



Participant Information Sheet/Consent Form

Monash University

Title	Metformin for low back pain – a randomised, double-blind, placebo-controlled trial to examine the effectiveness of metformin for chronic low back pain
Short Title	Metformin for low back pain
Project Number	392/21
Project Sponsor	Monash University
Principal Investigators	Professor Flavia Cicuttini, Assoc Prof Donna Urquhart, Dr Yuanyuan Wang
Associate Investigators	Prof Anita Wluka, Ms Molly Bond, Ms Mahnuma Estee, Dr Yuan Lim, Dr Louisa Chou, Ms Ekjyot Kaur, Mr Sai Prasad Badam, Mr Ashish Dinesh Nair
Location	School of Public Health and Preventive Medicine, Monash University

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have low back pain. The research project is testing a new treatment for low back pain. The new treatment is metformin, a drug widely used to treat type 2 diabetes that has not been tested in low back pain.

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. The Participant Information and Consent Form is 12 pages long in total. Please make sure that you have all the pages.

2 What is the purpose of this research?

Low back pain is the leading cause of disability globally. It is very common, with 80% of people experiencing back pain during their lifetime. Although low back pain causes significant pain and impaired physical function, there are currently limited treatments.

Metformin is an oral biguanide (a group of oral type 2 diabetes medications that work by preventing the production of sugar in the liver) that is a widely used and effective treatment for patients, including children, with type 2 diabetes mellitus (a condition with abnormally high levels of glucose in the blood). The main effect of metformin is to reduce blood glucose levels, resulting in sustained modest weight loss, and lowering of lipids (or fats) and inflammation. There is emerging evidence suggesting metformin may have the potential to reduce pain in people with low back pain. Metformin is well-tolerated, inexpensive and has a long history of safe clinical use.

The 'Metformin for low back pain' study is a randomised clinical trial with the aim to compare the effect of metformin with an inactive 'dummy' tablet (that is called a placebo) on low back pain and function. If metformin is effective, it will offer a new way to improve pain and function in those with low back pain.

Metformin has been approved in Australia (by the Australian Government's Therapeutic Goods Administration) to treat type 2 diabetes mellitus for more than 20 years. However, it is not approved to treat low back pain. Therefore, it is an experimental treatment for low back pain. This means that it must be tested to see if it is an effective treatment for low back pain.

The research team conducting this study includes rheumatologists, medical doctors and physiotherapists extensively experienced in the treatment of back pain.

A total of 123 participants will participate in this project. They will be randomly allocated into two groups, with one group receiving metformin and the other group receiving a placebo.

This research is a clinical trial being conducted by Monash University. This research has been initiated by the study investigators; Professor Flavia Cicuttini, Assoc Prof Donna Urquhart and Dr Yuanyuan Wang.

This research has been funded by Monash University.

The results of this research may be used by student investigators to obtain their Honours, Masters or PhD degree.

3 What does participation in this research involve?

If you agree to participate in the study, we will ask you to do the following:

1. Participation in this trial will initially involve a screening process. You will be screened for your suitability for the study over the phone by answering simple questions about your health.

If you meet the inclusion criteria, a Participant Information Sheet and consent form will be mailed out to you. You will have an interview with a research assistant and a study doctor through telehealth or onsite study visit at our Clinical Trials Centre (553 St Kilda Road) Monash University, during which any of your questions can be answered. If you agree to participate in the study, you will be asked to provide consent, by signing the consent form (either with a pen, if you are at the study site, or electronically, if the visit is conducted by Telehealth).

If you have your initial appointment over telehealth, we will explain the PICF to you while you look at the copy that has been previously posted to you. We will provide opportunities to ask questions and if you would like to participate, then we will ask you to sign the consent form electronically in REDCap (i.e. Research Electronic Data Capture, a secure web platform to capture data for clinical research) which can be accessed on a computer, mobile phone, or tablet.

You will open the survey and read through the consent form (which you have already received). When you get to the bottom of the consent form, you will have the opportunity to fill in your information and 'sign' your consent by typing in your name or by utilizing REDCap's 'Signature' field type on the survey. You will select "Next Page" and a read only copy of the consent will be generated that you can review, download, and print. At the bottom of the page you will need to select "I certify that all the information in the document above is correct. I understand that clicking "Submit" will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document" and "Submit". Following the Telehealth screening/baseline appointment, the research assistant will post a hard copy of the signed eConsent pdf form to you to ensure you have a copy.

You will undergo a clinical assessment and complete questionnaires. In order to further assess your eligibility for the study, you will have blood tests at Melbourne Pathology.

During this screening period, at any stage, if the researchers identify any reason that would put you at increased risk by being involved in the study, or any reason that would make it inappropriate for you to participate in the study, you will be asked not to continue in the study.

2. If you are eligible to participate, you will be randomly assigned to either the treatment or the control group. The term "randomised" means you will not have a choice regarding which group you are in, and you will have equal chance of receiving the active study medication or placebo.

You will be sent the medication or placebo by Syntro Health, a company which specialises in the manufacturing and dispensing of medications for clinical trials. Four months of the medication/placebo will be couriered to you by Syntro Health and if you are not at home, will be left in a safe place and the company will be in contact with you to confirm that you have received the medication. The treatment group will receive metformin tablets (up to a dose of 2000 milligrams, 2 tablets, once daily) and the control group will receive a placebo (up to 2 tablets, once daily). A placebo is a medication with no active ingredients. It looks like the real thing but is not.

You will initially take 500 milligrams (1 tablet) per day for 2 weeks. Providing you do not experience any adverse effects, the dose will be increased by 500 milligrams (1 tablet) per day every 2 weeks until you are taking 2000 milligrams per day. You will take this dose for the rest of the study. So you will take study medication (metformin or placebo) for 4 months.

Week 1-2: 500mg (1 x 500mg tablet) per day
Week 3-4: 1000mg (2 x 500mg tablets) per day
Week 5-6: 1500mg (3 x 500mg tablets) per day
Week 7-8 and onwards: 2000mg (2 x 1000mg tablets) per day

As this is a "double-blind" trial, neither you nor the study investigator will know which treatment you are receiving until the study is completed. However, in certain circumstances the study investigator may find out which treatment you are receiving.

3. The trial will go for 4 months to examine the effect of metformin on reducing low back pain.

Prior to starting the trial, you will have 1 study visit [through telehealth or attending our Clinical Trials Centre (553 St Kilda Road)] that will take about 60 minutes. We can provide an

attendance certificate signed by the research investigator for each in-person onsite study visit.

At baseline and 4 months, you will receive daily text messages for 1 week asking you about your pain intensity and inviting you to reply to the message with a number from 0 to 10 indicating your current low back pain intensity level (where 0 is no pain and 10 is the worst pain imaginable).

At baseline and 4 months, you will be asked to wear an accelerometer (AX3, Axivity (UK)), which is a small device that measures your physical activity levels, for 7 days.

You will also have a monthly telephone contact to collect information about your use of medications.

4. The following measurements will occur during the study period.

- At screening/baseline:
 - (1) measurement or self-report of height, weight, and waist and hip circumference
 - (2) questionnaires (electronic or paper-based surveys) –to collect information about your medical history/conditions, medication, employment, education, smoking, alcohol intake, low back pain intensity and disability, physical activity levels, use of narcotics, perceived improvement, quality of life, psychosocial factors and neuropathic pain.
 - (3) blood test for kidney and liver function, fasting glucose and lipids, vitamin B12, and inflammatory biomarkers.
 - (4) measurement of current pain intensity on a daily basis for 7 days using text messaging.
 - (5) measurement of physical activity levels using an accelerometer for a 7 day period
- Monthly telephone call during the 4 month trial: to collect information about pain, medication use (including narcotic use), treatment adherence and adverse events.
- At final (4 month) follow-up:
 - (1) questionnaires (electronic or paper-based surveys) – to collect information as per baseline;
 - (2) blood test for kidney and liver function, fasting glucose and lipids, vitamin B12, and inflammatory biomarkers.
 - (3) measurement of current pain intensity on a daily basis for 7 days using text messaging.
 - (4) measurement of physical activity levels using an accelerometer for a 7 day period.
- Compliance will also be assessed by pill count at 4 months.

At baseline and final (4 month) study visits, you will be asked to complete questionnaires online in REDCap (i.e. Research Electronic Data Capture, a secure web platform to capture data for clinical research and create online databases and surveys), facilitated by the research assistant. If you prefer a hard copy, you will be provided with printed questionnaires to complete manually; the research assistant will add the data online.

The following table shows you the procedures that are done at each study visit and telephone interview.

Table 2. Schedule of assessments

	Screening		Trial period	
	Screening/ baseline assessment	Randomisation	1, 2, 3 months	4 months
Phone screening	X			
Informed consent	X			
Study visit (telehealth or study visit)	X			
Telephone interview				X
Blood test	X			X
Medications	X			X
Medical history / treatment	X			X
Questionnaires				
Low back pain intensity	X^		X	X^
Low back disability	X			X
Physical activity	X			X
Narcotic use	X		X	X*
Global improvement	X			X
Quality of life	X			X
Psychosocial factors	X			X
Neuropathic pain	X			X
Explanatory factors eg medication	X			X
Physical examination				
Height, weight, waist and hip circumference	X			
Compliance and safety (adverse events)	X		X	X
Dispense medication		X		

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

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 will be reimbursed for any reasonable travel and parking associated with the research project visit (maximum \$30). If study visits are via telehealth, you will receive a gift voucher (\$10) after your baseline and final visits.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we will provide a letter to your local doctor informing them of your participation in this research project.

If you choose to withdraw from this study before 4 months, you will be asked to participate in a follow-up phone call to allow collection of information regarding your health status.

4 What do I have to do?

You will be required to initially take 500 milligrams (1 tablet) per day with your evening meal for 2 weeks. Providing you do not experience any adverse effects, the dose will be increased by 500 milligrams (1 tablet) per day every 2 weeks until you are taking 2000 milligrams per day. You will take this for the rest of the study (2 tablets, 1000 milligrams/tablet). So you will take study medication for a total of 4 months.

You will need to commit to taking the investigational medication regularly. You will need to attend the initial study visit and participate in the monthly phone calls.

Whilst involved in this study, you can take your regular medications. We will screen for medications unsuitable for this study. You will need to record all medications and report these when phoned every month. You may not be able to donate blood while you are in the study.

You should tell your doctor and study personnel if you are taking any other medications, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Some medications may be affected by metformin or may affect how well metformin works. It is also important not to start taking any other medications during the study without talking to your doctor and research staff. If you start any new medications during the study please tell your doctor and the research staff.

5 Other relevant information about the research project

A total of 123 participants with low back pain aged between 18-65 years will be recruited in Melbourne. The project will have two groups, with one group receiving metformin and the other group receiving a placebo. All participants will be followed up over 4 months to examine whether metformin has an effect on symptoms.

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.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy 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 Monash University.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment. You can see your doctor or health care professional to discuss different treatment options for your low back pain, such as physiotherapy and medications for pain relief. 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 before deciding whether or not to take part in this research project.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, some participants may experience possible benefits, such as improvement in their low back pain. If this study shows that metformin is effective in reducing low back pain, it may enable this treatment to be available to more people in the future.

We will inform you of any abnormal findings from your blood tests, so that you can then consult with your doctor.

9 What are the possible risks and disadvantages of taking part?

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.

Side effects of metformin

Use of metformin is an established safe and well-tolerated treatment to lower blood glucose. The dose of metformin we use in this study is commonly used for type 2 diabetes mellitus. Metformin may have unwanted side effects in some people.

Most common side effects (affects 1 in 10 to 1 in 100 users) include:

- gastrointestinal symptoms: diarrhoea, nausea, vomiting, abdominal pain, indigestion, loss of appetite
- taste disturbance
- headache

Uncommon or rare side effects (affects 1 in 10,000 users) include:

- skin reactions: erythema, pruritus, urticarial
- lactic acidosis
- decrease of vitamin B12 absorption
- liver function test abnormalities or hepatitis resolving upon metformin discontinuation

Pregnancy risks

The effects of metformin on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding.

If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project.

If you are male, you should not father a child or donate sperm for at least three months after the last dose of study medication.

Both male and female participants are strongly advised to use effective contraception during the course of the research and for a period of three months after completion of the research project. You should discuss methods of effective contraception with your study doctor.

If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary.

Unknown side effects

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Tell the study doctor if you have any problems. Your study doctor will monitor for and discuss the best way of managing any side effects with you, should they occur.

Risks of procedures in this study

Having blood taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated. Blood samples is collected by a qualified venpuncturist. We endeavour to make the collection process as simple and as stress free as possible.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team.

10 What will happen to my test samples?

This research project involves the collection, testing and analysis of your blood samples.

The collection and testing of your blood sample is a mandatory component of the research. This is done to examine your liver function, kidney function, blood lipids, blood glucose, vitamin B12, and inflammatory biomarkers in order to assess your suitability for the study and monitor the safety and efficacy of the treatment.

Your blood samples will be re-identifiable (i.e. coded, without your name on them), and will be tested at Melbourne Pathology for the proposed blood tests. Blood samples will be destroyed after testing.

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?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. 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 also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

It may also be necessary for you to take medication during or after the research project to address side effects or symptoms caused by participation in the study that you may have. This will be paid for by the sponsor of the study.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, 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 investigator 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. You should be aware that data collected by the study investigator 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.

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:

- Unacceptable side effects
- The drug/treatment being shown not to be effective
- The drug/treatment being shown to work and not requiring further testing

15 What happens when the research project ends?

At the completion of the trial, if you wish to know whether you received metformin or the placebo, please contact the research personnel for further information.

We will send you a follow-up letter to inform you of the findings of the study.

Metformin or placebo will be provided to you during the trial for a 4 month period at no cost. Once the trial has finished we will not be able to continue to provide this treatment to you. However, if your doctor is in agreement with continuing the treatment after the trial, he/she can provide you with a prescription for metformin. From this point you will need to cover the cost of your medication.

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 investigator 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.

Monash REDCap will be used for collection and storage of data. The data we collect or use will be individually identifiable or re-identifiable (i.e. coded which means that the data we collect from you will be directly linked to your study ID number). All electronic data will be kept in password-protected databases, separate from identifying information. The completed eConsent PDFs are stored in REDCap in a File Repository under "PDF Survey Archive". The REDCap is password protected and access restricted to study investigators. Hard copies of eConsent form and data will be kept in locked filing cabinets with restricted key access, at the Department of Epidemiology and Preventive Medicine, Monash University.

Access to data will be limited to the principal and associate investigators and support staff only. Data transfer will occur so that the final dataset with re-identifiable (i.e. coded) data can be accessed by all the chief investigators of the study. Identifiable information will not be released to anyone outside the research team.

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.

By signing the consent form you consent to the study investigator using your data collected for this project for extended related research. Your data collected for this project may be combined with data collected from other studies for meta-analyses. In this case only re-identifiable data will be used.

Information from questionnaires and physical examinations will be retained for at least 15 years upon completion of the study. This research project does not involve the establishment of a databank.

It is necessary that your local doctor be advised of your decision to participate in this research project. By signing the consent section, you agree to your local doctor being notified of your decision to participate in this research project.

It is anticipated that the results of this research project will be published and presented in a variety of forums. In any publication, report, or presentation, information will be provided in such a way that you cannot be identified, except with your permission. This confidentiality will be maintained by presenting aggregate data.

Should any sharing of data be considered (e.g. for combining data with other studies), then data sharing will only involve re-identified (i.e. coded) data, i.e. data that is shared will not include identifiable information. In the event where personal information (e.g. name, date of birth) may need to be shared (e.g. data linkage), we will contact you or your guardian for consent for data sharing.

In accordance with relevant Australian and Victorian 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.

If you are not satisfied with how your personal information has been handled (as laid out in the Privacy Act, 1988), then you can make a complaint to the Office of the Australian Information Commissioner (OAIC). Please refer to <http://www.oaic.gov.au/privacy/privacy-complaints> for more information.

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.

18 Who is organising and funding the research?

This research project is being conducted in Melbourne by Professor Flavia Cicuttini, Assoc Professor Donna Urquhart, and Dr Yuanyuan Wang and is being funded by the National Health and Medical Research Council.

By taking part in this research project you agree that data generated from this project may be provided to Monash University. Monash University may directly or indirectly benefit financially from knowledge acquired through analysis of your data.

You will not benefit financially from your involvement in this research project even if, for example, knowledge acquired from analysis of your data prove to be of commercial value to Monash University.

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

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

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 Alfred Hospital Ethics Committee.

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

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 investigator:

Professor Flavia Cicuttini (Monash University): 9903 0158, flavia.cicuttini@monash.edu

Clinical contact person

Name	Professor Flavia Cicuttini	
Position	Head Rheumatology, Alfred Hospital Head Musculoskeletal Unit, Monash University	Alfred Hospital Rheumatology Registrar (outside office hours)
Telephone	9903 0158	9076 2000
Email	flavia.cicuttini@monash.edu	

Project team contact information

Name	Ms Molly Bond
Position	Project officer
Telephone	9903 0553
Email	jointstudy@monash.edu

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

Complaints contact person

Position	Complaints Officer (Alfred Health)
Telephone	03 9076 3619
Email	research@alfred.org.au

Position	Complaints Officer (Monash University)
Telephone	03 9905 2052
Email	muhrec@monash.edu

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Alfred Hospital Ethics Committee
Position	HREC Executive Officer
Telephone	03 9076 3619
Email	research@alfred.org.au

Consent Form

Title Metformin for Low Back Pain – a randomised, double-blind, placebo-controlled trial

Short Title Metformin for Low Back pain

Project Number 392/21

Project Sponsor Monash University

Principal Investigators Professor Flavia Cicuttini, Assoc Prof Donna Urquhart, Dr Yuanyuan Wang

Associate Investigators Prof Anita Wluka, Ms Molly Bond, Ms Mahnuma Estee, Dr Yuan Lim, Dr Louisa Chou, Ms Ekjyot Kaur, Mr Sai Prasad Badam, Mr Ashish Dinesh Nair

Location School of Public Health and Preventive Medicine, Monash University

Consent Agreement

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 for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Monash University 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.

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____
Signature _____ Date _____

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.

Name of Study Doctor/ Senior Researcher [†] (please print) _____
Signature _____ Date _____

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

Note: All parties signing the consent section must date their own signature.