Participant Information Sheet/Consent Form for Carers

Title	Identifying and Responding to the Health Literacy Needs of People Living with MND/ALS – A Coordinated National Approach
Short Title	Finding Clear and Useful Health Information about MND/ALS
Protocol	Version 3. 26 May 2021
Principal Investigator	Dr Susan Mathers
Location	Calvary Health Care Bethlehem, 152 Como Parade West, Parkdale 3195

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this online research project. This is because you care for a person with Motor Neurone Disease (MND), also known as amyotrophic lateral sclerosis (ALS).

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

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to document your consent. By consenting you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the study questionnaires and research that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

This project aims to understand how easy or difficult it is for those caring for people with Motor Neurone Disease (MND) in Australia to find, understand and make use of information about MND and health care. Clear information in plain language helps people to understand the disease. It can help people find their way around our health care system and the services which provide support. To make decisions which are right for them and their family, people need timely access to reliable sources of information. Health professionals and other service providers also need to share knowledge and be good communicators to more effectively support people living with MND.

Also, in today's world, people often need to access information and services on-line. Not everyone is comfortable with this technology. Not all of the information is reliable. E-health literacy examines how people decide what digital information to use; how they view the security of their data and their overall comfort with the technology. This is particularly relevant to people with MND who may have problems with speech, writing or typing.

Health literacy is the term used to describe a person's ability to obtain and understand the health information and services that are available to them in order to make decisions about their health and care. Research has shown that countries or communities with low health literacy are associated with poor health outcomes, increased risk of hospitalisation, higher health care costs and increased mortality. Addressing problems with health literacy has therefore been identified by the Australian Commission on Safety and Quality in Health Care 'as an issue that requires national focus and attention'.

This project will, for the first time, define the health literacy needs of Australians with MND and their family carers. Lastly the project aims to develop innovative ways of providing information and communicating about health care that consumers of health services find useful.

This research is being funded by an innovation grant from the Motor Neurone Disease Research Institute of Australia.

3 What does participation in this research involve?

We will ask you to read this form. Please ask the research nurse or one of the investigators to explain anything you are uncertain about, (contact details are at the end of this information sheet). If you wish to participate in this study, please sign and date the consent form, where indicated and return in the reply-paid envelope.

This research project involves completing a number of short surveys or questionnaires, which are outlined below in section 4.

Once we receive your consent, we will mail you copies of these questionnaires to complete in your own time. Please return the completed forms in the reply-paid envelope provided.

We also have the main questionnaires in other languages. Please contact the study coordinator if you would like us to mail you the questionnaires in your language, if available.

Study Procedures

4 What do I have to do?

You will be asked to complete:

- a demographics form, including information about your age, postcode, occupation etc.
- HLQ and eHLQ - two questionnaires about how you find, understand and use health information, including on-line / digital information
    - these 2 questionnaires were developed at Deakin University in Melbourne and have been used in groups of people with other diseases and in population studies by the Australian Bureau of Statistics and the World Health Organisation. Prof Richard Osborne leads the team of researchers who developed these questionnaires and he is an investigator on this project. The HLQs will be completed by ticking boxes on a computer or i-pad screen. Approximate time taken is 20 minutes.
- Brief Zarit Burden Interview-12
    - This is a 12 item questionnaire. You will be asked to respond to statements about your role as carer using a rating scale. Approximate time taken is 10 minutes.

The research team will be available to assist you to complete all of these assessments if required, either via phone or video-call.

5 Other relevant information about the research project

There are no costs associated with participating in this research project, nor will you be paid.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage with no consequences to your usual care.

7 What are the possible benefits of taking part?

You may not personally benefit from this research. We hope that this research will clarify the information and health literacy needs of people with MND, those who care for them and helps us to support people living with MND better in the future.

8 What are the possible risks and disadvantages of taking part?

Participating in research can be fatiguing and answering some questions can cause distress. You are welcome to take rest breaks during the assessments or to cease your involvement in the study at any time. If you become upset or distressed as a result of your participation in the research, the study doctor will be available to discuss this with you and help you arrange support in your local area. Please contact the research team as detailed in section 13 below.

9 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team.

The study doctor and relevant study staff will not collect additional personal information from you. Information already collected will be retained and may be used in the analysis of the results of this project unless you request that all of your data is withdrawn from the project.

10 What happens when the research project ends?

If you wish, the study doctor will provide you with a summary of the results of the study when they become available, usually about 6 months after the study ends. Please tell us where you wish this summary to be sent.

11 What will happen to information about me?

By giving consent, you are agreeing to the research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. We will take the following steps to ensure confidentiality.

A research code will be assigned to you and your data. Any identifying information such as your name and postcode in the demographics form, will be stored separately to the coded information you provide in the health literacy questionnaire and other study assessments. The only people who will have access to your individual identity are the Principal Investigator and the authorised research staff. The master list of participants and codes will be stored securely in a locked research cabinet at Calvary Health Care Bethlehem in Melbourne. Answers that you provide will not be released or shared in any way with your relatives, insurance companies, or any third party not involved in research. Research data held as paper-copy will be securely stored for 7 years after the completion of the study and then securely destroyed.

Your information collected through this research project will be stored on secure servers behind the University of Queensland (UQ)'s security firewall. UQ and the principal investigator will take all reasonable measures to protect the confidentiality of your records and your identity will not be revealed in any publication or presentation that may result from this study. Electronic data will be securely stored indefinitely.

Calvary Health Care Bethlehem, the University of Queensland (QU), and project staff are bound to undertake this research in accordance with the Australian Privacy Principles 2014, the Australian Code of the Responsible Conduct of Research and NHMRC National Guidelines for the Ethical Conduct of Human Research (2018).

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

12 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 Research Ethics and Ethics Committee of Calvary Health Care Bethlehem

13 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project, you can contact the principal study doctor on (03) 9596 2853 or any of the following people:

Clinical contact person

Name	Ruth Krasniqi
Position	Study Coordinator
Telephone	(03) 9595 3294 / (03) 9596 2853
Email	Ruth.Krasniqi@calvarycare.org.au

If you have a complaint or concerns about the conduct of the Project you should contact the General Manager prior to consideration by the REEC (Research Ethics and Ethics Committee).

Complaints contact person

Position	General Manager, Calvary Health Care Bethlehem
Telephone	(03) 9595 3290

Consent Form - *Carer*

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Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I understand my identity will not be disclosed to anyone else or in publications or presentations.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my relationship with Calvary Health Care Bethlehem.

I understand that I will be given a copy of this document to keep.

I consent to sharing my research data with other projects relevant to MND:

YES ☐ **NO** ☐

I would like a summary of the research outcomes to be sent to:

Mail or email address……..

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to sign the consent form

Witness to the informed consent process

Name (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/

Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior 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.