***Approved by the Health and Disability Ethics Committee on*** ***18/05/21***

|  |  |
| --- | --- |
| ***Participant Information Sheet***  | ***Logo, company name  Description automatically generated*** |

***Project Title****Preliminary investigation into the acceptability, safety and efficacy of a small, battery powered device applied to the nose that creates vibrations in the nose during spontaneous nasal breathing.*

***Sponsor:*** *AUT Ventures*

***Principal Investigator:*** *Jim Bartley*

***Health and Disability Ethics Committee Application Number:* 21/CEN/99**

***An Invitation****My name is Jim Bartley. I would like to invite you to participate in a study, to evaluate a small, battery powered device that plugs into the nose to create internal nasal vibrations during nasal breathing. The device is designed to increase the levels of a gas in the nose called nitric oxide. This may help people with nasal symptoms particularly nasal congestion. We are keen to make sure the device is comfortable and easy to use.*

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

*If you agree to trial the device, you are free to stop using the device at any time while using it, 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 small, battery powered device that plugs into the nose that may help nasal breathing. The researchers have trialled the device, but it has not been assessed in a formal study. This project aims to assess the comfort and ease of use of the device prior to a larger study in people with nasal and sinus disease.*

***How was I identified and why am I being invited to participate in this research?****The principal investigator Jim Bartley has identified you as having nasal congestion and that you might potentially benefit from using the device.*

*You are able to take part in this study if you are between 18 and 80 years old and a non-smoker. You cannot take part in this study if you suffer from cystic fibrosis, hypo-gammaglobulinaemia, a fixed cause of nasal obstruction or if you have problems with nasal crusting or nose bleeding.*

***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 would allow the use of the results obtained during the testing to 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 a clinic session of approximately 30 minutes. The principal investigator will try to ensure this is scheduled at a time that is convenient to you. You will be shown the device, asked to fill out a brief questionnaire, have the front of your nose examined and then sit quietly with the device applied to your nose for 15 minutes. At the end of 15 minutes, the front of your nose will be re-examined and you will be asked to assess the comfort and acceptability of the device and whether it has made any difference to your nasal symptoms.*

*For a number of ethnic groups including Māori, the head is the most sacred area of the body. I 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 in your nose is unwelcome to you.*

***What are the benefits?****The potential benefits of the study are that increasing levels of endogenous inhaled nitric oxide offers the opportunity to safely and possibly more effectively treat both allergic rhinitis and chronic rhinosinusitis patients with none of the risks associated with prolonged oral antibiotic or oral Prednisone use.*

***What are the discomforts and risks?****This device works by causing nasal vibrations that mimic humming during spontaneous breathing. No harmful effects are anticipated but participation in this study will be stopped immediately should any harmful effects appear. The purpose of the study is to assess the comfort, safety and acceptability of the device.*

***How will these discomforts and risks be resolved?****If the device is too uncomfortable the study will be stopped. If there are any problems the principal investigator is able to diagnose and treat any problems.*

***What are the costs of taking part in this study?****This study will require a total of approximately 30 minutes of your time and the cost of travel to attend the assessment. A $50.00 fuel voucher will be provided to cover your travel costs.*

***What compensation is available for injury or negligence?*** *If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.*

*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?****During this study Dr Bartley and other staff will record information about you and your study participation. This includes the results of the study assessments. If needed,**information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.*

*To make sure your personal information is kept confidential, information that identifies you will not be included in any reports or publications generated by Dr Bartley and any study information sent to the sponsor. Instead, you will be identified by a code.*

*All details will be locked in a secure cabinet in the investigator’s office and will only be available to the principal investigator directly involved in the study. Coded data will be stored in a password protected file on a password protected computer. The data will be stored for ten years. 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 24/08/21 to email/call the principal investigator (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 principal investigator:*

Jim Bartley *Email:* jimbartley56@gmail.com *Phone: 021 1485077*

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: Wiremu McFater; ORL registrar

 Telephone number: 021 02661219

 Email: Wiremu.MacFater@middlemore.co.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:***

Jim Bartley *Email:* jimbartley56@gmail.com *Phone: 021 1485077*

# Consent Form

***Project title:*** *Preliminary investigation into the acceptability, safety and efficacy of a small, battery powered device applied to the nose that creates vibrations in the nose during spontaneous nasal breathing.*

***Project Research Team****: 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) :

Date: