Participant Information Sheet/Consent Form

Title	The use of a patient centred educational exchange model to improve patient's self-management of medicines after a stroke
Short Title	A conversation with patients about medications after a stroke
Coordinating Principal Investigator/ Principal Investigator	Mrs Judith Coombes
Associate Investigators	Associate Professor Neil Cottrell Dr Graham Hall Dr Nabeel Sheikh Dr Leena Aggarwal Ms Marie Williams Ms Debra Rowett
Location	Princess Alexandra Hospital

Part 1 What does my participation involve?

Introduction

You are invited to take part in this research project, "A conversation with patients about medications after a stroke." This is because you have been diagnosed with a stroke or Transient Ischemic Attack (TIA). The research project is aiming to test a program designed to educate people about the medications prescribed after they have had a stroke or TIA.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the 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 any research project is voluntary. If you do not wish to take part, you do not have to. 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 Princess Alexandra Hospital.

If you decide you want to take part in the research project, you will be asked to sign the consent section. There are two forms.
By signing the first form, "The study consent form" 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.
The second form is "The participant consent form for release of Medicare and PBS data. Here you will be asked to fill out a consent form authorising the study access to your complete Medicare and Pharmaceutical Benefits Scheme (PBS) data as outlined below. Medicare collects information on your medical visits and procedures, and the associated costs, while PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to the Department of Human Services who holds this information confidentially.

Definitions of Data used in this study:

Medicare (MBS)

- Date of service *(Date that the service was rendered by the provider, to the patient)*
- MBS Item number *(Items Numbers as per the Medicare Benefits Schedule)*
- MBS Item description *(describes the service as per the Medicare Benefits Schedule)*
- Item category *(where the service sits in the hierarchical structure according to the Medicare Benefits Schedule)*

Pharmaceutical Benefits Scheme (PBS)

- Date of supply *(Date the prescription was supplied by the pharmacy)*
- Date of Prescribing *(Date that the prescription was prescribed by a Medical Practitioner to a patient)*
- PBS Item Number *(Items Numbers reflected in the Pharmaceutical Benefits Scheme)*
- PBS Item Description *(the item description as noted in the Pharmaceutical Benefits Scheme Book)*
- Patient category e.g. general, concession, safety net, doctor's bag *(Patient's eligibility status at the time of supply)*
- Patient contribution *(the contribution paid by the patient)*
- Form category *(Original or repeat prescription)*
- ATC Code *(the code allocated by the World Health Organisation Collaborating Centre for Drug statistics Methodology)*
- ATC Name *(the group the drug falls under in the Anatomical Therapeutic Chemical (ATC) classification system*

What is the purpose of this research?

The purpose of this project is to test a program designed to educate people about the medications people are prescribed after they have a stroke or TIA. The program is designed to improve understanding and organisation of ongoing use of the participants' medications. A total of approximately 200 people will participate in this project.

The results of this research will be used by the study pharmacist, Judith Coombes, to obtain a Doctor of Philosophy (PhD) degree.

What does participation in this research involve?

Participation will only take place after you have given signed consent.

Participation in this project will involve completing a questionnaire on three or four occasions.

The first will be before you are discharged from hospital, the second will take place over the telephone about 3 months after your discharge from hospital and the third over the telephone at

12 months after discharge from hospital. The questionnaire will take about ten minutes to complete. You will be asked about your views of your illness (stroke), your view and opinion of your medicines used for stroke about the way you take your stroke medicines and about your quality of life. There are no right or wrong answers to any of the questions in the interview; it is your view and opinion that is important.

About half of the participants in this study will be chosen by chance (random), to have a longer interview with the researcher to have a conversation about their stroke medications prior to their discharge from hospital. This will take about a further ten minutes. These participants will also be contacted by telephone 7-10 days after discharge from hospital. The telephone call will last for about 10 minutes. The telephone call will involve completing the questionnaire and an opportunity to follow-up on any questions they may have about their medicines.

You will also be asked for consent for the release of your Medicare/PBS claims information.

What are the possible benefits of taking part?
No payment will be provided for participation in this study. We cannot guarantee or promise that you will receive any benefits from this research; however possible benefits may include better understanding of the medications you are using to reduce the risk of a further stroke. It may also help you to organise ongoing use of your medications.

What are the possible risks and disadvantages of taking part?
This study involves completing a questionnaire and for about half the participants discussing your stroke medications through one face to face interview and one telephone call. There is no foreseeable added risk to you above the risks of everyday living.

What if I wish to withdraw from this research project?
If you decide to take part and later change your mind, you are free to withdraw from this research project at any stage. You can ask to withdraw during the interview or you can inform Mrs Judith Coombes your desire to withdraw by telephone on 3346 1944 or 0428814397, email Judith@pharmacy.uq.edu.au or by mail addressed to Judith Coombes, Pharmacy Department, Princess Alexandra Hospital, Ipswich Rd, Woolloongabba QLD 4102.
If you do withdraw your consent during the research project, the investigator will not collect additional information from you or about you, although information already collected will be retained to ensure that the results of the research project can be measured properly. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want the researcher to do this, you must tell the researcher.

What happens when the research project ends?
You may request the study results when it is completed by providing an address that the report can be sent to or at a later date by contacting Judith Coombes (contact details above).

Part 2 How is the research project being conducted?

What will happen to information about me?

By signing the consent form you consent to the study pharmacist collecting and using personal information about you for the research project. Information about you may be obtained from your health records held at this hospital 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.

Any information obtained in connection with this research project that can identify you will remain confidential. In all reports from this research, information will be provided in such a way that you cannot be identified.

The information collected on paper will be stored in a locked filing cabinet in a locked office, with access only to the principal investigator stated above. Both written and electronic information containing confidential data will be stored for a period of seven years after publication of the final report or for 10 years, whichever is earlier, and then destroyed.

Who is organising and funding the research?

This research project is being conducted by *Mrs Judith Coombes, Associate Professor Neil Cottrell and Dr Graham Hall ,Dr Nabeel Sheikh, Dr Leena Aggarwal, Ms Marie Williams, Ms Debra Rowett and Associate Professor Jenny Whitty*
Mrs Coombes, Associate Professor Cottrell, Ms Rowett and *Associate Professor Whitty* are affiliated with the School of Pharmacy at The University of Queensland and Dr Hall, Dr Sheikh, Dr Aggarwal, Ms Williams and Mrs Coombes are affiliated with the Princess Alexandra Hospital.

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 *The Princess Alexandra Hospital*. This study adheres to the Guidelines of the ethical review process of the University of Queensland.
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.

11 Who to contact

If you have any queries or any problems concerning this research project, please contact

Name	Judith Coombes
Position	*Advanced Pharmacist Education*
Telephone	*0428814397, 33461944 or contact the switchboard 3176 2111 pager number 8009*
Email	*Judith@pharmacy.uq.edu.au*

If you would like to speak to an officer not involved in the study or 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:

Position	Coordinator, Metro South Hospital and Health Service Human Research Ethics Committee
Telephone	*3343 8049*
Email	*ethicsresearch.pah@health.qld.gov.au* or
Position	Human Ethics Unit Coordinator, University of Queensland
Telephone	*3365 3924*

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Study Consent Form

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Location	Princess Alexandra Hospital

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

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (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 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 Senior Researcher (please print) _____

Signature _____ Date _____

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

Form for Withdrawal of Participation -

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Location	Princess Alexandra Hospital

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 Princess Alexandra Hospital

Name of Participant (please print) _____

Signature _____ Date _____

Participant ID:

PARTICIPANT CONSENT FORM FOR RELEASE OF MBS/PBS DATA

Consent to release of Medicare and/or Pharmaceutical Benefits Scheme (PBS) claims information for the purposes of "The use of a patient centred educational exchange model to improve patient's self-management of medicines after a stroke" Study

Important Information

Complete this form to request the release of personal Medicare claims information and/or PBS claims information to "The use of a patient centred educational exchange model to improve patient's self-management of medicines after a stroke "study.

Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with your information.

By signing this form, I acknowledge that I have been fully informed and have been provided with information about this study. I have been given an opportunity to ask questions and understand the possibilities of disclosures of my personal information.

PARTICIPANT DETAILS

1. Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name: _____ First given name: _____

Other given name (s): _____

Date of birth: DD/MM/YYYY

2. Medicare card number: _____

3. Permanent address: _____

Postal address (if different to above): _____

AUTHORISATION

4. I authorise the Department of Human Services to provide my:

☐ Medicare claims history OR

☐ PBS claims history OR

☒ Medicare & PBS claims history

for the period 01/07/2014 to: 31/10/2018 to "The use of a patient centred educational program to improve patient's self-management of medicines after a stroke" Study.

*Note: The Department of Human Services can only extract 4.5 years of data (prior to the date of extraction), The consent period above may result in multiple extractions.

DECLARATION

I declare that the information on this form is true and correct.

5. Signed: _____ (participant's signature) Dated: DD/MM/YYYY **OR**

6. Signed by _____ (full name) _____ (signature) on behalf of participant

Dated: DD/MM/YYYY

☐ Power of attorney** ☐ Guardianship order**

** Please attach supporting evidence

APP 5 – PRIVACY NOTICE

Metro South Health Queensland Government The University Of Queensland AUSTRALIA

Your personal information is protected by law, including the Privacy Act 1988, and is collected by the Australian Government Department of Human Services. The collection of your personal information by the department is necessary for administering requests for statistical and other data.

Your information may be used by the department or given to other parties for the purposes of research, investigation or where you have agreed or it is required or authorised by law.

You can get more information about the way in which the Department of Human Services will manage your personal information, including our privacy policy at humanservices.gov.au/privacy or by requesting a copy from the department.

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.

A sample of the information that may be included in your Medicare claims history:

Date of service	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Bill type
20/04/09	00023	Level B consultation	$38.30	$34.30	$34.30	$4.00	Cash
22/06/09	11700	ECG	$29.50	$29.50	$29.50		Bulk Bill

Scrambled ordering Provider number*	Scrambled rendering Provider number*	Date of referral	Rendering Provider postcode	Ordering Provider postcode	Hospital indicator	Item category
	999999A		2300		N	1
999999A	999999A	20/04/09	2300	2302	N	2

* Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.

A 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 category	Patient contribution (this includes under copayment amounts**)	Net Benefit (this includes under copayment amounts**)	Scrambled Prescriber number*	Pharmacy postcode
06/03/09	01/03/09	03133X	Oxazepam Tablet 30 mg	Concessional Ordinary	$5.30	$25.55	9999999	2560
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85		9999999	2530

Form Category	ATC Code	ATC Name
Original	N05 B A 04	Oxazepam
Repeat	N05 B A 01	Diazepam

* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.

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