Participant Information Sheet and Consent Form for Interview/Focus Group
For someone providing consent on behalf of a person with an intellectual disability
Improving palliative care for people with Intellectual Disability
Professor Julian Trollor, Dr Janelle Weise & Dr Rachael Cvejic

Health/Social Science Research - *Guardian providing consent*

MASTER University of New South Wales (UNSW)

Title	Improving palliative care for people with intellectual disability
Short Title	Palliative care for people with ID
Protocol Number	2021/ETH11030 V2.0
Project Sponsor	Australian Government, Department of Health (Public Health and Chronic Disease Grant Program, National Palliative Care Projects).
Coordinating Principal Investigator/ Principal Investigator	Professor Julian Trollor
Location	UNSW Sydney

Part 1 What does my participation involve?

1 Introduction

The person with an intellectual disability that you support is invited to take part in this research project, which is called “Improving palliative care for people with intellectual disability”.

This Participant Information Sheet and Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want the person you support to take part in the research.

Before you decide to consent to the person you support to participate in this research project, we need to ensure that it is ok for them to take part. The research project is looking for people who:

- Self-identify as having an intellectual disability
- Are aged 18 years old and over
- Live in NSW
- Have a life-limiting condition or complex health needs

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about.

Participation in this research is voluntary. If you do not wish the person you support to take part, they do not have to.

If you decide you want them to take part, you will need to read and sign the Consent Form below. You will be given a copy of this Participant Information Sheet to keep.

2 What is the purpose of this research?

This research aims to design, implement, and evaluate a new palliative care service for people with intellectual disability. This is important because people with intellectual disability often find it hard to access palliative care that is tailored to their needs.

To do this we are first speaking to people with intellectual disability, their support networks, and health professionals to find out about access to palliative care for people with intellectual disability. We want to know:

1. What makes good palliative care for people with intellectual disability? and
2. How could palliative care services best operate to meet the end of life needs of people with intellectual disability?

The data will be used to help us to design a new model of palliative care. This new model of palliative care will be piloted in 2022 in South Western Sydney Local Health District.

This research has been initiated by a team led by Professor Julian Trollor from the Department of Development Disability Neuropsychiatry, UNSW Sydney with funding from the Australian Government, Department of Health (Public Health and Chronic Disease Grant Program, National Palliative Care Projects).

3 What does participation in this research involve for the person I support?

If you consent to the person that you support participating in this study, they will be asked to attend an interview and/or focus group. Please contact our Project Officer Sara Elsie Walker on (02) 9065 7786 or IDPalliativeCare@unsw.edu.au, to let them know that the person that you support would like to take part.

3DN are also interested in the experiences of family members, friends and support people (both paid and un-paid) of people with intellectual disability during the end of their life. If you are interested in participating in the research project yourself, there is the option to separately complete a survey or participate in an interview or focus group. If you would like more information on this, please contact our Project Officer Sara Elsie Walker on (02) 9065 7786 or IDPalliativeCare@unsw.edu.au.

The first part of this process will determine if the person that you support is eligible to take part. Completing the screening questionnaire will take approximately five minutes over the phone with us. If the screening questionnaire shows that they meet the requirements, then the person that you support will be able to start the research project. If the screening questionnaire shows that they cannot be in the research project, the research coordinator will discuss other options with you/them.

If you consent to the person you support taking part they will be asked to participate in an interview or focus group. Individuals can participate in an interview by themselves or with a support person present. Alternatively, they can choose to take part in a focus group with other people with intellectual disability (they can also have a support person present if they wish).

The interview/focus group will take a maximum of 2 hours and will ask the person you support i) demographic questions (e.g., about their age and gender), ii) about current palliative care services and their ability to meet the needs of people with intellectual disability, and iii) how best a palliative care service for people with intellectual disability could operate.

There are no costs associated with this research project.

Any information obtained in connection with this research project will remain confidential.

We would like to take notes during the interview and seek your permission to record what the person that you support says to make our notes better.

If the person you support uses communication aids, we may also want to take pictures of these aids.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way.

4 Other relevant information about the research project

This project will regularly seek input from an advisory group that is made up of people with intellectual disability, people who support a person/people with intellectual disability and healthcare and disability professionals. We would also like to share de-identified feedback from participants with our research advisors to ensure we understand and appropriately manage any participant feedback that we receive. An option is included on the Participant Consent Form asking if you would be happy for us to share any feedback you or the person you support give us with our research advisory network.

5 Does the person I support have to take part in this research project?

Participation in any research project is voluntary. If you do not want the person you support to take part/if they do not want to take part, they do not have to. If you consent to the person you support taking part and later change your mind, you are free to withdraw the person you support from the study at any stage.

If you/the person you support decide to take part and later change your/their mind, you are free to withdraw them from the project at any stage by signing and returning the Withdrawal of Participation Form provided below.

If you decide you want the person you support to take part in the research project, you will need to read this information sheet carefully. You will also be given a Participant Consent Form to sign, and you will be given a copy of this Participant Information Sheet to keep.

Your decision whether to have the person you support take part or not, or to take part and then withdraw, will not affect their routine care, nor your/their relationship with professional staff or UNSW, Sydney.

6 What are the possible benefits of the person I support taking part?

We cannot guarantee or promise that the person you support will receive any benefits from this research; however, a possible benefit may include improvement in the standard of palliative care services for people with intellectual disability. We hope that this project will enable the Australian Government to fulfil their commitment to the National Palliative Care Strategy, which includes assuring that evidence-based and quality palliative care is available to everyone. This may or may not directly or indirectly affect the quality of palliative care possibly experienced by the person you support.

There will be no clear benefit to them personally from their participation in this research.

7 What are the possible risks and disadvantages of the person I support taking part?

The person you support may feel that some of the questions we ask are stressful or upsetting for them. If they do not wish to answer a question, they may tell us they wish to skip it and go to the next question, or they may stop immediately.

If the person you support becomes upset or distressed because of their participation in the research project, the research team will be able to recommend counselling or other appropriate support. E.g., we can assist you/them in contacting your GP to discuss the possibility of attending sessions with a psychologist. Please contact our Project Officer, Sara Elsie Walker, on (02) 9065 7786 or IDPalliativeCare@unsw.edu.au, who can help to arrange this support.

Alternatively, you/they can contact several free services directly, including:

Name/Organisation	Beyond Blue
Telephone	1300 224 636
Email	www.beyondblue.org.au

Name/Organisation	Lifeline Australia
Telephone	13 11 14
Email	https://www.lifeline.org.au/

8 What if the person I support withdraws from this research project?

If the person you support decides to leave the research project, the researchers will not collect additional information from them. If you/they no longer wish to have their data stored or do not wish to be contacted for research purposes you can withdraw their information by completing the withdrawal of consent form below or by phoning our Project Officer, Sara Elsie Walker, on (02) 9065 7786 or IDPalliativeCare@unsw.edu.au, and letting them know. Please note, their data would not be able to be removed from any data analysis or publications already developed.

Please note, if you/they decide to withdraw part way through a focus group, we will not be able to remove their comments from the recording. However, we will not transcribe what they say or use their input in the data analysis.

9 Could this research project be stopped unexpectedly?

There are no foreseeable reasons as to why this project will be stopped unexpectedly.

10 What happens when the research project ends?

The research team intend to publish and report the results of the research project in a variety of ways. All information published will be done in a way that will not identify you/the person you support.

You/they have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by emailing IDPalliativeCare@unsw.edu.au. This feedback will be in the form of a one-page lay summary. You/they will receive this feedback after the study is finished.

Part 2 How is the research project being conducted?

11 What will happen to information about the person I support?

By signing the Consent Form below, you consent to the research team collecting and using personal information about the person you support for the research project. Their information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law.

Any information obtained in connection with this research project that can identify them will remain confidential.

Electronic data collected from the person you support will be stored on UNSW servers that require UNSW staff authorisation and a password to gain access. Individual logins must be used to access files. Access levels are set by UNSW IT. Data will be stored in adherence to UNSW IT Security Standards and Guidelines Policy.

Hard copies of data collected from the person you support will be stored in a locked cabinet at the Department of Developmental Disability Neuropsychiatry, UNSW Sydney, 34 Botany Street, UNSW Sydney, Sydney 2052. Access to this data is restricted to research team members.

Audio or video recordings of the person you support will be stored on a UNSW password protected OneDrive only accessible to the approved research investigators. It will be made available to a professional transcription service. Recordings will only be made available after a confidentiality agreement has been signed.

Data will be retained for 5 years post publication of resulting manuscripts. After this time, electronic data will be permanently deleted from all storage devices and paper-based data will be shredded.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the person you support cannot be identified.

In accordance with relevant Australian and/or NSW privacy and other relevant laws, you/they have the right to request access to the information about you/them that is collected and stored by the research team. You/they also have the right to request that any information with which they disagree be corrected. Please inform the research team member named at the end of this document if you or the person you support would like to access your/their information.

12 Compensation

The person you support will receive a $120 gift voucher for their time.

If the person you support suffers any distress or psychological injury because of participation in this research project, you should contact the research team as soon as possible. You/they will be assisted with arranging appropriate treatment and support.

13 Who is organising and funding the research?

This research project is being conducted by Dr Julian Trollor, Dr Janelle Weise, Dr Rachael Cvejic, Dr Preeyaporn Srasuebkul, and Dr Simone Reppermund from the Department of Developmental Disability Neuropsychiatry, UNSW Sydney, as well as Professor Meera Agar, Professor David Currow, Dr Rebecca Strutt, Associate Professor Claire Vajidic, Associate Professor Richard Chye, Tracey Szanto, Janeane Harlum, and Professor Irene Tuffrey-Wijne. This research is being funded by the Australian Government, Department of Health (Public Health and Chronic Disease Grant Program, National Palliative Care Projects).

No member of the research team will receive a personal financial benefit from the involvement of the person you support in this research project (other than their ordinary wages).

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of NSW Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you/the person you support want any further information concerning this project or if you/they have any problems which may be related to their involvement in the project, you can contact the following people:

Dr Janelle Weise
Lecturer
j.weise@unsw.edu.au

Dr Rachael Cvejic
Lecturer
r.cvejic@unsw.edu.au

Sara Elsie Walker
Project Officer
sara.walker@unsw.edu.au

16 Complaints of contact person

This study has been approved by the South Western Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of

this study should contact the Research and Ethics Office, Locked Bag 7103, LIVERPOOL BC NSW 1871 on 02 8738 8304 / fax 02 8738 8310 / email SWSLHD-ethics@health.nsw.gov.au, website: https://www.swslhd.health.nsw.gov.au/ethics/information.html and quote [2021/ETH11030].

Thank you for taking the time to consider this study.

If you wish the person you support to take part in it, please sign the attached consent form.

This information sheet is for you/them to keep.

Declaration by the Parent/Guardian

- I understand I am being asked to provide consent for the person I support to participate in this research study;
- I have read the Participant Information Sheet, or someone has read it to me in a language that I understand;
- I understand the purposes, study tasks and risks of the research described in the study;
- I understand that the research team will audio/video record the interviews/focus groups or take pictures of communication aids if neccessary; I agree for the person I support to be recorded for this purpose.
- I understand that the person I support will need to maintain group confidentiality and not talk about what was said in the focus group.
- I provide my consent for the information collected about the person I support/myself to be used for the purpose of this research study only.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received;
- I freely agree to the person I support participating in this research study as described and understand that they are free to withdraw at any time during the study and withdrawal will not affect their access to care, nor my/their relationship with any of the named organisations and/or research team members;
- I understand that I will be given a signed copy of this document to keep.

Sharing de-identified participant feedback with a research advisory network (please circle one option)

- I have read the participant information sheet and consent to sharing of any feedback I or the person I support give in a de-identified format to a network of research advisors

YES / NO

Parent/Guardian Signature

Name of Parent/Guardian (please print):	
Signature of Parent/Guardian:	
Date:	

Declaration by researcher*
I have given a verbal explanation of the research project, the project activities and the risks and I believe that the support person has understood the explanation.

Name of Researcher (please print):	
Signature of Researcher:	
Date:	

*An appropriately qualified member of the research team must provide the explanation of, and information concerning the research project.

Note: all parties signing the consent section must date their own signature.

Withdrawal of Participation Form

I wish to **WITHDRAW** my consent for the person I support to participate in the research project described in the Participant information Sheet and understand that such withdrawal **WILL NOT** affect their access to care, nor my/their relationship with any of the named organisations and/or the named research members.

Parent/Guardian Signature

Name of Parent/Guardian (please print):	
Signature of Parent/Guardian:	
Date:	

The Withdrawal of Participation Form should be forwarded to:

Chief Investigator Name:	Professor Julian Trollor
Email:	j.trollor@unsw.edu.au
Postal Address:	34 Botany St, Randwick, NSW, 2031