NSW GOVERNMENT Health

Mr Alan Cameron AO
Chairperson
NSW Law Reform Commission
GPO Box 31
SYDNEY NSW 2001

Your ref

By email: nsw-lrc@justice.nsw.gov.au

Dear Mr Cameron

Review of the Guardianship Act 1987 – Question Paper 5 – medical and dental treatment and restrictive practices – NSW Health submission

The NSW Ministry of Health appreciates the opportunity to comment on *Question Paper 5: Medical and dental treatment and restrictive practices*. The issues canvassed in Question Paper 5 are highly significant for the NSW Health system and legislation and policy in the Health portfolio.

Introduction

The responses to specific questions in this submission raise common themes.

- The Ministry submits that the definition in the *Guardianship Act* (the Act) to medical and dental treatment should be replaced with treatment provided by 'registered health practitioners', to better reflect modern team based healthcare and the evolving scope of practice of other practitioners who may perform procedures previously only performed by medical practitioners.
- The Act allows persons responsible to consent to the 'carrying out' of medical and dental treatment for the 'health and wellbeing' of the patient. The Ministry requests that this be replaced with a best interest's test, as these terms are overly restrictive and confusing, particularly in the end of life context.
- Decisions for consent to 'special' medical treatment, forensic examinations and clinical trial participation must be referred to NCAT. These decisions are often time critical and effort should be made to ensure that decisions in these matters can be made in a timelier manner.

Capacity to consent to medical and dental treatment

Question 2.1: "incapable of giving consent"

(1) Is the definition of a person "incapable of giving consent to the carrying out of medical or dental treatment" in s33 (2) of the Guardianship Act 1987 (NSW) appropriate? If not, what should the definition be?

Section 33 (2) defines a person as incapable of giving consent to the carrying out of medical or dental treatment where the person:

(a) is incapable of understanding the general nature and effect of the proposed treatment, or
(b) is incapable of indicating whether or not he or she consents or does not consent to the treatment being carried out.

NSW Ministry of Health
ABN 92 697 899 630
73 Miller St North Sydney NSW 2060
Locked Mail Bag 961 North Sydney NSW 2059
Tel. (02) 9391 9000 Fax. (02) 9391 9101
Website. www.health.nsw.gov.au

This should be aligned with the common law definition of capacity established in Re C[1] and the definition for capacity used by NSW Health by including a requirement that the person be able to consider the consequences of consenting to, or refusing the treatment.

The NSW Health system understands a patient to have capacity if they can:
1) understand the facts and choices involved;
2) weigh up the consequences; and
3) communicate their decision.

(2) Should the definition used to determine if someone is capable of consenting to medical or dental treatment align with the definitions of capacity and incapacity found elsewhere in the *Guardianship Act 1987* (NSW)? If so, how could we achieve this?

Yes. The definition for capacity suggested above should apply throughout the Act.

Types of medical and dental treatment

Question 3.1: Withholding or stopping life-sustaining treatment

(1) Should Part 5 of the *Guardianship Act 1987* (NSW) state who, if anyone, can consent to withholding or stopping life-sustaining treatment for someone without decision-making capacity?

Yes. As noted in NSW Health's preliminary submissions to this review, NSW public health services and staff have provided continuous feedback to the Ministry of Health over many years relating to the challenges implementing the case law and legislation governing the role of a substitute decision maker in relation to end of life care and treatment.

(2) If so, who should be able to consent and in what circumstances?

Section 36 of the Act allows a "person responsible" to consent to the *carrying out* of medical or dental treatment on a patient to whom Part 5 of the Act applies. The objects of Part 5 are set out in section 32 and require any medical or dental treatment to be carried out for the purpose of *promoting the health and wellbeing* of the patient.

Interpretation of both "carrying out" and "promoting and maintaining health and wellbeing" in the end-of-life context are restrictive and confusing in clinical practice.

At present, a person responsible can consent to palliation, but cannot consent to withdrawing 'active' treatments, although in reality, this may amount to the same thing.

The Act should give persons responsible the same authority to consent to end of life decisions that enduring guardians with end of life functions have, that is, persons responsible should be able to consent to withdrawing or withholding life sustaining treatments, provided that they are acting in the patient's best interests. In order to achieve this

- the words "carrying out" of treatment should be removed from the section, as they are too restrictive.
- the current test of "promoting health and wellbeing" of the person should be replaced with a requirement to act in the person's best interests. This would align the Act with the common law and several other Australian jurisdictions. As noted in NSW Health's preliminary submission, cases have interpreted best interests to encompass enabling a more peaceful dignified death, without the burden of continuing treatments which are therapeutically ineffective, or are excessively burdensome or intrusive.

[1] Re C (Re C (adult refusal of medical treatment [1994] 1 WLR 290, [1994] 1 All ER 819)

Question 3.2: Removing and using human tissue

(1) Should Part 5 of the *Guardianship Act 1987* (NSW) state who, if anyone, can consent to the removal and use of human tissue for a person who lacks decision-making capacity?

No, as it would conflict with current provisions in the *Human Tissue Act 1983* (HTA). Consent to the donation of both regenerative and non-regenerative tissue from living (and deceased) donors is already dealt with in the HTA.

Current NSW Health position on both living kidney and living liver donation is that only a competent adult donor can consent to the donation and substitute consent to donation is not permitted, as a result, adults who lack decision making capacity should not be accepted by clinicians as living donors because of their inability to fully understand the risks and decide voluntarily on the donation.

Living kidney and liver donors undergo surgical procedures that are not therapeutic for the donor and pose considerable risk - e.g. evidence suggests there is a 2% mortality risk for living liver donation. Essentially a healthy donor will be exposed to potential harms. The risks to the donor include:

- Surgical risks
- Immediate complications as a result of the procedure including risk of their own kidney/liver failure and the potential need for their own transplant.
- Risk of death
- Other long terms risks.

Due to the level of risk, the preferred position is that these donations only occur after the donor has given informed consent.

In any event, there are alternative sources of therapies (usually) available for tissue transplantation e.g. unrelated bone marrow /cord blood donation; deceased solid organ donation; dialysis etc. This means that cases requiring substitute consent to the removal of tissue for transplantation are rare.

S21Z of the HTA does allow a person responsible/Guardian to consent to the retention and use of tissue that is removed during a medical, dental or surgical procedure that has been performed in the interests of the health of the person.

(2) If so, who should be able to consent and in what circumstances?

Currently courts exercising *parens patriae* jurisdiction are empowered to authorise removal of human tissue where it is not for the therapeutic benefit of the person under guardianship. Removal of tissue for the purposes of transplantation into another person cannot be said to promote the health and wellbeing of the donor, but could potentially be in the best interests of the donor, as it may have a positive impact on relationships between the donor, recipient and other family members.

The NSW Supreme Court *has* authorised cases of living tissue donation (bone marrow donation) on the basis that the possibility of experiencing the psychological harm that might arise from not attempting to save the life of a sibling and the effect that the death of the sibling might have on the potential donor's future living and care arrangements was not in the donor's best interests.

However, if requiring a family to approach a Court for these types of applications is viewed as creating an unnecessary burden, NSW Health is not averse to considering alternatives.

The Question Paper recognises that other guardianship regimes in Australia allow equivalents to the Guardianship Division of NCAT (NCAT) to authorise the removal of tissue for transplantation from a person without capacity. These regimes require certain factors to be satisfied before the Tribunal can provide authorisation, such as that the risk to the person

is low. If amendments were to be considered for NSW, it would be preferable to adopt an approach with similar protections for persons without capacity.

To maintain consistency with the existing guidelines in NSW in relation to assessment of a living donor (*with* decision making capacity) a Tribunal should consider guidelines on assessment of the following factors (this is not an exhaustive list):

- The relationship between the potential donor and recipient (normally this would be assessed as part of the live donor assessment)
- The potential for a conflict of interest or coercion in the relationship (again, normally assessed as part of a live donor assessment)
- The alternative sources of therapy available –e.g. unrelated bone marrow /cord blood donation; deceased solid organ donation; dialysis etc
- The degree of risk to the donor posed by the donation
- Whether the potential donor (if previously competent) had ever indicated willingness or objection to donation.

If this is pursued, NSW Health would appreciate being involved in further consultations.

Question 3.3: Treatment by a registered health practitioner

Should the definition of medical and dental treatment in Part 5 of the *Guardianship Act 1987* (NSW) include treatment by a registered health practitioner?

Yes. NSW Health considers the definition of medical and dental treatment in Part 5 of the Act should include treatment by a registered health practitioner. 'Registered health practitioner' should be defined in the Act using the definition found in the *Health Practitioner Regulation National Law* (NSW). Amendments to include the term 'health practitioner' rather than only medical or dental practitioners would enable the Act to be more contemporary in referring to the changing health landscape and evolving scope of practice of other healthcare practitioners who may perform procedures traditionally performed by medical or dental practitioners (such as nurse practitioners and surgical or physicians assistants).

Paramedics are not currently registered health practitioners and should also be included in the definition in the Act, although it is expected that paramedics will become a registered health profession in late 2018.

Question 3.4: Types of treatment covered by Part 5

(1) Are there any other types of treatment excluded from Part 5 of the *Guardianship Act 1987* (NSW) (or whose inclusion is uncertain) that should be included?

Withdrawing / withholding life sustaining treatment

If Part 5 is not amended to remove the reference to "carrying out" treatment and adopt a best interests test in place of the requirement that treatment promote the health and wellbeing of the patient, the definition of medical and dental treatment ought to include the withdrawal or withholding of life sustaining treatment.

(2) Should any types of treatment included in Part 5 of the *Guardianship Act 1987* (NSW) be excluded?

See responses above.

Consent to medical and dental treatment

Question 4.1: Special treatment

Timeliness of decision making

The main issue with the current provisions relating to special treatment is timeliness. In terms of pregnancy, terminations, sterilisation and implementation of long acting contraceptives, timeliness of decision making and implementation of decisions is critical as delay may be life threatening or increase the risk of procedures. For example, in the context of pregnancy terminations where the risk must be proportionate, a delay of a number of weeks may significantly increase the risk to the health of the woman or their future fertility. In some cases, a delay may result in the procedure carrying too much risk to be undertaken despite the risks associated with an ongoing pregnancy.

Currently if a decision is required to be reviewed by NCAT a timely decision is not able to be made. The experiences of NSW Health clinicians indicate that it may take months for NCAT to process requests. It is recognised that some delay at the NCAT level may be of an operational manner and therefore outside the scope of the review of the legislation.

Terminology

References in the Act and in the *Guardianship Regulations 2016* should be consistent with respect to 'special medical treatment'. 'Special medical treatment' is defined in s 33 of the Act while the *Guardianship Regulations 2016* appears to use the terms 'special treatment' and 'special medical treatment' interchangeably. The use of 'special medical treatment' should be used throughout and should be consistent with the terminology used in the *Children and Young Persons (Care and Protection) Act 1998.*

(1) Is the definition of special treatment appropriate? Should anything be added? Should anything be taken out?

The classification of termination of pregnancy as special medical treatment is different from the definitions of special medical treatment in both the *Mental Health Act 2007* (the MHA) and the *Children and Young People (Care and Protection) Act 1998* (the Care Act).

The MHA contains provisions regulating the carrying out of special medical treatment on "involuntary patients." Special medical treatment is defined under the MHA as any treatment, procedure, operation or examination that is intended, or is reasonably likely, to have the effect of rendering the patient permanently infertile. The definition of special medical treatment in the MHA is more limited than the expansive definition given in the Act and does not include termination of pregnancy, which means it is not necessary to seek consent from the Mental Health Review Tribunal for that treatment. The Secretary, NSW Health, can provide consent for surgical terminations.

The Care Act also sets out a regime requiring consent from NCAT for the carrying out of special medical treatment, for minors aged 15 and under, however, termination of pregnancy is not special medical treatment for the purposes of the Care Act.

There may be merit in considering whether the inclusion of termination of pregnancy as a special medical treatment in the Act remains appropriate given the approach taken in other legislation. The fact that medical terminations can now be provided without the need for surgery is also a relevant consideration.

Further, the current differences between the legislative regimes have some operational impact in NSW Health. For example, the differences require clinicians (particularly in the mental health field) to be aware of different substituted decision making regimes that are dependent on a patient's status and the nature of the treatment required and not necessarily on the needs or interests of the individual patient themselves. The differences have the

potential to lead to different outcomes for similar patients requiring the same types of treatment (noting that these different legislative regimes may have some different considerations that apply).

In deciding whether to continue to classify termination of pregnancy as special medical treatment under the Act, it should be noted that there are existing legal requirements in place which provide safeguards around the provision of treatment for the termination of pregnancy. In NSW, termination will only be lawful where the medical practitioner procuring the termination has an honest belief based on reasonable grounds that the procedure is necessary to preserve the woman from serious danger to her life, or physical or mental health, and the procedure must not be out of proportion to the danger intended to be avoided. These requirements should be taken into account in considering whether the additional approval (?) of NCAT remains appropriate.

If concerns were held about the potential risks of removing the oversight by NCAT in this area, one option may be for termination of pregnancy to be classified as major medical treatment (although it is not associated with a high level of clinical risk to the patient, as are many other types of major medical treatment). Consideration could be given to distinguishing medical and surgical terminations, based on the risk that each type of treatment poses to the patient.

Overall, NSW Health's concern is that categorisation of terminations as a special treatment significantly impedes timeliness. Given the current legislative and case law restrictions to the provision of terminations, in practice, a termination would only be considered for a patient covered by the Act where the pregnancy would place the patient at risk due to their comorbidities. Given the escalation of risks which occurs with delay in the case of terminations and the significant existing restrictions on the use of the procedure, the current classification of termination as special medical treatment and the delayed decision making that then follows has a significant clinical impact on NSW Health patients.

(2) Who should be able to consent to special treatment and in what circumstances?

Special medical treatment should only be able to be carried out if an order is obtained from NCAT or a court or by a guardian as currently required under the Act.

(3) How should a patient's objection be taken into account?

The current provisions are appropriate.

(4) In what circumstances could special treatment be carried out without consent?

It should be permissible to provide special treatment in an emergency, as is the current situation.

Question 4.2: Major treatment

(1) Is the definition of major treatment appropriate? Should anything be added? Should anything be taken out?

Testing for human immune-deficiency virus (HIV) should be removed from the category of major treatment. Any treatment involving testing for the HIV is currently classified as major medical treatment. HIV is now considered to be a chronic disease, and managed accordingly. The view of the NSW Ministry of Health is that classification of HIV testing as "major medical treatment" does not reflect the current policy context for HIV testing in NSW.

The NSW HIV Strategy 2016-2020 aims to achieve the virtual elimination of HIV transmission in NSW by 2020. As part of the strategy, regular and routine HIV testing (2-4 times per year for gay and homosexually active men) is recommended. Frequent testing of patients in at-

risk populations facilities early diagnosis of HIV and treatment initiation which provides better health outcomes for patients and prevents onwards transmission.

Current policy and practice therefore aims to de-stigmatise HIV and make HIV testing routine, which is inconsistent with the classification of HIV testing as major medical treatment. Most other treatment listed as major treatment in the Regulation is treatment that has a permanent impact on a patient, or carries a significant risk. HIV testing is neither.

(2) Who should be able to consent to major treatment and in what circumstances?

The current framework is appropriate.

(3) How should a patient's objection be taken into account?

If a person does not have capacity to consent to medical treatment there would only be limited circumstances where the patient's objection should impact on the person responsible or guardian's authority to consent to or refuse medical or dental treatment, particularly as the person responsible/guardian is bound to only consent to treatment that will promote the patient's health and wellbeing (or preferably, be in the patient's best interests). However, circumstances where objections should **always** be taken into account would include where the patient previously refused the treatment by creating a valid Advance Care Directive at a time when they had capacity to do so.

(4) In what circumstances could major treatment be carried out without consent?

The current framework is appropriate.

Question 4.3: Minor treatment

(1) Is the definition of minor treatment appropriate? Should anything be added? Should anything be taken out?

The current definition is appropriate.

(2) Who should be able to consent to minor treatment and in what circumstances?

The current framework is appropriate.

(3) How should a patient's objection be taken into account?

The current framework is appropriate.

(4) In what circumstances could minor treatment be carried out without consent?

The current framework is appropriate.

Question 4.4: Treatment that is not medical or dental treatment

Does the *Guardianship Act 1987* deal with treatments that fall outside of the Part 5 regime adequately and clearly?

NSW Health considers that the Act should replace all references to medical and dental practitioners with health practitioners as defined in the *Health Practitioner Regulation National Law* (NSW). The Act needs updating to reflect that medical and dental practitioners are no longer the only health professionals providing health treatment.

Question 4.5: Categories of treatment as a whole

(1) Does the legislation make clear what consent requirements apply in any particular circumstance? If not, how could it be clearer?

See response to 4.4.

(2) Do you have any other comments about the treatment categories and associated consent regimes in Part 5?

No.

Question 4.6: Person responsible

(1) Is the "person responsible" hierarchy appropriate and clear? If not, what changes should be made?

NSW Health finds that in most cases the person responsible hierarchy operates well in practice, however, there are examples of conflict between persons responsible which can be extremely distressing for patients, families and staff, particularly in the end of life context.

It is suggested that that consideration be given to the following:

- Clarification as to what should occur if there is conflict between more than one guardian or person responsible with equal status on the hierarchy. In this situation clinicians attempt to reach consensus. It could be specified in the Act that if consensus cannot be reached an application to NCAT or the Public Guardian is required, as in QLD.

- Breaking the categories in the hierarchy down further to create additional categories would reduce the potential for conflict between persons' responsible. One option would be to align the definition of person responsible more closely with the definition of a Senior Available Next of Kin (SANOK) in the HTA. The HTA definition of a SANOK is:

  (i) a person who was a spouse of the deceased person immediately before the deceased person's death,
  (ii) where the deceased person, immediately before death, had no spouse or where the deceased person had a spouse but the person who was then the deceased person's spouse is not available—a son or daughter (if any) of the deceased person, being a son or daughter who has attained the age of 18 years,
  (iii) where no person referred to in subparagraph (i) or (ii) is available—a parent of the deceased person, or
  (iv) where no person referred to in subparagraph (i), (ii) or (iii) is available—a brother or sister of the deceased person, being a brother or sister who has attained the age of 18 years.

NSW Health does not agree with the Council on the Ageing NSW suggestion that if a person revokes their responsibility then it should automatically pass to the next person and not be required to be in writing. In practice, where families are in conflict, it is best for the protection of health professionals and health services to have a revocation in writing.

Whilst an application can be made to NCAT in circumstances where health services consider that a person responsible is not acting in the patient's best interests, perhaps consideration could be given to a provision allowing health professionals to automatically obtain consent from the next person down on the hierarchy in circumstances where the person responsible is a person of interest or suspected perpetrator of family violence or other abuse towards the patient.

(2) Does the hierarchy operate effectively? If not, how could its operation be improved?

See response to 4.6 (1) above.

Question 4.7: Factors that should be considered before consent

Are the factors a decision-maker must consider before consenting to treatment appropriate? If not, what could be added or removed?

The person responsible/NCAT should be required to consider whether the person has a valid Advance Care Directive (ACD) and should be required to give effect to directions made in that ACD.

Question 4.8: Requirement that consent be given in writing

Is the requirement that consent requests and consents must be in writing appropriate? If not, what arrangements should be in place?

NSW Health implements this requirement by mandating the use of a specific form for substitute consent for adult patients without capacity. There have not been significant issues raised with the current requirements.

Question 4.9: Supported decision-making for medical and dental treatment decisions

(1) Should NSW have a formal supported decision-making scheme for medical and dental treatment decisions?

Yes. NSW Health's policy is that where patients have a sensory disability (for example, they may be deaf, hearing impaired, blind, vision impaired) or have a communication disability (for example impairment of language, complex communication needs) the health practitioner should rely on appropriate communication aids according to the circumstances.

Discrimination law requires health services to make "reasonable adjustments" to accommodate patients with disabilities. NSW Health considers that reasonable adjustments that could be made in the context of obtaining consent in a public hospital could include:

- Adjusting communication methods by taking into account the patient's communication needs
- Allowing extra time to provide the support that is required
- Including and supporting the patient's carer, family member, guardian or disability support staff as expert care partners
- Providing patient information in alternate formats such as 'easy read' documents.

The NSW Council for Intellectual Disability Fact Sheet *Consent to Medical Treatment* (which will be referenced in the forthcoming NSW Consent to Medical Treatment Manual), suggests the following tips to assist health practitioners when seeking consent from a patient with an intellectual disability to ensure the person understands and can make their own decision:

- Involve someone who the person likes talking to
- Talk about the treatment somewhere that is quiet and where the person feels relaxed
- Try to use words the person knows. If you have to use difficult words, try to explain them simply
- If the person has an alternative communication system, use that
- Use pictures that show the problem and the proposed treatment
- Stick to the basic information. Do not overload the person with detail
- Give the person time to think about the information and then have another talk.

However, this aspect of the NSW Ministry of Health submission proceeds on the premise that Part 5 of the Act does and would continue to only apply to people who are unable to make a decision, even with supported decision making. Part 5 of the Act is clearly the last resort for people that do not have capacity. If a patient is able to make a decision (whether due to supports or otherwise) Part 5 will not be invoked.

(2) If so, what should the features of such a scheme be?

Victoria's *Medical Treatment Planning and Decisions Act 2016* (VIC) could be used as a guide, as long as it does not raise any conflict with the MHA, or any other law in NSW.

Question 4.10: Consent for sterilisation

NSW Health has no specific comment in response to the questions in this section.

Question 4.13: Legislative recognition of advance care directives

(1) Should legislation explicitly recognise advance care directives ("ACD")?

The definition for an ACD in the Question Paper is not the definition used in the NSW public health system. NSW Health defines an ACD as a person's record of decisions or value statements that describes their future preferences relating to medical treatment, to be used in circumstances where the person loses capacity. This includes treatments the person would accept or refuse if they had a life-threatening illness or injury.

NSW Health considers that the question of whether ACDs should be legislated is primarily a matter for the Minister for Health. To date, NSW Health's position has been that the common law is preferable, as it provides sufficient guidance and flexibility. NSW Health is concerned that legislation would make ACDs less accessible for people, for example, if requirements for witnesses, or discussion with medical practitioners were mandated. There may also be a risk that ACDs are assumed to be invalid and not followed because they did not comply with a technical requirement in the legislation. Whilst it is recognised that many other jurisdictions have legislation for ACDs, these jurisdictions do not have the benefit of a strong Supreme Court judgment (as does in NSW)[2].

However, the Act could make it clear that a person responsible/Enduring Guardian cannot override a valid Advance Care Directive.

(2) If so, is the *Guardianship Act 1987* (NSW) the appropriate place to recognise advance care directives?

No. The Act is not the appropriate place to recognise ACDs. The Act relates to persons without capacity whereas an ACD is a document completed a person with capacity. In any event, if there is to be legislation relating to ACDs it should be legislation sitting within the Health portfolio.

Question 4.14: Who should be able to make an advance care directive?

ACD can only be made by an adult with decision making capacity.

Persons responsible or guardians can contribute to advance care planning but cannot complete an ACD on behalf of another person.

Question 4.15: What form should an advance care directive take?

Whilst NSW Health is not in favour of a single form for ACDs, NSW Health is in the process of finalising an ACD Template which will be recommended for use in NSW. The template will

[2] Hunter and New England Area Health Service v A [2009] NSWSC 761

be available on both the NSW Health and the *Get it in Black And White: Planning Ahead Tools* websites. The template will assist people in preparing an ACD and to be confident that their decision and wishes are understood by health care professionals.

Question 4.16: **What matters should an advance care directive be able to cover?**

An ACD can cover whatever future medical treatment the person would like to cover.

Question 4.17: In what circumstances should an advance care directive be invalid?

An ACD is valid if it is made voluntarily by a capable adult, is clear and unambiguous and relates to the clinical situation at hand.

Question 4.18: Part 5 Offences

(1) Are the various offences of treating without authorisation and the maximum penalties that apply appropriate and effective?
(2) Is there a need for any other offences relating to medical and dental treatment?

NSW is not aware of any prosecutions for these offences and is therefore unable to comment on whether they are appropriate.

Clinical trials

Question 5.1: How should the *Guardianship Act 1987* (NSW) define "clinical trial"?

NSW Health would like the current definition of clinical trials at section 33(1) of the Act revised as it is broadly drafted and open to interpretation.

The most widely used definition of clinical trial in Australia is the definition provided by the World Health Organisation:

> *'A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.*

NSW Health encourages the amendment of the Act in order that clinical trials can be conducted without the requirement for any specific interpretation of the term "clinical trial".

For example, the *Guardianship and Administration Act* 1986 (VIC) establishes a scheme for consenting to 'medical research procedures', which includes procedures carried out as part of a clinical trial. A medical research procedure constitutes a broad range of activities, but importantly, includes a statement of that which is not captured within the definition.

medical research procedure *means—*

a) a procedure carried out for the purposes of medical research, including, as part of a clinical trial, the administration of medication or the use of equipment or a device; or
b) a procedure that is prescribed by the regulations to be a medical research procedure for the purposes of this Act
but does not include—
c) any non-intrusive examination (including a visual examination of the mouth, throat, nasal cavity, eyes or ears or the measuring of a person's height, weight or vision); or
d) observing a person's activities; or
e) undertaking a survey; or
f) collecting or using information, including personal information (within the meaning of the Privacy and Data Protection Act 2014) or health information (within the meaning of the Health Records Act 2001); or
g) any other procedure that is prescribed by the regulations not to be a medical research procedure for the purposes of this Act

NSW Health considers that the Victorian legislation provides a workable definition, given that it also provides an alternative regime for conducting clinical trials involving those without capacity to consent.

Question 5.2: Categories of medical research

(1) Should there be more than one category of medical research?
(2) If so, what should those categories be and what consent regimes should apply to each?

Rather than attempt to define a number of categories of medical research, each of which may be open to interpretation, NSW Health considers that a more useful distinction is whether the medical research procedure itself involves an intervention that is different to that which the patient would receive in standard clinical practice or not.

If the research involves an intervention other than standard clinical practice then a substitute consent regime would be followed; however, if no intervention was present in the research, then the normal research approvals, such as HREC approval, would be sufficient, with the attendant procedural safeguards that can be made by the review body.

With regard to consent regimes, there is a good argument for distinguishing between critical care research and non-emergency care research. Critical care patients are usually unable to give consent for participation in a clinical trial.

The mechanisms in place in Part 5 of the Act have been interpreted by NCAT as being for 'new and experimental therapies' and were written specifically so that patients who cannot consent for themselves were not excluded from the benefits of participating in clinical trials. An NCAT order under the Act allows for prospective proxy consent by a 'person responsible', where otherwise the only option is individual prospective consent. NSW Health understands that this current framework works well only when there is a window of opportunity (commonly 12 or 24 hours) to find a 'person responsible'. However, a different regime is required when there is a research intervention in a time critical care area such as a pre-hospital ambulance or intensive care setting, when many times even establishing identifying details about the patient is difficult, let alone identifying and contacting the person responsible.

Question 5.3: Who can consent to clinical trial participation

(1) Who should be able to approve a clinical trial?

A number of international and Australian jurisdictions provide for a mechanism other than a Guardianship Tribunal (or similar) to approve a clinical trial that involves the participation of patients who lack capacity to consent for themselves. [3]

There are examples of legislation in Australian jurisdictions that already address these issues.

Victorian legislation: Guardianship and Administration Act 1986 (Vic)

The Victorian legislation establishes a scheme for consenting to 'medical research procedures'.[4] This involves a four-step procedure:

1) Ensure the research project is "approved by the relevant Human Research Ethics Committee" (HREC) (s42Q);
2) Determine whether the patient is likely to be capable to consent to the procedure within a reasonable time (s42R);
3) Seek the consent of the person responsible for the patient (s42S); and

[3] The Medicines for Human Use (Clinical Trials) Regulations 2004 (UK)
[4] Guardianship and Administration Act 1986 (Vic), Part 4A, Div 6.

4) Provide for authorisation where the person responsible cannot be ascertained or contacted (s42T).

Steps 2, 3, and 4 do not apply to the carrying out of a medical research procedure if such a procedure constitutes emergency medical or dental treatment (under s42A).

The person responsible may only consent to the carrying out of the procedure if he or she believes that the carrying out of the procedure would not be contrary to the 'best interests' (s42U) of the patient (s42S(3)). The person responsible may seek advice and direction from the Victorian Civil and Administrative Tribunal (VCAT) (s42W), which has jurisdiction to determine whether consent to medical research procedures ought to be given (ss 42V, 42W, 42X). There are offence provisions for registered health practitioners who fail to comply with the Division (s42Y) and protections for those who do comply (s42Z).

In reference to Question 5.3(3) below, the entire Victorian legislation Division is subject to s41, which prohibits a registered practitioner from carrying out any medical treatment (including a medical research procedure and emergency treatment) if there is a refusal of that treatment in force under the *Medical Treatment Act* 1988 (Vic).

(2) Who should be able to consent to a patient's participation in a clinical trial if the patient lacks decision-making capacity?

See response above.

(3) How can the law promote the patient's autonomy in the decision-making process?

No comment

Question 5.4: Considering the views and objections of patients

(1) If the patient cannot consent, should the decision-maker be required to consider the views of the patient?

No comment

(2) What should happen if a patient objects to participating in a clinical trial? Should substitute consent be able to override a patient's objection? If so, in what circumstances?

No comment

Question 5.5: What preconditions should be met before a decision-maker can consent to participation?

The Victorian *Guardianship and Administration Act* 1986 contains a number of preconditions prior to a registered practitioner carrying out a medical research procedure on a patient without the consent of the person responsible:

- The patient is not likely to be capable, within a reasonable time of giving consent to the carrying out of the procedure (s42T(2)(a));
- Reasonable steps have been taken to ascertain whether there is a person responsible (and who) and if so that they are contacted to have their consent sought (s42T(2)(b));
- There is a reasonable grounds belief that the procedure is not contrary to the best interests of the patient (s42T(2)(c));
- There is no reason to believe the procedure would be against the patient's wishes (s42T(2)(d));

- There is a reasonable belief that an HREC has approved the project with knowledge that a patient may participate without prior consent (s42T(2)(e));
- There is no greater risk to the patient than the risk that is inherent in the patient's condition and alternative treatment (s42T(2)(f)(ii));
- There is a reasonable grounds belief that there is a reasonable possibility of benefit for the patient as compared with standard treatment (s42T(2)(g)).

The Ministry of Health considers that these preconditions would be an appropriate starting point for any legislative amendment. .

NSW Health agrees that Article 31(1) of Regulation (EU) No 536/2014 on Clinical Trials on Medicinal Products for Human Use contain suitable preconditions to be taken into account before consenting to treatment in the course of a clinical trial *in non-emergency situations.*

EU Regulation No. 536/2014 also contains an Article on Clinical Trials in Emergency Situations (Article 35). The Article contains three paragraphs which contain a useful regime for consideration alongside any additional preconditions in non-emergency situations. These include:

- A recognition that due to the urgency of the situation, the 'subject' is unable to provide prior informed consent or to receive prior information on the trial (Art 35 (1)(a));
- There is a scientifically-grounded expectation that participation will potentially produce a direct clinically relevant benefit to the 'subject' (Art 35 (1)(b));
- The therapeutic window is too short to provide information and obtain consent from the person responsible (Art 35 (1)(c));
- There are no objections to participate previously expressed by the patient (Art 35 (1)(d));
- The trial intervention poses minimal risk to and imposes a minimal burden on the subject in comparison with the standard treatment of the subject's condition (Art 35 (1) (f)).

Many of these elements would be appropriate to preconditions to consider where participation was based on either substitute decision-making consent, deferred consent, or the waiver of consent.

Question 5.6: What should researchers be required to do after consent is obtained?

Following enrolment in a clinical trial through substitute consent mechanisms, other jurisdictions require ongoing assessments of capacity as part of the continued participation in the research including those enrolled through the special emergency provisions.

The EU Regulation[5] provisions require informed consent to be sought to continue to participate in the trial through the regular mechanisms of a 'legally designated representative' or the 'subject' themselves should they regain capacity.

Finally, if the 'subject' or their 'legally designated representative' should not give consent, they must be informed of the right to object to the use of data obtained from the clinical trial.[6]

Question 5.7: Are there any circumstances in which the individual consent requirements for clinical trials should be waived?

In addition to the provision in the Victorian *Guardianship and Administration Act* 1986, both the US and EU law allow 'deferred consent' in the emergency setting provided certain strict criteria are met. Both place the responsibility for the review of these consent procedures with the HREC.

[5] EU Regulation No. 536/2014, Article 35 (Clinical Trials in Emergency Situations) Paragraph 2.
[6] EU Regulation No. 536/2014, Article 35 (Clinical Trials in Emergency Situations) Paragraph 3.

The response to 5.5 outlines the Article 35 preconditions present in EU Regulation No. 536/2014. These reflect the requirements for clinical trials in the emergency setting across both Europe and the United States. Both UK and European law also places the responsibility for the review of these consent procedures with the HREC.

In the United States, Part 50 of the US Code of Federal Regulations[7] mirror European law by allowing deferred consent in certain circumstances and placing the responsibility for this decision with the IRB (Ethics Committee).

NSW Health submits that a waiver of consent in certain circumstances is entirely appropriate and aligns with national and international guidelines and legislation relating to consent and the approval of consent procedures. A number of the protections available for clinical trial participants in other jurisdictional requirements including the assessment of a patient's capacity, the preconditions to their participation, and the requirements on researchers after enrolment have been identified in this submission as appropriate.

NSW Health considers that the Victorian legislation provides an appropriate standard that NSW could align with in creating a regime for clinical trial participation of those who lack capacity to consent.

Question 5.8: Other issues
Do you have any other comments about the consent requirements for clinical trials?

NSW Health would seek revision of the clinical trials section of the Act to reflect both inter-jurisdictional and international norms, particularly with reference to the mechanisms contained in the Victorian *Guardianship and Administration Act* 1986.

Preferred option 1: Adopt the provisions in the Victorian Act.

This option would involve comprehensive changes to the current NSW Act. It adopts the mechanisms in Division 6 of the Victorian Act necessary to provide evidence that contributes to patient benefit as well as protections for both clinical trial participants who cannot consent and practitioners who conduct the research. The approval mechanism is the Human Research Ethics Committee (HREC), which is already a body that is designated to provide legally-required approvals,[8] rather than the NCAT. One advantage is that the situation is avoided whereby researchers are required to consider whether their research constitutes a 'clinical trial' as defined in the, and submit an application to NCAT, either to obtain approval to proceed, or to obtain a dismissal (that the research does not constitute a clinical trial), in order to proceed. In all cases, researchers would be required to submit to an HREC in order to conduct a medical research procedure under the Victorian 42Q mechanism.

The key features of the Victorian model are a requirement of patient capacity assessment, seeking consent from the person responsible and mandatory procedural authorisation from the HREC.

The alignment of clinical trial provisions in NSW and Victoria would enhance consistency and clarity across the two largest research communities, and enable the same research protocol to be conducted across the same study in both jurisdictions, allowing for greater statistical significance in results and thus a more robust evidence base in research designed to provide benefit to these patient populations.

[7] CFR – Code of US Federal Regulations Title 21; US Food and Drug Administration; Part 50 Protection of Human Subjects.

Preferred option 2: Provide minimal, yet significant, amendment to the current Guardianship Act

This model would retain the two-step process currently reflected in Division 4A, however, this should be simplified:

(i) S45AA to be amended to require all research involving a medical research procedure (in line with the Victorian definition), regardless of whether the study may be technically defined as a 'clinical trial' or not, that intends to enrol participants who cannot consent for themselves to be presented to the Guardianship Division for initial approval;

(ii) S45AB to be amended to provide for a third option for NCAT to provide orders in line with the procedural authorisation in s42T, that is, deferred consent (??). The 42T mechanism contains a number of safeguards, set out in Question 5.5 above, which should also be adopted in a revised s45AB. In parallel with 42T, the practitioner could be required to forward a copy of a certificate certifying those items and that the patient will be informed of their inclusion in the trial (if they recover) to NCAT either before, or as soon as reasonably practicable after, the medical research procedure is carried out.

The relationship between the Guardianship Act and the Mental Health Act

Question 6.1: Relationship between the *Guardianship Act* and the *Mental Health Act*

(1) Is there a clear relationship between the *Guardianship Act 1987* (NSW) and the *Mental Health Act 2007* (NSW)?

Questions 6.1.1, 2 and 3 are answered below.

Admission and discharge from mental health facilities

There is a lack of clarity between the MHA and the Act around discharge of voluntary patients from mental health facilities (MHFs). The MHA allows a voluntary patient to discharge themselves or for an authorised medical officer (AMO) to discharge a voluntary patient; whereas a guardian under the Act will often have the power to make decisions about accommodation and medical treatment, and to enforce those decisions.

Guardian's decision making powers relating to discharge

The Mental Health Review Tribunal (Tribunal) has submitted that the Act should prohibit a guardian from making decisions about a voluntary patient's discharge from a MHF and from re-admitting a patient who has discharged themselves.

NSW Health considers that a guardian should not be able to mandate that the person remain as a voluntary patient if the MHF AMO thinks the person should be discharged. Instead, the AMO's views should override the views of the guardian. This view is consistent with the AMO's powers under section 8 of the MHA, i.e. that an AMO "*may discharge a voluntary patient at any time if the officer is of the opinion that the person will no longer benefit from further care or treatment as a voluntary patient*". It is also consistent with the MHA's principles for care and treatment, which in part state that people with a mental illness should receive care and treatment in the least restrictive environment possible, and that care and treatment should be designed to assist such people to live, work and participate in the community wherever possible (s68 (a) & (c)).

It is also noted that, under section 79 of the MHA, the AMO is already required to take all reasonably practicable steps to consult with any designated carer as defined in the MHA in relation to planning the patient's discharge; so the designated carer (who may be patient's guardian) is already given an opportunity to put forward their views about potential discharge.

NSW Health considers that the Act should be amended to make it clear that a guardian does not have any power to override a decision made by an AMO to discharge a patient under the MHA.

Voluntary patient's power to discharge themselves

There is less clarity in relation to what process should apply where a voluntary patient who does not have the capacity to consent wishes to discharge themselves, as they are allowed to do at any time under section 8(2) of the MHA. Clarification as to whether patients with guardians appointed to make health and /or accommodation decisions should be assumed not to have capacity to decide to discharge themselves would be welcome.

A voluntary patient's right to discharge themselves is in line with the principles for care and treatment in the MHA (s68).

An AMO is able to detain a voluntary patient under s10 of the MHA if they consider the patient to be a mentally ill or mentally disordered person.

It is noted that s11 of the MHA allows for a voluntary patient who has been refused admission or has been discharged by an AMO to request that the medical superintendent of the MHF review the AMO's decision. A compromise might be to amend the MHA to allow a guardian to also request such a review. This retains the MHF's decision making powers while allowing the guardian an opportunity to seek a formal review of an AMO's decision. This is an issue that requires further investigation and consultation.

Guardian's powers to not admit or discharge person

Under section 7 of the MHA, a person must not be admitted to a MHF as a voluntary patient if the guardian objects, and the person must be discharged by the AMO if the guardian so requests.

It is noted that the guardian is only able to request a person's admission as a voluntary patient under the MHA, not mandate the person's admission. The decision about admission is made by the AMO. NSW Health considers that the current provisions are appropriate and do not require amendment.

Types of treatment

The MHA and the Act are both important pieces of legislation that have different objectives – the Act focuses on best interests and welfare of the person, whereas the MAA seeks to both protect the civil rights of mental health patients while also providing for a treatment and detention regime for patients who pose a risk to themselves or others.

In view of the need to protect public safety, NSW Health supports the continued recognition that the MHA should prevail over the Act in the event of any inconsistency. In general this would mean that all treatment decisions of patients detained under the MHA (or the *Mental Health (Forensic Provisions) Act*) should be covered by the MHA rather than the Act. However, NSW Health recognises that the area of non-mental health treatment provided to patients falling under the MHA is an area that is in need of review.

Currently the MHA has provisions relating to provision of mental health treatment, non-mental health treatment, surgical treatment, special medical treatment and ECT.

Some of the issues associated with the different types of treatment are set out below.

Non-mental health treatment (other than surgery or special medical treatment)

Section 84 of the MHA allows for an AMO to "give, or authorise the giving of, any treatment (including any medication) the officer thinks fit to a [detained person]". This includes forensic and correctional patients.

In relation to non-mental health treatment (other than surgery or special medical treatment), it is noted that the broad terms of s84 (MHA) mean that this provision can also be interpreted as allowing the AMO to authorise the giving of general non-surgical medical or dental

treatment. There may not always be a clear divide between mental health and non-mental health treatment. For example, the administration of mental health medication may cause interactions with other medication a patient is taking and therefore require an AMO to alter the other medication. Alternatively, prescribing mental health medication may require the prescription of other medication to address any side effects of the mental health medication. There are therefore good reasons to give a broad interpretation to s84.

However, the Part and Division of the MHA under which s 84 falls (Division 2 of Part 2) are entitled "Mental Health Treatments" and "General provisions about mental health treatment" respectively. It could therefore be argued that s84 is only intended to apply to mental health treatment.

Although the matter is not beyond doubt, s84 has been given a broader interpretation. AMOs may therefore in some cases rely on s84 to authorise non-mental health treatment (other than surgery or special medical treatment) rather than relying on the Act. While this can have benefits in ensuring appropriate treatment is promptly given to detained patients, the MHA lacks safeguards contained in the Act in relation to the information provided to, and considered by, substitute decision makers. On the other hand, having one regime in respect of substitute decision making for detained mental health patients can lessen confusion among clinicians.

Surgery and special medical treatment

In relation to surgery and special medical treatment, it is noted that the definitions of these, the criteria for approving them, and the decision-making bodies all differ between the two Acts.

The MHA provides specific provisions that provide substituted consent for surgical procedures. These provisions vary depending on the status of the patient (i.e. whether the patient is an involuntary patient or a forensic/correctional patient not suffering from a mental illness), or whether the designated carer has agreed in writing to the surgery. If the designated carer has agreed to the surgery, the matter is considered by the Secretary of the Ministry of Health (Secretary); if they have not agreed, then the matter goes before NCAT.

Unlike the Act, the provisions in the MHA do not currently explicitly require relevant information, such as information on the effects of the treatment or alternative course of treatment, to be provided to the Secretary or NCAT.

The MHA does not require the Secretary or NCAT to consider the views of the patient (although this is likely to occur in practice) before deciding whether or not to consent to surgery, as would be the case if substituted consent was given in accordance with the Act.

It is noted that under the MHA, termination of pregnancy is considered surgical treatment not special medical treatment as in the Act. This results in different tests for the same procedure.

Under the MHA, the Secretary can consent to a termination of pregnancy if it is "desirable, having regard to the interests of the patient, to perform the surgical operation" (s101). In contrast, under the Act, NCAT can only consent if it is "necessary to save the patient's life or to prevent serious damage to the patient's health". The LRC Question Paper states that "it is arguable that this [the Act test] is the more appropriate test".

It is unclear as to the LRC's reasoning in stating that it is arguable that the Act test for terminations is the more appropriate test. As stated above in relation to special medical treatment, there is already a legal common law test to be applied before a termination can be lawfully carried out which considers issues relating to the risk to the patient. A more detailed analysis of the pros and cons of each approach, taking into consideration the common law test that already applies, should be provided to allow further consideration of this matter. It would also be appropriate to consult further on this matter with key mental health and other stakeholders.

(2) What areas, if any, are unclear or inconsistent?

See above.

(3) How could any lack of clarity or inconsistency be resolved?

See above.

Question 6.2: Relationship between the *Guardianship Act* and the *Forensic Provisions Act*

(1) Is there a clear relationship between the *Guardianship Act* and the *Forensic Provisions Act*?
(2) What areas, if any, are unclear or inconsistent?
(3) How could any lack of clarity or inconsistency be resolved?

It is clear from the Act that, in the event of an inconsistency between the medical and dental provisions of the Act (Part 5) and the *Mental Health (Forensic Provisions) Act* (MHFPA), the MHFPA prevails. However, the Act gives no guidance about how the MHFPA interacts with any other part of the Act. It is therefore unclear as to what should happen if the two Acts come into potential conflict.

NCAT may make a guardianship order for a forensic patient. It may limit the decision-making of a guardian where a Mental Health Review Tribunal MHFPA order sets out conditions (e.g. about accommodation). NCAT has also questioned whether a guardianship order made primarily to ensure that a forensic patient complies with conditions under a MHFPA conditional release order would be consistent with general principles set out in section 4 of the Act (e.g. that the welfare and interests of persons with disabilities should be given paramount consideration; and that the freedom of decision and freedom of action of such persons should be restricted as little as possible).

NSW Health considers that it is important to provide clarity around resolution of potential conflicts between the two Acts. As the MHFPA deals with forensic and correctional patients, over whom the Mental Health Review Tribunal (?) has decision making power regarding care, treatment, detention, leave and release; it would seem appropriate that the MHFPA prevail over the Act in general and not only in relation to Part 5.

Question 6.3: Whether mental health laws should always prevail

(1) Is it appropriate that mental health laws prevail over guardianship laws in every situation?
(2) If not, in which areas should this priority be changed?

Many of the differences between the Act and mental health laws arise from the different objectives of the two Acts – the Act focuses on best interests and welfare of the person, whereas under mental health laws there is a need to balance the interests of the person with the need to protect the safety of the person and the general community.

In general, it appears to be appropriate that mental health laws continue to prevail over the Act due to the need to protect the public.

Restrictive Practices

In response to the questions on restrictive practices generally, NSW Health considers that it is premature to consider the interaction of the proposed NDIS framework and NSW laws until such time as the NDIS legislation has been enacted.

The Commission should also be aware of the current review taking place in relation to the use of seclusion and restraint in NSW mental health facilities.

The MHA and existing policy require that NSW Health staff undertake all possible measures to prevent and minimise disturbed or aggressive behaviour, and reduce the use of restrictive practices such as seclusion and restraint.

The MHA requires that (s68):

- people with a mental illness or mental disorder receive the best possible care and treatment in the least restrictive environment enabling the care and treatment to be effectively given, and that
- any restriction on the liberty of patients and other people with a mental illness or mental disorder and any interference with their rights, dignity and self-respect is to be kept to the minimum necessary in the circumstances.

The existing NSW Health Policy *Aggression, Seclusion and Restraint in Mental Health Facilities in NSW* emphasises the role of prevention and the use of a range of therapeutic interventions in reducing seclusion and restraint.

In relation to the seclusion, restraint and observation of mental health patients in NSW Health facilities and services, the review will:

1. Consider whether existing legislation, policy, clinical governance and oversight, principles and practice standards are consistent with national standards, leading evidence and international best practice principles, and the expectations of patients and the community
2. Examine the application of existing mental health legislation, policy, clinical governance and oversight, principles and practices, and the extent to which these have been adhered to across NSW Health facilities
3. Taking into consideration the findings at (1) and (2), make recommendations for amendment to
   a) legislation
   b) policy
   c) reporting
   d) clinical governance and oversight
   e) practice standards; and
4. Make recommendations for any system capability building required to support clinical and non-clinical staff to implement any proposed legislation, policy or practice changes.

The Review will be undertaken by an expert panel led by the NSW Chief Psychiatrist, Dr Murray Wright.

The review will:

- undertake site visits to NSW hospitals with acute mental health units, mental health intensive care units and declared emergency departments
- undertake a review of a sample of cases which involved the seclusion of a patient with a mental illness or disorder, to determine the extent to which existing legislation, policy, clinical governance and oversight, and practice standards have been applied
- undertake review and analysis of the existing NSW policies (including revised policy on restrictive practices, and patient observations, which are currently under review), legislation and practice, and leading evidence and international best practice
- call for written submissions, and undertake thematic analysis
- facilitate face to face consultations with key stakeholders through one-to-one meetings and consultation workshops with key stakeholders, including bodies that are representative of people with a lived experience of mental illness
- make a recommendation on a pathway for the reduction of seclusion and restraint practices in NSW
- provide a final report and recommendations.

The review will report to the Minister for Mental Health and the Minister for Health by Friday 8 December 2017.

Additional Comments

Aged Care

Under the *Aged Care Act 1997*, the Commonwealth Government is responsible for aged care. The Commonwealth Government has a comprehensive national framework for aged care incorporating regulation, funding, accreditation and compliance.

It is noted, however, that there are some potential overlaps between Commonwealth and NSW Guardian issues, such as whether 'medical and dental treatment' includes health treatment provided by aged care workers and care assistants

Consent in the context of sexual assault medical and forensic examinations

NSW Health provides medical and forensic examinations for children, young people and adults who have experienced sexual assault. These examinations are provided by NSW Health Sexual Assault Services located in each Local Health District and Speciality Health Networks.

This process is established through interagency guidelines with NSW Police Force, NSW Department of Family and Community Services, NSW Health (including Forensic and Analytical Science Service) and the Office of the Director of Public Prosecution. The aim of these interagency guidelines is to provide timely and professional psychosocial, medical and forensic responses to victims of sexual assault.

The aim of this response is to address the health impacts of sexual assault for the patient as well as maximise their opportunity to access the criminal justice system as a victim of crime.

The sexual assault medical and forensic examinations are provided by NSW Health Medical and Forensic Examiners who may be doctors or specially trained nurses. These examinations are provided as part of an integrated psychosocial and medical and forensic response with an on-call Sexual Assault Counsellor coordinating the response in consultation with the Examiner. Presentations/Police/JIRT referrals to NSW Health services may occur 24 hours per day / 7days per week.

The medical care of people who have experienced sexual assault includes the assessment and treatment of injuries, provision of post exposure prophylaxis for sexually transmitted infections and pregnancy.

The collection of forensic evidence , including biological samples and injury documentation, occurs in accordance with established interagency forensic guidelines (evidence based) and should occur as a soon as practicable after the sexual assault.

The requirements around consent vary if the collection of forensic evidence happens in the cause of other medical treatment or where no other medical treatment is required.

Under current procedures, where a patient lacks capacity to consent and no other medical treatment is required, the process to obtain consent for the conduct of the forensic examination, collection of forensic samples (biological and toxicology), which form part of the Sexual Assault Investigation Kit (SAIK), is by application to the NCAT, where a Guardian is appointed for this purpose. These examinations are considered special treatment under the Act.

Sexual assault forensic examinations

Although sexual assault forensic examinations are not "medical treatment", NSW Health would like the review of the Act to consider whether the mechanisms for obtaining timely consent to these examinations could be improved.

Currently there is no specific reference to a sexual assault forensic examination in the Act. It is NSW Health's preference that a regime similar to that in place for consenting to major medical treatment apply to forensic examinations.

It is well known that young people and adults living with a disability are subjected to sexual assault at disproportionally higher rates compared to the general community. People with a disability, particularly those with an intellectual disability, cognitive and communication and cognitive and /or sensory impairments, high support needs and behaviours of concern, are more likely to experience abuse, including sexual assault, than the general population. It is important that the ability of this vulnerable cohort to see perpetrators brought to justice is supported.

In clinical practice, a sexual assault medical and forensic examination can occur without specific separate consent from a person responsible/ Guardian if it forms part of the medical treatment of that patient. However, if no medical treatment is required, or the forensic examination is not part of the medical treatment for the patient it is unclear whether a forensic examination could to be said to be promoting the health and wellbeing of the patient, as its primary purpose is to preserve evidence (although potentially a forensic examination could be carried out in a patient's best interests on the basis that facilitating access to the child protection and criminal justice system is in the person's best interests).

As a result, at present, in these circumstances, specific consent for a forensic examination that is not an adjunct to medical treatment needs to be obtained from a Guardian with a specific power to consent to a forensic examination, which involves an application to NCAT.

Forensic timeframes for the collection of biological samples and toxicology screening are particularly time sensitive, and the utility of an examination can be lost due to delays in approaching NCAT and obtaining consent.

Although NSW Health would like to see a regime in place that makes it possible for persons responsible/Guardians to consent to forensic examinations, this is a complex area, and the following factors need to be considered:

- The relationship between the *Children and Young People (Care and Protection) Act* and the Act in relation to the provision of sexual assault medical and forensic examinations of children needs be addressed to ensure consistency and reduce confusion.
- If persons responsible/Guardians were able to consent to forensic examinations there would need to be some protection for patients where their person responsible may also be 'person of interest' or a suspect in the investigation of the sexual assault. This person could potentially decline to consent to the sexual assault examination.

Collection of toxicology samples to compile an Early Evidence Kit

NSW Health would also like to see mechanisms in place to enable the collection of small toxicology samples from suspected victims of crime who are unable to consent, in the same way that minor medical treatment can be provided. An Early Evidence Kit or other toxicology specimens might be collected during routine care of a patient who is being provided with for urgent medical care but is unable to consent as they are unconscious. This evidence may prove very useful if a crime has been committed and cannot be collected later due to time frames and the risk of contamination related to clinical care procedures. The specimens are not released to police without formal consent which can be obtained either from the patient when they recover or from NCAT.

The collection of forensic evidence (biological samples and toxicology) is time sensitive and must occur within established forensic timeframes to maximise the evidentiary value of those samples. Recover rates diminish rapidly over time.

At present a separate consent is required in relation to the release the Sexual Assault Investigation Kit (SAIK) to NSW Police Force for the purposes of forensic testing and the investigation of a sexual assault.

In some cases a patient lacks capacity for a relatively short period (e.g. if they were intoxicated and are now sober, an acute mental health issue has resolved or they have regained consciousness as a result of injuries related to in the sexual assault) . When they regain capacity they can consent to the release of the SAIK. However, if they do not regain capacity then a Guardian with this function (the authority to provide consent to release the SAIK to the Police for forensic testing as part of a Police investigation of the sexual assault) needs to be appointed.

The requirement to seek a separate consent for the release of the SAIK to the Police when a patient does not regain capacity to consent is complex and a review of the process to find a more efficient and less cumbersome process.

The NSW Ministry for Health has received feedback from NSW Health Sexual Assault Service (SAS) Coordinators and Medical Directors about their experiences in applying to NCAT to obtain substitute for the conduct of a sexual assault medical and forensic examination. SASs have reported that process is protracted and often causes significant delays in this examination. These delays may impact on the quality of the forensic samples collected as these deteriorate over time.

A number of senior NSW Health Sexual Assault Medical and Forensic examiners have considered relevant provisions around this practice area in other states and recommend that the Queensland guardianship provisions relating to forensic procedures are considered for adoption in NSW.

Further consultation

Several branches of the Ministry of Health and clinical experts have contributed to this submission. Should the Commission wish to discuss any aspect of this submission, or seek additional advice on the matters raised, I would be happy to facilitate meetings with relevant personnel.

Thank you for the opportunity to provide comments to this inquiry. If you have any queries about this submission, please contact Ms Blaise Lyons, Principal Legal Officer, Legal & Regulatory Services, NSW Ministry of Health, email [redacted] telephone [redacted].

Yours sincerely

Elizabeth Koff
Secretary, NSW Health