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| **Human Research Ethics Committee****Information Statements and Consent Forms** |

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| **When are Information Statements and Consent Forms needed?** |

Whenever the consent of individuals or communities is required, potential participants must be given a written **plain language Information Statement**. This must be at their level of comprehension, and provide information about the purpose, methods, demands, risks, inconveniences, discomforts, and possible outcomes of the research, including the likelihood and form of publication of research results (see Chapter 2.2 of the [*National Statement on Ethical Conduct in Human Research*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__244)).

Information Statements can take different forms, depending on the nature of the research and the method used to initially approach potential participants. For example, a generic statement, a personalised letter, or a detachable cover page on a survey. Whatever is used, the Information Statement must provide the details above.

A Consent Form is usually also required, especially when a participant is identifiable from the information they provide to the researchers. An obvious exception is a survey in which participants can remain anonymous.

The Information Statement and Consent Form are extremely important documents as they constitute an Agreement and provide evidence of informed consent. For example, legally, research involving medical procedures must not be undertaken without the consent of those involved, or without other lawful justification.

**Participants must be given copies of the Information Statement to retain.**

**Quick tips:**

 - Keep language simple, do not use jargon. Write it at the language level of the potential participants. A good rule of thumb for general community population is to use a level of language that does not exceed a Year 8 comprehension. Explain specialised terms for lay people.

 - Information Statements and/or Consent Forms for children must be as brief as the detail will allow and the language appropriate for their age.

 - Use small paragraphs and dot points, rather than large blocks of text.

 - Use a font size which is appropriate for the readers, *eg* larger for those who may have impaired sight.

 - Emphasise important information.

 - Use section headings as shown in the examples.

 - Have a colleague, friend or family member, who is not familiar with the focus of your research, read a draft of the Information Statement and Consent Form. If they are unclear what the research is about and what is asked of participants, the HREC is also likely to find the documents inadequate.

 - Grammatical or typographical errors, or unprofessional presentation of documents, make reviewing applications more difficult and reflect poorly on the researcher and the University. They can reduce clarity of Information Statements and Consent Forms and even prevent an informed decision regarding participation. Check and proofread all documents carefully. If necessary, seek assistance from people who have the skills to advise you.

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| **Content of Information Statement**  |

The document should be no longer than necessary, however provide sufficient information for the reader to make an informed decision. Don’t include unnecessary detail. Its length will depend on the complexity of the research project. If a document is complex due to the nature of the research, consider the inclusion of an executive summary at the beginning of the document so the key points required to facilitate basic informed consent are easily accessed.

Refer to the template documents available on our [web site](https://www.newcastle.edu.au/research-and-innovation/resources/human-ethics/application-procedures/forms-and-guidelines) for the essential detail. **Failure to include essential points will result in the Information Statement having to be revised and resubmitted.** This is the single most common reason for ethics approval being delayed or deferred.

**Note:**  If you require approval from more than one HREC or authority then the Information Statement needs to take account of the requirements of all HRECs or authorities involved. For example, for research to be conducted in NSW government schools and TAFE, the NSW Department of Education and Training (DET) requires specific statements to be included in the Information Statement. The Information Statement that is submitted to the NSW DET must be the same version as that submitted to and/or approved by the University's HREC.  Therefore, it will be necessary to draft a document that incorporates the guidelines of both the NSW DET and the University's HREC.

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| **Information Statements - Special Cases** |

**⬩ Compromised capacity to give consent**

 In some cases additional strategies will be required to ensure informed consent.

 **Consent of caregiver / guardian**

Appropriate consent from a ‘person responsible’ may be required if the participant’s capacity to assess the risks, including loss of privacy, may be impaired.

A 'person responsible' is one of the following (in hierarchical order) and is not necessarily the next of kin:

* an appointed guardian (including an enduring guardian); **or**, if there is no guardian:
* the most recent spouse or de facto spouse where there is a close relationship; **or**, if there is no spouse or de facto spouse:
* the unpaid carer or the carer at the time the person entered residential care (note: recipients of a government carer benefit are not considered to be paid); **or**, if there is no carer:
* a relative or friend who has a close personal relationship with the person.

A ‘person responsible’ cannot consent to special or experimental medical procedures, or consent to treatment if the patient objects. *(Source:* [*Office of the Public Guardian*](https://www.publicguardian.justice.nsw.gov.au/)*)*

 **Unable to give written consent**

 Potential participants may be competent to give consent but unable to sign a consent form, eg due to a temporary or permanent physical disability. In such cases the researcher could audio record the wording of a consent form and then record the participant’s verbal consent.

 Alternatively someone close to the potential participant could sign a consent form on their behalf at their direction. The Consent Form should include the statement “*In signing this form at the direction of ……… I confirm that he/she has read, or had read to them, the contents of the Information Statement and Consent Form and has made an informed choice to participate.”*  This strategy could be used where the potential participant is unable to read the documents.

 These are just examples of situations where the normal consent procedures would not be appropriate. It is up to the researcher to be aware of such constraints and to propose appropriate alternatives to the HREC.

**⬩ Telephone Interviewing**

 The usual minimum requirement is to provide the target population with a written Information Statement which forewarns them of any telephone contact. Include the normal content for an Information Statement and address the following:

* How names, addresses and telephone numbers of the target population were obtained.
* The desired interviewee and why that person.
* Details of the nature of the questions to be asked.
* When the interview will take place and its expected duration.
* How recipients (the target population) may decline the invitation or prevent telephone contact, eg simply advise the caller that they are not interested, or be given a contact number to call to register a do-not-call instruction.

⬩ Internet and On-Line Surveys

 If your research proposal involves a survey to be distributed via the internet or completed on-line, it must still have an Information Statement which meets the requirements as set out above (*Content of Information Statement*). It can be presented on-line with the survey provided visitors to the site see it before the survey and, if they choose not to participate, easily and anonymously exit.

 Give careful thought to assurances of anonymity. Participants must know what information about them will be transmitted with the completed survey. For example, will any encryption devices be used? If participants are returning surveys via email they will be identifiable by their email address. A possible assurance is that the email address will be separated from the survey as soon as it is received.

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| **Content of Consent Form** |

The Consent Form is much shorter than the Information Statement, usually no more than one page, and restates the key points from the Information Statement.

Please refer to the template documents available on the [web site](file:///C%3A%5CUsers%5Cmjm326%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5CAXVHAEWZ%5Ca2%20Information%20Statements%20Consent%20forms%20-%202020).