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Submission to the NSW Law Reform Commission
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REVIEW OF THE GUARDIANSHIP ACT 1987: QUESTION PAPER 5 MEDICAL AND DENTAL TREATMENT AND RESTRICTIVE PRACTICES

The Australasian College for Emergency Medicine (ACEM) welcomes the opportunity to provide feedback to the *NSW Law Reform Commission* (the Commission) on the desirability of making changes to the *Guardianship Act 1987 (NSW)* (the Act). As it stands, the Act allows formal decision makers to be appointed to make personal, financial and medical decisions for individuals who are incapable of making such decisions because of a disability.

ACEM is the not-for-profit organisation responsible for the training of specialist emergency physicians and advancement of professional standards in emergency medicine in Australia and New Zealand. As the peak professional organisation for emergency medicine, ACEM has a vital interest in ensuring the highest standards of emergency medical care are maintained for all patients across Australasia. ACEM commends the Commission for the Review and the willingness to seek input from stakeholders.

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 presenting with a spectrum of undifferentiated physical and behavioural disorders.[1] Thus, ACEM's submission to the Commission focuses on aspects of the review that are relevant to emergency medicine, namely *Question Paper 5: Medical and dental treatment and restrictive practices* and Term of Reference 8: *The provisions of Division 4A of Part 5 of the Guardianship Act relating to clinical trials.*

BACKGROUND

ACEM understands that, in NSW, legal restrictions are imposed on the participation of persons with impaired decision making in medical research and that these restrictions are over and above the provisions of the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (the National Statement).[2,3] The National Statement is broadly consistent with the World Medical Association's Declaration of Helsinki[4], providing clear ethical guidance to researchers and Human Research Ethics Committees (HRECs). Researchers and HRECs are also bound by relevant jurisdictional legislation, such as the Act in NSW.

ACEM notes that the multiple research governance structures across Australia and New Zealand can be significant impediments to the conduct of multi-jurisdictional collaborative research[2], with the National Statement remaining open to different interpretation by different lawyers and ethicists. ACEM proposes that the Act is changed in NSW to explicitly endorse and align with the National Statement to remove unnecessary barriers to collaborative clinical research in Australia. ACEM draws the Commission's attention to the Australian Government's 2017-18 budget, in which $33 million from the Medical Research Future Fund has been allocated

[1] ACEM. Policy on standard terminology (P02). Melbourne: ACEM, 2014.
[2] Turner, E. Substitute decision-making for participation in medical research. Australian Health Law Bulletin. 2015 May: 66-70.
[3] National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellors' Committee. National Statement on Ethical Conduct in Human Research (Updated May 2015) [Internet]. Canberra: Commonwealth of Australia; 2007 [updated 2015 May; cited 2017 May 4]. Available from: https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf.
[4] World Medical Association. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects [Internet]. 2017 [updated 2013 Oct 19; cited 2017 May 8]. Available from: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.

to clinical trials and 'to ensure Australia is a preferred destination for clinical trial research'.[5] This outcome includes improving Australian health policy research and data capacity, and planning 'work with States and Territories to redesign clinical trial operating systems to make it easier to conduct and participate in safe, high quality clinical trials, in accordance with the Government's *More Clinical Trials for Australia* measure'.[5] ACEM welcomes any investment in health policy research and, particularly, improvements to and streamlining of jurisdictional clinical research governance systems.

INFORMED CONSENT

ACEM considers that patients who are treated in emergency, critical care, stroke and trauma contexts should be provided with the opportunity to participate in clinical research from which they – or the broader community – might benefit, as long as risks and burdens related to their vulnerability are justified by potential benefits.[2] The concept of informed consent for clinical trial participation is often understood by policymakers and the public in the context of a consultation in a traditional clinic setting, with this model informing contemporary research ethics approval processes. In the emergency medicine context, this conceptualisation of consent is problematic for patients with acute and urgent aspects of illness and injury who are unable to participate in an informed discussion about potential research participation. A concerning trend in some jurisdictions, such as NSW, is to adopt a conservative approach to clinical trial participation, whereby only patients who are able to provide prospective informed consent are allowed to be enrolled in research. **Such an 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.** ACEM considers that this approach is inequitable and unethical, and a considerable threat to knowledge advancement in the emergency medicine specialty. Thus, ACEM advocates for legislative reform in this area.

However, ACEM does not advocate any move to a sweeping 'implied consent' model, whereby patients who are able to give informed consent are not provided with information about the research or are exposed to the risks of an experimental treatment, with consent being given by dint of institutional, organisational or clinical paternalism. Clinical guidelines for some treatments that are still not universally accepted are currently under consultation, and ACEM has grave concerns regarding the belief that consent should be assumed in treatments – established, experimental or otherwise – in which significant material risk is still present.

QUESTION 5.1: DEFINITION OF 'CLINICAL TRIAL'

ACEM notes the absence of a universally agreed, consensus definition of a clinical trial. For instance, the World Health Organization's International Clinical Trials Registry Platform defines a clinical trial for the purposes of registration as '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'.[6] In Australia, the National Statement provides a more detailed definition and describes clinical trials as a 'form of human research designed to find out the effects of an intervention, including a treatment or diagnostic procedure. A clinical trial can involve testing a drug, a surgical procedure, other therapeutic procedures and devices, a preventive procedure, or a diagnostic device or procedure'.[3] Clinical trials using new therapeutic substances, procedures or devices are then categorised as Phase I, II, III and IV studies, depending on which stage of research the new treatment is at.[3,7]

[5] Australian Government Department of Health. Budget 2017-18: Portfolio Budget Statements 2017-18 Budget Related Paper No. 1.10 Health Portfolio [Internet]. Canberra: Commonwealth of Australia; 2017 [cited 2017 May 10]. 466 p. Available from: http://www.health.gov.au/internet/budget/publishing.nsf/Content/2017-2018_Health_PBS_sup4/$File/2017-18_Health_PBS_Complete.pdf.

[6] World Health Organization. Clinical trials [Internet]. Geneva: WHO; 2017 [cited 2017 May 4]. Available from: http://www.who.int/topics/clinical_trials/en/.

ACEM endorses the National Statement's definition of a clinical trial and recommends that the Commission considers adopting this within the Act to promote a nationally consistent approach to research governance in NSW. In addition, ACEM is cognisant of the difficulty in forming a consensus definition of clinical trials and suggests that any definition within the Act should be constructed according to the level of potential risk to research participants. For instance, with respect to comparative trials of acceptable treatment alternatives, ACEM considers that in the existence of true clinical equipoise, the additional protections afforded by strong clinical trial governance systems outweigh experimental aspects of the research, such as randomisation and blinding. ACEM members' experiences of differing NSW Civil and Administrative Tribunal decisions[7,8,9] regarding the types of research classified as clinical trials under the Act demonstrate the need for a nationally consistent approach to the definition of clinical trials in emergency, critical care, stroke and trauma medical research settings.

QUESTION 5.2: CATEGORIES OF MEDICAL RESEARCH

Typically, there are three overarching categories of primary medical research, as shown in Figure 1.[10] Clinical research is generally described as either observational or interventional. Observational clinical research involves the collection of data (e.g. blood or tissue samples) as part of routine medical care from patients, who are then followed up over time to a specified period or outcome to assess health and/or determine relationships between selected variables. Interventional studies assign patients to one or more treatment approaches, who are then followed up to a specified period. Research in this category may compare novel treatments against controls, such as placebo or standard medical care. Because treatments are modified from the standard, interventional studies require higher levels of consent from patients who wish to participate. For instance, prospective informed consent is required for a new drug trial; however, in patient surveys or collation of patient administrative data, verbal, implied or even a waiver of consent sometimes applies. Again, as outlined in the National Statement[3], ACEM considers that the level of risk to the participant is the most important aspect of research participation, rather than study design.

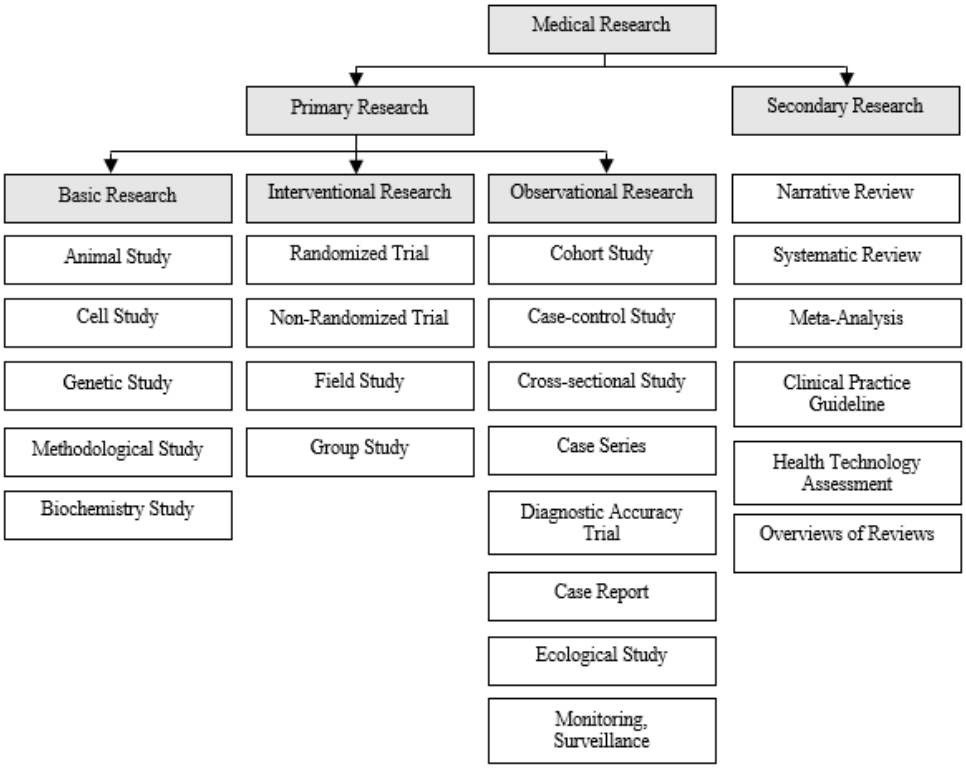
[7] NSW Civil and Administrative Tribunal. Application for approval for adults unable to consent to their own treatment to participate in a clinical trial (SPICE III Trial). Sydney: NSW Civil and Administrative Tribunal; 2013. 34 p.

[8] NSW Civil and Administrative Tribunal. Application for approval for adults unable to consent to their own treatment to participate in a clinical trial (ADRENAL Trial). Sydney: NSW Civil and Administrative Tribunal; 2013. 33 p.

[9] NSW Civil and Administrative Tribunal. Application for approval for adults unable to consent to their own treatment to participate in a clinical trial (TRANSFUSE Trial). Sydney: NSW Civil and Administrative Tribunal; 2013. 13 p.

[10] Zeng, X., Zhang, Y., Kwong, J.S., Zhang, C., Li, S., Sun, F., Niu, Y., Du, L. The methodological quality assessment tools for preclinical and clinical studies, systematic review and meta-analysis, and clinical practice guideline: A systematic review. J Evid Based Med [Internet]. 2015 Feb [cited 2017 May 12]; 8(1): 2-10. Available from: https://www.ncbi.nlm.nih.gov/pubmed/25594108.

Figure 1 Classification of medical research



Source: J Evid Based Med; 2015 Feb; 8(1):2-10.

QUESTION 5.3: WHO CAN CONSENT TO CLINICAL TRIAL PARTICIPATION

ACEM is of the strong view that responsibility for approving and governing clinical trials should rest with relevant institutional HRECs and local research governance structures. The National Statement provides researchers with guidelines for the ethical conduct of clinical trials in which informed consent from people highly dependent on medical care cannot be obtained, with the process for obtaining informed consent in these circumstances clearly outlined in chapter 4 in sections 4.9 to 4.14.[3] For instance, section 4.9 states that 'consent should be sought from people highly dependent on medical care wherever they are capable of giving consent and it is practicable to approach them'.[3] Section 4.10 provides researchers with guidance on appropriate substitute decision makers for people unable to provide consent, with section 4.13 outlining the conditions for additional prescriptions 'when neither the potential participant nor another on his or her behalf can consider the proposal and give consent'.[3] Given the complex ethical considerations involved in ensuring autonomy among participants who lack decision making capacity in these situations, ACEM recommends appointing individuals to HRECs with specific expertise in emergency, critical care, stroke and trauma medical research contexts.[11] Moreover, ACEM recommends the need to balance the ethical principles of autonomy and justice. Individuals who are unable to provide prospective informed consent in the above research contexts should not be denied the opportunity to participate in clinical trials solely because they cannot consent. In cases in which the individual's prior wishes are explicitly known, ACEM considers that such wishes should be respected.

[11] Furyk, J., Lawton, LD., Ting, JYS., Taylor, DMcD. Informed consent in emergency care research: An oxymoron? Emerg Med Australas [Internet]. 2016 Jul 28 [cited 2017 May 13]; 29(1):110-112. Available from: http://onlinelibrary.wiley.com/doi/10.1111/1742-6723.12642/pdf.

QUESTION 5.4: CONSIDERING THE VIEWS AND OBJECTIONS OF PATIENTS

As above, ACEM considers that the principle of autonomy determines that the decision making surrogate should act in accordance with what they believe the potential participant would wish for, should they be able to independently participate in the treatment discussion. After recovering capacity, as soon as practicable the participant should be informed of their clinical trial enrolment and given the opportunity to withdraw without prejudice, as per chapter 4 section 4.14 of the National Statement[3], regardless of any prior consent provided on their behalf by their decision making surrogate.

QUESTION 5.5: PRECONDITIONS FOR CONSENT

ACEM supports the preconditions for surrogate decision maker consent to participation as outlined in chapter 4 section 4.10 in the National Statement. Surrogate decision makers should be the 'participant's guardian, or person or organisation authorised by law', except under the circumstances prescribed in chapter 4 section 4.13.[3]

QUESTION 5.6: REQUIREMENTS AFTER CONSENT

When consent is obtained, ACEM deems that clinical researchers should be required to document discussion of the individual's clinical trial participation and provision of consent in the patient's record. Surrogate decision makers should be provided with the participant information statement and signed copies of the consent form, along with the researcher's and relevant HREC's institutional contact details. If and when the patient regains capacity, the researcher is obliged to explain to the participant that they have been enrolled in a clinical trial and provide them with the option of either (i) continuing their participation, (ii) withdrawing their participation while allowing retention of their data collected so far, or (iii) withdrawing completely without prejudice from the trial.

QUESTION 5.7: WAIVER OF CLINICAL TRIAL CONSENT REQUIREMENTS

Again, ACEM draws the Commission to chapter 4 section 4.13 of the National Statement, in which clauses (a) to (f) clearly outline the circumstances in which individual consent requirements for clinical trials should be waived.[3] However, despite guidance provided by the National Statement regarding waiver of individual consent requirements, this section remains open to interpretation (as evidenced by the NSW Civil and Administrative Tribunal decisions on the SPICE III, ADRENAL and TRANSFUSE trials referenced above).[7-9]

In addition, ACEM wishes to emphasise to the Commission consideration of time-critical issues related to waiver of clinical trial consent requirements in emergency, critical care, stroke and trauma medical research contexts. These include (1) time to intervention, (2) situational incapacity in urgent and acute emergency situations, (3) the potential for coercion in seeking informed consent in time-pressured environments, (4) timely availability of surrogate decision makers in time-pressured environments and time-critical interventions, and (5) the reality that surrogate decision makers may not have knowledge of the patient's explicit wishes regarding their medical treatment and clinical trial participation.

QUESTION 5.8: OTHER ISSUES

ACEM wishes to underscore to the Commission that specialist emergency physicians are strong advocates for their patients and are experts in the assessment of cognitive capacity in emergency, critical care, stroke and trauma medical care settings. In these contexts, ACEM stresses that advocacy means providing the highest level of evidence-based care to the sickest and most vulnerable patients. Clinical trials are essential to determine the best treatments for acutely ill and injured patients. Ethical responsibility to act in accordance with the patient's best interests when the individual is unable to articulate their preferences or wishes is taken extremely seriously by specialist emergency physicians. **This responsibility includes the ability to offer such patients the opportunity to participate in research 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.**

Finally, according to email correspondence in May 2017 from ACEM Clinical Trials Group member Dr Jeremy Furyk (MBBM, MPH & TM, MSc, FACEM, Emergency Physician, Department of Emergency Medicine, Townsville Hospital; Adjunct Associate Professor, Public Health and Tropical Medicine, College of Public Health and Medical and Veterinary Sciences, James Cook University, Townsville), a national telephone survey of over 1,200 people was recently conducted on their attitudes to research participation without informed consent in Australia. Consistent with international research, unpublished data show that the public is generally supportive of this concept and the need for such research within the boundaries of an appropriately specific clinical trials ethical framework.

Thank you for the opportunity to provide feedback to the *NSW Law Reform Commission*. [redacted]

Yours sincerely,

[redacted]

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