

Supporting capacity

What is capacity?

Decision-making capacity is the ability to determine one's own life and make one's own decisions. In human research, capacity is required for informed consent. If a person does not have capacity, they cannot give informed consent to participate in research.

The National Statement on Ethical Conduct in Human Research states that:

Respect for human beings involves giving due scope, throughout the research process, to the capacity of human beings to make their own decisions.

And:

Where participants are unable to make their own decisions or have diminished capacity to do so, respect for them involves empowering them where possible and providing for their protection as necessary

Researchers should consider capacity as an important component in supporting research participation, not as a way to exclude certain groups of people from participating in research.

When should capacity be considered?

In most cases, it will be enough to ensure that a person understands they are participating in research. Researchers only need to consider a person's capacity if a person does not appear to understand that they are participating in research or the nature of the research they are participating in.

Researchers must presume that prospective participants have capacity, and must not assume that a prospective participant does not have capacity just because they have a certain diagnosis or disability. However, when researching with some groups, such as people with psychosocial disability, intellectual disability, acquired brain injury,

neurodegenerative diseases like dementia, researchers must carefully consider strategies might be necessary to support capacity.

What is a capacity test?

When assessing if a person has capacity to make a decision, there are a range of different approaches. The most commonly used in Victoria is in section 5 of the *Guardianship and Administration Act 2019* (Vic).

A person has capacity to make a decision if they are able:

- to **understand** the information relevant to the decision and the effect of the decision; and
- to **retain** that information to the extent necessary to make the decision; and
- to **use or weigh** that information as part of the process of making the decision; and
- to **communicate** the decision and the person's views and needs as to the decision in some way, including by speech, gesture or other means.

Capacity is decision specific, meaning a person might be able to decide about one thing, such as who to live with, and not about another thing, such as buying a house.

Capacity also fluctuates over time, which means a person may be able to decide about a thing one day and not another day. During periods of acute stress or illness, for instance, people can experience problems making decisions. Capacity must be assessed at the best time and place for the person.

This is particularly important in research projects that take place over a period of time, as capacity may need to be assessed multiple times during a project. People must give free and informed consent every time they participate in a research activity.

Researchers may need to seek consent after the data collection has concluded, by providing

the person's data to them and ensuring they still consent to the use of that data.

For decisions about research, the decision must be about the whole research process, not just the person's participation. For example, a person must understand that a report will be written that will include their information, not just that they are participating in an interview.

What if a person does not have capacity to make a decision?

For research projects in Victoria, it is not usually possible for another person to consent on behalf of a potential participant. There are two exceptions to this.

Firstly, for medical research, a substitute decision-maker may consent on a person's behalf. See the Resources section below for a link to guidance for capacity in medical research.

Secondly, if a court or tribunal (such as VCAT) explicitly gives a substituted decision-maker (such as a guardian) the specific power to make decisions about research participation.

It is never appropriate for a person to consent for another person to participate in research unless they are legally empowered to do so.

What should researchers do?

Researchers must shift their approach from just assessing capacity to supporting capacity. Rather than asking:

'Does this person have capacity?'

Researchers must instead consider:

'How can I support this person so they can make their own decision?'

If the researcher cannot pass this test, the person cannot participate in the research, other than if a substitute decision-maker has been legally given this power or a waiver of consent is granted.

How can I support participants to make their decision?

The appropriate supports will be different for each participant in each research project. The vast majority of human research participants will require only the minimum of supports, such

as the participant information sheet and the opportunity to ask questions of the researcher. Other people may require additional supports.

Often, people who require support for decisions have someone who helps them make decisions. These might be family members, support workers or legally appointed decision supporters. These people cannot consent on behalf of a person (unless they have been given the legal power to do so), but they can help them make a decision. Researchers should involve these support people and provide them with resources so they can assist the person to make a decision.

Researchers can consider each aspect of capacity to identify ways to provide support.

For example, to help people **understand** the research and what their participation involves, researchers can provide plain language, easy read or other resource. Researchers might find out what time of day they find best for making decisions, or what communication medium people prefer. Offering a range of options is usually best, as some people find receiving information over phone or face-to-face difficult.

Researchers should consider a staged approach to enable people to **retain** information. For example, researchers might post paper copies of easy read documents to the person, email a plain language information sheet to their supporter, then organise a video call with both a week before the actual research activity.

Researchers might present a clear list of the anticipated risks and benefits of participating in the research, to assist people to **use or weigh** the relevant information. Researchers should help participants understand how these risks and benefits apply to the person directly.

Researchers should ensure that people receive whatever **communication** supports they require. This may involve using interpreters, including sign language, technological solutions or non-verbal cues. The researcher will need to understand what works best for each participant.

Researchers will need to demonstrate that they have the skills, resources and expertise to support a person to exercise their capacity. In many cases, this will require co-designing

research with people from the groups being researched. This should include, where appropriate, paid researchers from the target groups as investigators on the research project.

What if I can't support the person to make a decision?

In some cases, the researcher may not be able to support a person to make their own decision. In these cases, the person cannot give informed consent and will not be able to participate unless a substituted decision-maker has been given the legal power to make research participation decisions or a waiver of consent is granted.

In some circumstances, in which the only foreseeable risk is one of discomfort, it may be possible to apply for a waiver of consent. The *National Statement on Ethical Conduct in Human Research* lays out the conditions in which a waiver may be given. Waivers should not be used to circumnavigate the capacity support process. Instead, a waiver might be used to allow people who want to participate in research but cannot be supported to make the decision.

For example, a researcher may seek to collaborate with a group of people with intellectual disabilities to produce a resource. In a situation where some of the members of the group cannot, even with support, understand that a deidentified report will be published about the group process but still want to participate in the group, a waiver might be an appropriate way to allow for their participation. For those members of the group who can be supported to make the decision or do not require support, their explicit informed consent should be sought. If any group member did not wish to participate, they could not be made to do so.

Resources

Supported Decision-Making in Victoria:

<https://www.publicadvocate.vic.gov.au/resource/31-supported-decision-making-in-victoria#:~:text=Supported%20decision%2Dmaking%20is%20a,they%20require%20to%20do%20so>

Easy Read Style Manual:

<https://www.stylemanual.gov.au/content-types/easy-read>

Consent process for **medical** research involving people without decision-making capacity:

<https://www.thermh.org.au/research/researcher/s/ethics/consent-procedures-research-non-capacity>

Further information

For further advice on this topic or other human research ethics matters, please email humanethics@rmit.edu.au. A Research Governance and Ethics Coordinator will assist you and may connect you to one of the CHEAN or HREC members in your discipline who can offer expert ethics advice.