

Guidelines for Preparation of the Participant Information and Consent Form

The Human Research Ethics Committee will pay particular attention to the PI&CF

- The Participant Information and Consent Form is to be an **integrated document** with sequential **page numbering**, it must have a **version number** and **date** on each page
- If the project contains any **genetic testing** the Austin Health Genetics Check List 3 must be attached as the final page of the integrated document
- It is a **different** and **separate** document from the Lay Summary (*Question 1.3*) and it is not sufficient to just copy or 'paste' from one document to the other
- It should provide an accurate description of the nature of the study and any potential risks, discomforts or inconveniences that may be encountered by the participant
- It must be **consistent** with information provided in the Protocol
- It should be expressed in **plain language**, in the **second person**
- The preferred font is **Arial 12 point**
- It is preferably that participants initial each page of this document during the consent process to indicate they have read and understood the requirements of the study.

You MUST use one of the ATTACHED templates

PICF template for Clinical Drug Trial or Device Trial

http://www.health.vic.gov.au/ethics/downloads/picf_drug.doc

PICF template for Clinical Non-drug/device trial

http://www.health.vic.gov.au/ethics/downloads/picf_nondrug.doc

PICF template for Health and Science Research -

http://www.health.vic.gov.au/ethics/downloads/picf_health.doc

The Participant Information and Consent Form should include:

- Full project title
- Principal Investigator's name, and title or position
- At the beginning, an invitation to take part in the study (eg: " You are invited to participate in a research project involving..... because.....")
- That it is a research project and that participation is entirely voluntary and can be terminated at any time, for any reason, without prejudice and without giving any reason
- The treatment/s and the use of a placebo with a clear statement that some participants may receive an inactive substance. This should be included on page 1. Do not refer to a placebo as a 'dummy drug'.
- A clear indication if it is a student project and the full name of the degree the student is aiming for
- Encouragement to ask questions
- The nature or purpose of the study including, where appropriate:

- The possibility of random assignment to different treatment groups, and this means by which this is done eg: 'like the tossing of a coin
- All procedures, drugs or radiation including all invasive procedures, venipuncture or exercise tests, together with an assessment of any potential risks, foreseeable side effects and discomforts
- A clear statement as to what in the study is additional to standard treatment / care
- If any usual treatment is being withheld and the implications of this
- A clear statement whether or not males should avoid fatherhood while on a study drug and for any period after the end of the trial
- It is essential that for all blood/tissue samples it is noted whether they are for routine tests (and will be destroyed after testing) or for trial tests. If they are for trial tests, the following must be noted:
 - The limits of testing allowed on the samples, the use to which they can be put and who will oversee the adherence to these conditions.
 - Whether the samples will be identified, coded or de-identified
 - Where (city and country) for how long and by whom (name) storage of samples will occur
 - Final fate of the samples
- What is required of the participant, ie; lifestyle changes, diet, visits to the hospital and the likely time involved, the duration of the study and any out-of-pocket expenses
- A clear indication if audio or videotaping is required, or any questionnaires to be answered
- The precautions that will be taken to ensure the confidentiality of the participant
- A description how any risk of physical and/or psychological stress, therapeutic failure or adverse events in either the short or the long term from participation will be dealt with
- Whether or not travel and parking expenses will be reimbursed and how this will occur e.g. taxi vouchers will be supplied or expenses will be reimbursed on production of a receipt (and state the maximum amount available per visit).
- The amount of any payment, when it will be paid and what amount the pro rata payment will be if they withdraw before completion.
- A description of circumstances under which participation may be terminated - including consideration that will be given to new findings arising during the study period
- A statement that the records dealing with the participant will be kept under safe storage for 15 years after completion (25 years in the case of trials involving children and 7 years in the case of non drug trials) and will then be destroyed, or if retained that no further testing will be performed without a further consent being obtained
- A statement that participant records may be inspected for purposes of data audit by authorised persons and whose authorised persons may be
- That in drug trials, compensation will be available should serious injury occur that is directly related to the study medication
- The name of, and means by which, an appropriate person may be contacted by a participant during the course of the study or in the case of an emergency
- Serious risks arising from involvement in research, such as driving a vehicle after treatment or pregnancy risks or risks to embryo, foetus or breast-feeding infants **should be highlighted in bold**
- The name, and means by which, the Ethics Committee may be contacted by a participant the required wording, **in bold** is:

If you wish to contact someone, independent of the study, about ethical issues or your rights or to make a complaint, you may contact Jill Davis, Manager Research Ethics Unit, Austin Health , Telephone 9496 4034

You may need to use a number of PICFs depending on your target audience.

- Participant
- Parent / Guardian – for use when participants are under the age of 18
- Person Responsible – for use when participants are not competent
- Older Child Under 18
- Carer – participating in a trial in their own right.

Investigators are encouraged also to have a Participant Information and Assent Form for older children to sign, written at a level appropriate for the age of the children being recruited.

Investigators should have a Participant Information Sheet and Consent for Continuation in Research Form in instances where participants are likely to regain capacity and original consent was obtained from the Person Responsible.

Austin Health does not required a Revocation of Consent form since participants are not required to withdraw in writing.