***Approved by the Health and Disability Ethics Committee on type the date on which the final approval was granted Reference number type the reference number***

*Note: The Participant should retain a copy of this form*

***Participant Information Sheet***

***Date Information Sheet Produced:***

***3/07/2018***

***Project Title***

*RACer–PAP. Investigating the utility and acceptability of a new non invasive ventilatory assist device during exercise in a population of normal healthy adults.*

***An Invitation***

*Kia Ora, Talofa and Hello.*

*My name is \_\_\_\_\_\_\_\_\_\_\_ and I am a researcher at Auckland University of Technology (AUT) and I would like to invite you to participate in a study, to evaluate the acceptability and usefulness of a new breathing assist device called the Rest and Activity Cycler – Positive Airway Pressure (RACer-PAP) designed to help lung function during activity for people with Chronic Obstructive Pulmonary Disease (COPD). However, before we ask people with COPD to try out the device, we are keen to make sure the devices are comfortable during exercise in healthy people.*

*Your participation is entirely voluntary (your choice). You do not have to take part in this study, and if you choose not to take part this will not affect you in any way.*

*If you agree to take part in the study, you are free to withdraw from the study at any time, without having to give a reason.*

*You may have a friend, family or whānau support to help you understand the risks and/or benefits of this study and any other explanation if you wish.*

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

*We are trialling a ventilatory assist device that we believe helps some people to breathe easier. This device has been trialled in people at rest however we would like to test the comfort and acceptability of the device during exercise. The researchers hope to gain a better understanding of the comfort and likely usefulness of the RACer-PAP during exercise. This is because RACer-PAP has the potential to be useful for people who have lung disease enabling them to undertake normal everyday activities which they may find difficult because of their lung disease. This project aims to test the RACer-PAP during exercise in healthy individuals, with a view to determining the comfort and ease of use of the device prior to assessing the device in those with lung disease.*

***How was I identified and why am I being invited to participate in this research?***

*You expressed an interest in our posters advertised around AUT and have contacted us to express your interest in our study. You are able to take part in this study if you are over 20 years old and in good health. You cannot take part in this study if you suffer from heart disease, high blood pressure, sinus or respiratory conditions, illness/neuromuscular problems or injury that impairs your physical performance, or any infection. You must also be a non-smoker.*

***How do I agree to participate in this research?***

*You will be required to complete a consent form to show you understand what the study involves and whether you consent to the use of your results obtained during the testing which is likely be published as a journal article. Your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you. You are able to withdraw from the study at any time. Once you have signed the consent form you are still able to withdraw from the study. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been analysed, removal of your data may not be possible.*

***What will my participation in this study involve?***

*During this study you will be required to attend two sessions at AUT of approximately 1.5 hours duration each. The research team will try to ensure these are scheduled at a time that is convenient to you. At the first session you will be screened by a healthcare professional who will take a brief history. You will also be asked to perform a breathing test (spirometry) and perform a practice 6 minute walk test. After 30 minutes rest we will ask you to perform another 6 minute walk test. Participants will then be asked to trial the RACer-PAP device. We will have a questionnaire for you to fill out on what you thought about our device.*

*At the following session which will be within a week of the first session will also be required to perform the same breathing test ( spirometry) you completed in the first session and 2 x 6 minute walk tests with and without the device fitted in a random order. There will be at least 30 minutes between the two walk tests. You will then be asked to fill out a questionnaire to see what you thought about exercising with the device on. Refreshments will be available following completion of the testing.*

*Throughout both sessions you will be monitored for how breathless you feel and we will take non invasive measurements of heart rate, blood pressure and oxygen levels. You are able to discontinue at any time and ask any questions at any point before, during and after the study. The information collected will be recorded and analysed to determine if there are any changes in lung function, the distance walked during testing and to consider the feedback given from the questionnaires.*

*For a number of ethnic groups including Māori, the head is the most sacred area of the body. We will always ask your permission to touch your head if help is required with the device and you may elect not to continue with the study should you feel the device on your face is unwelcome to you .*

***What are the benefits?***

*The benefits of this study are as follows:*

* *It may possibly enable you to perform better during exercise and make it easier to breathe.*
* *You will be involved in a study that may potentially lead to a form of treatment that will be used in the future to help people suffering from chronic lung disease and improve their ability to exercise and quality of life.*

***What are the discomforts and risks?***

*This device works by blowing air in through your nose via an oxygen mask worn on the nose and may cause discomfort or cause a dry nose in some individuals. You will be asked to try and breathe through your nose for the duration of wearing the device however, this can prove difficult as, some people prefer to breathe through their mouth, particularly during exercise. The device (RACer-PAP) has been developed to work in the same way as similar devices that have been safely tested and used during exercise. All devices and measures are non-invasive. No harmful effects are anticipated (or have been reported with previous use of the device) but participation in this study will be stopped immediately should any harmful effects appear.*

*There have been no reports of any decline in function or measures taken during previous RACer-PAP trials and this device has been reported to be more comfortable than other current devices available. We will monitor your lung function by spirometry during which you need to blow out as fast and as hard as you can for as long as possible. This does not cause any risk nor discomfort but involves a hard effort to breathe out. You will be asked to undertake a 6 minute walk test in which you will walk as far and as fast as possible over six minutes on a hard flat surface. You will be fully monitored throughout the test and as you choose the pace of the test there are few risks. In addition, we have excluded anyone from this study for whom the 6 MWT is deemed unsafe. However, the effort involved in the test may be uncomfortable for you as you are asked to exercise to full capacity.*

***How will these discomforts and risks be resolved?***

*We will closely monitor all tests and activities undertaken at AUT clinic. Anyone who presents with any concerns arising from testing will have their vital signs and breathing status measured by the attending healthcare professional and if necessary referred to an appropriate healthcare professional.*

***What are the costs of taking part in this study?***

*This study will require a total of approximately 3 hours of your time and the cost of travel to and parking at AUT to attend the two sessions.*

***What compensation is available for injury or negligence?***

*As this research study is for the principal benefit of its commercial sponsor [RACER-PAP], if you are injured as a result of taking part in this study you will not be eligible for compensation from ACC.*

*However, Julie Reeve has satisfied the Northern B Health and Disability Ethics Committee that approved this study that it has up-to-date insurance for providing participants with compensation if they are injured as a result of taking part in this study.*

*New Zealand ethical guidelines for intervention studies require compensation for injury to be at least ACC equivalent. Compensation should be appropriate to the nature, severity and persistence of your injury and should be no less than would be awarded for similar injuries by New Zealand’s ACC scheme.*

*Some sponsors voluntarily commit to providing compensation in accordance with guidelines that they have agreed between themselves, called the Medicines New Zealand Guidelines (Industry Guidelines).These are often referred to for information on compensation for commercial clinical trials. There are some important points to know about the Industry Guidelines:*

* *On their own they are not legally enforceable, and may not provide ACC equivalent compensation.*
* *There are limitations on when compensation is available, for example compensation may be available for more serious, enduring injuries, and not for temporary pain or discomfort or less serious or curable complaints.*
* *Unlike ACC, the guidelines do not provide compensation on a no-fault basis:*
* *The Sponsor may not accept the compensation claim if:*
* *Your injury was caused by the investigators, or;*
* *There was a deviation from the proposed research plan, or;*
* *Your injury was caused solely by you.*

*An initial decision whether to compensate you would be made the by the sponsor and/or its insurers.
If they decide not to compensate you, you may be able to take action through the Courts for compensation, but it could be expensive and lengthy, and you might require legal representation. You would need to be able to show that your injury was caused by participation in the trial.
You are strongly advised to read the Industry Guidelines and ask questions if you are unsure about what they mean for you.
If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.*

***How will my privacy be protected?***

*All details that will identify you will be not be included in any publications arising from this study eg. Name, address, contact details. All details and data collected will be kept in locked in a secure cabinet on AUT premises and will only be available to those healthcare professionals directly involved in the study. You will be able to indicate on the consent form if you would like to receive a summary of the results from this study. Should you wish, you have the right to access information about yourself collected as part of the study. You will be informed of any new information related to the study about adverse or beneficial effects that may have an impact on your health if these become available during the study*

***What opportunity do I have to consider this invitation?***

*You will have until the (Date) to email/call the researcher (see below for contact details) to confirm your participation in this study. You will also be able to email or call the researcher regarding any further questions you may have.*

***Will I receive feedback on the results of this research?***

*You will indicate on the consent form whether or not you would like to receive the results summary.*

***What do I do if I have concerns about this research?.***

*If you have any questions, concerns or complaints regarding the nature of this project these should be notified in the first instance to the Project Supervisor:.*

Dr Julie Reeve *Email:* julie.reeve@aut.ac.nz *Phone: 09 9219999 extension 7085*

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

For Maori health support please contact :

*Name, position J J Johnston*

 *Telephone number*

 *Email* jj.johnston@auckland.ac.nz>

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

 Phone: 0800 4 ETHICS

 Email: hdecs@moh.govt.nz

***Whom do I contact for further information about this research?***

*Please keep this Information Sheet and a copy of the Consent Form for future reference. You are also able to contact the research team as follows:*

***Researcher Contact Details:***

*Dr Julie Reeve Email:* julie.reeve@aut.ac.nz *Phone: 09 9219999 extension 7085*

*Dr Sarah Mooney Email:* sarah.mooney@aut.ac.nz *Phone: 09 9219999 extension 6208*

***Approved by the Health and Disability Ethics Committee on type the date on which the final approval was granted Reference number type the reference number***



# Consent Form

***Project title:***

*RACer–PAP. Investigating the utility and acceptability during exercise of a new ventilatory assist device in a population of normal healthy adults.*

***Project Research Team****: Dr Julie Reeve, Dr Sarah Mooney, Dr David White, Dr Jim Bartley*

*Participant:*

⭘ I have read and understood the information provided about this research project in the Information Sheet dated (place date here)

⭘ I have had an opportunity to ask questions and to have them answered.

⭘ I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without being disadvantaged in any way.

⭘ I understand that if I withdraw from the study then I will be offered the choice between having any data or material that is identifiable as belonging to me removed or allowing it to continue to be used. However, once the findings have been produced, removal of my data may not be possible.

⭘ I agree to take part in this research.

⭘ I wish to receive a summary of the research findings (please tick one): Yes⭘ No⭘

Participant’s name: .....................................................…………………………………………………………

Participant’s signature : .....................................................…………………………………………………………

Participant’s Contact Details (if appropriate):

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………………………………………………………………………………………..Date: