

Checklist for Participant Information Sheets & Consent Forms (PICFs)

The National Health and Medical Research Council (NHMRC) provide researchers with PICF templates. It is not compulsory to use these templates however they are useful tools and accepted by Human Research Ethics Committees (HRECs).

The National Health & Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research, 2007 advises “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 [in research] 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”.

The researcher/investigator is responsible for providing the participant, at his/her level of comprehension (generally no greater than English at the comprehension level of a 12-year-old person), with information about the research, purpose and background, why they have been chosen, risks and benefits.

Considerations:

- Consider the timeframe between providing the patient with the Participant Information and Consent Form and signature confirming consent – establish a timeframe and include this in your Project Plan.
- This checklist outlines the minimal information required for a Participant Information and Consent Form, depending on your study further detail may be necessary. Please review this website <https://www.nhmrc.gov.au/book/chapter-2-2-general-requirements-consent>
- Consult with the HREC you intend to submit your project to for ethics approval to understand their requirements.
- For PICF templates please visit the NHMRC website: <https://www.nhmrc.gov.au/health-ethics/national-approach-single-ethical-review/standardised-participant-information-and>

Participant Information & Consent Form Checklist	Yes	No	N/A
TITLE Project Title (if this is long you may like to consider recommending an additional shorter title)			
CONTACT INFORMATION Include the Investigator(s) Name/s, Qualifications and Contact details: <ul style="list-style-type: none"> • Patient Information Sheet • Consent Form • Revocation (Withdrawal) of Consent Form 			
PURPOSE Is this project being conducted as part of a higher degree? If so, this must be included immediately below the contact information for the Investigator.			
STUDY DETAILS An explanation in plain language inviting participation in a research study including: <ul style="list-style-type: none"> • Study Purpose • Background • Procedures involved in participation of the study • Expected duration of the study • What will happen to the information gathered, the samples/tissue collected? • Acronyms should be described in detail the first time they are used. • "Australian" spelling is preferred in the Participant Information Sheet, e.g. organisation not organization. 			
RISKS Description of possible risks to the participant that might arise during and/or after the study. Including: <ul style="list-style-type: none"> • The likelihood that a harm (or discomfort or inconvenience) will occur; and • The severity of the harm, including its consequences. 			
BENEFIT A description of the benefit to the participant or to others that may result from the research or a statement that there will not be any direct benefits from conducting the research.			
DATA CONFIDENTIALITY Description of the specific steps being taken to protect confidentiality of the data or personal records that identify the participant; explain that the research may include access to medical records; explain if tissue or genetic samples are taken and that they will only be used for the current study, unless permission is given for future research that will be ethically approved at that time.			
PARTICIPATION IS VOLUNTARY Reassurance for patients/participants that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without comment or penalty. It is recommended that all clinical trials provide a "Withdrawal/Revocation of Consent Form", to enable participants to notify of withdrawal if they choose to do so by this route. Receipt of a Withdrawal Form is not required from the participant to make their withdrawal valid.			
CONTACTING THE INVESTIGATOR Information about how participants can contact the Principal Investigator about any matter of concern (the contact number(s) of the investigator(s) need to be given here or refer to above). The Hospital switchboard telephone number should not be the only contact number.			
FEEDBACK TO PARTICIPANTS Description regarding how the researcher/investigator(s) will provide feedback to the participants, or their next-of-kin, where this is requested by the participants and is practicable.			

CLINICAL TRIAL INFORMATION (if applicable) Advice to participants so that they clearly understand that they may be randomised (by chance): that one of the consequences may be that they may not, in fact, receive the treatment that is being tested.			
LEGAL OBLIGATIONS In some research studies participants will be asked to disclose information regarding illegal activity – e.g. illicit drug use. In the confidentiality clause in the Information Sheet it is recommended that participants are advised that this information is confidential “except as compellable by law”. An example of this wording follows: The information you give to ... will remain confidential taking into account any legal requirements imposed on ... It is also recommended that this point also be included in the Consent Form.			
EXCLUSION CRITERIA If tests will be conducted to exclude patients who may have HIV or Hepatitis C etc., it should be explained in the Information Sheet that these are notifiable diseases and positive results must be provided to the Health Department. In addition, a separate point should be added to the Consent Form so it clearly states that participants give informed consent for these tests to be carried out.			
CONSENT In research involving adults who are competent and can consent for themselves, a witness signature is not required on the Consent Form although the person who conducted the informed consent discussion (Researcher, Principal Investigator) should sign and date the form. Consent is a requirement for recruitment in any research project. For more detail: https://www.nhmrc.gov.au/book/chapter-2-2-general-requirements-consent			
REVOCATION OF CONSENT It is recommended that all clinical trials provide “Withdrawal of Consent Form”. Please provide a Withdrawal of Consent Form, to enable participants to notify of withdrawal if they choose to do so by this route. Please note that receipt of a Withdrawal Form is not required from the participant to make their withdrawal valid. I no longer wish to participate in the research study named above. I understand that the medical information I have already supplied may still be reviewed but that no new information can be reviewed. For more detail: https://www.nhmrc.gov.au/book/chapter-2-2-general-requirements-consent			
HREC CONTACT DETAILS “This study has been reviewed and approved by the Committee Hospital Human Research Ethics Committee. Should you wish to discuss the study in relation to your rights as a participant, or should you wish to make an independent complaint, you may contact the Coordinator or Chairperson, Human Research Ethics Committee, or telephone / email: <i>Example -</i> HREC Chair Mackay Hospital and Health Service PO Box 5580, Mackay MC QLD 4740 Phone: 07 4885 6000 Email: MKY-RGO@health.qld.gov.au			