Informed consent is required by all research participants. This means that 'a person’s decision to participate in research must be voluntary; based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it' (Section 2.2.1, National Statement on Ethical Conduct in Human Research, 2007, p19). The most common way to get informed consent is to provide a Plain Language Statement.

The Plain Language Statement must be written in plain, simple language for your particular research project. It should be suitable for the potential participants; at their comprehension level in language appropriate to them. If children are the participants the statement should be in language they understand, as well as a statement suitable for their parents/guardian.

It must provide information about the purpose, methods, demands, risks and potential benefits of the research. It should not be long but must provide sufficient information for the potential participant to make an informed decision.

Plain Language statements can take different forms depending on the nature of the research, usually they are written. Select a communication method that helps participants make good choices about their participation, and the method used to approach potential participants.

If written, the Plain Language Statement must be a separate document from the Consent Form so that the participant can retain a copy. They are important as they constitute an Agreement and together, provide evidence of informed consent.

Failure to include essential points will result in the Plain Language Statement having to be revised and resubmitted. This is a common reason for ethics approval being delayed or deferred.

Plain Language Statement Checklist

The Plain Language Statement must include the following:

1. Clear identification of the Institute, the Faculty/Department or Unit involved (or Faculties/Departments or Units involved). The Plain Language Statement must be printed on Holmesglen letterhead. The letterhead does not necessarily need to be in colour – it can be photocopied or printed. If you are conducting multi-site research, you can use more than one logo on the Plain Language Statement.

2. Project title

3. The name of the principle investigator and other investigators with their contact details (including a direct telephone number).

4. If the investigation is a student research project, the name and contact details of the supervisor(s) and identification of the investigator as a student(s) and the degree for which the research is being undertaken.

5. A brief statement, in lay terms, of the aim of the project, its methodology and procedures (eg surveys, interviews, video-taping, audio-taping, taking of photographs, publishing of participants names).

6. Full disclosure of what is required and expected of the research participant, including the anticipated time requirement of the research participant.
7. A detailed explanation and full disclosure of any possible risks, discomfort, inconvenience or side effects resulting from the research procedures (and plans to minimise or avoid them). This should include, where relevant, details of:
   - arrangements for debriefing or follow-up where this is necessary to secure the well-being of the participant
   - counselling/treatment available for research participants who risk suffering emotional/physical injury as a result of the project.

8. Details of any payments to participants (see sections 2.2.10 and 2.2.11 of the 2007 National Statement on Ethical Conduct in Human Research for what is ethically acceptable in terms of payment).

9. A clear indication that participation is voluntary, and a statement that consent, participation and previously supplied data may be withdrawn at any time until data is processed. If consequences may arise from the withdrawal, advice must be given to participants about these before consent to involvement in research is obtained.

10. If focus group participation is to occur the researcher should include advice detailing the staged withdrawal process.

11. If there is a dependency relationship between the research participant and the investigator, the Plain Language statement should state that non-participation or withdrawal will not result in any penalty or discriminatory treatment. Similarly, if provision of services, benefits, medical treatment, education or other care is involved, a statement that involvement or non-involvement in the project will not affect ongoing management, treatment, assessment/results or employment situation should be included.

12. Details and an explanation of the anticipated use of the data (eg assignment, thesis, publication) and whether copies of reports will be given to participants.

13. An explanation of how the confidentiality of the participants will be protected, including procedures adopted to ensure confidentiality of data and any limits to confidentiality (subject to legal requirements, mandatory reporting requirements, duty of care to third party etc). As it is not possible to make an absolute guarantee of confidentiality/anonymity, the Plain Language Statement should simply describe what steps are being taken to protect this.

14. Information about how the data will be used and, where necessary, the steps to be taken to ensure participants will not be identified.

15. If you want to have the option to use the data for purposes outside the current research, or for the data to be available to other researchers, you must obtain explicit permission by describing what you want the participants to agree to, and asking for permission on the consent form (refer to section 2.2.14 – 2.2.18 of the 2007 National Statement on Ethical Conduct in Human Research for further information about consent for future use of data in research).

16. An explanation of when you will destroy the data, or a statement informing participants about the purposes of keeping the data, such as a longitudinal study where you may need to re-contact them.

17. Identification of funding bodies and sponsors of the research and any other relevant declarations of interest.

18. A question seeking the participant’s agreement to participate in the research, including details of who to contact if they have any questions or require any further explanation, instructions on how to confirm their agreement to participate and, if applicable, what will happen next.

   Parent/Guardian consent (if applicable):
   A statement that prior to consent being given by Parent/Guardian on behalf of a child or young person under 18 years of ages, the project is discussed with them prior to making a decision. Where a parent/guardian consents to their child/young person participating, the final decision to participate will rest with the child/young person.

19. You must insert the Holmesglen Ethics Review Panel (HERP) Complaints Clause on EVERY explanatory statement (the Complaints Clause is included at the end of this requirements sheet).

   Note: Please replace the HERP contact details with the details of that person. This person should be fluent in English and not associated with the research. Please include this person’s written approval agreeing to take on this role with the ethics approval application documentation.
Plain Language Statement – special cases

- Internet or On-line surveys
  
  If your research proposal involves a survey to be distributed via the internet or completed online, it must still have a Plain Language Statement which meets the stated requirements. It can be presented online with the survey, provided visitors to the site see it before the survey. If they choose not to participate; they can easily and anonymously exit.

  Careful consideration needs to be given to assurances of anonymity. It must be made clear to participants what information about them will be transmitted with the completed survey. For example, will encryption devices be used? If participants return 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.

- Telephone interviewing
  
  The usual minimum requirement is to provide the target population with a written Plain Language Statement which forewarns them of any telephone contact. This should include the normal content for a Plain Language Statement and specifically address the following:
  
  - How the 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 the target population may decline the invitation or prevent telephone contact (eg advise the caller that they are not interested, or be given a contact number to call to register a ‘do-not-call’ instruction, or provide a refusal form which can be returned to the researcher).

  If for some reason it is not possible to pre-send a written Plain Language Statement, the investigator must clearly inform research participants of the details which would normally be included in the information sheet outlined above. The phone call would need to be recorded to prove that this had happened.

- Compromised capacity to give consent
  
  In some cases, additional strategies will be required to ensure informed consent. Refer to Chapters 4.2, 4.4 and 4.5 of the 2007 National Statement on Ethical Conduct in Human Research for further information and implications

  Consent of caregiver/guardian

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

  Unable to give written consent

  Potential participants may be competent to give consent but unable to sign a consent form. It is up to the researcher to be aware of such constraints and to propose appropriate alternatives to the Ethics Review Panel.
Note:
The Plain Language Statement should be written in a personal style, and in simple non-technical terms. It is not necessary to provide every detail of the procedures; rather, it should be an incisive summary of the essential points which any reasonable person would wish to know before agreeing to participate.

Format and layout tips:

- Keep language simple, do not use jargon. Write it at the language level of the potential participants. Use shorter words. Break up long sentences into two or three shorter sentences. Explain technical terms for lay people.
- Use section headings as shown in the examples. Organise your content with your participant’s needs in mind.
- Use small paragraphs and dot points, rather than large blocks of text.
- Use a font size which is appropriate for the readers, e.g., larger for those who may have impaired sight.
- Emphasise important information.
- Limit the use of italics and ALL CAPITALS. Align to the left rather than justify.
- Plain Language Statements and/or Consent Forms for children must be as brief as the detail will allow and the language appropriate for their age.
- Double-check names and contact information.
- Ask someone who is unfamiliar with the project to read a draft of the Plain Language Statement and Consent Form. If they are unclear what the research is about and what is asked of participants, the HERP 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 Institute. They can reduce clarity of Plain Language 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.

Avoid

- Coercive language, or wording that suggests that the ‘future of the universe’ depends on their participation.
- Promises you cannot keep, like promising confidentiality. Rather specify how the data will be handled, how the subject’s identity will be protected, how the data will be stored and for how long.
- Use of a personal phone number. The HERP does not approve researchers disclosing their home phone numbers for contact purposes on the Plain Language Statement. This is to protect the researcher’s privacy. A Departmental/Faculty phone number and Holmesglen email address should be used, or a mobile phone number.

Be alerted to

- Translation of the Plain Language Statement: This must be provided where the participant(s) may not speak English. It is the responsibility of the principle investigator/researcher to ensure that all foreign language documents (e.g., Plain Language statements, consent forms) are accurately translated copies prior to final approval and to provide a copy to the Higher Education Support Unit to be placed on file. Should an issue arise due to inaccurate or inappropriate translation of foreign language documents, the principle investigator/researcher will be accountable.
- Sensitive and contentious research: Put a sentence in the Plain Language Statement that is apparent and upfront, ‘Distress, due to recent life events may occur (unawares to the researcher) and if so, please discontinue reading about the following research’.
Holmesglen Ethics Review Panel (HERP) Complaints Clause

For Minimal Risk Review Applications:
This project has been approved by Holmesglen’s Ethics Review Panel, HERP Approval No. <insert the HERP approval number which will be identified in the written acknowledgement of your application>. If you have any concerns about your rights as a participant in this research, or you have any complaints or reservations about the ethical conduct of this project, it may be given to the project researcher or, if an independent person is preferred, to the Ethics Review Panel Executive Officer. You may contact the Review Panel through the Executive Officer:

The Executive Officer
Ethics Review Panel
c/- Higher Education Support Unit
Holmesglen
Batesford Road
Chadstone VIC 3148
Tel.: +61 3 9564 1886
Email: EthicsReviewPanel@holmesglen.edu.au

Any issues you raise will be treated in confidence and investigated fully and you will be informed in writing of the outcome.

For Greater than Minimal Risk Review Applications:
This project has been approved on behalf of the Holmesglen Ethics Review Panel by <Insert name of partnership institution and name of Ethics Committee>, with <insert partnership Institution Ethics Committee acronym and approval number> and HERP Approval No. <insert the HERP approval number which will be identified in the written acknowledgement of your application>. If you have any concerns about your rights as a participant in this research, or you have any complaints or reservations about the ethical conduct of this project, it may be given to the project researcher or, if an independent person is preferred, to the Ethics Review Panel Executive Officer. You may contact the Review Panel through the Executive Officer:

The Executive Officer
Ethics Review Panel
c/- Higher Education Support Unit
Holmesglen
Batesford Road
Chadstone VIC 3148
Tel.: +61 3 9564 2630
Email: EthicsReviewPanel@holmesglen.edu.au

Any issues you raise will be treated in confidence and investigated fully and you will be informed in writing of the outcome.

Compiled from:
- the National Statement on Ethical Conduct in Human Research, 2007
- the information statement guidelines and examples of Curtin University, Charles Sturt University, Monash University, University of Melbourne and the University of Newcastle.