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#### Participant Information Sheet and Informed Consent Form

**Title: Clinical Effectiveness of Atrial Anti-tachycardia Pacing Therapy in**

 **Sick Sinus Syndrome with Previous Atrial Fibrillation Ablation**

**Short Title: Anti-tachycardia Pacing and Atrial Fibrillation**

**Ethics Approval Number: Pending**

**Principal Investigators: Professor Prash Sanders, Dr Rajiv Mahajan, Dr Dennis Lau**

**Student Researcher: Dr. Dian Andina Munawar**

**Associate Researchers: Dr. Dian Andina Munawar, Thomas Agbaedeng BSc (Hons), Dr Sharath Kumar, Dr Kashif Khokhar**

**Location: Royal Adelaide Hospital**

## 1. Introduction

It is our pleasure to invite you to participate in a Research Project that is explained below. Thank you for taking the time to read this information. The research project is investigating the development of atrial fibrillation in the patients who have pacemaker device.

This Participant Information Sheet and Informed Consent Form tell 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 the following information carefully. Please feel free to ask questions about anything that you don’t understand or want to know more about. You may wish speak with a relative, friend, or your local doctor before making your decision on participation.

The participation in this research is voluntary. If you don’t wish to participate you don’t have to. You will receive the best possible care irrespective of your decision regarding participating in the study.

If you decide you want to take part in the research project, you will be asked to sign the Informed Consent Form. 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 procedures 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 Sheet and Informed Consent Form to keep.

## 2. What is the purpose of this study?

The scientific literature shows that there is an increased risk of developing AF in patients implanted with a pacemaker due to sinus node dysfunction. To overcome this, advance algorithms were developed to reduce the AF burden.

The purpose of this study is to evaluate whether the specific pacemaker algorithms in question contribute to the suppression of AF. It is expected that the finding of this research will aid in the development of best practice guidelines for patients with pacemaker devices.

## 3. How long will this study go?

After the recruitment process, the device will be tested non-invasively by placing a wand (from the interrogation device) over your chest at 4 weeks. The arrhythmia logs will be checked to assess burden of atrial arrhythmia to decide your eligibility to participate in the study. If you are eligible to the study, you will be enrolled in the next 12 months. We will arrange for a clinical follow-up every six-month period, and for device interrogation (home monitoring) every three-month period. The whole period of the study will take 13 months. If you are not eligible, you will be provided with usual clinical care but will not take part in the other assessments.

## 4. What does participation in the research involve?

If your study doctor determines that you are eligible to take part in the study, and you decide to take part in this study, you will be asked to read and sign the Informed Consent Form.

Please note that you will be assigned to one of three groups: in the first group your pacemaker as per the standard programming without AF suppression algorithms. The benefits of AF suppression algorithms and anti-tachycardia pacing algorithms are not clear but have been demonstrated to be safe. The second and third group will have AF suppression and anti-tachycardia therapy enabled.

The results of the study will not be available immediately and will have to wait completion and publication after peer review.. Neither you nor your study doctor will know which group you are in and you cannot choose. You should discuss with your study doctor what pacing modes would be used if you were not part of the study.

***Pre-Recruitment Investigations***

A medical exam and a medical history interview will be conducted by the study team. You will also be asked about the medications that you take every day. You will undergo an electrocardiogram (ECG) to record the heart's activity.

Next, we will take some images of your heart using an echocardiogram (ultrasound of your heart). An echocardiogram is a test that uses sound waves to create a moving picture of the heart. This involves moving a wand on your chest while images are taken and displayed on a monitor.

We will check your pacemaker device using a programmer to make sure that the device is working correctly and the settings are right for you. This process of checking your pacemaker settings is called interrogation. This examination will be able to activate or deactivate the algorithm equipped in your pacemaker device. This also records any arrhythmic events prior to examination. To perform this, your doctor will place a special programming tool on your chest and the tool automatically sends back information.

##### Study Visits

You will be required to return for follow-up study visits. These visits will be scheduled as follows:

• 4-weeks post recruitment

• Clinical evaluation every six month and device evaluation every three month for 12 months.

At each follow-up visit, we will conduct some tests as outlined below.

##### Visit at 4 weeks after recruitment

During your visit, the study team will:

* Ask you about the medications that you take every day
* Review medical problems (if any) you have experienced since your last visit
* Take an assessment of electrocardiogram recording, echocardiography, exercise test, and blood samples.
* Device interrogation
* You will be asked to complete a short questionnaire. This should take few minutes to complete.

##### Device follow up at 3-Months

* Device interrogation at pacing clinic or home monitoring

##### Visit at 6-Months

During your visit, the study team will:

* Ask you about the medications that you take every day
* Review medical problems (if any) you have experienced since your last visit
* Take an assessment of electrocardiogram recording, echocardiography, exercise test, and blood samples.
* Device interrogation
* You will be asked to complete a short questionnaire. This should take few minutes to complete.

##### Device follow up at 9-Months

* Device interrogation at pacing clinic or home monitoring

##### Visit at 12-Months (completion of study)

During your final visit at 12-months, the study team will:

* Ask you about the medications that you take every day
* Review medical problems (if any) you have experienced since your last visit
* Take an assessment of electrocardiogram recording, echocardiography, exercise test, and blood samples.
* Device interrogation
* You will be asked to complete a short questionnaire. This should take few minutes to complete.

## 5. What do I have to do?

As a study participant, you are asked to follow the study requirements, attend study clinic visits, follow medical instructions given by the study team, inform your study team of any changes in your health, and of any other medical care or drugs you are receiving (whether prescribed by another doctor or bought over the counter). In addition, the study team will ask you if you have experienced any hospitalizations, illnesses or issues since the previous visit.

## 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 Sheet and Informed 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 care at Royal Adelaide Hospital.

## 7. What are the alternatives to participation?

You do not have to be in this study to receive medical care for your AF.

If you are not in the study, you and your doctor will decide how your pacemaker will be programmed. This may be the same as one of the pacing modes used in the study.

## 8. What are the possible benefits to you or to others?

## This study is trying to find out if using different pacing modes can help in preventing AF. However we will not know this until the results from many participants are analysed. As such the study may not have any benefit to you in the short term but we hope that it will help doctors to decide on the best pacing modes in future.

## 9. What are the possible discomforts and risks?

In this study you will have one of two different pacing modes, which are both thought to be safe. However, there may be side effects that the researchers do not expect or do not know about.

There are some risks associated with several tests that will be performed during follow up period. There may be a bruise or infection developed from blood taking. The risks associated with exercise test are fatigue, muscle soreness, irregular heartbeat, chest pain, or sudden heart attack. There is small risk of allergy with the gel used for echocardiography or with the electrodes of electrocardiogram recording. Please note that all tests are standard of care. Therefore, this test would have been performed even if you were not part of this study.

There were no data regarding the safety of the pacemaker algorithms that will be used in this study in pregnancy. Therefore, you should not be pregnant to take part in the study.

Tell the study team immediately about any new or unusual symptoms that you get. You are advised to contact the study team whenever you have any of these side effects, or are worried about them, on **08 8222 2723**.

## 10. 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, the contact person of the study will tell you about it and discuss with you whether you want to continue in the research project. If you decide to continue in the research project, you may be asked to sign an updated Informed Consent Form.

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

## 11. Can I have other treatments during this research project?

Whilst you are participating in this research project, your doctor may change some or all of the medications or treatments you have been taking for your condition. It is important to tell the study team about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments at each study visit. You should also tell the study contact person about any changes to these during your participation in the research.

## 12. What if I withdraw from this research project?

If you decide to with draw from the project, please notify a member of the study team before you withdraw.

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

## 13. What happens when the study ends?

After the termination of this investigation, your physician will see you per routine practice and the pacing mode will be programmed according to your clinical condition.

## 14. Confidentiality and data security

By signing the Informed Consent Form, you consent to the study team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your personal information may be accessed by, or disclosed to, regulatory authorities or ethics committees in so far as this relates to the clinical investigation. 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. Blood samples will be taken as part of the study. By signing the consent form, you agree to the study team accessing health records and taking blood samples 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 regulatory authorities and the institutions relevant to this Participant Information Sheet, Royal Adelaide Hospital and University of Adelaide, or as required by law. By signing the Informed Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel, the relevant institution, and regulatory authorities as noted above.

All data will be stored at the Centre of Heart Rhythm Disorders. Any blood samples which are taken as part of the study will be disposed of after they have been analysed. All datas will be kept for 5 years after the date of publication.

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. Information that is collected from the study and/or used in publications will be de-identified using a special code (number combination). This de-identified or coded (your study doctor uses this code to identify you but your identity will not be made public) information may be disclosed to public bodies, to ethics committees and to other doctors and other researchers.

Information about your participation in this research project may be recorded in your health records. In accordance with relevant Australian and/or South Australia 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. Any information obtained for the purpose of this research projectthat can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

In addition to the processes described above, data may otherwise be discoverable through processes of law or for assessing compliance with research procedures. You have a right to access the information collected and stored by researchers about you. You also have a right to request that any information with which you disagree be corrected. You have a right to ask that any stored specimens be destroyed but should be aware that data which has already been derived from those specimens may not be able to be destroyed.

## 15. Do I need to give permission for other information to be collected?

By signing this document, you give permission for the study team to obtain information from ambulance transportation, any admission to any hospital, Emergency Department/s visits, stays in observation unit/s, information from your local doctor, or any procedures for the term of the study period after signing this form. The information collected from these places/persons will only be requested if it is required for this study and will only be used for the purpose of this study.

## 16. Who is organizing and funding the research?

This study is funded by Centre for Heart Rhythm Disorders, Royal Adelaide Hospital.

## 17. 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 University of Adelaide and Royal Adelaide hospital’s Human Research Ethics Committee, Adelaide, Australia*.*

This project will be carried out according to the *National Health and Medical Research Council Statement on Ethical Conduct in Human Research (2007 – updated 2015)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

## 18. Who can you contact for study information?

If you want any further information concerning this project or if you have any medical problems that may be related to your involvement in the project (for example, any side effects), you can contact the Study Doctor on:

##### Investigator:

|  |  |
| --- | --- |
| Name | Dian Munawar |
| Position | PhD Candidate |
| Telephone | (08) 8222 2723 |

## A description of this clinical trial will be available on www.anzctr.org.au, as required by the Ethics Committee. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

## 19. Complaints and compensation.

If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the Chairperson, Research Ethics Committee, Royal Adelaide Hospital.

##### Reviewing HREC approving this research and HREC Executive Officer details:

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| Reviewing HREC name | Royal Adelaide Hospital Human Research Ethics Committee |
| Telephone | **08 8222 4139** |
| E-mail | **rah.ethics@health.sa.gov.au** |

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#### INFORMED CONSENT FORM

**Title: Clinical Effectiveness of Atrial Antitachycardia Pacing Therapy in**

 **Sick Sinus Syndrome with Previous Atrial Fibrillation Ablation**

**Protocol Number Pending**

**Principal Investigators: Professor Prash Sanders, Dr Rajiv Mahajan, Dr Dennis Lau**

**Associate Investigators: Dr. Dian Andina Munawar, Thomas Agbaedeng BSc (Hons), Dr Sharath Kumar, Dr Kashif Khokhar**

**Location: Royal Adelaide Hospital**

Thank you for your time to read this information sheet and consider taking part in this clinical investigation. If you agree to take part in this clinical investigation, please date and sign two of these documents on the last page together with your doctor. One signed document is for you, the other one will remain at this hospital.

1. I understand that my participation is voluntary.
2. I understand that I am free to choose not to participate in the proposed investigation, without giving any reason and without my medical care or legal rights being affected.
3. I understand that I am free to withdraw from the proposed investigation at any time, without giving any reason, without my medical care or legal rights being affected.
4. I understand that anonymised data collected during the investigation prior to the withdrawal will be used in the analysis and communicated in publications.
5. I confirm that I have read and understood the information presented for the investigation and have had the opportunity to ask questions, which were answered to my satisfaction.
6. I understand that I may not benefit from taking part in this study.
7. If female, I understand that I must not be pregnant to take part in this study.
8. I understand the purpose, procedures and risks associated with the study. I understand them and agree to participate in the proposed investigation and to comply with the procedures related to it.
9. I give my permission to have my local doctor informed of my taking part in the investigation.
10. I give my permission that sections of any of my medical notes may be inspected by representatives of the sponsoring company, the ethics committee and / or regulatory authorities.
11. I give my permission that my medical information can be obtained for any other health providers during the term of the study period. I understand that this will only be requested if required for the study and will only be used for the purpose of this study.

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| Name of Participant |  | Signature of Participant |  | Personally Dated |

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| Name of Investigator  |  | Signature of Investigator |  | Personally Dated |

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Revocation of Consent Form - Participant

**Title: Clinical Effectiveness of Atrial Antitachycardia Pacing Therapy in**

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**Protocol Number Pending**

**Principal Investigators: Professor Prash Sanders, Dr Rajiv Mahajan, Dr Dennis Lau**

**Associate Investigators: Dr. Dian Andina Munawar Thomas Agbaedeng BSc (Hons), Dr Sharath Kumar, Dr Kashif Khokhar**

**Location: Royal Adelaide 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 Royal Adelaide Hospital.

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| Name of Participant |  | Signature of Participant |  | Personally Dated |

If desired you can give a reason for withdrawal:

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project, of the necessity for future follow-up of the leadless pacemaker and implications if the follow-up requirements are not kept, and I believe that the participant has understood that explanation.

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| --- | --- | --- | --- | --- |
| Name of Investigator  |  | Signature of Investigator |  | Personally Dated |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project and the requirement for regular follow-up of the leadless pacemaker.

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