

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Improving participation of women in stroke clinical trials through consumer engagement

1. What is the research study about?

You are invited to take part in this research study. The research study aims to explore the barriers and facilitators that influence women's participation in stroke clinical trials. The study seeks to generate insights that will guide the development of inclusive, patient-centred recruitment and consent processes to improve gender equity in stroke research.

2. Who is conducting this research?

The study is being carried out by the following researchers: Zoe Chen (UNSW Honours student), Dr Cheryl Carcel, Dr Menglu Ouyang.

Research Funder: This research is being funded by the George Institute.

3. Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that it is okay for you to take part. The research study is looking recruit people who meet the following criteria:

- Women aged 18 years or older
- Lived experienced of stroke
- Able to provide consent

Participants who meet the following criteria will be excluded from the study:

- Cognitive, communication, or other support needs that cannot be sufficiently addressed through adaptations such as alternative formats, communication aids, or the involvement of a trusted support person

We can provide translation services for participants who do not speak English as their first language.

The research team is committed to making participation as accessible as possible, and will work with each person to identify and provide the communication or accessibility supports to best enable their involvement.

4. Do I have to take part in this research study?

Participation in this research study is voluntary. If you do not want 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 study at any stage.

If you decide you want to take part in the research study, you will be asked to:

- Read the information carefully (ask questions if necessary);
- Sign and return the consent form if you decide to participate in the study;
- Take a copy of this form with you to keep.

5. What does participation in this research require, and are there any risks involved?

If you agree to participate you will be asked to complete the following research procedures.

Focus Group: All focus group sessions will take place at The George Institute or online and will take approximately 1 hour. During the focus group you will be asked questions about what factors make it easier or harder for women to take part in stroke clinical trials. With your permission the research team would like to video record the interview. If you decide to participate in the focus group, your comments along with other participants will be video recorded during the group discussions. Because of the way

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in which the focus group discussions are recorded, the research team will not be able to withdraw or destroy individual participant responses.

Potential Risks to Participants: Participation in this focus group discussion is considered to involve minimal risk. However, the following potential risks have been identified:

Discomfort: Participants may experience mild discomfort when discussing personal experiences or be tired due to the one-hour discussion. Participants will be informed that they are free to decline to answer any question or to withdraw from the discussion at any time.

Time burden: The time commitment required to participate may represent a minor inconvenience.

Additional Costs and Reimbursement: There are no costs associated with participating in this research project, nor will you be paid. However, you will receive a prepaid gift card to reimburse you for any reasonable travel, parking, meals and other expenses while completing the focus group.

6. What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using information about you for the research study.

The research team will store the data collected from you for this research project for a minimum of 5 years after the publication of research results. The information about you will be stored in a non-identifiable format where your identity will be unknown.

- Information collected from you in an electronic format stored on a UNSW password protected OneDrive only accessible to the approved research investigators.
- Information collected from you using paper-based measures will be stored in The George Institute and only the approved research investigators will have access to this information.
- Video recordings will be stored on a TGI password protected OneDrive only accessible to the approved research investigators

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the [UNSW Privacy Management Plan](#).

7. How and when will I find out what the results of the research study are?

The research team intend to publish and/ report the results of the research. All Information will be published in a way that will not identify you.

If you would like to receive a copy of the results you can let the research team know by inserting your email or mailing address in the consent form. We will only use these details to send you the results of the research.

8. What if I want to withdraw from the research study?

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If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document or you can ring the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney or The George Institute. If you decide to leave the research study, the researchers will not collect additional information from you. You can request that any identifiable information about you be withdrawn from the research project.

9. What if I have a complaint or any concerns about the research study?

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Complaints Contact

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	10088

10. What should I do if I have further questions about my involvement in the research study?

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member of the research team:

Research Team Contact Details

Name	Zoe Chen
Position	UNSW Honours Student
Telephone	0474840860
Email	Z5487115@ad.unsw.edu.au

Support Services Contact Details

If at any stage during the study, you become distressed or require additional support from someone not involved in the research please call:

Name/Organisation	Stroke Recovery Association NSW Telephone Counselling
Telephone	1300 650 594

Name/Organisation	Strokeline Telephone Counselling
Telephone	1800 787 653



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Consent Form – Participant providing own consent

Declaration by the participant

- ☐ I understand I am being asked to provide consent to participate in this research study;
- ☐ I have read the Participant Information Sheet, or someone has read it to me in a language that I understand;
- ☐ I understand the purposes, study tasks and risks of the research described in the study;
- ☐ Recordings: I understand that the research team will video record the focus groups; I agree to be recorded for this purpose.
- ☐ I provide my consent for the information collected about me to be used for the purpose of this research study only.
- ☐ 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 study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- ☐ I understand that I will be given a signed copy of this document to keep.
- ☐ I understand that the results of the research will be made available on the George Institute website.
- ☐ I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only.

Name: _____

Address: _____

Email Address: _____

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

Declaration by Researcher*

- ☐ I have given a verbal explanation of the research study; its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

***An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study.**

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

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Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales or The George Institute.

- ☐ I am withdrawing my consent and I understand that any information already published and/or not linked to my identity cannot be withdrawn from the research.

Participant Name

Name of Participant (please type)	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	Zoe Chen
Email:	UNSW Honours Student
Phone:	0474840860
Postal Address:	Z5487115@ad.unsw.edu.au