

**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

Royal North Shore Hospital

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| **Title** | STimulating 3 Adrenergic Receptors to improve clinical outcomes in patients with Peripheral Arterial Disease. |
| **Short Title** | *STAR PAD trial* |
|  |  |
| **Project Sponsor** | *Northern Sydney Local Health District* |
| **Coordinating Principal Investigator** | *Professor Gemma Figtree* |
| **Principal Investigator at site** | Professor Gemma Figtree |
| **Location** | Royal North Shore Hospital |

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

**1 Introduction**

You are invited to take part in this research project. This is because you have *Peripheral Arterial Disease (PAD)*. The research project is testing a new treatment for *PAD*. The new treatment is called *Mirabegron*.

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 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 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?**

The purpose of this study is to investigate whether treatment with Mirabegron will improve the symptoms of patients with peripheral arterial disease (PAD). Mirabegron is currently approved for use in a different condition, overactive bladder, both in Australia and overseas, but is not approved for use for PAD in any country. We now aim to test if this drug is effective in improving leg blood flow and reducing symptoms in human patients with PAD.

Mirabegron is a drug that causes stimulation of a specific type of protein that are located on the surface of cells. These proteins are called beta 3 adrenergic receptors.. Stimulation of these receptors activates a series of other biological events that ultimetely result in positive effects on blood vessels, and greater blood flow. Because PAD is generally caused by poor blood flow, Mirabegron is a highly relevant potential therapy for that disease. We have experimentally tested its use on mice with reduced blood flow in their legs and saw an improvement compared to untreated mice. As this drug has a good safety profile in humans, it could be indicated for use in PAD relatively quickly if proven to benefit patients.

As part of the project, we will collect and store your blood and the cells extracted from your blood, along with the data from your physical assessments and some of your medical information, to use for this project and potentially for research in the future if new techniques become available. The main reason for storing your blood and data long term is to allow for further testing in the future as technology improves and allows new information to be obtained from the samples. This may be a long way down the track when we have started new projects that are related to this one and have new ideas to trial, or if our colleagues at different research facilities have exciting ideas for treating PAD that can benefit from applying their tests to the samples that we have collected. The sharing of datasets between research groups is an excellent way to get new information about the disease without having to spend an enormous amount of time and effort finding new patients. When consenting to take part in this study you will be giving consent for the storage and use of your blood samples for this specific research project, other research projects that are closely related to this project and any future research. If you do not consent to having your samples stored, you cannot take part in this study.

This research has been initiated by the study doctor, Dr/Professor *Gemma Figtree* and is sponsored by the Northern Sydney, Sydney and Western Sydney Local Health Districts. It will involve patients from Royal North Shore Hospital, North Shore Private Hospital, Royal Prince Alfred Hospital and Westmead Hospital. These hospitals and Local Health Districts are part of a group called Sydney Health Partners, which is one of four Advanced Health Research and Translation Centres in Australia, recognised by the National Health and Medical Research Council in 2015 for being a world leader in translating research into better health outcomes for our community.

This research has been funded by several funding bodies, including a grant from the Heart Foundation of Australia. We are also currently seeking funding from the National Health and Medical Research Council and the New South Wales Department of Health.

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

Participation in this study involves 8 clinic visits over 13 weeks. Participation in the study involves collection of blood, participation in a treadmill test, blood pressure cuffs on the arms and legs to measure blood pressure and the ability of blood vessels to relax, MRI scanning of blood flow in the legs, as well completion of several questionnaires. The type and amount of blood collected will depend on the tests and other procedures that you are having. What you can expect from each visit is detailed below:

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| **Visit** | **Why?** | **What will happen?** | **How long will it take?** |
| 1 | This is the screening visit | We will begin to assess your eligibility for the trial. Before we begin assessment we must receive your written consent to be a participant. After obtaining consent we will take up to 50 ml of blood (about 3 tablespoons) using a cannula in your vein to check for any signs of renal or liver functional impairment or oxidative stress. You will undergo a standard physical examination, where we will collect data about your height, weight and medical history. You will fill out a walking impairment questionnaire so that we can determine how PAD is affecting your lifestyle. We will also need to perform a validated treadmill test to quantify your ability to walk before and after the drug treatment. This will involve walking on a treadmill at 3.2 km/hr speed with the gradient increasing from 0% by 2% every 2 min until you can no longer continue. | This visit will take approximately 2-3 hours |
| 2 | To confirm you meet the study criteria | You will repeat the treadmill test. Once you have finished the test, we will inform you of whether you meet the eligibility requirements. If so, we will collect baseline data including the following: ankle-brachial index measurements, using blood pressure cuffs on your limbs while you rest for 10 min; a blood sample for baseline measurements of various biomarkers and molecules that are relevant to this study and a quality of life questionnaire. | This visit will take approximately 2 hours |
| 3 | To have an MRI | You will be referred to North Shore Radiology within 2 weeks of visit 2 for magnetic resonance imaging (MRI) of your lower limbs. This involves your lower body going inside the MRI machine, where your legs will be scanned. The imaging technique may require contrast agent to be injected for better quality images. If this is the case this will be injected in your forearm vein. | This will take approximately 1 hour |
| 4 | Additional measurements and receive prescription | You will be asked to return to the clinic on another morning, within 2 weeks of visit 2, after 8 hours of fasting, to undergo brachial artery reactivity measurements. This test involves assessing the reactivity of the blood vessels in your forearm, after inflation and slow release of a pressure cuff on your arm. This allows us to determine how well your blood vessels relax under standardised conditions and gives information about the health of your blood vessels. At this appointment, you will also receive your prescription of either placebo or Mirabegron tablets. A placebo is a medication with no active ingredients or a procedure without any medical benefit. It looks like the real thing but is not. This is a double-blinded study and so neither the investigator nor yourself will know whether you are taking placebo or Mirabegron until the study has been completed and finalised by all participants. After this visit you will need to continue taking 1 tablet per day until the study is complete after 12 weeks | This visit will take approximately 1 hour |
| 5 | 4 week follow-up appointment | After 4 weeks of taking the drug you will return to the clinic for follow-up assessment. This will involve a similar physical examination and blood tests as before and you will have the opportunity to report any adverse effects of the drugs you have been taking. | This visit will take approximately 1 hour |
| 6 | 12 week follow-up appointment | After 12 weeks of taking the drug you will undergo all of the tests that you did during the baseline and screening visits. i.e. treadmill test, ankle-brachial index, walking impairment questionnaire, quality of life questionnaire, physical examination and adverse event reporting. | This will take approximately 2-3 hours |
| 7 | Subsequent MRI | You will also be referred for a subsequent MRI, to be completed within one week either side of your visit 6 appointment. | This will take approximately 1 hour. |
| 8 | Additional test and stop medication | You will be asked to return for brachial artery reactivity testing within one week of your previous visit, following an 8 hour fasting period. Once you have completed this visit, you can stop taking the tablets and return all un-used tablets. | This visit will take approximately 1 hour |

Post-study follow-up: The research team will be available to answer any questions you have either during or following the end of your protocol. A follow-up phone call to assess any adverse outcomes following cessation of the drug will occur within 3 months. Your involvement will be part of a large, multi-centre study and results of the study will not be available immediately after you complete the protocol.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are

no additional costs associated with participating in this research project, 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.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

**4 What do I have to do?**

You do not have to do anything specific to take part in the study. Taking part in this study is in addition to your standard treatment and will not affect your normal health care in any way. At this first visit, your study doctor or study staff will ask you about any medication that you are taking. It is very important to tell them about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments so that the study doctor can assess your eligibility to participate. Certain medications are excluded from use at the same time as taking Mirabegron and, for your safety, we need to know if you are taking any of them before determining if you are eligible. It is important that you continue to take all medications prescribed by your doctor and follow their instructions during this study. It is also important not to start taking any new medications during the study without talking to your doctor and research staff. If you start taking any new medications in the time between your procedure and any of the times you complete the follow-up questionnaire, please let the research team member know.

In addition, if you go to a different hospital for care of your peripheral arterial disease while you are involved in the study, please let the study doctors know so that they can collect information about your care and disease from that hospital.

The only restriction in the study will immediately pre-cede visit 4 and visit 8, where you will be asked to fast for 8 hours prior to undergoing brachial artery reactivity testing.

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

It is expected that this study will involve about 100 people over at least 3 years. We hope to continue the study for longer than 3 years, and in future it may also involve people from other hospitals around the world.

**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.

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 any of the hospitals involved in the study.

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include the standard treatment for this disease, including lifestyle modification and surgical intervention, if required. Your study doctor 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.

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

There will be no clear benefit to you from your participation in this research. We hope, however, that this research will provide valuable information to improve the treatment and care of people with peripheral arterial disease in the future.

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

The risks of harm from this study are low and are separated into categories (see below).

**Blood sample collection:**

There are minor risks associated with blood sample collection by venepuncture which include:

* Minor discomfort at the site of the puncture,
* Mild bruising or swelling at the site of the puncture,
* A slight risk of infection.

If you are concerned about this, please discuss with study staff before the sample collection.

In all cases, only a relatively small sample of blood will be collected.

**Treadmill tests:**

You may feel some physical discomfort due to the symptoms of your PAD. As part of this test you will be instructed to continue to exercise until you can no longer tolerate the pain, and it is entirely up to you to choose when to stop the treadmill.

**Ankle-brachial index and brachial artery reactivity:**

You will feel some discomfort from the inflated cuff, but this will be short-lived and not severe. At the end of brachial artery reactivity testing, you will be given a spray of medicine under your tongue that dilates your blood vessels. This medicine may cause a headache, but if this happens it will usually last for less than 10-15 minutes. You will not be able to participate in this test if you have either of the following: hypotension (systolic blood pressure <100mmHg) or Phosphodiesterase inhibitor (eg. Viagra, Levitra) medication administration in the previous 24hrs.

**MRI:**

MRI images are made without using any radiation, so patients are not exposed to the harmful effects of radiation. But while there are no known health hazards from temporary exposure to the MRI environment, the MRI environment involves a strong magnetic field which carries specific safety concerns:

* Care will be taken to avoid you taking any metallic objects into the scanner. The strong magnetic field will attract magnetic objects (i.e. small items such as keys and mobile phones), and may cause injury to the patient.
* Ear protection will be provided as the magnetic fields that change with time create loud knocking noises which may harm hearing if adequate ear protection is not used.
* The use of contrast agents also carries some risk, including side effects such as allergic reactions to the contrast agent.
* Some patients find the inside of the MRI scanner to be uncomfortably small and may experience claustrophobia. You should discuss with trial staff if you are worried about this as options may be available to make the experience easier for you.

**Effects from taking medication:**

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.

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| **Potential serious side effects** | **How often is it likely to occur** | **Advice** |
| Irregular heart beat | Uncommon – may affect 1/100 people | Medication should be ceased immediately |
| Sudden, migraine-like throbbing headaches | Rare – undetermined incidence | Tell your doctor; it could be a sign of elevated blood pressure |
| **Other side effects: inform your doctor or trial staff** | | |
| **Common side effects May affect 1/10 people** | **Uncommon side effects**  **May affect 1/100 people** | **Rare side effects**  **May affect 1:1000 people** |
| Increased heart rate (tachycardia) | Bladder infection | Swelling of the eyelids |
| Infection of the structures that carry urine (urinary tract infections) | Feeling your heartbeat (palpitations) | Swelling of the lip |
| Nausea | Vaginal infection | Swelling of the deeper layers of the skin caused by a build-up of fluid, which can affect any part of the body including the face, tongue or throat and may cause difficulty in breathing (angioedema) |
| Constipation | Indigestion | Small purple spots on skin |
| Headache | Infection of the stomach (gastritis) | Inflammation of small blood vessels, mainly affecting skin |
| Diarrhoea | Swelling of the joints | Inability to completely empty the bladder (urinary retention) |
| Dizziness | Itching of the vulva or vagina |  |
|  | Increased blood pressure | **Very rare side effects -affects less than 1/10,000 people** |
|  | Increase in liver enzymes | Hypertensive crisis |
|  | Itching, rash or hives |  |

If an underlying condition is uncovered by this research, you will have a choice as to whether or not you wish to be informed now or in the future of results that might be of significance to your health. If you decide that you do wish to be informed of possibly important findings in the future, you can indicate this on the consent page at the end of this information sheet. In the event that we do discover results in the future that may be significant, we will confirm with you at the time whether or not you still wish to have these results returned to you. We will also, with your permission, provide these results to your GP.

The effects of Mirabegron 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.

For female participants:if you are a woman of child bearing age, you must be using 2 acceptable methods of birth control. These include IUDs; injectable, implantable or oral contraceptives, double barrier (ie combination of spermicide and condom), history of vasectomy, or abstinence. If you are trying to become pregnant or stop using contraception you should advise your study doctor immediately.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.

**10 What will happen to my test samples?**

After collection, your samples will be transferred to a secure laboratory located in the Kolling Building (at Royal North Shore Hospital) in the RNSH Cardiology Department’s research offices, and stored. Access to both the building and the laboratory is controlled, and only authorised members of the research team may access your samples.

Your samples and all data will be labelled with a study code, rather than any information that can directly identify you. This means that they will be ‘re-identifiable’. The master list that links your study code to your identity is stored on a secure networked computer that is separate from both the study samples and the study data. It is important that we are able to link your samples back to your identity so that we can add the clinical information from your 12-week follow-up, and in case we ever need to verify or double-check the clinical information that goes with your sample.

If your samples/data are ever sent off-site (for example, to our colleagues who may have access to specialised equipment, or who may be experts in one particular technique), they will be labelled with your study code only, and thus will not be identifiable as yours.

Your samples will be stored indefinitely. We would like to store your blood samples for use in any future research studies that may or may not be related to the original research project. In the future, other doctors and scientists at this and other medical and research centres may use your blood samples to learn about many different diseases and conditions. Their goal is to improve health outcomes and develop new treatments. If your samples are used in future, related or unrelated studies, the samples will remain in re-identifiable (coded) form. The master list that links your identity to your samples will never be released to any other researchers aside from those authorised in this study, therefore your identity will always be protected.

**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?**

At this first visit, your study doctor or study staff will ask you about any medication that you are taking. It is very important to tell them about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments so that the study doctor can assess your eligibility to participate. Certain medications are excluded from use at the same time as taking Mirabegron and, for your safety, we need to know if you are taking any of them before determining if you are eligible. It is important that you continue to take all medications prescribed by your doctor and follow their instructions during this study. It is also important not to start taking any new medications during the study without talking to your doctor and research staff. If you start taking any new medications in the time between your procedure and any of the times you complete the follow-up questionnaire, please let the research team member know.

**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 being shown not to be effective

• The drug being shown to work and not need further testing

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

At the end of the study, this drug will not be available to you anymore. You will continue to have available the standard treatment for this disease, including lifestyle modification and surgical intervention, if required. Your study doctor will discuss these options with you if you want to.

Results from the study will be analysed at the conclusion of the study, once all participants have finished the protocol. Once results are known, reports will be generated and results of the study will be provided to you, if you wish.

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

**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. Your samples and all data will be labelled with a study code, rather than any information that can directly identify you. This means that they will be ‘re-identifiable’. The master list that links your study code to your identity is stored on a secure networked computer that is separate from both the study samples and the study data*.* 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, except with your permission.

**17 Complaints and compensation**

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment. You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the drugs or procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

**18 Who is organising and funding the research?**

The study is being sponsored by several competitive grants awarded to Gemma Figtree and her colleagues to complete the study.

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 HREC of Northern Sydney Local Health District.

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 (study reference: RESP/18/27) 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 9926 4915 or any of the following people:

**Clinical contact person**

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| --- | --- |
| Name | *Gemma Figtree* |
| Position | *Professor/Cardiologist* |
| Telephone | 02 9926 4915 |
| Email | gemma.figtree@sydney.edu.au |

If you have any complaints about any aspect of the project (study reference: RESP/18/27), the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | *Northern Sydney Local Health District HREC* |
| HREC Executive Officer | *Research Ethics Manager* |
| Telephone | *02 9926 4590* |
| Email | *NSLHD-research@health.nsw.gov.au* |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Research Governance Officer at [LHD] authorising the conduct of this study at [site]**

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| --- | --- |
| Name | *Northern Sydney Local Health District HREC* |
| Position | Research Governance and Compliance Manager |
| Telephone | *02 9926 4590* |
| Email | *NSLHD-research@health.nsw.gov.au* |

**Thank you for taking the time to consider participating in this study. If you would like to take part, please sign the attached consent form.**

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

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | STimulating 3 Adrenergic Receptors to improve clinical outcomes in patients with Peripheral Arterial Disease |
| **Short Title** | STAR-PAD trial |
|  |  |
| **Project Sponsor** | Northern Sydney Local Health District |
| **Coordinating Principal Investigator** | Professor Gemma Figtree |
| **Principal Investigator at site** | Professor Gemma Figtree |
| **Location** | Royal North Shore 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 Royal North Shore Hospital, North Shore Private Hospital, Royal Prince Alfred Hospital or Westmead Hospitalconcerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

**Return of results**

In the event that information that may be of potential importance to my future health is discovered, I wish to be informed of the results (participant to tick box and initial):

**Yes**

**No**

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

I consent to the storage and use of blood and tissue 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

• Any future research.

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

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

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|  | 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*

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| --- | --- |
| **Title** | STimulating 3 Adrenergic Receptors to improve clinical outcomes in patients with Peripheral Arterial Disease |
| **Short Title** | STAR-PAD trial |
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| **Project Sponsor** | Northern Sydney Local Health District |
| **Coordinating Principal Investigator** | Professor Gemma Figtree |
| **Principal Investigator at site** | Professor Gemma Figtree |
| **Location** | Royal North Shore 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 [insert study site].

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|  | 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.*

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**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.

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|  | 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.