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MEDICAL RESEARCH ETHICS

Keeping ethics at the forefront of medical research: the *Guardianship and Administration Amendment (Medical Research) Act (WA) 2020*

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Abstract

This article describes early researcher experience with applying the *Guardianship and Administration Amendment (Medical Research) Act 2020* (GAA) in Western Australia. The Act provides legislative authority for health research involving adults unable to make reasonable judgements about their participation in research ("incapacitated candidates"). The GAA is undergoing statutory review of its operation and effectiveness. Early researcher experience and stakeholder feedback were the focus of a panel discussion organised by the St John of God Health Care (SJGHC) Human Research Ethics Committee (HREC) held on 9 September 2021. The Panel comprised nine participants including a chairman. It represented a cross-section of key personnel working in health care research across the Western Australian private and public health care hospitals and academic institutions. This article provides an overview of the content and discussion points of the Panel which highlighted the perceived strengths of, and challenges in, implementation of the GAA, and which concluded with some suggested improvements. We elaborate on the discussion points raised by the Panel and comment broadly on wider implications of issues related to consent by incapacitated research candidates.

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Introduction

Most ethical dilemmas arising in research are contextual. What is ethically appropriate in one study may not be appropriate in another. Whilst in WA the *National Statement on Ethical Conduct in Human Research* (National Statement)[1] guides ethical review, the *Guardianship and Administration Act 1990 (WA)* (incl. amendments) (GAA[2]) has legislative force. With the recent *Guardianship and Administration Amendment (Medical Research) Act 2020,*[3] WA joined other Australian states (with the remaining exceptions of South Australia and Tasmania) in enacting legislation specifically dealing with involvement of incapacitated research candidates in medical research.[4] However, WA has gone much further than any of the other jurisdictions (except Victoria) in allowing enrolment of incapacitated research candidates in urgent circumstances under strict controls – Section 110ZS of the GAA.[3(pp 18-20)] Prior to April 2020, research involving incapacitated candidates occurred in WA based on legislation governing *medical treatment* ie the *Guardianship and Administration Act 1990*.[2] The unamended GAA made no specific provision for *medical research.* Based on legal advice to government on that omission, the Western Australian Department of Health's (WA Health) interpretation was that medical research in incapacitated research candidates was not permitted in WA. A directive[5 (p 7 Appendix 4)] which had the effect of halting all research involving incapacitated candidates, including projects that had received ethical

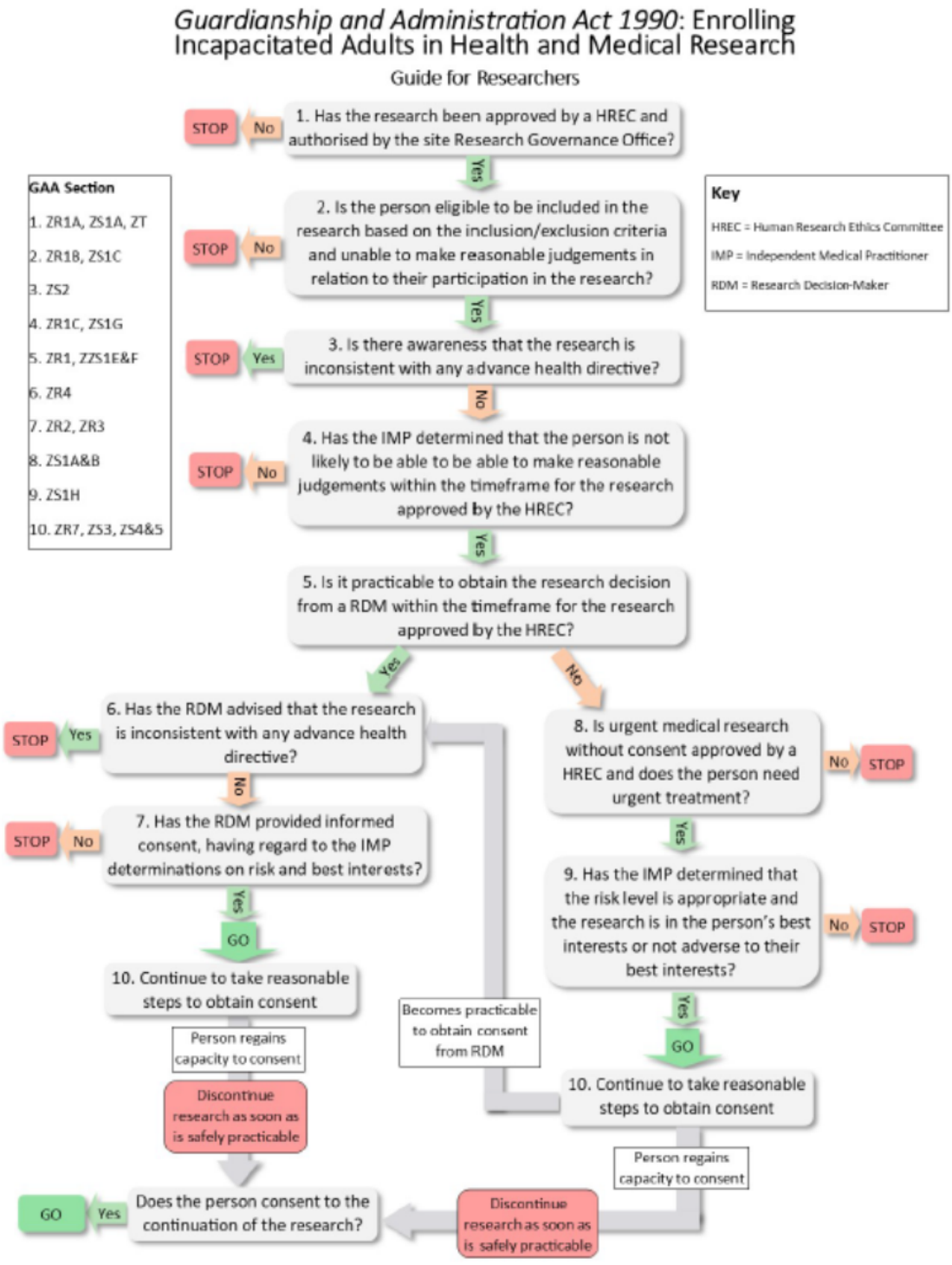

Fig. 1: Flowchart of legal requirements in Western Australia for enrollment of incapacitated subjects in medical research projects approved by a duly constituted Human Research Ethics Committee.[6 (p 9)]

approval, was issued in 2018 by WA Health. Subsequent to strong advocacy and with the impetus of the COVID pandemic, an amendment to the GAA was enacted in April 2020.[3] The early effect of the amended legislation on research in incapacitated patients was examined by a Panel established by the St John of God Health Care (SJGHC) Human Research Ethics Committee (HREC) and held on 9 September 2021, in order to summarise researcher experience thus far and obtain stakeholder feedback. We describe here the outcome and implications of the Panel's deliberations.

Research in incapacitated subjects as provided for in the GAA

The GAA as amended has two pathways to recruit incapacitated candidates: non-urgent and urgent[6 (p 9)] (Fig. 1).

Research in this group requires:

1. Prior HREC approval.
2. A protocol to assess candidate capacity or otherwise to consent, and the course of action to take if candidates regain capacity at any time during the research.
3. Determination that any Advance Health Directive (AHD) does not preclude the candidate's participation in the research. If any AHD precludes the candidate's participation in the research, then as per the GAA, the researcher cannot enrol the candidate in research.
4. An Independent Medical Practitioner (IMP) must declare that there are no substantial risks relative to existing treatments and that participation is not contrary to the candidate's best interests.
5. A Research Decision Maker (RDM) must be appointed and consent on behalf of the candidate. For urgent research, it must be determined that it is not practicable and it is unlikely to be practicable to obtain a RDM decision in time. The Panel noted that the urgent pathway is particularly complex and time consuming involving both an overall determination by the HREC and by the researcher on a candidate by candidate basis, with the assessment and approval of an IMP and with various conditions to be satisfied as specified in section 110ZS of the amended GAA,[3] including a 'time frame' approved by the HREC. Barriers to appointment of a RDM and follow up to determine potential regained capacity of candidates also pose significant challenges in non-urgent research (outlined below), particularly when candidates are living in the community, and connection to formal medical channels can be tenuous.
6. For continuation of urgent medical research, the lead researcher persists with taking "reasonable" steps (as legally interpreted) to seek consent from a RDM[3] whilst the urgent medical research is being conducted. Otherwise, and in preference, consent should be sought directly from the research candidate should they regain capacity to consent.
7. Discontinuation from the research as soon as safely practicable, if consent is declined.

Limited time has passed since implementation of the GAA and hence only a few studies exist from which to report on researcher experience to date. The GAA is currently undergoing a statutory review. The overview of themes extracted from the Panel discussion, with further elaboration by the authors, highlights the perceived strengths and challenges in implementation of the GAA amendments, and includes suggested improvements to further strengthen the contribution of research to advancing patient care. We also discuss implications that require broader discussion surrounding the global challenges of including vulnerable populations in research,[7] such as defining 'incapacity' and methods of establishing its presence. We do not attempt to resolve these issues but rather raise them as important considerations in the discourse of health research decision-making from ethical, legislative and practical perspectives, with the aim that these three aspects should not be mutually exclusive.

Diversity of type of incapacity and context

Incapacitated research candidates are a heterogeneous group. It includes people who have a developmental disability, an acquired brain injury, or dementia, as well as those who present to hospital in emergency situations requiring life-saving treatments or intensive care.

There are multiple reasons for incapacity to consent. Incapacity may be permanent or transient, and occur in diverse settings: urban, rural, community, hospital, ambulance or home. Some potential participants are "highly dependent on care" e.g. at imminent risk of death. Their family/potential RDM are likely to be distressed, for example, in an ambulance or hospital emergency department setting. This emotional state and dependency on medical care may compromise autonomy to make research decisions and impede consent processes. Conversely, some community-based studies may be considered low-risk, for example trialling different types of support groups for people after brain injury, or circumstances in which the potential research candidate has a chronic condition but family or RDM may not be available. If individuals are excluded from research due to incapacity to consent, they may be seen to be discriminated against. Thus, context must be factored into pragmatic decisions about GAA requirements for individual studies. However, the GAA provides for the same process regardless of context or risk.

Definition of incapacity

Defining 'incapacity' is complex and somewhat problematic.[8,9] For many years, this has led to exclusion of individuals or groups from research, for example, stroke patients.[10-12] Methods for establishing incapacity (approaches to screening and core tools used) are varied, and there is no clear consensus. [8,13-14] Furthermore, capacity to give consent for research may be different from capacity to make decisions in other spheres. *"Incapacitated research candidates"* in the GAA refers only to those unable to make reasonable judgements about whether or not they should participate in medical research. However, assessing decision-making capacity proves logistically difficult when there is no universally agreed nor prescribed assessment method. Although not specifically addressing medical research, the Australian Commission on Safety and Quality in Health Care (ACSQHC) NSQHS Standards guide for health service organisations providing care for patients with cognitive impairment or at risk of delirium, suggests that *"…informed consent processes must comply with state or territory legislation [specifically guardianship legislation] and best practice principles for informed consent…"*.[15 (p 39)] The primary principle is *"…always presume a person has capacity to make their own decisions"* and include and support a person where possible to make their own decisions.

The Panel suggested that researchers may need to employ innovative consent approaches, for example use of audio-visual tools, and consent procedures tailored to meet the needs of specific participants, particularly in research settings less suited to traditional consent procedures for example intensive care. Indeed, there appear to be trends emerging that online/electronic consent tools to help enhance processes for those considering participation in clinical trials (not necessarily with impaired capacity), improves knowledge and satisfaction.[16]

Challenges of the IMP role

Meeting IMP criteria is especially difficult in time-critical research, for example, in pre-hospital cardiac arrest research. In these circumstances, complex consent processes have been found to delay therapy, that is, the processes are "anti-therapeutic".[17,18] Furthermore, an IMP may be unnecessary when the research is of relatively low risk, as in comparative effectiveness trials in intensive or emergency care settings that compare two or more usual treatments. It follows that for some research where it is difficult to source an IMP (a medical practitioner who is not involved in providing treatment to the research candidate, not involved in the research study, not the spouse, *de facto* partner or other specified relative of the research candidate, and is not a member of the approving HREC),[3 (p 10)] other arrangements may be appropriate.

The Panel suggested that researcher access to IMPs could be facilitated by establishing a pool of available IMPs at all hours in metropolitan and country regions, but some members considered this to be clinically impractical. Rather, it may be sufficient to rely on the assessment and approval of a HREC given its principal role, its independent and multidisciplinary composition, and its accessibility to researchers. According to the National Statement[1] (Section 2.1), a HREC has the task of assessing *overall* risks weighed against benefits and to grant ethical approval of research with potential to improve health care, whilst monitoring research progress for changes in the *overall* risk-benefit ratio.[1]

Potential exclusion of vulnerable populations in a 'one size fits all' approach

Informed consent for research should be given on a voluntary basis after a participant has had sufficient opportunity for decision-making, based on sufficient information that is adequately understood, easily accessible, and commensurate with the risk level of the study. The danger with a single legislated approach that makes consent processes convoluted is that important research involving incapacitated candidates becomes impracticable[19] especially in time-critical research. According to the World Health Organisation Helsinki Statement: *"…the primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality"*.[20 (p 373)] This surely includes time-critical research in incapacitated subjects.

In keeping with the National Statement, we suggest that the GAA should be amended to consider modified processes and qualifications to consent based on risk stratification of the research and contextual factors. This would require researcher justification as part of HREC approval, but would be consistent with the National Statement Section 4.4.13,[1 (p 72)] which states:

"When neither the potential participant nor another on his or her behalf can consider the proposal and give consent, an HREC may, having taken account of relevant jurisdictional laws, approve a research project without prior consent if:

(a) there is no reason to believe that, were the participant or the participant's representative to be informed of the proposal, he or she would be unwilling to consent;

(b) the risks of harm to individuals, families or groups linked to the participant, or to their financial or social interests, are minimised;

(c) the project is not controversial and does not involve significant moral or cultural sensitivities in the community; and, where the research is interventional, only if in addition:

(d) the research supports a reasonable possibility of benefit over standard care;

(e) *any risk or burden of the intervention to the participant is justified by its potential benefits to him or her; and inclusion in the research project is not contrary to the interests of the participant."*

Underlying ethical principles

The GAA implies ethical principles consistent with the National Statement, namely engagement (health equity), public trust, mutual respect, and research quality and safety. Nonetheless, the Panel supported even greater alignment of the GAA with the National Statement, by including risk stratification of research and pragmatic interpretation by HRECs, to accommodate the full spectrum of research. This includes support for key recommendations already made by the Standing Committee on Legislation,[5] including (a) definition of IMP to include an incapacitated candidate's treating doctor if not otherwise associated with the research, (b) qualification of the need for an IMP in all cases, (c) use of telehealth in rural areas to obtain IMP contact, (d) defining a lead researcher as any qualified health professional formally registered with the Australian Health Practitioner Regulation Agency (AHPRA), not just a medical practitioner, and (e) repeal of the Act's 4-year sunset clause (section 110ZS) which militates against securing research grants.

The role of the lead researcher

As 'medical research' encompasses a variety of research and is led by a large range of health professionals from different disciplines, the Panel's sentiments were that health research can and should be led by any duly qualified health professional as above and that this should be explicitly provided for in the GAA.

National comparisons

The Panel's view was that overall the GAA facilitates important research. In Australia, the various state and territory guardianship laws fall into two categories: jurisdictions that have laws specifically governing *medical research* and those that conduct medical research pursuant to non–specific laws governing *medical treatment*. The GAA as amended moves WA into the former category.

In WA, the State Administrative Tribunal is not required to approve medical research and/or grant consent for 'incapacitated candidate' research studies. Instead, this remains within the remit of the HREC. Not all Australian jurisdictions permit the involvement of incapacitated research candidates in urgent medical research without the substitute consent of a Tribunal or a substitute decision-maker.

The Australian state and territory laws differ in terms of scope/coverage or type of research (for example psychological research) and research design (ie clinical trials versus non-clinical trials). These laws represent attempts to stratify risk to participants and implicitly acknowledge the broad spectrum of 'medical research'. For example, the Guardianship and Administration Act 2000 (Qld) defines 'clinical' research as a subcategory of 'medical' research[21 (S74A)] and states that comparative assessment of health care already proven to be beneficial (for example, comparison of different forms of administration of a drug) is not medical research. Nonetheless, incorporating the complexity of 'medical research' into legislation is not an easy task and any residual confusion can potentially result in inconsistent application.

Conclusion

'Research' in humans encompasses a broad spectrum of activity from lower risk service-oriented and comparative effectiveness studies to higher risk trials of novel treatments. Whilst there is considerable overlap between medical research and treatment, medical research aims to generate new knowledge to advance patient care.

The GAA is a significant advance in supporting health research particularly in intensive and emergency care, dementia, stroke, brain injury, intellectual disability and chronic psychiatric illness. It allows incapacitated candidates to benefit directly from involvement in research. Interestingly, while WA awaits the imminent outcome of the statutory review of the GAA (expected to be tabled in Parliament during 2022), the NHMRC is in the midst of revising the National Statement Section 4: ethical considerations for vulnerable participants. The draft revision states that *prima facie "…obtaining valid consent from the research participant is the standard for all research, including emergency care research, intensive care research and research involving terminally ill participants, unless otherwise justified"*.[22(p 22)]

Justification for qualification of consent lies in risk level and context. By employing nuanced processes commensurate with risk and context rather than the present "one size fits all" approach, candidate

engagement will improve and logistical difficulties will be resolved.

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Note: Ms Gorette De Jesus assisted in organising the Panel. The Hon. Eric M Heenan QC, Prof Elizabeth Armstrong and Prof Daniel Fatovich were also participants of the Panel Discussion.

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