The Royal Melbourne Hospital

Participant Information & Consent Form

Title	A randomised double-blind dose non-inferiority trial of a daily dose of 600mg versus 300mg versus 100mg of enteric coated aspirin as a cancer preventive in carriers of a germline pathological mismatch repair gene defect, Lynch Syndrome.
Short Title	A randomised double-blind dose non-inferiority trial of aspirin in Lynch Syndrome.
Central HREC number	HREC/16/MH/39
Principal Investigator	Prof Finlay Macrae
Location	The Royal Melbourne Hospital Level 3 Centre Department of Colorectal Medicine & Genetics

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have Lynch Syndrome. The research project focuses on finding the right dose of aspirin for cancer prevention in people with Lynch Syndrome.

This Participant Information Sheet and 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.

2 What is the purpose of this research?

This study will focus on finding the right dose of aspirin for cancer prevention in people with a mismatch repair (MMR) gene defect, the underlying cause of Lynch syndrome, also known as HNPCC (Hereditary Non-Polyposis Colon Cancer). Our previous study CaPP2 showed that 600mg of aspirin was effective at reducing the risk of cancer in people with Lynch Syndrome and in this study (CaPP3) we would like to determine if 100mg and 300mg of aspirin will be as effective as the higher dose. Aspirin sometimes causes side effects. About one person in every 1000 develops an ulcer which can cause bleeding in the stomach. This side effect occurs more often when people take bigger doses of aspirin. We want to give as little aspirin as possible for cancer prevention but we need to be sure that the smaller dose still works.

Aspirin is approved by the Therapeutic Goods Administration in Australia for the relief of pain and fever, and to help reduce blood clotting. Taken every day, aspirin helps to reduce the risk of heart attack and stroke in patients with known diseased blood vessels supplying the heart and brain. However it is not approved by the Therapeutic Goods Administration in Australia for cancer prevention in patients who have Lynch Syndrome. Therefore, it is an experimental cancer prevention treatment for Lynch Syndrome sufferers.

This research project has been initiated in Australia by the study doctor, Professor Finlay Macrae, in collaboration with colleagues in the United Kingdom at Newcastle University.

This research has been co-funded by Cancer Australia and Cancer Council New South Wales. Professor Finlay Macrae's department, Colorectal Medicine & Genetics at the Royal Melbourne Hospital, will also cover some costs in relation to this study.

This research is being conducted in Australia by the Royal Melbourne Hospital and the Peter MacCallum Cancer Centre in Melbourne, St Vincent's Hospital (Sydney), the Royal Brisbane and Women's Hospital and the King Edward Memorial Hospital in Western Australia.

3 What does participation in this research involve?

This study involves comparing 3 different dose levels of aspirin (100mg, 300mg or 600mg) in patients who have Lynch Syndrome.

If you decide to take part in this study, we will make an appointment for you to come in and talk about the study with the study team doctor or delegate. After you are satisfied and are happy to go ahead with participating in this study, we will ask you to sign the attached consent form with the study doctor. The consent form will need to be signed prior to any study assessments being performed.

All studies have different inclusion and exclusion criteria. After the consent form has been signed, the study staff will go through the following with you to determine if this study is suitable for you to participate. Some of this information may have been obtained from your medical record but it is always good to confirm this medical information with you. The following information will be collected from you:

- Demography (Eg. Birth date, place of birth, gender, ethnicity)
- Medical Illness History
- Medication History
- Ability to swallow tablets
- Known hypersensitivities or allergies
- Pregnancy status and breastfeeding status
- Previous clinical trials
- Smoking and alcohol history
- Vital signs (blood pressure, height, weight, temperature, pulse)
- Optional Blood sample

If after collecting this information, the study is found to be suitable for you, you will be randomly allocated to one of the following doses through a computer program.

Some people will be on **600mg** of aspirin each day.
Some people will be on **300mg** of aspirin each day.
Some people will be on **100mg** of aspirin each day.

There is **no** placebo group; everyone will be on active aspirin.
This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

This study is a randomised controlled research project. We do not know which dose is best for cancer prevention. To find out we need to compare different doses. We put people into groups and give each group a different dose. 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). You will have a 4 out of 10 chance of receiving the 600mg dose, and a 3 out of 10 chance of receiving either the 300mg or 100mg dose.

You will be given a blister pack of aspirin. Each day you will be required to take 3 tablets which make up your randomised dose. The tablet is for oral consumption and must be swallowed.

You will be participating in a double-blind study. This means that neither you nor your study doctor will know which treatment you are receiving. However, in certain circumstances your study doctor can find out which treatment you are receiving. This information will be made available to the study team when the results are being analysed at the end of the study.

You will be on the randomised daily aspirin dose (either 600mg or 300mg or 100mg) for 2 years. After the 2 years, everyone will be asked to take a 100mg daily dose of aspirin for another 3 years.

There are only three visits as part of this study. This will be a initial visit to sign consent, one at 24 months and then at 5 years. Vital signs (blood pressure, temperature, heart rate) will be done at each of these visits.

If you agree and participate in the optional blood collection, a small amount of blood will be collected from you at your first visit, at the 24 months visit and at the 5 year visit. This blood will be used to extract genetic material such as deoxyribonucleic acid (DNA) and serum.

You will be regularly contacted by the CaPP3 study team for updates on your progress and to ask you some questions about your health. You will be contacted at 3, 6, 12, 18 and 24 months and then annually at 3 years and 4 years. After 5 years we will ask you if you would like to be followed up for a further 10 years with an annual phone call. The phone calls should take no longer than 30 minutes.

Visit /Phone Call	Screening/ Baseline/ Consent	First phone call 3 months	Follow Up phone calls 6, 12 18 months	Switch to open label 24 month visit	3 and 4 year follow up	5 year follow up visit	6, 7, 8, 9, 10, 11, 12, 13, 14, 15 year follow up phone calls
Study Procedures							
Informed Consent	X						
Medical History/ Health Questionnaire	X						
Optional blood sample (FOR RMH SITE ONLY – DELETE AS REQUIRED)	X			X		X	
Vital Signs	X			X		X	
Randomised Dose Dispensing	X		X				
Open Label Dose Dispensing				X	X		
Medication and Adverse Events Check	X	X	X	X	X	X	X

The aspirin will be dispensed through the trial pharmacy and in some circumstances delivered to your home every 6 months; your first aspirin package will be available after you have been consented into the study.

Before signing this consent form, please be sure that you will be committed to this research study and are willing to take aspirin for the duration of the study. We will also need you to be contactable throughout the study to check on your progress.

There are no additional costs associated with participating in this research project, nor will you be paid. All study medication, tests and medical care required as part of the research project will be provided to you free of charge, though your regular colonoscopies and other medical needs will be done as per usual standard of care.

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 strongly recommend that you inform them of your participation in this research project.

You can contact your research nurse or doctor at any time (contact details below) if you have any problems/questions during the trial.

4 What do I have to do?

You will be advised to avoid taking any aspirin-containing over-the-counter pain relief medication and to take an alternative (such as paracetamol) when pain relief is necessary. You will need to check with the pharmacist before purchasing if you are not sure. Medications that are not allowed while in the trial are methotrexate, regular (more than 3 x per week) use of aspirin, and regular (more than 3 x per week) non-steroidal anti-inflammatory drugs (NSAIDs) such as Nurofen, Voltaren, Brufen.

We request that you advise us of a diagnosis of a new cancer of any kind. A full medical report will be requested from your treating medical specialist and reviewed by the chief investigator who will make any further enquiries necessary. In the event of a new cancer diagnosis, you will

not be required to stop taking aspirin however if you wish to withdraw from the study and stop taking aspirin you can withdraw at any time.

Your normal colonoscopy scheduling will not be affected by this study.

5 Other relevant information about the research project

This study is part of a much larger study run at the Institute of Genetic Medicine in Newcastle University, United Kingdom.

180 participants will take part in this study in Australia. Overall, the Newcastle University would like to recruit 3000 participants worldwide, including 1500 from UK.

The previous trial, CaPP2, demonstrated a significant 63% reduction in colorectal and related cancers using 600mg of aspirin per day. The current trial is trying to show if lower doses of aspirin will have the same beneficial results, with fewer side effects.

Five hospitals will take part in this study in Australia: the Royal Melbourne Hospital, the Peter MacCallum Cancer Centre, St Vincent's Hospital (Sydney) and the Royal Brisbane and Women's Hospital.

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 the Royal Melbourne Hospital.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Your other option is to continue with colonoscopic surveillance which is the standard treatment for your condition and not take aspirin.

Your study doctor will discuss this option with you before you decide whether or not to take part in this research project. You can also discuss this 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; however, possible benefits may include a reduction in cancer incidence particularly of those cancers associated with Lynch Syndrome, and a reduction in the occurrence of heart attacks and strokes. The data the study will generate will hopefully also benefit future generations.

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

Medications can 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.

As aspirin has been used for over 100 years we are not anticipating any side effects not already recognized to be associated with aspirin. This is not a novel drug. It is important to remember that side effects are rare. Millions of people take aspirin daily around the world with very few side effects. However, tell your study doctor immediately about any new or unusual symptoms that you get.

Low doses of aspirin are commonly prescribed to prevent blood clots. This reduces the risk of stroke and heart attack. People who have recently had surgery on clogged arteries (such as bypass surgery, carotid endarterectomy, coronary stent), may be prescribed aspirin in low doses as a "blood thinner" to prevent blood clots.

Higher doses of aspirin are used to reduce fever and relieve mild to moderate pain from conditions such as muscle aches, common cold, and headaches. It may also be used to reduce pain and swelling in conditions such as arthritis. Aspirin is known as a salicylate and a nonsteroidal anti-inflammatory drug (NSAID). It works by blocking a certain natural substance in your body to reduce pain and swelling.

Like all drugs, there are some side effects to aspirin, contact your study doctor if you get any of these side effects listed below:

Common side effects (More than 1 in 100 people) include:
- nausea
- vomiting
- indigestion (dyspepsia)
- stomach ulcer or bleeding
- bleeding that takes longer than normal to stop
- headache
- dizziness
- noises or ringing in the ears or head (tinnitus; common with high doses)

Uncommon (Less than 1 in 100 people) include:
- skin reactions
- anaemia due to low blood iron
- kidney problems
- ulcers in the food pipe (oesophagus)

Rare (Less than 1 in 1000 people):
- major bleeding (in the gut, stomach, or elsewhere)
- Reye’s syndrome Reye's syndrome is a rare but serious condition that causes swelling in the liver and brain particularly in children who have taken aspirin.

Aspirin prevents blood clotting and reduces the risk of heart attacks and strokes but increases the risk of bleeding. About 1 in 10,000 people taking aspirin suffers a significant bleed inside the head which can cause a stroke or very rarely death. Any amount of aspirin carries this risk but most cases occur in older people. There is some evidence that strokes due to bleeding happen in people with high blood pressure. You should have your blood pressure checked occasionally by your local doctor. We will let your local doctor know that you are taking aspirin as part of the CaPP3 trial. We will check your blood pressure at the start of the study and you will be informed of the result. You can make an appointment at any time to have your blood pressure checked by your local doctor or the practice nurse. If your blood pressure is high it is advisable to have this treated before starting the CaPP3 trial.

If there is a big bleed in the stomach or gut, this may cause a change in your bowel motion. Your stools may take on a black appearance. The medical name is melaena. If you pass black stool, contact your doctor immediately.

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. Your study doctor will discuss the best way of managing any side effects with you.

Should you get sick whilst on the study, you will be treated by the Royal Melbourne Hospital as a public patient. In the event of a serious illness you will be able to take a break from taking the study drug or withdraw from participating in the study.

The doctor or study staff will check if you are suitable for the study by assessing if you have any pre-existing conditions that might make aspirin unsuitable for you or if you are taking any other drugs which might interact with aspirin.

Aspirin in the doses used in this study is not considered dangerous in early pregnancy but may cause some problems in late pregnancy. If you become pregnant while on the study we recommend that you stop taking the tablets until after you finish breast feeding. Please contact your study doctor if you become pregnant.

If you are pregnant you cannot be entered into the study, but you can contact us again after your pregnancy.

If you are planning to become pregnant within the next two years, it would be best to come back after your pregnancy to join the study.

Side effects of having your blood taken may include pain, redness, swelling, and/or bruising where the needle enters the body. Rare instances of fainting, excess bleeding, blood clotting, or infection have occurred.

10 What will happen to my test samples?

Upon diagnosis of a new cancer, your cancer treating doctor may want you to have a biopsy as part of your standard of care. If this happens, we will contact your pathology/hospital to access the biopsy sample and corresponding pathology report which was used for diagnosis. The biopsy will be used for analysis in to the mechanism of aspirin action in Lynch Syndrome and to try to understand the process of cancer development in Lynch Syndrome.

Collection of blood samples for this study is optional. If you consent to take part in the collection of blood for this study, blood samples will be collected at the baseline, 24 month and 5 year visits. Blood samples collected will be for serum (antibody measurement), plasma and DNA (biobanking). In lynch syndrome, the cancer produces abnormal proteins and the body produces antibodies against them – which is what we will be measuring in the patients agreeing to the blood collection. DNA is short for deoxyribonucleic acid. DNA is the material that carries all the information about how a living thing will look and function. Each piece of information is carried on a different section of the DNA. These sections are called genes. Genes are made of DNA – the chemical structure carrying your genetic information that determines many human characteristics such as the colour of your eyes or hair. Researchers study genes in order to understand why some people have a certain condition and why some people do not. Understanding a person's genes also may be able to explain why some people respond to a treatment, while others do not, or why some people experience a side effect and others do not. DNA samples from blood will be processed, frozen and stored in a secure location until they are shipped.

To ensure privacy, all of your research samples will be labeled with a code number and kept in a secure location at the Australian study site before they are shipped to Newcastle University,

UK. Only your study doctor and authorised personnel at the study site will have access to your coded samples and be able to link your samples with your identity.

The sample/s will be shipped in a re-identifiable manner to Newcastle University, UK for analysis. Your samples will be kept in a secure location at Newcastle University and only CaPP3 authorised personnel will have access to your samples. At the end of the study the samples will be fed into the Newcastle University biobank and all the identifiers will be removed. This biobank is based in Newcastle University Institute of Genetic Medicine and is available to researchers worldwide and samples may be shipped abroad during the course of research projects in collaboration with other groups. Only researchers who have ethics committee approval for their project will be able to access these samples for their research.

This consent is for the use of samples for this research project, any projects related to this research and for any future research.

Once your samples are transferred to Newcastle University, UK, the Royal Melbourne Hospital will not be able to control whether the Newcastle University, UK, transfers your samples at some future date. However, Newcastle University, UK, will not knowingly transfer your samples to anyone who has expressed intent to sell the samples, nor will it sell the samples itself.

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 medications especially non steroidal anti inflammatory agents, any products containing aspirin or methotrexate. 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 should also 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?

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 doctor and relevant study staff will not collect additional personal information from you unless you specify, 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 team 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.

You can withdraw from the study at any time, please let the study team know. You can either withdraw completely from the study or stay on the study but stop the study medication.

If you just want to stop taking the study medication you will be asked to confirm if you are still willing to provide any of the following information:

- Continued collection of cancer follow up data via national registries and healthcare records and/or by continuing to send patient-reported cancer diagnosis form.
- Collection of end of study blood samples.
- Collection of pathology specimen from any cancers (collected as standard of care).
- Retention of existing samples in the study biobank. If you do not wish for the research team to retain these samples please notify us and these will be destroyed.

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 being shown not to be effective
- The drug being shown to work and not need further testing
- Decisions made by local regulatory/health authorities
- Lack of funding

15 What happens when the research project ends?

After the end of the study treatment phase (2 years randomised and 3 years open label) you will not receive any further aspirin. The CaPP3 study team will ask you at 5 years if you would like to be contacted annually for health updates for a further 10 years after you have completed 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. To ensure privacy, your name and other identifying information will not be attached to records released for research purposes. Instead, you will only be identified by a code. Only the study doctor and authorised people will be able to connect this code to your name, by a list that will be kept securely by the hospital. Study information will be retained for a minimum of 15 years after which it will be destroyed in a confidential manner.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

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 Sponsor, Melbourne Health Human Research Ethics Committee, Newcastle University UK, the institution relevant to this Participant Information Sheet, the Royal Melbourne Hospital, 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.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. No information will be included that would reveal your identity.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or 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. (However, in order to protect the scientific integrity of the study, the treatment you received in this study needs to remain unknown (blinded) until the study data is analysed). Please contact the study team member named at the end of this document if you would like to access your 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 by Prof Finlay Macrae in collaboration with Newcastle University in the UK.

The Royal Melbourne Hospital will receive a payment from Cancer Australia and Cancer Council of New South Wales 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).

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 Melbourne Health HREC.

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 study doctor on 9342 7580 or any of the following people:

Clinical contact person

Name	Virginia Bird
Position	Research Manager
Telephone	03 9342 8995
Email	Virginia.Bird@mh.org.au

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

Name	Dr Angela Watt
Position	Director Research Governance and Ethics
Telephone	03 9342 8530
Email	research@mh.org.au

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	Melbourne Health HREC
HREC Executive Officer	Ms Jessica Turner
Telephone	03 9342 8530
Email	research@mh.org.au

Local HREC Office contact (Single Site - Research Governance Officer)

Name	Dr Angela Watt
Position	Director Research Governance and Ethics
Telephone	03 9342 8530
Email	research@mh.org.au

Consent Form - *Adult providing own consent*

Title	A randomised double- blind dose non-inferiority trial of a daily dose of 600mg versus 300mg versus 100mg of enteric coated aspirin as a cancer preventive in carriers of a germline pathological mismatch repair gene defect, Lynch Syndrome.
Central HREC number	HREC/16/MH/39
Principal Investigator	Prof Finlay Macrae
Location	The Royal Melbourne Hospital Level 3 Centre Department of Colorectal Medicine & Genetics

Declaration by Participant

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 the Royal Melbourne Hospital 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.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

Only initial and date if you consent to the following:

I consent to the storage and use of my tissue samples, as described in this document for use in this project and any future research. Initial:____ Date: _____

I do not consent to the storage and use of my tissue samples, as described in this document for use in this project and any future research. Initial:____ Date: _____

I consent to the storage and use of my blood samples, as described in this document for use in this project and any future research. Initial:____ Date: _____ (DELETE IF YOU ARE NOT RMH)

I do not consent to the storage and use of my blood samples, as described in this document for use in this project and any future research. Initial:____ Date: _____ (DELETE IF YOU ARE NOT RMH)

I consent to the annual follow phone calls after my 5 year visit for a further 10 years, as described in this document. Initial:____ Date: _____

I do not consent to the annual follow phone calls after my 5 year visit for a further 10 years, as described in this document. Initial:____ Date: _____

By signing this consent section, I agree for the study staff to the access and use of my tissue samples for testing, as outlined in the relevant Section of the Participant Information Sheet.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older. Witness is required when the participant cannot read the document for him/her self.

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.