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## Addressing challenges in gaining informed consent for a research study investigating falls in people with intellectual disability

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**TITLE: Addressing Challenges to Engage People with intellectual disability in Research**

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### **Accessible Summary**

- Individuals with intellectual disabilities have low levels of meaningful participation in research
- Conducting appropriate informed consent processes are an important part of engaging people with intellectual disability in research
- This paper describes and reflects on an informed consent process developed to engage people with intellectual disability in a research study investigating falls in people with intellectual disability

### **Abstract**

#### *Background*

People with intellectual disability encounter multiple barriers to accessing quality, evidence based health care which is detrimental to their quality of life (QoL) and mortality. Engaging people with intellectual disability when conducting research is vital to address these QoL issues. People with intellectual disability have the right to engage in research pertinent to them but at present, they are under-represented in research and there are limited methods available to ensure that people with intellectual disability are fully supported to provide informed consent. Therefore the aim of this paper is to describe an informed consent process and reflect on the methods used when recruiting persons with intellectual disability

for a research study which is currently investigating falls among people with intellectual disability.

### *Materials and Methods*

A systematic and holistic consent process was developed as part of an ongoing prospective observational study and is being used throughout the recruitment procedure. Materials that are suitable for people with intellectual disability were prepared and are being used to explain the consent process and how potential participants can be involved in the study.

### *Results*

The informed consent procedure has been used for the first 40 participants. The consent procedure was found useful in determining a person with intellectual disability's capacity to consent and to indicate need for proxy consent. It also ensured that the person with intellectual disability was fully supported by the research team, their family and caregivers as far as possible, to make their own decision to participate in the study. Appropriate communication was found to be the most important strategy required to maximize the person with intellectual disability's participation during the consent procedure. The adapted information sheets were of secondary importance.

### *Conclusion*

Researchers should respect the rights of people with intellectual disability to participate in research of their choice and provide a structured, supportive procedure to facilitate such participation in a respectful manner.

### **Key words**

Intellectual disability, Informed consent, Mental competency, Research participation,  
Accidental falls

## **INTRODUCTION**

Developmental intellectual disability (ID) has been estimated to affect approximately 153 million people worldwide (GBD, 2016). In Australia as an example, intellectual disability occurs in 1.9 per 100 children equating to approximately 5000 children born each year (Leonard, Petterson, Bower, & Sanders, 2003). People living with ID experience more mental and physical health problems than the general population (Cooper et al., 2015). They also face substantial barriers to accessing optional health care (Ali et al., 2013) and participating in a variety of activities including physical activity (Taliaferro & Hammond, 2016).

Reports over the last decade suggest that significant healthcare discrepancies amongst people with intellectual disability persist (Ward, Nichols, & Freedman, 2010), including poor detection of treatable life-threatening conditions resulting in potentially preventable and premature deaths (Trollor, Srasuebkul, Xu, & Howlett, 2017). Furthermore, health care providers are generally ill-equipped to effectively manage people with ID contributing to poorer health outcomes (Weise, Pollack, Britt, & Trollor, 2017). There is a critical need for research and improved services aimed at improving the lives of people with ID (Brolan et al., 2012; Trollor et al., 2017).

However, people with ID are underrepresented in medical research (Feldman, Bosett, Collet, & Burnham-Riosa, 2014) and researchers face multiple barriers to enable their participation (Iacono, 2006; Iacono & Murray, 2003). Inclusion in research is one

pathway to the provision of better health services. However, researchers have highlighted that comparatively lengthy consent processes (Taua, Neville, & Hepworth, 2014), recruitment legalities around this hard to reach population (Lennox et al., 2005) and limitations in the participant's ability to provide consent independently (Dye, Hare, & Hendy, 2007) are barriers to the including of people with ID in research studies. There is still no clear consensus about how to meaningfully include people with ID in the informed decision making processes for research participation (McDonald & Kidney, 2012; McDonald & Patka, 2012). Nevertheless, regardless of their ability to understand their involvement in research, people with intellectual disability not only have the equal right to but can also make valuable contributions to the betterment of their lives through meaningful participation in research (McDonald, Kidney, & Patka, 2013).

Upholding the ethical principle of respect (NHMRC, 2007) when involving people with intellectual disability in research can be challenging and further investigation of the optimal mechanisms to include people with intellectual disability in research is much needed. Therefore, the aim of this paper is to describe an informed consent process used when recruiting persons with intellectual disability for a study which is currently investigating falls among people with intellectual disability and to reflect on the informed consent methods.

## **METHODS**

### **Research Aims and Study Design**

The primary aim of the study is to investigate the rate of falls in older adults with intellectual disability living in the community. The secondary aim of the study is to explore the participant's experiences when seeking healthcare services after having a fall. The study

uses a convergent parallel mixed methods research design (Creswell, 2013). In phase one (quantitative), participants and/or caregivers are asked to complete a daily falls calendar for six months. When they have a fall, a telephone interview follows, wherein the researcher collects information about the circumstances of the fall. In phase two (qualitative), semi-structured interviews are being undertaken with participants and/or caregivers who are reporting a fall in phase one regarding their post-fall experiences.

### **Participants**

Participants are older adults, 35 years and over with a diagnosis of intellectual disability or a diagnosis in which intellectual disability coexists (e.g. Downs syndrome). The study focuses on older adults with intellectual disability living within the community; therefore, participants are either living at home with their family, in independent units with or without paid support, or in small group homes with up to two to four co-inhabitants with paid support.

### **Procedure and Materials**

### **Ethics**

The study aligns with human research ethics guidelines from the National Health and Medical Research Council (NHMRC) and the specific ethical guidelines for researchers in Western Australia (WA) in relation to adults who may lack the capacity to give consent (WA Health Ethics Application Form, 2013). Where there is any uncertainty regarding the ability of the potential participant to provide informed consent, their guardian or next-of-kin is asked to sign a separate consent form which records that they agree to the person under their legal care participating in the study and that they believe the person is not likely to

object. The study has received ethics approval from The University of Notre Dame Australia, Human Research Ethics Committee (015067F) and the affiliated local organization for people with intellectual disability (Rocky Bay Inc. 2017).

### **Informed consent procedure**

Informed consent is gained directly from the potential participant with intellectual disability where possible. It can be challenging to determine if a person with intellectual disability has the capacity to provide consent (Teresa Iacono & Murray, 2003) and there is currently no consensus on how this should be determined (McDonald & Patka, 2012). The informed consent process for the current study was designed to provide a collective perspective of the capacity of the person with intellectual disability to consent. It involves the researcher undertaking repeated observations of the participant and gives the caregiver the opportunity to provide their opinion as to whether the individual with an intellectual disability can understand what the study involves and has capacity to provide consent. It also includes a Three-item Decisional Questionnaire adopted from Palmer et al, 2005, (Figure 1). The researcher adapts the wording of questions, when required, to ensure that the person with intellectual disability understands the questions in their own context as far as possible. A score of more than three out of a total score of six suggests that the potential participant adequately understands the research and the extent of their participation, thereby signifying their ability to provide informed consent independently. Figure 2 presents a description of the informed consent procedure.

Adapted plain language statements were prepared and used with the person with intellectual disability when the study is first discussed. The study is explained using an information sheet prepared according to recommendations for engaging people with



intellectual disability in research (Kidney & McDonald, 2014), (Appendix 1). The next of kin, family member or caregiver is asked to be present during this process to provide a supportive, comfortable environment and to provide oversight to the discussion.

Each meeting is an opportunity for the researcher to engage with the person with intellectual disability and their caregiver as relationship-building with the person with intellectual disability and their caregiver is crucial for the researcher to gain an understanding of the capacity of the person with intellectual disability and their interest to participate in the study.

### **Consent forms**

Three consent forms have been prepared: i) a consent form adapted to facilitate the participant's understanding of the study and the procedures; ii) a version for a family member or legal guardian to record their agreement for the person with intellectual disability to participate in the study (Appendix 2); iii) a form for the caregiver(s) to provide informed consent that they are willing to support the participant with daily falls recordings and facilitate communications with the researcher.

### **Results**

From October 2015 to January 2017, 68 potential participants with intellectual disability were approached after they or their caregiver agreed to an initial discussion. Of these 28 (42%) did not proceed, either because the person with intellectual disability was not interested, or their caregiver declined on their behalf. Caregivers most often expressed that they felt that it was not convenient for them to participate or judged that the person they cared for was not suitable. The informed consent procedures were therefore

conducted with 40 participants who all subsequently enrolled in the study. The consent procedure often involved between one to three meetings (average 1.5 time) with the person with intellectual disability and their primary and/or their secondary caregivers, and some meetings took up to an hour or more. This process allowed time for the researcher to build a rapport with the person with intellectual disability and to understand if there were any special considerations required to communicate effectively, for example the use of signs, Pragmatic Organisation Dynamic Display (PODD) books or any other Augmentative and Alternative Communication (AAC) device.

Participants median age was 42.5 years (range 35-86 years) and further demographic information is presented in Table 1. Responses from the participants and their caregivers during the consent process are recorded in Figure 3. A total of 25 participants indicated interest and participated in the discussion when the researcher was explaining the study. Only three participants were deemed capable of providing consent independently by successfully scoring four or more on the Three-item Decisional Questionnaire (Figure 1), showing their ability to understand risks, benefits and purpose of the study. These three participants signed the consent form independently and 22 participants signed the consent form with the support and in the presence of their caregiver (Appendix 2). With these latter 22 enrolments the caregivers also signed the Next-of-Kin/Guardian consent form which recorded their opinion that the person with intellectual disability will not object to participating. All paid and unpaid caregivers who were required to support the person with intellectual disability to complete the daily falls recordings and facilitate communication with the researcher were asked to complete the caregiver consent form.

Table 1. Participant demographics

<b>Variable</b>	<b>Categories</b>	<b>n (%)</b>
<b>Age (year)</b>	35– 40	4 (10)
	41– 50	17 (42.5)
	51 – 60	8 (20)
	61 - 70	4 (10)
	71 – 80	4 (10)
	> 80	3 (7.5)
<b>Gender</b>	Male	25 (62.5)
	Female	15 (37.5)
<b>Living arrangements</b>	Independent living with paid support	4 (10)
	Living at home with family with paid support	17 (42.5)
	Group home <sup>a</sup> with paid support	19 (47.5)
<b>Mobility status when indoors</b>	Independent without aid <sup>c</sup>	21 (52.5)
	Independent with aid	9 (22.5)
	Dependent <sup>b</sup> without aid	2 (5.0)
<b>Mobility status when outdoors</b>	Dependent with aid	8 (20.0)
	Independent without aid	19 (47.5)
	Independent with aid	7 (17.5)
	Dependent with aid	14 (35.0)

a: A group home is where 3-6 people with a disability are provided with paid support staff to live in the community

b: To be dependent for mobility is to have another person support

c: An aid is either a walking aid, a shopping scooter, a manual wheelchair or a powered wheelchair

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Supportive communication strategies that the researcher undertook to engage with the person with intellectual disability during the consent process were as follows. First, the caregiver's opinion was sought to determine if the researcher could directly make arrangements with the person with intellectual disability for an initial meeting to discuss their participation in the study. If the arrangement was made directly with the person with intellectual disability, the researcher also sought support from caregivers for the best method to confirm the organised appointment, such as making contact prior to the appointment, asking the person with intellectual disability to record it in their dairies or having the caregiver remind them of the appointment. Extra attention was required when the person with intellectual disability resided in more than one residence (e.g. living divided between family homes and supported accommodation) or if more than one caregiver provided their care. Secondly at the initial meeting, the researcher relied on the caregiver for guidance and support understand and utilise the most suitable communication style to interact with the person with intellectual disability. In the majority of the cases, interpretation from the caregiver was required which often involved the use of simple words and sentences, objects of reference and pictorial images. Of the 25 individuals who participated in this discussion about their potential participation in the study, eight subsequently participate in the Three-Item Decisional Questionnaire (with three scoring more than three, three scoring two and two scoring one and one scoring zero out of 6). Five of these eight participants also required used of prompts and interpretation at this stage of

the consent, in order to answer the questions. Two examples of the consent process undertaken are presented as case studies below in case studies 1 and 2.

Case study 1: Illustrates the consent process undertaken with a participant who was unable to independently provide informed consent.

#### Case Study 1

Participant 24 was a 56-year-old gentleman. The researcher was alerted to Participant 24 being potentially eligible for inclusion in the study when he attended respite at the supporting organisation. Support staff members at respite advised that the most suitable person to contact to discuss the study was his mother. A phone call was made to the family home where his mother, 'A', received the call. The researcher was invited to the house in the early afternoon on a week day when the rest of the family was not home.

Participant 24, was seen standing in the middle of the driveway in front of the house and swinging his arms in a playful manner. After noticing that the researcher parked the car on the road in front of the house, Participant 24 walked back into the house.

The researcher was greeted at the front door by A. The researcher was shown to the back of the house where Participant 24 was standing in the middle of the sitting area, swinging his arms. Participant 24 responded to the researcher's presence with a nod and a smile while still swinging his arms. Participant 24 only took a seat next to A when A beckoned him to sit on the couch next to her.

It was noticed that Participant 24's response was very compliant in nature. He responded with a definite nod with questions he understood such as "it's a wonderful day, isn't it?", and a smile with open ended questions he did not quite understand for example, "do you know why I am here?"

As the study was being explained to Participant 24 and A, A used references and examples to Participant 24's life. For example, when a 'fall' was mentioned, A provided the reference to the fall Participant 24 had about a year ago at the Perth Royal Show.

To convey in simple terms regarding risk and benefits, the researcher explained to Participant 24 that he would not get hurt by participating in the study and that he was not going to get any sweets if he participated.

When asked if he would still like to participate, Participant 24 smiled and nodded. A, supported his decision and stated that he would not object to participating.

Prompts were provided to Participant 24 while he was carrying out the Three-Item Decisional Questionnaire:

1. What is the purpose of the study?

Prompt: *"What is Portia here for? You remember we talked about you falling at the Royal show. She is here to study your falls. Yes?"*

Response: Smiled and nodded. (Score 2)

2. What are the risks?

Prompt: *"Will you get hurt if are in Portia's study? Yes or no? "*

Response: No – shook head (Score 2)

3. What are the benefits?

Prompt: *"Can Portia give you any candy? Yes or no?"*

Response: No (Score 2)

A, advised that she was confident that Participant 24 was agreeable to participate, but she was also certain that he did not understand the broader purpose of the research. His

understanding was limited to task specific instructions such as 'have your dinner' or 'go change'. Participant 24 signed the consent form in the presence of A. A, also gave consent to Participant 24 participating.

Although Participant 24 participated in the Three-Item Decisional Questionnaire, he did not demonstrate adequate understanding of the study and therefore, his next-of-kin, A was asked to provide consent.

Case study 2: Illustrates the consent process undertaken with a participant who was able to independently provide informed consent.

#### Case Study 2

Participant 6 is a 58 year old gentleman who lived alone in an independent unit. He had support for personal care, cleaning and meal preparation. The researcher was alerted that Participant 6 could be potentially eligible for inclusion in the study from a fellow colleague providing in-home physiotherapy services.

Participant 6 was contacted by phone and he mentioned that his physiotherapist had told him that the researcher was going to make contact. The appointment was organised over the phone and his physiotherapist informed, who reminded him about the appointment.

She reported that her experience with Participant 6 was that he could get confused with dates and events that were not routine. He retained events in his memory that were associated with the day of the week.

Participant 6 was a large tall man, in a manual wheelchair. The researcher was pleasantly invited in. He initiated and completed this task himself and did not require any caregiver support to do this or to suggest that the interview commence. Participant 6 parked his

wheelchair in front of the television and continued to watch the program that was on television. Respecting that he did not want to turn off this television, the researcher explained the research to him, interrupting him only at commercial breaks. The researcher used short sentences and frequently asked Participant 6 what he understood from what the researcher said prior. Clarification was required on several occasions. After the explanation of the study, the researcher administered the Three-Item Decisional Questionnaire to Participant 6:

1. What is the purpose of the study?

Response: About falls. (Score 2)

2. What are the risks?

Modification: *“Will any harm come to you if you take part in my study?”*

Response: No (Score 2)

3. What are the benefits?

Modification: *“Can I give you any money or rewards if you participate in the research”*

Response: No (Score 2)

Participant 6 required some modifications to the questions to correspond to the language and words the researcher used during the explanation of the study. He did not elaborate when asked about what the study was, other than it was about falls, despite the researcher’s previous efforts to describe and discuss the research. The responses, which he provided independently with no prompting or caregiver support, showed reasonable understanding of the research and his involvement, therefore, Participant 6 provided consent independently.



Monthly follow-ups (either by phone or face-to-face contact) provided the opportunity for participants to ask any questions they may have had regarding the research, including any issues related to their participation. To date 27 of the 40 participants have completed the 6-month observational period.

## **Discussion**

### **Key findings**

Given appropriate strategies and availability of resources, it was possible to conduct a thorough procedure to support the person with intellectual disability through the informed consent process for a research study to ensure that wherever possible, potential participants are making independent choices regarding their participation in the research. This study found that the systematic approach described in Figure 2 was useful in ascertaining the individual's capacity to consent from a holistic perspective: the procedure provided the opportunity for caregiver's opinion, researcher's clinical judgement and the participant themselves, within the limits of their cognitive abilities. Building rapport during the consent process was noted to be imperative as it gave the researcher the insight to utilise the suitable community style when communicating with the person with intellectual disability, thereby ensuring that the person with intellectual disability was fully supported to make the decision to participate in the study.

### **Learnings from the research to date:**

This study has identified similar issues to other researchers in the field in terms of the use of a proxy, barriers and challenges that researchers face in obtaining informed

consent, and engaging people with intellectual disability and their support systems when conducting research (Lennox et al., 2005; McDonald & Kidney, 2012).

#### *Informed consent and use of proxy*

Out of 40 participants enrolled, only three could successfully and independently answer the questions about the study and were considered to have understood the potential risk involved. All participants who were able to provide informed consent did so in the presence of a caregiver, and the remainder had a legal guardian or a next-of-kin consent document. However when considering all eligible potential participants, slightly more than 40% of caregivers declined for family reasons or on behalf of the person with intellectual disability. Reasons given by family were illness (family member or the individual), they had “too much going on”, or they believed that the person with intellectual disability had nothing valuable to contribute. On one occasion the legal guardian from the Office of the Public Advocate declined to provide informed consent for an eligible person with intellectual disability, stating that in her opinion, the research objectives were not beneficial to the individual. This was in spite of the individual’s primary paid caregiver giving her opinion that the study would not only be of value to the individual but that the individual herself was keen to participate. The ability for people with intellectual disability to be involved in research is largely influenced by the people whom they are directly dependent on.

#### *Making contact and maintaining engagement with the research*

To lead a meaningful life, the individual with intellectual disability requires a support network to ensure that needs for personal care, engaging in meaningful employment, recreation and leisure activities of their choice are achieved. One of the many challenges of

this project has been to ensure that all parties involved in the care of the participant were aware of the participant's involvement in the study and could contact the researcher when required. Participants had high levels of contact with their support network and the researcher relied heavily on this network for feedback regarding the participant to ensure meaningful study outcomes. Our study demonstrated that to conduct high quality and ethical research with people with intellectual disability, the time taken to establish complex communication networks in relation to participants with intellectual disability needs to be appropriately considered for study budgets.

### *Overall learnings*

Current experience in using the jurisdictional ethics guidelines (NHMRC) and recommendations published in the literature (Kidney & McDonald, 2014; Palmer et al., 2005) formed a useful checklist during the study preparation especially for the development of the recruitment procedure. The toolkit for accessible and respectful engagement (Kidney & McDonald, 2014) of people with intellectual disability in research was helpful to explain the current study in some instances, particularly when individuals with intellectual disability were interested and could understand the pictures used to represent their involvement. However, caregivers were still required to provide further explanations using familiar references from their daily lives (Case Study 1). For other participants who did not engage in conversation with the researcher (n=15), the toolkit was not useful. These participants were more severely affected and more dependent on care support. When developing the toolkit, the authors (Kidney and McDonald, 2014) consulted with people with intellectual disability who had responded to flyers in the community who may have been less cognitively affected than some of the participants it was used with in this study. It has also been reported that

other strategies including using photographs and presenting information in small sections followed by questions to clarify understanding had limited success in facilitating the provision of information to people with intellectual disability (Dye et al., 2007). The research team in this study had extensive experience in working with people with intellectual disability, with the lead researcher employed full time in an organisation that provides services to people with disability including a large proportion of people with intellectual disability. Appropriate training and experience are required to successfully interact and achieve good research outcomes in this group.

Other than the three participants who provided consent independently, all of the other participants, who participated in the Three-Item Decisional Questionnaire, required support to interpret the questions asked. This is similar to Palmer et al (2005) where the questions were re-explained or clarified when the response was vague or indicated a misunderstanding. The questions were still good guiding questions to determine whether they understood the researcher adequately and their involvement in the study. The participants who scored four or more out of a total six, indicating adequate understanding was equal to the number of participants who were engaged with the researcher during the discussion of the study giving an accurate representation of their decision-making capacity. Palmer et al 2005, also concluded that the Three-Item Decisional Questionnaire was sensitive to individuals with impaired understanding.

## **Conclusion**

Reaching out to people with intellectual disability and their families is best accomplished through their support networks. Though it was challenging to overcome the many hurdles to reach individuals with intellectual disability, it was encouraging to note that

people who provided their care guarded their privacy and protected their well-being. A patient (often time-consuming), sincere and flexible approach was taken in order to overcome barriers and to build trust and respect between the researcher, people with intellectual disability, and their support network. Many of the successful approaches taken in this study echo the efforts taken in other studies reporting success in reaching out to people with intellectual disability (Horner-Johnson & Bailey, 2013; Kidney & McDonald, 2014; Lennox et al., 2005). Successful strategies included a multilevel strategy for the provision of information and gaining of consent, making the effort to be mindful of their abilities, lifestyle, family, formal and informal care supports. Researchers should continue to investigate and report on the methods for conducting research in this hard to reach population in order to provide more opportunities for people with intellectual disability to benefit from research.

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