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for Emergency Medicine

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Submission to the Tasmanian Government Department of Justice on the Guardianship and Administration Amendment Bill 2022 (TAS)

1. Introduction

The Australasian College for Emergency Medicine (ACEM; the College) welcomes the opportunity to provide comment on the operation and effectiveness of the Part 6A (Medical Research) Amendments to the Tasmanian Guardianship and Administration Amendment Bill 2022 (the Amendments, the Bill, AA).

2. Background

2.1 About ACEM

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.

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.

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 emergency departments (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 emergency departments with serious and time-critical illnesses such as cardiac arrest, major trauma, or shock where the ability of the patient to provide informed consent is impaired.
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.
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 mean patients continue to be exposed to unproven treatments. In the context of Emergency Medicine, this can mean 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 in fact 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 by 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 (National Statement). 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.

2.2 Emergency Medicine and Research Principles

An important ethical principle in the delivery of medical care is consent. This applies to both treatment and to research participation. Some patients do not have capacity to provide informed consent. This is of relevance in emergency care settings where illness or injury is typically acute and unforeseen. A patient can have impaired consciousness, be in pain and distress, or require immediate intervention such that an informed discussion about treatment or research participation is not possible.

Emergency Physicians are strong advocates for the interests of their patients. This is not altered when it comes to consideration of enrolling patients into research. Indeed, the delivery of high-quality evidence-based clinical care depends upon the ability to undertake clinical research and is entirely consistent with our patient advocacy role. There is abundant evidence that enrolment into research is beneficial for patients, improves enrolled patients' care and improves outcomes for the wider community.

The ethical principles which underpin medical care are beneficence, non-maleficence, equity and justice. Individual autonomy allows for personal choice when it comes to the receipt of medical care. Acutely ill or injured patients who have impaired capacity are unable to exercise this autonomy. There is ethical and legal provision which allows for the delivery of clinical care in such circumstances. Access to ethically approved clinical research which aims to improve outcomes is a fundamental right. Denial of access to such research on the basis of lack of capacity to provide consent violates the principle of equity. In addition, the principle of justice requires that the burdens of research participation should be borne equally by those eligible for that research. Excluding patients based on their ability to provide consent is contrary to this principle.

It is worth considering that the aim of research is to optimise the likelihood of recovery for the participant, thus restoring their autonomy and hence their ability to partake in a discussion about ongoing participation in the research. This includes providing the right to withdraw from the research if they so choose.

2.3 Experience of the Guardianship and Administration Act

In Tasmania, the Guardianship and Administration Act (1995) (the Act) provides for a substitute decision maker (typically a close family member or 'next-of-kin') to provide consent on behalf of a patient for treatment and medical care. In December 2018, the Review of the Guardianship and Administration Act, Final Report, No. 26 (the Report) was released. The Report offered multiple recommendations for refinement to reform the Act. The Report highlighted emerging issues for the health and medical research sector. In particular, the Act does not provide provision for substitute consent for participation in research for adults that do not have the decision-making ability to provide their own consent. This means that the Tasmanian publicly funded health service cannot systematically offer the Tasmanian community access to novel medical research treatments. The Report included Recommendation 13.10 and Recommendation 13.11 to enable substitute consent for participation in health and medical research for adults that do not have the decision-making capacity to provide their own. The Office of the Public Guardian (OPG) did not acknowledge the two recommendations made in favour of health and medical research.

Since the release of the Report in December 2018, there have been no changes to the Guardianship and Administration Act to enable substitute consent for participation in health and medical research as recommended in the Report.

From the perspective of emergency medicine, there are several aspects of the amendments which still pose barriers to the effective operationalisation of the legislation. This is evidenced by the fact that no clinical research study has yet been authorised to commence recruiting patients under these provisions. This is important because, to produce valid results, research in emergency and critical care needs to be offered to all eligible participants. Excluding those who are unable to provide consent due to the severity or the time-critical nature of their illness will lead to skewed and unreliable results.

The Act as it currently stands has significant prohibitive implications for Tasmanian publicly or privately funded health services to participate in innovative and international medical research and engage in the national research reform agenda.

3. Overview of Submission

The Tasmanian Faculty of the College broadly supports the Amendments as a positive step towards resolving the legal uncertainty and enabling acutely ill and injured patients in Tasmania the opportunity to participate in research studies.

However, the College, through its Tasmanian based members, has identified several issues that will impact on both the effectiveness and operationalisation of the Amendments. Further amendments are required to ensure the fair and equitable access to emergency medicine research studies for patients in Tasmania, to deliver the best possible clinical care while protecting the safety and rights of research participants. 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 multicentre research studies.

The Tasmanian Faculty of the College therefore welcomes the opportunity to provide input into this inquiry with the objective of clarifying these issues for the benefit of Fellows who may be involved in the care and treatment of patients who are research candidates, for the administrators and research governance officers who are responsible for the authorisation of Human Research Ethics Committee (HREC) approved research within our health system, and ultimately for our patients and the wider community.

4. Recommendations

The College recommends the following changes that would significantly improve the effectiveness and operation of Part 6A 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 protection for their rights.

1. Updates to, and expansion of, the definition of 'medical research' at item 6.2.

2. Addition of definitions of what *excludes* medical research at item 6.3.

3. Inclusion of a provision at 48K (1) (c) allowing for deferred consent where a responsible person has been identified but there is not the time to seek and gain consent prior to participation in medical research.

5. Rationale for Recommendations

1. Updates and expansion of the definition of 'medical research' at item 6.2

It should be made explicit that while the amended Act will cover both "medical treatment" and "medical research", these terms are separately defined in the Act and at no point used interchangeably. Further, the provisions in relation to medical research only apply to participants unable to give their own consent.

The definition of medical research as it currently stands in the Bill has exclusions that do not align with accepted definitions and are at risk of misinterpretation. Medical research is a rapidly evolving field, and it is essential that amendments in this Bill do not have unintended preclusions, preventing Tasmanians from accessing the latest medical research.

We highlight and recommend the definition included in the recent *Western Australian Guardianship and Administration Amendment (Medical Research) Bill 2020,* which follows the definition in the National Statement.

We suggest use of the wording in Western Australian Part 9E (Medical Research) Guardianship and Administration Act 1990 (WA) Amendment Bill 2020[1], the following wording of 3AA (2) (g) to 3AA (2) (l) for the meaning of medical research:

> (2) Without limiting subsection (1), medical research includes the following —
> ...
> (g) any non-intrusive examination, including —
> (i) a visual examination of the mouth, throat, nasal cavity, eyes or ears; or
> (ii) the measuring of an individual's height, weight or vision;
> (h) observing an individual;
> (i) undertaking a survey, interview or focus group;
> (j) collecting, using or disclosing information, including personal information;
> (k) considering or evaluating samples or information taken under an activity listed in this subsection;
> (l) any other activity prescribed by the regulations to be medical research.

The College notes (2) (g), (h) and (j) above are listed in the Amendments at 6.3 as 'medical research does not include'. This definition poses risk of interpretation and requires clarification as it may imply either:

- the listed types of examinations are excluded from research, or
- there is no impediment for these activities to occur in medical research.

The College strongly advises that the former interpretation excluding these examinations from research would have significant impacts on research outcomes that can improve healthcare.

2. Additional definitions of what *excludes* medical research at item 6.3

There is value in additional definitions to what excludes medical research and we suggest adopting the following wording in the WA Amendment (Medical Research) Bill 2020, 3AA (3):

> (3) Despite subsections (1) and (2), medical research does not include —
> (a) research conducted about individuals, or their data or tissue, in the field of medicine or health that —
> (i) only involves analysing data about the individuals; and
> (ii) does not result in the disclosure or publication of personal information;
> and
> (b) any other activity prescribed by the regulations not to be medical research.

Further we suggest adding to exclusions from the definition of medical research a subsection:

- Research on a person without decision making capacity that is approved by an accredited Human Research Ethics Committee to be conducted without the need for third party consent.

3. Inclusion of a provision in definition of deferred consent

The Bill in its current form allows in 48K (1) (a) and (b) for deferred consent (participant lacking capacity, no advance care directive, no person responsible available). It does not, however, allow for deferred consent where there is a person responsible identifiable, but there is no time, or no right time, to seek and gain consent for medical research. This should be considered as per approach in the principles in paragraph 4.4.13 of the National Statement on Ethical Conduct in Human Research:

[1] Western Australia *Guardianship and Administration Act 1990,* Part 9E

'As soon as reasonably possible, the participant and/or the participant's relatives and authorised representative should be informed of the participant's inclusion in the research and of the option to withdraw from it without any reduction in quality of care[2].

Therefore, we suggest that a provision 48K (1) (c) be included allowing for deferred consent where a responsible person has been identified but due to the urgency of medical treatment and care, as is often in emergency medicine there is insufficient time to seek and gain consent prior to participation in medical research. Delaying consent can also increase the likelihood of morbidity or mortality in a patient. Some argue this compromises patient safety and is unethical itself[3].

6. Summary of Recommendations

The Tasmanian Faculty of the College generally supports the amendments to the Act as a positive step towards restoring the Tasmanian communities access to research when and if acutely ill or injured. However, there is concern that some requirements in the amended Act will not achieve the desired aim of providing protection to patients but instead impede the recruitment of patients with time critical serious illnesses into research which is designed to improve outcomes. This places sick and vulnerable Tasmanians at a disadvantage compared to their peers in other jurisdictions.

Therefore, the College's submission intends to highlight the importance of medical research definitions and inform where lack of or restricted definition may have unintended consequences to medical research. The submission explains the importance of these inclusions from an emergency medicine perspective in the interest of improving patient healthcare outcomes.

Further, the submission recommends adopting the principle of deferred consent that adheres to the National Statement on Ethical Conduct in Human Research. This is critically important in the context of emergency medicine whereby patients often require urgent medical response to illness or injury; decision-making capacity, and ability to consent may be impacted and a suitable person is unable to consent on their behalf within urgent timeframes.

7. Conclusion

The Tasmanian Faculty of the College is grateful for the opportunity to provide a submission to this inquiry. It looks forward to an outcome that achieves the best possible clinical outcomes for patients presenting to emergency departments in Tasmania by providing access to essential clinical research in accordance with the ethical principles enshrined in the National Statement, and brings Tasmania once again into alignment with the other states and territories in Australia.

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 Jesse Dean, General Manager, Policy and Regional Engagement (jesse.dean@acem.org.au; +61 423 251 383).

Yours sincerely

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Chair, Tasmanian Faulty Board

[2] National Health and Medical Research Council, National Statement on Ethical Conduct in Human Research 2007, (Updated 2018)
[3] Chalmers I. Regulation of therapeutic research is compromising the interests of patients. Int J Pharm Med. 2007; 21: 395-404