Including People with Dementia in Research: An Analysis of Australian Ethical and Legal Rules and Recommendations for Reform

Nola M Ries, Katie AThompson and Michael Lowe

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N.M. Ries [corresponding author]
Faculty of Law, University of Technology Sydney, Broadway, NSW 2007, AUSTRALIA
e-mail: Nola.Ries@uts.edu.au

K.A. Thompson
School of Law, University of Newcastle, Callaghan, NSW 2308, AUSTRALIA
e-mail: katie.a.thompson@uon.edu.au

M. Lowe
Royal Darwin Hospital, Darwin, NT 0811, AUSTRALIA
e-mail: michael.lowe@nt.gov.au

Abstract Research is crucial to advancing knowledge about dementia, yet the burden of the disease currently outpaces research activity. Research often excludes people with dementia and other cognitive impairments because researchers and ethics committees are concerned about issues related to capacity, consent, and substitute decision-making. In Australia, participation in research by people with cognitive impairment is governed by a national ethics statement and a patchwork of state and territorial laws that have widely varying rules. We contend that this legislative variation precludes a consistent approach to research governance and participation and hinders research that seeks to include people with impaired capacity. In this paper, we present key ethical principles, provide a comprehensive review of applicable legal rules in Australian states and territories, and highlight significant differences and ambiguities. Our analysis includes recommendations for reform to improve clarity and consistency in the law and reduce barriers that may exclude persons with dementia from

participating in ethically approved research. Our recommendations seek to advance the national decision-making principles recommended by the Australian Law Reform Commission, which emphasize the rights of all adults to make their own decisions and for those with impaired capacity to have access to appropriate supports to help them make decisions that affect their lives.

Keywords Research ethics; Law; Dementia; Consent; Substitute decision-making; Advance directives

1. Introduction: The Imperative of Including People with Dementia in Research

Dementia, a clinical syndrome caused by various neurological diseases, is one of the most pressing health issues in industrialized countries with ageing populations. Dementia can affect the ability to understand, retain, apply, and act on information. It can impair communication, cause behavioural changes, and limit abilities to carry out activities of daily life (Burns and Iliffee 2009). Globally, an estimated 46.8 million people live with dementia, and this number is expected to double every twenty years, reaching 131.5 million people in 2050 (Alzheimer's Disease International 2015). In Australia, over 400,000 people are living with dementia and around 240 new diagnoses are made each day (Alzheimer's Australia 2017). It is the second leading underlying cause of death (Australian Bureau of Statistics 2016). By 2050, an estimated one million Australians will be living with dementia.

Research is crucial to advancing knowledge about dementia, including its causes, possible therapeutic interventions, and ways to improve the quality of life of people living with dementia. People with dementia should receive respectful, beneficent, and just care that optimizes their outcomes. Appropriate care depends upon the availability of well-designed research, conducted and analysed with rigour (LeBlanc, Wheeler, and Abernathy 2010). Yet, the burden of the disease outpaces research activity, and there are many inadequacies in the knowledge base that informs clinical care (Lam et al. 2015). For instance, of 109 recommendations in recently published Australian practice guidelines for dementia care, only twenty-nine are categorized as evidence-based recommendations, meaning they are formulated from a systematic analysis of published research findings (Guideline Adaption Committee 2016). Of these, twenty-two recommendations are based on evidence assessed as being of low or very low quality and only seven are based on moderate-quality evidence. None of the recommendations are based on high-quality evidence. A clinician's confidence in the effectiveness of these recommended actions must necessarily be guarded.

The 2015 World Alzheimer's Report urges an increase in research investment for dementia proportionate to the social cost of the disease (Alzheimer's Disease International 2015). In Australia, dementia is a National Health Priority Area, and research funding has been targeted to dementia (Australian Institute of Health and Welfare n.d.). We are concerned, however, that differing legal frameworks across the country may restrict the types of research undertaken and inappropriately exclude people with dementia from participating in research. As a consequence, research may fail to tackle some of the more pressing issues, especially for people in later stages of dementia and those living in socially isolated circumstances.

Research often excludes people with cognitive impairment (Taylor et al. 2012) because "many researchers and ethics committees are nervous about including this population in their studies" (Pachana et al. 2015, 705). Relying on the participation of those who are judged to be unequivocally competent is problematic for all research but particularly for dementia research, as these individuals comprise a potentially small and atypical subset of people with dementia. Excluding those who have reduced decisional capacity raises doubt about the external validity of research findings (Kim 2011).

Scientific study to advance knowledge about dementia and improve the quality of evidence to inform care depends on people with the condition participating in research (Dresser 2001). Literature reports "differences in the issues of concern, experiences and needs of people with dementia at the mild, moderate and severe stages" and stresses that "inclusion [in research] of persons with dementia at all stages is essential" to understand and respond to their varying needs (Murphy et al. 2015, 800). Yet, researchers who propose to include people with dementia in research have reported obstacles arising from the complexities of obtaining ethical and legal approval, including issues of capacity, and the challenges of seeking consent from substitute decision-makers who are uncertain about what the person with dementia would want (Cubit 2010; Monroe 2013). Special complexities arise in multi-jurisdiction studies that require compliance with differing legislative rules and processes.[1]

[1] Despite a process for National Mutual Acceptance of the scientific and ethical review of multisite human research in Australia (NSW Government 2017a), jurisdiction specific laws impose varying consent and substitute decision-making rules that must be followed.

In Australia, participation in research of people with cognitive impairment is governed by the National Statement on Ethical Conduct in Human Research[2] (the "National Statement") (NHMRC 2007) and a patchwork of state and territorial laws that establish rules for how decisions concerning health and personal matters should happen for a person who lacks capacity. There is significant variation across the country. The law in several jurisdictions is largely silent on research participation by people with impaired capacity, meaning researchers must follow the National Statement and any specific policies on research developed by health departments or facilities. Other jurisdictions set out detailed statutory rules governing approvals and substitute decision-making for research involving people who lack capacity to give their own consent. In some cases, statutes impose greater restrictions than what is laid out in the National Statement. A further complexity is that statutes vary in how they define research, meaning some types of research (such as clinical trials) are covered by legislation and other types (such as observational studies) are excluded from statutory rules. Statutes also allow people, when they have capacity, to designate individuals who will act as decision-makers for health and personal matters should the appointer lose capacity in the future. Yet some statutes preclude a designated decision-maker from making choices about certain types of research. People have a legal right—recognized at common law and in statutes in some states and territories—to record their wishes on health and personal matters in advance directives with the expectation that their wishes will be respected during periods of incapacity. Advance directives for research are rarely encountered in practice, however. In our view, this wide legislative variation has no rational foundation, precludes a consistent approach to research governance and participation, and hinders research that seeks to include people with impaired capacity, especially multi-jurisdictional studies. This article analyses the ethical and legal rules in Australia relevant to the inclusion of people with dementia in research. We present key ethical principles in the National Statement, provide a comprehensive review of applicable legal rules in state and territorial statutes, and highlight significant differences and ambiguities. Our analysis includes recommendations for reform to improve clarity and consistency in the law and reduce barriers that may exclude persons with dementia from participating in ethically approved research. Our recommendations seek to

[2] The National Statement is produced by the National Health and Medical Research Council in accordance with its statutory obligations under s10 of the *National Health and Medical Research Council Act* 1992 (Cth) to issue guidelines for research involving humans.

advance the national decision-making principles advocated by the Australian Law Reform Commission (2014), which emphasize the rights of all adults to make their own decisions and for those with impaired capacity to have access to appropriate supports to help them make decisions that affect their lives.[3] Our focus is on dementia, but our recommendations are relevant for research that involves people with other conditions or injuries that impair cognitive abilities.

We start from the premise that the National Statement provides an equitable set of core values and principles for individuals and organizations that carry out human research. We agree with its aims to protect vulnerable persons, empower people with reduced autonomy, and advance knowledge through meritorious research. Compliance with the National Statement is mandatory for "research that is funded by, or takes place under the auspices of" any of the national bodies that developed it, which are the National Health and Medical Research Council, the Australian Research Council, and Universities Australia (NHMRC 2007, 6). The statement also sets standards for "human research undertaken by governments, industry, private individuals, organisations, or networks of organisations" (NHMRC 2007, 6). Consistent with the principles in the National Statement, we assert that people with cognitive impairment are entitled to participate in research and, where they are able, they should be supported to express their preferences regarding research participation, including future participation, and have those wishes respected. The law should not, as a default, preclude a decision-maker appointed by a person from making choices about research participation for that person should he or she lose capacity. Clear and timely processes are needed to allow substitute decision-making about research participation for people with impaired capacity

[3] The four national decision-making principles contained in the report are (see p 11):

(1) The equal right to make decisions: All adults have an equal right to make decisions that affect their lives and to have those decisions respected.

(2) Support: Persons who require support in decision-making must be provided with access to the support necessary for them to make, communicate, and participate in decisions that affect their lives.

(3) Will, preferences, and rights: The will, preferences, and rights of persons who may require decision-making support must direct decisions that affect their lives.

(4) Safeguards: Laws and legal frameworks must contain appropriate and effective safeguards in relation to interventions for persons who may require decision-making support, including to prevent abuse and undue influence.

who do not have family members or friends available to make such choices. Law reform should eliminate duplication and inconsistencies; in particular, laws should not require a duplicative review by a body such as a guardianship tribunal where a research ethics committee has already reviewed and approved a research study. Indeed, the National Statement requires that *all* research that proposes participation by people with cognitive impairment be reviewed and approved by a human research ethics committee, unless the research involves only negligible risk (i.e., no foreseeable risks of discomfort or harm) or the use of previously collected non-identifiable data, such as an anonymized chart review (NHMRC 2007, 69, [5.1.6]).

As will be discussed in the following section, statutes in some states and territories set out rules that apply for certain types of research. Whether and how a research project falls into a category covered by legislation has important consequences for researchers, potential participants, and substitute decision-makers. For example, in New South Wales and Queensland, research covered by state laws triggers a requirement to obtain the approval of a guardianship tribunal to include people with impaired capacity. Other jurisdictions do not require a process of tribunal approval for ethically approved research but may define research in a statute that establishes rules for substitute decision-makers, for instance, by identifying who can act as a decision-maker and the factors they must consider in making choices for a person with impaired capacity. Legally and ethically, however, the starting point is that consent for research participation must be sought from the adult if she or he has decision-making capacity in relation to the proposed research activities.

2. Respecting the Right of a Person with Dementia to Make Their own Decisions Where Able

There is clear legal and ethical recognition of the right of adults with capacity to make decisions about their own body and personal interests.[4] If a person with a diagnosis of dementia, or other condition that affects cognition, has capacity to make decisions about a proposed research study, consent must be sought from that individual, not a substitute decision-maker. Making assumptions that people with dementia are unable to make decisions

[4] In *Schloendorff v Society of New York Hospital* (1914) 211 NY 125, Cardozo J famously wrote that "[e]very human being of adult years and sound mind had has a right to determine what shall be done with his own body" (at 129). This principle has been adopted in Australian law: see for example, *Rogers v Whitaker* [1992] HCA 58 and *Hunter and New England Area Health Service* (2009) 74 NSWLR 88.

about participating in research reinforces negative stereotypes of dementia (NHMRC 2007) and denies them the opportunity to make meaningful contributions to research and share in its benefits (Slaughter et al. 2007).

According to the National Statement, consent requires the capacity to form an "adequate understanding of both the proposed research and the implications of participation in it" (NHMRC 2007, 16, [2.2.2]). The statement notes that the law may prescribe further rules for determining when capacity is present. The law assumes adults have capacity to make their own decisions unless there is evidence to the contrary (Re MB [1997] 2 FCR 533). In most states and territories, a person would be considered to have capacity to consent to a research study if she or he understands the general nature and effect of procedures or activities involved in the study and is able to communicate a decision (*Guardianship Act 1987* (NSW) s 33(2); *Guardianship and Administration Act 2000* (Qld) Sch 3; *Guardianship and Administration Act 1986* (Vic) s 36(2); *Consent to Medical Treatment and Palliative Care Act 1995* (SA) s 4(2); *Advance Personal Planning Act 201*3 (NT) s 6(1)).

Some legislation reinforces the point that fluctuating capacity does not mean a person should be labelled as incompetent to make choices. Victoria's *Guardianship and Administration Act* explicitly recognizes that capacity to consent may fluctuate and, in relation to research, requires an assessment of whether the person is likely to be able to consent to the research procedure within a reasonable time (*Guardianship and Administration Act 1986* (Vic) s 42R). If this is the case, the research procedure cannot be carried out on the basis of consent from a substitute decision-maker. Similarly, South Australian legislation states that a person should not be considered incapable simply because their cognitive function fluctuates and they have difficulty understanding technical details or retaining information for more than a short period (*Advanced Care Directive Act 2013* (SA) s 7(2); *Consent to Medical Treatment and Palliative Care Act 1995* (SA) s 4(3)). Legislation in the Northern Territory lists factors that, on their own, do not indicate that capacity is impaired, including having a diagnosis of disability or illness, engaging in "unconventional behaviour," having a lifestyle or making decisions with which others disagree (e.g., choice of living arrangement), or engaging in particular cultural practices (*Advance Personal Planning Act 2013* (NT) s 6(5)). Some statutes articulate a principle of minimal interference with the rights of people with impaired capacity. In New South Wales, the *Guardianship Act* instructs that individuals with conditions that affect capacity should be "restricted as little as possible" in their "freedom of decision and freedom of action" (*Guardianship Act 1987* (NSW) s 4). Queensland's statute recognizes "the right of an adult with impaired capacity to the greatest possible degree of

autonomy in decision-making" as well as the need for "adequate and appropriate support for decision-making" (*Guardianship and Administration Act 200*0 (Qld) s 6).

To give effect to these ethical and legal principles, the decision to participate in research should, first and foremost, be that of the individual. People living with dementia or other conditions that affect cognition should not be routinely excluded from the opportunity to participate in research based on assumptions about decisional capacity. At the conclusion of this article, we offer some recommendations for assessing a person's capacity to consent to a research study and supporting people with dementia in making their own choices. If, however, a person is determined to lack capacity to make a decision about participating in a study, the National Statement and relevant state and territorial laws establish rules that determine whether and how that person may participate in research.

3. The Rules Governing Research Participation for People Who Lack Capacity

If an individual does not have capacity to consent to take part in a study, the National Statement requires researchers to seek consent for research participation from a legally appointed guardian or from any other person or organization authorized by law to provide consent for the individual (NHMRC 2007, 59, [4.5.5]). A researcher must then look to relevant law to determine the rules and processes that must be followed. There is significant variation across the states and territories, first, in defining categories of research covered by the law, and second, in the rules for substitute decision-making for a person who lacks capacity to give their own consent. Laws dealing with advance directives are also relevant as they enable people to record their wishes for health and personal matters in advance of loss of decisional capacity, and to appoint trusted individuals to act as decision-makers on specified matters. Each of these issues is discussed for the jurisdictions that have relevant law.

New South Wales

The *Guardianship Act* requires researchers to obtain approval from a guardianship tribunal if they wish to involve people who lack capacity in a clinical trial or give them "special treatment," a term that encompasses innovative clinical practices that have not yet gained common acceptance (*Guardianship Act 1987* (NSW) s 33).[5] The Guardianship Division of

[5] At the time of writing, the NSW *Guardianship Act 1987* is under review and the NSW Law Reform Commission has been charged, *inter alia*, with examining the statutory rules concerning clinical trials (NSW Government 2017b).

the NSW Civil and Administrative Tribunal has offered some inconsistent interpretations of what constitutes a clinical trial (Turner 2015) but recently stated that the statute would not apply to "trials of a currently accepted treatment for the condition in question" (Application for approval for adults unable to consent to their own treatment to participate in a clinical trial (ADRENAL Trial) [2015] NSWCATGD 23 [125]). From a research perspective, the difference between "special treatment" and a "clinical trial" would not always be apparent, yet the statutory categorization dictates the legally required consent process. Only the tribunal can consent for a person who lacks capacity to receive "special treatment," but a legally authorized substitute decision-maker (who may be a spouse or other family member) can give consent for participation in a clinical trial. The following discussion focuses on the statutory rules that must be followed in order to enrol people who lack capacity in a trial.

A principal investigator or a representative of a pharmaceutical company conducting the trial must apply for approval from the tribunal (NCAT 2016). The tribunal requires evidence that an ethics committee has approved the proposed research in accordance with any relevant NHMRC guidelines. This requires investigators to go through the ethics process first and then apply to the tribunal, providing copies of the clinical trial protocol, the ethics committee application, the ethics committee approval, the information sheet that explains the study and any risks of participation, and the consent form. The tribunal, comprised of a legal, a professional, and a community member, conducts a hearing and the applicant must attend in person, and other knowledgeable people, such as a clinical trial coordinator, should be available in person or by phone to answer questions (NCAT 2016). To approve the application, the tribunal must be satisfied that several criteria are met: the intervention being studied in the trial must be "intended to cure or alleviate" a condition the participant has; there must be no "known substantial risk" of harm to participants, or any material risks must not be not greater than those involved in current treatments for the condition; "safety and ethical considerations" must militate in favour of making the intervention available to persons with the target condition, even though they are unable to give consent; and weighing up the risks and potential benefits, it is in the best interests of people with the condition to participate in the trial (*Guardianship Act 1987* (NSW) s 45AA(2)(a)-(e)).

If the tribunal approves a clinical trial, it then determines if consent for specific individuals who lack capacity will be sought from someone recognized as a decision-maker for the prospective participant (known as a "person responsible") or by application to the tribunal (*Guardianship Act 1987* (NSW) s 40). The "person responsible" is, in hierarchical order: the person's guardian, if a guardianship appointment is in place that confers power to consent to

medical treatment; the person's spouse, as long as they are in a close and continuing relationship; the person's carer (unpaid); or a close friend or relative who has regular contact with the person and an interest in their welfare. In making its determination, the tribunal reviews the consent document and information statement proposed for use in the research and determines their adequacy in enabling a person responsible to make a decision (*Guardianship Act 1987* (NSW) s 45AB(2)). The person responsible has a statutory duty to take into account the views, if any are known, of the person who lacks capacity to make their own choice about research participation.

If tribunal consent is sought to enrol a specific person who lacks capacity in a trial, notice of the application must be given to the proposed participant, the person proposing the treatment as part of a trial, and each person responsible who can be located (*Guardianship Act 1987* (NSW) s 43). In considering the application, the tribunal must take account of any known views of these parties. If the person with impaired capacity previously prepared an advance directive that recorded preferences for research participation, these wishes would be considered if the directive is produced to the tribunal.

Queensland

Similar to the law in New South Wales, the Queensland *Guardianship and Administration Act* requires researchers to seek Guardianship Tribunal approval in order to include people without decisional capacity in two categories of research: (1) "special medical research or experimental health care," categorized together in the Act as "special health care," and (2) "clinical research" (*Guardianship and Administration Act 2000* (Qld), Schedule 2, s 12(1), 13). The Act clarifies that clinical research does not include "a comparative assessment of health care already proven to be beneficial" (*Guardianship and Administration Act 2000* (Qld), Schedule 2, s 13(1A)). The Act also does not apply to psychological research, a term not defined in the Act (*Guardianship and Administration Act 2000* (Qld), Schedule 2, s 12(2)).

The tribunal is charged with making consent decisions in relation to special healthcare for people who lack capacity. For clinical trials, once the tribunal has approved the research, investigators must seek consent from an individual with legal authority to make decisions for the prospective participants who lack capacity. As in New South Wales, the distinction between the categories of "special care" and "clinical research" is sometimes blurry and, where possible, the tribunal may be inclined to categorize activities as clinical research to

avoid the delays that would ensue if it were "special care" that required tribunal consent for each participant (*Re Application of Dr. Matthew Hope* [2012] QCAT 191).

Once it is determined that a study involving people with impaired capacity constitutes a clinical trial, the tribunal may approve the study if it is satisfied that: it has been approved by an ethics committee; any drugs or techniques being trialled are intended to diagnose, maintain, or treat a condition affecting the research participants; the research will not involve any known substantial risks, or any known material risks are no greater than those a participant would face in existing healthcare interventions for the condition; it is appropriate on safety and ethical grounds to trial experimental drugs or techniques on participants who cannot give their own consent; and "having regard to the potential benefits and risks of participation, on balance it is not averse to the interests of the participants to participate" (*Guardianship and Administration Act 2000* (Qld), Schedule 2, s 13(3)). If the tribunal approves the clinical research, consent to enrol a specific person with impaired capacity must then be sought from a legally authorized decision-maker for the person (*Guardianship and Administration Act 2000* (Qld), Schedule 2, s 13(5)). This may be a health decision-maker appointed by the person (an attorney for health decisions appointed under the *Powers of Attorney Act 1998*), a guardian for health decisions appointed under the *Guardianship and Administration Act 2000*, or a decision-maker set out in the statutory hierarchy that includes a spouse, unpaid carer, close friend, or relative (*Powers of Attorney Act 1998* (Qld), s 63).

The guardianship and powers of attorney statutes set out principles that guide those who make decisions on behalf of a person who lacks capacity (*Guardianship and Administration Act 2000* (Qld), s 11 and Sch 1; *Powers of Attorney Act 1998* (Qld), s 76 and Sch 1). Decision-makers must consider the importance of empowering an adult to exercise their basic human rights, an individual's right to respect for their human worth and dignity, the individual's value as a member of society, and how best to maximize the person's participation in decisions affecting their life. Substitute decision-makers should make choices that are the least restrictive of the adult's rights and that promote the adult's health, well-being, and best interests. The substitute decision-maker should seek the adult's views and wishes and take them into account, along with any information given by the adult's healthcare provider.

The *Powers of Attorney Act* enables an adult to make a statutory healthcare directive and prescribes a lengthy advance directive form (see Queensland Government 2004). After twelve pages covering instructions for future healthcare, page thirteen provides a section for a personal statement on additional matters, which could include wishes concerning research

participation. The healthcare instructions must be signed and witnessed by a doctor, and the entire form must be witnessed by a qualified person, such as a justice of the peace, lawyer, or notary public. The legislation *does not* allow a decision-maker appointed in a directive to make decisions about special experimental treatments (*Powers of Attorney Act 1998* (Qld), s 35). The guardianship legislation states that the tribunal may not give consent for a person with impaired capacity if the person has an advance directive that indicates an unwillingness to participate in the type of research or experimental care proposed (*Guardianship and Administration Act 2000* (Qld) s 72(3)).

Victoria

In Victoria, the *Guardianship and Administration Act 1986* deals with research participation for adults who lack capacity to consent. The Act defines a "medical research procedure" to mean "a procedure carried out for the purposes of medical research, including, as part of a clinical trial, the administration of medication or the use of equipment or a device" (*Guardianship and Administration Act 1986* (Vic) s 3(1)). The Act specifically excludes certain activities from the definition of a medical research procedure: non-intrusive examinations, such as measuring height and weight or visually examining a person's eyes or mouth; observing a person's activities; administering a survey; and collecting or using identifiable information about a person, including details about their physical, mental, or psychological health.

Prior to 2006, the Victorian Civil and Administrative Tribunal had to approve research participation for people who lacked decisional capacity (Victorian Law Reform Commission 2012). Statutory amendments in 2006 eliminated the need for tribunal approval, a change described as an important way "to provide a balance between advancing medical knowledge and protecting vulnerable people from exploitation or unnecessary intrusion" (Victorian Law Reform Commission 2012, 309). The Act now focuses on consent processes for including a person with capacity impairment in research that has been approved by an ethics committee. If a person with impaired capacity is likely to regain the capacity to consent to the research within a reasonable time, the research activity must be delayed until that time to ensure the individual has an opportunity to make their own choice about consenting or refusing to take part (*Guardianship and Administration Act* 1986 (Vic) s 42R). If this is not likely, a "person responsible" has legal authority to give consent for a person with impaired capacity to participate in medical research procedures (*Guardianship and Administration Act* 1986 (Vic) s 42S). The "person responsible" is, in order of priority, a person legally appointed as a

healthcare decision-maker, the person's spouse, the primary carer, or a nearest relative (*Guardianship and Administration Act 1986* (Vic) s 42S). The person responsible must be reasonably available and willing and able to make a decision about research participation (*Guardianship and Administration Act 1986* (Vic) s 37). The person responsible must believe that the research procedure would not be against the person's best interests, and the consent must accord with any requirements specified in the ethics approval (*Guardianship and Administration Act 1986* (Vic) s 42S(3)-(4)).

If a person responsible cannot be identified or contacted despite adequate steps to do so, the statute authorizes a registered practitioner to carry out or supervise a research procedure without the consent of a person responsible if the practitioner reasonably believes: the research procedure is not contrary to the person's best interests; the procedure would not be against the person's wishes; the ethics committee has approved the research knowing that a person responsible may not be available to give consent; the research aims to assess the effectiveness of the therapy being studied; the risk of the research is no greater than the risk "inherent in the patient's condition and alternative treatment" (*Guardianship and Administration Act 1986* (Vic) s 42T(2)(f)(ii)); and the research is "based on valid scientific hypotheses that support a reasonable possibility of benefit for the patient as compared with standard treatment" (*Guardianship and Administration Act 1986* (Vic) s 42(2)(g)). The practitioner must sign a certificate attesting to their beliefs, maintain a copy on the patient's clinical file, and promptly send a copy to the Public Advocate and the ethics committee (see Office of the Public Advocate 2013). For a study involving repeated procedures, monthly certificates must be submitted (see Office of the Public Advocate n.d.). If the participant regains capacity or a person responsible is identified, the practitioner must inform them about the research and, if relevant, provide an opportunity to withdraw from continued participation. For an ongoing study, continuing steps must be taken to locate a person responsible to seek consent (*Guardianship and Administration Act 1986* (Vic) s 42T(8)).

The *Medical Treatment Planning and Decisions Act 2016* (Vic), set to come into effect in March 2018, confirms the processes summarized above for including a person with impaired capacity in research and also establishes a statutory framework for advance directives both for healthcare treatment and participation in medical research.

South Australia

In South Australia, statutory changes that took effect in 2014 substantially reformed the law to consolidate the rules for healthcare consent, including consent to research, into one statute,

the *Consent to Medical Treatment and Palliative Care Act 1995* (SA). A statutory "person responsible" may consent for a person who lacks capacity to participate in research that investigates healthcare or medical treatment, broadly defined in South Australian legislation to encompass studies into preventive, diagnostic, and treatment services and procedures, including physical, surgical, psychological, and drug therapies (*Consent to Medical Treatment and Palliative Care Act 1995* (SA). S 4 and 14).

The statutory decision-making hierarchy of a "person responsible" is as follows: an appointed guardian, if one is in place and the appointment would reasonably cover health-related matters relevant to the proposed research; a relative; a friend; or a person with responsibility for the person's care and well-being. Relatives or friends must have a close and continuing relationship with the person, and, in all cases, the person responsible must be willing to make a decision. The decision of the person responsible must "as far as is reasonably practicable, reflect the decision that the patient would have made in the circumstances had his or her decision-making capacity not been impaired" (*Consent to Medical Treatment and Palliative Care Act 1995* (SA) s 14C). If no person responsible is available or willing to act, the tribunal may, on application by a relative, medical practitioner proposing treatment, or another person with a valid interest, become the legally authorized decision-maker.

The 2014 *Advance Care Directives Act* creates a statutory form for individuals to express wishes and instructions for future healthcare, living arrangements, and other personal matters. The aim of this Act is to give people, at a time when they have capacity, the right to express wishes and values and give directions about future personal affairs, including interventions they wish to avoid (*Advance Care Directive Act 2013* (SA) s 9). The Act defines neither "personal affairs" nor "interventions," but a decision about participation in research fits within the concept of a "personal affair" and, depending on the research, could involve "interventions." In a directive, the maker may designate a person to have decision-making authority should the maker lose capacity in the future. A directive must be in the form prescribed by the statute (Government of South Australia n.d.) and any designated decision-maker must agree in writing to that role. The form does not specifically prompt a person to record preferences concerning research participation, but invites a person to record matters of importance to them, outcomes they prefer to avoid, and dying wishes. The Act disallows a person from including a provision in a directive that would, "if given effect, cause a health practitioner or other person to contravene a professional standard or code of conduct (however described) applying to the health practitioner or person" (*Advance Care Directive Act 2013* (SA) s 12(1)(a)(iii)). For example, a person could not in a directive authorize

medical researchers to use experimental dementia drugs without the need for ethical approval.

Australian Capital Territory

In the Australian Capital Territory, the *Powers of Attorney Act 2006* (ACT) was recently amended by the *Powers of Attorney Amendment Act 2016* (ACT) "to remove barriers to people with impaired decision-making capacity participating in medical research" (Legislative Assembly for the Australian Capital Territory 2015). The amendments came into force in September 2016 and have changed the law that previously prevented a person from giving their enduring power of attorney authority to make decisions about medical research or experimental care (*Powers of Attorney Act 2006* (ACT), ss 35, 37). The amendments enable a person to designate a decision-maker to make choices about research participation (a medical research power of attorney) and give directions about their preferences for research participation. It also sets out principles substitute decision-makers must follow when making a choice about research participation on behalf of a person who lacks capacity. These rules apply to several categories of decision-makers, including enduring attorneys appointed under the *Powers of Attorney Act*, and a guardian or health attorney appointed under the *Guardianship and Management of Property Act 1991*.

The Act as amended applies to participation in "low risk research" and "medical research" (defined collectively in the Act as a "medical research matter") (*Powers of Attorney Act 2006* (ACT), s12A). Low-risk research is defined to mean "research carried out for medical or health purposes that pose no foreseeable risk of harm to the person, other than any harm usually associated with the person's condition and does not change the treatment appropriate for the person's condition" (*Powers of Attorney Act 2006* (ACT), s 41A). Low-risk research does not include any activity that is part of a clinical trial (*Powers of Attorney Act 2006* (ACT), s 41A). The Act gives examples of low-risk research, such as studies using personal health information collected during routine healthcare, non-intrusive examinations for research purposes, observing the person's activities, and collecting information through a survey ((*Powers of Attorney Act 2006* (ACT), s 41A). A statutory substitute decision-maker may consent to the person with impaired capacity participating in low-risk research provided the research has been ethically approved (*Powers of Attorney Act 2006* (ACT), s 41C and 41D).

"Medical research" is defined to mean research "in relation to the diagnosis, maintenance, or treatment of a medical condition that a person has or has had or to which the person has a

significant risk of being exposed" (*Powers of Attorney Act 2006* (ACT) s 41a). Medical research includes experimental healthcare, defined as "research into health care that has not yet gained the support of a substantial number of practitioners in that field of health care and may but need not be medical in nature and delivered as part of a test or a trial" (*Powers of Attorney Act 2006* (ACT), s 41a). Examples include a trial of increased physical therapy for patients on a ventilation apparatus or a trial of a new absorbent material after bathing to treat a dermatological condition (*Powers of Attorney Act 2006* (ACT), s 41a). Medical research also covers the administration of medication or the use of equipment or a device as part of a clinical trial (*Powers of Attorney Act 2006* (ACT), s 41a).

A medical research power of attorney must be satisfied that the person is not likely to regain decision-making capacity in time to make their own choice about participating in a study (*Powers of Attorney Act 2006* (ACT), s 41D(2)(b)). An independent doctor must assess the likelihood of the person regaining decision-making capacity (*Powers of Attorney Act 2006* (ACT), s 41D(2)(b)). Before providing consent, the attorney must be satisfied that: the research relates to the diagnosis or treatment of a condition the person has or has had or to which the person has a significant risk of being exposed; the research may benefit the person or others with the condition and the potential benefit outweighs risks of participation; and participating in the research will not unduly interfere with the person's privacy (*Powers of Attorney Act 2006* (ACT), s 41D(2)).

Substitute decision-makers must exercise their authority in accordance with specified decision-making principles (*Powers of Attorney Act 2006* (ACT), s 41B). For instance, they must give effect to the person's wishes as far as they can be determined and, if specific wishes are unknown, the person's interests must be promoted (*Powers of Attorney Act 2006* (ACT), s 41B). Decision-makers must comply with any directions the person has expressed in accordance with the *Medical Treatment (Health Directions) Act 2006* (*Powers of Attorney Act 2006* (ACT), s 41B(2). Amendments to this latter Act enable a person to give directions about their preferences in regard to medical research matters.

The Act now establishes a limited role for the ACT Civil and Administrative Tribunal (ACAT) to assist a decision-maker to make a research participation choice for a person who lacks capacity and to review consent or refusal decisions on application from an "interested person." Such a person includes the individual who designated the medical research power of attorney and enables a person with fluctuating capacity to seek review of decisions made on their behalf during periods of incapacity (*Powers of Attorney Act 2006* (ACT), s 74). The ACT Government rejected the New South Wales and Queensland models and chose not to

give ACAT a statutory role of making decisions about research participation for individuals. It did so for three reasons: to avoid workload burdens for ACAT; to encourage research decision-making by a decision-maker designated by the person with impaired capacity rather than an "unknown person or panel"; and to reduce barriers to research involving people with cognitive impairments (Legislative Assembly for the Australian Capital Territory 2015, 2–3).

Northern Territory

The *Guardianship of Adults Act 2016* (NT) was revised and assented to in June 2016. Under this Act, the Civil and Administrative Tribunal may appoint a guardian to make decisions for an adult who lacks capacity; however, a guardian with authority to make healthcare choices cannot make consent decisions concerning "restricted health care" (*Guardianship of Adults Act 2016* (NT) s 23). Restricted healthcare is defined to include healthcare provided for medical research purposes but excludes from this definition research that involves non-intrusive examinations, observing a person's activities, and collecting information from or about a person (*Guardianship of Act 2016* (NT) s 8). For research activities that fall into the category of restricted healthcare, consent would need to be sought from a local court.

The *Advance Personal Planning Act*, implemented in 2014, allows a person who has capacity to make a written plan to express "advance consent decisions," "advance care statements," and to appoint a decision-maker to act in the event of future periods of incapacity (*Advance Personal Planning Act 2013* (NT) s 8(1)). Advance-consent decisions are statements in which people either consent to or refuse future healthcare actions, including lifesaving or other measures (*Advance Personal Planning Act 2013* (NT) s 8(1)(a)). Advance-care statements "set out the adult's views, wishes and beliefs as the basis on which he or she wants anyone to act if they make decision for him or her" (*Advance Personal Planning Act 2013* (NT) s 8(1)(b)). A person's views on participation in research could be included in an advance personal plan, particularly as an advance-care statement, and provide guidance to researchers and decision-makers as to the person's preferences during future periods of incapacity.

In an advance personal plan, the maker may designate one or more people as decision-makers to make decisions about healthcare, finances, and property. The decision-maker cannot, however, make consent decisions about medical research participation, unless the consent is for a psychological study or approved clinical research (though both these terms are not defined in the legislation) (*Advance Personal Planning Act 2013* (NT) s 4(3)). For other types of medical research, consent from a local court would need to be sought under the *Adult Guardianship Act 2016*.

A decision-maker for a person who lacks capacity must comply with the decision-making principles set out in the Act (*Advance Personal Planning Act 2013* (NT) s 22). For example, the decision-maker must follow any relevant advance care statements, take account of any currently expressed views and, so far as possible, make a decision the person would make if she or he had capacity to do so. If the decision-maker is unable to form a reasonable belief about what the adult would have done in the circumstances, they must exercise their authority in the way they believe is in the adult's best interests. A decision-maker may make a decision that reasonably benefits another person if the benefit is of a kind that the adult could be expected to provide and would not significantly adversely affect the adult's best interests. The Act gives as an example a decision-maker consenting to an adult who lacks capacity undergoing a bone marrow donation procedure to treat the adult's child who has leukemia, even though the procedure would involve some degree of risk to the adult. Similarly, a decision-maker could agree to research participation that, in some sense benefits a researcher or other people with dementia, provided these criteria are met.

Northern Territory law does not include any hierarchy of "persons responsible" who may make decisions for a person who lacks capacity. This further restricts the opportunity to include people with dementia in research. Many people living with dementia do not have an advance personal plan that appoints a decision-maker who could make research decisions, and it is burdensome to seek a guardianship order or court approvals for each individual with dementia who could be invited to participate in a research study. Moreover, a guardianship order implies stripping away some degree of autonomy from a person, and a tribunal seems unlikely to impose guardianship merely so that a person can participate in research.

Other States and Territories

The other states and territories do not have specific statutory regimes that deal with research participation by people who lack capacity, but researchers may nonetheless need to be aware of other laws that touch on research issues or policies developed to fill legislative voids.

In Western Australia, the *Guardianship and Administration Act 1990* (WA) does not include rules about substitute consent for research participation by an individual who lacks capacity. The Western Australia Department of Health has adopted research governance policy and procedures that say researchers may only include people who do not have capacity to consent to a study in circumstances where they consider that it would not be against the best interest of the person to participate (Department of Health 2012). The policy states that, in practice, this means the only research studies that can involve people who lack capacity are those that

are observational in nature and where there is no best standard of care already in place (Department of Health 2012). An intervention being studied for research purposes must be considered an important part of the treatment of the participant (Department of Health 2012). Under WA Health's Research Governance Policy and Procedures, the "senior responsible person," who is the participant's nearest relative or guardian, is required to sign a consent form that provides information about the research project (Department of Health 2012). The researcher seeking consent should ask the responsible person whether the participant has ever expressed views regarding research participation to ascertain whether or not the participant would be likely to consent or object to participation (Department of Health 2012).

4. Analysis and Recommendations

Tribunal Review and Definitions of Research

The National Statement requires ethical review and approval of any research above negligible risk that proposes to involve people with cognitive impairment. Legislators in New South Wales and Queensland should consider the value, if any, in mandating a guardianship tribunal approval that creates a duplicative process that can introduce significant delays to the process.[6] If the aim is to protect people who may be vulnerable due to impaired capacity, existing ethics review processes can achieve that goal by requiring researchers to minimize risks in the design of research and by requiring ethics committee review of protocols and ongoing monitoring for compliance with the National Statement.

Moreover, requiring tribunal approval of research that proposes to include people with dementia or other conditions where capacity may fluctuate is different from research where it is reasonable to assume that nearly every participant for a proposed study will lack capacity (e.g., a study of people with serious head injuries arriving at an emergency department). In New South Wales and Queensland, researchers who propose to include people with cognitive impairment must get tribunal approval in advance of recruitment. However, some potential participants may well have capacity to give their own consent. The need to obtain tribunal approval of a proposed research study accentuates a presumption of incapacity in relation to

[6] A submission to the NSW Government about the *Guardianship Act* 1987 (NSW) reform noted that it took eighteen months to obtain a tribunal decision on a research study that sought to include people with impaired capacity (South Eastern Sydney Local Health District Human Research Ethics Committee 2016).

people with dementia that is at odds with respect for equal decision-making rights for people with decision-making disabilities.

A guardianship tribunal should be a dispute resolution and review venue, instead of an approver of research that has already been approved by a human-research ethics committee. In Victoria, for example, the Civil and Administrative Tribunal does not approve research but has statutory authority to make orders or give opinions related to an individual's participation in medical research procedures and to issue guidelines on such procedures (See *Guardianship and Administration Act 1986* (Vic) ss 42V, 42W and 42X). It may hear applications to resolve questions or disputes as to whether research participation is in the best interests of the patient. However, a health practitioner involved in the research cannot seek tribunal review if the person responsible refuses to consent to the individual having a research procedure (See *Guardianship and Administration Act 1986* (Vic) ss 42V). Reforms in the Australian Capital Territory adopt a similar model.

Legislative definitions of research covered by statutory rules should be clarified, and the purpose and aims of regulating certain types of research and excluding others should be made explicit. The boundary between categories of research is not always clear, and some laws say they do not apply to certain kinds of research, such as "psychological research," but do not define the meanings of such terms. Statutory definitions of research are not explicitly risk-based, however; they mostly cover research involving medical treatments or procedures, which implies some degree of physical intervention and thus a potential for harm that exceeds mere inconvenience. If the intent is to regulate the inclusion of people with impaired capacity in higher-risk research, the indicia of such research should be stated and done so in a way that does not introduce inconsistency with the National Statement.

Substitute Decision-Making

The National Statement requires the consent of a legally authorized decision-maker for a person with cognitive impairment to participate in research. It is up to state and territorial laws to set out clear rules for who is authorized to make decisions. In general, existing laws deal with the appointment of a guardian to manage the affairs of a person who lacks capacity and to make decisions on health, financial, and other personal matters. Some statutes prescribe a decision-making hierarchy of "persons responsible" and other statutes allow a person to designate decision-makers to act during future periods of incapacity. Decision-making about research participation is handled variably in state and territorial legislation and inconsistencies and gaps create obstacles for researchers who seek to include people with

dementia in research. For instance, some statutes that establish such decision-makers say that the substitute decision-making function does not extend to choices about research covered by the legislation. Statutes that empower a person to designate their own decision-maker for future periods of incapacity may similarly preclude the decision-maker from making research decisions.

Legislation should allow a person to give a trusted decision-maker authority to make decisions about research participation. The justification for excluding research decisions from the substitute decision-making power is unclear, especially when decision-makers may be called on to make profound decisions about healthcare. The appointment of a person to make health-related decisions, including choices about research participation, can support the expression of the appointer's wishes (Porteri and Petrini 2015). The appointer can select a trusted person and discuss their wishes and values with that person. It is generally thought that a person entrusted to make healthcare decisions would also be likely to safeguard a person's interest in the research context (Dresser 2001). Some studies have found that older adults generally support allowing substitute consent for participation in dementia research (De Vries 2013). Amendments to the ACT *Powers of Attorney Act* provide a helpful model for a medical research power of attorney.

Legislators may be concerned about substitute decision-makers making choices that could put the person at risk of harm without a reasonable prospect of benefit. However, research ethics committees must review and approve any study that is more than negligible risk and be satisfied that the potential benefits of the research outweigh any risks to participants with a cognitive impairment. Thus, this general risk–benefit assessment will have occurred before substitute decision-makers are called upon to consider the interests of the specific person for whom they are making choices.

If research consent is sought from a substitute decision-maker, statutory rules generally limit purely altruistic participation. Instead, participation in research must have some connection to treatment relevant to a condition the person has or has had or be the best way of providing treatment to the person (Parker 2013). The motivation is presumably to ensure that people who do not have capacity to make their own choices are not recruited into research that offers no prospect of personal benefit. However, statutory rules that have this effect limit the National Statement's broad principle that a person with cognitive impairment is entitled to participate in research for altruistic reasons. One approach to this problem would be moving away from the need to enrol people with dementia in research only "in their best interests" but allow such enrolment when it is not *against* their best interests; Victoria's *Guardianship*

and Administration Act already incorporates this principle (s 42(S)). The importance of this seemingly subtle shift is apparent when considering that the principle of therapeutic equipoise would argue that much research cannot be considered in a person's best interests, and many types of research such as questionnaire-based research are clearly unlikely to benefit (or harm) participants.

When no Decision-Maker is Available

Legislation should set out a clear process for dealing with research consent if a person does not have a decision-maker, sometimes because no one eligible for this role is able to be located or there may be no one willing or able to make a decision. This would help overcome additional obstacles to including people with dementia in research. Researchers may find it too onerous in such cases to apply to a guardianship tribunal to make a determination about including the person with dementia in a research study, and guardianship bodies may not see enrolling patients in research as an appropriate reason to seek guardianship.

As a consequence, the people who participate in research may be only those who have supportive family members, carers, or friends. People who live alone, are distant from family members, or have dysfunctional families may be excluded from research. As one Australian researcher said in a recent survey:

> It is very difficult to conduct research with older people who do not have a carer or family member who can give consent in addition to the older person. As a result, older people who do not have a carer tend to not be included in the sample. (Pachana et al. 2015, 704)

The Victorian legislation deals with this problem by allowing a registered practitioner to carry out or supervise the carrying out of a medical research procedure on a person who does not have capacity to give consent and does not have a person responsible (*Guardianship and Administration Act 1986* (Vic) s 42S). While this provision allows researchers to overcome the need to resort to a tribunal, it has been criticized for creating a conflict of interest by inappropriately delegating decision-making authority to researchers (Victorian Law Reform Commission 2012). This problem could be rectified by authorizing a practitioner to consent for a person with dementia to participate in research only if the practitioner has no connection to or interest in the research being conducted.

Eliciting and Respecting the Wishes of the Person with Dementia

People with dementia who are able to give consent to participate in research and who choose to do so should be afforded the opportunity to express their wishes for future participation. The National Statement recommends that, when seeking consent from the person with a cognitive impairment, researchers should discuss with the person their wishes regarding continued research participation in the event of temporary or permanent loss of capacity in the future:

> The process of seeking the person's consent should include discussion of any possibility that his or her capacity to consent or to participate in the research may vary or be lost altogether. The participant's wishes about what should happen in that circumstance should be followed unless changed circumstances mean that acting in accordance with those wishes would be contrary to the participant's best interests. (NHMRC 2007, 59, [4.5.7])

In effect, this recommendation contemplates the making of advance research directives (ARD). The common law recognizes a person's right to document in a directive personal wishes and instructions about what is done to their body (*Hunter and New England Area Health Service* (2009) 74 NSWLR 88). As discussed earlier, some states and territories have legislation covering advance directives that would enable a person to make a directive that expresses wishes about research participation.

When a person with dementia consents to participate in a particular study, they should be given an opportunity to document wishes about their continuing participation should they experience reduced capacity in the future, as suggested in the National Statement (Pierce 2010). This measure would be most effective for research that is expected to continue as participants' cognitive capacity declines, such as a longitudinal study of ageing and cohort studies of people with dementia. When making an ARD, a person would need to consider how study participation could affect them if they lose capacity and the degree of risk they would accept. There is debate as to whether advance consent may be given for research above minimal risk (Buller 2015; Jongsma and van de Vathorst 2015; Andorno et al. 2016). This is an important matter to consider, particularly for researchers who adopt the practice recommended in the National Statement of offering ARDs to participants whose condition will likely cause periods of cognitive impairment. Future research activities and their attendant risks and benefits must be carefully explained to participants. At all times, researchers must ensure they minimize risks in their research design and ensure that the potential benefits of participation outweigh any risks.

Improved information statements and consent materials could be used to overcome the difficulties created by the future-oriented nature of ARDs. Videos, observations of research taking place with people with dementia, and discussions with current dementia research participants would help newly recruited participants make choices about continuing to be a part of a research study during future periods of incapacity. Adopting these measures would increase the "moral legitimacy" of ARD and ensure they are not merely a formalistic consent document (Dresser 2001). Some studies report that older adults favour greater education and support for people to make research directives early in a dementia diagnosis (De Vries 2013). Advance research directives are more problematic when they purport to consent to research that has not commenced when the person still has capacity. It may be possible to specify some research projects well enough that legitimate consent can be obtained for them. In other cases, general statements about wishing (or not) to participate in future research would be useful as evidence of the person's preferences that an authorized decision-maker takes into account in making a decision about a specific research study. Statutorily prescribed advance directive forms could be amended to prompt people to document any values or wishes they have in relation to participation in medical research.

Advance planning documents, including ARDs, are sometimes criticized on the grounds that the impact of dementia on memory and personality fundamentally changes a person and they should not be bound to the choices made by their "former self" (Pierce 2010, 626). However, the National Statement and some legislation requires that dissent from a person with dementia must be respected, including verbal utterances or body language indicating the person opposes or does not wish to take part in a research procedure or activity (Slaughter et al. 2007). Where dissent is respected, a person with dementia may opt out of research even if they have previously consented to be involved.

5. Conclusion

Law reforms should reduce unjustified legal barriers that do not serve a defensible protective purpose and have the effect of excluding people with cognitive impairments from opportunities to participate in ethically approved research. Recent statutory changes in South Australia and the two territories indicate that some legislators are concerned with modernizing laws that impact the lives of people with impaired capacity. Further reforms should promote the equal human rights of people with conditions that affect cognition and should enable them to make choices about their own lives and to be supported in doing so, including in relation to research participation.

There is also a need to build greater awareness of research inclusion issues specifically in relation to dementia, including rights to make advance research directives and to appoint decision-makers for research purposes. Education and resources should be tailored for people with dementia and those who help support them, for healthcare practitioners, and for researchers.

Those involved in recruiting people with dementia into research should adopt a supported decision-making approach to maximize the individual's capacity to make their own choice about research participation. Information to enable decision-making should be presented in a manner suited to individuals' needs. Researchers should be aware of factors that affect capacity and seek consent at a time and under conditions when capacity is maximized. Practical measures include discussing research participation when energy levels and cognition are likely to be higher; use of decision aids and enhanced consent forms where information is communicated using techniques such as audio narration, videos, and graphics; and leaving time for longer and repeat discussions. We also encourage researchers to evaluate consent strategies to produce evidence on the measures that help maximize decisional capacity for people with dementia or other cognitive impairments, including the effects of different strategies on participant understanding of studies, satisfaction with consent processes, and consent rates (Nishimura et al. 2007; Mittal et al 2007). Researcher experiences with consent strategies and cost implications should also be studied.

To facilitate the appropriate inclusion of people with dementia in research, more work needs to be done to develop valid and convenient tools to assess participants' comprehension of information presented in research consent discussions. American researchers have developed a brief capacity assessment tool that has been validated to assess participants' understanding and reasoning in regard to an invitation to participate in research (Jeste 2007). They explain that "an ideal capacity screening tool would need to include assessment and documentation of additional essential elements such as comprehension of protocol procedures, appreciation of the potential significance of study risks, and the voluntary nature of participation" (Jeste 2007, 966). This tool has been piloted with promising findings in a sample of people with mild to moderate cognitive impairment (Seaman et al. 2015; Duron et al. 2013). Further research is also needed to develop consensus on advance research directives and possible templates and to study stakeholder attitudes towards research directives, including the views of people with dementia, researchers, and members of research ethics committees.

The law reforms and strategies we recommend here can help to promote the appropriate inclusion in research of people with dementia and ultimately improve the evidence base for

prevention, treatment, and cure of conditions that comprise a major and growing burden of disease in Australia.

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