PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM
INTERACT4 Expansion

INTEnsive ambulance-delivered blood pressure Reduction in biomarker-identified hyper-ACute intracerebral haemorrhage Trial

Focus Group Discussion with Stroke Survivors and Carers

1. What is the research study about?

You are invited to take part in a focus group for a research study. This study wants to hear the views of stroke survivors, carers, and the community regarding a new test before the clinical trial begins. The clinical trial is called INTERACT4 Expansion and will look at a new blood test called GFAP. This test may help paramedics quickly tell if a stroke is caused by bleeding in the brain.

Medical tests can provide useful information, but they are not always 100% accurate. Researchers would like to understand how people feel about using this type of test in emergency stroke care and how the test result may be used to help guide care in the ambulance.

If the test works, paramedics could:

- find out faster if the stroke is a bleeding type,
- give the appropriate treatment (blood pressure medicine) earlier in the ambulance.

We want to hear about your thoughts and concerns before the study starts.

2. Who is conducting this research?

The study is being carried out by the following researchers:

Name	Position	Affiliation
A/Prof Cheryl Carcel	Associate Professor/Senior Research Fellow	UNSW/The George Institute
Dr Alexia Rohde	Program Manager & Senior Research Fellow	The George Institute
Dr Qiao Han	Research Assistant	The George Institute

Research Funder: This research is being funded by NSW Health CV Collaborative Grant.

3. Inclusion/Exclusion Criteria

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

- Stroke survivors, family carers, or community representatives who would like to share their views about health care, stroke, emergency care, or community wellbeing. This may include

people involved in consumer or community groups, people from multicultural or local community organisations, or people with personal experience of hospital or emergency care.

- are adults aged 18 years or older who are able to understand the study and provide informed consent, with communication support if needed (for example, plain-language explanations, visual aids, or support from a trusted person).
- able to communicate in English(with or without support)

A trained member of the research team will also assess whether you are able to understand the study and make a decision about taking part. This will be done through a simple conversation to check that you can:

- understand what the study is about
- understand what taking part involves
- understand that taking part is voluntary
- communicate your decision

If needed, we will support you by using plain language, aphasia-friendly materials, and allowing extra time. You may also have a trusted person present to support you.

You will only be invited to take part after an initial screening conversation confirms that you meet the study requirements and are able to provide informed consent.

You will not be able to take part if:

- you are unable to provide informed consent, even with communication support, or
- you have a conflict of interest (for example, you are part of the research team).

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, or

- Provide verbal consent if you are unable to sign (this will be recorded by the researcher)
- 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 take part, you will be invited to join a focus group discussion.

Focus Group

The session will take place in person at:
The George Institute for Global Health,
L8, Health Translation Hub, 55 Botany Street, Randwick NSW.

The session will last about 60 minutes.

The venue is accessible (including lift access and accessible toilets). You may take breaks at any time and may bring a support person if needed.

What will you be asked about?

During the discussion, you will be asked about:

- your thoughts on a new blood test (GFAP) that may help identify bleeding in the brain
- your views on a small testing device (LVOne) used in the ambulance, recognizing the medical tests are not always 100% accurate
- your views on decision-making and consent in emergency situations
- your thoughts on the idea of earlier blood pressure treatment in the ambulance

Audio Recording

With your permission, the session will be audio-recorded.

- your comments will be recorded together with other participants
- recordings will be used for research purposes only

Because this is a group discussion:

- it may not be possible to remove your voice from the recording once the session is completed
- however, if you withdraw during the session, any information you have provided will not be used in the study where possible

Risks and Discomforts

This study involves low risk.

Some participants may:

- feel tired during the session
- feel uncomfortable discussing stroke or emergency care

To support you:

- you may skip any question
- you may take a break at any time
- you may stop participating at any time

If you feel distressed, you can stop the discussion, and support services are listed in the last Section.

Additional Costs and Reimbursement: There are no costs associated with participating in this research.You will receive $50 in cash as reimbursement for taking part in the focus group. This is to help cover reasonable expenses such as:

- travel
- parking
- meals

This reimbursement is provided as a token of appreciation for your time and participation.

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 the research results.

The information about you will be stored in an/a:

- re-identifiable format, where identifiable information (e.g. your name and contact details) will be stored separately from the research data and replaced with a unique study code.

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 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?

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 withdraw before or during the focus group, the research team will not collect any more information from you. Because the focus group will be audio-recorded, if you choose to leave partway through, your voice will still be on the recording along with everyone else's. However, any comments you made before leaving will not be included or used in the study.

This means the researchers cannot remove your individual comments from the recording once the session has finished. However, no new information will be collected after you withdraw.

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	iRECS10428

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/s of the research team:

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Research Team Contact Details

Name	Qiao Han
Position	Research Assistant
Telephone	+61483209661
Email	qhan@georgeinstitute.org.au

Chief Investigator

Name	A/Pro Cheryl Carcel
Position	Senior Research Fellow
Telephone	+61280524508
Email	ccarcel@georgeinstitute.org.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:

- StrokeLine (Stroke Foundation) – 1800 787 653 (free call, Mon–Fri, 9am–5pm AEST)
- Lifeline – 13 11 14 (24 hours, confidential support)
- Beyond Blue – 1300 22 4636 (24 hours, mental health support)
- If you need urgent help, please call 000 or go to your nearest emergency department.

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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 audio 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 would like to receive a copy of the study results via email, I have provided my details below and ask that they be used for this purpose only;
- ☐ 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 The George Institute of Global Health website.

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 for Global Health.

☐ I am withdrawing my consent. I understand that any information about me that has already been collected will not be used in the study, but it will be retained in the video recording.

Participant Name

Name of Participant (please type)	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	A/Pro Cheryl Carcel
Email:	ccarcel@georgeinstitute.org.au
Phone:	+61280524508
Postal Address:	L8, Health Translation Hub, 55 Botany Street Randwick NSW 2031 PO Box 6366 UNSW SYDNEY NSW 1466