Government of **Western Australia**
North Metropolitan Health Service
Mental Health, Public Health and Dental Services

Acknowledgment of the Take 5 concept developed by RPH

Informed consent for research in psychiatric populations

A key concern for ethics committees, clinicians and researchers alike, when conducting clinical studies with people with a severe mental illness is their capacity to consent; how consent will be obtained?

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Endorsed by: Insert committee name
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Capacity to provide informed consent

Informed consent means that potential participants are given the key facts of a study before deciding whether or not to take part.

Capacity to make and give informed consent requires the person to be able to:

- Understand what the study is about, and what it entails for them
- Understand that they have the right to decide participate or decline, and withdraw from the study at any time
- Remember that information
- Communicate their decision

Mental illness and informed consent

- Individuals diagnosed with schizophrenia, psychosis or another severe mental health have the capacity to provide informed consent.
- Sometimes, their capacity to make informed decisions is temporarily affected because of acute or distressing symptoms.
- In some cases, family members or guardians are needed to help a person make a decision whether or not to participant in research, even though the person will need to provide their own consent.

- Some people cannot give the informed consent if they have severe cognitive impairments or intellectual disability.
- People under a guardianship order are not in a legal position to provide consent.

How to evaluate the capacity to give consent?

This should entail an evaluation of whether the person

1) Appears coherent and able to have a simple conversation
2) Is able to demonstrate an 'understanding' of the study methods and requirements
3) Understands that they have a choice in taking part
4) Fully appreciates the risks and benefits of taking part.

This can be done by asking participants to repeat back what has been said to them, and asking participants to use their own reasoning.

It is also helpful to speak to the person's case manager or treating clinician and enquire if there are any known factors precluding the person from participating in research

Information Sheet and Consent Form

Researchers are required to provide an information sheet and consent form to participants to disclose the details of the study.

These forms often need to be adapted for people with mental health issues.

Adaptations should include the following:

- Lay language, which is clear and easily understood
- Write the text at a level of comprehension which is understandable to Grade 8 students (aged 13 years)
- Choose a large font style which is easily readable (11 points+)

Where can I learn more?

NHMRC – Informed Consent

https://www.australianclinicaltrials.gov.au/how-be-part-clinical-trial/informed-consent

Include this link to evaluation form:

Please complete the 1 minute evaluation of this Take 5 education HERE.