



**Full Project Title: ASPREE- (Aspirin in Reducing Events in the Elderly)**

**Participant Information and Consent Form**

**Version # 7      Dated # 6 March 2008**

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This Participant Information and Consent Form is 5 pages long. Please make sure you have all the pages

This Participant Information 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 Participant Information carefully. Feel free to ask questions about any information in the document. 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?**

You have been identified from your doctor's practice list as being 70 years or more. We are interested in identifying people in this age group who do not

have blood vessel disease or diabetes and are not taking aspirin.

**What is the study about?**

Aspirin is a drug proven to prevent blood clotting and therefore heart attacks and strokes. However, thinning the blood can itself lead to strokes 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.

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 a 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

- University of Melbourne
- Menzies Research Institute, Tasmania
- The Canberra Hospital, Australian National University

Your GP is a co-investigator and will receive \$100 for the use of the practice facilities.

### **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
- Diabetes
- Serious illness
- Are taking aspirin, are allergic to it, or cannot take it
- Have had or are at risk of serious bleeding
- Are taking other 'blood thinning' drugs

### **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 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 an inactive tablet once daily for four weeks, and to

see your own doctor before the next visit.

The research nurse will also ask you to attend a local pathology 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.

Based on the blood results, the physical examination and your medical and medication history, your 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 inactive 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, or 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, your 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 and activities.

**Annual Visit:** The study the nurse will continue to see you once a year and

conduct the same tests and ask the same questions as above for approximately 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 nurse.

### **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 from this project, please notify a member of the research team 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 and will not prejudice your future relations with your GP.**

### **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 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 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.

There may be additional unforeseen or unknown risks

### **If you need more information?**

Please ask the research nurse 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 Henry Krum

**Address:** Centre for Cardiovascular Research and Education in Therapeutics, Department of Epidemiology and Preventive Medicine, Monash University  
89 Commercial Rd  
MELBOURNE VIC 3004

**E-mail:** henry.krum@med.monash.edu.au

**Tel:** (03) 9903 0048

**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 the Royal Australian College of General Practitioners, Monash University, University of Tasmania 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.

### **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](mailto:ethics@racgp.org.au)

### **Monash University Ethics Committee**

The Secretary, SCERH  
Research Grants and Ethics Branch  
PO Box 3A  
Monash University  
Victoria 3800  
Tel: (03) 9905 2052

### **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

### **ACT Health Human Research Ethics Committee**

Chair, ACT Health Human Research Ethics Committee  
Level 3, 11 Moore St  
Canberra City ACT 2601  
Phone 02 6205 0846

