



## **PARTICIPANT INFORMATION SHEET AND CONSENT FORM**

**STUDY TITLE:** Role of home telemonitoring of lung function using the forced oscillation technique in assessing and predicting asthma control.

### **LOCAL INVESTIGATORS:**

- Associate Professor Cindy Thamrin: Coordinating Principal Investigator, affiliated with The Woolcock Institute of Medical Research and The University of Sydney
- Associate Professor Claude Farah: Principal Investigator at Concord Repatriation General Hospital, affiliated with The Woolcock Institute of Medical Research, The University of Sydney and Macquarie University
- Professor Gregory King: Principal Investigator at Royal North Shore Hospital, affiliated with The Woolcock Institute of Medical Research and The University of Sydney
- Professor Helen Reddel: Associate Investigator, affiliated with The Woolcock Institute of Medical Research and The University of Sydney
- Professor Matthew Peters: Associate Investigator, affiliated with The Woolcock Institute of Medical Research and The University of Sydney
- Dr Farid Sanai: Associate Investigator, affiliated with The Woolcock Institute of Medical Research and The University of Sydney.

### **INTERNATIONAL COLLABORATORS:**

Professor Raffaele Dellaca and Dr Alessandro Gobbi are overseas study collaborators from Politecnico di Milano University, Italy.

### **PROJECT SPONSOR:**

This is a collaborative group research project between investigators from The Woolcock Institute of Medical Research and Sydney Local Health District. This project is funded by the NHMRC Centre for Research Excellence in Severe Asthma (\$20,000) and The Woolcock Institute of Medical Research. There is no commercial funding for this project.

### **DISCLOSURE OF INTERESTS:**

The Woolcock Institute of Medical Research has a contractual relationship with a device manufacturing company called Restech srl. One of the devices used in this research project is the Resmon Pro Diary, and this will be provided on loan by Restech srl, a spin-off company from the Politecnico di Milano University, where the overseas collaborators are based. The Woolcock does not derive financial benefit from the results of the trial. Restech srl may derive financial benefit from the results of the trial, and information generated by the trial will be jointly owned by the Woolcock and Restech. The collaborators and/or the company will have access to de-identified data generated from the study for their own analyses, despite Restech srl not being listed as investigators on the trial.

### **INTRODUCTION:**

You are invited to take part in a research study looking at the usefulness of long-term monitoring of lung function at home for people with asthma. You will be asked to undertake daily lung function tests at home using the forced oscillation technique (FOT), with measurements being recorded via a Resmon Pro Diary and peak expiratory flow (PEF) measurements using a digital spirometer device, the Spiro PD.

The Resmon Pro Diary is not registered for normal use in Australia. It is a modified version of a device that is registered for use in Australia, i.e. with its software adapted



for home monitoring use. The researchers submitted a Clinical Trial Notification (CTN) to the Therapeutic Goods Administration (TGA) on 2 October 2017, which allows them to use this device in Australia for medical research purposes based on assessment and approval by the authorised Human Research Ethics Committee. The Spiro PD was registered for use in Australia at the time the devices were purchased and its use in this study is lawful and appropriate, as it is being used for its intended purpose.

The research study will also review the performance of the Resmon Pro Diary, but this is not the primary purpose of the study.

This Participant Information Sheet will tell you about what is involved in the study and help you decide whether or not you wish to take part. Please read this information carefully. If there is anything you do not understand or if you feel you need more information about anything, please ask. Before you make a decision, please feel free to talk things over with a relative, a friend or your own doctor.

### **WHAT IS THE PURPOSE OF THIS RESEARCH?**

Asthma is a common respiratory disease that is potentially dangerous, even in those with symptoms that appear mild. Its current management is largely based on patients reporting symptoms, and it is often difficult for patients to detect changes in their condition. Changes can occur in response to environmental factors, general health and activity, or in response to medical treatment.

Asthma flare-ups (i.e. respiratory symptoms worsen over a few days) may occur in some people and can result in long-periods of hospitalisation. There are currently no tests that predict the likelihood of a flare-up.

Likewise the patient's condition is not currently measured on a day-to-day basis when the treating doctor changes the treatment or the dose of medication prescribed.

In this study, we will see whether daily measurements at home, using a breathing test, can accurately measure the effect of medications, and/or predict the likelihood of asthma exacerbations.

You will continue taking your usual medications and care plan for your disease. Should you experience an asthma flare-up during the study, you will be treated in the standard manner by your usual doctor.

### **WHAT WILL HAPPEN TO ME IF I TAKE PART?**

If you agree to participate in this study you will be asked to sign the Participant Consent Form.

This is a long-term study lasting for 2-6 months, and requires daily measurements, done by you at home which will take about 5 minutes, weekly 5-10 min-interviews by telephone and occasional 1-hour study visits, which may coincide with your normal clinic visit. During the study period, you will attend the clinic for assessments on two or three occasions usually 8 weeks apart.

At your initial clinical assessment you will complete the usual standard clinic questionnaire that asks you questions about your symptoms, medical history and medications and takes approximately 10 minutes to complete. You will also complete the standard lung function tests that involves breathing quietly or blowing into a mouthpiece while seated and takes approximately 20 minutes.



Following this you will be asked to undertake daily morning lung function tests at home for 10-24 weeks using the forced oscillation technique (FOT), with measurements being recorded via a **Resmon Pro Diary**, followed by peak expiratory flow (PEF) measurements using a digital spirometer device, **the Spiro PD**. FOT involves normal quiet breathing into a mouthpiece for 2 minutes. PEF involves you blowing 3 times into a mouthpiece. A study investigator or research assistant will visit you at home to set up the devices and teach you how to use them. **Information leaflets for the devices and how to use them will be provided to you.**

The daily measurements themselves are quick, **and in most cases** simple to perform, and the device is user-friendly. The measurements will be done each morning prior to taking your inhaled medication and you will be guided by the instructions of the Resmon Pro Diary device. This includes sitting down in front of the device with a nose-clip in place and sealing your lips around the breathing filter attached to the device. You will then support your cheeks with your hands as demonstrated during your training session and perform the measurement during relaxed normal breathing for approximately 2 minutes.

**The Resmon Pro Diary** device will also ask you a few simple questions regarding your respiratory symptoms and your responses will be recorded in an electronic diary. Your **de-identified** breathing test and symptom data will be automatically transmitted via the mobile internet network to the Woolcock Institute of Medical Research and secure servers in Milan, Italy **where the manufacturer Restech srl is located**. No personal information is recorded or transmitted by the device.

Following this, you are asked to perform the PEF test using the **Spiro PD device**. Your **de-identified** age, height, weight and PEF data will be recorded by the device, but no automatic data transfer will be made. At the end of the study, this data will be downloaded from the device by study personnel at the Woolcock Institute of Medical Research.

Once a week, a study investigator or research assistant will conduct a brief telephone interview at a mutually agreed time, to assess your respiratory health and any changes to your treatment made by your usual caregiver, and determine whether you have an exacerbation. The weekly phone interviews will take approximately 5-10 minutes each time.

At the end of the study, a study investigator or research assistant will visit you again in your home to retrieve the devices.

### **CAN I WITHDRAW FROM THE STUDY?**

Taking part in this research study is entirely voluntary. You do not have to take part in it. If you do decide to take part you can withdraw at any time without having to give a reason. Please be assured that, whatever your decision, it will not affect your routine treatment, your relationship with those treating you or your relationship with <<institution>>.

If you withdraw from this study please let the study investigator know if you would like your study data withdrawn or if you are happy to for it to be included in the results.

### **COSTS**

Participation in this study will not cost you anything, nor will you be paid. However, if you are attending the clinic outside of your normal clinic visit schedule, you will be reimbursed (\$50) for your travel expenses for each study visit.



### **WHAT ARE THE ALTERNATIVES TO PARTICIPATION?**

You can choose not to participate in the study without any impact on your usual care. This study differs from standard treatment in that you will have additional assessments of your disease over a period of 2-6 months. You can discuss your options with the study doctor or your usual doctor before deciding whether or not to take part in the study.

### **WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?**

While this research study will further medical knowledge and may improve assessment and management of asthma in the future, it may not be of direct benefit to you. However, your disease will be monitored more closely compared to standard care.

### **WHAT ARE THE RISKS OF TAKING PART?**

You will undergo standard lung function tests as part of this study. The tests require blowing into a mouthpiece using maximal effort, which may cause some fatigue or light-headedness. Some participants may experience difficulties when undertaking PEF testing at home. If you encounter any issues, stop using the device and inform the study investigators immediately.

In the event that you develop an asthma flare-up (exacerbation), you should follow your normal action plan and see your usual doctor (if needed). In an emergency you should call an ambulance (on 000) or attend your nearest emergency department. Your treatment will follow standard clinical care. In the case of any adverse event or any other difficulties that may be encountered including hospitalisation due to your asthma we ask that you notify the study investigators as soon as possible. Please contact the Coordinating Principal Investigator Dr Cindy Thamrin on 9114 0440 or the study telephone number on 9114 0146 for advice or assistance.

Your normal caregiver/GP will be informed about your participation in the study. No medical records will be accessed; your lung function test results and questionnaire data will be obtained on the day of your study visits from the Lung Function Laboratory at the Department of Thoracic Medicine. We may contact your treating physician to confirm if any changes to your treatment has occurred.

You will be able to travel for holidays or work during the duration of the study as long as this is limited to a maximum of three weeks of absence in total.

You are not required to make any changes to your lifestyle, diet or medication other than that recommended by your usual doctor. However, you will be asked about any such changes that may occur during your weekly interviews.

### **WHAT IF NEW INFORMATION BECOMES AVAILABLE?**

Sometimes during the course of a study new information becomes available about the treatment that is being studied. While you are participating in the study you will be kept informed of any significant new findings that may affect your willingness to continue in the study.

### **CONFIDENTIALITY**

If you consent to take part in this study your hospital medical records may be inspected by the researchers, by regulatory authorities or by the Human Research Ethics Committee. The researchers will also collect basic data on your health and lung function. By signing the consent form you are giving permission for this to be done. All details obtained by those named will remain confidential and will be stored on a secure



research database held at the Woolcock Institute of Medical Research. Only the researchers and collaborators named above will have access to the information. The data will be analysed at the Woolcock Institute of Medical Research and only the researchers will have access to the analysed data. A report of this study may be submitted for publication but individual participants will not be identifiable.

A description of this clinical trial is available on the Australian New Zealand Clinical Trial Registry under the trial registration IDs ACTRN12617001650381 and ACTRN12618000837224.

### **COMPENSATION**

Every reasonable precaution will be taken to ensure your safety during the course of the study. In the event that you suffer any injury as a result of participating in this research project, please contact the study investigators and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive medical treatment as a public patient in any Australian public hospital free of charge.

### **FURTHER INFORMATION**

When you have read this information, the study investigator will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact <<name of local primary investigator>> or Dr Cindy Thamrin (Coordinating Principal Investigator, Woolcock Institute of Medical Research) on 9114 0440 or the study telephone number on 9114 0146. This information sheet is for you to keep.

### **ETHICS APPROVAL AND COMPLAINTS**

This study has been authorised by the Human Research Ethics Committee – CRGH of the Sydney Local Health District. If you have any concerns or complaints about the conduct of this research study, you may contact the Executive Officer of the Ethics Committee on (02) 9767 5622.

The conduct of this study at <<name of hospital>> has been authorized by <<name of organisation>>. Any person with concerns or complaints about the conduct of this study may contact the Research Governance Officer on <<phone number>> and quote protocol number <<number>>.





**STUDY TITLE:** Role of home telemonitoring of lung function using the forced oscillation technique in assessing and predicting asthma control.

**PARTICIPANT CONSENT FORM**

I, .....[name]

of.....[address]

have read and understood the Information for Participants for the above named research study and have discussed the study with .....

- I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.
- I understand that, during the course of this study, my medical records may be accessed by the researchers, by regulatory authorities or by the Ethics Committee approving the research in order to verify results and determine that the study is being carried out correctly.
- I freely choose to participate in this study and understand that I can withdraw at any time.
- I understand that my non-identifiable data will be automatically transmitted sent overseas to the telemonitoring servers at Restech srl who are located in Milan, Italy and I agree to this. I understand that no personal data will be transferred to Restech srl.
- I also understand that the research study is strictly confidential.
- I hereby agree to participate in this research study.

**Name (Please Print):** .....

**Signature:** ..... **Date:** .....

**Name of Person who conducted informed consent discussion (Please Print):**

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**Signature of Person who conducted informed consent discussion:**

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**Date:** .....