

Enhancing the participation of people with communication disabilities in research by optimising informed consent processes.

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know why it's important

The systematic exclusion of people with communication disabilities from relevant research has a significant impact on the field's knowledge and limits the development of effective evidence-based practices. The NHMRC National Statement on Ethical Conduct in Human Research (2023) indicates that researchers should acknowledge that some participants may have communication disability and account for this when developing a study protocol:

"The research design should take into account factors that may affect the capacity to receive information, to consent to the research, or to participate in it." Section 4.5.1

"People ... may have impaired capacity for verbal or written communication. Provision should be made for them to receive information, and to express their wishes, in other ways." Section 4.5.5

embed flexibility within study protocols

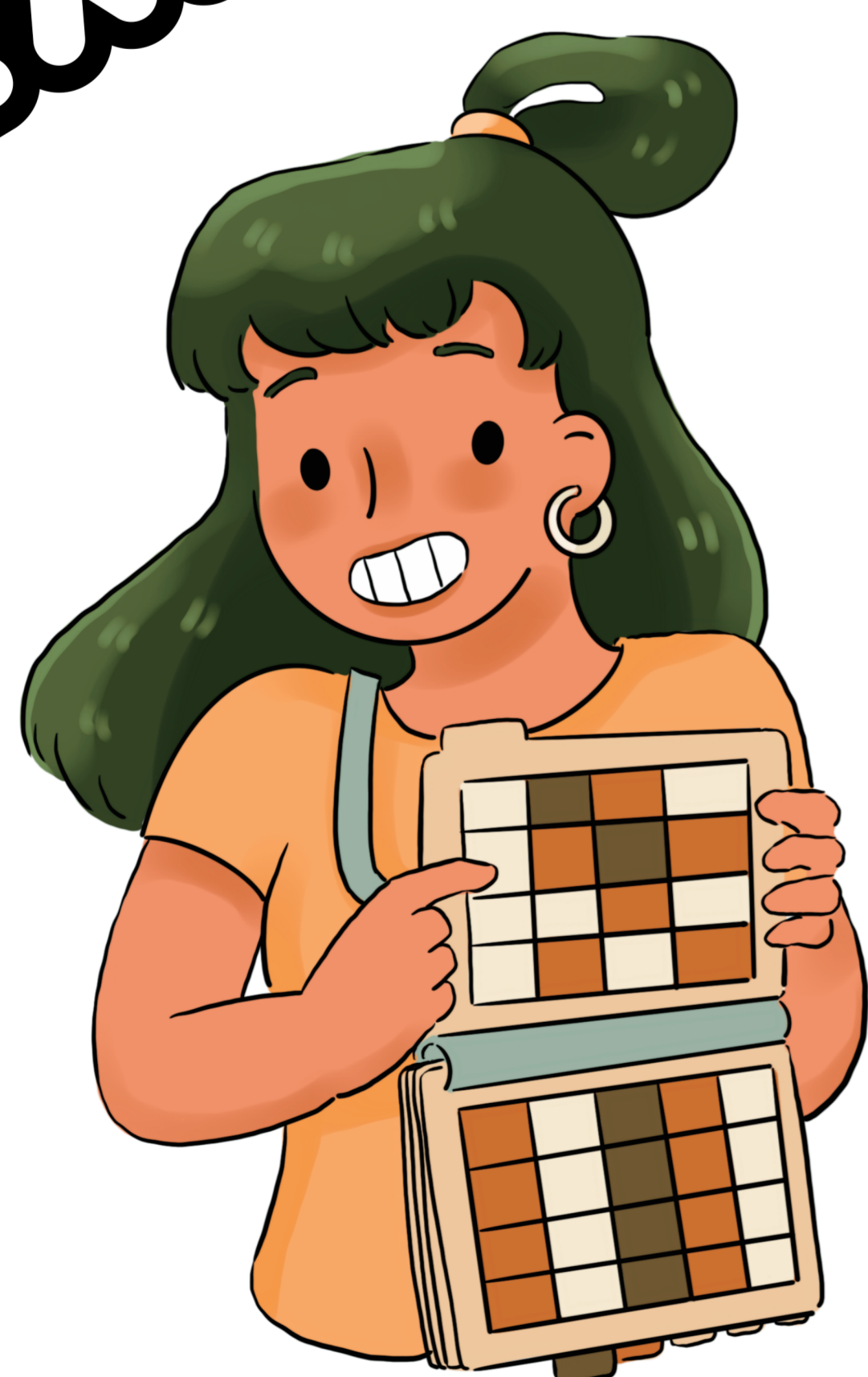
Some people with communication disability may be able to use standard written consent procedures – and these should be available to them so as not to make providing consent an unintentionally disengaging process.

Other people may require an 'adapted verbal informed consent' process. In our experience, this would occur at an initial meeting and includes:

- obtaining information about how the participant indicates "yes", "no", "unsure", "I need a break", and "I want to stop"
- providing information about the study in an accessible format and checking the participant is OK with all aspects
- asking "How do you feel about taking part/doing this survey/chatting with me today?"

We recommend using vignettes (such as the one below) to describe potential participants and the process by which they could provide consent. This will illustrate the considerations you need to make when obtaining consent from a person with communication disability.

EXAMPLE



22-year-old Gwen has moderate-severe intellectual disability. She has receptive and expressive language impairments. She uses a 20-cell PODD book for both receptive input and expressive communication. She combines 2-3 cells to create a message. Gwen is a multi-modal communicator so she also uses gesture. For example, to indicate that her leg is sore she would: vocalise, look at her communication partner, and grimace; point to [Something's wrong] > [Sore] in her PODD; reach toward her leg. She points to Picture Communication Symbols (PCS) to indicate yes and no. Gwen has some sensory needs and uses a chew necklace to self-regulate.

To obtain consent from Gwen, we would:

1. Provide her with information about the study. Since she has impaired receptive language, we would use her PODD book, e.g., saying "This [activity] is about [feelings]. [I] will [ask questions] and [you] can [tell] me what you think with your PODD".
2. Give her the *Young Person Information Sheet* so she has information about the study to keep.
3. Provide information about the study to her guardian. (Even though Gwen is an adult, she would have a guardian due to her intellectual disability.)
4. Proceed through the informed adapted verbal consent process described above, incorporating Gwen's PODD book and PCS. Her guardian can support the researcher to learn more about her communication during this consent process.
5. Obtain informed written consent from her guardian after obtaining consent from Gwen.