



The Hon. John Quigley MLA
Attorney General of Western Australia
5th Floor, Dumas House
2 Havelock Street
West Perth WA 6005

Via email: Minister.Quigley@dpc.wa.gov.au

17 January 2019

Dear Minister

Re: Western Australian Department of Health recommendations regarding amendment of the *Guardianship and Administration Act 1990* to enable participation of incapacitated adults in research: *Guardianship and Administration Amendment (Medical Research) Bill 2018*

We write to express our concerns regarding aspects of the recent Western Australian Department of Health's recommendations to you regarding proposed amendments to the *Guardianship and Administration Act 1990* (the Act) as it relates to time-critical clinical emergency medicine, prehospital care and intensive care research (henceforth emergency research) involving the participation of incapacitated adults. We are particularly concerned about the *Guardianship and Administration Amendment (Medical Research) Bill 2018* (the Amendment Bill).

In our experience, there are circumstances in which we strongly believe that research without consent should be retained. There are provisions in other jurisdictions' legislative frameworks that allow research without consent and, if this is not retained in emergency research, Western Australian patients will be adversely affected. Compared with other jurisdictions, Western Australia underperforms in National Health and Medical Research Council (NHMRC) funding, with patients denied the right to participate in emergency research purely because of their incapacitated health state. Indeed, this is already occurring, with an NHMRC funded clinical trial recruiting patients in Victoria, but disallowed in Western Australia based on State Solicitor advice.

The Australasian College for Emergency Medicine (ACEM, the College) is the not-for-profit organisation in Australia and New Zealand responsible for training and educating specialist emergency physicians and advancing professional standards in emergency medicine, including the study, research and development of the science and practice of emergency medicine.¹ The practice of emergency medicine is concerned with the prevention, diagnosis and management of *acute* and *urgent* aspects of illness and injury among patients of all ages who present to emergency departments with a spectrum of undifferentiated physical and behavioural disorders.² As the peak professional organisation for emergency medicine, the College has a vital interest in ensuring the highest standards of emergency medical care are maintained for all patients.

Our concerns regarding the Amendment Bill specifically relate to Section (d) *Research in emergency situations* on page 6 of the Department of Health's recommendations.³ The proposed legislative environment following the Amendment Bill stipulates in the consent pathways for research that, should the requirements for research in emergency contexts be satisfied (as defined by the Act), the Health Professional is required to (i) check for the individual's wishes, (ii) keep checking for individual consent and (iii) keep checking for substitute decision maker

¹ Australasian College for Emergency Medicine. Constitution [Internet]. Melbourne: ACEM; 2016. Available from: <https://acem.org.au/getmedia/66230b2a-3aa4-40e1-960e-d75bffd5015f/Constitution.aspx>.

² Australasian College for Emergency Medicine. Policy on standard terminology (P02). Melbourne: ACEM; 2014.

³ Government of Western Australia Department of Health. Department of Health recommendations: Amendment of the *Guardianship and Administration Act 1990* to enable participation of incapacitated adults in research. Perth; Department of Health WA; 2018.

consent.⁴ However, there are situations when this process is not possible or appropriate. These include cases of patients with major trauma with severe injuries, cardiac arrest, and altered states of consciousness from illicit drug ingestion.

Patients with acute severe injuries are often unable to provide valid informed consent due to impairment from psychological distress, pain, lack of oxygen or blood supply, and/or reduced levels of consciousness. The patient's next of kin or family may also be incapable of providing informed consent due to similarly high distress levels, and in some cases they may have even been involved in the same accident. Medical and surgical care in trauma is often performed without consent in emergency settings to avoid any delays that might risk the life of a patient or exacerbate patient harm. Previous emergency research has shown that seeking next of kin consent is associated with delays to initiating care, resulting in avoidable harm to patients.⁵

Unfortunately, most people who have a cardiac arrest out-of-hospital in the community do not survive the event. Some of these people have no registered substitute decision maker. (Indeed, sometimes identifying the deceased in these cases can be problematic, let alone locating such a patient's substitute decision maker or next of kin). We know from our colleagues' experiences in other Australian jurisdictions that seeking delayed consent for the deceased's participation in medical research can be perceived as insensitive and traumatic for families and next of kin. Our colleagues in other states and territories have received feedback from relatives in these circumstances, such as "we didn't need to know this", stating that these processes have caused them additional grief and anguish.

Another concern relates to the effects of illicit drug use on patients in the context of emergency research. Pursuing substitute decision maker consent for this population is highly unethical and a profound violation of privacy. Sadly, many patients in this group do not regain the capacity to provide informed consent. Some die, while others remain in a prolonged state of drug induced psychosis, particularly in cases involving methamphetamine use. Scenarios like these reinforce our consensus view that for the benefit of the community, the Amendment Bill requires legislative provisions for research without consent in some emergency situations. At all times, we strongly believe that patient privacy must be respected and upheld.

There are varying types of clinical research with important distinctions that should be taken into account when crafting legislation in this area. Some research is observational, during which patient care is not altered and measurements of their condition, results of investigations and blood tests and progress are recorded. Some research might compare two established treatments with equipoise to determine which might be more effective, while some might trial a new therapy with a limited evidence base. While only a third of these has been termed a "clinical trial" by the New South Wales Civil and Administrative Tribunal Appeal Panel (2016) as it applies to the NSW Guardianship Act,⁶ all types of clinical research in Western Australia will be affected by the Amendment Bill.

Strict ethical requirements as laid out in the NHMRC's National Statement on Ethical Conduct in Human Research⁷ (the National Statement) are mandatory for the ethical approval of research to proceed without consent. In these settings, there must be no more than low risk to participants, it must be impractical to obtain informed consent, the benefits from the research must justify the risk associated with not seeking consent, and there must be no known or likely reason for believing that participants would not consent should they have been

⁴ Government of Western Australia Department of Health. Research involving incapacitated adults. Perth: Department of Health WA; 2018.

⁵ Roberts I, Prieto-Merino D, Shakur H, Chalmers I, Nicholl J. Effect of consent rituals on mortality in emergency care research. *Lancet* [Internet]. 2011; 377: 1071–2. Available from: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(11\)60317-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60317-6/fulltext).

⁶ *Shehabi v Attorney General (NSW)* [2016] NSWCATAP 137; BC201605193.

⁷ The National Health and Medical Research Council, the Australian Research Council and Universities Australia. National Statement on Ethical Conduct in Human Research 2007 (Updated 2018) [Internet]. Canberra: Commonwealth of Australia. Available from: <https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#block-views-block-file-attachments-content-block-1>.

asked. We ask that the Amendment Bill allows for certain emergency research to proceed without consent when the ethical conditions of the National Statement are met and when approved by an independent Human Research Ethics Committee.

The College strongly believes that emergency research without consent for participation in these contexts should be available as part of the Amendment Bill. We emphasise that emergency research without consent is and has been for many years an essential element for improving patient care in these areas. The Amendment Bill should recognise this where possible so that data and research samples can be used for the sole purpose of improving patient care for other community members who find themselves in similar future situations. In fact, we respectfully contend that deceased patients often provide the greatest contribution to clinical information, which advances scientific knowledge and patient care.

As specialist emergency physicians, our mission is to deliver the best possible health and psychosocial outcomes to all populations presenting to emergency departments in the Western Australian community. In summary, we strongly believe that this problem can be addressed by amending the Act to truly reflect the spirit and intent of the National Statement. This amendment would include acknowledging that research without consent can be and is a valid ethical and legal framework, especially for people who are highly dependent on medical care. We need laws that ensure compliance with the National Statement. We re-emphasise our goal of ensuring that all patients receive the highest quality emergency medical care based on the best available research evidence, and that incapacitated patients have access to the same opportunities as their fellow citizens. While we have highlighted trauma, cardiac arrest and illicit drug research in this correspondence, other acute conditions that require emergency research will also be impacted by the Amendment Bill, including stroke, septic shock (severe blood infection) and dementia, to name a few.

We would be delighted to meet with you in person to discuss with you and explain the specific nuances of emergency research to help inform the best possible amendment to the Act. Should you wish to discuss any aspect of this correspondence, in the first instance please contact the College's Executive Director of Policy and Strategic Partnerships, Ms Nicola Ballenden, on (03) 9320 0444 or via email at Nicola.Ballenden@acem.org.au. We look forward to hearing from you at your earliest convenience.

Yours sincerely



Doctor Simon Judkins
President



Doctor Peter Allely
Chair, WA Faculty



Professor Yusuf Nagree
Chair, Council of Advocacy, Practice
and Partnerships

Cc: Deputy Premier, Minister for Health (WA), [the Hon. Roger Cook MLA](#)
Director General of the Department of Health (WA), [Doctor David Russell-Weisz](#)
State Solicitor's Office Department of Justice (WA), [General Manager](#)
Australian Medical Association (WA) President, [Dr Omar Khorshid](#)

Attachment 1 ACEM letter to the Hon. John Quigley MLA regarding the State Solicitor's Office interpretation of the Guardianship and Administration Act 1990 (WA), dated 26 July 2018