Government of **Western Australia**
Department of **Health**

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Hon Dr Talbot MLC
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Dear Dr Talbot

RESPONSE TO REQUEST FOR SUBMISSIONS IN RESPONSE TO THE *GUARDIANSHIP AND ADMINISTRATION AMENDMENT (MEDICAL RESEARCH) BILL 2020*

Request for Submissions

By a letter dated 22 April 2020, the Standing Committee on Legislation invited the Department of Health (Department) to provide a written submission on matters relating to the scope, purpose and structure of the *Guardianship and Administration Amendment (Medical Research) Bill 2020.*

Background

The *Guardianship and Administration Act 1990* (WA) (Act) is under the administration of the Attorney General, under the Department of Justice portfolio. The Act enables a substitute decision-maker to be appointed to make decisions in the best interests of an adult with a decision-making disability.

Prior to the enactment of the *Guardianship and Administration Amendment (Medical Research) Bill 2020* (Amendment Act), the Act allowed treatment decisions to be made on behalf of an incapacitated person by a substitute decision-maker and for a health professional to provide urgent treatment to a patient in the absence of a treatment decision.

However, the Act did not provide for adults without the ability to provide informed consent to be involved in health and medical research. This situation inhibited research involving some people who are highly dependent on medical care or those with a cognitive impairment who are unable to provide informed consent.

In a contemporary health system, integration of health services and research is encouraged, as research is essential to improve health policy and practice. Denying incapacitated adults the ability to be involved in research creates an inequity and prevents discoveries related to the care of these persons.

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As well as potential direct benefits to research participants, such as access to new treatments being tested in clinical trials, research benefits the community by generating evidence which improves the promotion of health and wellbeing and the provision of care for all.

The Amendment Act provides critical legislative amendments to the Act to enable Western Australian researchers to include incapacitated people in research, which can provide benefits to those involved in the research as well as the broader community. The Amendment Bill was passed as a matter of urgency in the context of the COVID-19 pandemic and the provisions of the Amendment Act are assisting researchers in their efforts to develop means to prevent and treat COVID-19, but its benefits are not confined to COVID-19. The Amendment Act facilitates a broad range of health research and the need for the amendments effected by the Amendment Act was identified well before the COVID-19 emergency.

The provisions of the Amendment Act reflect a cautious approach to allowing people to be included in medical research when they do not have the capacity to provide consent. The Amendment Act includes various protections to ensure that a person without capacity is only included in medical research when it is in their best interests or not adverse to the person's interests (having regard to the factors listed in s.110ZU), and not inconsistent with the person's known wishes.

Under the Amendment Act, a person cannot be involved in medical research unless it has been ethically approved by a Human Research Ethics Committee (HREC) in accordance *National Statement on Ethical Conduct in Human Research 2007*[1] (National Statement). There are also various review and reporting provisions, which allow for oversight and transparency. The efficacy of these provisions can only be determined after a reasonable period of time has passed, such as after a twelve month period from the date substantive provisions of the Amendment Act became operational.

Relevant Recommendations of the Statutory Review 2015

A statutory review of the Act was released by the Department of the Attorney General in 2015 (2015 Review). The 2015 Review included the following recommendations related to consent to medical research:

> *Recommendation 6.1*
>
> *That in addition to treatment decisions, a decision may be made on behalf of a person, including a represented person, for that person to participate in medical research, including treatment that is part of research when:*
> - *It is deemed to be in the person's best interests*
> - *the research will not involve any known substantial risks to the participants or if there are existing treatments for the condition concerned, will not involve material risks greater than the risks associated with those treatments*

- *the research has been approved by a human research ethics committee*

and consideration is given to:

- *the wishes of the person, so far as they can be ascertained*
- *the nature and degree of any benefits, discomforts and risks for the person in having or not having the procedure*
- *any other consequences to the person if the procedure is or is not carried out*
- *any other prescribed matters.*

Recommendation 6.2

Health professionals acting under the urgent provisions in sections 110ZI and 110Z1A will not be permitted to make a decision on behalf of a represented person for that person to participate in medical research, including treatment that is part of the research.

It is noted by the Department that the elements of Recommendation 6.1 (best interests, risks and HREC approval) have been incorporated into the Act and this is supported. It is noted that in response to research and consumer stakeholder feedback, Recommendation 6.2 has not been actioned via the Amendment Act. Rather s.110ZS enables a person to be included in medical research in an urgent treatment setting where defined protections for this vulnerable group have been satisfied.

The *Guardianship and Administration Amendment (Medical Research) Act 2020*

The amendments made to the Act by the Amendment Act, which commenced on 7 April 2020, create a legislative basis for people without the capacity to provide informed consent to be included in medical research in two broad sets of circumstances provided relevant criteria are met:

- Firstly, where a research decision-maker is available and makes a decision on behalf of the person to include the person in the research; and
- Secondly, where a person requires urgent treatment and it is not practicable for the researcher to obtain a research decision in relation to the person from a research decision-maker.

The enactment of the Amendment Act has already facilitated the instigation of research which involves incapacitated adults. This is particularly important at this time with the local and global threat of COVID-19, but also has broader application including research involving aged-care residents.

One example of COVID-19 research that has benefited from the Amendment Act is the REMAP-CAP clinical trial which is designed to evaluate the effect of a range of interventions to improve outcomes of persons admitted to intensive care with community-acquired pneumonia. Initially designed by a global network of clinicians during the 2009 H1N1 pandemic, the REMAP-CAP has been adapted for intensive care unit patients with COVID-19.

As the Amendment Act came into effect on 7 April 2020 and the inquiry submission date represents only two months from that date, the Department is still in the process of developing standard processes and procedures and there is limited operational feedback to inform this submission. As mentioned above, the efficacy of the Amendment Act can only be determined after a reasonable period of time has passed, such as after a twelve month period from when the date substantive provisions of the Amendment Act became operational.

Notwithstanding this, the following comments are provided for consideration.

Scope of medical research

The Amendment Act amended the Act to include a definition of 'medical research' in section 3AA. Medical research is defined to mean research conducted with or about individuals, or their data or tissue, in the field of medicine or health, and includes activities undertaken for the purpose of that research.

Although the definition of medical research has been defined as 'medicine or health' in order to capture research in a wider health context, including nursing, allied health, health sciences and mental health, it is noted that generally 'medicine' is viewed as a sub-set of 'health' and not vice versa.

Placebos

Section 3AA(2) of the Act lists specific activities that fall within the definition of medical research and expressly provides that medical research includes the administration of placebos. A placebo is defined in the Act to mean "*a substance not containing an active agent under study, administered to some individuals to compare the effects of the active agent administered to other individuals*". This definition is consistent with the definition contained in the National Statement.

Placebos are a standard control component of many clinical trials and allow participants (for example, those with cognitive impairment), family members and staff to be 'blind' to the intervention while the research is underway. To exclude the use of placebos would be against fundamental standards of research methodology (which also include randomisation and 'blinding') and would make it impossible to enrol people in clinical trials for drug treatments and vaccines. The use of placebos must not result in care less than the standard treatment.

Research decision-maker

Under s.110ZR of the Act, a research decision-maker can consent on behalf of a person without the ability to make reasonable judgments in respect to their participation in medical research subject to certain requirements. The process for determining who is a research decision-maker in respect to a person is established by s.110ZP and 110ZQ of the Act.

These provisions reflect the existing process for determining who could make a treatment decision in respect to a person under Part 9C of the Act and this is supported by the Department.

Medical research with consent of research decision-maker

Under s.110ZR, a research decision-maker may make a decision to include the person in medical research if:

- The research has been approved by a HREC; and
- The person is unable to make reasonable judgments about their participation in the research; and
- An independent medical practitioner has determined that the person is not likely to regain the ability to make a reasonable judgment and consent to their participation within the timeframe approved by the HREC.

Before consenting to include a person in medical research, the research decision-maker must receive the determination of an independent medical practitioner that:

- Having regard to the matters listed in s.110ZU, the medical research is in the best interest of the person or is not adverse to their interests; and
- The person's participation will only involve observing the person or carrying out another non-invasive examination, treatment or procedure; or
- If the research involves an invasive treatment or procedure, the medical research does not involve any known substantial risks to the person; or
- If the above points do not apply, the medical research will not involve substantial risks to the person greater than if that person did not participate in the research.

As noted previously, the 2015 Review Recommendation 6.1 included consideration of best interests and risks, however it was not stated that determination regarding this would need to be undertaken by an independent medical practitioner.

Urgent medical research without consent

As previously noted, the 2015 Review recommended that health professionals acting under urgent treatment provisions in sections 110ZI and 110ZIA not be permitted to make a decision on behalf of a represented person to participate in medical research, or treatment that is part of research.

This recommendation was not adopted. The adoption of this recommendation would prevent research in emergency situations where participation in research is time critical and a research decision-maker is not available or able to make a decision on behalf of the person. There is a significant niche of research that focuses on the discovery and application of time critical diagnostics, decision-making and treatment that saves lives, prevents or reduces disability and restores health. This research is essential to generate evidence to support a new treatment or demonstrate which treatment has the best health outcomes.

Following feedback provided by research stakeholders, the Attorney General and Minister for Health requested the Department to provide recommendations with regards to research in emergency situations, so this could be considered in the Act amendments. In light of this, the Amendment Act amended the Act to include s.110ZS, which allows for a person needing urgent treatment to be included in medical research approved by a HREC without a research decision maker.

However, in order for a person to be included in medical research under s.110ZS, the following criteria must be met:

- The person must require urgent treatment as defined in s.110ZH of the Act to mean treatment that is urgently needed to save the person's life, prevent serious damage to the person's health or prevent the person from suffering or continuing to suffer significant pain or distress.
- The person must be unable to make reasonable judgments as to their participation in the research;
- The person must not be subject to an existing research decision regarding the research.
- It must not be practicable for the researcher to obtain a research decision in relation to the person.

In addition to these criteria, the researcher must receive determinations from an independent medical practitioner that:

- It is not likely that the person will be able to make reasonable judgments in respect to their participation in the research within the timeframe for the research approved by the HREC.
- The research is in the candidate's best interests or not adverse to their interests.

The researcher must also receive from the independent medical practitioner a determination that:

- The research candidate's participation will only involve observing the person or carrying out a non-invasive examination, treatment or procedure; or
- If the above point does not apply, the research will not involve any known or substantial risk to the person; or
- If the above two points do not apply, and there is an existing treatment available to the research candidate, the medical research will not involve any known substantial risk to the person greater than the risks associated with the treatment; or
- If all of the above points do not apply, the medical research will not involve substantial risk to the research candidate greater than if that person did not participate in the research.

Sunset Provisions

The Amendment Act includes a sunset clause which will repeal the urgent medical treatment provision (s.110ZS) four years after its commencement.[2] The sunset clause reflects the cautious approach that has been adopted in introducing legislation

[2] 7 April 2024

allowing for people without capacity to be enrolled in medical research in an urgent treatment setting. The sunset clause was introduced in the Legislative Council as an amendment to the original Amendment Bill introduced in both the Houses of Parliament.

The Department of Health is cognisant that the repeal of the urgent medical treatment provision will create barriers to the availability of research treatments. While the COVID-19 pandemic has made enacting the Amendment Act an urgent matter, the urgent medical treatment provisions are not intended to be confined to research related to COVID-19. The urgent medical treatment provisions can provide benefits by allowing a person who presents in an urgent treatment setting to be provided with a new treatment that is subject to a clinical trial where a research decision-maker cannot be located, provided an independent medical practitioner determines that inclusion in the medical research is in the person's best interests or not adverse to the person's interests and is not inconsistent with their wishes.

The sunset clause presents significant practical difficulties for medical research projects. The time-limit affects the viability of research projects because funding and ethics research approvals cannot be given if the project is not considered feasible. A typical research project has a lifespan of three to five years. If there is a question as to whether a project can be completed, it is unlikely to obtain approval to proceed and therefore, the treatment that is subject to the research may not be available to a person presenting in an urgent care setting.

The Department of Health supports the removal of the sunset clause.

Independent medical practitioner

The requirement for determinations by an independent medical practitioner reflects the cautious approach to enabling persons to be enrolled in medical research. There is no such requirement in respect to standard treatment under Parts 9C or 9D.

The term independent medical practitioner is defined in s.110ZO to mean, in relation to medical research, a medical practitioner who:

a) is not involved in providing treatment to the person under Part 9E;
b) is not involved or connected to the research other than having a professional interest in the area of the research;
c) is not the spouse, de facto partner, parent, grandparent, sibling, child or grandchild of the person; and
d) is not a member of the HREC that approved the research.

The treatment referred to in s.110ZO(a) is confined to treatment provided under Part 9E, it does not capture other general treatment provided to a person. Accordingly, a person's GP may act as the independent medical practitioner for the purposes of Part 9E provided that the GP is not involved in providing the treatment that forms part of the medical research and does not fall within any of the other exceptions. This is considered desirable as the person's GP may be well placed to determine whether inclusion in research is in the person's best interests.

The practicality of the independent medical practitioner determination requirement is yet to be evidenced in operational environments, especially in emergency situations. In addition to having sufficient knowledge of the research protocol, the independent medical practitioner must take account of the wishes of the person (to the extent that their wishes can be ascertained) , the person's health status (in order to be in a position to assess the person's best interest and risks) and the likelihood of the person regaining the ability to consent in the research timeframe.

The requirement for an independent medical practitioner's determination in non-time critical research imposes a much higher bar to be satisfied than is required for standard treatments. There is no requirement for a person responsible for a patient to obtain a determination from an independent medical practitioner in respect to a decision to provide standard treatment to a patient under Part 9C of the Act.

With regards to best interests and risk, the Department's view is that consideration ought to be given to whether it should be necessary to obtain a determination from an independent medical practitioner where there is a research decision-maker who has had the opportunity to consult with a medical practitioner and has been fully informed about the research by appropriate documentation. This would include participant information and consent forms, which would reflect the process where a person provides consent for themselves.

The Department has received inquiries on the meaning of the term 'independent medical practitioner'. Since the purpose of this requirement is to ensure impartiality of the independent medical practitioner determination, the Department is of the view that this should be considered in the context of whether there may be a conflict of interest as to whether the person is or is not enrolled in the research. All investigators on the research project and persons who have any vested interests that prevent them from providing an independent determination would not meet this requirement.

One option that is under consideration, is the establishment of panels of independent medical practitioners at research sites who would be required to familiarise themselves with the research protocols and make themselves available to provide a determination when necessary.

The Department is collaborating with research governance and ethics offices to develop a 'Research Decision Checklist' which will facilitate the provision of the independent medical practitioner determinations to the research decision-maker or researcher and guide the correct interpretation of 'independence', 'best interests', 'risks' and 'the likelihood of the person regaining ability to consent'.

Best interests

Sections 110ZR(2)(b) and 110ZS(h) require a determination that research is in the best interests of the person or not adverse to the interests of a person before they can be included in research under Part 9E of the Act. The wording which allows for research to be in the person's "best interests or not adverse to their interests" recognises and supports that research methodology may require the use of placebos

which may have no material effect and additionally that the outcome of research participation is not known before that participation occurs.

Likelihood of person regaining ability to consent

Sections 110ZR(1)(c) and 110ZS(1)(f) of the Act requires that an independent medical practitioner must determine that the research candidate is not likely to be able to make reasonable judgements within the timeframe for the research approved by the HREC.

The Department has received queries about the meaning of this requirement. The Department understands that the intent of this is to protect a person's rights by ensuring they are not enrolled in research when it is likely that they will be able to make a decision with the timeframe that is required for the validity of the research to be maintained.

The Department is recommending that the 'timeframe' be clearly indicated by researchers within the research protocol so this can be considered by the HREC and notes that the timeframe may not necessarily be numerically defined (for example, minutes/hours/days) as in many circumstances it may be more appropriate to define the 'timeframe' as an event occurring, or milestone being reached (for example, the point at which the patient requires the treatment).

Lead researcher to continue to seek consent

Under s.110ZR(7), if research participation is with consent of a research decision-maker and the person regains the ability to provide their own consent then the lead researcher must discontinue the research as soon as safely practicable and recommence only if person provides consent to continue.

Under s.110ZS(2) of the Act, while a researcher is conducting medical research in relation to a person in accordance with an urgent medical research decision (i.e. no consent), the lead researcher must continue to take reasonable steps to obtain a research decision. If either the research decision-maker decides to refuse to consent to the person continuing to be involved in the research, or the person regains the ability to make reasonable judgements about the medical research, the lead researcher must ensure that the research is discontinued as soon as is safely practicable and only continue if the person provides that consent. The requirement to stop research upon the person regaining capacity could impact the integrity of research if there is a disruption to the research activities, even if the person consents to the research at the first opportunity; for example, if continuous observation cannot be maintained.

The term lead researcher is defined in s.110ZO, which provides that, in relation to medical research, the term lead researcher means "a medical practitioner who has sole or joint responsibility for conducting the research".

In practice the lead researcher would be the lead at each institution or site at which the research is being undertaken. It is noted that restricting the lead researcher to a 'medical practitioner' prevents research involving incapacitated adults where the lead researcher is of another health profession, for example, nurses or allied health

professionals. This restriction could lead to situations where a medical practitioner is nominally included as a lead researcher. This would result in issues in attribution and authorship, and would potentially deny other health professionals who led the research appropriate acknowledgement.

State Administrative Tribunal

Under s.110ZZ of the Act, a person who, in the opinion of the State Administrative Tribunal (the SAT), is interested in a decision Made under Part 9E of the Act may apply to the SAT for review of the decision made under the medical research provisions. Upon a review, the SAT may vary or cease the decision. Under s.110ZZB, a decision by the SAT upon review is only to have prospective effect and so will not have any effect on the validity of anything done pursuant to a decision under Part 9E prior to the SAT's decision.

Reporting requirements for researchers

Section 110ZZC requires that if a researcher conducts medical research in relation to a research candidate under Part 9E, the researcher must give the Health Minister a written notice in the Form Approved by the Minister for Health stating:

- that the researcher is conducting the research in relation to the person;
- whether the medical research is carried out pursuant to:
    - a research decision; or
    - an urgent medical research decision.
- the type of medical research the researcher is conducting;
- the purpose of the research; and
- any other information required by the approved form.

The Department is developing a template for researchers to complete to ensure mandatory data to meet the requirements of s.110ZZC is captured and there is consistency in data collection.

It is proposed that researchers state-wide (public and private) will be required to submit the completed report templates to the Department by 1 February each year (for the previous calendar year) so that this data can be collated by the Department and provided to the Minister for Health by 1 March each year in order that the Minister can meet the requirement to report to Parliament "as soon as practicable after each anniversary of the day on which the Act amendment came into operation" (7 April).

The "type of research" has been aligned with s.3AA (2) and "purpose of research" has been combined with "Grouping of Research" and "Field of Research" to align with the Australian and New Zealand Standard Research Classifications (ANZSRC).

In addition, to the information listed in s.110ZZD, it is proposed to collect information as to whether a research decision-maker consents for research to continue if a person was enrolled under s.110ZS (urgent medical research) or if the person chooses to continue in the research if they regain the capacity to make this decision.

The processes and forms for reporting under Part 9E of the Act are being developed by the Department. Due to the need to expediate COVID-19 research, it is intended that the form will be trialled in the REMAP-CAP study.

Closing Comments

The Department supports the amendments effected by the Amendment Act, which enable Western Australian researchers to include incapacitated people in research. These amendments will provide benefits to those involved in the research as well as the broader community.

- The Department recommends that the sunset clause that applies to s.110ZS of the Act should be removed as retention of s.110ZS is essential to enable research that improves the treatment of patients in emergency situations. Further, it is recommended that the sunset clause be removed as soon as possible as the four-year limitation restricts the recruitment period and hence the feasibility of projects where the enrolment period would extend beyond the repeal date.
- The Department recommends that consideration should be given to the need for an independent medical practioner to make a determination with regards to best interests and risk when there is a research decision-maker available who is willing to make a decision as their decision will be based on the provision of information as per the process applicable to a person making their own decision.
- The Department recommends that consideration be given to removing the default requirement for research to be discontinued as soon as is safety practicable if a person regains capacity, as this may impact on the integrity of the research if the person makes a decision to continue in the research.
- The Department recommends that consideration be given to the requirement for a lead researcher to be a medical practitioner as there are situations when it is appropriate for the lead researcher to be a health professional such as allied health, nursing or mental health.

Yours sincerely

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DIRECTOR GENERAL

09 June 2020