Participant Information Sheet
Interventional Study - Adult providing own consent

Woolcock Institute of Medical Research

Title
RCT of the efficacy and safety of an ICS/LABA reliever therapy regimen in asthma

Short Title
Novel START (Novel Symbicort Turbuhaler Asthma Reliever Therapy)

Protocol Number
MRINZ/15/A1 Version 2.2 (3 September 2015)

Project Sponsor
Woolcock Institute of Medical Research

Coordinating Principal Investigator/Principal Investigator
Associate Professor Helen Reddel

Associate Investigator(s)
Dr Gloria Foxley

Location
Woolcock Institute of Medical Research

Part 1 What does my participation involve?

1. INTRODUCTION

You are invited to take part in this research project. This is because you have asthma. The research project is comparing the effectiveness of three different inhaled treatments for people with asthma.

This Participant Information Sheet 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.
2. WHAT IS THE PURPOSE OF THIS RESEARCH?

Asthma is a major health problem globally and Australia has high rates of asthma. This study is interested in investigating the effects of three different inhaled treatments in patients with asthma. The three treatments we are investigating are:

1. Ventolin inhaler when you need it (as-needed Ventolin)
2. Symbicort inhaler when you need it (as-needed Symbicort)
3. Twice-daily Pulmicort inhaler, and Ventolin inhaler when you need it (Regular Pulmicort and as-needed Ventolin).

More information about these treatments can be found in Section 3.

Medications, drugs and devices have to be approved for use by the Australian Federal Government. Ventolin, Symbicort and Pulmicort have all been approved by the Australian Federal Government for many years, for use by people with asthma.

However, at present, Symbicort is only approved by the Australian Federal Government for as-needed use for relief of asthma symptoms if the patient is also prescribed regular daily or twice daily Symbicort treatment. This means that use of Symbicort only as-needed for relief of asthma symptoms (without a regular inhaler as well) is an experimental treatment for mild asthma. This means that it must be tested to see if it is as effective a treatment as other current treatments for mild asthma.

We are interested in whether being on one of these treatments influences:

1. Your likelihood of having an asthma flare-up (exacerbation)
2. Your asthma symptoms
3. Your medication use

This study was designed by clinicians, including Associate Professor Helen Reddel, who were interested in finding out which inhaler treatment works best in asthma.

The research is being conducted by the Medical Research Institute of New Zealand. In Australia, the study is being sponsored by the Woolcock Institute of Medical Research. The study is fully funded by AstraZeneca, which is the company that makes Symbicort and Pulmicort.

If you have any questions about the study please feel free to contact the study doctor. Their details are included on page 14.

3&4 WHAT DOES PARTICIPATION IN THIS RESEARCH INVOLVE?

We have asked you to participate because you have mild asthma, are aged between 18 and 75 years and use only a reliever inhaler for your asthma.

The study runs for one year, during which you would receive one of the following three inhaled treatments described in the previous section:

1. As-needed Ventolin
   You will be provided with a Ventolin inhaler which you will take when you have symptoms of asthma. This medication quickly opens up the airways.

2. As-needed Symbicort
   You will be provided with a Symbicort inhaler which you will take when you have symptoms of asthma. Symbicort contains two medicines. One medicine will quickly open up your airways and the other medicine is a low dose corticosteroid which will
reduce airway inflammation.

3. Regular twice-daily Pulmicort and as-needed Ventolin
You will be provided with two types of inhaler. The Pulmicort inhaler is a low dose corticosteroid which will reduce airway inflammation and you will take this twice each day. The Ventolin inhaler will quickly open up your airways and you will take this when you have symptoms of asthma.

The inhalers you are given as part of this study contain an electronic monitor which records when you use it. It is therefore important that while you are on the study you only use the inhalers you have been allocated (unless directed otherwise by a doctor) and do not share your inhalers. You will be shown how to use the inhalers correctly.

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). This means that you will have a 1 in 3 chance of receiving each one. In this study, the study doctor will not know which treatment you will be given until it is time for them to give you your study inhalers.

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

You will be asked to sign a consent form before any study procedures are carried out.

The study involves at least seven visits to The Woolcock Institute of Medical Research. Each visit is expected to take between 30 and 60 minutes. You can take your medication as normal on the day of study visits (you do not need to withhold any medication prior to your visits).

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.

You may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the study visits, up to a maximum of $50 per visit.

Initial visit
There will be an initial visit to explain the study and for you to provide your written informed consent to participate. This visit should take between 30 and 60 minutes. We will collect some information about your health to check whether you are eligible to take part in the study.

You will not be eligible to take part in the study if:
- You are identified by the Study Doctor as having asthma that is too severe to take part
- You have other medical conditions which may impact on your response to the inhalers or your safety on the study
- You are unwilling to change your current asthma treatment medications
- There is any other factor which may adversely impact on your safety or the study results, as identified by the Study Doctor

If you are eligible to take part you will be invited to attend Visit 1. If it is convenient for you, Visit 1 will take place immediately following the Initial Visit. If it is not convenient for you we can schedule Visit 1 to take place at another time.
If you decide to participate in this research project, the study doctor will inform your local
doctor.

Visit 1
At this visit we will confirm that you are still eligible to take part and may ask further
questions about your health. We will ask you to fill in two short written questionnaires about
your asthma (which include questions about your symptoms and how you find using your
medication). Your height and weight will be recorded.

We will then measure your fractional exhaled nitric oxide levels (a gas you normally breathe
out). This is a simple test involving breathing into a mouthpiece and gives information about
inflammation in your lungs.

We will also measure spirometry. This involves blowing forcefully into a tube. This gives us
information about how your lungs are working. Some people feel light headed after
performing spirometry, this resolves quickly and you will be able to stop at any time.

A blood test will be taken, to measure the following:
- Full Blood Count
- Periostin (an asthma blood marker)

These tests are being done to give us information about your asthma severity and type.
We will take around 10mls of blood in total, however in some cases we may require extra
samples, for example to re-do a test that could not be analysed.

You will then be assigned one of the inhaler regimens. We will collect all of your usual
inhalers and provide you with the study ones. We will provide information on how to use the
inhalers and check your inhaler technique.

You will be given a written Asthma Action Plan to help you understand how to take your
inhalers and when to seek medical help. If you regularly use a peak flow meter to help you
manage your asthma, you will able to continue doing this throughout the study. You will also
be given information about how to care for your inhalers and when to contact the Study
Investigator.

This visit will take approximately one hour.

Visits 2-6
You will be asked to attend Visit 2 six weeks after Visit 1. After this, Visits 3 to 6 will take
place every 10 weeks. At these visits we will supply you with new inhalers, get you to fill in
one short written questionnaire (which includes questions about your symptoms), and
perform spirometry. At Visit 3 we will also repeat the fraction of exhaled nitric oxide test. We
will ask you how your health has been and check your inhaler technique. Each visit should
take between 30 and 60 minutes.

Visit 7
This will be your final visit and will take place 1 year after you started the study, or earlier if
the study doctor has to withdraw you from the study for safety reasons. We will ask you to fill
in two short written questionnaires about your asthma (which include questions about your
symptoms and how you find using your medication). We get you to perform the fraction of
exhaled nitric oxide test and spirometry again. We will ask you how your health has been
since the last visit and also ask you questions on exercise and inhaler use. The decision of
what asthma inhalers you will be prescribed after the study will depend on your usual GP.
We will inform your GP that you have completed the trial.

This visit will take approximately one hour.

Between Visits
Between visits you will be under the care of your usual GP or specialist. Should you need to seek medical assistance for your asthma, please go to your usual health care provider (GP, after hours service or hospital as appropriate). You will be treated in accordance with standard clinical care.

Please do not contact the Study Doctor for medical assistance as they are required to direct you to your usual health care provider.

You will be given a list of circumstances where you are asked to contact the Study Doctor. They will be available to take your call/email during business hours.

These are if:

1. You have sought medical help for your asthma (e.g. by going to a GP, after hours service or hospital) or you have started corticosteroid tablets (such as prednisone).
2. Your GP or another healthcare provider makes any changes to your asthma treatment (including changing your inhaler or giving you any new medications to help treat your asthma)
3. You are concerned you will run out of inhaler medication prior to the next study visit.
4. You are concerned any of your inhalers are not operating correctly
5. Any of your inhalers got wet, damaged or lost
6. You wish to withdraw from the study
7. You discover you are pregnant (Female participants)

You are free to withdraw from the study at any time, without giving a reason. Please inform the Study Investigator if this is the case as soon as you can, so that they can refer you back to your GP for follow up.

If you become pregnant or there is concern about your health or wellbeing during the study you will be withdrawn by the Study Investigator. This will be discussed with you at an Unscheduled Visit (see below).

Unscheduled visits
You may be asked to attend an additional study visit to check how you are and collect your inhalers if:
- We have concerns around your safety to continue in the study
- You are concerned you will run out of your inhaler medication before the next scheduled visit or any of your inhalers are not operating correctly
- You wish to withdraw from the study

This visit will take approximately half an hour.

Study Interview
On completion of the study we may ask you if you would be willing to complete an interview. This is with a Study Investigator who is interested in asking about how you found your time on the study. The aim is to enhance understanding of the study findings on patterns of medication use and the impact of treatment on patient beliefs.

You are welcome to decline taking part in this portion of the study. If you are willing to discuss your experience we will ask you to read a separate information sheet and sign a study interview consent form, then we would give your contact details to a Study Investigator in Australia who would contact you.
5. OTHER RELEVANT INFORMATION ABOUT THE RESEARCH PROJECT

This project involves researchers from New Zealand, Australia, the United Kingdom and Italy, working in collaboration.

The study is being conducted in New Zealand, Australia, the United Kingdom and Italy. In total, 675 participants with asthma will be recruited.

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; you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

If you do decide to take part, you will be given a Consent Form to sign and you will be given a copy of this document 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 relationship with The Woolcock Institute of Medical Research.

7. WHAT ARE THE ALTERNATIVES TO PARTICIPATION?

You do not have to take part in this research project to receive treatment at The Woolcock Institute of Medical Research. Other treatment options are available. These include continuing treatment with only an as-needed reliever such as Ventolin. For people with an asthma flare-up in the last 12 months, or with asthma symptoms more than twice a month, Australian asthma guidelines (Australian Asthma Handbook 2015) recommend taking regular treatment with a low dose inhaled corticosteroid preventer (such as budesonide [Pulmicort]) with an as-needed reliever, in order to reduce your risk of flare-ups and to reduce asthma symptoms. This preventive treatment needs to be taken regularly to be effective.

Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

8. WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

We cannot guarantee or promise that you will receive any benefits from this research. We are uncertain which participants will benefit the most from each of the study treatments. However, it is likely that most participants will obtain better asthma control during the study, through being provided with asthma education and inhalers for the duration of the study, having their inhaler technique checked, and being provided with a written asthma action plan.

Current research mainly focuses on moderate to severe asthma, however most adults with asthma have mild disease. This study will provide evidence to help guide clinical management of people with mild asthma and improve asthma guidelines. The information
we get from this study may therefore help us to better treat patients with asthma in the future.

9. WHAT ARE THE POSSIBLE RISKS AND DISADVANTAGES OF TAKING PART?

Risk of poor asthma control
We are uncertain which of the regimens will provide the best treatment for your asthma. It is possible that, given your asthma symptoms, you might be allocated to inhalers that are not what you would usually be given by your doctor, based on the current guideline recommendations. All inhalers used in this study have been commonly used in Australia and internationally for decades for the treatment of asthma.

We will be checking very carefully that your asthma is not too severe for you to take part in this study (see page 3). However, once you are enrolled in the study, the chance of you being allocated to a particular regimen will not be based on your asthma symptoms, it will be by chance.

At each visit you will be asked about how your asthma is and the data recorded by the inhaler monitors will be collected. Between visits you will be asked to contact the investigator if you have a worsening of your symptoms requiring you to seek medical review. If you or the Study Doctor are concerned about your asthma control you may be withdrawn from the study for your safety. You would be referred back to your GP who would place you on the inhalers appropriate for you, based on your symptoms and other medical history.

Risk of medication side effects
Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

All of the medications that are being used in this study are already approved for asthma by the Australian Federal Government on the basis of their benefits outweighing their known or expected risks. Although there could be other side effects that we are unaware of, this is unlikely as the inhalers have been commonly used in the treatment of asthma for decades.

It is important that you contact the Study Doctor to let them know if you have any new or unusual symptoms. You should not let this delay you seeking medical help if you require it. Many side effects go away shortly after treatment ends or if the medication dose is reduced. Your study doctor will discuss the best way of managing any side effects with you.

For each of the study medications, most of the side-effects listed below are only seen at doses substantially higher than will be used in this study.

Ventolin:
Common (1 in 10 – 100 people): Increased heart rate (heart beating fast), tremor, headache.

Uncommon (1 in 100 to 1000 people): Mouth and throat irritation, muscle cramps, irregular heart rhythms.
Rare (1 in 1,000 - 10,000 people): low levels of potassium in the blood, peripheral vasodilatation.

Very Rare (Less than 1 in 10,000 people): Severe allergic reaction, bronchospasm (bronchospasm (sudden tightening of the air way)), hyperactivity, changes in blood pressure, sustained heart rhythm disturbances.

Symbicort:
Common (1 in 10 – 100 people): Heart palpitations, thrush in the mouth and throat after long term use, headache, slight muscle shaking, mild throat discomfort, coughing, hoarseness, dry mouth.

Uncommon (1 in 100 to 1000 people): Increased heart rate (heart beating fast), nausea, diarrhoea, muscle cramps, dizziness, light headedness, bad taste, thirstiness, tiredness, agitation, restlessness, nervousness, sleep disturbances, weight gain.

Rare (1 in 1,000 - 10,000 people): Severe allergic reaction, irregular heart rhythms, bronchospasm (sudden tightening of the air way), skin bruising, low levels of potassium in the blood.

Very Rare (Less than 1 in 10,000 people): Severe pain/tightening in the chest, hormone disturbances, high blood sugar, depression, behavioural disturbances, changes in blood pressure.

Pulmicort:
Common (1 in 10 - 100 people): hoarseness; sore, irritated throat; irritation of the tongue and mouth; dry mouth; thrush in the tongue and mouth after long term use; cough.

Uncommon (1 in 100 to 1000 people): Mild throat discomfort; bad taste; diarrhoea; nausea; immediate and delayed mild allergic reactions (eg rash); severe allergic reactions; angioedema (swelling). Headache, lightheadedness, thirst, tiredness, weight gain.

Rare (1 in 1,000 – 10,000 people): Skin bruising; bronchospasm (sudden tightening of the airway).

Risks associated with pregnancy (Female Participants)
Females pregnant, breastfeeding or planning pregnancy at the time of recruitment will be excluded from participating in the study. Should you become pregnant during the course of the trial you should inform investigators at the earliest opportunity and be withdrawn from the study. While current clinical practice recommends active treatment of asthma during pregnancy, and allows for the use of the study inhalers during pregnancy, it is important that while you are pregnant your asthma treatment is tailored to your symptoms, particularly as they can change during pregnancy. As a result you would be withdrawn from the study so that you could be placed under the care of your GP, who will place you on the most appropriate inhaler treatment for you during your pregnancy.

Female participants are requested to use effective contraception during the study. The Study Doctor can discuss methods of effective contraception with you.
Risks associated with blood tests
You may experience some discomfort during the taking of a blood sample and there is always the risk of bleeding, swelling and bruising at the site of the sampling. All samples will be taken by trained staff.

Risks associated with spirometry tests
You may feel some discomfort during or after performing the breathing exercises, however this will be temporary and you will be monitored constantly throughout the tests by study staff. You will be seated at all times for the tests.

10. WHAT WILL HAPPEN TO MY BLOOD SAMPLES?
A local laboratory will analyse your full blood count sample. Periostin will be analysed at a central laboratory outside of Australia, by Covance. This laboratory is based in the USA.

If you choose to withdraw and your blood sample has not yet been analysed, you may ask the study doctor to destroy it. If your blood sample has been analysed before you have withdrawn, you may ask the study doctor to withdraw this data from the study results, if you wish. The study doctor will contact the Sponsor, who will organise the withdrawal of data and samples, as per your wishes.

11. 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.

12. CAN I HAVE OTHER TREATMENTS DURING THIS RESEARCH PROJECT?
While you are participating in this research project, you should not take any other treatment for your asthma. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor will explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

13. WHAT IF I WITHDRAW FROM THIS RESEARCH PROJECT?
You may withdraw from the study at any time. If you decide to withdraw from the study, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your 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 law.

We will ask you to attend an optional final visit in order to return the study inhalers and discuss any study questions with you. We will also ask if you wish to sign an optional withdrawal form, to confirm if we are able to use your study data up until your withdrawal. If you do not attend the withdrawal visit and complete the withdrawal form, we will use the data you have provided up until the point of your withdrawal.

14. 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:
- One treatment being shown to be much more effective than the other treatments
- Decisions made by local regulatory or health authorities.

15. WHAT HAPPENS WHEN THE RESEARCH PROJECT ENDS?

The decision of what asthma inhalers you will be prescribed after the study will depend on your usual GP. We will inform your GP that you have completed the trial.

At the completion of the study we can give you a summary of the results if you wish. This can be e-mailed or posted to you. There may be a substantial delay between taking part in the study and receiving the results due to ongoing recruitment for the study.

Part 2 How is the research project being conducted?

16. 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 research project. Any information obtained in connection with this research project that can identify you will remain confidential. 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.

We may also need to access your hospital, afterhours or GP records to check health care information (for example to check the date you last visited your GP and whether they prescribed you with prednisone).

The data we collect for the study will be coded, so that your name (and other identifiable information) is removed and replaced with a unique participant identification number. This means that the data sent to the Sponsor (or their representative) will not be identifiable. Your blood samples will also be coded in the same way, to protect your privacy. The study site staff will have access to your health information during the study and will keep a confidential log to link your unique number to your name and other identifiable information. Original data records will be kept in a secure place for 15 years and then destroyed.

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 International Sponsor (Medical Research
Institute of New Zealand), the Australian Sponsor (Woolcock Institute of Medical Research), the institution relevant to this Participant Information Sheet (The Woolcock Institute of Medical Research), 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.

The Study Staff, Sponsor and all other parties will keep your information secure and confidential, as per the law. Your health information may be given if required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. No material which could personally identify you will be used in any reports on this study.

In accordance with relevant Australian and/or NSW 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 and for the future research described in Section 16 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.

17. 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.

In the event of loss or injury, the parties involved in this research project have agreed to follow the Medicines Australia “Guidelines for Compensation for Injury for Injury Resulting from Participation in a Clinical Trial”.

18 WHO IS ORGANISING AND FUNDING THE RESEARCH?

This research project is being conducted by the Medical Research Institute of New Zealand, and sponsored in Australia by Woolcock Institute of Medical Research. It is being funded by AstraZeneca, the company that produces Symbicort and Pulmicort.

The funder, AstraZeneca, may benefit financially from this research project if, for example, the project assists them to obtain approval to use their drug in a greater number of patients.

By taking part in this research project you agree that samples of your blood or tissue (or data generated from analysis of these materials) may be provided to the Australian Sponsor, Woolcock Institute of Medical Research or Global Sponsor, Medical Research Institute of New Zealand.
You will not benefit financially from your involvement in this research project even if, for example, knowledge acquired from analysis of your samples prove to be of commercial value to AstraZeneca.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to AstraZeneca, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

Woolcock Institute of Medical Research and Liverpool Hospital will receive a payment from Medical Research Institute of New Zealand for undertaking this research project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**Declarations of interest**

**Medical Research Institute of New Zealand**: has received funding from AstraZeneca, GSK, Novartis, Genentech Inc, Roche, Teva (previously Cephalon Inc), Covance, Sanofi Aventis, Adherium (previously Nexus6) and Fisher and Paykel Healthcare in the form of sponsorship of clinical research studies, independent investigator led research funding and provision of medical devices for research purposes.

**Woolcock Institute of Medical Research**: has received funding from AstraZeneca, Aspen Pharma, Boehringer Ingelheim, GSK and Novartis in the form of support for Postgraduate Student Research Symposium awards, sponsorship of trade displays and educational events, venue hire and sponsorship of some clinical research studies.

**Associate Professor Helen Reddel**: has received reimbursement for the following activities in the past 3 years: provision of independent medical education at symposia funded by AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Merck, Mundipharma, Novartis, Teva; provision of independent advice in advisory boards and/or safety monitoring boards for AstraZeneca, GlaxoSmithKline, Merck and Novartis; and has received independent research funding from AstraZeneca and GlaxoSmithKline.

**Professor Guy Marks**: has received reimbursement for the following activities in the past 3 years: independent research funding from AstraZeneca; funding for research sponsored by GlaxoSmithKline and provision of independent advice on an advisory board for Novartis.

19. **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 South Western Sydney Local Health District.

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.
20 FURTHER INFORMATION AND WHO TO CONTACT?

If you have any questions, concerns or complaints about the study at any stage, you can contact one of the Study Investigators:

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 02 9114 0437 (during business hours) or any of the following people:

**Clinical contact person**

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<thead>
<tr>
<th>Name</th>
<th>Associate Professor Helen Reddel</th>
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<tbody>
<tr>
<td>Position</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>Telephone</td>
<td>0412 360 205</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:helen.reddel@woolcock.org.au">helen.reddel@woolcock.org.au</a></td>
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<tr>
<th>Name</th>
<th>Dr Gloria Foxley</th>
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<tr>
<td>Position</td>
<td>Clinical Research Coordinator</td>
</tr>
<tr>
<td>Telephone</td>
<td>02 9114 0444</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:gloria.foxley@woolcock.org.au">gloria.foxley@woolcock.org.au</a></td>
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For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Reviewing HREC approving this research and HREC Executive Officer details**

This study has been approved by the South Western Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Ethics and Research Governance Office, Locked Bag 7279, LIVERPOOL BC, NSW, 1871 on 02 8738 8304, fax 02 8738 8310, email research.support@sswahs.nsw.gov.au, website: http://www.sswahs.nsw.gov.au/swslhdeurope/default.html and quote 15/306.

The conduct of this study at The Woolcock Institute of Medical Research has been authorised by the Woolcock Institute of Medical Research, any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on (02) 9114 0412, email: joanne.elliot@woolcock.org.au and quote project number [15/306]

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form. This information sheet is for you to keep.