**Health/Social Science Research** -*Guardian providing consent*

*MASTER South Western Sydney Local Health District*

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| **Title** | Implementing a tailored model of palliative care for people with intellectual disability |
| **Short Title** | Tailored palliative care for people with intellectual disability |
| **Protocol Number** | 2023/ETH01786 V2.0 |
| **Project Sponsor** | Australian Government, Department of Health and Aged Care (Public Health and Chronic Disease Grant Program, National Palliative Care Projects). |
| **Coordinating Principal Investigator/ Principal Investigator** | Professor Julian Trollor |
| **Location** | South Western Sydney Local Health District |

**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 implementing a tailored model of 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
* Currently access palliative care within South Western Sydney or South Eastern Sydney local health district.

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 test new information resources to help people with intellectual disability, their supporter/s and health workers have a better experience in palliative care.

The resources aim to:

a. Increase awareness of health rights when accessing palliative care among people with intellectual disability and their supporters

b. Increase understanding of palliative care among people with intellectual disability and their supporters

c. Improve identification of personal preferences and questions about palliative care for the person with intellectual disability and their supporters

d. Increase awareness of local palliative care services and supports among people with intellectual disability and their supporters

e. Improve identification and engagement of key team members (including supporters and health professionals) working with the person with intellectual disability.

We will interview people with intellectual disability, their supporter/s, and palliative care health professionals after they use the resources to understand their experiences of the resources.

This is important because research tells us that people with intellectual disability find it hard to access palliative care that meets their needs.

It is expected that any experiences shared from this study inform the development of a national Toolkit on tailoring palliative care for people with intellectual disability. The Toolkit will be launched in 2024.

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 and Aged Care (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 initial interview and be provided with information resources and then asked to attend a follow-up interview one month later. Please contact our Program Manager, Olivia Burton on 02 9348 1732 or [IDPalliativeCare@unsw.edu.au](mailto:IDPalliativeCare@unsw.edu.au), to let them know that the person that you support would like to take part.

The research team are also interested in the experiences of family members, friends and support people (both paid and un-paid) of people with intellectual disability for this study. If you are interested in participating in the research project yourself, there is the option to separately complete a Participation Information Sheet and Consent Form. If you would like more information on this, please contact the Program Manager, Olivia Burton on 02 9348 1732 or [IDPalliativeCare@unsw.edu.au](mailto:IDPalliativeCare@unsw.edu.au).

If the person you support would like to take part, we will first do a screening questionnaire to determine if they are 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 the person you support does not meet the requirements, they will not be able to take part.

If you consent to the person you support taking part, they will be asked to participate in two interviews. The first interview will take about 90 minutes. In the first interview we will first ask the person demographics and health questions, followed by questions about the resource topics such as palliative care and health rights. We will also go through the resources with them.

After the first interview, we will invite the person to a second interview. The second interview will be about one month after the first interview. The second interview will take about 90 minutes. In the second interview, we will ask the person questions about the resource topics, what they think about the resources, and their experiences of using the resources.

The participant can have a support person attend the interviews with them. We can also arrange for interviews to take place over shorter sessions if they would prefer. The research team will try their best to adjust the format, time and location of meetings and interviews. For example, this might be face to face at South Western Sydney Local Health District, at your home, over the phone, or online (for example through Zoom).

There are no costs associated with this research project. However, the person you support will be given a $100 gift card for their participation in each interview.

We would like to take notes during the meeting and follow-up 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.

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

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. We would not share any personal information that could identify the person you support (e.g., their name). An option is included on the Participant Consent Form asking if you would be happy for us to share any feedback 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 their awareness and understanding of palliative care as the resources have been designed with the aim of improving palliative care. Another benefit may include improvement in the standard of palliative care services for people with intellectual disability. This may or may not directly or indirectly affect the quality of palliative care possibly experienced by the person you support.

**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 Program Manager, Olivia Burton, on 02 9348 1732 or [IDPalliativeCare@unsw.edu.au](mailto:IDPalliativeCare@unsw.edu.au), who can help to arrange this support.

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

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| **Name/Organisation** | Beyond Blue |
| **Telephone** | 1300 224 636 |
| **Email** | [www.beyondblue.org.au](http://www.beyondblue.org.au) |

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| **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 Program Manager, Olivia Burton, on 02 9348 1732 or [IDPalliativeCare@unsw.edu.au](mailto: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.

**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](mailto:IDPalliativeCare@unsw.edu.au). This feedback will be provided in plain English and Easy Read formats. 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, UNSW Medicine & Health, Discipline of Psychiatry & Mental Health, Room 241, Level 2, Biolink Building E25, UNSW SYDNEY NSW 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 to the transcription service 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**

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 Professor Julian Trollor, Dr Rachael Cvejic, Dr Janelle Weise, Ms Olivia Burton, Mr Amanuel Hagos, Dr Preeyaporn Srasuebkul and Associate Professor Simone Reppermund from the Department of Developmental Disability Neuropsychiatry, UNSW Sydney, as well as Professor Meera Agar, Professor David Currow, Dr Rebecca Strutt, Professor Claire Vajdic, Associate Professor Richard Chye, Ms Tracey Szanto, Ms Vanessa Evans, Ms Maria Heaton, and Ms Janeane Harlum. This research is being funded by the Australian Government, Department of Health and Aged Care (Public Health and Chronic Disease Grant Program, National Palliative Care Projects).

No member of the research team will receive a personal financial benefit from your involvement 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:

**Ms Olivia Burton**

Program Manager

[o.burton@unsw.edu.au](mailto:o.burton@unsw.edu.au)

**Dr Rachael Cvejic**

Senior Research Fellow

[r.cvejic@unsw.edu.au](mailto:r.cvejic@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](mailto:SWSLHD-ethics@health.nsw.gov.au), website: <https://www.swslhd.health.nsw.gov.au/ethics/information.html> and quote 2023/ETH01786.

The conduct of this study at South Western Sydney Local Health District (site) has been authorised by the South Western Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on (02) 8738 8304, email: [SWSLHD-Ethics@health.nsw.gov.au](mailto:SWSLHD-Ethics@health.nsw.gov.au) and quote project number 2023/STE03494.

**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 or take pictures of communication aids if neccessary; I agree for the person I support to be recorded for this purpose.
* I provide my consent for the information collected about the person I support 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**

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

**Declaration by researcher\***

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

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| 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**

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

**The Withdrawal of Participation Form should be forwarded to:**

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| Chief Investigator Name: | Professor Julian Trollor |
| Email: | j.trollor@unsw.edu.au |
| Postal Address: | Room 241, Level 2, Biolink Building E25  UNSW SYDNEY NSW 2052 AUSTRALIA |