Participant Information Sheet/Consent Form
Interventional Study - *Adult providing own consent*

Title	The Effect of an Outpatient Exercise Training program on haemodynamics and cardiac magnetic resonance parameters of right ventricular function in patients with pulmonary arterial hypertension (PAH)
Short Title	Exercise Training in PAH
Protocol Number	HREC/14/SVH/340
Project Sponsor	St Vincent's Hospital, Sydney.
Coordinating Principal Investigator/ Principal Investigator	Associate Professor Eugene Kotlyar/Dr Karen Chia
Associate Investigator(s)	Associate Professor Steven Faux
Location *(where CPI/PI will recruit)*	*[insert site details]*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project because you have Pulmonary Arterial Hypertension (PAH). The research project is testing a new treatment for Pulmonary Arterial Hypertension. The new treatment is called outpatient Exercise Training.

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?

Pulmonary Arterial Hypertension (PAH) is a cause of breathlessness due to abnormal lung blood vessel changes, resulting in elevated blood pressure in the lung circulation. This may cause limitations in physical activity, reduced quality of life, right heart failure and death in people with PAH. Despite many recent advances in drug treatment, treatment options and prognosis of PAH remains poor. Only a few studies have looked at the effect of exercise in patients with PAH. However, these studies have found that exercise can improve breathlessness and quality of life.

Exercise is able to be done by most people and has few side effects. However, it is uncertain how often and how intense the exercise must be to benefit patients with PAH. This study looks at the effect of an outpatient exercise program on how the heart functions, using the latest technology (cardiac magnetic resonance imaging) and standard tests of blood flow through the heart on right heart catheterisation (the same test that was done to diagnose your Pulmonary hypertension). It also looks at how exercise affects your lungs, and examines the effect of exercise on patient endurance and quality of life. The results of this study will help guide doctors about how to best treat patients with PAH.

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, you will be put into a group by chance (random). You will have a one in two chance of being allocated to the exercise group or the usual care (non exercise) group.

After you have carefully considered your willingness to participate in the study and read the Consent Form, you will be asked approximately one week later to sign the Consent at the Screening visit, during which time the other tests will be arranged.

The Screening Visit
A doctor will perform a physical examination (listening to your heart and lungs, and looking for swelling of the feet). This visit (including waiting time) will usually take less than one hour. You will also have appointments booked for each of the following:
1) Right Heart Catheterisation to establish how your blood flows through the heart (also known as haemodynamics, including pulmonary artery pressures)
2) Cardiac MRI
3) Lung function tests
4) Blood Tests
These all require separate visits.
Please note that if your kidney function tests indicate that you have impaired kidney function (eGFR<60ml/min) then you will not be eligible to participate in the study. If you have not had a kidney function test in the past 3 months, you will have a kidney function test when you have your other blood tests. If your kidney function tests indicate impaired kidney function, then you will not be eligible to participate in the study.

The maximum number of visits possible is 15 visits. If you are in the Exercise group, you will have an additional 24 visits (as you attend for your Exercise classes twice weekly for 12 weeks).

You will be contacted by phone and/or letter to inform you of the appointment times.

Baseline Visit: with the Study Doctor
The Baseline Visit will occur between 1-4 weeks after the Screening Visit, by which time all results should be available to determine whether you are able to participate in the Trial. This visit should also take less than one hour. At that time the following will also occur:
Repeat Physical Examination;
Collecting Demographic (age, gender, ethnicity) information;
Vital signs – Blood pressure, pulse, respiratory rate, oxygen saturations, temperature and weight.

The baseline visit with a physiotherapist or Allied Health Worker (AHW)
This will occur either on the same day as your baseline visit with the study doctor, or at a time arranged by your physiotherapist/AHW. We have listed it as a separate visit.
You will do a walking test (six minute walk test) and simple muscle testing with the physiotherapist, and fill out questionnaires. This should take approximately one hour.
After this visit you will find out whether you are in the Control Group or the Exercise Group. You will have a one in two chance of being in the Exercise group. Your study doctors will purposely not know which group you are in, so that they can look at the results of the study objectively.

What will happen if I am in the Exercise group?
If you are randomized into the Exercise Group you will need to attend twice weekly exercise classes. You will be informed when these classes will occur. These will last for approximately one hour. You will need to be able to attend twice weekly for a period of 12 weeks. As per standard clinical practice, your physiotherapist will be keeping a record of the exercises that you are able to do during your exercise class, so that they can increase the intensity as you

improve. The total number of visits will be 39 (15 visits and 24 exercise class visits).

The Exercise Program will involve endurance training for your legs (walking and/or stationary cycling), respiratory muscle training, and may include some light weight training for your arms (starting at half to one kilogram weights, and increasing as you able). The physiotherapists will monitor the intensity of your program by how breathless you feel, and will adjust your program accordingly. You will be supervised by physiotherapists or exercise physiologists with a particular interest in Pulmonary Rehabilitation. After approximately week 3, your physiotherapist may give you a written home exercise program with a diary to keep a record of your exercise done at home.

The Exercise Program also involves some psychological training to teach you strategies to cope better with hyperventilation, any anxiety during breathlessness, as well as progressive muscle relaxation. Our study psychologist will telephone you at home to support you in coping with anxiety during breathlessness. They will undertake three 20 minute sessions with you (during the 12 week exercise study period). You will be given a workbook with information about your psychology training, as well as space to keep a record of your strategy practice.

If you require further psychological input, you may be referred for ongoing psychology assessment. If you require psychiatry input, you will be referred to a local psychiatrist. The criteria for referral to either psychologist or psychiatrist are 1) the study doctor's clinical judgement and 2) if you score in the "Severe" range for any of Depression, Anxiety or Stress on one of the questionnaires, the DASS-21.

What will happen if I am in the Control (Home exercise program) group?

If you are in the Control group, you will still attend all the visits. However, if you are in the Control group, you do not attend any of the Exercise classes. You will not have any Psychology intervention. Instead, you will be sent a letter explaining the benefits of exercise and suggestions for exercising at home. If you are in the Control group, your total number of visits will be 13.

Follow up for all participants

Approximately three months after your initial tests, you will need to visit again to see the study doctor. You will also need to visit to the physiotherapist/AHW to repeat the walking test, muscle testing and questionnaires. Each of these visits will take approximately one hour. You will have appointments booked for:

-repeat right heart catheterization
-repeat cardiac MRI
-repeat lung function tests
-repeat blood test

All these tests will require separate visits.

The reason for doing these tests again are to see if exercise had any benefit on participants who were allocated to the Exercise group, compared to the Control group. For the Control group, the main benefit of repeating these tests is to see if there has been any worsening of your condition.

Around this time, you will also be asked to complete one follow-up assessment via phone, with a member of the research team. This assessment will be a questionnaire and you will be asked a series of questions about exercise, your health condition, and your experience of participating

in the exercise program allocated to you in this study. You will answer the questions over the telephone while talking to the researcher, and this will take approximately 15-20 minutes in total. The research team will arrange a time that is convenient for you to be contacted via phone to complete this assessment.

What would stop me taking part?

During this study you will have cardiac magnetic resonance (CMR) scans to allow us to see how your heart and blood vessels are functioning in detail. These scans are painless but involve the use of a strong magnetic field, and a dye (called "contrast") that can affect people with kidney disease. If you have any of the following, you will not be suitable for a scan, and you will not be able to take part:

- a permanent pacemaker or implantable defibrillator
- metal clips in blood vessels of the brain
- an injury to the eye involving fragments of metal
- if you are pregnant, intending to become pregnant, or breastfeeding
- metal
- other metal or electronic implants affected by the magnetic field
- kidney disease

Should you have any queries regarding your eligibility to the study, please contact one of the study investigators. 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.

Costs and reimbursement:

There are no additional costs associated with participating in this research project, nor will you be paid. All 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 parking expenses associated with the research project visit on provision of a receipt. Reimbursement will be according to parking fee paid; maximum reimbursement will be $30 per participant for each visit. A parking ticket receipt must be presented.

Applies to Coffs Harbour based participants (delete for other sites): Your parking ticket will either be validated or reimbursement will be made according to parking fee (if any) paid; maximum reimbursement will be $5 per visit.

Who will tell my local doctor about this 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?

The participant should continue on all usual medications. If you are female, you must undertake not to become pregnant during the study, as this study does involve a small amount of ionising

radiation (Xrays). If your medications are changed, or you are hospitalised, it is important to let your study doctors know. There are no additional lifestyle or dietary restrictions.

What will happen to me if I take part?

You will need to attend the hospital/clinic to have the following tests:

Blood tests to measure:

a. your kidney function (if you haven't had a blood test for kidney function in the last two months). This is to check that your kidneys are functioning well and can process the contrast agents we use in some of the scans. If your test shows reduced kidney function, you will not be able to take part in this study.
b. how well your heart is functioning (called NT-proBNP).
c. Other tests that may be affected by PAH (IL-6)

*Cardiac Magnetic Resonance scans***:**

we will make measurements of your heart using a magnetic resonance scanner. The MRI scan takes approximately 60minutes, and measures the size, the blood circulation in your heart muscle and the heart tissue composition. For the MRI, you will lie comfortably on your back. We will insert a cannula (or "drip") into your arm to pass a contrast dye (called "gadolinium") into your bloodstream. This dye helps to make images of your heart and blood flow clearer and is routinely used in MRI. During the scan we will ask you to hold your breath for a few seconds. These scans are also noisy (we provide headphones to shield your ears) and you will have to lie still in a confined space (called the "bore" of the scanner, which is the central hole in the middle of the picture below) for up to 1 hour. However, we can remove you from the scanner at any time and you do not have to finish the scan if it is too uncomfortable.

Right heart catheterisation

You will be familiar with right heart catheterisation from having had the procedure previously to make your initial diagnosis of PAH. These right heart catheterisations are exactly the same. The catheter is inserted into the right side of your heart via a vein in your neck or groin. This study requires that you have a right heart catheterization conducted prior to the study to assess the current status of your blood flow, and again between Weeks 12 and 16. This procedure may be uncomfortable and does have some risks associated with it, but is standard procedure to confirm a diagnosis of pulmonary hypertension.

For Sydney based participants, there is an optional addition to the right heart catheterisation procedure that involves exercising (whilst lying flat) using a leg cycle during your right heart catheterisation. This will give us additional valuable information on how exercise affects the heart and lung, as it is more sensitive than usual right heart catheterisation. If you agree to the exercise right heart catheterisation, this is done at the same time as the usual catheterisation- it does not involve a separate visit. You will be asked to pedal at a certain rate (60 repetitions per minute); the resistance will be increased every 3 minutes if you are able to tolerate it, to a set maximum (40W).

Lung Function tests

These tests measure the function of the lungs and muscles that control breathing.
Most lung function tests involve only simple tasks like fast breathing. This may be tiring but is usually not uncomfortable.
You will be asked to breathe in deeply, and blow out as hard and as fast as you can into a tube that measures your breath. This test is usually repeated a few times, and takes 10-20 minutes.

How often would I have to come for the tests, and how long does it take?
For all participants, there are:
-four medical clinic visits with the study doctor
-three assessment visits with the physiotherapist/Allied Health Worker (AHW) for walking test and questionnaires
-eight visits for investigations (four visits for tests at the start of the study, and another four visits for tests 12 weeks later)
-total number of visits is 15 visits.
If you are in the exercise group, in addition, you will attend twice weekly for 12 weeks.

These visits are summarised as below:

Visit	**Intervention group**	**Control group**
Medical screening visit with study doctor (Clinic visit)	✓	✓
Appointment for baseline right heart catheterisation	✓	✓
Appointment for baseline cardiac MRI	✓	✓
Appointment for baseline Lung function tests	✓	✓
Appointment for baseline Blood tests	✓	✓
Baseline visit with study doctor (clinic visit)	✓	✓
Baseline visit with physiotherapist/AHW (baseline walking test, questionnaires)	✓	✓
Week 1	Attend physiotherapy twice weekly for one hour	x
Week 2	Attend physiotherapy twice weekly for one hour	x
Week 3	Attend physiotherapy twice weekly for one hour	x
Week 4	Attend physiotherapy twice weekly for one hour	x
Week 5	Attend physiotherapy twice weekly for one hour	x

Week 6	Attend physiotherapy twice weekly for one hour	x
Week 7	Attend physiotherapy twice weekly for one hour	x
Week 8	Attend physiotherapy twice weekly for one hour	x
Week 9	Attend physiotherapy twice weekly for one hour	x
Week 10	Attend physiotherapy twice weekly for one hour	x
Week 11	Attend physiotherapy twice weekly for one hour	x
Week 12	Attend physiotherapy twice weekly for one hour	x
Clinic visit with study doctor week 12-14 (Visit 1)	✓	✓
Physiotherapist/AHW visit 2 for outcome measures at week 12-14	✓	✓
Follow up right heart catheterisation	✓	✓
Follow up cardiac MRI	✓	✓
Follow up Lung function tests	✓	✓
Follow up blood tests	✓	✓
Clinic visit with study doctor week 26 (Visit 2)	✓	✓
Visit with physiotherapist/AHW for follow up walk test and questionnaires	✓	✓
Follow-up telephone questionnaire		✓

Time required:
You should allow at least two hours for Right heart catheterisation.
You should allow at least two hours for the Cardiac MRI (the actual procedure takes approximately one hour).
You should allow at least 1.5hours for Lung function tests.
The blood test should take less than 30 minutes.
If you are in the Exercise group, you should allow 1.5-2hours per class (exercise component is 1hour).

5 Other relevant information about the research project

This study involves doctors from two regions working together- St Vincent's Hospital Sydney, and from Coffs Harbour, NSW. The study is being conducted at St Vincent's Hospital Sydney and at the Coffs Harbour Health Campus and the University of New South Wales Rural Clinical School).

We hope to recruit at least 44 participants overall (from both the St Vincent Hospital site and Coffs Harbour Site). Approximately half will be in the Exercise group, and the other half will be in the Home Exercise (control) group.

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 the hospital.

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 usual care (this includes advice regarding exercise, and referral to a general pulmonary rehabilitation program if desired). 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?

We cannot guarantee or promise that you will receive any direct benefits from this research; however, possible benefits may include improvement in your symptoms of PAH, improved exercise capability and quality of life if you are in the exercise group. Regardless of which group you are allocated to, you will also receive the benefit of being monitored very closely.

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.

Risks related to blood tests:

Insertion of the catheter or having blood taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

Risks related to exercise

Studies of exercise in patients with Pulmonary hypertension have shown that exercise is generally very safe. For the exercise group, the risks related to exercise include dizziness (Grunig, Ehlken et al. 2011) and breathlessness causing a temporary decrease in oxygen saturation "sats" as measured by a finger probe (Mereles, Ehlken et al. 2006). During the exercise program you will be monitored by your physiotherapist/exercise physiologist for these symptoms, and you will have a short rest (a few minutes) from the exercise until you feel better.

Risks related to the investigations: Lung function tests

Lung function tests are very safe. Risks related to lung function tests are that you may feel 'puffed' (breathless) and dizzy/light-headed. These symptoms usually resolve with rest.

Risks related to the investigation: cardiac MRI

MRI stands for magnetic resonance imaging. A MRI scanner is a machine that uses electromagnetic radiation (radio waves) in a strong magnetic field to take clear pictures of the inside of the body. Electromagnetic radiation is not the same as ionising radiation used, for example, in X-rays. The pictures taken by the machine are called MRI scans.
We will ask you to lie on a table inside the MRI scanner. The scanner will record information about your heart. It is very important that you keep very still during the scanning. When you lie on the table, we will make sure you are in a comfortable position so that you can keep still. The scanner is very noisy and we can give you some earphones to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. If you do experience discomfort at any time during the scan, you will be able to alert staff by pressing on a call button provided to you.

Risks related to contrast used during the MRI:

The gadolinium contrast agent has occasionally been thought to cause headache, mild rash and very rarely (less than one in a thousand times) a more severe allergic reaction called

nephrogenic systemic fibrosis, which is uncommon, particularly if you have normally functioning kidneys (this is why we do a blood test to check your kidney function if you haven't had your kidney function checked in the preceding 2 months). Your kidneys remove the gadolinium from your bloodstream within a few hours. You will only need the gadolinium for your first cardiac MRI.
There are no proven long-term risks related to MRI scans as used in this research project. MRI is considered to be safe when performed at a centre with appropriate procedures. However, the magnetic attraction for some metal objects can pose a safety risk, so it is important that metal objects are not taken into the scanner room. We will thoroughly examine you to make sure there is no reason for you not to have the scan. You must tell us if you have metal implanted in your body, such as a pacemaker or metal pins.

Risks related to the investigations: right heart catheterisation

Most of the potential serious side effects are related to right heart catheterisation, and are listed below. However, it should be noted that right heart catheterisation is required for the diagnosis and ongoing management of patients with PAH, so is a well utilised procedure. Figures quoted are based on a large research study that looked at the side effects from right heart catheterisation over a five and a half year period, in over 7200 patients (Hoeper, Lee et al. 2006).

Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Abnormal heart rhythm	Approximately three in one thousand	May require medication or electrical cardioversion	1-5 days
Slow heart rate and or low blood pressure	Less than one in one hundred	Might require fluids through a vein	24-48 hours
High blood pressure	Less than one in one hundred	Medication for blood pressure	24-48 hours
Punctured lung	Less than one in one hundred	May resolve spontaneously, or may need chest drain inserted	3-5 days
Death from one of the above complications	0.05%		

Risks related to radiation used during right heart catheterisation

This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background

radiation and receives a dose of about 2 millisieverts (mSv) per year. The effective dose from this study is about 14 mSv per year. The dose from this study is comparable to that received from many diagnostic medical x-ray and nuclear medicine procedures. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure.

What will happen to me if I have a serious side effect?
If you experience a serious side effect requiring medical attention you will be referred to either the relevant doctors in the hospital or the closest hospital emergency department if required.

What if I am pregnant, breastfeeding, or planning to become pregnant?
Right heart catheterisation involves ionising radiation (XRays). Although the risk from the XRays in this study is low, the effect on an unborn child is unknown. Because of this, it is important that study participants are not pregnant and do not become pregnant during the course of the study project. You must not participate in this study if you are pregnant, or trying to become pregnant. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the study project. Female participants need to avoid pregnancy during the course of the study. You should speak to the study doctor about the need to avoid pregnancy during this study.

10 What will happen to my test samples?

You will be asked to provide additional consent for the collection of your blood during the research project.

Why take blood tests?
We will be doing blood tests on participants to measure if the heart is under any strain (NT-proBNP) and to measure a marker called interleukin-6 (IL-6) which can be raised in people with Pulmonary arterial hypertension. NT-proBNP is very useful for doctors but is not collected routinely, due to expense. IL-6 is not routinely collected, as its role in PAH is still being worked out. Your blood tests will be coded once the results have been reviewed. Your results will be analysed in coded form. Privacy and confidentiality of blood samples will be as per protocol of the accredited Pathology provider.

What will the blood tests be used for?
The blood tests will give the study doctors valuable information about your heart that will add to the information from the other investigations. This will be useful for our research.

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.

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. Although exercise is recommended in patients with PAH, there are no known health risks if you withdraw from the study.

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 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
- Lack of funding to continue

15 What happens when the research project ends?

When the research program ends, usual care will resume by your PAH specialist.
When the project is completed, in approximately 5 years time, if you are
Interested you can request any articles published as a result of the research project.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

The results of your tests will be coded (that is, potentially identifiable) for storage and analysis. The data will be kept on electronic file and paper records. Paper records will be kept in a locked secure, location . Data on electronic file will be kept on double password protected computers (Dr Karen Chia's computer). Some information (for example, results of investigations such as six minute walk test, quality of life questionnaires, blood tests, right heart catheterisation, lung function tests and cardiac MRI may be kept in your medical record.
Access to the study data will only be by people involved directly in the research project (the study doctors and nurses, physiotherapists, and exercise physiologists, statistician).
Data from the project will be stored for a period of 15 years on electronic files on computers that are password protected.

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 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.

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 study 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) by the relevant authorities the institution relevant to this Participant Information Sheet, ***[Insert site Name]***, 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. Information regarding participants will be general demographic data only (age, gender, ethnicity). Results of tests will not be identifiable.

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

In accordance with relevant Australian and/or NSW privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. 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 Complaints and 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 research project is being conducted by Dr Karen Chia, Dr Eugene Kotlyar and Dr Steven Faux. By taking part in this research project you agree that samples of your blood or tissue (or data generated from analysis of these materials) may be provided to St Vincent's Hospital Sydney and may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to St Vincent's Hospital Sydney, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

However, we do not anticipate that any financial benefits will arise as a result of this 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 HREC of St Vincent's Hospital.

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 ***[insert details of local site investigator and contact number]*** or any of the following people:

Clinical contact person

Name	
Position	
Telephone	

Email	

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	Research Office Manager
Position	Research Office Manager
Telephone	02 8382 4960
Email	SVHS.Research@svha.org.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 name	St Vincent's Hospital
HREC Executive Officer	Research Governance Officer
Telephone	02 8382 4960
Email	SVHS.Research@svha.org.au

Reviewing HREC approving this research and HREC Executive Officer details

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

Name	
Position	
Telephone	
Email	

Consent Form - *Adult providing own consent*

Title	The effect of an outpatient exercise training program on haemodynamics and cardiac magnetic resonance parameters of right ventricular function in patients with pulmonary arterial hypertension
Short Title	Exercise Training in Pulmonary Hypertension
Protocol Number	HREC/14/SVH/340
Project Sponsor	St Vincent's Hospital, Sydney, NSW, Australia.
Coordinating Principal Investigator/ Principal Investigator	Associate Professor Eugene Kotlyar/Dr Karen Chia
Associate Investigator(s)	Associate Professor Steven Faux
Location	***[Insert site name]***

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 St Vincent's 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 I will be given a signed copy of this document to keep.

Name of Participant (please _____

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.

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 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

Name of Participant (please _____

Signature _____ Date _____

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.

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*

Title	The effect of an outpatient exercise training program on haemodynamics and cardiac magnetic resonance parameters of right ventricular function in patients with pulmonary arterial hypertension
Short Title	Exercise Training in Pulmonary Hypertension
Protocol Number	HREC/14/SVH/340
Project Sponsor	St Vincent's Hospital, Sydney, NSW, Australia.
Coordinating Principal Investigator/ Principal Investigator	Associate Professor Eugene Kotlyar/Dr Karen Chia
Associate Investigator(s)	Associate Professor Steven Faux
Location	*[Insert site name]*

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…….

Name of Participant (please _____

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.