HUNTER STROKE RESEARCH UNIT
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Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

John Hunter Hospital

Title	A Phase III, Multicentre, Prospective, Randomised, Placebo-controlled, Double-blind, Parallel group, with an Adaptive Sample size re-estimation Study in Stroke Survivors
Short Title	Modafinil In Debilitating Fatigue After Stroke 2 (MIDAS 2)
Protocol Number	NTA1703
Project Sponsor	Neuroscience Trials Australia
Principal Investigator	Prof. Neil Spratt
Associate Investigator(s)	Dr Carlos Garcia Esperon
Location	John Hunter Hospital

1 Introduction

You are invited to take part in this research project. This is because you have had a stroke three (3) or more months ago. The research project is testing to see if taking a medication modafinil will reduce post stroke fatigue and improve quality of life of patients.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments 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, friend or your local doctor.

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 you take part or not.

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 treatments that are 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.

2 What is the purpose of this research?

Modafinil is approved in Australia for the improvement of wakefulness in people with excessive daytime sleepiness associated with the medical conditions such as narcolepsy or with Obstructive Sleep Apnoea/Hypopnoea Syndrome (OSAHS) or shift work sleep disorder (SWSD). It is not approved to treat stroke related fatigue and is therefore an experimental treatment for the purposes of this research. This means that it must be tested to see if it is an effective treatment.

This research has been initiated by Dr Andrew Bivard and Professor Christopher Levi affiliated with University of Melbourne and University of Newcastle. They will be working with the doctors at your hospital during the period of the study.

The most common post-stroke symptom is 'fatigue', affecting up to 70% of stroke survivors. Fatigue has been defined as '*a feeling of early exhaustion with weariness, lack of energy and aversion to effort that develops during physical or mental activity and is usually not improved by rest*'. Stroke related fatigue has been shown to be a predictor of needing help in activities of daily living, and is also associated with poor quality of life, inability to return to work, and increased mortality within the first year of stroke. Most importantly, there are currently no therapies available for stroke survivors to help manage their fatigue.

A previous study tested modafinil in stroke survivors with severe persisting fatigue and found that 6 weeks of modafinil treatment reduced fatigue and improved the quality of life for the participants. The aim of this study is to confirm the previous study results, by testing if 200mg of modafinil taken daily for 56 days can alleviate stroke related fatigue and if modafinil is safe in a large population of stroke survivors. Additionally, the study also aims to perform a short assessment of the participant's caregiver/carer to identify if modafinil treatment taken by the participant reduces the carer burden on the caregiver. Thus, the study seeks to consent your caregiver for their participation if permission to do is obtained from you. You can remain a participant on the study regardless of their willingness to participate. If you do not wish for your caregiver to take part in the study, please inform your study team.

3 What does participation in this research involve?

You will be participating in a double-blind study. This means that neither you nor your study doctor will know which treatment you are receiving. However, in certain circumstances such as a medical emergency, your study doctor can find out which treatment you are receiving. You may be randomly allocated (like tossing a coin) into one of the two treatment groups:

- Modafinil Group (200 mg daily)
- Placebo Group

You will have a 1 in 2 or a 50% chance of being allocated to the modafinil treatment group. If you are not allocated to Modafinil group, you will receive the placebo medication. A placebo is an identical looking tablet with no active ingredients. It has no medicinal benefit. The use of a placebo allows the researchers to determine whether there are any real benefits from Modafinil in a fair and appropriate way.

Participation in the study will last a total of up to 56 days. Participation may be extended to a total of 12 months if you choose to also be included in the optional sub studies as described later in this Participant Information Sheet/form.

If you choose to participate in the study, you will be asked to attend the hospital on four occasions. These visits include:

- Initial Visit – to determine whether the study is suitable for you
- First Study Visit (Day 0)
- Second Study Visit (Day 28 (+/- 4 days)
- Third Study Visit Day 56 (+/- 4 days)

If you and your caregiver have consented to their participation on the study, your caregiver will accompany you at each of these visits and will be asked carer-related questions to measure their carer burden/strain.

Screening Visit
The screening visit is used to determine if this study is suitable for you. You will undergo the following assessments and the visit will approximately take 1-2 hours:

- *Informed Consent*- this ensures that you understand what will be required of you during and after the study. Your doctor will provide information about the study and answer any questions you have

- *Inclusion/Exclusion Criteria*- This ensures that this study is suitable for you

- *Medical History*- your doctor will ask you about your stroke, any other medical conditions you have and any medications you are taking.

- *Urine Pregnancy Dipstick Test (only applicable for female participants of child-bearing potential)*- this will be used to determine if you are pregnant. Women who are pregnant or planning to become pregnant cannot participate in this study because it is not known what the effect of the drug may have on a developing foetus.

- You will be asked questions about how you are managing with everyday activities, how you are feeling about your health, your fatigue level, your stroke symptoms and if you have any depression, anxiety or feel stressed.

First study visit (Day 0)
If after the screening visit it has been determined that this study is suitable for you and you wish to continue, you will be assigned to either of the study treatment groups - Modafinil (200mg daily) or Placebo Group. There is a 50% chance that you will be placed in either group.

Once you are assigned to a group, the following will be asked:
- Questions about how you are managing with everyday activities, how you are feeling about your health, fatigue, stroke symptoms and if you have any depression, anxiety or stress.
- Copies of any scans performed to assess your stroke at the time of the event will be collected by the study team at this time.
- A list the medications you are currently taking. This includes any over the counter (OTC) or prescription medications, vitamins or herbal supplements.

At this visit you will be provided with bottle(s) of modafinil or placebo, according to your allocation.

Treatment Schedule
You will take one tablet once a day orally (by mouth) with water. **Modafinil is ideally taken with breakfast** and at the same time each day for 56 days. You will be asked to return your pill bottle(s) at each visit. The study team will count the pills to record that you are taking your study medication appropriately.

Second and third study visits (Day 28 and Day 56)
For these visits your study doctor will review your data and perform some tests to determine whether it is safe for you to continue in the study. These visits will take approximately 1-2 hours.

Your study doctor or study staff will ask:
- How you are feeling?
- Whether you have been in hospital or have been seriously ill.
- Whether you are taking any new medications since your last visit. This includes any OTC or prescription medications, vitamins, or herbal supplements.
- Questions about how you are managing with everyday activities, how you are feeling about your health, fatigue, stroke symptoms and if you have any depression, anxiety or stress.

Optional Sub studies

You can also choose to take part in any of the three optional sub-studies (listed below) or **choose to not take part in any of these**. The optional sub-studies are listed below:

- Sub study 1 – Follow up 12 months after enrolment
- Sub study 2 – Physical Activity Monitoring
- Sub-study 3 – Cognitive (mental/psychological function) assessment

Sub study 1 – Follow up 12 months after enrolment

This sub study will assess the ongoing safety and tolerability of modafinil. The sub study will be open-label. This means that both you and your study doctor will know that you are now taking the study drug Modafinil. You will be given the option to participate in this sub study after your day 56 visit. If you opt in, you will receive a 10-month supply of modafinil (200mg daily) to take once daily for 10 months.

The study staff will contact you 1 month and 3 months into this sub study to check how you are feeling and if you are taking your study treatment every day. Once the 10 months is finished you will return to the hospital to be asked questions about how you are managing with everyday activities, how you are feeling about your health, fatigue, stroke symptoms and if you have any depression, anxiety or stress.

You will be asked to return your pill bottle(s) to this visit. The study team will count the pills to be record that you were taking your study medication appropriately.

Sub study 2 – physical activity monitoring

This sub study will be measuring the amount of physical activity you complete over a 7-day period. If you choose to participate in this study, you will be given fitness tracking device to wear on either your wrist or ankle for 7 days. You will need to keep this on at all times. This will measure how many steps you take each day and how many hours you sleep over the 7-day period. The data will be used to see if there are any changes associated with these activities and modafinil use. While every effort is made to ensure that these devices are comfortable, some skin irritation may occur such as a rash or severe irritation. If there is any irritation or the device is uncomfortable, please discuss this with the study staff. The data stored on these devices will be accessible by you, however you will need to return the device to the study staff. The study team will discuss the most feasible option for delivery and return of the device with you.

Sub study 3 – Additional cognitive (mental/psychological function) assessments

This sub study will assess if you have experienced any mental or psychological change while you have been on the study. If you choose to participate in this sub study, you will be asked to complete a suite of cognitive assessments at each visit you attend at the clinic. This will be done together with the other assigned tests for that visit. This cognitive assessment will be completed on an iPad. This will take an additional 1-2 hours on top of the standard visit time.

There are no additional costs associated with participating in this research project or any of its sub studies, nor will you be paid. All medication, tests and medical 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 visit.

If you decide to participate in this research project, the study doctor will inform your local doctor.

4 What do I have to do?

If you decide to take part in this study, you will be asked to follow the study doctor's instructions to help ensure your safety. To be in this study, you must agree to:

- Follow directions from the study staff.
- Make and keep study appointments.
- Take your study drug(s) as instructed. Participants are advised to take the study drug in the morning with breakfast. If you are unable/forget to take the study drug in the morning, do not take the study drug for that day as it may upset your sleep cycle
- Tell the study staff about all the medicines you take during the study.
- Tell the study staff about any changes to your health during the study.
- Not be part of any other interventional research study while participating in this study.
- Not allow anyone else to use your study drugs.
- Return all empty study drug bottles and all study drug that you do not use to each visit.
- Advise the study staff if you are become pregnant. Sexually active women of child-bearing potential should be established on a contraceptive program before taking modafinil. The effectiveness of hormonal contraceptives (including the contraceptive pill, implants, intrauterine devices (IUDs) and patches) may be affected when on Modafinil. Participants are recommended to use alternative or concomitant methods of contraception which include levonorgestrel-releasing intrauterine system (LNG-IUS), depot medroxyprogesterone and use of additional barrier methods of contraception. You should discuss methods of effective contraception with your study doctor.

5 Other relevant information about the research project

This study will include a minimum of 300 participants over approximately 12 study centres across Australia and may include other countries globally.

6 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 routine treatment, your relationship with those treating you or your relationship with John Hunter Hospital.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive any medical care you may require. There are currently no proven or validated therapies available for stroke survivors to help manage fatigue. You will be otherwise treated in the routine manner for stroke care if modafinil is not appropriate for you and/or you choose not to participate. You can also discuss your options with your study doctor and/or your local doctor before you decide whether to take part in this research project.

8 What are the possible benefits of taking part?

There will be no clear or definite benefit to you from your participation in this research. However, you will be contributing to the research efforts to discover treatments that work for stroke related fatigue.

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

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

Modafinil has been evaluated for safety in over 3500 patients, of whom more than 2000 patients with excessive sleepiness associated with primary disorders of sleep and wakefulness were given at least one dose of modafinil. In clinical trials, modafinil has been found to be generally well tolerated and most adverse experiences were mild to moderate.

In clinical trials involving patients with narcolepsy, obstructive sleep apnoea, and shift-work sleep disorder, modafinil is generally reported to be well-tolerated. The most common adverse effect reported is headache, occurring in approximately one in six patients. Headaches were severe enough to require discontinuation of the drug in approximately 1% of patients. Nausea, dizziness, and insomnia are also reported, occurring in approximately 1 in 20 patients. Anxiety can be presented in up to 1 in 20 patients as well and requires medication cessation. Lastly severe rash can occur in less than 0.1% of patients, however this event requires urgent medical attention.

Adverse effects – Adapted from the Australian Medicines Handbook
Common, >1%
Nausea, Diarrhoea, anorexia, dry mouth, headache, anxiety, nervousness, depression, hypertension (high blood pressure), tachycardia (increased heartbeat) and palpitations.

Rare, <0.1%
Allergic reactions, multi-organ hypersensitivity syndrome, psychosis, hallucinations, aggression, mania, suicidal ideations, dyskinesia (abnormal, uncontrolled, involuntary movement), tremor, ischemic heart disease and atrial fibrillation (rapid and irregular heartbeat).

The effects of modafinil on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project. If you are male, you should not father a child or donate sperm for at least two months after the last dose of study medication.

Both male and female participants are strongly advised to use effective contraception during the course of the research and for a period of two months after completion of the research project. Modafinil may reduce the effectiveness of oral contraceptives. Participants are recommended to use alternative or concomitant methods of contraception. You should discuss methods of effective contraception with your study doctor.

For female participants: If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

For male participants: You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary.

If you become upset or distressed as a result of your participation in the research, the study doctor 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.

10 What will happen to my test samples?

If you are female and of child-bearing potential, a urine sample will be collected to screen for pregnancy (to confirm whether you are pregnant or not). This test will be performed by your study staff and upon analysis, your sample will be destroyed as per the standard hospital procedures.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff 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 by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 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:

- Unacceptable side effects
- The drug/treatment being shown not to be effective
- The drug/treatment being shown to work and not need further testing
- Decisions made by investigators or local regulatory/health authorities

15 What happens when the research project ends?

Medical follow-up through the outpatient clinic and general practitioner will continue as appropriate. Once the study is complete and the final study report is released, your study doctor will be able to supply you with the study results. These can be made available to you upon request. To obtain this please contact the study staff listed in Section 20.

16 What will happen to information about me?

By signing the consent form, you consent to the study doctor and relevant research 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 and securely stored. Your collected information will be labelled with a unique study code only, not your name or hospital number. 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.

All study documentation will be maintained in a secure area which is only accessible to authorised staff. This information will be stored for a period of 15 years and then disposed of according to the John Hunter Hospital policy for disposal of confidential data.

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) by the relevant authorities and authorised representatives of the Florey Institute of Neuroscience and Mental Health, the institution relevant to this Participant Information Sheet, John Hunter Hospital , the John Hunter New England Human Research Ethics Committee or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.
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, except with your permission. Individual patient data will not be shown.

Information about your participation in this research project may be recorded in your health records. It is desirable that your local doctor be advised of your decision to participate in this research project. By signing the consent section, you agree to your local doctor being notified of your decision to participate in this research project.

In accordance with relevant Australian and New South Wales privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team, however the study treatment may need to remain unknown until the study data analysis is completed. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

17 Compensation

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.

18 Who is organising and funding the research?

This study is sponsored in Australia by The Florey Institute of Neuroscience and Mental Health (The Florey) and supported by philanthropic funding allocated to this project by the Greater Building Society under the auspices of the Hunter Medical Research Institute. The Investigators are in the process of applying for grant(s) from Australian government research organisation(s).

John Hunter Hospital will receive a payment for undertaking 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).

19 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 Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference – *18/03/21/3.03*

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.

20 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 principal study doctor on 02 49 213490 or any of the following people:

Clinical contact person

Name	*Linda Belevski*
Position	*Stroke Research Nurse*
Telephone	*(02) 49 223187*
Email	*Linda.belevski@hnehealth.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

Name	*Dr Nicole Gerrand*
Position	*Manager, Research Ethics & Governance Office*
Telephone	*(02) 49214950*
Email	*HNELHD-hrec@hnehealth.nsw.gov.au*

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	*Hunter New England Human Research Ethics Committee*
HREC Executive Officer	*Dr Nicole Gerrand*
Telephone	*(02) 49214950*
Email	*HNELHD-hrec@hnehealth.nsw.gov.au*
Reference Number	*18/03/21/3.03*

Local HREC Office contact (Single Site -Research Governance Officer)

Name	*Dr Nicole Gerrand*
Position	*Manager, Research Ethics & Governance Office*
Telephone	*(02) 49214950*
Email	*HNELHD-hrec@hnehealth.nsw.gov.au*

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Consent Form - *Adult providing own consent*

Title	A Phase III, Multicentre, Prospective, Randomised, Placebo-controlled, Double-blind, Parallel group, with an Adaptive Sample size re-estimation Study in Stroke Survivors
Short Title	Modafinil In Debilitating Fatigue After Stroke 2 (MIDAS 2)
Protocol Number	NTA1703
Project Sponsor	Neuroscience Trials Australia
Principal Investigator	Prof. Neil Spratt
Associate Investigator(s)	Dr Carlos Garcia Esperon
Location	John Hunter Hospital

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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to John Hunter Hospital concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 study without affecting my future health care.

I understand that my follow-up stroke imaging data (e.g. CT or MRI) will be requested and uploaded to the study database for the purposes of this research. Any information obtained in that can identify me will remain confidential and will only be used for this research project. The collected information will be labelled with a unique study code only and not identify me by name or hospital number.

I understand that modafinil is best taken in the morning, and if taken after noon can result in substantial sleep disturbance that night.

Participation in the optional sub studies:

I have been informed of the sub studies and I freely agree to participate as indicated below:

Sub study 1 – Follow up 12 months after enrolment	☐ Yes or ☐ No
Sub study 2 – Physical Activity Monitoring	☐ Yes or ☐ No
Sub-study 3 – Cognitive assessment	☐ Yes or ☐ No

I understand that my caregiver can take part in this research if I approve, and should they wish to consent to participation in the research. If they choose to participate in this research, they will be provided a separate carer information sheet/consent form and they will also accompany me for all study visits.

☐ I do consent to my caregiver being approached regarding participation, and their name is _____ (*please insert caregiver name*)

☐ I do not consent to my caregiver being approached regarding participation

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

Name of Participant (please print) _____

Signature _____ Date _____

Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9*) a witness* to informed consent is required.*

Name of Witness* to
Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. 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.

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

Title	A Phase III, Multicentre, Prospective, Randomised, Placebo-controlled, Double-blind, Parallel group, with an Adaptive Sample size re-estimation Study in Stroke Survivors
Short Title	Modafinil In Debilitating Fatigue After Stroke 2 (MIDAS 2)
Protocol Number	NTA1703
Project Sponsor	Neuroscience Trials Australia
Principal Investigator	Prof. Neil Spratt
Associate Investigator(s)	Dr Carlos Garcia Esperon
Location	John Hunter Hospital

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.*

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

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.