



# Medical Research for Patients who Cannot Consent

## *The person responsible*

The person responsible may consent to the carrying out of a medical research procedure on a patient who cannot themselves provide consent.

### What is a medical research procedure?

A medical research procedure is a medical procedure that is carried out for the purposes of medical research. The medical research procedure may be:

- part of a clinical trial
- the administration of medication
- the use of equipment or a device.

Not all medical research involves medical research procedures. Some medical research may involve observations of the patient, non-intrusive examinations, surveys or collecting information. These types of medical research may be carried out without the consent of the person responsible.

### Is the medical research procedure legal?

To be legal, the medical research must be approved by a human research ethics committee. The human research ethics committee may be based at the hospital where the patient is being treated or it may be at another hospital, a university or institution. The medical practitioner will know where the committee is and how it can be contacted.

### Is the medical research procedure safe for the patient?

Not all medical procedures are safe, and not all medical research procedures are safe. However, there are protections.

When approving research for people who cannot provide consent, a human research ethics committee will consider factors such as:

- that the research is therapeutic and the research procedure poses no more of a risk than the risks that are already part of the patient's condition and in alternative methods of treatment
- the research is based on valid scientific principles which support a reasonable possible benefit over standard care
- the patient or the person responsible will be informed about the research and have the option to withdraw from the research without any reduction in the quality of care.

### What if the medical research procedure is contrary to the patient's best interests?

The patient should not be worse off for being involved in the medical research procedure when compared to other medical procedures. If the patient will be worse off, then it would be contrary to their best interests to participate in the medical research procedure.

The person responsible needs to take into account the following when making a decision:

- a. the wishes of the patient (if known)
- b. the wishes of the nearest relative or any other family members of the patient
- c. the nature and degree of any benefits, discomforts and risks for the patient in having or not having the procedure (including comparing the medical research procedure to alternative procedures)
- d. any other consequences to the patient if the procedure is or is not carried out.

### Further information

The human research ethics committee may have set out requirements of obtaining consent of the person responsible when it approved the research project. Speak to the doctor or the ethics committee about any special requirements.



## Other issues

### If the patient is an involuntary patient under the *Mental Health Act 1986*, is the person responsible still able to provide consent?

Yes, if the procedure is a medical research procedure then the person responsible can provide consent.

The only exception to this is that a patient can object to certain relatives being involved in any decisions to do with them regarding medical research procedures.

### Can a medical research procedure go ahead without the consent of the person responsible?

Yes, if:

- it is an emergency, or
- the medical practitioner was unable to find the person responsible to provide consent and believed the procedure was not contrary to the best interests of the patient and followed the procedure set down in the *Guardianship and Administration Act 1986*.

### What if the medical research procedure began without consent of the person responsible?

When the person responsible becomes aware of the medical procedure they may consent to its continuing or withhold consent. When making a decision they must give regard to whether the continuation of the treatment is not contrary to the best interests of the patient.

## Where to go for help

To find out more about the medical research procedure, the person responsible can:

- discuss any questions about the project or the patient's involvement with the medical practitioners involved
- discuss the matter with a doctor known to them, or a doctor who treats the patient
- contact the person nominated on the information sheet provided by the researchers. This document will have been assessed by the human research ethics committee which has approved the research, and will include the name of a person to contact (this might be a person who works at the committee or a hospital patient advocate).

The person responsible can also call the Office of the Public Advocate's Advice Service on 1300 309 337 for assistance.

For further advice, VCAT can be approached to:

- give advice
- make an order that the proposed medical research procedure is not contrary to the best interests of the patient
- give directions to help resolve conflicts between people who have different views about what to do.

VCAT can also appoint a guardian if required.

The information provided in this fact sheet is in addition to the Office of the Public Advocate fact sheet *Medical/Dental Treatment for Patients Who Cannot Consent – the person responsible*.