Advance research planning as a response to consent challenges in research involving adults lacking capacity

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Research involving people with impaired decision-making

- In some contexts (e.g intensive care, advanced dementia, palliative care) potential participants may be **unable to consent** due to impaired decision-making
- Research is key to improving care but exclusion of people with conditions that can lead to impaired decision-making is **widespread** (Shepherd et al 2020)
- As medical treatment applies to those with impaired decision-making, important that they are **not excluded** from research if unable to consent (National Ethical Standards 2019, NZ)
- Leads to **evidence-*biased* care** as insufficient research evidence is available
- Creates **inequitable opportunity** to participate in research, and **epistemic injustice**
- **Growing** number affected by cognitive impairment – increasingly important to address

Under-served populations with impaired capacity to consent

Hip fracture

1 in 3 patients with a **hip fracture** also have a cognitive impairment, have **worse** care and outcomes, yet excluded/ignored in 8 out of 10 hip fracture trials

Stroke

Stroke patients unable to consent are more severely affected, older and more likely to develop fever and infections .. trials are affected by this selection bias

Emergency care

Trials in **emergency and critical care** four times more likely to be discontinued due to slow recruitment compared with other settings

Dementia

People with **more advanced dementia** are frequently excluded from research, but should have an equal opportunity to be involved regardless of disease stage

Alternative arrangements for adults lacking capacity to consent

- Provided there is an acceptable risk-benefit, most jurisdictions have provision for an alternative decision-maker to be involved if a participant lacks capacity to consent, usually a relative or close friend
- Legal basis for their decision varies, but usually based on a form of **substituted judgement**
- UK: Advise researchers about the **person's wishes and preferences**, or for a clinical trial give consent based on the person's '**presumed will**' (Clinical Trial Regulations)
- Australia: Potential **participant's wishes** about what should happen in that situation should be followed (National Statement on Ethical Conduct Human Research 2025)
- New Zealand: Seek views of people interested in the person's welfare on whether participation is **consistent with** the informed choice the participant would make if they were competent (National Ethical Standards 2019)

Note: in New Zealand, the legality of undertaking research with adults who cannot consent has 'significant gaps in application'

Consent challenges encountered by researchers

Complexity of involving adults with impaired capacity

> It feels like an **insurmountable black box of horrendousness** that I dare not go. It feels very much [that] if you get this wrong you will be **illegal** ….. and the **ethics police** will come for you!

Uncertainty about who acts as alternative decision-maker

> You identify that someone might be eligible, and you want to get them involved, and not **spend months and months contacting every relative**

Lack of knowledge about person's wishes

> It's hard to try and say what that person would want if you **haven't specifically had that conversation** with them previously about whether they'd want to be involved in research or even what types of research

CONSULT-ENABLE Study https://doi.org/10.1186/s13063-022-06422-6

Consent challenges encountered by alternative decision-makers

- Family members express **uncertainty** about making what can be complex and challenging decisions about research participation
- Can lead to **psychological stress** experienced by family members
- Particularly stressful in some settings/contexts - reported that nearly all experience some degree of **emotional or decisional burden**
- Contributes to higher proportion of families **declining** participation than patients
- Concerns about '**accuracy**' of decisions made by alternative decision-makers, 32%-76% in hypothetical studies - 'no higher than the decisions of randomly assigned, unrelated proxies'
- Although **authenticity** rather than 'accuracy' might be the intended target

> “I think that **if my Dad had at any time discussed it or given any indication** then maybe my decision would have been different. But he didn't. It felt that it is my decision. Whether it's the right decision or not who knows … [Daughter]

Shepherd et al 2020 https://bit.ly/3h0U3BT

Does 'advance research planning' have a role?

“

A voluntary process that involves **thinking about, discussing and documenting preferences** for taking part in research in the future.

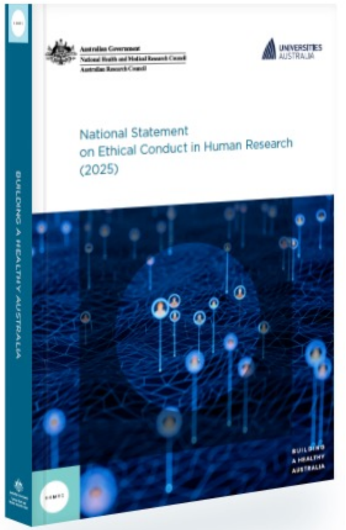
This process may include making an **advance research directive** and **naming trusted people** to be involved in decisions about research participation.

May be **tailored to a specific research project** where it is anticipated that participants may experience cognitive changes during the term of the study (sometimes described as 'advance consent')

Or **general views** about taking part in research during future periods of incapacity (Ries et al 2022)

Advance research planning included in recent ethical guidelines

> Potential participants, researchers and reviewers **should consider the use of advance planning and advance directives** to record the views of potential participants about their participation in research when their ill-health or disability is fluctuating or when a decline in the capacity to make decisions related to research is anticipated.
>
> Similar to the scope of consent, advance directives may be **project-specific**, applicable to **related** future research ('extended') or **broadly applicable** to future research activities ('unspecified').
>
> Advance directives in research must not be used if their use is prohibited by relevant jurisdictional legislation



(National Statement on Ethical Conduct Human Research (Australia) 2025; 4.5.6)

Potential benefits

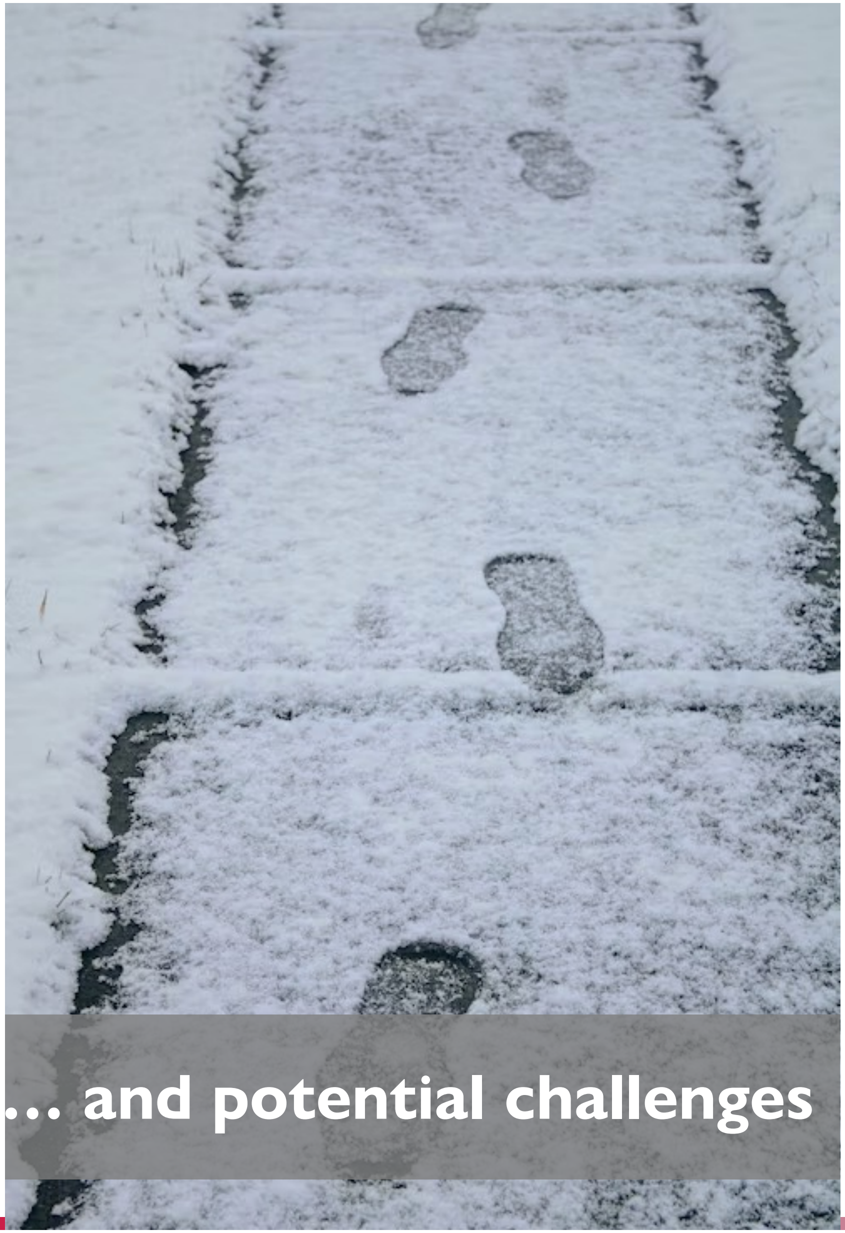
Over past 30 years, studies (Australia, Canada, US, EU) found widespread support for ARP:

May extend and support a person's (precedent) autonomy through making wishes known about who acts as alternative decision-maker and the contents of their decisions

Improve proxy decisions through ensuring they are (more closely) based on the person's preferences

Reduce decisional burden on proxies by improving their confidence

Support greater inclusion of people with impaired capacity in research by reducing ethical concerns – including for research ethics committees and clinical staff



… and potential challenges

Legitimacy of preferences - may be challenging for people to imagine how it would be to participate in research if cognitively impaired – '*it may be a rare person who can genuinely achieve this level of understanding*'

Informational standard required for informed consent – could it be sufficiently informed to constitute consent

Exacerbating current complexities - integration of advance research planning into established legal planning arrangements could lead to misunderstandings (e.g therapeutic misconception)

Practical questions - implementation, uptake, and usability of advance research directives given the current challenges of engagement with incapacity planning and end-of-life decision-making – research less foreseeable

Require careful interpretation of an advance research directive

Exploring acceptability and feasibility of ARP

- Survey of members of the public (n=277) including people living with impairing conditions, and healthcare professionals and researchers (n=50) in UK
- Semi-structured interviews (n=27); data analysed thematically
- High levels of ***willingness to participate*** in research if they lacked capacity to consent, although this varied by study type
- Found ***high levels of support*** for advance research planning, with differing views about how binding an advance research directive should be depending on context (e.g risk-benefit profile)
- Identified ***barriers*** to implementation such as informational needs, and ***facilitators*** including embedding ARP in existing processes such as ACP

90% **People willing to participate in research should they lose capacity**

97% **Members of public interested in taking part in ARP**

94% **Professionals though it important people undertake ARP**

Shepherd *et al. BMC Medical Ethics* (2024) 25:80
https://doi.org/10.1186/s12910-024-01081-5

BMC Medi

RESEARCH Open

'It's not making a decision, it's prompting the discussions': a qualitative study exploring stakeholders' views on the acceptability and feasibility of advance research planning (CONSULT-ADVANCE)

Victoria Shepherd[1*], Kerenza Hood[1] and Fiona Wood[2,3]

Shepherd *et al. BMC Medical Ethics* (2023) 24:70
https://doi.org/10.1186/s12910-023-00948-3

BMC Medical Ethics

RESEARCH Open Access

Planning ahead for research participation: survey of public and professional stakeholders' views about the acceptability and feasibility of advance research planning

Victoria Shepherd[1*], Kerenza Hood[1] and Fiona Wood[2,3]

Acceptability of advance research planning – creating opportunities

Planting a seed – creating opportunities to initiate or engage with ARP

‘I was struck by how brilliant a concept that was. We are making great strides in trying to advance people’s forward planning when it comes to their own death. So, things like research and the ability to be useful and **have some kind of utility and impact** … to have something like that in place so that I can continue to be useful in some way’

[Researcher]

The vast majority of people haven’t really even thought about it. So, it **just plants a seed there**, and the seed may well come to fruition; it may not. Hopefully it wouldn’t, because I wouldn’t get anything that needs studying, but it’s just there, it gets the discussion going’

[Family member]

Multiple opportunities suggested for engaging with ARP

Opportunities to initiate advance research planning

Donation

Undertaking altruistic acts such as donating blood, opting in via the organ donor registry, registering as a bone marrow donor, donating brain or body for medical research

Care planning

Part of advance care planning discussion, processes for Advance Decision to Refuse Treatment or advance statement/directive, part discussions around resuscitation

Legal planning

Making or updating formal arrangements such as Lasting Power of Attorney for Health and Welfare or Finance and Property, or writing or updating a will

Life changes

Intervention points may include a change in care arrangements such as moving into a care home, or when diagnosed with a condition that may affect future capacity

Research

Agreeing to participate in a research study, signing up to a research registry, participating in a longitudinal study, joining a biobank

Engagement

Publicity campaigns, opportunistic contact with a charity or campaigning organisation, peer support groups, community groups, third sector, religious organisations

Acceptability of advance research planning – getting timing right

Finding the 'sweet spot' *– optimising the timing of people engaging with ARP*

'If you ask people **too early**, they're just going to be like 'what are you talking about I'm never going to get dementia', so it has to be at the sweet spot'

[Researcher]

'Although they may be distressed because of a life-threatening illness they would be capable of making a decision … but down the line you need to have already made the decision, otherwise it's **too late**'

[Member of the public]

Acceptability of advance research planning – (non)binding nature

A missing part of the puzzle – how preferences expressed through ARP could help to inform decisions

‘It’s **more a general sense of what I would prefer rather than it being legally binding** or having that much weight. It’s more of an advisory document that says this is what I would like’

[Researcher]

‘No, I think **it should be legally binding**. That’s how I would rationalise it, in essence, that these are the wishes of this person. If I’m giving unconditional support to the research and signing a document, that is my wish’

[Person living with a capacity-affecting condition]

‘If you express a preference to take part in certain research and then your consultee comes along and says no, they’re **undermining your wishes** but at the same time having that **secondary check when the context is known** feels like a relief to me…’

[Researcher]

Acceptability of advance research planning – information needs

Keeping the door open to future opportunities – *the risk of uninformed decisions*

‘It would be a travesty if loads of people said they didn’t want to take part in research, especially if that was because **they didn’t understand** the nature of research, like, what kind of research they were opting out from’

[Researcher]

‘I didn’t want somebody **without all of the facts**, saying no to participating in research, so that meant that we can’t approach them. Because actually, if you have a face-to-face conversation with somebody who’s ill, it’s a very different experience’

[Member of the public]

Acceptability of advance research planning – risk of making it worse

Navigating with a compass – *principles to ensure safeguarding and address inequalities*

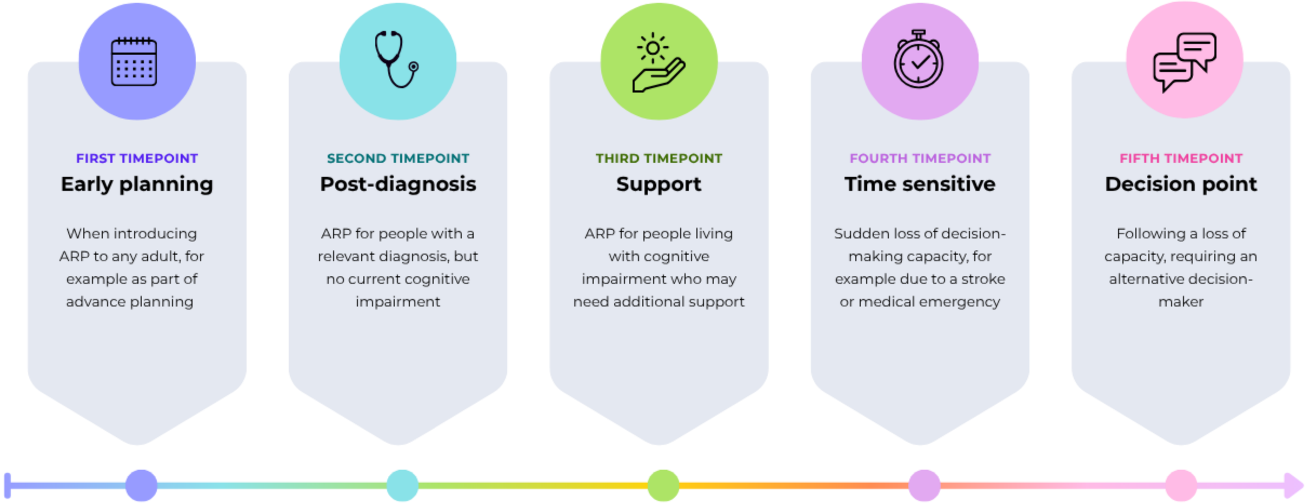
‘I’d worry that if we were forcing stuff on people, whether that would **worsen trust** in healthcare … if we’re saying we’re going to enroll them because they signed a piece of paper twenty years ago that said that they would love to take part in research’

[Clinician]

‘If we set up an advance research directive as a requirement for participation we are going to **filter out** anyone but the tertiary educated, white, well-paid, well-represented people in research. It’s going to become naturally exclusive through its attempts to include’

[Clinician]

Exploring the implementation gap: international case studies



FIRST TIMEPOINT
Early planning
When introducing ARP to any adult, for example as part of advance planning

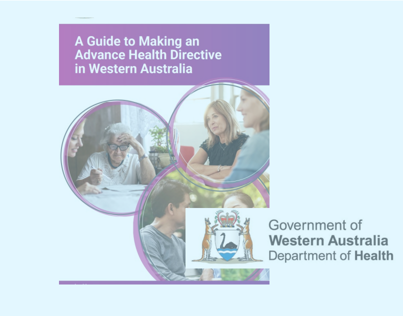
SECOND TIMEPOINT
Post-diagnosis
ARP for people with a relevant diagnosis, but no current cognitive impairment

THIRD TIMEPOINT
Support
ARP for people living with cognitive impairment who may need additional support

FOURTH TIMEPOINT
Time sensitive
Sudden loss of decision-making capacity, for example due to a stroke or medical emergency

FIFTH TIMEPOINT
Decision point
Following a loss of capacity, requiring an alternative decision-maker

Making



A Guide to Making an Advance Health Directive in Western Australia

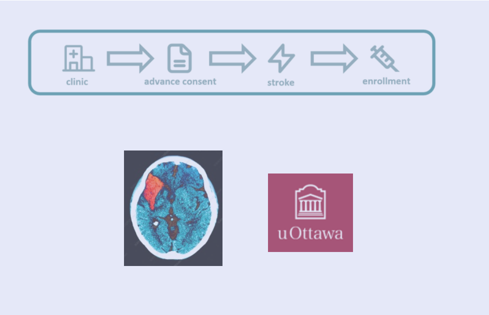
Government of Western Australia
Department of Health

Advance Research Directive form

UTS UNIVERSITY OF TECHNOLOGY SYDNEY

Step Up for Dementia Research

Using



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Lack of conceptual, regulatory, and implementation groundwork

Global issue requiring interdisciplinary approaches

Research is needed to explore the purpose of advance research planning, who it intends to benefit, and how we can measure whether it has achieved its aim

One size doesn't fit all - context matters

Work is needed to better understand the contextual factors that will influence the implementation of advance research planning

Importance of engagement with diverse communities

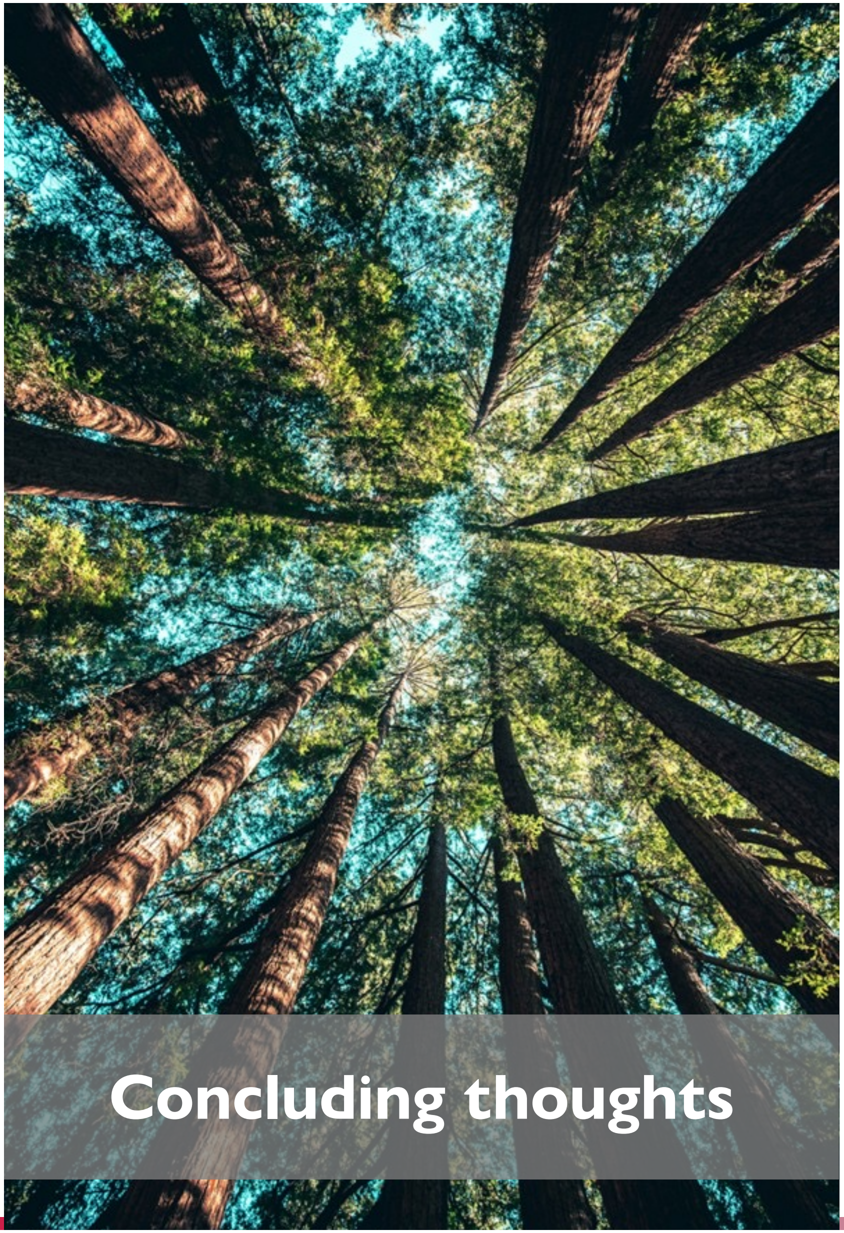
We need to plan to implement advance research planning equitably, with a focus on accessibility and inclusive design

A missing piece of the puzzle: international perspectives on advance planning for research

Dr Victoria Shepherd PhD MA BSc RN

the CHURCHILL fellowship

Concluding thoughts



- **Misalliance** between requirement that research decisions are based on wishes and preferences and how those can be known
- ARP's promising role hampered by **conceptual and regulatory uncertainties** (jurisdiction-specific)
- Diverging views about how **binding** advance research planning should be – and how balanced with current expression of wishes
- Greater clarity needed **about who ARP is intended to benefit** and how – may depend where on the ARP continuum
- Scoping review currently exploring the **effectiveness** of ARP interventions, and identifying priority populations
- Developing **international interdisciplinary research network** of those with an interest in ARP
- In 2026, Wellcome Trust funded project ACCORD to further explore **ethico-legal complexities** in research involving adults lacking capacity to consent and address barriers to inclusion

Image: Casey Horner, Unsplash

Thank you/Diolch!

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https://www.capacityconsentresearch.com

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