February 2017

Guide to the legislation relating to the provision of consent for an adult with impaired capacity to provide informed consent to participate in the conduct of human research

Northern Territory

This guide provides an outline of the relevant legal requirements in the Northern Territory regarding the provision of consent for an adult with impaired capacity to provide informed consent to participate in the conduct of certain types of human research. It has been prepared to assist researchers, HRECs and other stakeholders to understand the relevant legal requirements.

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.

Relevant legislation

The following legislation may be relevant to considerations of whether an adult with impaired capacity to provide informed consent can participate or be enrolled in certain human research activities:

- *Guardianship of Adults Act* (NT) (**GAANT**)
- *Guardianship of Adults Regulations* (NT) (**GAANTR**)
- *Advance Personal Planning Act* (NT) (**APPA**)
- *Advance Personal Planning Regulations* (NT) (**APPR**)

What types of research does the legislation apply to?

The legislation in the Northern Territory applies to certain research activities that an adult (a person over the age of 18 years) with impaired capacity may potentially participate in. A substitute decision maker's authority to provide consent for a person is generally defined according to whether the decision involves the making of a *consent decision* for a *health care action*. The legislation in the Northern Territory does not define 'clinical trial'.

What are the specific legal requirements for the conduct of research?

The legislation refers to various types of research. The relevant definitions include *restricted health care* and *restricted health care action*.

Restricted health care includes the following:

- Health care provided for medical research purposes. This excludes: a non-intrusive examination of an adult, observation of an adult's activities, collecting information from or about an adult, or health care prescribed by regulation as not provided for medical research purposes.
- New health care of a kind that is not yet accepted as evidence-based, best practice health care by a substantial number of health care providers specialising in the relevant area of health care.

Restricted health care action includes the following:

- *Special medical research or experimental health care* – this is defined as medical research or experimental health care relating to a condition the adult has or to which the adult has a significant risk of being exposed or intended to gain knowledge that can be used in the diagnosis, maintenance or treatment of a condition the adult has or has had. However, it excludes *psychological research* or *approved clinical research*. Unfortunately, the legislation does not define those terms.
- New health care of a kind that is not yet accepted as evidence-based, best practice health care by a substantial number of health care providers specialising in the relevant area of health care.

The Northern Territory legislation does not define 'clinical trial'. A clinical trial or any other type of research involving the giving of health care may fall within the definition of *restricted health care* and/or *restricted health care action*.

Who may consent?

An adult who lacks capacity to provide informed consent may be recruited into a research activity on the basis of: a consent decision they have made under an advance personal plan (made while they did not have impaired capacity); consent provided by a guardian appointed under a guardianship order; consent provided by a decision maker appointed under an advance personal plan; or consent provided by the Northern Territory Civil and Administrative Tribunal (**NTCAT**).

The nature of the research activity will dictate who may provide consent of behalf of the adult.

If an adult has made an advance consent decision under an advance personal plan about a research activity which involves the provision of health care, that decision has effect as if the decision had been made by the adult at the time it is proposed to take the health care action. However, NTCAT may order that the advance consent decision be disregarded. NTCAT may do so only if it is satisfied that:

- there is no reasonable possibility that the adult would have intended the advance consent decision to apply in the circumstances, and
- taking *health care action* in reliance on the advance consent decision would cause the adult unacceptable pain and suffering or would otherwise be so wholly unreasonable that it is justifiable to override the adult's wishes.

As a general rule, if the research activity involves the provision of health care, neither a guardian nor a decision maker will have authority to provide consent for the adult to participate in the research activity. However, a guardian or a decision maker may have authority to provide consent for other types of research activities – for example, research involving the collection of information about the adult, or the participation of the adult in an observational study.

Where there is no advance personal plan and where neither a guardian nor decision maker has authority to provide consent for the research activity, NTCAT may provide the requisite consent. Therefore, NTCAT may provide consent for an adult with impaired capacity to participate in a research activity that involves *health care action*.

Can a medical research procedure be carried out on an impaired capacity patient without consent in emergency circumstances?

There are no specific provisions in the Northern Territory legislation permitting the conduct of research in the emergency context on a person with impaired capacity without a requirement to obtain consent. The common law principles regarding the provision of treatment may apply to certain research. After reviewing this document, a Northern Territory Department of Health representative informed NHMRC that for certain research studies – for example, an ambulance-administered trial for head injuries - consent is not ordinarily sought from NTCAT for an adult who meets the relevant study's enrolment criteria, unless that person is already subject to a guardianship order. However, there is no decision of a Northern Territory court or NTCAT that supports this approach. Further, despite the absence of a guardianship order, the ability to enrol an individual in such circumstances may be limited by any advance consent decision.

Checklist of matters for HRECs to consider

- Does the research involve adult participants who lack the capacity to provide informed consent?
- Does the research involve *restricted health care* or *restricted health care action* as defined in the legislation?
- Has the researcher considered how he or she will ascertain whether a proposed participant has made an advance consent decision?
- Has the researcher considered how he or she will ascertain whether a guardian or a decision maker has been appointed in relation to a proposed participant?
- In respect of proposed participants who have not made an advance consent decision or in respect of whom a guardian or a decision maker has not been appointed, does the research proposal include the appropriate details for an application to be made to NTCAT to provide the requisite consent (where required for the specific type of research)?
- Is the HREC's approval conditional on 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?