Full Project Title: ASPREE (ASpirin in Reducing Events in the Elderly)
Participant Information and Consent Form
Version # 17   Dated June 2013

This Participant Information and Consent Form is 6 pages long. Please make sure you have all the pages.

This document contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this document carefully. Feel free to ask questions about any information it contains. You may also wish to discuss the project with a relative or friend or your local health worker. Feel free to do this.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research project.

You will be given a copy of the Participant Information and Consent Form to keep as a record.

**Why you are being given this Participant Information and Consent Form?**

We understand that you are aged 70 or older. We are interested in identifying people in this age group who do not have blood vessel disease and are not taking aspirin.

**What is the study about?**

Aspirin is a drug known to prevent blood clotting and therefore heart attacks and strokes. However, thinning the blood can itself lead to cerebral haemorrhage and bleeding from the stomach. We are investigating if the benefit of aspirin in reducing clotting events outweighs the side-effects of bleeding in people aged 70 and over. We will also see if it helps prevent a decline in the physical or mental abilities which are associated with ageing. We will also investigate whether aspirin affects the development or progression of eye diseases, specifically Age-related Macular Degeneration (AMD).

ASPREE will be conducted in general practices around Australia. Half of the participants will receive low dose aspirin and the other half a dummy tablet. We will then observe the 2 groups over an average 5 year period to see what differences there are for levels of physical disability, brain function, general quality of life, deaths, strokes, heart attacks and bleeding episodes.

We will collect this data from yourself, your doctor’s records, and any hospital or specialist who you may visit.

Providing this information greatly facilitates us knowing about your health status. We will also ask you to provide information that will allow us, in the unlikely event of your death, to ascertain the cause and date of your death for up to 5 years after the completion of the study using a government database known as the National Death Index.
**Who is running the study?**
The study is run by the Department of Epidemiology and Preventive Medicine, Monash University with the
- Menzies Research Institute, Tasmania
- The Canberra Hospital, Australian National University
- The University of Adelaide
- Centre for Eye Research Australia (CERA), at the Royal Victorian Eye & Ear Hospital, Melbourne

Your GP may be a co-investigator and may receive up to $100 for the use of the practice facilities.

**Who is funding the study?**
The main sponsor of the ASPREE clinical trial is the National Institute on Aging (NIA), one of the Institutes and Centers of the National Institutes of Health (NIH) in the USA.

**Who may join the study?**
People who are aged 70 or more can join the study. If you have any of the following you are unable to join.
- Blood vessel disease
- Serious illness
- Are allergic to aspirin, or cannot take it
- Have had or are at risk of serious bleeding
- Are taking other ‘blood thinning’ drugs
- Significant problems with thinking and memory
- Anaemia

**What are we asking you to do?**
**Visit 1:** If you agree to participate you will be asked to give your consent by signing this form. After you give your consent to enter this study, a member of the study team will take a brief look at your medical records to ensure there are no underlying conditions that would make you ineligible for the study, and to check any pathology results from the previous 6 months to ensure no tests are repeated unnecessarily. We will then measure your blood pressure and will ask you a number of questions about your medical history and the kinds of medicines you take or have taken over the past year, your daily activities, and your emotional well-being. We will also ask you to complete a questionnaire that will test your mental function.

We will then ask you to take a tablet of study medication once daily for four weeks, and we may ask you to see your own doctor before the next visit.

The research staff will also ask you to attend a local pathology service for a fasting blood test, where you will have approximately 12 ml (about 2 teaspoons) of blood taken. This blood sample will be used to check your kidney function, your cholesterol and sugar levels and your haemoglobin level. At the pathology centre you will also be asked to complete a urine spot test, which involves the collection of approximately 20 ml of urine. This will provide additional information about your kidney function and cardiovascular health.

Based on the pathology results, the physical examination and your medical and medication history, the study doctor will consider if it is appropriate for you to continue in the study and attend visit 2.

**Visit 2:** At the second visit, if you have taken your study medication, and you satisfy all other eligibility criteria, you will be randomly assigned to take either low dose aspirin (100mg) or placebo (a dummy tablet).
The treatment type will be provided by a computer program. Neither you, nor the research coordinator, nor your doctor will know if you are taking the active (aspirin) or placebo medication. You will have an equal chance (like flipping a coin) of receiving either aspirin or placebo.

In the event of an emergency, any doctor can find out what treatment you are taking if he/she needs to know.

In addition, during this visit, you will be asked to:

a) complete tasks that assess different types of mental function
b) complete a walk test and a hand grip strength test
c) have a brief physical examination including your weight, height, waist circumference
d) answer some questions about your general health, activities and family medical history.

**Retinal Photography:** If a retinal camera is available, you will be asked whether you would be prepared to have photographs taken of the back of your eyes (retinal photographs). This is a non-invasive procedure which takes about 5 minutes. You will be asked to put your chin on a chinrest and focus on a small illuminated dot within the camera. You will experience a small flash of light as the photo is taken.

The images will be used for research into eye health or age-related eye diseases such as a recent NHMRC-funded study investigating whether aspirin affects AMD (age-related macular degeneration). When images are analysed, any clinically significant findings that require further investigation or treatment will be notified to you and/or your GP. A copy of your images will be provided to you if you request.

Any future analysis of the images may be shared with ASPREE or other investigators in future analyses and research protocols. Consent to the retinal photography covers the collection at visit 2 and also at a future visit should the camera be available at that time.

**Annual Visit:** The study staff will continue to see you once a year and conduct the same tests and ask the same questions as above for an average of 5 years. The combination of tests that we ask you to complete will be alternated each year so that most tests will be administered only every second year. Each year you will be given your study medications. You will be asked to continue to come for study visits until the study is finished, even if you stop taking the study medication.

For the duration of the study you should not take any medication containing aspirin. If you have any questions in this regard please contact the study staff. You will also receive phone contact at regular intervals throughout the course of the study, to see how you are going with your study medication.

It is possible that the tasks assessing mental function may show a change over time. If this occurs, it will be important to confirm or refute this change with a different set of tests, and to look for any treatable cause with a range of standard blood tests and a brain scan.

**Cancer Sample:** During the course of the study, some people may have biopsies taken for cancer diagnosis or treatment. We ask you for permission to access a small sample of this biopsy, if available. ASPREE will not require you to undergo any additional biopsies or procedures for access to this sample. Please tick the box
at the end of this consent form to indicate permission for this access.

This tumour tissue may be used in future research studies to explore molecular mechanisms of aspirin’s protective effect against cancer.

**Can I leave the study?**

Participation in the study is voluntary. You can choose not to participate in part or all of the study and can withdraw at any stage without being penalised or disadvantaged in any way.

If you decide to withdraw altogether from this project, please notify a member of the research team in writing before you withdraw. This notice will allow that person or the research supervisor to inform you if there are any special requirements linked to withdrawing.

**Your decision whether or not to participate is entirely voluntary.**

**Privacy, Confidentiality and Disclosure of Information**

Any information collected in this study will not be published in any manner that could identify you as an individual, during or after conclusion of this project. We will only publish group data. The information collected for the purposes of this project will be stored indefinitely after the conclusion of this project, as required by Good Clinical Practice Guidelines.

Your personal information which we will collect as part of this study is reported on special forms by the research staff. Your name is not recorded on these forms. You are only identified by your initials and a study-specific number assigned by the research staff.

By signing the attached consent form, you are agreeing to the release of your Medicare number, your health and prescribing information held by Medicare and PBS, and medical records held with your doctor or hospital you may attend. This information will be collected, stored and analysed only for the purposes of this study, and possibly a clinical audit undertaken by your GP, and will be limited to medical details related to the study.

**What are the possible risks?**

Side-effects of low dose aspirin include abdominal upsets and bleeding. Possible risks, side effects and discomforts include possible pain, discomfort, bruising or infection (although this is uncommon) at the site where the blood samples are taken. You should not consume excessive amounts of alcohol on a regular basis while taking aspirin. There may be additional unforeseen or unknown risks.

**If you need more information?**

Please ask the research staff member if you have any further questions. You can also consult your own doctor if you have any concerns during the course of the research.

Specific enquiries related to this study can also be made to the following person at the Regional ASPREE Centre:

**Name:** Professor John McNeil  
**Address:** Monash University, School of Public Health & Preventive Medicine, Level 6 Alfred Centre, 99 Commercial Road, Melbourne VIC 3004  
**E-mail:** john.mcneil@monash.edu  
**Tel:** (03) 9903 0565  
**Fax:** (03) 9903 0556
**Ethical Guidelines**

This project will be carried out according to the National Statement on Ethical Conduct in Human Research 2007 (National Statement) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the Human Research Ethics Committees of Monash University, the Royal Australian College of General Practitioners, University of Tasmania, Australian National University and ACT Health.

If you wish to speak to someone not involved in the study about either the screening process or the study proper you can contact any or all of the ethics officers below.

**Monash University Human Research Ethics Committee (MUHREC)**

Executive Officer, Human Research Ethics, Building 3E, Research Office
Monash University
Victoria 3800
Tel: (03) 9905 2052

**RACGP Ethics Committee**

Executive Officer, National Research and Evaluation Ethics Committee
Royal Australian College of General Practitioners, College House
1 Palmerston Crescent
SOUTH MELBOURNE, VIC 3205
Tel: (03) 8699 0481
E-mail: ethics@racgp.org.au

**University of Tasmania Ethics Committee**

Executive Officer, Human Research Ethics Committee (Tasmania) Network
University of Tasmania Research House
Private Bag 01
Hobart Tasmania 7001
Tel: (03) 6226 2763

**Australian National University Human Research Ethics Committee**

The Secretary, Research Office
Australian National University
Acton ACT 0200
Tel: (02) 6125 7945

**ACT Health Human Research Ethics Committee**

The Secretary, ACTH-HREC, ACT Health Research Office, Building 10, Level 6
Canberra Hospital, Yamba Drive, Garran Canberra, ACT 2605
Tel: (02) 6205 0846

**RMIT University Ethics Committee**

Chairperson
Human Ethics Research Committee
RMIT University
GPO Box 2476
MELBOURNE VIC 3001
Tel: (03) 9925 4324

**The University of Adelaide Ethics Committee**

Convenor
Human Ethics Research Committee
The University of Adelaide
SA 5005
Tel: (08) 8303 6028
Consent Form
Version # 17   Dated June 2013

ASPREE (ASPirin in Reducing Events in the Elderly)

I have read and I understand the Participant Information version #17 dated June 2013

I freely agree to participate in this project according to the conditions in the Participant Information.

I will be given a copy of the Participant Information and Consent Form to keep

The researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

I agree to have retinal photographs taken. [ ] Yes [ ] No

I agree to allow ASPREE access to any of my tumour biopsy tissue. [ ] Yes [ ] No

Participant’s Name (printed) ……………………………………………………………………………………………
Signature Date

Name of Witness to Participant’s Signature (printed) ……………………………………………………………
Signature Date

Declaration by 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

Researcher’s Name (printed) ……………………………………………………………………………………………
Signature Date

- A senior member of the research team must provide the explanation and provision of information concerning the research project.

Note: All parties signing the Consent Form must date their own signature.