

**GUIDELINES FOR DRAFTING CONSENT FORMS
&
PARTICIPANT / PARENT INFORMATION SHEETS**

Produced by the Mater Research Ethics Coordinator

The *National Health and Medical Research Council National Statement on Ethical Conduct in Research Involving Humans* advises that the informed consent of any participant should be obtained in writing before any research is undertaken. To this end the investigator is responsible for providing the participant, at his/her level of comprehension (13 year old or Grade 8 English), with sufficient information about the purpose, methods, demands, risks, inconveniences and discomforts of the study.

INFORMATION SHEETS & CONSENT FORMS should be **separate documents** and copies of both documents must be given to participants. The **first page of Information Sheets and all Consent Forms should be printed on Mater Hospital letterhead**. To format your document: top margin 3.5 cm, bottom margin 4.0 cm, left and right margins 2 cm, header and footer approximately 5 cm above/below the margin. You will need to test print. It is not necessary to submit your information sheets and consent forms on Mater letterhead but they must be printed on letterhead after approval. Font: Arial Narrow or Arial size 11 or 12.

INFORMATION SHEETS

A typical information sheet should include the following elements:

AT THE TOP OF THE PAGE:

PROJECT TITLE (if this is long and detailed please also provide a lay title):

INVESTIGATOR(S): Name(s)
 Qualifications
 Contact details

Immediately under title and contact details please advise if a research **POSTGRADUATE STUDENT**, as part of a higher degree program, is conducting the project.

- i) A statement **in language readily understandable by the participant (13 year old or Grade 8 English)** that the study involves research; an explanation of the purpose of the research; the expected duration of the participant's involvement; a description of the procedures which are 'experimental', ie., those that will involve the participant personally. The language used in the statement should not be emotive or unduly persuasive. Please **invite participation** in the study.
- ii) A description of **ANY possible material risks** to the participant that might arise during and/or after the study. Material risks constitute those, which a reasonable person in the participant's position, if warned of the risks, would be likely to attach significance to. Alternatively, a risk is material if the researcher is or should reasonably be aware that the particular participant, if warned of the risk, would be likely to attach significance to it. Known risks should be disclosed when an adverse outcome is common, even if the detriment is slight, or when an adverse outcome is severe, even if its occurrence is rare.
- iii) A description of the **benefit to the participant** or to others that may result from the research; or, a statement that there may not be any direct benefits from conducting the research should be included.
- iv) A statement describing the specific steps to be taken to protect **confidentiality** of the data or personal records identifying the participant; that the research may include access of medical records, when appropriate; that tissue or genetic samples are taken, they will only be used for the current protocol, unless permission is given for future de-identified research either confirmatory of, or closed related to, the current protocol.

- v) A statement 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.
- vi) Advice that participants may **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).
- vii) Advice that this study has been approved by the Mater Health Services Human Research Ethics Committee and participants may **contact the Mater Research Ethics Coordinator** on 3163 1585, should they have any complaints about the conduct of the research, or wish to raise any concerns. The Research Ethics Coordinator may contact the Patient Representative or Hospital Ethicist at its discretion.
- viii) A statement that the investigator(s) will provide **feedback to the participants** involved in the study, where this is requested by the participants and is practicable. (This feedback should take the form of a lay summary of the overall outcomes of the research work.)
- ix) For participants in private hospitals - advice that **participants are responsible for all costs in relation to their medical care**; that these may then be recovered from Medicare and/or health fund in the usual way; that there will be no additional costs for participants in the study. (This statement should appear in any protocol being undertaken in a private hospital.)
- x) Advice that the **treatment may affect fertility**; that this will be discussed with participants by their doctor. (This statement should be included in any protocol where drug intervention, particularly cancer trials, will affect a patient's fertility).
- xi) Note, too, that the term **"birth control"** should be used rather than "contraception", and that both female and male participants should be warned of the possible effect of some drugs on pregnancy.
- xii) Advice to the relevant participants so that they clearly understand that **they may be randomised** (*a randomised trial is a study in which the participants are assigned by chance to separate groups to compare different treatments. Neither the researchers nor the participants choose which group the participant is entered into*); that one of the consequences may be that they may not in fact receive the treatment that is being tested (placebo etc).
- xiii) Note that **"Australian" spelling** is preferred in the Participant Information Sheet eg. anaemia not anemia.
- xiv) In some research studies participants will be asked to **disclose information regarding illegal activity** – eg illicit drug use. In the confidentiality clause on 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 .
- xv) Advice that if the tests to be conducted include HIV or Hepatitis A, 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. Details regarding HIV, Hepatitis A testing etc should also be clearly explained in the Information Sheet advising participants that these are notifiable diseases and positive results must be provided to the Health Department.

CONSENT FORM PRO FORMA FOR ADULTS

A consent form should reiterate the **title of the project** and the **qualifications** and **contact details** of the **investigator(s)**.

A declaration of consent should be included which reminds participants of their rights and responsibilities as follows:

I have:

- Read and understood the information package;
- Had any questions or queries answered to my satisfaction;
- Been informed of the possible risks or side effects of the tests or procedures being conducted;
- Understood that the project is for the purpose of research and not for treatment;
- Understood that the project may involve randomisation of participants;
- Been informed that the confidentiality of the information will be maintained and safeguarded;
- Given permission for access to my medical records, for the purpose of this research;
- Given permission for medical practitioners, other health professionals, hospitals or laboratories outside this hospital, to release information concerning my disease and treatment which is needed for this trial and understand that such information will remain confidential;
- Been assured that I am free to withdraw at any time without comment or penalty; and
- Agreed to participate in the project.

Signatures:
Participant Date

.....
Parent/Guardian (if applicable) Date

In the case of a mother under the age of 18 years of age, the consent of the mother's parent/guardian should be obtained unless the Principal Investigator determines otherwise.

.....
Witness Date

.....
Investigator (if applicable) Date

(NB A copy of the signed statement needs to be given to the participant(s))

GUIDELINES FOR DRAFTING ASSENT FORMS
&
CHILD / YOUNG PERSON INFORMATION SHEETS
Produced by the Mater Research Ethics Coordinator

The current National Statement advises:

4.2 RESEARCH INVOLVING CHILDREN AND YOUNG PEOPLE

Research involving children and young people raises particular ethical concerns about:

- their capacity to understand what the research entails, and therefore whether their consent to participate is sufficient for their participation;
- their possible coercion by parents, peers, researchers or others to participate in research; and
- conflicting values and interests of parents and children.

It is not possible to attach fixed ages to each level of assent– they vary from child to child. Moreover, a child or young person may at the one time be at different levels for different research projects, depending on the kind and complexity of the research.

Research merit and integrity

4.2.1 The research and its methods should be appropriate for the children or young people participating in the research.

4.2.2 In the research design researchers should:

- a. specify how they will judge the child's vulnerability and capacity to consent to participation in research;
- b. describe the form of proposed discussions with children about the research and its effects, at their level of comprehension; and
- c. demonstrate that the requirements of this chapter will be satisfied.

Respect

4.2.6 Researchers should be attentive to the developmental level of children and young people when engaging them in understanding the nature and likely outcomes of research, and when judging their capacity to consent to the research.

4.2.7 Except in the circumstances described in paragraphs 4.2.10 and 4.2.11, specific consent to a child's or young person's participation in each research project should be obtained from:

- a. the child or young person whenever he or she has the capacity to make this decision; and
- b. either
 1. one parent, except when, in the opinion of the review body, the risks involved in a child's participation require the consent of both parents; or where applicable
 2. the guardian or other primary care giver, or any organisation or person required by law.

4.2.8 An ethical review body may approve research to which only the young person consents if it is satisfied that he or she is mature enough to understand and consent, and not vulnerable through immaturity in ways that would warrant additional consent from a parent or guardian.

4.2.9 A review body may also approve research to which only the young person consents if it is satisfied that:

- a. he or she is mature enough to understand the relevant information and to give consent, although vulnerable because of relative immaturity in other respects;
- b. the research involves no more than low risk (see paragraph 2.1.6, page 20);
- c. the research aims to benefit the category of children or young people to which this participant belongs; and
- d. either:
 1. the young person is estranged or separated from parents or guardian, and provision is made to protect the young person's safety, security and wellbeing in the conduct of the research (see paragraph 4.2.5). (In this case, although the child's circumstances may mean he or she is at some risk, for example

- because of being homeless, the research itself must still be low risk);
or
2. it would be contrary to the best interests of the young person to seek consent from the parents, and provision is made to protect the young person's safety, security and wellbeing in the conduct of the research (see paragraph 4.2.5).

Best interests of the child

4.2.14 A child or young person's refusal to participate in research should be respected wherever he or she has the capacity to give consent to that same research (see levels of maturity (C) and (D) in the Introduction to this chapter). Where a child or young person lacks this capacity, his or her refusal may be overridden by the parents' judgement as to what is in the child's best interest.

Information and consent forms:

- Points i to xv as appropriate for the age range or design of the study.
- All children/young people from at least 10 years must be provided with age appropriate information regarding the research study. If the age range of participants is from 7 – 17 years eg you will need to prepare up to 3 different information sheets & assent forms. Design the information sheet in the same manner in which you would normally speak with the children/young people (at their level of understanding).
- Information sheets for children younger than 7 years may be at the discretion of the investigator.
- Consent Forms need not be as formal as those provided to parents.

ASSENT FORM PRO FORMA FOR CHILDREN

This pro forma has been designed for children between the ages of 13-17 years.

An assent form should reiterate the **title of the project** and the **qualifications** and **contact details** of the **investigator(s)**.

I have:

- read or have had read to me in my first language, and I understand the Participant Information Sheet dated xxxx;
- freely agreed to participate in this project according to the conditions in the Participant Information Sheet;
- been informed I will be given a copy of the Participant Information and Assent Form to keep;
- My doctor has agreed not to reveal my identity and personal details in any publication;
- I agree to the collection of as described in the Information Sheet.

Participant's Name:

Signature:

Date

Name of Witness:

Signature:

Date

Researcher's Name:

Signature:

Date