**Participant Information Sheet/Consent Form**

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

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| **Title** | Effect of warm humidified carbon dioxide insufflation on pericardial tissue viability during open-chamber cardiac surgery. A randomized controlled trial. |
| **Short Title** | MATCH – Myocardial de-Airing and Tissue preservation using CO2 with Humidification. |
| **HREC Number** | *2018.008* |
| **Principal Investigator** | Dr Irene Ng |
| **Associate Investigator(s)** | A/Prof Reny Segal, Dr Michael Kluger, Dr Roni Krieser, Dr Paul Mezzavia, Dr Francis Loh, Prof James Tatoulis, Mr Michael O’Keefe, Nicholas Quirk  |
| **Location**  | Royal Melbourne Hospital |

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

1. **Introduction**

You are invited to take part in this research project. This is because you are having open-heart surgery. The research project is testing a new device. The new device is called the HumiGardTM system.

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.

1. **What is the purpose of this research?**

The aims of this study are to investigate whether the use of humidified warm carbon dioxide delivered into the cardiac cavity via the HumiGardTM system can reduce heart tissue damage and also reduce the number of small gas bubbles within the heart and arteries following surgery when compared to traditional dry carbon dioxide delivery in adults undergoing open-heart surgery.

During open-heart surgery, small gas bubbles are commonly seen in the heart and bloodstream during and after your surgery. This is because during open-heart surgery your heart and blood vessels are open to the air and air may enter the chambers of your heart and get trapped there. Air does not easily dissolve in blood and small bubbles of air can sometimes get trapped in smaller arteries around your body. If these bubbles get trapped in small arteries within your brain it is thought to be associated with post-operative mental decline. To minimize this, it is common practice to reduce the risk of air which can obstruct tiny arteries by flooding the area surrounding the heart cavity with dry carbon dioxide via a small tube. It is believed that the use of carbon dioxide causes fewer gas bubbles because it is heavier and more soluble in blood than air. However, using dry carbon dioxide to inflate the cardiac cavity can cause tissue damage. A more sophisticated device, called the HumiGardTM system, is currently available. It allows a continuous flow of warm and humidified carbon dioxide to be delivered via a gas diffuser into the heart cavity.

In this study, we would like to test if warm and humidified carbon dioxide will reduce the amount of tissue damage and also the number of small gas bubbles travelling within the heart and to the brain, when compared to the current practice of using dry and cold carbon dioxideto inflate the cardiac cavity during open-heart surgery.

The HumiGardTM system is approved by the Therapeutic Goods Administration in Australia and is commonly used during keyhole surgery and other various surgeries however the use of HumiGardTM during open-heart surgery is relatively new.

1. **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, each participant is put into a group by chance (random). You will have a 1 in 2 chance of receiving either warm, humidified carbon dioxide into your cardiac cavity via the HumiGard TM system, *or* receiving the current standard treatment of dry carbon dioxidevia a standard oxygen catheter.

You will receive either the current standard of treatment of dry carbon dioxide or the warm humidified carbon dioxide via the HumiGardTM system during your operation. You will not be told which group you have been randomly allocated to. As you will be under anaesthesia when you receive the study intervention, you will be unaware of a change in your care.

You will receive an anaesthetic for your operation and carbon dioxide into your chest cavity during the operation regardless of whether or not you participate in this study.

The researchers will collect some information about you before your surgery such as your gender, age, height and weight, the type of anaesthesia and the type of cardiac operation you will be having. During your operation, information about your procedure will be collected.

During all heart surgery the outer layer of tissue that surrounds and protects your heart (known as the pericardium) is opened in order to access the heart for the procedure. During your surgery, two biopsies of this outer layer will be collected at specific time points. A biopsy in this case is when a very small amount of this outer layer of tissue is collected by your surgeon. This type of biopsy is commonly performed in patients that have heart surgery. The biopsies taken for this study will be examined by Scientists at Peter MacCallum Cancer Centre to determine if there are any changes to this outer layer of tissue. The number of small gas bubbles within your heart will also be measured during your surgery via an ultrasound procedure called transoesophageal monitoring. This procedure works by taking pictures of your heart through a thin probe that is passed down through your mouth and throat into your oesophagus. All patients that have open heart surgery have pictures of their heart taken using transoesophageal monitoring as a standard part of the procedure.

 \After you are discharged from hospital, the researchers will gather information from your hospital record about your length of hospital stay and any complications you may have experienced post-operatively.

Your participation in this study will finish when you are discharged from hospital.

The data collected during this research study will help determine the best treatment for individuals having open-heart surgery in the future.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and the design of the research will help to avoid 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.

1. **What do I have to do?**

You are not required to do anything extra for this study. There are no restrictions on your lifestyle, diet, medications or ability to donate blood that occur because of your participation. If you decide to participate you will be given this Participation Information and Consent Form to sign and you will be given a copy to keep.

1. **Other relevant information about the research project**

This is a study that is conducted at the Royal Melbourne Hospital, and is independent of any other studies. Scientists at the Peter MacCallum Cancer Centre are involved in the study to analyse biopsies taken as part of the study. Researchers involved are employed by the Royal Melbourne Hospital and the Peter MacCallum Cancer Centre.

1. **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.

1. **What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project.

1. **What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, the results of this study may provide us with a better understanding of the effect of inflating the heart cavity using a continuous flow of warm and humidified carbon dioxide when compared to inflation with dry carbon dioxide into the heart cavity for open heart surgery.

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

As carbon dioxide is used to inflate the heart cavity as part of your normal care for open heart surgery, there are no extra risks associated with it as a participant in this study. There is a small risk of bleeding from the biopsy sites at the time the sample of tissue is taken from the heart muscle. Any bleeding after the biopsy can be easily identified and treated by the surgeon using a heat device to seal off the bleeding blood vessel at the time of biopsy.

1. **What will happen to my test samples?**

Your heart biopsies will be placed in a preservative fluid and transferred to Peter MacCallum Cancer Centre for analysis. Once this analysis is complete your tissue samples will be discarded.

Your tissue sample will be labelled with a study number and not your name. The data which is generated from the analysis of the biopsy samples will be in the form of images. These images will be stored to compliment the information we collect on tissue damage. The images will be kept for 5 years following the completion of the study.

1. **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.

1. **Can I have other treatments during this research project?**

There are no limitations on receiving other treatments during this research project.

1. **What if I withdraw from this research project?**

Participation in any research project is voluntary. If you do not wish to take part you don’t have to. If you decide to participate and later change your mind, you are free to withdraw and you will be given the option to withdraw from the project. There are no health implications for withdrawing from this research project.

If you decide to withdraw 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 the law. You should be aware that data collected by the study team 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.

Your decision whether to take part or not to take part, or to take part and then withdraw will not affect your relationship with the Royal Melbourne Hospital.

1. **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 device being shown not to be effective.

• The device being shown to work and not need further testing.

1. **What happens when the research project ends?**

No specific follow-up is required with participation in this study. If you choose to participate you will receive routine post-operative care and follow-up identical to the care you would receive if you had not been involved in this research. Should you wish to contact someone at the end of this project, the principal researcher Dr Irene Ng can be contacted on 03 9342 7540.

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

1. **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 purpose of this research project. Any information obtained in connection with this research project that can identify you will remain confidential. Each patient will be assigned a study number. Any information about you will be labelled with the study number and not your name. The data will be transferred onto paper report forms and kept in a locked cabinet in the Department of Anaesthesia until all the participants have been recruited and will then be destroyed after 15 years. Data coded with your study number will be stored on a Microsoft Excel spreadsheet which will be password protected and stored on a hospital computer which is also password protected. Only members of the research team will have access to the information. 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.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of The Royal Melbourne Hospital, 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.

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

In accordance with relevant Australian 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 project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

1. **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.

1. **Who is organising and funding the research?**

This research is being organised by anaesthetic staff at the Royal Melbourne Hospital who are receiving no funding for this research.

1. **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 Melbourne Health.

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.

1. **Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on (03) 93427540, or the research nurses on (03) 9342 8126 or any of the following people:

 **Clinical contact person**

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| --- | --- |
| Name | Dr Irene Ng |
| Position | Staff Consultant Anaesthetist |
| Telephone | (03) 9342 7540 |
| Email | Irene.Ng@mh.org.au |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

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| --- | --- |
| Reviewing HREC name | Melbourne Health HREC |
| HREC Executive Officer | Manager HREC |
| Telephone | (03)9342 8530 |
| Email | Research@mh.org.au  |

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

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| **Location**  | Royal Melbourne 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 to the Royal Melbourne Hospital to release information to the researchers 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.

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|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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|  |
|  | Name of Witness\* (please print) |  |  |
|  |
|  | Signature |  |  Date |  |  |
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\* 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. Witness is required when the participant cannot read the document for him/her self.

**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 |  |  |
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† A senior member of the research team must provide the explanation of, and information concerning, the research project.

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

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| --- | --- |
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| **Short Title** | MATCH – Myocardial de-Airing and Tissue preservation using CO2 with Humidification. |
| **HREC Number** | 2018.008 |
| **Coordinating Principal Investigator/****Principal Investigator** | Dr Irene Ng |
| **Associate Investigator(s)** | A/Prof Reny Segal, Dr Michael Kluger, Dr Roni Krieser, Dr Paul Mezzavia, Dr Francis Loh, Prof James Tatoulis, Mr Michael O’Keefe, Nicholas Quirk  |
| **Location**  | Royal Melbourne 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 The Royal Melbourne Hospital.

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