



PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM
Understanding upper limb function in stroke patients
Professor Simon Gandevia

The study is being carried out by the following researchers:		
Role	Name	Organisation
Chief Investigator	Prof Simon Gandevia	NeuRA
Co-Investigator/s	Prof Stephen Lord Dr Annie Butler Dr Jasmine Menant	NeuRA
Student Investigator/s	Lewis Ingram	
Research Funder	This research is being funded by the National Health and Medical Research Council	

What is the research study about?

You are invited to take part in this research study. You have been invited because we aim to measure the upper limb function of adults who have suffered from a stroke.

To participate in this project you need to meet the following inclusion criteria:

- You are aged 20 years or older.
- You are able to sit unassisted for the duration of the testing.
- You have previously suffered a stroke, with a score of 2-4 on the Modified Rankin Scale.

The research study is aiming to investigate upper limb function in patients with neurological conditions, including Parkinson's disease, multiple sclerosis, stroke and essential tremor, to develop a new physiological profiling assessment focused on function of the upper limb.

Do I have to take part in this research study?

Participation in this research study is voluntary. If you don't wish to take part, you don't have to. Your decision will not affect your relationship with The University of New South Wales or Neuroscience Research Australia.

This Participant Information Statement and Consent Form tells you about the research study. It explains the research tasks 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 or friend.

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

- Sign the consent form ;
- Keep a copy of this Participant Information Statement;

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

If you decide to take part in the research study, you will be asked to fill out questionnaires which relate to your general health, physical ability and the function of your upper limb.

We will then ask you to perform a range of simple functional tests with your hand or arm that will take approximately 60 minutes. Measurements from these tests will determine the functional ability of your upper limb.



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These tests will take place either at Neuroscience Research Australia or your place of residence and include;

Description:

- **Visual acuity (near vision):** We will test the clarity of your vision using an eye chart with high contrast letters.
- **Joint position sense:** We will measure your ability to match the angles of your elbow and wrist with a simple joint matching task.
- **Skin sensation:** We will measure your ability to detect a small thin filament applied to your hand.
- **Two-point discrimination:** To measure your ability to detect two points on your finger, we will ask you to move your index finger along a set of strings on a Perspex plate.
- **Muscle strength:** *Elbow strength* – To test the strength of your arm we will ask you to make a voluntary contraction of your elbow. *Hand grip strength* – Your hand grip strength will be measured as you grasp a hand held dynamometer as strongly as possible.
- **Hand dexterity:** This will be measured with the 9-hole peg board test. You will be asked to place pegs as quickly as possible into a series of holes.
- **Upperlimb dexterity:** We will test your ability to negotiate/track a convoluted 3D path with a hand-held wand.
- **Finger Tapping:** We will measure how fast you can tap your index finger over a period of 10s.
- **Reaction time:** We will measure your reaction time by recording how quickly you are able to respond to a light with a finger tap.
- **Arm stability:** We will ask you to hold your arm out in front of you as you hold a light weight. We will measure its movement with a camera.
- **One-hand co-ordination:** You will be asked to toss a bean bag to a target 3 meters away as accurately as possible.
- **Two-hand co-ordination:** This will be measured as the time taken to complete a simple nut-and-bolt task that requires the use of both hands.
- **Overall upper-limb function:** This will be tested simply by timing how quickly you can put on and take off a standard buttoned overshirt.

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Risk: There is a rare risk of muscle soreness following the strength tests but these symptoms normally resolve within 2-3 days. For all other tests, aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

You will not be pushed beyond your limit and you can stop the study at any time. You will be encouraged to take as many rest breaks as necessary and can stop testing at any time.

You will be asked to complete several paper based questionnaires, which will ask you questions about your general health and upper limb function. We expect this activity to take up to 5-10 minutes.

Visit #	Procedures	Location*	Visit Length
Visit 1	<ul style="list-style-type: none"> • Questionnaires • Upper limb functional testing 	Neuroscience Research Australia	~45mins

Will I be paid to participate in this project?

You will be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research study. Please provide receipts for travel expenses and a cash reimbursement will be provided during of after your visit.

What are the possible benefits to participation?

We hope to use information we get from this research study to better understand motor impairments associated with stroke.

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. We will keep your data for 15 years. We will store **all** information about you at Neuroscience Research Australia. Your information will only be used for the purpose of this research study and it will only be disclosed with your permission.

Photographed digital recordings of your hand movements are for the purposes of the research. We will measure and keep your photographic files for 15 years. Your confidentiality will be ensured by using deidentified files which include only your hand movements.

It is anticipated that the results of this research study will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be published, in a way such that you will not be individually identifiable.

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. You can do this by contacting a member of the research team.



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

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback using the tick box below. This feedback will be in the form of a lay summary of the results. You will receive this after the study is finished.

- I wish to receive a copy of the lay summary of results / scientific publication.

We may invite you to participate in a **future follow-up study** of your upper limb function in 5 years. Please indicate below if you give Neuroscience Research Australia permission to contact you for this purpose.

- I give my permission for Neuroscience Research Australia to contact me for this purpose.

We may invite you to participate in **other** future studies. Please indicate below if you give Neuroscience Research Australia permission to contact you for this purpose.

- I give my permission for Neuroscience Research Australia to contact me in the future to ask if I would like to participate in future studies.

What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw at any time. If you do withdraw, you will be asked to complete and sign the 'Withdrawal of Consent Form' which is provided at the end of this document. Alternatively you can ring the research team and tell them you no longer want to participate.

If you decide to leave the research study, the researchers will not collect additional information from you.

Submitting your completed questionnaire is an indication of your consent to participate in the study. You can withdraw your responses if you change your mind about having them included in the study, up to the point that we have analysed and published the results.

You are free to stop upper limb tests at any time. Unless you say that you want us to keep the results, any data will be erased and the information you have provided will not be included in the study results. You may also refuse to perform any tests that you do not wish to undertake.

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 want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the following member/s of the research team:



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Research Team Contact

Name	Lewis Ingram
Position	PhD candidate
Telephone	0434 825 572
Email	l.ingram@neura.edu.au

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

If you have any complaints about any aspect of the project, the way it is being conducted, then you may contact:

Complaints Contact

Position	Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	HC 15607

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Consent Form – Participant providing own consent

Declaration by the 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, study tasks 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 study as described and understand that I am free to withdraw at any time during the project 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;

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 Participant (please print)	
Signature of Research Participant	
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 the research proposal described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales, or Neuroscience Research Australia.

Participant Signature

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

The section for Withdrawal of Participation should be forwarded to:

CI Name:	Professor Simon Gandevia
Email:	s.gandevia@neura.edu.au
Phone:	93991616
Postal Address:	Barker St, Randwick NSW 2031