**Participant Information Sheet/Consent Form**

**Health/Social Science Research** -*Adult providing own consent*

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| --- | --- |
| **Title** | Exploring the unmet rehabilitation needs of stroke survivors in Australia: A qualitative study |
| **Short Title** |  |
| **Protocol Number** | 2024/ETH01885 |
| **Project Sponsor** | St Vincent’s Health Network Sydney |
| **Coordinating Principal Investigator** | Dr Lauren Christie |
| **Site Principal Investigator** | Dr Lauren Christie |
| **Associate Investigator(s)** | Professor Natasha LanninKate MakroglouDr Christine ShinerDr Kate ScrivenerMaddison SmithA/Professor Erin Godecke Kelvin HillDr Angela Dos Santos |
| **Location**  | St Vincent’s Health Network Sydney |

**Part 1 What does my participation involve?**

**1 Introduction**

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. 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. Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.

**What is the research about?**

You are invited to take part in this research project, which is aiming to investigate the unmet rehabilitation needs of stroke survivors in Australia. This research will ask for your feedback on the care you received immediately after your stroke, during rehabilitation and after discharge from the hospital. We are specifically interested in what your main needs are as a stroke survivor and how these needs were or were not met by healthcare services.

**Who is doing the research?**

This research is being undertaken by Dr Lauren Christie, and the Allied Health Research Unit. This research has been funded by St Vincent’s Health Australia Health Equity Program and is sponsored by St Vincent’s Health Network, Sydney. A portion of these funds are allocated to researchers who are part of the Allied Health Research Unit and associated with this project.

**Why have you asked me to take part?**

You have been invited because you have experienced a stroke in the past 10 years and have completed some form of inpatient or outpatient rehabilitation for stroke.

**2 What is the purpose of this research?**

There are currently gaps in our knowledge concerning how health services are meeting the needs of stroke survivors in Australia. A recent report revealed that many stroke survivors experience challenges that can persist for years after stroke. However, these needs may not be met by rehabilitation and support services. The outcomes of this project will provide key insights into the specific unmet needs of stroke survivors who have received care at St Vincent’s Health Network, Sydney and as well as in the broader community. Your participation in this project and feedback about rehabilitation for stroke will help us to support stroke survivors.

**3 What does participation in this research involve?**

A member of the research team will contact you and ask you some basic questions to make sure you’re eligible to participate. If these questions show that you meet the requirements, then you will be able to start the research project. If the questions show that you cannot be in the research project, the research coordinator will discuss other options with you, including checking if you require additional support from a health professional.

If you are eligible and provide consent, you will be invited to complete an online survey. We can help you complete this survey over the phone, a video call or in person. The survey will ask you some basic information about you, your stroke and your experience of care in rehabilitation. After you complete the survey, you will attend a one-on-one interview (45 minutes) to provide your feedback on the support you received in rehabilitation after stroke. This interview will either be conducted face to face at St Vincent’s Hospital Sydney or online, depending on your preference and availability.

A summary of the interview findings from all study participants will also be emailed to you to read and comment on to ensure all important points regarding unmet stroke rehabilitation needs have been captured. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way.

**Will I be paid?**

You will be offered a $50.00 gift card once you complete the study to reimburse you for the time spent completing the survey and/or any expenses you incur to attend the interview. The gift card is provided by the Coles-Myer group.

**4 Other relevant information about the research project**

We are recruiting stroke survivors who have completed some form of inpatient or outpatient rehabilitation for stroke. Rehabilitation may have taken place through St Vincent’s Health Network, Sydney but we are also recruiting in the broader community and regional areas. About 15-20 people will take part in this project.

**5 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. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with professional staff or your relationship with St Vincent’s Health Network, Sydney.

If you decide you want to take part in the research project, you will be asked to sign the consent section of this form. By signing it you are telling us that you:

* Understand what you have read
* Consent to take part in the research project
* Consent to be involved in the research 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.

**6 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, the project provides an opportunity to contribute to stroke survivorship research which may be appealing for you as a person who has experienced stroke. Information gathered from this research may improve our understanding of the unmet rehabilitation needs stroke survivors face and how health services can be improved.

**7 What are the possible risks and disadvantages of taking part?**

There is a potential risk for discomfort and/or distress related to reflecting on your experience of stroke and the risk of inconvenience related to the time taken to participate in the interview. We do not anticipate that this will happen and you will have the opportunity to withdraw from the study at any time if you do not want to continue.

If you do experience discomfort or distress, we will discuss this with you and refer you to support services such as:

* StrokeLine: strokeline@strokefoundation.org.au or 1800 787 653, Monday to Friday 9 am to 5 pm
* Beyond Blue: [www.beyondblue.org.au](http://www.beyondblue.org.au) or 1300 22 46 36, 24 hours a day, 7 days a week
* Lifeline: ph. 13 11 14, 24 hours a day, 7 days a week

In addition, you may consider talking to your GP or specialist heath care team for personalised clinical support. If you are eligible for Medicare, you can access subsidised psychology support through your GP.

**8 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. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do 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 decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. 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 your data to be included, you must tell the researchers when you withdraw from the research project.

**9 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:

* Loss of funding; the study team no longer has the resources required to conduct the study procedures
* Limited participants; limited number of participants meet the inclusion criteria,
* Lead Investigator/s leaving the organization.

**10 What happens when the research project ends?**

When the research project ends, the data collected will be used to inform improvements of stroke rehabilitation systems at St Vincent’s Health Network and broader recommendations for stroke care in Australia. If you would like to, you can receive a summary of the results when the research project is completed by ticking the box in the consent form below.

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

**11 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. Your name and any identifying information will be replaced with a code.

The personal information that the research team collect and use is your personal experience of rehabilitation after stroke and unmet needs related to stroke recovery.

We will collect audio recordings of the interviews so we can transcribe them. By agreeing to take part in the research, you consent to the research team collecting and using this information for the research project. Your information will be collected and managed using REDCap electronic data capture tools hosted by St Vincent’s Health Network. REDCap (Research Electronic Data Capture) is a secure, web based application designed to support data capture for research studies.

All audio-recordings, transcripts, information and analysed data will be securely stored and password protected electronically on a secure St Vincent’s Health Network server. Only the project research team will have access to data collected in this study. Any written information collected from you will be de-identified, meaning any personal details that can identify you will be removed. This data will be maintained securely for 5 years from the time of publication. 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.

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.

In accordance with relevant Australian and/or New South Wales 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

**12 Complaints and compensation**

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.

**13 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 St Vincent’s Hospital Sydney and the Aboriginal Health and Medical Research Council Human Research Ethics Committee.

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.

**14 Further information and who to contact**

If you have any complaints or questions 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 one of the following people.

Name: Lauren Christie

Position: Principal Investigator

Telephone: +61 436 853 797

Email: lauren.christie@svha.org.au

**Complaints contact person**

Name Research Office Manager

Position Research Office Manager

Telephone 02 8382 4960

Email SVHS.Research@svha.org.au

**Local Research Office contact (Research Governance Officer)**

Name Research Governance Officer

Position Research Governance Officer

Telephone 02 8382 4960

Email SVHS.Research@svha.org.au

**Thank you for taking the time to consider this study.**

**If you wish to take part in it, please sign the attached consent form.**

**This information sheet is for you to keep.**

**Consent Form (Patient participant) -** *Adult providing own consent*

|  |  |
| --- | --- |
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| **Location** | St Vincent’s Health Network Sydney |

**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 care.

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

**Please tick the appropriate boxes:**

* **I would prefer to participate in an in-person interview**
* **I would prefer to participate in an online interview**
* **I would like to receive a summary of the research findings once the project is complete by email.**
* **My contact details to arrange the interview are:**

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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**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.

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|  | Name of Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† 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.

**Form for Withdrawal of Participation -** *Adult providing own consent*

|  |  |
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| **Location** | St Vincent’s Health Network Sydney |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or my relationships with the researchers or St Vincent’s Health Network.

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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In the event that the participant’s decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

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**Declaration by Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  |
|  | Name of Researcher (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

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