Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult close other of individual with traumatic brain injury providing own consent*

National Survey sub-study

Monash University

Title	Implementing evidence-based care for cognitive and psychosocial consequences of moderate-to-severe traumatic brain injury	
Short Title	Implementing evidence-based care for TBI	
Protocol Number	TBI-IGAP	
Project Sponsor	Not applicable	
Coordinating Principal Investigator	Professor Jennie Ponsford	
Associate Investigator(s)	Dr. Cynthia Honan Prof. Leanne Togher Assoc. Prof. Dana Wong Prof. Jennifer Fleming Prof. Tamara Ownsworth Dr. Jessica Trevena-Peters Assoc. Prof. Grahame Simpson Emer. Prof. Jacinta Douglas Dr Zoe Adey-Wakeling Dr Clare Ramsden	Assoc. Prof. Rene Stolwyk Dr. Travis Wearne Dr. Bruce Powell Nick Rushworth Dr. Ann Livingstone Dr. Marina Downing Janet Wagland Dr. Dean McKenzie Miffy Durham
Location	Monash University University of Tasmania University of Sydney Macquarie University La Trobe University University of Queensland Griffith University Western Sydney University Metro South Health, QLD State Head Injury Unit, WA	Liverpool Hospital – South Western Sydney District Westmead Hospital Epworth HealthCare Brightwater Care Group Central Adelaide Local Health Network South Adelaide Local Health Network Tasmanian Health Service, WA

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, *Implementing evidence-based care in traumatic brain injury*. This is because you have a close other or family member who has had traumatic brain injury. The research project aims to understand your experiences following their injury, your needs, and barriers and facilitators of therapy and ongoing care.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide whether 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 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 research that is 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 study will aim to obtain a better understanding of the experiences and needs of individuals following traumatic brain injury and their close others and family members. By obtaining this information, we hope to provide the most appropriate care to individuals with traumatic brain injury and their families, particularly addressing cognitive and psychosocial difficulties.

This research has been initiated by Professor Jennie Ponsford from the Monash Epworth Rehabilitation Research Centre. It will be conducted in collaboration with the investigators listed on the first page. This is a collaboration across several institutions, including Monash University (Victoria), University of Sydney (New South Wales), University of Tasmania (Tasmania), Macquarie University (New South Wales), Liverpool Hospital (New South Wales), and Westmead Hospital (New South Wales).

This research has been funded by the Medical Research Future Fund - Traumatic Brain Injury Mission.

3 What does participation in this research involve?

We will ask you to complete the consent form online before we begin. We will then ask you to complete an online survey, which will take approximately 15 minutes. This will begin with questions regarding your demographic information (e.g., age, gender) and some information about the injured individual's traumatic brain injury. For example, date and cause of injury, duration of loss of consciousness and confusion, other injuries sustained at the same time, and rehabilitation history. We will then ask you questions regarding rehabilitation that they received.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study investigators or participants jumping to conclusions.

There are no costs associated with participating in this research project. You will also receive a $20 groceries voucher on completion of the survey to thank you for your participation. If you prefer to remain anonymous, then you do not need to provide your contact details but know that we won't be able to send you a voucher.

Also following survey completion, we will ask you if you are interested in participating in a more in-depth interview. If you are, you will be asked to provide your contact details so that a member of the research team can contact you.

4 What do I have to do?

In order to participate in this study, you are required to indicate 'YES' within the online survey to indicate you consent to the study. You will then be prompted to complete survey questions. It is not necessary for your family member who has had a traumatic brain injury to be present as you complete the survey.

5 Other relevant information about the research project

We hope to receive online survey responses from 50 individuals with traumatic brain injury and their close others and carers, as well as 150 clinicians who provide rehabilitation in this area.

This study contains two parts: one part involves completion of the online surveys by individuals with traumatic brain injury, their close others and clinicians, and one part involves interviews with each of these groups. The information obtained from both parts will be used to assist healthcare professionals to provide better care for individuals who have a traumatic brain injury and their families. Some aspects of this research project may form part of Monash University PhD student studies.

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.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with any hospitals or treatment centres involved in your care.

7 What are the possible benefits of taking part?

There will be no direct benefit to you from your participation in this research. You will however, contribute towards evidence-based information that will assist the study investigators to improve care for individuals with traumatic brain injury and their families Australia-wide.

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

Although it is considered unlikely, if you become upset or distressed as a result of your participation in the research, the study team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

9 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. You can contact the research team via email (merrc@epworth.org.au) or phone call (03 9426 8923).

If you do withdraw your consent during the research project, the study investigators and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the team up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

10 What happens when the research project ends?

Upon completion, the results of this study will be combined with the results obtained from the survey and interview completions by other individuals with traumatic brain injury, close others and clinicians. These combined results will be aggregated, analysed and published in a research report or journal publication. You may request to have access to this journal publication once it is provided.
The results will also provide the evidence-base needed to implement Australian guidelines addressing cognitive and psychosocial difficulties experienced by individuals with traumatic brain injury and their families. We anticipate this will take up to 5 years.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

By signing the consent form you consent to the study investigators and relevant 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. You will be assigned a study ID, which will be used to re-identify you should this be required. Your 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.

All survey data will be stored on password-protected secure services in a de-identified format for 10 years. Survey data will be stored on the Monash University servers. Study team members will have full access to the data. After 10 years, it will be ensured that the disposal process will involve an irreversible method that renders that data unreadable.

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 you cannot be identified, except with your permission. Results will be presented at a group level.

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

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

12 What if I get injured in the research?

Any complaints about the research study can be directed to any research study team member, or the Human Research and Ethics Committee (see Section 14). If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

13 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 Alfred Hospital Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2023)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

14 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 any of the following people:

Primary Investigator

Name	Professor Jennie Ponsford
Position	Primary Investigator and Professor of Neuropsychology
Telephone	0419 320 671
Email	jennie.ponsford@monash.edu

Associate Investigator

Name	Dr Jessica Trevena-Peters
Position	Chief Investigator
Telephone	0407806575
Email	jessica.trevena-peters@monash.edu

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Position	Complaints Officer, Office of Ethics & Research Governance, Alfred Health
Telephone	(03) 9076 3619
Email	research@alfred.org.au

Please quote the following Project ID number: 625/24

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Position	Complaints Officer, Office of Ethics & Research Governance, Alfred Health
Telephone	(03) 9076 3619
Email	research@alfred.org.au

Please quote the following Project ID number: 625/24

Local research governance Office contact

Name	Epworth Research
Position	Research Development and Governance Officer
Telephone	(03) 9936 8058
Email	research@epworth.org.au

Consent Form (digital) – *Adult close other of individual with traumatic brain injury providing own consent*

Title	Implementing evidence-based care for cognitive and psychosocial consequences of moderate-to-severe traumatic brain injury	
Short Title	Implementing evidence-based care for TBI	
Protocol Number	TBI-IGAP	
Project Sponsor	Not applicable	
Coordinating Principal Investigator	Professor Jennie Ponsford	
Associate Investigator(s)	Dr. Cynthia Honan Prof. Leanne Togher Assoc. Prof. Dana Wong Prof. Jennifer Fleming Prof. Tamara Ownsworth Dr. Jessica Trevena-Peters Assoc. Prof. Grahame Simpson Emer. Prof. Jacinta Douglas Dr Zoe Adey-Wakeling Dr Clare Ramsden	Assoc. Prof. Rene Stolwyk Dr. Travis Wearne Dr. Bruce Powell Nick Rushworth Dr. Ann Livingstone Dr. Marina Downing Janet Wagland Dr. Dean McKenzie Miffy Durham
Location	Monash University University of Tasmania University of Sydney Macquarie University La Trobe University University of Queensland Griffith University Western Sydney University Metro South Health, QLD State Head Injury Unit, WA	Liverpool Hospital – South Western Sydney District Westmead Hospital Brightwater Care Group Central Adelaide Local Health Network South Adelaide Local Health Network Tasmanian Health Service, WA

Consent Agreement

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 participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that information about me will be used for the purpose of this research project and may also be used to form part of Monash University PhD student studies.

[optional tick box] I consent to be contacted about participating in another part of this research project (in-depth interview). I understand that I can accept or decline participating in the interview at the time of the invitation, and that separate consent will be sought for the interview.

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

Do you consent to the above?

- Type full name
- Date
- Signature

Yes – proceed to survey questions
No – proceed to ineligible message

Consent Form (hardcopy) – *Adult close other of individual with traumatic brain injury providing own consent*

Title	Implementing evidence-based care for cognitive and psychosocial consequences of moderate-to-severe traumatic brain injury	
Short Title	Implementing evidence-based care for TBI	
Protocol Number	TBI-IGAP	
Project Sponsor	Not applicable	
Coordinating Principal Investigator	Professor Jennie Ponsford	
Associate Investigator(s)	Dr. Cynthia Honan Prof. Leanne Togher Assoc. Prof. Dana Wong Prof. Jennifer Fleming Prof. Tamara Ownsworth Dr. Jessica Trevena-Peters Assoc. Prof. Grahame Simpson Emer. Prof. Jacinta Douglas Dr Zoe Adey-Wakeling Dr Clare Ramsden	Assoc. Prof. Rene Stolwyk Dr. Travis Wearne Dr. Bruce Powell Nick Rushworth Dr. Ann Livingstone Dr. Marina Downing Janet Wagland Dr. Dean McKenzie Miffy Durham
Location	Monash University University of Tasmania University of Sydney Macquarie University La Trobe University University of Queensland Griffith University Western Sydney University Metro South Health, QLD State Head Injury Unit, WA	Liverpool Hospital – South Western Sydney District Westmead Hospital Brightwater Care Group Central Adelaide Local Health Network South Adelaide Local Health Network Tasmanian Health Service, WA

Consent Agreement

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 participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.
I understand that information about me will be used for the purpose of this research project and may also be used to form part of Monash University PhD student studies.

I consent to be contacted about participating in another part of this research project (in-depth interview). I understand that I can accept or decline participating in the interview at the time of the invitation, and that separate consent will be sought for the interview.

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

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and 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. Witness must be 18 years or older.

Declaration by Study 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 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.

Form for Withdrawal of Participation - *Adult close other of individual with traumatic brain injury providing own consent*

Title	Implementing evidence-based care for cognitive and psychosocial consequences of moderate-to-severe traumatic brain injury	
Short Title	Implementing evidence-based care for TBI	
Protocol Number	TBI-IGAP	
Project Sponsor	Not applicable	
Coordinating Principal Investigator	Professor Jennie Ponsford	
Associate Investigator(s)	Dr. Cynthia Honan Prof. Leanne Togher Assoc. Prof. Dana Wong Prof. Jennifer Fleming Prof. Tamara Ownsworth Dr. Jessica Trevena-Peters Assoc. Prof. Grahame Simpson Emer. Prof. Jacinta Douglas Dr Zoe Adey-Wakeling Dr Clare Ramsden	Assoc. Prof. Rene Stolwyk Dr. Travis Wearne Dr. Bruce Powell Nick Rushworth Dr. Ann Livingstone Dr. Marina Downing Janet Wagland Dr. Dean McKenzie Miffy Durham
Location	Monash University University of Tasmania University of Sydney Macquarie University La Trobe University University of Queensland Griffith University Western Sydney University Metro South Health, QLD State Head Injury Unit, WA	Liverpool Hospital – South Western Sydney District Westmead Hospital Brightwater Care Group Central Adelaide Local Health Network South Adelaide Local Health Network Tasmanian Health Service, WA

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Monash University, Epworth HealthCare, University of Tasmania, University of Sydney or Macquarie University.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

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