Who must comply with this procedure?

Principal Investigator and members of the research team for a research project.

This procedure applies in the following setting:

This procedure is applicable to all research conducted at, or under the auspices of, Monash Health.

Precautions and Considerations:

All researchers at Monash Health must strive to conduct research in the manner indicated in the Human Research Strategic Policy.

Research should be conducted strictly in accordance with the *National Statement on Ethical Conduct in Human Research* (NHMRC 2007) as amended under rolling review, and the *Australian Code for the Responsible conduct of Research* (NHMRC 2007), and the Victorian Managed Insurance Authority guidelines.

The process for obtaining consent for medical research procedures conducted on incompetent adults should be conducted strictly in accordance with the Medical Treatment Planning and Decisions Act 2016 and amendments to the Guardianship and Administration Act 1986 as amended from time to time.

Definitions:

Advance care directive is a document that sets out a person's binding instructions or preferences and values in relation to the medical treatment of that person in the event that the person does not have decision-making capacity for that medical treatment in the future.

Decision - making capacity: Under law, all adults are presumed to have decision - making capacity, unless proven otherwise. To have decision - making capacity, a person must be able to:

- *understand* the information relevant to the decision and the effect of the decision;
- *retain* that information to the extent necessary to make the decision;
- *use* or *weigh* that information as part of the process of making the decision; and
- *communicate* the decision and the person's views and needs as to the decision in some way, including by speech, gestures or other means.

Decision - making capacity may vary depending on the decision and the circumstances. Patients may have capacity to make some decisions, even if they do not have capacity to make others.

Human research ethics committee means—

(a) a human research ethics committee established in accordance with the requirements of—
  (i) the National Statement on Ethical Conduct in Research Involving Humans published by the National Health and Medical Research Council; or
  (ii) any superseding document of the statement referred to in subparagraph (i) published by the National Health and Medical Research Council that covers the same subject matter; or

(b) an ethics committee established under the by-laws of any of the following within the meaning of the **Health Services Act 1988**—
  (i) denominational hospital; (ii) multi purpose service; (iii) public health service; (iv) public hospital;

Medical research practitioner means—

(a) a registered medical practitioner; or

(b) a person registered under the Health Practitioner Regulation National Law—
  (i) to practise in the dental profession as a dentist (other than as a student); and
  (ii) in the dentist division of that profession;

Medical research procedure means—

(a) a procedure carried out for the purposes of medical research, including, as part of a clinical trial—

(i) the administration of pharmaceuticals; or

(ii) the use of equipment or a device; or

(b) a prescribed medical research procedure—

but does not include any of the following—

(c) any non-intrusive examination including—

(i) a visual examination of the mouth, throat, nasal cavity, eyes or ears; or

(ii) the measuring of a person's height, weight or vision;

(d) observing a person's activities;

(e) undertaking a survey;

(f) collecting or using information, including either of the following—

(i) personal information within the meaning of the **Privacy and Data Protection Act 2014**;

(ii) health information;

(g) any other procedure prescribed not to be a medical research procedure;

Medical treatment means any of the following treatments of a person by a health practitioner for the purposes of diagnosing a physical or mental condition, preventing disease, restoring or replacing bodily function in the face of disease or injury or improving comfort and quality of life—

(a) treatment with physical or surgical therapy;

(b) treatment for mental illness;

(c) treatment with—

(i) prescription pharmaceuticals; or

(ii) an approved medicinal cannabis product within the meaning of the **Access to Medicinal Cannabis Act 2016**;

(d) dental treatment;

(e) palliative care—

but does not include a medical research procedure;

Medical treatment decision maker: A person's medical treatment decision maker is the first reasonably available and willing person from the list below: -

(1) a person formally appointed as a medical treatment decision maker.

Note

- This includes persons appointed under the *Medical Treatment Planning and Decisions Act 2016* and any persons validly appointed prior to 12 March 2018 under the *Medical Treatment Act 1988* and *Powers of Attorney Act 2014* to make medical treatment decisions on behalf of the patient.
- There can only ever be one medical treatment decision maker at any one time. Therefore, if a patient has appointed more than one person, the decision maker is the first named person on the appointed document who is ready, willing and able to perform the role.

(2) a guardian appointed by VCAT under the **Guardianship and Administration Act 1986;**.

(3) the first of the following persons who is in a close and continuing relationship with the person:—

(a) the spouse or domestic partner of the person;

(b) the primary carer of the person;

(c) the first of the following and, if more than one person fits the description in the subparagraph, the oldest of those persons—

(i) an adult child of the person;

(ii) a parent of the person;

(iii) an adult sibling of the person.

Values directive means –

A statement in an advance care directive of a person's preferences and values as the basis on which the person would like any medical treatment decisions to be made on behalf of the person, including, but not limited to, a statement of medical treatment outcomes that the person regards as acceptable.

Instructional Directive means –

An express statement in an advance care directive of a person's medical treatment decision; and takes effect as if the person who gave it has consented to, or refused the commencement of, medical treatment, as the case may be.

Procedure:

Preliminary:

Administration of a medical research procedure to an adult who does not have decision making capacity in relation to the procedure

(1) This applies to the administration of a medical research procedure to an adult who does not have decision-making capacity in relation to the procedure.

(2) If a person is likely to recover decision-making capacity within a reasonable time to make a medical treatment decision in relation to a medical research procedure, a medical research practitioner must not administer the medical research procedure to that person.

(3) A reasonable time is the time by which, given the nature of the relevant research project, the procedure would need to be administered to the person, having regard to the following—

(a) the medical or physical condition of the person;

(b) the stage of medical treatment or care;

(c) other circumstances specific to the person.

Requirement to ascertain existence of advance care directives and medical treatment decision makers

(1) Before a medical research practitioner administers a medical research procedure to a person, the medical research practitioner must make reasonable efforts in the circumstances to ascertain if the person has either or both of the following—

(a) an advance care directive;

(b) a medical treatment decision maker.

Note: Contravention of this requirement is unprofessional conduct.

Protection of medical research practitioner

(1) A medical research practitioner who, in good faith, administers a medical research procedure to a person and believes on reasonable grounds that the requirements have been complied with is not—

(a) guilty of an offence of assault or an "**Offence to administer medical research procedure without consent or authorisation" (see below)**; or

(b) liable for unprofessional conduct or professional misconduct; or

(c) liable in any civil proceeding for assault or battery; or

(d) liable for contravention of any code of conduct.

(2) Nothing in this section affects any duty of care owed by a medical research practitioner to a person.

Approval and Consent:

Approval to administer a medical research procedure

A medical research practitioner must not administer a medical research procedure to a person who does not have decision-making capacity to make a medical treatment decision in respect of that procedure unless—

(a) the relevant research project has been approved by the relevant human research ethics committee; and

(b) subject to medical treatment and medical research procedures in an emergency

(i) the person has consented to the procedure being administered under an instructional directive; or

(ii) if there is no relevant instructional directive, the person's medical treatment decision maker has consented to the procedure being administered; or

(iii) if the person does not have a medical treatment decision maker, the procedure is authorised under "**Medical research procedures without consent**" (see below)

Medical research procedure to be administered in accordance with approval

A medical research procedure must be administered in accordance with the relevant human research ethics committee approval, including any conditions of that approval.

Consent of medical treatment decision maker

(1) In circumstances where a person does not have decision - making capacity to consent to a medical research procedure and the person has not previously consented to the procedure being administered under an instructional directive, a person's medical treatment decision maker may consent to the administration of a medical research procedure to the person if the medical treatment decision maker reasonably believes that the person would have consented to the procedure if the person had decision-making capacity.

(2) To make a decision, the medical treatment decision maker must do the following—

(a) first consider any valid and relevant values directive;

(b) next consider any other relevant preferences that the person has expressed and the circumstances in which those preferences were expressed;

(c) if the medical treatment decision maker is unable to identify any relevant preferences give consideration to the person's values, whether—

(i) expressed other than by way of a values directive; or

(ii) inferred from the person's life;

(d) also consider the following—

(i) the likely effects and consequences of the medical research procedure, including the likely effectiveness of the procedure, and whether these are consistent with the person's preferences or values;

(ii) whether there are any alternatives, including not administering the medical research procedure, that would be more consistent with the person's preferences or values;

(e) act in good faith and with due diligence.

(3) If the medical treatment decision maker is unable to apply this process because it is not possible to ascertain the person's preferences or values, the medical treatment decision maker must—

(a) make a decision that promotes the personal and social wellbeing of the person, having regard to the need to respect the person's individuality; and

(b) consider the following—

(i) the likely effects and consequences of the medical research procedure, including the likely effectiveness of the procedure, and whether these promote the person's personal and social wellbeing, having regard to the need to protect the person's individuality;

(ii) whether there are any alternatives, including refusing the medical research procedure, that would better promote the person's personal and social wellbeing, having regard to the need to protect the person's individuality.

(4) The medical treatment decision maker must also consult with any person who the medical treatment decision maker reasonably believes the person would want to be consulted in the circumstances.

(5) The consent must be consistent with any requirements for consent specified in the relevant human research ethics committee approval for the relevant research project or the conditions of that approval.

Medical research practitioner must record basis for administering medical research procedure in clinical records

Before, or as soon as practicable after, administering a medical research procedure to a person who does not have decision-making capacity in relation to the procedure, a medical research practitioner must record in writing in the person's clinical records—

(a) that the practitioner was satisfied that—

(iii) the person did not have decision-making capacity; and

(iv) the person was not likely to recover decision-making capacity within a reasonable time; and

(b) the reason or reasons for being so satisfied.

Medical Research Procedures in an emergency

(1) Subject to subsection (2), a health practitioner may administer a medical research procedure to a person without consent or the required authorisation described in this procedure, if the practitioner believes on reasonable grounds that the medical research procedure is necessary, as a matter of urgency to—

(a) save the person's life; or

(b) prevent serious damage to the person's health; or

(c) prevent the person from suffering or continuing to suffer significant pain or distress.

(2) A health practitioner is not permitted however to administer a medical research procedure to a person under subsection (1) if the practitioner is aware that the person has refused the particular procedure, whether by way of an instructional directive or a legally valid and informed refusal of treatment by or under another form of informed consent.

(3) A health practitioner is not required to search for an advance care directive that is not readily available to the practitioner if the circumstances set out in subsection (1) apply to the person to whom a medical research procedure is being administered.

Medical research procedures without consent:

Application

This section applies if it is not an emergency and a medical research practitioner has taken reasonable steps in the circumstances to—

(a) locate a person's instructional directive (if any), but has been unable to do so; and

(b) identify and contact the medical treatment decision maker of the person to obtain consent to the administration of a medical research procedure to the person but has been unable to do so.

Administering a medical research procedure if person has no medical treatment decision maker

(1) A medical research practitioner may administer a medical research procedure without consent to a person who does not have a medical treatment decision maker if—

(a) the medical research practitioner believes on reasonable grounds that inclusion of the person in the relevant research project, and being the subject of the proposed procedure, would not be contrary to the following—

(i) the person's values, whether—

(A) expressed by way of a values directive or otherwise; or

(B) inferred from the person's life;

(ii) any other relevant preferences that the person has expressed, having regard to the circumstances in which those preferences were expressed;

(iii) the personal and social wellbeing of the person, having regard to the need to respect the person's individuality; and

(b) the medical research practitioner believes on reasonable grounds that the relevant human research ethics committee has approved the relevant research project in the knowledge that a person may participate in the project without the prior consent of—

(i) the person; or

(ii) a medical treatment decision maker; and

(c) the medical research practitioner believes on reasonable grounds that—

(i) one of the purposes of the relevant research project is to assess the effectiveness of the procedure being researched; and

(ii) the medical research procedure poses no more of a risk to the person than the risk that is inherent in the person's condition and alternative medical treatment; and

(d) the medical research practitioner believes on reasonable grounds that the relevant research project is based on valid scientific hypotheses that support a reasonable possibility of benefit for the person as compared with standard medical treatment.

(2) A medical research practitioner must continue to take reasonable steps to identify and contact the person's medical treatment decision maker to seek consent to the continuation of the procedure on the person.

Medical research practitioner's certificate

(1) Before, or as soon as practicable after, administering a medical research procedure (and in the case of a procedure lasting longer than 30 days, at intervals of no longer than 30 days), a medical research practitioner a must sign a certificate—

(a) certifying—

(i) that the person to whom the medical research procedure is being administered does not have decision-making capacity to make a medical treatment decision in respect of that

procedure; and

(ii) that the person's medical treatment decision maker cannot be identified or contacted (as the case may be); and

(iii) as to each of the matters set out in "**Administering a medical research procedure if person has no medical treatment decision maker"** above; and

(b) stating that—

(i) the person's medical treatment decision maker (if one is subsequently identified) will be informed of the procedure; or
(ii) if the person recovers decision-making capacity, the person will be informed of the procedure.

(2) The medical research practitioner must inform the person's medical treatment decision maker (if one is subsequently identified) or, if the person recovers decision-making capacity, the person, as soon as reasonably practicable of—
(a) the person's inclusion in the relevant research project; and
(b) the option to refuse the continuation of the procedure and withdraw the person from future participation in the project without compromising the person's ability to receive any available alternative medical treatment or care.

(3) The medical research practitioner must—
(a) forward a copy of each certificate to the Public Advocate and the relevant human research ethics committee—
(i) in the case of the first certificate, as soon as practicable (and in any event within 2 business days) after administering the procedure; or
(ii) in any other case, at intervals of no more than 30 days; and
(b) ensure that each certificate is kept in the person's clinical records.

(4) A medical research practitioner must not sign a certificate under this section that the practitioner knows to be false.

Applications to VCAT:

Applications to VCAT

(1) Each of the following persons may apply to VCAT in relation to any matter, question or dispute relating to the administration of a medical research procedure to a person—

(a) the person's medical treatment decision maker;

(b) a person who, in the opinion of VCAT, has a special interest in the affairs of the person, including a medical research practitioner.

(2) Despite subsection (1)(b), a medical research practitioner who is involved in the relevant research project is not entitled to apply to VCAT in relation to a refusal of a medical research procedure by a medical treatment decision maker.

(3) If an application is made under subsection (1), the person to whom the medical research procedure is being administered is a party to the proceeding.

(4) The principal registrar of VCAT must give notice of an application, of the hearing of the application and of any order of VCAT in respect of the application to—

(a) the Public Advocate; and

(b) any other person whom VCAT considers has a special interest in the affairs of the person.

(5) On an application, VCAT may—

(a) make an order declaring that any proposed medical research procedure is or is not contrary to any known preferences and values of the person to whom medical treatment is being administered, whether—

(i) expressed by way of a values directive or otherwise; or

(ii) inferred from the person's life; or

(b) if the person's preferences and values are not known, order that any proposed medical research procedure is or is not contrary to promoting the personal and social wellbeing of the person, having regard to the need to respect the person's individuality; or

(c) make an order declaring that a decision relating to a medical research procedure is valid or invalid or effective or ineffective; or

(d) give an advisory opinion or directions in relation to the scope or exercise of the medical treatment decision maker's authority; or

(e) make any other orders it considers necessary.

Medical treatment decision maker may seek advice

(1) A person's medical treatment decision maker may apply to VCAT for directions or an advisory opinion on any matter or question relating to the scope or exercise of the person's authority to consent to a medical research procedure on behalf of the person.

(2) The principal registrar of VCAT must give notice of the application, of the hearing of the application and of any order, directions or advisory opinion of VCAT in respect of the application to any person the affairs of the person.

(3) VCAT may—

(a) give any directions or advisory opinion it considers necessary; and

(b) make any order it considers necessary.

VCAT Contact Details:

Web Site: https://www.vcat.vic.gov.au/

Phone Number: 1300 018 228

Email for Guardianship and Administration: humanrights@vcat.vic.gov.au

Offences:

Offence to administer unapproved medical research procedure

A medical research practitioner must not administer a medical research procedure to a person who does not have decision-making capacity to make a medical treatment decision in respect of the procedure unless the relevant research project has been approved by the relevant human research ethics committee.

Offence to administer medical research procedure without consent or authorisation

Subject to Medical treatment and medical research procedures in an emergency, a medical research practitioner must not administer a medical research procedure to a person who does not have decision-making capacity to consent to the procedure unless—

(a) the person has consented, by an instructional directive, to the procedure being administered; or

(b) the person's medical treatment decision maker has consented to the procedure; or

(c) the procedure is authorised in accordance with the '**Medical research procedures without consent'** section of this *Recruitment of Incompetent Patients into Research Procedure* (being Part 5, Division 3 of the *Medical Treatment Planning and Decisions Act 2016)* or otherwise by law.

Useful Information and Resources

Access to medicinal cannabis act 2016

Guardianship and administration act 1986

Health Records Act 2001

Health Services Act 1988

Medical Treatment Act 1988

Medical Treatment Planning and Decisions Act 2016

Powers of Attorney Act 2014

Privacy and Data Protection Act 2014

Document Governance
Policy supported: Research and Ethics
Executive sponsor: Chief Medical Officer
Person responsible: Director of Clinical Research