



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

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

26 July 2018

Dear Minister

Re: State Solicitor's Office interpretation of the Guardianship and Administration Act 1990 (WA) regarding consent issues for research participation in emergency contexts

We write to express our concern regarding the recent State Solicitor's Office interpretation of the principles underpinning the *Western Australian Guardianship and Administration Act 1990* (WA) (the Act) as it relates to clinical research in emergency medicine, prehospital care and critical/intensive care, and other groups with limited capacity. As it stands, the Act does not include provisions for consent by a substitute decision maker for a person to participate in medical research. Under the Act, consent may only be provided by a substitute decision maker for a person to participate in treatment that is deemed to be in the best interests of the patient.¹ Contrary to previous advice, recently the State Solicitor's Office advised that in the absence of a clear guideline within the Act, differing forms of consent are now incompetent and illegal (e.g. waivers of consent, proxy consent from the next of kin, and deferred consent), which is of serious concern.

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. 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.

Many patients, including those who require emergency and/or intensive medical care, lack the capacity to provide informed consent, including informed consent to participate in medical research. As specialist emergency physicians, we are strong advocates for our patients and experts in the assessment of cognitive capacity in emergency, critical care, stroke, trauma and prehospital care settings. In this context, we stress that patient advocacy means providing the highest level of evidence-based medical care to the sickest and most vulnerable patients. Patients in this group include (but are not limited to) those experiencing out-of-hospital cardiac arrest, stroke, major trauma, septic shock, drug intoxication, dementia and seizures. The time critical nature of much emergency medical care and emergency medicine research precludes the involvement of next of kin for consent. At the time of these emotionally charged situations, it is also often inappropriate to seek consent. Waiver of consent for emergency medicine research is, and has been for many years, an essential element of clinical research to improve patient care in this area.

¹ Government of Western Australia Department of Health. WA Specific Information. Adults with Impaired Capacity or Unable to Consent. Research Governance Service [Internet]. Perth; Department of Health WA; 2018. Available from: <https://rgs.health.wa.gov.au/rgshelp/Pages/WA%20Specific%20Information.aspx>.

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

In the emergency care setting, it is also vital to appreciate that critically unwell patients may not have next of kin present, nor may they be readily identifiable, nor easily contactable, particularly in cases of out-of-hospital cardiac arrest, injury resulting from major trauma, or head injury. *Such events are unplanned and, therefore, research into improving diagnosis and treatment cannot be scheduled nor consented to in advance.*

It is worth highlighting that much current clinical emergency medicine practice is still not based on gold standard, level one evidence. The worst scenario for emergency medicine is for changes in clinical management to occur within a vacuum of scientific evidence. The College believes that clinical research in contemporary emergency medicine is absolutely essential to determine the best treatments for acutely ill and injured patients. The Australian Government, through the National Health and Medical Research Council (NHMRC), provides guidelines for the ethical conduct of research in which informed consent cannot be obtained (National Statement chapters 2.3 and 4.4).³

In contrast to other Australian jurisdictions, there is no legislation in Western Australia that explicitly addresses the needs of people who are highly dependent on medical care and who may be unable to give consent for research participation, including in clinical trials. Historically, there have been cases in Western Australia in which human research ethics committees (HRECs) have approved the conduct of such research. However, the College is specifically concerned about an emerging conservative legal interpretation in Western Australia whereby only patients who are able to provide prospective informed consent are allowed to be enrolled in clinical research. As such, the opportunity to participate in research being conducted in other Australian jurisdictions is now being denied to patients in Western Australia.

We have grave concerns that research specifically designed to improve Western Australian patient health and safety outcomes can no longer proceed. *This approach can lead to perverse situations in which the sickest and most vulnerable patients continue to be given outdated, unproven and possibly harmful treatments because they are denied the right to participate in clinical trials that seek to test new treatments and address questions of efficacy or harm.* This denies future patients (or the same patient who re-presents with future episodes) and the Western Australian public the chance of better health outcomes from early application of new techniques, interventions and insights. We believe that this approach is inequitable and unethical, and a considerable threat to knowledge advancement in the emergency medicine specialty and better health outcomes for Western Australians.

The lack of a specific provision in the Act that explicitly considers research in emergency contexts, and/or in participants who lack the capacity to provide informed consent, has proven problematic for research governance and HRECs in Western Australia. Research governance entities and HRECs need to be able to base their decisions for the conduct of research on relevant legislation, as well as in consideration of the ethical principles inherent in the National Statement.

Specialist emergency physicians and researchers take extremely seriously their ethical responsibility to act in accordance with the patient's best interests when the individual is unable to articulate their preferences or wishes. Patients and the health system need opportunities for research participation to determine the best course of treatment when this is uncertain and, when the likelihood of benefit outweighs potential harm, as determined by a robust and independent HREC review process. Consistent with international research, the public is generally supportive of this concept and the need for research within the boundaries of an appropriately

³ National Health and Medical Research Council. National Statement on Ethical Conduct in Human Research (2007) (Updated 2018) [Internet]. Canberra: NHMRC; 2018. Available from: <https://www.nhmrc.gov.au/files/nhmrc/file/publications/national-statement-2018.pdf>.

specific ethical framework.⁴ Participation in research can lead to improved clinical care, with research activity also improving the clinical performance of physicians. *Contemporary medical practice integrates research within treatment, such that research is a component of treatment*, and research to evaluate the efficacy of treatment lies within the continuum of best practice. In our Constitution, the first object for which the College is established is to promote and encourage the study, research and advancement of the science and practice of emergency medicine.⁵

A solution to this problem can be addressed by amending the legislation so that the Act reflects the spirit and intent of the National Statement in governing research participation for people highly dependent on medical care who may be unable to provide consent. The overriding principle for participation should be the scientific merit of the research and the relative balance of the benefits and risks to participants, which is best addressed by a properly constituted HREC together with local research governance systems. Depending on the nature and design of the research, we provide the following options in these circumstances:

- (1) Waiver of consent
- (2) Abbreviated verbal consent to allow initiation of care, followed by more formal consent processes to continue or withdraw research participation once medically stabilised
- (3) Proxy consent from the patient's next of kin or guardian, and
- (4) Delayed/deferred consent under an initial waiver or next of kin consent.

We reiterate our goal of ensuring that all patients receive the highest quality emergency medical care based on the best available evidence, and that vulnerable patients have access to the same opportunities as their fellow citizens. As specialist emergency physicians, we want to be able to deliver the best possible health and psychosocial outcomes to all populations presenting to emergency departments in the Australian community. We would be very keen to meet with you to discuss how we can work with you as the Western Australian Attorney General to promote these outcomes. Should you wish to discuss any aspect of this correspondence, in the first instance please contact the College's Executive Director of Policy, Research and Advocacy, 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



A/Prof David Mountain
Chair, WA Faculty



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

Cc: 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](#)

⁴ Furyk J, Franklin R, Watt K, Emoto T, Dalziel S, McBain-Rigg K, et al. Community attitudes to emergency research without prospective informed consent: A survey of the general population. *Emerg Med Australas* [Internet]. 2018 May 2. Available from: <https://onlinelibrary.wiley.com/doi/epdf/10.1111/1742-6723.12958> DOI: 10.1111/1742-6723.12958.

⁵ Australasian College for Emergency Medicine. Constitution [Internet]. Melbourne: ACEM; 2016. Available from: <https://acem.org.au/getmedia/66230b2a-3aa4-40e1-960e-d75bffd5015f/Constitution.aspx>.