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

Tasmania

Disclaimer: The information provided in this guide is an overview of the relevant legal requirements and is of a general nature only. The guide does not provide legal advice in relation to any specific human research project or clinical trial. You should obtain legal or other professional advice appropriate to your circumstances before acting or relying on any matter referred to in this guide.

This guide provides an outline of the relevant legal requirements in the State of Tasmania regarding the giving of consent for the provision of medical or dental treatment to a person who lacks the capacity to provide informed consent. These principles *might* apply in relation to the participation of a person with impaired capacity to provide informed consent in a human research project to the extent that the human research involves or constitutes the giving of medical or dental treatment.

Relevant legislation

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

However, other legislation may be relevant to considerations of whether a person with impaired capacity to provide informed consent can participate or be enrolled in a clinical trial, including:

- *Guardianship and Administration Act 1995* (Tas) (**GAAT**)
- *Guardianship and Administration Regulations 2007* (Tas) (**GAAR**)

Researchers may wish to consult the Guardianship and Administration board's existing resources on consent to medical or dental treatment available at: http://www.guardianship.tas.gov.au/__data/assets/pdf_file/0005/67055/4_Consent_to_Medical_or_Dental_Treatment_.pdf

In what circumstances does the legislation apply?

The procedures for the provision of consent to *medical or dental treatment* of a person who is incapable of giving consent to the carrying out of *medical or dental treatment* are set out in Part 6 of the GAAT. These procedures potentially apply to a minor or an adult – see the definition of *person responsible* below.

For the purposes of the GAAT, a person is *incapable of giving consent* to the carrying out of medical or dental treatment if the person is incapable of understanding the general nature and effect of the proposed treatment or is incapable of indicating whether or not he or she consents or does not consent to the carrying out of the treatment. Failure to obtain the necessary consent or

authorisation before carrying out *medical or dental treatment* on a person to whom the GAAT applies may be a criminal offence.

Who can give substitute consent for 'medical or dental treatment'?

Under the GAAT, consent to the carrying out of medical or dental treatment on a person 'with a disability' who is incapable of giving consent may be given by the Guardianship and Administration Board of Tasmania (**GABT**) or by the *person responsible* for that person. Treatment may also be given without consent in certain, limited circumstances. This includes if the *medical or dental treatment* is needed as a matter of urgency (under section 40 of the GAAT).

Special rules apply to *special treatment*, which may only be consented to by the GABT.

Medical or dental treatment is:

- medical treatment (including any medical or surgical procedure, operation or examination and any prophylactic, palliative or rehabilitative care) normally carried out by, or under, the supervision of a medical practitioner
- dental treatment (including any dental procedure, operation or examination) normally carried out by or under the supervision of a dentist
- an intimate forensic procedure and a non-intimate forensic procedure normally carried out by a person authorised to carry out the procedure under section 40 of the Forensic Procedures Act 2000 (Tas), or
- any other act declared by the GAAR to be medical or dental treatment. (No other act has been declared to date).

It does not include any non-intrusive examination for diagnostic purposes, first-aid, or medical dental treatment, the administration of a pharmaceutical drug for which a prescription is not required and which is not normally self-administered.

Special treatment is defined at section 3 of the GAAT and regulation 6 of the GAAR as meaning:

- treatments likely to lead to permanent infertility
- termination of pregnancy
- removal of tissue for transplant
- psychosurgery
- any treatment involving an aversive stimulus.

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

<u>Consent given by the GABT</u>

The GABT may give consent to a proposed *medical or dental treatment* on behalf of a person who is incapable of understanding the general nature and effect of the proposed treatment or is incapable of indicating whether or not he or she consents or does not consent to the carrying out of the treatment if satisfied that:

- The *medical or dental treatment* is otherwise lawful ; and
- The *medical or dental treatment* would be in the best interests of that person.

The GABT may give consent to a proposed treatment if the treatment is *special treatment*.

Consent given by person responsible

A *person responsible* for another person is:

- where the other person is under the age of 18 years and has a spouse, the spouse
- where the other person is under the age of 18 years and has no spouse, his or her parent
- where the other person is of or over the age of 18 years, one of the following persons, in order of priority:
    - his or her guardian
    - his or her spouse
    - the person having the care of the other person, or
    - a close friend or relative of the other person.
- If a person is under the guardianship of the Secretary of the Department administering the *Children, Young Persons and their Families Act 1997* pursuant to a care and protection order made under that Act, the Secretary of that Department is taken to be the person responsible for the person.
- For an *intimate* or *non-intimate forensic procedure*, the person responsible is the Public Guardian.

A *person responsible* for a person who is incapable of giving consent to the carrying out of medical or dental treatment may consent to the carrying out of *medical or dental treatment* that is not *special treatment* if he or she is satisfied of all of the following:

- The relevant person is incapable of giving consent
- The *medical or dental treatment* would be in the best interests of that person, having regard to the following matters:
    - the wishes of that person, so far as they can be ascertained
    - the consequences to that person if the proposed treatment is not carried out
    - any alternative treatment available to that person
    - the nature and degree of any significant risks associated with the proposed treatment or any alternative treatment, and
    - that the treatment is to be carried out only to promote and maintain the health and wellbeing of that person.

A person who resides in a hospital, nursing home, group home, boarding-house or hostel or any other similar facility is taken to remain in the care of the person in whose care he or she was immediately before residing in the facility.

Can *medical or dental treatment* be given to a person with impaired capacity without consent or in emergency circumstances?

Section 41 of the GAAT provides that medical or dental treatment can be carried out without consent where:

- the medical or dental treatment is not considered *special treatment* (to which Part 6 of the GAAT applies) or a type prescribed in clause 7 of the GAAR (as a type of treatment where consent is required)
- there is no *person responsible* for that person,

- the treatment is necessary and the treatment will most successfully promote that person's health and well-being, and
- that person does not object to the carrying out of the treatment.

Section 41(3) of the GAAT imposes certain clinical record-keeping requirements for treatment carried out without consent.

In emergency circumstances, the GAAT (section 40) allows a medical practitioner or dentist to carry out *medical or dental treatment* on a person who is incapable of giving consent without consent if he or she considers the treatment is necessary, as a matter of urgency to:

- save the person's life
- prevent serious damage to the person's health, or
- except in the case of *special treatment*, prevent the person from suffering or continuing to suffer significant pain or distress.

To the extent that a person's participation in a research project might involve or constitute the provision of *medical or dental treatment* or *special treatment* that satisfies the above requirements, a medical practitioner or dentist might be able to rely on these provisions to include the person in the research without the requirement to obtain consent. In practice, there may be few human research projects which would satisfy the above requirements.

Is there a requirement for the Guardianship and Administration Board of Tasmania (GABT) to approve the research?

GABT does not have a specifically defined or direct role in relation to the approval of human research or a clinical trial - there is no requirement to submit a research project or a clinical trial to GABT for approval. Of course, to the extent the research activity might involve or constitute *medical or dental treatment* or *special treatment*, the GABT may have a role in providing consent under the GAAT.

GABT may also have a role in relation to the consideration and determination of issues related to guardianship and disputes under the GAAT.

Checklist of matters for an HREC to consider

- Does the research involve participants who lack the capacity to provide informed consent?
- Does the research involve the provision of *medical or dental treatment* or *special treatment* as defined in the GAAT?
- Does the proposal clearly document how the researcher will seek consent from any substitute decision maker, including the GABT 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?