

ALFRED ETHICS COMMITTEE POLICY: OBTAINING PARTICIPANT CONSENT

PURPOSE AND SCOPE

This document describes the requirements of Bayside Health for obtaining the valid informed consent of participants in the research. This policy is based on the principles described in Section 2 of the [National Statement on Ethical Conduct in Human Research 2007](#).

POLICY

1. Principles of informed consent

The guiding principles governing informed consent are:

- (i) A person's decision to participate in research should be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participating in it;
- (ii) Consent to participate must not involve any coercion or inappropriate inducement;
- (iii) Consent must be sought by an individual who is qualified to clarify participants' questions about any risks, discomfort or inconvenience, associated costs, as well as any benefits they are likely to experience as a result of participation;
- (iv) Consent must be authorised, usually in writing, by research participants prior to their commencement in the project;
- (v) Participants must be free to withdraw consent at any time and for any (or no) reason.

2. Limited Disclosure

When the aims of the research cannot be achieved if information about the research is fully disclosed to participants, researchers may be justified in 'limited disclosure'. This may range from not fully disclosing the aims or methods of the research, to actively concealing information and planning deception of participants.

The Ethics Committee will consider approval for a study to proceed with limited disclosure only if the same or equivalent information cannot be collected with fuller disclosure; and when one or more of the following conditions apply:

- (i) the study poses no more than low risk;
- (ii) the potential benefits of the research are sufficient to justify the limited disclosure to participants;
- (iii) the precise extent of the limited disclosure is defined;
- (iv) whenever possible and appropriate, and after their participation has ended:
 - participants will be provided with information about the aims of the research, and an explanation of why the omission or alteration was necessary; and
 - participants will be offered the opportunity to withdraw any data or tissue provided by them.

3. Waiver of consent

The Ethics Committee will consider approval for a study to proceed without consent only when the same or equivalent information cannot be collected from patients who can give consent, or their proxy; and when one or more of the following conditions apply:

- (a) The study poses negligible risk;
- (b) The Ethics Committee judges that the anxiety or consequences to participants as a result of the consent process is likely to outweigh other considerations;
- (c) Medical emergencies (where the procedure is necessary, as a matter of urgency, to save life, prevent serious damage to health, or prevent significant pain or distress).

4. Types of consent

(a) Written consent: In general researchers must obtain the written consent of participants. Participants should receive an information sheet containing relevant details about the research, and a copy of the consent form. Information must be written in simple language that can be understood by the average teenager.

(b) Verbal consent: The ethics committee may approve verbal consent where participants are present and mentally competent, but physically unable to give written consent;

(c) Telephone consent: Researchers may consider consent of participants over the telephone in the case of a telephone survey for example. This must be clearly explained in the application to the ethics committee. Researchers must also include the following information in the medical records of each participant:

- who the discussion was with
- what was covered in the discussion
- any other specific issues raised

(d) Implied consent: In some cases, a participant's action may imply consent as for example completing an anonymous questionnaire, where signing a form may negate the anonymity of the process;

(e) Consent by a Third Party:

Research involving adults:

- for projects involving medical research procedures, see details in Section 10 below;
- for projects not involving medical research procedures, see details in Section 11 below.

Research involving minors:

Research involving participants under the age of 18 years generally requires the consent of both the young person and their parent or guardian. Information and Consent Forms should be provided for both, with the young person's information suitably worded for their level of comprehension.

In some cases, the involvement of parents or guardians may not be in the young person's best interests. If the young person is able to understand the relevant information, and the research is of no more than low risk and likely to benefit that particular category of participant, the Ethics Committee may approve research to which only the young person consents.

For further information on ethical issues raised by research involving young people, please refer to the National Statement on Ethical Conduct in Human Research (2007), Chapter 4.2: Children and Young People.

5. Parameters of consent

(a) Consent is 'specific' when it is limited to the specific project under consideration.

(b) Consent is 'extended' if it is given for use of data or tissue in future research projects that are either related to the original project or are in the same general area such as genealogical, ethnographical, epidemiological, or chronic illness research.

(c) Consent is 'unspecified' if it is given for use of data or tissue in any future research, including permission to enter the original data or tissue into a databank or tissue bank. The terms and wide-ranging implications of unspecified consent must be clearly explained to potential participants, as well as clearly recorded. Subsequent projects that rely on unspecified consent should describe these terms.

6. Participant Information and Consent Forms (PICFs)

Appropriate PICFs must be used for clinical and non-clinical research projects. The preferred templates are:

[Form for use in clinical research projects](#)

[Form for use in non-clinical research projects](#)

The original signed copy of the PICF should be kept with study records. One signed copy should be given to all study participants, and one copy should be filed in their medical records.

The PICF is only an aid to the consent process. Researchers must have a discussion with participants so that they have the opportunity to seek further information.

While it is not expected that every possible risk however rare or trivial, is mentioned, researchers must detail all risks that participants might reasonably face as a result of participation. Whenever possible the extent of the risk should be described, both in absolute terms (eg. 1 chance per 1000 procedures), and by comparison with commonly understood risks.

When the research involves substantial risks, discomfort or inconvenience (eg. invasive studies, drug trials etc) and a decision about participation is not urgent, patients should be given the information sheet and invited to discuss its contents with others prior to making a decision.

When the research involves the recruitment of patients who have had a long-term doctor/patient relationship with the investigator, an independent researcher may be required to take major responsibility for discussing participation with the patient and seeking her/his consent.

7. Witness to consent

It is generally expected that a witness will also sign the Consent Form. The witness may be anybody who can certify that a person they believe to be the named project participant has actually signed the Consent Form.

8. Participants in a dependent or unequal relationship with researchers

The Ethics Committee requires researchers to have carefully considered measures to avoid coercion where the research involves people in dependent or unequal relationships, including:

- persons with chronic conditions or disabilities and their carers;
- doctor / patient
- teacher / student
- prisoner
- persons involuntarily committed to care
- employers or supervisors/employees

9. Patients who cannot consent to participation in research involving a medical research procedure

When research involves a medical research procedure and 'patients' who may be incapable of giving consent, researchers must comply with the requirements of the Guardianship and Administration Act. <http://www.health.vic.gov.au/legislation/medicalresearch.htm>

The Act governs medical research procedures on a person aged 18 years or older who has a disability (defined as an intellectual impairment, mental disorder, brain injury, or physical disability or dementia), where that person is incapable of deciding whether to consent to the carrying out of a medical research procedure.

Separate requirements apply for research involving involuntary patients, forensic patients or security patients. <http://www.health.vic.gov.au/mentalhealth/mh-act/forms.htm>

NOTE

It should be noted that a registered medical practitioner must not authorise or carry out a medical research procedure that is medical treatment (including emergency treatment), if a refusal of that treatment is in force under the Medical Treatment Act (section 41).

Who is a 'patient' lacking capacity to consent?

- Any individual incapable of understanding the general nature and effect of the proposed procedure; or
- Any individual incapable of indicating whether or not he or she, consents or does not consent to the carrying out of the proposed procedure.

This includes:

- (a) patients with short-term disabilities in the emergency, intensive care and trauma contexts, who are incapable of consenting;
- (b) all other patients with short or long-term disabilities who lack capacity to consent.

What is a 'medical research procedure'?

Any procedure carried out for the purposes of medical research including, as part of a clinical trial, the administration of medication, or the use of equipment or a device¹.

If a procedure falls within the scope of this definition, but might also be thought of as relating to the treatment of the patients by the registered medical practitioner conducting or supervising the research, the provisions in the Act regarding medical research procedures apply.

The following are not 'medical research procedures':

- any non-intrusive examination (including a visual examination of the mouth, throat, nasal cavity, eyes or ears or the measuring of a person's height, weight or vision);
- observing a person's activities or undertaking a survey;
- collecting or using information, including personal or health information;
- any other procedure that is prescribed by regulations not to be a medical research procedure. (There are no such regulations at this stage.)

10. Consent process for research involving medical research procedures

Researchers must follow the steps outlined below for consent in the case of a medical research procedure on a 'patient'. These are described more fully in the following document: 'Medical Research Procedures involving patients under a legal incapacity'.

<http://www.health.vic.gov.au/legislation/info-paper.doc>

<http://www.health.vic.gov.au/legislation/flowchart.pdf>

Step 1: Obtain the approval of the Ethics Committee

- (i) The project must have ethics approval.
- (ii) If the application to the Ethics Committee involves approval for 'procedural authorisation' (see step 4), this must be made clear to the Committee.
- (iii) The medical research procedure must be carried out as approved.
- (iv) Where the Ethics Committee approves a project that may involve the consent of the 'person responsible' or 'procedural authorisation' each step required by the Act and described below must be complied with for each participant.

Step 2: Wait to seek consent of the patient if possible

If the patient is likely to recover capacity to consent to the procedure within a 'reasonable time', researchers must wait and seek the patient's own consent.

¹ It would also include a procedure prescribed by regulations to be a medical research procedure. There are no regulations at this point in time.

NOTE

What is a 'reasonable' time will vary, depending upon each patient's circumstances. For instance, if the research protocol approved by the Ethics Committee involves assessing the effectiveness of a proposed new treatment for brain injury that typically occurs to road trauma victims, and it is necessary to perform the relevant new treatment immediately upon admission to hospital, the relevant question to ask is whether the patient is likely to regain capacity by that time. If so, then the patient's own consent must be sought. If not, Step 3 and Step 4 will apply.

In contrast, a clinical trial may test the effectiveness of two different medications over a number of years, and under the criteria for the research protocol, the patient may be eligible to participate at any time. In such a case the researcher should wait until the patient regains capacity and seek the patient's own consent. If the patient is unlikely to regain capacity to consent, Step 3 and Step 4 will apply.

Step 3: Seek consent of the 'person responsible'

If the patient is not likely to recover capacity to consent to the procedure within a reasonable time, researchers must seek and obtain consent from 'the person responsible'. If the 'person responsible' declines to consent, the medical research procedure cannot be performed.

The 'person responsible' must believe that the medical research procedure is not contrary to the best interests of the patient, and must take into account the wishes of the patient and family members, as well as the benefits, risks and consequences of having or not having the procedure.

Definition of 'person responsible'

The Act describes this as the first person listed below who is responsible for the patient and who, in the circumstances, is reasonably available and willing and able to make a decision:

- (a) a person appointed by the patient under section 5A of the Medical Treatment Act 1988;*
- (b) a person appointed by VCAT to make decisions in relation to the proposed procedure;*
- (c) a person appointed under a guardianship order with power to make decisions in relation to the proposed procedure;*
- (d) a person appointed by the patient (before the patient became incapable of giving consent) as an enduring guardian with power to make decisions in relation to the proposed procedure;*
- (e) a person appointed in writing by the patient (being the person appointed last in time before the patient became incapable of giving consent) to make decisions in relation to medical research procedures that includes the proposed procedure;*
- (f) the patient's spouse or domestic partner;*
- (g) the patient's primary carer;*
- (h) the patient's nearest relative as defined by the Act.*

Ongoing consent by the participant

If the participant regains capacity to consent during the course of the medical research procedure, researchers need to obtain her/his ongoing consent for continued participation in the research. Participants must also be informed about their option to withdraw from participation without compromising their ability to receive any available alternative treatment or care

Ongoing consent of the participant may or may not be required if data collection is still underway. The Ethics Committee will determine this on a case-by-case basis.

Where consent for continued participation is being sought, the researcher must make clear to participants what this entails.

If the participant regains capacity to consent only after the data has already been used, or after the research is complete, it may be appropriate for the researcher to provide a brief information sheet for the participant explaining the research and what took place.

Step 4: Procedural authorisation

If the 'person responsible' is not able to be identified and contacted in time, or is not willing or able to make a decision, procedural authorisation will apply.

Criteria:

All of the following criteria must be met before procedural authorisation will apply:

- (a) the patient is unlikely to be capable of giving consent within a reasonable time; and
- (b) it has not been possible to contact the 'person responsible'; and
- (c) the researcher believes that inclusion of the patient in the relevant research project would not be contrary to the best interests of the patient; and
- (d) the researcher has no reason to believe that the carrying out of the procedure would be against the patient's wishes; and
- (e) the Ethics Committee has approved the relevant research project in the knowledge that a patient may participate in the project without the prior consent of the patient or the person responsible; and
- (f) the researcher believes that:
 - one of the purposes of the relevant research project is to assess the effectiveness of the therapy being researched; and
 - the medical research procedure poses no more of a risk to the patient than the risk that is inherent in the patient's condition and alternative treatment; and
- (g) the researcher believes that the relevant research project is based on valid scientific hypotheses that support a reasonable possibility of benefit for the patient as compared with standard treatment.

NOTE

1. If all the above criteria are met, the supervising registered practitioner must complete and forward an [S 42T certificate](#) to the Ethics Committee and to the Office of the Public Advocate.
2. If all of these criteria are not met, procedural authorisation does not apply in relation to that patient. The patient cannot participate unless another form of lawful authority exists. (For example, the patient regains capacity and gives consent, or a person responsible for the patient is found and gives consent.)
3. If Step 3 or 4 apply, then before carrying out the medical research procedure, or as soon as practicable after, the researcher must state in writing in the patient's clinical records:
 - his or her belief that, at the time of the procedure, the patient is or was not likely to be capable of giving consent within a reasonable time; and
 - the reason for that belief.

Continuing obligations when relying on procedural authorisation

As procedural authorisation involves performing a procedure without the consent of the patient or their person responsible, the Act imposes a number of additional requirements to ensure adequate accountability for the decision making process. These relate to certification and notification, and what to do if the procedure is to continue for any period of time.

They are as follows:

a) Continuing to try to locate the person responsible: if a medical research procedure has commenced, reasonable steps must continue to be taken:

- to ascertain whether there is a person responsible and, if so, who that person is; and
- if the person responsible is ascertained, to contact that person to seek his or her consent to the proposed procedure.

b) Seeking consent, if circumstances change: a registered practitioner involved in the research must inform the person responsible or the patient (if the patient gains or regains capacity) as soon as reasonably practicable of:

- the patient's inclusion in the relevant research project; and
- the option to refuse consent for the continuation of the procedure, and to withdraw the patient from future participation in the project, without compromising the patient's ability to receive any available alternative treatment or care.

c) Certification and notification: The research coordinator must continue to submit a signed copy of an [S 42T certificate](#) to the Public Advocate and the Ethics Committee at monthly intervals while the medical research procedure continues, and if:

- the person responsible has not been able to be contacted; and
- the patient has not gained or regained the capacity to consent

A copy of each certificate must be kept in the patient's medical records.

PRIVACY NOTE: Researchers should note that if the project is likely to involve participants who cannot consent, the Privacy section of the core ethics application module (Module One, Section E) should be completed if access to patient information is required,

11. Patients who cannot consent to participation in research that does NOT involve a medical research procedure.

Research which does not involve a medical research procedure is outlined in Section 9.

Proxy consent for such research is not possible except when given by a legal guardian; however researchers are generally encouraged to seek the acknowledgment of the patient's next-of-kin or another appropriate person. This 'third party' should receive an information sheet and sign a ['Third Party Acknowledgment' form](#) in lieu of a consent form. The signed form should be kept in the study file, medical record, and a copy given to the 'third party'.

A 'Participant Continuation' Information and Consent form should be provided for participants who regain the capacity to consent when they are still actively involved in the research and/or when data collection involving their information is still underway.

PRIVACY NOTE: Researchers should note that if the project is likely to involve participants who cannot consent, the Privacy section of the core ethics application module (Module One, Section E) should be completed if access to patient information is required.

FURTHER INFORMATION

Any enquires regarding submission forms and processes, documentation, or variations to the procedures outlined above should be directed to the Ethics Manager.

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References

Guardianship and Administration Act, 1986, available at
<http://www.health.vic.gov.au/legislation/medicalresearch.htm>

Medical Research Procedures Involving Patients under a Legal Incapacity; available at
<http://www.health.vic.gov.au/legislation/info-paper.doc>

Mental Health Act, 1986, available at
<http://www.health.vic.gov.au/mentalhealth/mh-act/forms.htm>

Section 42T certificate, available at
<http://publicadvocate.vic.gov.au/Publications/Medical-consent/Section-42T-Certificate-Medical-research-procedure-on-a-patient-who-is-unable-to-consent-and-there-is-no-person-responsible-to-provide-consent.html>