NT Health

Procedure

Due for review: 01/01/2028

Approved Procedure 30

Non-psychiatric Treatment, Major Medical Procedures, Clinical Trials and Experimental Treatments

Mental Health and Related Services Act 1998

Sections 63, 64 and 65

Contents

Applicability

This procedure applies to:

- All NT Health employees

NORTHERN TERRITORY GOVERNMENT

Procedure details

The Mental Health and Related Services Act 1998 (the Act) regulates the delivery of non-psychiatric treatment and major medical procedures to patients under the Act and their involvement in clinical trials and experimental treatments. When a patient is incapable of giving informed consent, the Act sets out a process for exploring options for obtaining substitute consent on their behalf.

The purpose of this procedure is to outline the requirements for compliance with sections 63, 64 and 65 of the Act, including consent to non-psychiatric treatment, major medical procedures, clinical trials and/or experimental treatments.

This document also identifies the medical procedures that have been specified by the Chief Health Officer to be major medical procedures.

Informed consent

Under the provisions of section 7 of the Act, informed consent is given when:

(a) the person's consent is freely and voluntarily given without any inducement being offered;
(b) the person is capable of understanding the effects of giving consent; and
(c) the person communicates his or her consent on the approved form.

Section 7(3) of the Act states that a person can give informed consent only when he or she has been given:

(a) a clear explanation of the assessment and possible diagnosis, the nature of the proposed treatment, including sufficient information about the type of treatment, its purpose and likely duration to permit the person to make a balanced judgment regarding undertaking it; and
(b) an adequate description, without concealment, exaggeration or distortion, of the benefits, discomforts and risks associated with the treatment; and
(c) an adequate description of any appropriate alternative form of treatment that is reasonably available; and
(d) a clear answer to all relevant questions asked by the person (and the answer has been understood by the person); and
(e) advice that the treatment may be refused or consent may be withdrawn at any time while the treatment is being undertaken; and
(f) advice that independent legal or medical advice may be obtained in relation to the treatment before giving consent (and reasonable assistance is provided to obtain that advice, if requested); and
(g) advice of all rights of review and appeal under this Act; and
(h) advice of any relevant financial advantage that may be gained by a medical practitioner proposing the treatment and by the approved treatment facility or approved treatment agency where the treatment is to be undertaken; and
(i) advice of any relevant research relationship between a medical practitioner proposing the treatment and the approved treatment facility or approved treatment agency where the treatment is to be undertaken; and
(j) explanations, descriptions and advice in a manner or form that the person is used to communicating in (and due regard is to be given to age, culture, disability, impairment and any other factors that may influence the person understanding the explanation).

Practice Note: Consent for a patient under 18 years

It is now accepted as part of the common law that a child may have capacity to give informed consent to a treatment if the child has enough intelligence and maturity to fully understand the nature and consequences of the treatment. It is necessary to look at the individual child's capacity and maturity as well as the seriousness of the proposed type of treatment. Where the child can give a valid consent, the consent of the parents or guardians is not strictly necessary. However, parents and guardians should be involved in the decision wherever possible. The National Health and Medical Research Council guidelines about research involving children and young people require that consent be obtained from the child (if they have sufficient competence) and their parents/guardians in all but exceptional circumstances.

Where a patient under the age of 18 years is incapable of giving consent, the parent or guardian may give consent on their behalf. Authorisation by the Family Court of Australia may also be necessary if the treatment, procedure or clinical trial involves:

- difficult ethical issues;
- irreversible procedures;
- life-threatening situations;
- treatments of significant risk; and/or
- disputed treatments (where the child or the child's parents or guardians are in dispute about the proposed treatment).

The APP should seek advice from the Public Guardian if there is any doubt about whether a parent or guardian has the power to give consent on behalf of a child.

Practice Note: Advance Personal Plans and enduring power of attorney

When considering, consent, a reasonable attempt must be made to determine whether the person has an Advance Personal Plan or enduring power of attorney in place. If so, there may be provisions that impact upon medical or other clinical management and care for the person.

Checks must therefore be made with the person' family, the public trustee and within hospital records. If such a document in place, it must be examined to determine if:

(a) there is a decision maker appointed (which there will be with a power of attorney; and
(b) if they are appointed to make decisions in relation to medical treatment.

If there is no decision maker appointed in an Advance Personal Plan, the direction the patient has given in that document in relation to medical treatment must be considered and their wishes followed as applicable.

If the matter is to go before the Tribunal, the documentation provided to the Tribunal is to include any relevant details of the Advance Personal Plan and power of attorney.

The person must also must be given adequate time to consider the information under the requirements of section 7(3) before being asked to give his or her informed consent and if a person is unable to communicate adequately in English but able to communicate adequately in another language, they are to be assisted by a competent interpreter (see section 7(5)).

Practice Note:

The person should be given adequate time to consider their response before providing consent. In the case of clinical trials or experimental treatment, clinicians should provide enough time for the person to obtain legal advice or a second medical opinion.

Factors that may impact on a person's willingness or ability to communicate include:

- a lack of trust because of previous experiences with mental health services;
- confusion or feeling unsafe,
- past trauma,
- currently living with domestic/family violence, homeless, addiction, financial distress and/or other health concerns; and/or
- needing someone to look after their children and/or pets while they are in hospital.

It is important for clinicians to consider these factors while interacting with the person over required treatment, medical procedures or participation in clinical trials.

Section 7(6) allows for the person, whose informed consent is being sought to request that another person be present while the informed consent is obtained.

Practice Note:

The person should be given verbal and written information regarding their rights as a patient undergoing non-psychiatric treatment, major medical procedures, and/or clinical trials and experimental treatments.

More information regarding consumer and carer rights can be accessed from the guides located on the Department of Health internet site.

If the person appears not to have understood the explanation, arrangements must be made to convey the information to the person in the language, or mode of communication or terms that the person is most likely to understand, including in writing.

Clinicians are to ensure that the level of protection of patient rights intended by sections 63 - 65 of the Act including the need for consultation with the patient's primary carer have been observed and related actions and decisions are to be adequately documented in the patient's clinical records including the basis for clinical decision making and plans for treatment and management.

Procedure

Requirements under the Act

Non-psychiatric treatment

Under the provisions of section 63(2) and (2A), it is an offence for a person to perform non-psychiatric treatment on another person who is:

(a) an involuntary patient or subject to a community management order; and
(b) being assessed or receiving treatment under the Act,

unless the treatment is in accordance with section 63 of the Act.

Section 63(1) states that non-psychiatric treatment means any of the following treatment, if the primary purpose is not directed at the treatment of a mental illness, mental disturbance or complex cognitive impairment or its effects:

- Any surgical operation or procedure or a series of related surgical operations or procedures.
- Administration of an anaesthetic for the purposes of medical investigation.
- Administration of a course of treatment or medication requiring a prescription or medical supervision.

Consent to treatment

Under the requirements of section 63 non -psychiatric treatment must not be performed unless:

(a) the informed consent of the person is obtained; or
(b) the treatment is approved by the Tribunal; or
(c) informed consent for the treatment is obtained from an adult guardian or decision maker for the person, or from the Northern Territory Civil and Administrative Tribunal (NTCAT), in accordance with Part 4 of the Advance Personal Planning Act 2013.

Treatment in the case of an emergency

Section 63(4) allows for non - psychiatric treatment to be performed without being approved or without consent, where it is immediately necessary for the following:

(a) to save the person's life or to prevent irreparable harm to the person; or
(b) to remove a threat of permanent disability to the person; or
(c) to remove a life threatening risk to, or to relieve acute pain of, the person.

In which case, the person performing the procedure must report the fact to the Tribunal as soon as possible after the treatment is performed (section 63(5)). Also, if the person undergoing the treatment has an adult guardian or decision maker, the person performing the procedure must report the fact to the adult guardian or decision maker as soon as possible after the treatment is performed under section 63(6).

Refer to Attachment A - Non-psychiatric treatment flowchart for further information.

Major medical procedures

Under section 64(1) and (1A), it is an offence for a person to perform a major medical procedure on a person who is an involuntary patient or subject to a community management order unless the procedure is performed in accordance with section 64 of the Act.

Under the provisions of section 64(5), the Chief Health Officer specifies those medical procedures that are major medical procedures for the purposes of this section of the Act.

Practice Note:

The Chief Health Officer has specified the following medical procedures as major medical procedures:

- any surgery performed under a general or regional anaesthetic;
- use of general or regional block anaesthetic for any purpose;
- a course of contraceptive medication commenced during involuntary admission;
- chemotherapy; and
- radiotherapy.

Consent to treatment

Section 64(2), states that a major medical procedure must not be performed on a person unless:

(a) it is approved by the Tribunal; or

(b) informed consent is obtained from a decision maker for the person, or from the Northern Territory Civil and Administrative Tribunal (NTCAT), in accordance with Part 4 of the Advance Personal Planning Act 2013.

Treatment in the case of an emergency

However section 64(3), allows for an APP to authorise the performance of a major medical procedure on a person where it is immediately necessary to:

(a) save the life of the person; or

(b) prevent irreparable harm to the person.

In which case, under section 64(4), the APP must notify the following **no later than one day** after authorising the procedure:

(a) the Tribunal; and

(b) the person's adult guardian; and

(c) if the person has a decision maker – the decision maker.

Refer to Attachment B – Major medical procedure flowchart for further information.

Clinical trials and experimental treatments

Practice Note:

Generally, a procedure would involve some physical or pharmacological intervention for it to be considered a clinical trial or experimental procedure. Questionnaires or research involving non-intrusive examinations would not generally be considered to be procedures and therefore would not fall within the provisions of section 65.

This procedure does not consider how research should be designed, approved or conducted to conform to the ethical principles and values that govern research-involving humans in Australia. Researchers must comply with all relevant guidelines issued by the National Health and Medical Research Council. Information is available from their website at: https://nhmrc.gov.au/.

Consent to treatment

Under the provisions of section 65 of the Act, it is an offence for a person to perform a clinical trial or experimental treatment on a person who is an involuntary patient or subject to a community management order unless:

(a) the trial or treatment is approved by an ethics committee nominated by the Chief Health Officer; and

(b) either:

(i). the person, or a decision maker for the person, gives informed consent to the trial or treatment; or

(ii). the Tribunal gives approval to the trial or treatment.

Practice Note: Authorisation by the Tribunal

An APP cannot consent to involvement in a clinical trial or experimental procedure on behalf of the patient, even when the research may be considered to be a psychiatric treatment, for example, a drug trial intended to treat the person's mental illness.

The Tribunal may consent to the patient's involvement, if the patient is incapable of giving consent and the procedure would be in the best interests of the patient.

Where researchers propose to enrol patients into a research project, the research protocol should be lodged with the Tribunal so that the Tribunal is fully cognisant of the project before considering the matter.

In deciding whether to consent to a clinical trial or experimental procedure the Tribunal must be satisfied that the research would be in the best interests of the patient. One of the matters the Tribunal must take into account when deciding whether the research would be in the best interests of a patient is the wishes of any nearest relative or other family members.

Recording Consent

Non–psychiatric Treatment and Major Medical Treatment

Voluntary patients

Informed consent for a voluntary patient is recorded via **2 Admission and Treatment as a Voluntary Patient Form**, where the patient is able to give consent.

Involuntary patients or patients under a community management order

Authorisation of the Tribunal can be requested via **23 Non - Psychiatric or Major Medical Treatment Authorisation or Notification Form**.

Consent by the person's Adult Guardian or nominated decision maker is to be requested via **23 Non - Psychiatric or Major Medical Treatment Authorisation or Notification Form**.

Clinical trials or experimental procedures

25 Clinical Trials or Experimental Procedures Consent Form may be used to record consent to involvement in a clinical trial or experimental procedure

Authorisation by the Tribunal can be requested via **24 Clinical Trials or Experimental Procedures Tribunal Approval Form**.

Notification following emergency treatment

Non-psychiatric treatment and major medical procedures may also be undertaken on involuntary patients or patients under a community management order in emergency situations as previously described.

If this has occurred, the Tribunal can be notified via **23 Non - Psychiatric or Major Medical Treatment Authorisation or Notification Form** and, if appropriate, the person's Adult Guardian or nominated decision maker can be notified via **Form 56 Adult Guardian Approval or Notification**.

Operational requirements not prescribed by the Act

Other Documentation

In addition to the statutory requirements for documentation, good clinical practice requires that the clinical record show documentation of the requirements of professional standards of practice, guidelines and relevant local policy and procedures, including:

- any risk assessment undertaken;
- a treatment plan;
- the rationale for the proposed non-psychiatric treatment or major medical procedure;
- details of the process of gaining consent;
- details of any second opinions, where applicable;
- details of the practitioner who performed the non-psychiatric treatment; and
- the person's response to the treatment.

Where a substitute decision maker has given consent to the non-psychiatric treatment, a copy of the relevant document or order giving authority for the person to consent to the treatment (for example, a guardianship order or some other evidence of the person's power to give consent) should be in the clinical record.

Practice Note:

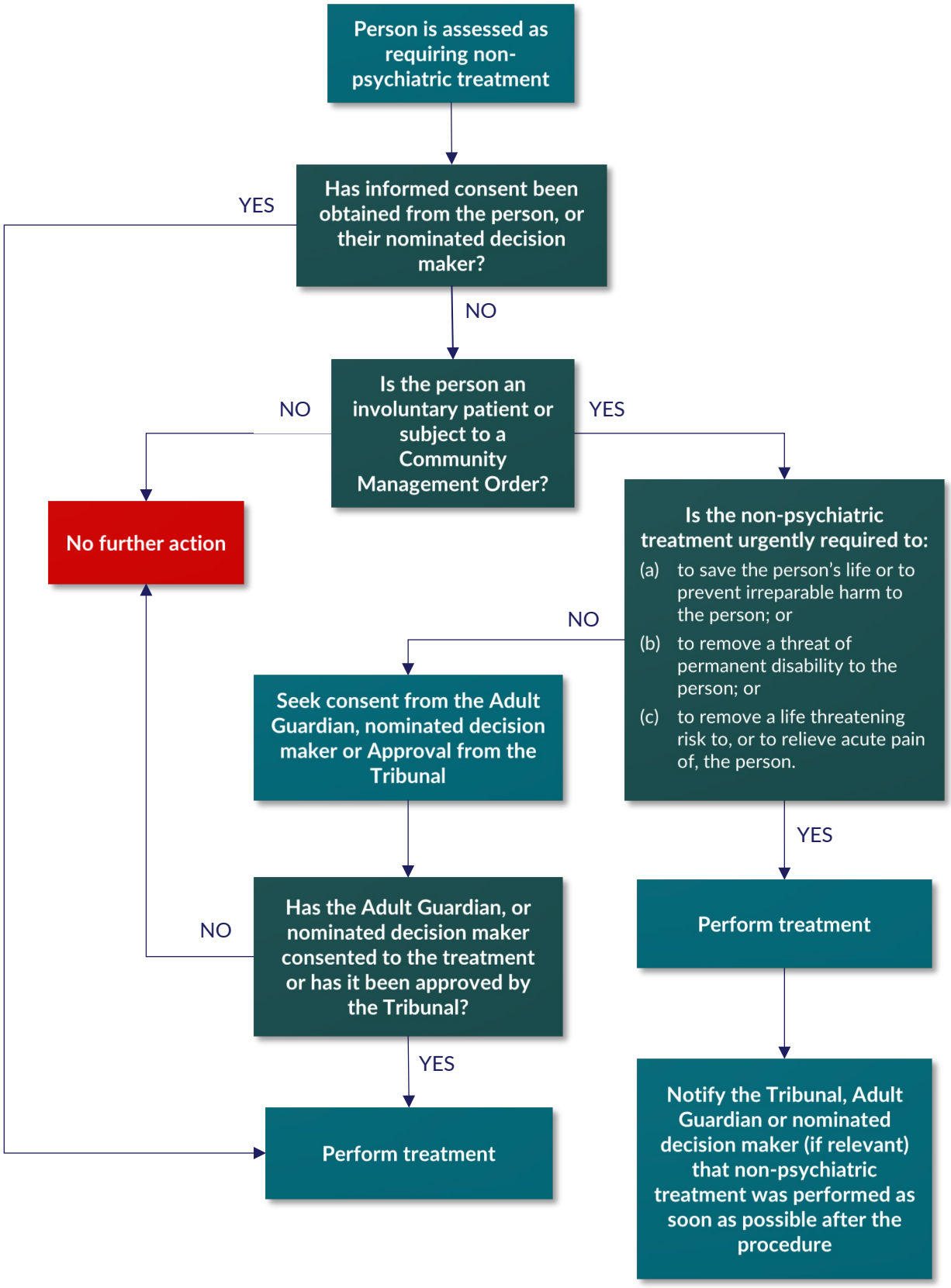
If a person is involved in a clinical trial or experimental treatment they should be provided with a full copy of information pertaining this that is theirs to keep. If they are unable to accept it at the time, then it should be provided with discharge documentation and sent to their General Practitioner with the discharge summary.

Key Associated Documents

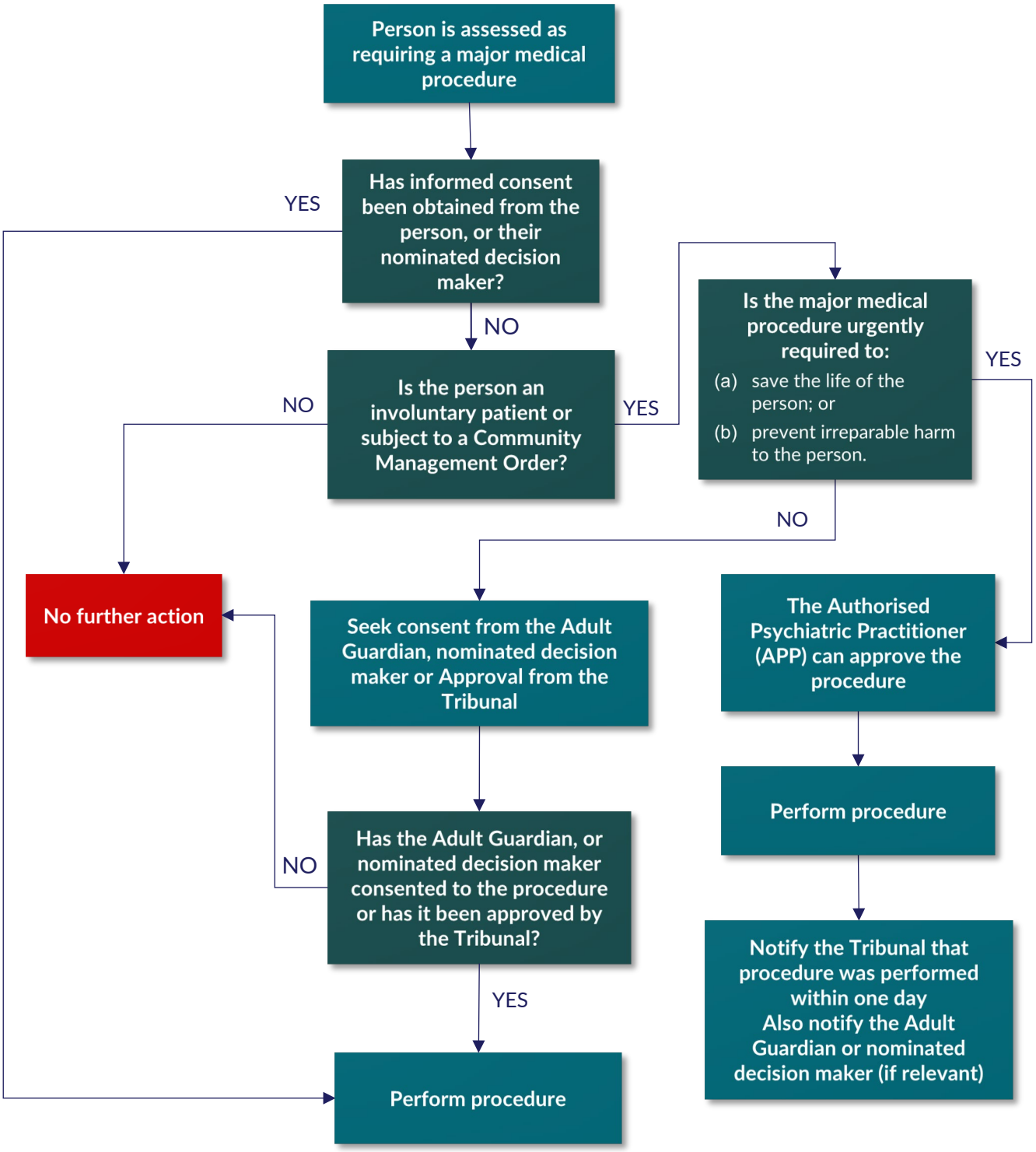
All related material produced by the Northern Territory Department of Health is available from: https://health.nt.gov.au/professionals/mental-health-information-for-health-professional

Mental Health and Related Services (MHARS) Act 1998

Attachment A - Non-psychiatric treatment flowchart



Attachment B – Major medical procedure flowchart



Definitions

Term	Definition
APP	Authorised Psychiatric Practitioner
APQAC	Approved Procedures and Quality Assurance Committee
Informed Consent	Consent that meets the provisions of section 7 of the Mental Health and Related Services Act 1998, as described in the content of this procedure.
Major Medical Procedure	Pursuant to section 64(5) of the Mental Health and Related Services Act 1998, the Chief Health Officer has specified the following medical procedures as major medical procedures: • any surgery performed under a general or regional anaesthetic; • use of general or regional block anaesthetic for any purpose; • chemotherapy; and • radiotherapy.
MHARS Act	*Mental Health and Related Services Act 1998*
Nominated decision maker	Someone nominated by a person to make decisions on their behalf under an Advance Personal Plan or enduring Power of Attorney.
Non-psychiatric treatment	Includes any of the following treatment if its primary purpose is not directed at treating a mental illness, mental disturbance or complex cognitive impairment or its effects: (a) a surgical operation or procedure or a series of related surgical operations or procedures; (b) the administration of an anaesthetic for the purposes of medical investigation; the administration of a course of treatment or medication requiring a prescription or medical supervision.
Patient	A person who is being assessed or receiving treatment under the Mental Health and Related Services Act 1998

Document history

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National Safety and Quality Health Service standards

National Safety and Quality Health Service standards							
Clinical Governance	Partnering with Consumers	Preventing and Controlling Healthcare Associated Infection	Medication Safety	Comprehensive Care	Communicating for Safety	Blood Management	Recognising & Responding to Acute Deterioration
☒	☒	☐	☐	☐	☐	☐	☐