Australasian College
for Emergency Medicine

Position Statement

Consent for Research

This statement sets out the position of the Australasian College for Emergency Medicine (ACEM) with respect to clinical research undertaken in Australian and New Zealand hospitals that involves participants highly dependent on medical care, who are unable to provide consent. This statement supports Fellows and trainees of ACEM, and other emergency care researchers, in Australia and New Zealand in designing (and justifying the design of) clinical trials. Also – and of equal importance – it supports the right of critically ill patients to be involved in research in a timely manner.

ACEM believes that research is essential to deliver high quality, evidence-based clinical care. Emergency Medicine practice often involves time-critical scenarios and people who are highly dependent on medical care who lack capacity to partake in decisions about their care.

ACEM advocates that relevant legislation at state/territory and national/federal level should enshrine both the spirit and intent of the *National Statement on Ethical Conduct of Human Research*.[1]

It is in the best interests of society that all patients receive the highest quality emergency medical care based on the best available research evidence. Where this is lacking, research is required to address clinical uncertainties and drive optimal patient outcomes.

People highly dependent on medical care who are unable to provide consent are entitled to receive care which is of proven benefit, and therefore require access to the same opportunities to participate in research as their fellow citizens.

Obtaining proxy consent from next of kin, while the ideal, may be impractical in time-critical situations, and can raise distress levels.

ACEM believes that regulation should remove unnecessary obstacles for the conduct of clinical trials assessing the comparative effectiveness of (at the very least) standard interventions, especially where they pose negligible risk to participants.

ACEM also supports a pragmatic approach to supervised waivers, and variations to standard consent processes, for the conduct of research into interventions specific to the critically unwell and those with a time-critical element.

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Document Review

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Revision History

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1	July 2020	Endorsed by Council of Advocacy, Practice and Partnerships

1. Definitions

Emergency Medicine

A field of practice based on the knowledge and skills required for the prevention, diagnosis and management of acute and urgent aspects of illness and injury affecting patients of all age groups with a full spectrum of undifferentiated physical and behavioral disorders. It further encompasses an understanding of the development of pre-hospital and in-hospital emergency medical systems and the skills necessary for this development.

Informed Consent

A person's or group's agreement, based on adequate knowledge and understanding of relevant material, to participate in research.

Justice

Regard for the human sameness shared by all human beings, expressed in a concern for fairness or equity.

Negligible Risk

Research in which there is no foreseeable risk of harm or discomfort, and any foreseeable risk is of inconvenience only.

Research

Includes, at least, investigation undertaken to gain knowledge and understanding, or to train researchers.

2. The Challenge of Emergency Medicine Research

Research in emergency medicine presents distinct challenges. Assessing whether undifferentiated patients are eligible for recruitment into a clinical trial, when such patients have a time-critical and potentially life-threatening illness or injury, requires both speed and pragmatism. This can be achieved through good study design, robust research infrastructure and a supportive organizational culture underpinned, naturally, by human ethics approval.

Securing consent is a specific challenge in groups of very sick patients (see selected scenarios in Appendix). The standard procedure for obtaining written informed consent for research participation has been developed for situations where patients have time to process information and ask questions, for example in an outpatient clinic setting with an established doctor-patient relationship. It is not possible to obtain consent from someone in advance of their acute illness or injury, and patients are often too unwell to provide informed consent.

Obtaining proxy consent from next-of-kin, who may or may not be present, can be impractical for a time-critical situation. Presenting a distressed family member with a multi-page consent document can be intrusive and unreasonable.[2] Indeed, there have been calls for special training or accreditation for Human Research Ethics Committees (HRECs) considering emergency care proposals.[2]

The *National Statement on the Ethical Conduct of Human Research*[1] (the 'National Statement') is developed jointly by the National Health and Medical Research Council (NHMRC), the Australian Research Council and Universities Australia. Compliance with the National Statement is a prerequisite for receipt of NHMRC funding.

The National Statement describes how patients '*highly dependent on medical care*' may be '*incapable of comprehending their situation or of communicating about it*' but that '*research on those interventions and treatments is necessary to assess and improve their efficacy*'. A Human Research Ethics Committee (HREC), in considering a research protocol involving such individuals, will consider such issues as the importance of the clinical problem, quality of the evidence of any existing treatment or procedure, and the potential risk to participants of participating in research compared to usual care.

It is important to understand that many research studies are observational, involving no deviation from usual practice, or are clinical trials comparing existing standard treatments which are of unproven efficacy. Depending upon the specific circumstances, a HREC may approve a research protocol with the requirement for consent devolved to a proxy decision maker or waived altogether. ACEM supports the recommendations of Chapter 4.4 of the National Statement with respect to the process considerations in meeting such conditions.

3. Policy Rationale

ACEM believes that research is required to advance emergency care in people who are highly dependent on medical care who are unable to provide consent. ACEM holds this position for reasons, which include the following.

- Many treatments that represent standard practice in critical care lack a strong evidence base. The sickest and most vulnerable patients will continue to be given unproven and possibly harmful treatments if they are denied the right to participate in research that at the least seeks to address questions of the efficacy or harm of existing interventions.
- Patients participating in research may benefit directly from closer monitoring and follow up, receive life-saving therapies which they would not otherwise have access to, with potential for better outcomes. From this perspective, as well as from a justice standpoint, critically ill and injured patients should have the same right to participate in clinical research as their fellow citizens.
- Australian research has found that the community supports waiver of consent for medical research in the critically ill.[3]
- It is a professional imperative, and a fundamental element of reflective practice, that all doctors have the opportunity to help resolve uncertainties in the effect of the treatments they give to their patients.
- Delays resulting from the pursuit of consent results in preventable morbidity and avoidable mortality, and can obscure or reduce a beneficial treatment effect.[4] Some have argued that this in itself is unethical.[5]

References

1 National Health and Medical Research Council. National Statement on Ethical Conduct in Human Research. 2007 (Updated 2018). https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018 (accessed 09 May 2019).

2 Furyk JS, Lawton LD, Ting JY, Mc DTD. Informed consent in emergency care research: An oxymoron? Emerg Med Australas 2017; 29(1): 110-2.

3 Furyk J, Franklin R, Watt K, et al. Community attitudes to emergency research without prospective informed consent: A survey of the general population. Emerg Med Australas. 2018; 30(4): 547-555.

4 Roberts I, Prieto-Merino D, Shakur H, Chalmers I, Nicholl J. Effect of consent rituals on mortality in emergency care research. Lancet. 2011; 377(9771): 1071-2.

5 Chalmers I. Regulation of therapeutic research is compromising the interests of patients. Int J Pharm Med. 2007; 21: 395-404

Appendix

Scenarios – Informed Consent

Note that the items below are selective, and by no means represent a definitive set of scenarios exemplifying the barriers to securing informed consent in emergency medicine.

Cardiac Arrest

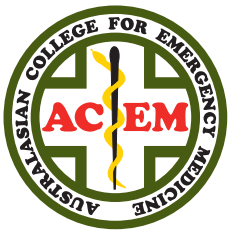
Survival from Out of Hospital Cardiac arrest is highly variable. It is known to be higher if the arrest is due to a shockable rhythm, and with very early access to defibrillation and good quality CPR there is significantly improved survival. Research in this area requires the seeking of delayed consent, either from the survivor, or from registered next of kin. Consent cannot be obtained at or during the initial phase of the resuscitation. It is challenging to request such consent during the early phases of grief, or survival with impairment. Obtaining evidence for interventions that might improve the likelihood of survival is crucial to increasing success in this area.

Illicit Drug Research

Next of kin consent is not appropriate for some incapacitated groups, even when time allows. This includes people under the effect of illicit drugs. People who are adversely affected by illicit drugs, and are brought to hospital, can be enrolled in medical research using waiver of consent in emergency situations. Pursuing a substitute decision maker consent for this group is unethical as it breaches patient confidentiality. Sadly, many of these patients do not regain the capacity to provide informed consent because of brain injury, drug-induced psychosis or even death.

Major Trauma

Patients with acute severe injuries are often unable to give valid informed consent, due to impairment from psychological distress, acute pain, lack of oxygen or blood supply, or reduced level of consciousness. However, the same distress may render next of kin or family members incapable of providing consent, and they may even have been involved in the same accident. Medical and surgical care in trauma is often performed without consent in emergency settings to avoid any delay which might risk life or patient harm. Seeking next of kin consent has been associated with a delay to initiating care in previous emergency medicine research and has been labeled unethical and results in avoidable mortality and probably morbidity.[4]



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