Participant Information Sheet / Consent Form

Staying connected: personalising stroke recovery and rehabilitation through new technologies for people with stroke living at home.

Observation and Interventional Study - *Adult providing own consent. Survivor of Stroke.*

Hunter New England Local Health District

Title	Staying connected: personalising stroke recovery and rehabilitation through new technologies for people with stroke living at home.
Short Title	TAILOR AND CONNECT: (**T**herapy and **A**rtificial **I**ntelligence **L**inked to **O**ptimise **R**ehabilitation & **CONNECT** with people living with stroke at home.
Coordinating Principal Investigator/ Principal Investigator	Professor Leeanne Carey
Site Principal Investigator	Assoc Professor Michael Pollack
Associate Investigator(s)	Professor Michael Nilsson Dr. Karen Ribbons
Location(s)	John Hunter Hospital, Hunter New England Local Health District Hunter Medical Research Institute

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Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

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

- Understand what you have read.
- Consent to take part in the research project.
- Consent to have the tests and undergo the therapy sessions that are described.
- Consent to the use of your personal and health information as described.
- Consent to taking part in video sessions as described.

You will be given a copy of this Participant Information and Consent Form to keep.

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 your local doctor.

Study Summary – page 1 of 3

What does my participation involve?

This study is for **people who have had a stroke 3-18 months ago**

Staying connected: personalising stroke recovery and rehabilitation through new technologies for people with stroke living at home.

Commitment: 12 months – study activities are spread out.

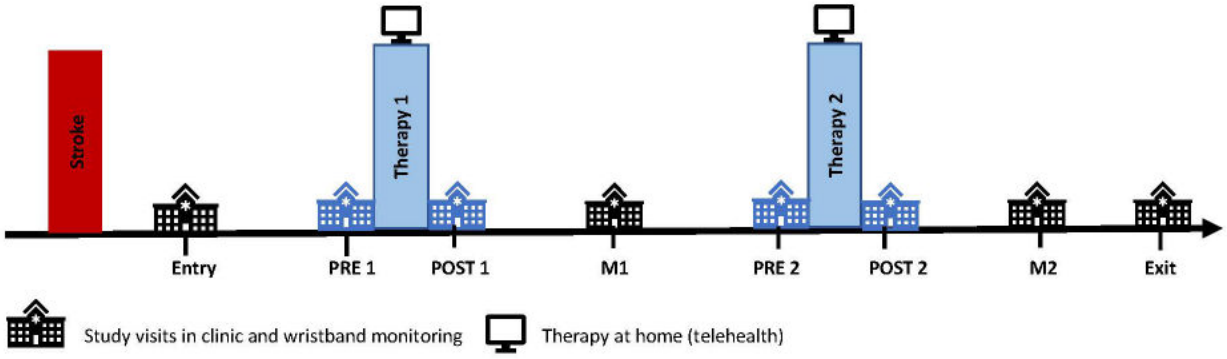
You will:

1. **Have 8 appointments** at set times (at home or at your local therapy centre), in which we **measure your recovery** including how you are able use your arm, and
2. **Help us to monitor your progress,** with some technology at home
    a. **Wear a wristband sensor** (leave on your wrist for 5-7 days at a time, a number of times throughout the 12 months)
    b. Use an app on your mobile phone to update us on your progress and your experience (over the same 5-7 day periods)
3. **Choose a Therapy Buddy –** you may choose to nominate someone who can attend and assist with therapy sessions at home with you – this will be guided by therapy needs and your needs/interest.
4. **Do 2 x 6-week periods** of **therapy at home**, guided by a rehabilitation therapist.

Appointment and therapy schedule

We will **set out the schedule** across the 12-month period, with you, **after you start** in the study. To help visualise this, please look at the diagram and table below:

Figure: Overview of study schedule (12 months)



Study Summary – page 2 of 3

Entry	Study visit 1	Study entry assessment
Pre 1	Study visit 2	Pre therapy block 1 assessment
Therapy 1		Therapy block 1 – 10 sessions over 6 weeks
Post 1	Study visit 3	Post therapy block 1 assessment
M1	*Study visit 4	Monitoring assessment 1
Pre 2	Study visit 5	Pre therapy block 2 assessment
Therapy 2		Therapy block 2 – 10 sessions over 6 weeks
Post 2	Study visit 6	Post therapy block 2
M2	*Study visit 7	Monitoring assessment 2
Exit	Study visit 8	Study exit assessment (12 months from entry)

* These assessments will be at dates that match with time-frames from when you had your stroke (e.g., at 6/12/18/24 months following your stroke) that occur while you are in this study.

The 8 appointments at the therapy centre will consist of 4 appointments at set times, based on when you commence in the study and the date of your stroke. The remaining 4 appointments will be before and after each of your therapy blocks. Each appointment will involve taking measurements of your recovery, in addition to setting up with the wristband sensor and the mobile phone app.

We will:

1. **Measure your recovery,** by
    - **asking you questions** about the activities you do
    - checking data from **wristband sensors** (leave on your wrist for 5-7 days at a time)
    - asking you to **use an app on your mobile phone** to update us on your progress and your experience
2. **Design a rehabilitation therapy tailored to your individual needs**
    - We will ask **what is important to you**
    - We will use new technologies that use **artificial intelligence** (AI) to help us make choices about which therapies and how much to put in your therapy plan
3. **Support you to do therapy at home**
    - guided by a qualified health professional over the internet, using a computer device such as a laptop, iPad, or tablet. This is called ‘Telehealth’.
    - You will connect with the health professional using video-calls

Study Summary – page 3 of 3

What is the purpose of this research?

The **research will test** whether **rehabilitation** programs delivered **in the home,** that are

- **tailored to each person**'s needs and capacity, and
- guided by **new technologies** that use **artificial intelligence (AI)** to

improve how well survivors of stroke recover their ability to **do everyday activities at home.**
It will also look at whether people feel that doing the program **improves** their **quality of life**.

If the outcomes are positive, the research will produce:

- scientific evidence that shows that home-based, technology-enabled, personalised rehabilitation methods work well,
- that they help stroke survivors to stay connected through these programs, and
- the research will provide guidance for health professionals in how to deliver these rehabilitation methods.

Lead Researcher:

This research project is being led by Professor Leeanne Carey. She is an occupational therapist and neuroscientist who works at La Trobe University in Melbourne.

Leeanne is recognised as a world leader in stroke rehabilitation science. She has made new discoveries that explain how sensation is affected in the arm after stroke and developed new and proven treatments for the recovery of arm function. Together with the team of scientists and health professionals around Australia, she thanks you for considering joining us as we test this program.

There is a short video of Leanne explaining the study at this link: bit.ly/TailorAndConnect

Funding: This research has been funded by a National Health and Medical Research Council (NHMRC) ideas grant.

Partners: The research is being conducted in partnership with La Trobe University, The Florey Institute of Neuroscience and Mental Health, The University of Newcastle, and the University of South Australia.

What's next? From here, this document outlines what to expect across the 12 months, in detail. It covers how we handle your data, and test samples, risks and possible benefits, your privacy, what your choices are, how to make a complaint, and what we'll do with the study results.

There is a lot to read! You are very welcome to ask us to help you go through this information.

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The Details

1 What does participation in this research involve?

When can I start?

You can **start in the study any time from 3 to 18 months after your stroke**.
If you take part, you will **be in the study for a whole 12 months** (unless you withdraw).
***First**, we need to talk to you to **check that the study is right for you**.*

'Screening' – how it works

- You tell us that you're interested
- We talk – on the phone, by email, or by videocall
- We answer any questions you have about the study
- We ask you questions about you, your health, your stroke and your lifestyle
- We check if the study is right for you – this includes decisions about whether it is likely to be safe for you, and whether it's likely to be the kind of therapy that you need
- If we feel that you can take part in the study, we will book a time for your first appointment at the Study Centre.

We can help with the cost of transport if needed, and we can reserve you a free car park when you come to a local study centre.

About other rehabilitation, exercise and your usual health regime

- You can usually keep going with or start other rehabilitation therapy during the study period - so long as you can find time and energy to do both.
- We will ask your permission to talk to any other therapists you have about what you're doing, to make sure that we all have clarity on which parts of your recovery we're responsible for together with you.
- If we think any arm therapy or task training therapies and the study program may conflict with each other, we may ask you to choose between staying in the study and pausing your other therapies, or stepping down from the study.
- If this happens, you will be given the chance to discuss your choice with other people, such as your doctor, before you decide what to do.

Study Consent – how it works

- You visit your local study centre
- We ask you a few more questions about yourself, your lifestyle and if you have chosen a Therapy Buddy.
- We will ask your Therapy Buddy to answer study questionnaires too, and they will also be asked to sign a consent form.
- You can ask more questions about the study at this time.
- Then we will decide whether the study is right for you. This is also called 'study eligibility'.
- You can still decide to talk about it with a friend or relative, or your local doctor, if you want.

If you are eligible, and want to do the study, then you sign the study ***Consent Form*** – on page 18 & 19 of this document.

Assessments and how we design your therapy program

Study Assessment visits – up to 8, spread across the 12 months

- The Study Assessor will be a qualified therapist and won't be the same person who will be running your therapy sessions.
- Our team will book a time with your study assessor at your local study centre

The visits will take approximately 2-3 hours. You can have rest breaks during the visit, so you don't get too tired. If you prefer, we can run a visit over 2 sessions, or do activities across 2 days close together. In certain situations, we can also run the visit in your home.

Visit 1:

The Study Assessor will ask you questions about:

- you (demographics)
- your lifestyle
- other health problems you may have
- how active you were before your stroke
- your stroke
- how you are currently coping with performing tasks at home that are important to you
- how you are feeling emotionally
- any pain you have
- how tired you get
- if you have recently accessed other healthcare services, including seeing your GP, other rehabilitation services or allied health professionals

The Study Assessor will measure:

- your arm function
- the sensation and movement of your arms (affected and non-affected)
- how you are currently performing tasks at home that are important to you
- your learning and memory function
- your body's built up stress levels – this is done by cutting a sample of your hair (less than a pencil-width) from the back of your head. The hair cortisol levels are then assessed in our laboratory, which provides us with a measure of stress.

The Study Assessor will help set you up with the 'Staying Connected' app on your mobile device and show you how to use it.

The app helps monitor your recovery and involvement in activities at home. You will need to use the app over a 5-7 day period. It will prompt you to answer several questions about what activities you are doing (at random times) and ask how you are coping with achieving certain tasks at home. This will occur no more than 4 times per day, and answering the questions should take 2-3 minutes each time.

You will also be fitted with a watch-like device, called a 'wearable sensor', to wear for each day across 5-7 day period. It will be programmed to measure your level of physical activity, the use of your arm and periods of sleep, over the 5-7 day period.

Please note: arrangements will be made for your Wearable Sensor to be collected from you after the 5-7 day period so we can download the information it has collected.

Visits before and after your study therapy sessions:

The Study Assessor will ask you questions about:

- your stroke
- how you are currently coping with performing tasks at home that are important to you
- how you are feeling emotionally
- any pain you have
- how tired you get
- if you have recently accessed other healthcare services, including seeing your GP, other rehabilitation services or allied health professionals

The Study Assessor will measure:

- your arm function
- the sensation and movement of your affected arm
- how you are currently performing tasks at home that are important to you

The Study Co-ordinator will co-ordinate access to and collection of your Wearable Sensor, so that you can wear the device for the 5-7day period before therapy and 5-7 day period after therapy.

Please note: arrangements will be made for your Wearable Sensor to be sent to you at least 5 days prior to the therapy sessions and collected from you after the 5-7 day period of wearing the sensor so we can download the information it has collected.

Two other during-program visits:

The timing of these depends on when you experienced your stroke. We'll determine the due dates for these when you start the study.
The questions and measures are the same as those from the initial study visit, (but only measuring your most affected arm), including taking the hair sample.

End of study visit:

At the end of your 12-months in the study.
The timing of this visit depends on when you experienced your stroke.
The questions and measures are the same as those from the initial study visit, (but only measuring your most affected arm), including taking the hair sample.

Therapy sessions:

What does the schedule look like?

Part of this research is testing whether it's better to use specialised technologies to work out the best timing of therapy than it is to schedule the therapy at random times, within 12 months.

Everyone will get two 6-week 'bursts' of therapy, at home, across the 12 months.

There will be at least 6-weeks break between bursts.

Half of participants will have the therapy scheduled at random times; half will have their schedule set with guidance from the computer's system that uses artificial intelligence to make predictions about your recovery. We will set out a schedule for you when you start.

You won't find out which group you were in unless you ask us after the study has finished.

What the sessions involve

In each **6-week long therapy 'burst'**

- there are approximately **10 sessions** (approximately 2 sessions per week) with a qualified **physiotherapist** or **occupational therapist.**
- **sessions that are usually 1-1.5h long**, including rests.
- you and your Therapy Buddy (if you choose to have one) will **usually** be **at home**, and
- the study therapist will usually be elsewhere, seeing you via a videocall over the internet.

If you don't think you're good with technology, so long as you can access, or borrow access to the internet at home, somehow, we can help to teach you how to use everything. If you're not sure if this can work for you, please do ask and we can try to problem-solve together.

We will take video recordings of you doing the specific tasks that you selected to work on. Your therapist will do this during session one, and at the end of each therapy burst. This allows our team to monitor your performance as you progress in the study.

Your therapy sessions will also be video recorded so that

- The therapist and other members of the research team can then review your progress
- We can give you specialised input and feedback during therapy, and
- we can review how the therapists are delivering the therapy.

Your program will be tailored to best suit you. We will:

- develop it in partnership with you
- use the information you give us about your stroke, the tasks that are important for you to achieve at home
- use our knowledge of best practice rehabilitation techniques to use exercises (therapy) that are already known to be effective at targeting the tasks you selected

Overall, the therapy will involve

- exercises and techniques to improve your arm skills – this includes therapies for strength, coordination, and sensation in your arm
- guidance on how to practice these skills at home between sessions, and
- guidance on discovering how to best use these skills in achieving the tasks you have chosen.

Costs

There are no specific costs to participate in this project, nor will you be paid. All therapy, tests and health care required as part of the research project will be provided to you free of charge.

You may be reimbursed for any reasonable travel, parking and other expenses associated with the research project visits. You can discuss these needs with one of the study team and they will arrange these reimbursements for you.

Other people to contact

It's a good idea to tell your local doctor / GP that you're participating in the research project.

2 What do I have to do?

To summarise the details above, to take part in the study you:

- will have 8 study visits at set times (at home or at your local therapy centre), in which we measure your recovery including how you are able use your arm, and
- will participate in some 5-7 day long monitoring periods at home, with wearable sensors and by using the 'Staying Connected' app
- may choose to nominate a Therapy Buddy - someone who can attend therapy sessions at home with you
- will do 2 x 6-week periods of therapy at home, guided by a rehabilitation therapist.

3 Other relevant information about the research project

The project is being undertaken at 3 sites across Australia located in Victoria, New South Wales, and South Australia, in collaboration with researchers from 8 universities from Australia, USA, Canada and Hong Kong. Overall, we plan to include 150 participants with stroke; 50 people from each site. All participants will receive the TAILOR and CONNECT Therapy.

4 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. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

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 Austin Health or healthcare provider.

5 What are the alternatives to participation?

You do not have to take part in this research project. Other options are available, such as standard rehabilitation or community services. We will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

6 What are the possible benefits of taking part?

We cannot guarantee, or promise, that you will receive any benefits from this research. However, possible benefits may include improving the way that your arm works, and how you're able to perform everyday activities that are important to you.

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

People can feel tired following the therapy. These issues generally improve after a short rest, or by pacing your activities through the day. Your therapist will be able to discuss the best way of managing any tiredness with you if you experience it.

If you become upset or distressed because of your participation in the research, we will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

8 What will happen to my test samples?

When your hair samples are collected, they will be stored in a sealed envelope labelled with a unique study code. No details about you will be written on the sample envelope. Your samples will then be transported and stored at the central testing facility: Centre for Rehab Innovations, New Lambton Heights, NSW 2305. All study samples will be stored in a secure manner at the site and will only be accessible to site study staff. The samples will be tested in batches and the results will be used to inform this project. We may also use the results we obtain from these samples in future research projects undertaken by our team. In this case, no identifiable details relating to you will be linked to the results and your sample will continue to be identified by the unique study code.

9 What if new information arises during this research project?

Sometimes during a research project new information becomes available about the therapy that is being studied. If this happens, we will tell you about it and discuss ongoing options with you. You would then have the option to continue with the therapy or not. If this happens, you will be asked to sign an updated consent form.

10 Can I have other treatments during this research project?

Yes. Participation in this study does not influence your medical treatments. You should continue to take your usual medication.

You can continue with your usual rehabilitation program while participating in this study. However, we would seek your permission to have a conversation with your treating therapist. This is to make sure that the goals addressed by each service were clear.

11 What if I withdraw from this research project?

If you decide to withdraw from this research 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 your consent during the research project, the research team will not collect additional personal information from you. However, personal information and test results that are already collected will be retained to ensure that the results of the study can be measured properly and to comply with law.

12 Could this research project be stopped unexpectedly?

This research project is unlikely to be stopped unexpectedly. There may however be minor delays in activities due to availability of staff.

13 What happens when the research project ends?

The findings of this study will be published on websites associated with TAILOR and CONNECT and presented at conferences and in journals. A summary of the findings can also be emailed to participants if requested. You can request for this to occur by indicating to the Associate Investigator during or after your involvement in the study. It is anticipated that the study will finish in 2025,and reports to be finalised by 2026.

How is the research project being conducted?

14 What will happen to information about me?

By signing the consent form, you consent to the research team and their support staff 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 personal information will be accessed, used and stored in accordance with Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002.

In summary, your personal and health information, videos, and all the data we collect is kept private to the research team, and stored securely, electronically, in ways that are compliant with Australian state and federal regulations for healthcare and health research information. There are a lot of details here, so please do feel free to ask us questions.

- All information will be stored on a secure, password-protected electronic network system.
- Only the research team will have access to the data.

- This system will allow data from each participating site to be transferred safely, stored securely and later analysed by the research team.
- This system will ensure compliance with local state regulations, and trans-border data flow policies.
- The data storage system will ensure your personal information and identity is kept private.
- Only the research team will have access to the data. Your information will be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law.
- If you give us your permission by indicating on the Consent Form, we will preserve your data obtained in this study for use in future ethically approved studies by the research team. Any use of data in future studies will be de-identified.

Information about you may be obtained from your health records held at this and other health services 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.

Your health records and any information obtained during the research project are subject to inspection for the purpose of verifying the procedures and the data. This review may be done by the relevant authorities, the institution relevant to this Participant Information Sheet, Austin Health, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

We expect the results of this research project to 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, except with your permission. Data will mainly be presented using group summaries. Any presentations that highlight an individual's comments or results will use a study code (e.g. Participant number 87) or fictional name, (e.g. John) to ensure that person's privacy. Specific consent would be obtained to use photographs or videos, and in those instances, identifying features (e.g. faces, tattoos) would be concealed.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

15 Complaints and compensation

If you have any concerns about this study, you can talk directly to us. If you prefer, you can contact the researchers, and / or the Austin Health Human Research Ethics Committee whose details are at the end of this statement.

All matters you raise will be discussed sincerely and handled seriously.

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

16 Who is organising and funding the research?

This research project is being conducted by Professor Leeanne Carey and colleagues and is being funded by a National Health and Medical Research Council (NH&MRC) Ideas grant.
You will not benefit financially from your involvement in this research project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

17 Who has reviewed the research project?

Ethics: 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 Austin Health.

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.

Governance: The conduct of this research has been authorised by the Hunter New England Local Health District to be conducted at the John Hunter Hospital site and at the Hunter Medical Research Institute.

18 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the coordinating principal investigator, Professor Leeanne Carey on (03) 9479 5600 or any of the following people:

Clinical contact person

Name	Assoc Professor Michael Pollack
Position	Site Principal Investigator District Director, Rehabilitation Medicine, Head, Department of Rehabilitation, John Hunter Hospital, HNELHD
Telephone	(02) 49214840
Email	michael.pollack@health.nsw.gov.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Complaints about conduct of this research within HNELHD: Should you have concerns or a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, please contact:

Position	HNE Research Governance Manager
Telephone	02 4921 4140
Email	HNELHD-ResearchOffice@health.nsw.gov.au and quote the reference number [2023/STE00841].

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:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Austin Health Human Research Ethics Committee
HREC Executive Officer	Ethics and Research Governance Manager
Telephone	(03) 9496 4090
Email	research@austin.org.au

Consent Form - *Adult providing own consent. Survivor of Stroke.*

Title	Staying connected: personalising stroke recovery and rehabilitation through new technologies for people with stroke living at home.
Short Title	TAILOR AND CONNECT: (**T**herapy and **A**rtificial **I**ntelligence **L**inked to **O**ptimise **R**ehabilitation & **CONNECT** with people living with stroke at home.
Coordinating Principal Investigator/ Principal Investigator	Professor Leeanne Carey
Site Principal Investigator	Associate Professor Michael Pollack
Associate Investigator(s)	Professor Michael Nilsson, Dr Karen Ribbons
Location(s)	John Hunter Hospital, Hunter New England Local Health District Hunter Medical Research Institute

<u>Consent Agreement</u>

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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the research team at Austin Health/Florey Institute/La Trobe University concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

I consent to the storage and use of hair samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project.
- Other research that is closely related to this research project.

I agree to audio-visual recording of my information and participation.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I consent to data obtained in this study being used in future ethically approved studies by the research team.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

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

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form

Witness to the informed consent process
Name (please print) _____

Signature _____ Date _____
* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

Declaration by Study Doctor/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 Study Doctor/
Senior Researcher† (please print) _____

Signature _____Date _____

† A senior 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. Survivor of Stroke

Title	Staying connected: personalising stroke recovery and rehabilitation through new technologies for people with stroke living at home.
Short Title	TAILOR AND CONNECT: (Therapy and Artificial Intelligence Linked to Optimise Rehabilitation & CONNECT with people living with stroke at home).
Coordinating Principal Investigator/ Principal Investigator	Professor Leeanne Carey
Site Principal Investigator	Associate Professor Michael Pollack
Associate Investigator(s)	Professor Michael Nilsson Dr Karen Ribbons
Location	John Hunter Hospital, Hunter New England Local Health District Hunter Medical Research Institute

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 John Hunter Hospital Hunter New England Local Health District or the Hunter Medical Research Institute.

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Name of Participant (please print) _____

Signature _____ Date _____

Circumstances relating to Withdrawal of Consent

Declaration by Study Doctor/Senior 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.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

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