Australasian College
for Emergency Medicine

34 Jeffcott Street West Melbourne Victoria 3003, Australia
+61 3 9320 0444 | admin@acem.org.au | ABN 76 009 090 715

# Submission to the Law Reform Commission Review of WA Guardianship and Administration Act 1990 (Project 114) Amendment Part 9E (Medical Research) 2020 and 2023

## Introduction

The Australasian College for Emergency Medicine (ACEM, the College) welcomes the opportunity to provide comment on the WA Guardianship and Administration Act, in particular the operation and effectiveness of the Part 9E (Medical Research) Amendments (2020 and 2023) (the Amendments).

ACEM is responsible for the training of emergency physicians and the advancement of professional standards, including the study, research and development of the science and practice of emergency medicine in Australia and Aotearoa New Zealand.

## 1. Background

In 2020, in response to uncertainty about the legal status of health research involving adults who are unable to provide consent, amendments to the Guardianship and Administration Act (1990) were passed by the WA Parliament. While providing clarity around the legal position, experience in practice over the past four years has identified some specific challenges to the operation of the Amendments. These are obstacles to research participation and are contrary to the intent of the Amendments to strengthen the protection of people who are incapacitated through sudden loss of capacity through injury or illness.

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 (EDs) with a spectrum of undifferentiated physical and behavioural disorders.

As the peak professional organisation for emergency medicine, ACEM has a vital interest in ensuring the highest standards of medical care are provided for all patients presenting to EDs.

The College's submission is informed by several guiding principles. These are set out in the College's Position Statement on Consent for Research (attached). In brief, these are:

1. Many patients present to EDs with serious and time-critical illnesses such as cardiac arrest, major trauma, or shock – where obtaining prospective informed consent is impossible.

2. Many routine standard treatments in emergency care are *not supported by high level evidence* but are based upon consensus. Consequently, the effectiveness of these routinely administered treatments is uncertain; some may in fact even be harmful. This would not be considered acceptable in other clinical fields such as heart disease, diabetes or cancer treatment.

3. Resolving treatment uncertainty can only be addressed by well-designed and ethically approved clinical research. Rather than protecting patients, unnecessary barriers to research participation means patients

continue to be exposed to unproven treatments. In the context of emergency medicine, this means the sickest and most vulnerable patients may not be receiving optimal care. *Excluding such patients from approved research designed to produce better outcomes for their condition is therefore unethical.*

4. Clinical Research is highly regulated. All research involving patients must be approved by an independent Human Research Ethics Committee (HREC) and research studies are subject to regular reporting and audit. In addition, clinical trials are required to have an independent data safety monitoring committee. Patients who are enrolled in research studies typically have better clinical outcomes due to the close monitoring of their condition. This includes those enrolled in the 'control' or usual care arms of clinical trials.

5. A large proportion of research in emergency medicine is observational research (*for example* investigating how well a new diagnostic test works), or clinical trials comparing two or more routinely used treatments to determine which is better. In these cases, the patient receives treatment no different to that if they were not enrolled in the research. Therefore, there is *no additional clinical risk* to the patient from participating in the research.

6. Internationally agreed principles informed by the Declaration of Helsinki allow for the participation in research by people who are unable to provide consent. In Australia, these are set out in the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research 2023. This is the guiding document on which all HRECs in Australia base their decisions. No research will be approved that does not meet the conditions set out in the National Statement.

## 2. Overview of submission

Emergency physicians in WA have specific concerns regarding the effectiveness and operationalisation of the Independent Medical Practitioner (IMP) role. The Act adopts a 'one size fits all approach' to the complexities of medical research and the requirement for an IMP decreases the safeguards for patients by increasing barriers to research – when we know that patients involved in research have better clinical outcomes, including a lower mortality.

## 3. Summary of Recommendations

The College recommends to the review that the following changes would significantly improve the effectiveness and operation of Part 9E of the Guardianship and Administration Act. These changes would allow for fair and equitable access by emergency patients who cannot consent due to the serious or time-critical nature of their condition to research while retaining appropriate safeguards.

ACEM makes the following recommendations regarding the IMP:

a. Remove requirement for an IMP determination from section 110ZR
b. Remove requirement for an IMP determination from low/negligible risk research under 110ZS
c. Change definition of an IMP to include the treating clinician
d. A streamlined process for the IMP to document their determination, where required. This could be a single page 'checklist' or written entry in the clinical notes
e. Change the terminology from IMP to Independent Health Practitioner

## 4. Response to review

### 4.1 Independent Medical Practitioner

a. The principle of involving a second practitioner is reasonable in some circumstances under section 110ZS. The College does *not* consider that the involvement of an IMP is necessary under 110ZR. College members report that the involvement of an IMP when a research decision-maker (RDM) is present and willing to provide consent is intrusive and confusing for the RDM. In some circumstances, the lack of availability of an IMP can mean that the patient cannot be enrolled in the research even though the RDM agrees that the participant would wish to participate. Good clinical practice allows for recourse to

a second opinion should this be thought necessary by the researcher or the RDM, but this should not be a legislative requirement. The requirement for an IMP in 110ZR should be removed.

b. The Amendments take no account of the *hierarchy of risk* in research. Much research in emergency medicine is low or negligible risk observational or comparative effectiveness research. These criteria are explicitly laid out in the National Statement. The requirement to involve an IMP where the HREC has determined that the research meets these criteria is disproportionate and confers no additional protection for the patient while imposing a significant obstacle to their participation. The requirement for an IMP determination should be removed from 110ZS where the HREC determines that the research is low or negligible risk.

c. The definition of an IMP requires that they be a) not involved in providing treatment to the potential research candidate and b) not involved or connected to the research. In practice, this means a researcher is required to explain not only the details of the patient's condition but also the research project to another doctor who is not familiar with either. This takes substantial time away from patient care and introduces greater risk by removing the decision from the immediate clinical scenario as well as potentially delaying the commencement of treatment. The College contends that the prime role for the IMP should be to satisfy themselves about the suitability of the patient for the research study, and to determine to the best of their knowledge that the research candidate would not otherwise decline to participate, or that there is no advance health care directive which would be contrary to their participation. Consideration of the wishes of the research candidate as stated in 110ZU(1)(a), in so far as they can be ascertained, is the paramount consideration. The treating clinician also has a professional responsibility to act as the patient's advocate in these circumstances which further reinforces their participation in the decision. The best decisions are most likely to be realised when the research decision is reached by *agreement between the treating clinician and a member of the research team.* The prohibition on the treating doctor being the IMP should be removed.

d. The requirement for the IMP to provide written reasoning to satisfy 110(1) (b-e) is unnecessary as it confers no additional protection to the research candidate. The required WA Health form is a four-page document and requires specific elements of the legislation be separately addressed, is written in legal language and bears little relationship to clinical norms. In practice, doctors operating as the IMP require considerable guidance to complete this document correctly. The process is time-consuming and *is a substantial obstacle to offering research participation to patients and their families*. The College notes that the IMP determination can be made verbally in an urgent clinical scenario, and it is important that this is retained. The process could be substantially improved, in the limited circumstances where the College believes an IMP determination is reasonable (see above), by having a simple checklist that the IMP could sign to confirm they have discharged their responsibilities under the Act. This would not detract from the protections while making the process workable and proportionate as well as improving transparency. The requirement for the IMP to provide written reasons for their decisions in each of the specific domains required by the Amendments should be removed.

e. The definition of the IMP does not recognise the research that is undertaken by other AHPRA registered health professionals such as nurses, psychologists, paramedics and other allied health professionals. The terminology for the IMP should be changed to Independent Health Practitioner.

The College supports an approach consistent with other Australian States and Territories and comparable overseas jurisdictions by removing the current impediments to involving acute and critically ill patients in WA in multicentre research studies. The abovementioned changes would achieve this.

## 5. Conclusion

Since the passage of the Amendments, only a small fraction of the number of patients who are unable to consent have been enrolled in emergency medicine research in WA compared to the period prior to 2018. This is directly due to the difficulties implementing the requirements of the Amendments in practice. Some areas of research which previously thrived in WA such as prehospital (ambulance) research have completely ceased.

In addition, the College notes that the Amendments do not optimally achieve their intent. An IMP who is not involved with either the research or the care of the patient is not best placed to carry out the required functions. An IMP determination provides no additional protection to patients in the setting of low and negligible risk research and unnecessary complicates the process where there is a RDM present for no additional benefit. The requirement for the IMP to provide written reasons is a substantial obstacle to research participation.

The demonstrated impact of these issues is that many patients are continuing to be denied the benefits from participating in research which was previously available in WA and continues to be available to their counterparts in other States and Territories.

Thank you again for the opportunity to provide this submission. If you require any further information about any of the above issues or if you have any questions about ACEM or our work, please do not hesitate to contact Hamish Bourne, Manager, Policy and Advocacy (policy@acem.org.au).

Yours sincerely,

Dr Vanessa Clayden
Chair, Western Australia Faculty
Australasian College for Emergency Medicine