearance by the University HREC and approval reference number.

3.1.21 An explanation for how feedback on the research outcomes will be provided to participants.

3.1.22 A footnote explaining complaints procedures as follows:

If participants have any complaint regarding the manner in which a research project is conducted, it should be directed to the Executive Officer of the Human Research Ethics Committee, Research Office, The University of Notre Dame Australia, PO Box 1225 Fremantle WA 6959, phone (08) 9433 0943, research@nd.edu.au.

3.2 University templates for Participant Information Sheets are available for use and can be found at the following link: https://www.notredame.edu.au/research/research-at-notre-

dame/ethics-and-integrity/hre/application-forms.

4 CONSENT FORM

4.1 The following should be included in the Consent Form:

4.1.1 The University of Notre Dame Australia logo or letterhead.

4.1.2 Information written in plain, "everyday" language at the comprehension level of the target participant group.

4.1.3 A short project title.

4.1.4 A statement that the participant consents to participating in the research project.

4.1.5 A statement acknowledging that the participant has read and understood the PIS relating to the research project.

4.1.6 A statement that involvement in the project is voluntary and that participants are free to withdraw at any time and free to withdraw any unprocessed identifiable data previously supplied (except for any limitations to data withdrawal).

4.1.7 Outline particular requirements of participation (e.g. whether interviews are to be audio and/or video-taped).

4.1.8 A statement that confidentiality of information provided is subject to legal limitations (i.e. it is possible for data to be subject to subpoena, freedom of information request or legal reporting obligations).

4.1.9 A statement that research outcomes will be published but that no identifying information will be disclosed.

4.1.10 Any plans to make the data available (in non-identifiable form) to other researchers for future research.

4.1.11 Be retained by the researcher (once signed and returned).

4.1.12 Space for name, signature and date for participant.

4.1.13 Space for name, signature and date for researcher.

4.2 UNDA templates for Consent Forms are available for use and can be found at the following link: https://www.notredame.edu.au/research/research-at-notre-dame/ethics-and-integrity/hre/application-forms

4.3 **Please note:** when a research project is conducted at another institution (such as a hospital), that institution may have additional requirements for PIS and CFs that are not listed in this Guideline.

Version	Date of approval	Approved by	Amendment
1	August 2005	Vice Chancellor	Effective date – new Guideline.
2	August 2006	PVC, Research	
3	December 2006	PVC, Research	
4	July 2010	PVC, Research	
5	September 2017	Vice Chancellor	
6	September 2018	PVC, Research	Updated nomenclature and weblinks, revised guideline format.
7	21 March 2019		Updated to new template.