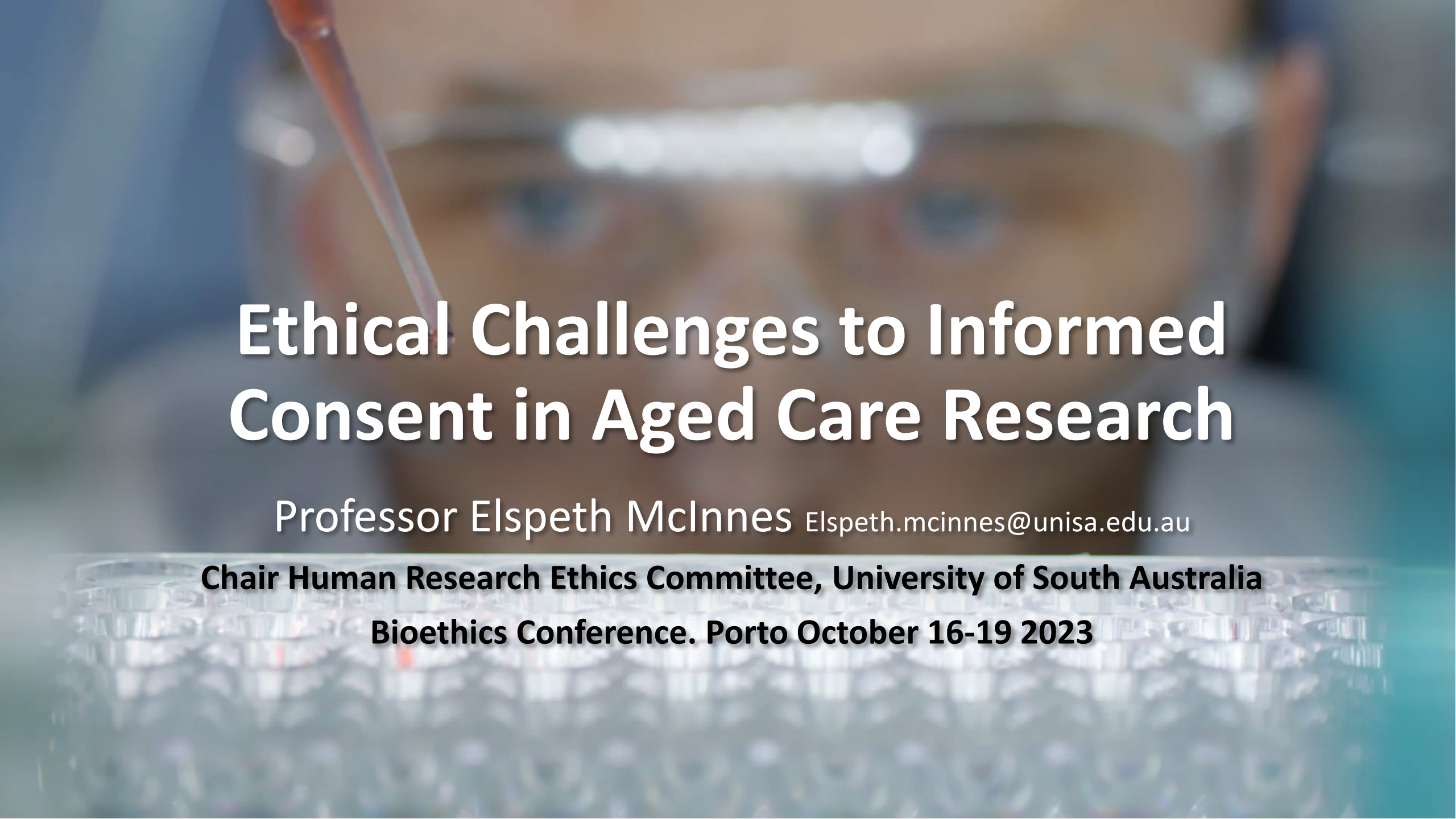

Ethical Challenges to Informed Consent in Aged Care Research

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Aged Care Contexts

- Residential aged care is provided for older people who need ongoing care & can no longer manage the day-to-day requirements of living at home.
- Australia provides institutional long term care for almost 20% of the population aged ≥ 80 years, and 6% of those aged ≥ 65 years (Dyer et al., 2020).
- Residential aged care environments include shared communal spaces and private living spaces for residents.

Research in Aged Care

- Clinical treatments and care for residents
- Staff conditions, qualifications and professional learning
- Institutional structures and practices
- Social & emotional environments for residents
- Physical environments for residents
- Family connections and interactions with residents
- Interactions with the wider community
- Characteristics, circumstances and needs of particular groups (health conditions, geography, group identities across culture, gender & sexuality)

Research ethics principles to be balanced against research risks

- Merit & Integrity – the research is well designed by qualified persons to access and analyse data addressing the research questions, which have been informed by relevant research literature.
- Justice – the research takes account of the potential impacts of the research for different groups or communities and aims to avoid unjust outcomes and avoids bias.
- Beneficence – the research has potential to benefit participants, groups, communities.
- Respect – the research takes account of the privacy, dignity and integrity of participants and upholds their rights.

Ethics & Consent to participate in research

- CHAPTER 2.2 : GENERAL REQUIREMENTS FOR CONSENT | NATIONAL STATEMENT ON ETHICAL CONDUCT IN HUMAN RESEARCH, 2007 (UPDATED 2018)
- "**Respect** for human beings involves giving due scope to people's capacity to make their own decisions. In the research context, this normally requires that participation be the result of a **choice** made by participants – commonly known as 'the requirement for consent'. This requirement has the following conditions:
- consent should be a **voluntary** choice, and should be based on **sufficient information** and adequate **understanding** of both the proposed research and the implications of participation in it.
- What is needed to satisfy these conditions depends on the nature of the project, and may be affected by the requirements of the codes, laws, ethics and cultural sensitivities of the community in which the research is to be conducted (NHMRC, 2018)."

Research risk to participants

- Risks to participants can be physical, psychological/ emotional, cultural, financial, reputational (to name some of the most common)
- **Vary with the vulnerability of participants' characteristics & contexts**
- Vary in risk combinations and degrees of severity and impacts
- May express immediately and/or at a later time
- May be more or less remediable
- Researchers need to acknowledge, assess and analyse risks to participants and have plans in place to manage these.
- The ethical weight of the responsibilities of researchers escalates with rising levels of risk.

Levels of Risk

- Negligible risk – no more risk than inconvenience, such as the time given to engage with data collection activities.
- Low risk – no more than ‘discomfort’
- Above low risk – full HREC review (NHMRC, 2018).
- [In Australia, university Human Research Ethics Committees are governed by the National Statement On Ethical Conduct In Human Research, 2007 (Updated 2018). University HRECs are comprised by discipline specific academic researchers including a First Nations researcher, plus community members including a health practitioner, a lawyer, a layman and a laywoman, & a pastoral care provider.]
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SHARK
SIGHTED
TODAY
ENTER WATER
AT OWN
RISK

Aged care resident issues affecting informed, voluntary consent to research participation

Risks impacting understanding of what research involves and their ability to provide **informed consent**:

- Declining/poor cognitive, intellectual, and/or physical capacity
- Medications impacting on cognitive functioning

Risks of **coercion** to participate:

- Dependence on institutional care
- Living in a dependent relationship to care providers

Conflicts of Interest Risks

- Aged care providers may commission research to validate elements of their care regimes.
- This can create a conflict of interest when aged cared provider staff are involved in selecting potential participants, recruitment and/or data collection as they are in a position to potentially coerce participation or selectively bias data collection.
- Participants may also feel pressure to respond positively or to conceal distress to avoid antagonising staff.
- The researcher needs to have strategies to identify and manage these possible risks impacting on voluntary, informed consent.

Limits of consent

Excluding people who do not meet consent capacity assessments from research carries risks that health and care practices do not take account of their views or experiences.

O’Connor et al (2021) argue that whilst the legally defined capacity to consent pertains to major life decisions, people with dementia or other forms of impaired cognition, may still be able to provide assent to give their perspectives to inform research.

Assessing capacity to consent (Hedge & Ellajosyula, 2016)

- Capacity evaluation for a person with a cognitive impairment (e.g. dementia or acquired brain injury) determines whether the person is capable of giving informed consent to participate in research.
- People with obviously impaired capacity may still be able to indicate a choice and show some understanding.
- Four key components of decision-making in a capacity evaluation include understanding, communicating a choice, appreciation, and reasoning.
- All capacity evaluations are situation specific, relating to the particular decision under consideration.
- Assessment takes time with the person and their family allaying their anxieties and also consider their sociocultural context.

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- the research purpose & data collection activities
- how the research will be monitored
- declaration of risks and supports for participants adversely affected by the research
- contact details of a person to receive complaints
- contact details of the researchers
- how privacy and confidentiality will be protected
- the participant's right to withdraw from further participation at any stage, along with any implications of withdrawal, and whether it will be possible to withdraw data
- the amounts and sources of funding for the research
- financial or other relevant declarations of interests of researchers, sponsors or institutions
- any payments to participants
- the likelihood and form of dissemination of the research results, including publication
- any expected benefits to the wider community
- any other relevant information

Communication

Ensuring the potential participant/ family member is able to understand what will happen if they agree to research participation.

- - using simple language
- - using the person's home language (family members may help)
- - involving the person's trusted and familiar people
- - providing opportunities to ask questions
- - providing paper copies of the research information for them to keep
- - repeating information and verifying consent at every data collection event

Consent as a process

Dewing (2007) argues for an approach which defines consent as an ongoing process rather than a one-off event.

1. Learning about the person - their self-presentation and self-expression, their carer and/or family
2. Learning about the person's cognitive capacity
3. Communicating what the research involves, assessing understanding and re-visiting assent at each data collection point with ongoing monitoring for changes in health and cognition
4. Feedback to the person + Family/carer and support

Managing risks of coercion

- Providing time between giving information and seeking consent for potential participants to consider and/or discuss with family.
- Avoiding using medical staff or care staff on whom the person directly relies for recruitment to limit the risk of the person feeling obligated to participate.
- Making it clear that it’s ok to say no or stop at any time without consequence.
- Finding ways to make it easy for people to say no.
- Providing opportunities for participants/family members to raise concerns if these emerge.

Alternative consent processes

Opt-out consent – providing information and including everybody in the participant group unless they actively choose not to participate.

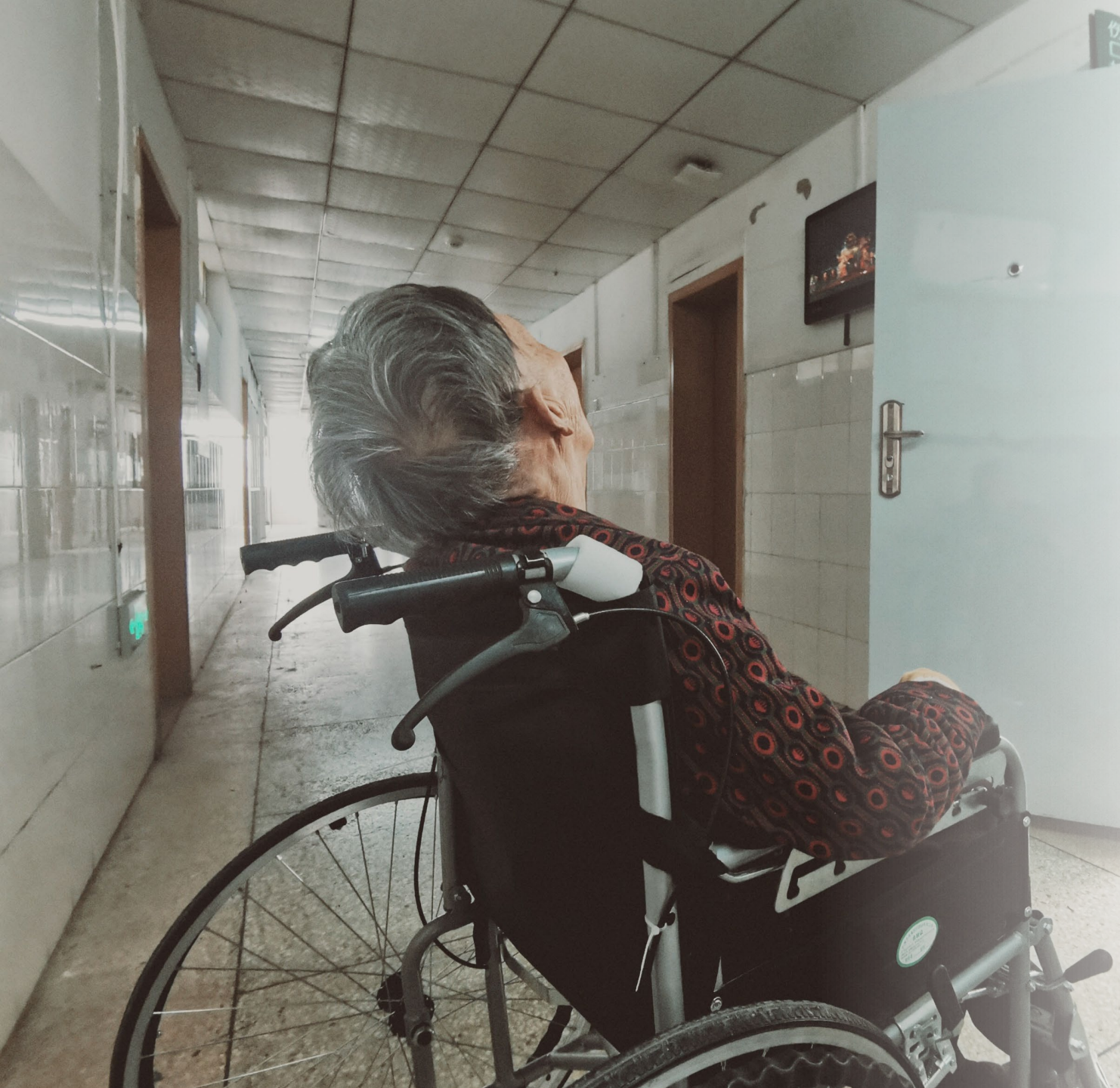
- Only suitable for low risk e.g. observations of patterns of use in the reception area of an aged care facility.

Consent waiver in cases where obtaining consent is impractical (e.g. archived data), data is not identifiable, that the research is low risk, that people would likely have consented if asked (NHMRC, 2018).

- Alternative modes of consent still need to protect privacy & secure data, and the research should have demonstrable benefit.

Using secondary data

- Using institutional collected data about aged care residents may be an alternative to manage the complexities of collecting data directly from residents.... E.g. health records, or collecting data from staff about residents.
- Informed consent to share residents' data is still required from residents or guardians if possible.
- Researchers can seek to waive consent requirements when already collected data shared is not identifiable, when it is impractical to obtain consent, when there are no foreseeable risks & where it is reasonable to expect they would have consented if asked (NHMRC 2018).



Research Inclusion

- Better knowledge
- Better outcomes for people living in aged care
- Advancing aged care clinical and institutional care models

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