Guide to the legislation relating to the provision of consent for a person aged 16 years or older with impaired capacity to provide informed consent for the provision of medical treatment (and which legislation may apply to such person's participation in human research)

South Australia

This guide provides an outline of the relevant legal requirements in the State of South Australia regarding the provision of consent for the provision of medical treatment to a person aged 16 years or older who lacks the capacity to provide informed consent. These principles *might* apply in relation to the participation of such a person in a human research project to the extent that the human research involves or constitutes the giving of medical treatment.

Relevant legislation

There is no South Australian legislation that *specifically* refers to or directly deals with the provision of consent for a person who lacks the capacity to provide informed consent to participate in a human research project, including a clinical trial.

However, other legislation may be relevant to considerations of whether such person can participate or be enrolled in a human research project (including a clinical trial), including the following:

- *Advance Care Directives Act 2013* (SA) (**ACDA**)
- *Consent to Medical Treatment and Palliative Care Act 1995* (SA) (**CMTPCA**)
- *Guardianship and Administration Act 1993* (SA) (**GAASA**)

In what circumstances does the legislation apply?

The CMTPCA provides that consent to *medical treatment* of a person who is 16 years or older who has impaired decision-making capacity may be given by a substitute decision maker – that is, a person appointed under an advance care directive or the person responsible.

'*Medical treatment*' is defined as the provision by a medical practitioner of physical, surgical or psychological therapy to a person (including the provision of such therapy for the purposes of preventing disease, restoring or replacing bodily function in the face of disease or injury or improving comfort and quality of life) and includes the prescription or supply of drugs.

To the extent that a human research project involves or constitutes *medical treatment*, the requirements of the CMTPCA **might** apply to it. In practice, there may be few human research projects which could be characterised as involving the provision of *medical treatment*.

What are the specific requirements for the carrying out of '*medical treatment*'?

In the event that a person is assessed as having impaired decision making capacity, consent to medical treatment for that person may be sought from a substitute decision-maker appointed in an

advance care directive if the person has one in place. Alternatively, if there is no appointed substitute decision-maker, then the medical practitioner should seek consent for medical treatment from a *person responsible* as per the CMTPCA.

A *person responsible* for a patient is in the following order of hierarchy:

- A guardian appointed in respect of the person by the South Australian Civil and Administrative Tribunal (**SACAT**) (formerly called the Guardianship Board) who is available and willing to make a decision.
- A prescribed relative (that is an adult related to the patient by blood, marriage, adoption or Aboriginal kinship/ marriage and includes an adult domestic partner) who is available and willing to make a decision about consent (see section 14(1) of the CMTPA for further guidance).
- An adult friend of the person who has a close and continuing relationship with the person who is available and willing to make a decision.
- An adult who is charged with overseeing the ongoing day-to-day supervision, care and well-being of the person who is available and willing to make a decision.
- If none of the preceding paragraphs apply, and on application to SACAT by a prescribed relative of the patient, the medical practitioner proposing to give the treatment, or any other person who SACAT is satisfied has a proper interest in the matter, SACAT itself.

Can *medical treatment* be carried out on an impaired capacity person without consent in emergency circumstances?

Section 13(1) of the CMTPCA allows a medical practitioner to lawfully administer *medical treatment* to a patient if the person is incapable of consenting if *all* of the following apply:

- The medical practitioner is of the opinion that the treatment is necessary to meet an imminent risk to life or health and that opinion is supported by the written opinion of another medical practitioner who has personally examined the person.
- The person (if 16 years of age or over) has not, to the best of the medical practitioner's knowledge, refused to consent to the treatment.
- The medical practitioner has made, or has caused to be made, reasonable inquiries to ascertain whether the person (if the person is 18 years of age or over) has given an advance care directive.

If these circumstances apply to a human research project, then it is possible that *medical treatment* could be given to an impaired capacity person in the course of that research in reliance on section 13(1). In practice, there may be few human research projects which would satisfy the above requirements.

Is there a requirement for the SACAT to approve a research project?

SACAT does not have a specifically defined or direct role in relation to the approval of human research or a clinical trial, or the giving of consent for an impaired capacity person to participate in human research or a clinical trial. In particular, there is no requirement to submit a research project or a clinical trial to SACAT for approval.

However, SACAT may have a role in relation to issues concerning the conduct of a human research project, to the extent that it has certain powers regarding the giving of consent by a *substitute decision maker* for the provision of *medical treatment* to a person who lacks the capacity to provide informed consent. For example, SACAT can determine issues and disputes arising in relation to such matters, as well as make orders regarding advance care directives and guardianship.

Checklist of matters for an HREC to consider

- Does the research involve participants aged 16 years or older who lack the capacity to provide informed consent?
- Does the research involve the provision of *medical treatment* as defined in the CMTPCA?
- Does the proposal clearly document how the researcher will seek consent from any *substitute decision maker* appointed under an *advanced care directive* or the *person responsible*?
- Has the HREC approval been given subject to the research being conducted in accordance with all relevant legal requirements regarding the obtaining of consent for participants who lack the capacity to provide informed consent?
- Having considered the above, does the HREC need to seek further advice from the researcher?