

02 June 2020

Hon Dr Sally Talbot MLC
Chair, Standing Committee on Legislation
Parliament House
PERTH WA 6000

By email to: lclc@parliament.wa.gov.au

Dear Hon Dr Talbot

Re: Inquiry into the Guardianship and Administration Amendment (Medical Research) Bill 2020

Thank you for providing the Western Australian Branch of the Royal Australian and New Zealand College of Psychiatrists (RANZCP WA Branch) the opportunity to provide feedback regarding the *Guardianship and Administration Amendment (Medical Research) Bill 2020* (the Bill). We note that the Bill has been passed and is now an amendment to the Guardianship and Administration Act 1990 (the Act).

The RANZCP is a membership organisation that prepares doctors to be medical specialists in the field of psychiatry, supports and enhances clinical practice, advocates for people affected by mental illness and advises governments on mental health care. The RANZCP is the peak body representing psychiatrists in Australia and New Zealand. The RANZCP WA Branch represents over 450 members, more than 340 of whom are qualified psychiatrists.

The Branch commends the decision of the government to act swiftly in passing legislation that brings WA into line with other states in enabling access and contribution to potentially life-saving health research. The development of a process for authorising substitute decision makers is a helpful step in this regard.

The RANZCP WA Branch would like to draw the Committee's attention to a number of concerns arising from the specific prohibition of electro-convulsive therapy (ECT) in the Bill. The RANZCP WA Branch's position aligns with that of WA's Chief Psychiatrist, Dr Nathan Gibson, we are supportive of ECT as a well-established and evidence-based treatment and believe that it should not be unnecessarily excluded by legislation.

The RANZCP WA Branch recognises that the use of substitute decision makers to consent to participation in research is an issue of heightened concern for people who are part of population groups that have been subject to unethical medical research practices and human rights abuses in the past. It is important that these concerns are recognised and responded to appropriately. The [National Statement on Ethical Conduct in Human Research](#)¹ outlines the additional ethical and human rights considerations to be taken into account with regards research with people with cognitive impairment, intellectual disability or mental illness. It is important that the heightened vulnerabilities of people in these communities are understood and considered in human in all

medical research – any research conducted where the research participant lacks capacity to consent requires additional care. It is also important that ensuring appropriate protections are undertaken is achieved without escalating stigma and community anxiety.

In the view of the RANZCP WA Branch the Bill's singling out ECT is a deeply unhelpful perpetuation of the stigma and stereotypes around the treatment. The lack of context as to the relative risks of ECT in comparison to some of the extremely high risk treatments being tested in clinical trials contributes to maintaining an unbalanced and unjustified public perception regarding contemporary treatment. This is not helpful for the many people who may benefit from a treatment that has been demonstrated to be highly effective and well tolerated by people with relevant severe and intractable mental illness. As stated in the RANZCP's [Position statement on Electroconvulsive Therapy](#)²;

"ECT is one of the best-tolerated biological therapies with low risk for severe complications, and is considered to be one of the safest medical procedures under anaesthesia (Baghai and Moller, 2008). There is clearly documented evidence for the effectiveness of ECT in relieving psychiatric disorder with studies showing that ECT is effective 70-90% of the time (Baghai and Moller, 2008; Fink and Taylor, 2007; Kellner, 2010) with an especially high success rate when used to treat severe depression."

Like most other standard treatment procedures practiced in modern medicine, there are risks and potential side-effects. These are carefully considered and balanced in developing treatment plans, and are subject to the same high standard of clinical oversight as other contemporary clinical interventions. RANZCP practice guidelines regarding ECT recommend it always be used with consent. There are however some conditions, such as catatonia, that may be so severe that it is not possible to attain consent and in these cases substitute decision making processes are required. Where ECT is required as a life-saving treatment or otherwise essential treatment for a person who does not have legal capacity, there is an extensive system of oversight via the Mental Health Tribunal for involuntary patients and for voluntary patients who can be treated under the *Guardianship Administration Act 1990*.

In preference to the inclusion of ECT in the legislation, the RANZCP WA Branch suggests that there should be clear standards related to the Act based on the actual risk, necessity and value of procedures and/or research proposal and that these standards are applied consistently across all human research. This would assist in ensuring that risks are properly identified and managed, rather than perpetuating stigma and misconceptions regarding a specific treatment. The [National Statement on Ethical Conduct in Human Research](#) and the WA Health Department's own [Research Governance Framework](#)³ established high standards of ethical approval for research proposals, and in the view of the RANZCP WA Branch the extension of these guidelines to cover urgent situations such as pandemics would be a more appropriate approach.

The RANZCP WA's Branch other major concern arising from the inclusion of ECT is the implications for oversight of practice standards and quality improvement. Because ECT is a legitimate and authorised treatment, data is collected to regularly to inform safety monitoring, quality improvement and clinical audit activities. Monitoring outcomes is integral to maintenance of standards and providing the best possible care for people receiving treatment. These processes are also governed by ethics frameworks and privacy protections. There can however be some overlap between monitoring, evaluation and research. In their paper [Ethical considerations in quality assurance and evaluation activities](#) The National Health Medical Research Council notes that "quality assurance, evaluation and research exist on a continuum of activity, and work that begins as one form of activity can evolve into another over time." ⁴

The RANZCP WA Branch would therefore suggest that if the Act continues to list ECT, much greater clarity is given regarding the meaning of 'research' and 'research candidate' to ensure that if data records are kept regarding ongoing treatments for quality improvement and clinical audit

activities, subsequent use of that data by services or researchers would not retrospectively expose the clinicians who had provided ECT to prosecution.

Lastly, the RANZCP WA Branch notes that research plays an important role in ensuring that the best possible treatments are provided. The Act precludes potentially clinically important research that can affect the use of ECT in very disadvantaged populations. As an example;, under the protection of the *Guardianship Administration Act 1990* and *Mental Health Act 2014* people with cognitive disability may access ECT, and their treatment is based on the best available evidence which may have been gathered from a broad population group. If people with cognitive disability were frequently experiencing significantly different outcomes it would be difficult to determine how or why outcomes vary and what might improve treatment for this cohort without research. The treatment options for this group would therefore remain sub-optimal.

The [National Statement on Ethical Conduct in Human Research](#) raises that there are issues of justice to be considered and balanced – that people who are dependent on medical care have a right to be involved in research that can improve the quality of treatment they receive. Some people with disability and mental health consumers may wish to participate in or co-lead research into ECT as improving the quality of their treatment provides tangible personal or altruistic benefit. It is also worth exploring avenues to facilitate supported decision making or varying the substitute decision making authorities – for example considering that people with mental illness may also have capacity that varies over time and be able to express their wishes through advanced health directives. The current legislation would be a barrier to consumer-led research to improve ECT.

Regardless of the potential benefits in improving treatment, whether it is consumer or clinician led, and independently of the desire of individual consumers to participate, it is still the case that these factors must be weighed by appropriately constituted ethics committees against the vulnerabilities or potential harms resulting from such research if they are to be approved. The RANZCP WA Branch suggests that the current legislation's blanket ban on ECT research does not allow for all of the factors regarding any research proposal to be considered and balanced on their merits.

If you would like to discuss any of the issues raised in the submission, please contact Zoe Carter, WA Branch Policy and Advocacy Officer via zoe.carter@ranzcp.org.

Yours sincerely



Professor Megan Galbally
RANZCP Western Australian Branch Chair

¹ National Health and Medical Research Council *National Statement on Ethical Conduct in Human Research (2007) – Updated 2015* [internet] 2015 [cited 29 May 2020] Available at: <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research>

²² Royal Australian and New Zealand College of Psychiatrists *Position Statement 95 Electronic Monitoring of people utilising forensic mental health services* [Internet] 2018 [cited 28 May 2020] <https://www.ranzcp.org/news-policy/policy-and-advocacy/position-statements/electronic-monitoring-of-people-utilising-forensic>

³ Government of Western Australia Department of Health research Governance Framework [internet] 2020 [cited 28 May 2020] Available at <https://rgs.health.wa.gov.au/Pages/Research-Governance-Framework.aspx>

⁴ National Health and Medical Research Council *Ethical considerations in quality assurance and evaluation activities* [internet] 2014 [cited 29 May 2020] Available at: <https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities>