

Participant Information Sheet

[The Allen Study: A longitudinal cohort study of stroke survivors]

You are invited to participate in the Allen Study - a long-term, follow-up cohort study exclusively focusing on the health care of people living with stroke. This study is being conducted by Distinguished Professor Jon Adams, Professor David Sibbritt, Professor Jane Maguire, and Dr Wenbo Peng at the University of Technology Sydney (UTS).

Before you decide whether you wish to participate in this study, it is important for you to understand why the study is occurring and what it will involve. Please take the time to read the following information carefully and discuss it with us or others if you wish.

Overview of study

Recovery from stroke is complex, long and often challenging. This study will broadly examine the health and health outcomes of stroke survivors throughout adult life from 2022 to 2031. Funding for this study has been received from the *Nancy & Vic Allen Stroke Prevention Memorial Fund*.

This study will use the online Consent Forms to collect your personal information (including full name, date of birth, sex, residential address, email address, and Medicare number), and the online survey to collect your demographic information (e.g. education), health behaviours (e.g. alcohol assumption), stroke duration, number of strokes, other medical conditions, and the use of medical, allied health, and non-conventional health services.

When you sign the online Consent Forms, you will also be asked to authorise the study to access your complete seven routinely collected administrative health datasets. They are:

- (1) NSW Admitted Patient Data Collection (i.e. collecting hospital records);
- (2) NSW Emergency Department Data Collection;
- (3) NSW Mental Health Ambulatory Data Collection;
- (4) The Registry of Births, Deaths and Marriages;
- (5) Australian Coordinating Registry Cause of Death Unit Record File;
- (6) Medicare Benefits Schedule (MBS); and
- (7) Pharmaceutical Benefits Scheme (PBS).

Your consent forms will be sent securely to the [1] **Centre for Health Record Linkage** (CHeReL) who holds the first five datasets confidentially and [2] **Services Australia** who holds MBS and PBS datasets confidentially. Then, these two professional data linkage units will link your online survey data with the above seven health datasets until the end of this study or for the duration of your involvement in this study. Such data linkage will exponentially increase the capacity of this study to better understand your health needs and those of the wider stroke community.

Below is the sample of the information that may be included in your Medicare claims (MBS) history:

Date of service	Item number	Item description	Provider charge	Patient out of pocket	Bill type	Date of referral	Item category
20/04/09	00023	Level B consultation	\$38.30	\$4.00	Cash		1
22/06/09	11700	ECG	\$29.50		Bulk Bill	20/04/09	2

Below is the sample of the information that may be included in your PBS claims history:

Date of supply	Date of prescribing	PBS item code	Item description	Patient contribution (this includes under co-payment amounts**)	ATC Code	ATC Name
06/03/09	01/03/09	03133X	Oxazepam Tablet 30 mg	\$5.30	N05 B A 04	Oxazepam
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	\$30.85	N05 B A 01	Diazepam

** Under co-payments can now be provided for data after 1 July 2012

Why are you inviting me to participate in this study?

You are invited by the Stroke Foundation or Stroke Recovery Association NSW. We are inviting you to participate in this study because: (1) you have been diagnosed as having had a stroke in the past; (2) you are 18 years or over; (3) you are living in NSW; and (4) you are able to read and understand English.

Your participation is voluntary

Your participation in this study is completely voluntary and there will be no cost to you. If you do not want to take part in this study you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care and your relationship with the Stroke Foundation or Stroke Recovery Association NSW in any way. You can withdraw your consent at any time.

Your withdrawal from the study

You are under no obligation to continue with the consented release of your MBS, PBS, and/or other health information. You may change your mind at any time about releasing your information to the Allen Study.

You can withdraw your consent to release your MBS, PBS, and/or other health information to the study at any time by completing the 'Participant Withdrawal of Consent Form' (https://utsau.au1.qualtrics.com/jfe/form/SV_38bx0xjgs8jSToq). This form is provided by the study and is to be completed by you and supplied to the team if you choose to withdraw your consent at a later date.

If you withdraw your consent to release your Centre for Health Record Linkage (CHeReL) and/or Services Australia personal information to the study, you will be able to choose whether the study will destroy or retain the MBS, PBS, and/or other health information it has collected about you. You should only choose one of these options. Where both boxes are ticked in error or neither box is ticked, the study will destroy all information it has collected about you.

If you withdraw your consent to release your MBS, PBS, and/or other health information to the study, your information that has already been analysed and/or included in a publication may not be able to be withdrawn or destroyed. In such circumstances, your personal information will continue to form part of the Allen Study records and results. Your privacy will continue to be protected at all times.

Storage, retention and destruction of your information

All your information collected for this study will be stored electronically and remain onshore within the Australian jurisdiction. Your personal information will be collected via your consent forms and used for the data linkage process only. In addition, each participant will have an anonymized study ID for their online survey data. All linked data that will be provided to the team by CHeReL and Services Australia will be de-identified (i.e. your personal information has been permanently removed). Both survey data and linked data will be used for statistical analyses only, and will not be used in any future or unspecified study/project outside of this study.

Your personal information (including consent forms) and online survey data will be stored on the network server (i.e. eResearch Storage workspace) in **separate password-protected folders** at UTS, which is physically located within Australian borders. This secure server is a UTS hosted online storage platform exclusively designed to store research data. Access to these two folders requires the UTS staff ID number, password, and multi-factor authentication code of the team members via their UTS operating system and applications. The password of team members is required to be changed every 6 months. Importantly, only the Lead Investigator Distinguished Professor Adams can access your personal information, Consent Forms, and Withdrawal of Consent Form for research purposes.

The data linkage procedure will be performed separately for Commonwealth datasets (i.e. MBS data and PBS data) and NSW Health databases due to the different jurisdictions. All linked data will be stored at the Secure Unified Research Environment (SURE). SURE is a secure computing

environment that has been purpose-built for analysis using linked health data, which is physically located within Australian borders. No linked data will be stored on a researcher's local computer or in their institutional computing environment. To access SURE, a user name, password and one-time access code provided by a physical token (Yubikey) are required. Within SURE, a user cannot access the internet, email, print or copy data to a USB memory stick or other removable media. Only the investigator Dr Peng can access the linked data for statistical analyses purposes.

The published data of this study will be de-identified. That is, the results of this study will be published or presented in a way that you cannot be identified. We will provide you with a summary of the study results if you indicate that you wish to receive them.

In accordance with the Australian Code for the Responsible Conduct of Research (2018), all data of this study will be stored for **five years** after the completion of the publications of this study. Once the retention period has passed, all electronic information including your MBS and/or PBS data and personal information will be destroyed using secure methods by the professional eResearch team of UTS and SURE team, respectively. Such data disposal method will ensure data is completely overwritten and there is no possibility that the records can be retrieved.

Your personal information within the online consent forms will be sent securely to CHeReL and Services Australia, separately, to authorise the release of your NSW Health data; and MBS and/or PBS information. CHeReL and Services Australia will retain the original consent form/data for the life of the study as a record of your consent. Your MBS, PBS, and/or other health information will not be sent outside of Australian jurisdiction and is governed by the Privacy Act 1988.

What do you need to do?

You will be asked to read this Participant Information Sheet and sign the online Consent Forms of this study prior to your participation. If you decide to participate, we will invite you to:

- (1) answer an online survey that will take approximately 30 minutes to complete; The online survey link is https://utsau.au1.qualtrics.com/jfe/form/SV_b8jRMJH86oiVmxo.
- (2) answer a follow-up online survey (the contents are the same as for the first survey) every year until 2031 or the duration of your involvement in this study; The surveys will be released in March each year and remain open for 9 months;
- (3) allow the team to collect your personal information including Medicare number in the consent form. All personal information will be **ONLY** used for linking your survey data with your administrative health data (the full list of datasets has been provided above);
- (4) allow the external professional Data Linkage Units - *Centre for Health Record Linkage* and *Services Australia* - to link your survey data with your administrative health data (from January 2012 to December 2031 or the duration of your involvement in this study);
- (5) allow the team to use your survey data and linked data to answer future research questions. All these data will not include your personal details (i.e. you will not be identified);
- (6) allow the team to contact you via email about further stroke-focused studies, and those new studies will not involve any data collected in this study. It is entirely your choice and you should feel under no obligation to participate in any other studies.

If you begin but do not fully complete the online survey, you can resume the progress later within one month as long as you return to the survey on the same internet browser on the same computer to finish the survey.

Please note, you **DO NOT** need to contact your GP or other health providers to complete the survey questions related to your health and health care. Your approximate answer is very valuable to us. The Allen Study team will also not contact your doctor(s) for any questions that you complete.

What does it mean to provide consent to linking my health information?

The NSW Ministry of Health uses personal and health information extracted from health records to run the health system. The health information exists in a number of NSW and Commonwealth administrative datasets and is **de-identified** to ensure your personal privacy is protected.

By supporting this study, you are agreeing to the use of your health information as held in the administrative databases that have come from your health records. On behalf of the team, the *Centre for Health Record Linkage and Services Australia* will link your health information from the following sources:

- Public and private hospital admissions, emergency departments records, mental health records, and the registry records of births, deaths & marriages held by the NSW Ministry of Health;
- MBS records (i.e. collecting information on your doctor visits and the associated costs);
- PBS records (i.e. collecting information on the prescription medications you have filled at pharmacies).

The linked health information provided to the Allen Study team will be in a form that will not identify you (i.e. without your personal information). Any health information used from these data sources are managed completely confidentially and are used only for the purpose of this study. With your agreement, your health information (as drawn from your health records in the administrative datasets listed above) will be included in the linked health information.

To participate in the study, do I have to consent to linking my health information?

Yes, only the participants who consent to their survey data being linked to their administrative health data will be included in this study.

Will I benefit from the study?

We cannot guarantee or promise that you will receive direct benefits from this study. However, if you take part in this study, you may help improve the post-stroke care and rehabilitation management for other people living with stroke in the future. Only you can tell us how your experiences have changed over time – we want you to be represented!

For the wider stroke community to benefit from this study, we plan to produce presentations and/or scientific articles that are publicly available and that can help inform improved clinical practice and policy for the stroke survivor community. We will ensure that in any publication, information will be presented in a non-identified and summary form so that you or anyone else cannot be identified. Your privacy will be protected at all times.

Will it cost me anything to take part in this study, and will I be paid?

Participation in this study will not cost you anything.

If you complete the online survey and provide personal information by 11:59 pm (AEST) April 30, 2024, you will automatically go into a prize draw with a chance to win a \$100 online supermarket gift card (10 winners in total). All prizes will be drawn using a random draw system. The prize draw will be conducted in the presence of a witness. Any personal details remain confidential and only the Lead Investigator Distinguished Professor Adams can access your details for the prize pool purpose. The team will contact the winners using the email address provided by the winners.

Are there risks to me in taking part in this study?

No medical treatment or medications will be involved in this study. However, there may be some risks associated with the study. (1) You may feel distressed or uncomfortable when you recall your stroke experience and recovery journey. (2) You may get tired while answering questions in the online survey. To manage the potential risks, you can access and return to the survey as many times as you need because your answers will be automatically saved in the survey. If you feel tired, please take a break. Also, you do not have to answer any question that you do not want to answer. You are very much encouraged to talk with the team members about any concerns and risks.

Who should I contact for further information?

If you have any concerns that may be related to your involvement in the study or would like to know further information concerning this study, you can contact the team on (2) 9514 8045 or send an email to allen@uts.edu.au. You can also directly contact the Lead Investigator Distinguished Professor Adams at 0404 933 790 or via Jon.Adams@uts.edu.au.

There are also other services available to help you:

- Lifeline (24 Hours): 13 11 14 - www.lifeline.org.au
- StrokeLine (provided by the National Stroke Foundation): 1800 787 653 - strokefoundation.org.au
- NSW Mental Health Line: 1800 011 511.

What if I have a complaint?

If you have a complaint about this study, you should contact the Executive Officer from the Human Research Ethics Committees that have approved this study and quote the HREC reference number:

- NSW Population & Health Services Research Ethics Committee (HREC Reference number: 2021/ETH10990/2021.41): via phone number: (02) 8374 3610 / (02) 8374 5689 or email: cinsw-ethics@health.nsw.gov.au.
- University of Technology Sydney Human Research Ethics Committee (HREC Reference number: ETH22-7570): via phone number: (2) 9514 2478 or email: Research.Ethics@uts.edu.au.
- If you have a privacy complaint in relation to the use of your MBS/PBS data you should contact the Office of the Australian Information Commissioner. You will be able to lodge a complaint with them. Website: www.oaic.gov.au, Telephone: 1300 363 992, Email: enquiries@oaic.gov.au or Mail: GPO Box 5218, Sydney NSW 2001

Any issues you raise will be treated in confidence and investigated fully and you will be informed of the outcome.

Privacy and your personal information

The privacy and security of your personal information is important to us, and is protected by law. We need to collect this information so we can process and manage your application and complaint, and provide services to you. We only share your information with other parties where you have agreed, or where the law allows or requires it. For more information, go to servicesaustralia.gov.au/privacy.

Thank you for taking the time to consider this study. If you wish to take part, please complete the following online consent forms. This information sheet is for you to keep.