Participant Information and Consent Form: Version 1, February 25th, 2022

PICF – Relative/Caregiver of the person with brain tumour

Project Title: Perceived need and benefits of extended psychological support via telehealth for individuals with brain tumour and their family caregivers

HREC Reference number: HREC/2022/QMS/83846

Project TEAM:

Prof Tamara Ownsworth	School of Applied Psychology, Griffith University
Dr Katarzyna Lion	Menzies Health Institute Queensland, Griffith
Ms Stephanie Jones	University
A/Prof Mark Pinkham	Princess Alexandra Hospital

*This Participant Information and Consent Form is **8** pages long. Please make sure you have all the pages.*

Part 1. What does my participation involve?

1. Introduction

This research project aims to better understand the needs and preferences for psychological support of people with brain tumour and their family members. It also aims to find out how well the Making Sense of Brain Tumour (MAST) program can meet these needs and preferences when provided through Zoom videoconferencing. You are invited to take part in this research project because you have a family member who has been diagnosed with a brain tumour.

The project is being conducted by researchers at Griffith University and the Princess Alexandra Hospital. It is funded by Brain cancer Rehabilitation, Assessment, Intervention of Survivor Needs (BRAINS), a program funded by a Medical Research Future Fund, 2019 Brain Cancer Survivorship Grant.

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

Please read this information carefully. Feel free to ask questions about any information that you don't understand or want to know more about. Before deciding whether or not to take part, you may wish to talk about it with a relative, friend or healthcare professional. Participation in this project is voluntary: if you don't want to take part, you don't have to. Your relative 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 sign the consent section. By signing it, you are telling us that you:

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

You will be given a copy of the Participant Information and Consent Form to keep as your record.

2. What is the Purpose of this research?

The purpose of this project is to better understand what people with brain tumour and family members need and want from psychological support and to find out how well the MAST program can meet this.

The MAST program has been running in Queensland since 2010. It has been found to help improve people's emotional well-being and quality of life. Through this research, this program is now available to people around Australia through videoconferencing (Zoom).

You will be asked about your preferences for receiving psychological support in the MAST program (e.g., number of sessions, how often, with or without family members). A psychologist will provide between 6 and 10 sessions (30-60 minutes) of psychological support to you and your family member in your home via Zoom on a home computer, laptop or tablet. You will be able to see and hear the psychologist and see pictures and documents shown on the psychologist's computer screen.

You are invited to participate in this research project because your relative has been diagnosed a brain tumour. You may take part by yourself or with the person with brain tumour.

This study has been started by the Principal Coordinating Researcher, Professor Tamara Ownsworth from Griffith University.

3. What does participation in the research project involve?

Participation in this project will involve:

- **A short assessment over the telephone to find out if you are eligible or able to take part in the MAST program (5-10 minutes).**
- **If you are eligible, you will receive a longer assessment over the telephone (about 30 minutes) which involves:**
    - **Being asked questions about the psychological support you have received since your relative's brain tumour diagnosis, your preferences for support and what you are hoping to gain from taking part in the program.**
    - **Answering questions about your own support needs and preferences, mood, coping and quality of life.**

This assessment will be recorded to make sure we do not miss important information from you.

The researchers will access information about your relative's brain tumour and treatment from the doctor, nurse or other health professional who referred you to the study.

If your family member with a brain tumour chooses to be involved in the study, he/she will also be asked questions about their support preferences, mood, emotional wellbeing and quality of life.

- **You will receive training in the use of the Zoom videoconferencing before commencing the program. This will involve using a personal computer, laptop or tablet in a quiet place that you choose.**
- **You will then receive between 6 and 10 sessions of psychological support from a psychologist through Zoom videoconferencing. You will be supported to identify what you would like the program to focus on, how many sessions you would like to receive, and how often the sessions are provided. A combination of individual, couple and family-based support sessions may be provided, depending on your goals and preferences.**

Assessments after the program

- **About one week after you have finished the MAST program, you will receive a telephone-based assessment about your experiences of**

taking part in the program and how well this met your preferences for support. You will also be asked questions about your support needs, mood, coping and quality of life (about 30 minutes). This will be recorded.

- **You will be contacted three months after your last session of the MAST program for a follow-up assessment. You will be asked questions about the longer-term benefits of taking part in the program and your support needs, mood, coping and quality of life (about 30 minutes). This assessment will also be recorded.**

During the time that you take part in this project, you and your relative will still be able to receive all other care and support as usual.

4. What are the possible benefits of taking part?

- **MAST is a psychological support program and may therefore provide some benefits for your emotional well-being. However, we cannot guarantee or promise that you will receive any benefits from taking part.**
- **By taking part in this research, you will help us to find ways of improving the quality of psychological support provided to people with brain tumour and their family members. This might help us to make support more available to people living around Australia.**

5. What are the possible risks of taking part?

- **The project is not likely to have any serious risks. However, some people might find it distressing to talk about their relative's brain tumour diagnosis and everyday support. If you become distressed during the study, the psychologist can provide immediate emotional support and, if required, discuss other options for psychological support.**
- **It is possible you may feel tired during an assessment or support session. You are free to take breaks at any stage during the assessment or spread this out over two sessions if required. You may also take breaks at any stage during the psychological support sessions, or request that they are shorter.**

6. Do I have to take part in the research project?

Taking part in this 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 at any stage.

Before you make your decision, a member of the research team will be available to answer any questions you may have. You can ask for any information you want in relation to the study. Sign the Consent Form

only after you have had a chance to ask your questions and have received satisfactory answers.

Your decision to take part or not, or to take part and withdraw, will not affect your and your relative's relationship with the Princess Alexandra Hospital, any other hospital or support service or Griffith University.

7. What if I want to withdraw from this research project?

You are free to withdraw from the study at any time and do not have to give a reason to do so. Withdrawal from the study will not impact on your or your relative's ongoing care at the Princess Alexandra Hospital, other hospital or support services or your relationship with Griffith University.

If you decide to withdraw, please let a member of the research team know (see contact details on page 6 of this form, under "*who can I contact?"*). If you are happy for us to use the information that we have already collected in the study but do not wish to participate further, we will note your withdrawal and make no further contact with you. However, at your request, it is also possible to remove all of the data collected about you on the study and have it destroyed.

8. What if my relative with brain tumour chooses to withdraw from this research project?

You do not have to have your relative with brain tumour to take part in this study. If your relative decides to take part in the study but later withdraws, this will not affect your ability to keep taking part should you wish to do so.

9. How will I be informed of the results of this research project?

A 1-2 page summary of the final results of the study can be provided to you on your request at the end of the study. This will be general information based on the entire study group, and not your personal results. You can indicate whether you would like to receive this summary by ticking the relevant box in the Consent Form. You can also email your request to Professor Tamara Ownsworth; t.ownsworth@griffith.edu.au

Part 2. How is the research project being conducted?

1. **What will happen to the information about me?**

By signing the consent form you consent to the research staff collecting and using personal information about you for the research project. Any information obtained in connection with this project that can identify you will remain confidential. You will be assigned a unique ID code with which all data relating to you will be labelled. Only members of the research team will

have access to the data you have provided. Your identifying information will be removed from all data records and stored in a de-identified form on completion of the study. Files will be kept locked in a filing cabinet (or electronic password protected file) at the School of Applied Psychology at Griffith University for a period of 7 years, then destroyed securely.

By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

The findings from this study will only be presented as group data. It is anticipated that these will be published/presented in a variety of forums. The results will not include any names or personal information that could identify you.

Any information obtained within this research project that can identify you will remain confidential and will only be used in this research project. It will only be disclosed to a third party with your explicit permission, except when required to do so by law.

2. How can I access my information?

In accordance with relevant Australian and/or Queensland privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information collected about you, with which you disagree, be corrected. Please contact one of the researchers if you would like to access your information.

3. Is this research project approved?

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 Metro South Hospital and Health Service (which governs Princess Alexandra Hospital) and Griffith University.

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.

If you would like any further information on the approval of this study, contact details for the Metro South HREC are:

Metro South Human Research Ethics Committee (EC00167) HREC Coordinator
Centres for Health Research
Level 7 TRI
37 Kent Street WOOLLOONGABBA QLD 4102
Ph: (07) 3443 8049 or 3443 8047

Fax: (07) 3176 7667
Website:
http://www.health.qld.gov.au/pahospital/research/gov/default.asp

4. Reimbursement for your costs

Apart from any potential costs of using your existing internet plan to access the MAST program, there are no costs associated with participating in this project and you will not be paid for your involvement.

5. Who can I contact?

Regarding further *information*, *problems with involvement*, or *withdrawal from the study*:

Name	**Tamara Ownsworth**
Position	**Coordinating Principal Investigator**
Telephone	**07 3735 3307**
Email	**t.ownsworth@griffith.edu.au**

Regarding *concerns or complaints* about the *ethical conduct* of the research project:

Name	**Metro South Human Research Ethics Committee (EC00167)**
Position	**HREC Coordinator**
Telephone	**07 3443 8047**
Email	**EthicsResearch.PAH@health.qld.gov.au**

Thank you for your interest in this research project.

Please keep this copy of the Participant Information Sheet for your records.

Consent Form

Consent Form for a relative/caregiver of the person with brain tumour
Version 1 Dated 25th February, 2022

Title: Perceived need and benefits of extended psychological support via telehealth for individuals with brain tumour and their family caregivers

HREC reference number:	**HREC/2022/QMS/83846**
Coordinating Principal Investigator:	**Prof Tamara Ownsworth**
Associate Investigator(s):	**Dr Katarzyna Lion** **A/Prof Mark Pinkham** **Ms Stephanie Jones**

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

I freely agree to take part in this study as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a copy of the Participant Information Sheet to keep.

I give permission for doctors or other health professionals to release information to the project researchers concerning my relative's brain tumour and treatment for the purposes of this research project. I understand that such information will remain confidential.

☐ **Please tick this box if you would like to receive a summary of the findings of this study sent to you when the study is finished (if so, please provide your email or postal address, as preferred).**

Participant's Name (printed)
.....

Signature…… Date ……

Email or Postal Address:

<u>Declaration by project researcher*:</u>

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

Researcher's Name (printed)
……

Signature…… Date ……

*** A member of the research team must provide the explanation and provision of information concerning the research project.**

Note: **All parties signing the Consent Form must date their own signature.**