# Participant Information Sheet/Consent Form: TBIconneCT Online Training Portal

**Interventional Study** - *Adult providing own consent*

| | |
|---|---|
| **Title** | Online communication partner training and social media initiatives for family members, carers and service providers of people with TBI |
| **Short Title** | TBI online communication partner training and social media initiatives |
| **Protocol Number** | 5 |
| **Project Sponsor** | icare NSW |
| **Coordinating Principal Investigator/ Principal Investigator** | Professor Leanne Togher |
| **Associate Investigator(s)** | Ms Trinette Dunkerley |
| **Location** | Westmead Brain Injury Service |

## Part 1 What does my participation involve?

### 1 Introduction

You are invited to take part in this research project. This is because you have had a traumatic brain injury, or because you are a family member, friend, or carer for a person with a traumatic brain injury. The research project is testing a new platform for a training program which supports people with traumatic brain injury have better conversations together. The new platform is called the "TBIconneCT online training portal".

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments 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 your 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 have the tests and treatments 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 develop online tools to support communication after traumatic brain injury (TBI). After a TBI, people can find communication difficult. Family members, friends, and carers can find it difficult to know what they can do to help. A training program, "TBIconneCT" has previously been found to be helpful in improving conversations between people with TBI and their communication partners. The current project is trialling a new version of TBIconneCT training, which uses an online training portal. This portal will support people with TBI, communication partners, and speech pathologists to connect to the training activities.

This research has been initiated by the researcher, Professor Leanne Togher, and has been funded by icare NSW.

## 3 What does participation in this research involve?

You will be asked to sign the attached consent form before participating in the study. All participation in this study can be done online from your home or another location convenient to you – there is no requirement to travel.

Before starting the training, you will complete one appointment of no more than two hours duration. During this appointment, you will complete assessments about communication.

You will then be provided with a link to the TBIconneCT online training portal. The portal will support you to work together through a step-by-step process of completing a communication skills training program. The steps will include tasks such as:

- Watching videos
- Reflecting on your own communication
- Videoconferencing check-ins with a speech pathologist
- Uploading practice conversation tasks to the portal for the speech pathologist to review
- Putting positive communication skills into practice

The total time commitment for the training program (including all the tasks outlined above) will be 15 to 20 hours across a three month period (i.e., one to two hours each week). The videoconferencing check-ins with the speech pathologist will be scheduled at a time that is convenient for you.

After finishing the training, you will complete another appointment of no more than two hours duration to complete assessments about communication, and an interview of no more than 90 minutes duration to give your feedback about the program. At three months after finishing the training, you will again complete an appointment of no more than two hours duration to complete the same assessments, to provide information about progress over the long term.

This study involves some videorecording during assessments and training sessions. You will always be informed when recording starts and stops. You may request that part or all of the recordings be deleted. The following aspects of your participation will be videorecorded:

- During the assessments before the training, after the training and three months after the training, you will be recorded completing three different conversation tasks together. These recordings will help us observe any changes in conversation skills.
- Videoconferencing sessions with the speech pathologist will be recorded. These recordings will be used to ensure that the training is being delivered consistently.
- During the interview after the training, you will be recorded providing your feedback about the training. Recording helps us to make sure that we keep track of all the feedback, so that we can consider all recommendations to help us improve the online portal.

The training portal is managed by Changineers. All data collected from the training portal is stored in cloud-based infrastructure which is supported and managed by Amazon/AWS security

services and is encrypted. Only the research team and Changineers staff have access to this information. Further detail is available at https://policies.changineers.com.au/.

Recordings will also be saved on a password-protected server at The University of Sydney which is only accessible to the research team. Recordings will be anonymized through use of a numbering system. Interview recordings may be transcribed by an Australian transcription service in compliance with the National Privacy Principles contained in the Privacy Act 1988 (Cth). Transcribers are subject to signed confidentiality agreements.

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

There are no additional costs associated with participating in this research project. To compensate you for your time and expenses, you will be reimbursed $50 after completing the first appointment, $100 after completing the training and post-training assessment appointment, $66.24 after the feedback interview, and $50 after completing the three-month follow-up assessment.

## 4 What do I have to do?

We ask you to access the training portal each week, and complete the tasks assigned to you.

## 5 Other relevant information about the research project

This project will involve a pilot study including 3 participants with TBI and their communication partners followed by a larger study including 10 participants with TBI and their communication partners. This is a collaboration between The University of Sydney, University of Technology Sydney, Changineers, Brain Injury Australia, icare and Westmead Brain Injury Unit. These are follow-on studies from previous work in which feedback from participants was used to co-design the content and format of the training portal.

## 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 The University of Sydney, University of Technology Sydney, icare, or the brain injury service.

## 7 What are the alternatives to participation?

You do not have to take part in this research project to receive training about communication skills. You are welcome to discuss any goals you have regarding communication with the staff who usually support your rehabilitation.

## 8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include improved communication skills.

## 9 What are the possible risks and disadvantages of taking part?

Participation in this study presents the same low level of risk as participating in usual rehabilitation programs. You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, please let a member of the research team know and they will be happy to have a discussion with you. Another option is to contact Lifeline on 13 11 14. With your consent, we could ask your usual support person (e.g., case manager or GP) to follow-up with you.

### 10 Can I complete other therapy or training during this research project?

There are no restrictions on completing other therapy or training during your participation in this project. If you are already working with a speech pathologist, we will ask your permission to discuss your participation in this study with your current speech pathologist.

### 11 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. You will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team. If you do not want data already collected to be included in the results, you must tell the researchers when you withdraw from the research project

### 12 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as change of project plan or funding.

### 13 What happens when the research project ends?

At the end of the project, we will email you with a summary of the findings regarding the online course. We expect to send you this email in early 2022.

## Part 2 How is the research project being conducted?

### 14 What will happen to information about me?

By signing the consent form you consent to the research team 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. Participant questionnaires, data files and recordings will be anonymized through use of a participant number. Data and recording files will only be accessible to members of the study team. All data will be stored on a password-protected server based at The University of Sydney. 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. The personal information that the research team will collect and use is information from a questionnaire about your background, results of assessments of communication skills, information on your engagement with the online portal, and transcripts from interviews.

If you are a person with a TBI, information about your brain injury (e.g., date and severity of injury) may be obtained from your health records held at this and other health organisations for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

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 express permission. Results will be

presented based on group findings. If findings are specific to an individual, then a pseudonym will be used.

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

On the consent form, you have the option to consent to use of your data in future research studies. If you do not consent for use of your data in future studies, any data collected from you will be erased 10 years after completion of the study. If you do consent for use of your data in future studies, your data will be stored in perpetuity. Any use of this data in future studies will require new approval from a Human Research Ethics Committee.

## 15 Complaints

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

## 16 Who is organising and funding the research?

This research project is being conducted by Professor Leanne Togher.

It is being funded by icare NSW.

The organisations collaborating on this project may benefit financially from this research project if, for example, the project assists these organisations in any commercial enterprise.

You will not benefit financially from your involvement in this research project even if, for example, knowledge acquired from your information proves to be of commercial value to these organisations.

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

## 17 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 Westmead Hospital.

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.

## 18 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 problems which may be related to your involvement in the project, you can contact the researcher on 02 9351 9639 or any of the following people:

**Research contact person**

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|---|---|
| Name | *Ms Trinette Dunkerley* |
| Position | *Senior Speech Pathologist* |
| Telephone | *(02) 9845 7941* |
| Email | *trinette.dunkerley@health.nsw.gov.au* |

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**

| | |
|---|---|
| Name | *Westmead Hospital Patient Advice and Liaison Service* |
| Telephone | *(02) 8890 7014* |
| Email | *wslhd-pals-mail@health.nsw.gov.au* |

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**

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|---|---|
| Reviewing HREC name | *Western Sydney Local Health District* |
| Telephone | *(02) 8890 9007* |
| Email | *Wslhd-researchoffice@health.nsw.gov.au* |

**Local HREC Office contact (Single Site -Research Governance Officer)**

| | |
|---|---|
| Name | *WSLHD Research Governance Office* |
| Telephone | *(02) 8890 9007* |
| Email | *WSLHD-ResearchOffice@health.nsw.gov.au* |

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| **Location** | Westmead Brain Injury Service |

**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 acknowledge that any regulatory authorities may have access to records **specifically related** to this project to monitor the research in which I am agreeing to participate. However, 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.

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

Name of Participant (please print) _____

I consent to use of my anonymized data in future projects: YES ❑ NO ❑
I consent to use of my video-recordings in future projects: YES ❑ NO ❑
I consent to be contacted by this research team about future studies relating to brain injury. I may withdraw this consent at any time by emailing leanne.togher@sydney.edu.au. YES ❑ NO ❑

**For participants with TBI** – I consent to the researcher contacting my usual health professional to discuss my involvement in this project. YES ❑ NO ❑

Name of health professional: _____

Type of professional: _____ Phone/email: _____

Participant signature: _____ Date: _____

**Witness (for participants with TBI only):** I am known and trusted by the participant as supporting their best interests. I verify that the participant was able to provide informed consent for participating in this research.

Witness Signature: _____ Date _____

Witness Name: _____ Phone/email: _____

**Declaration by 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 Researcher† (please print) _____

Signature _____ 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.