



Date: June 12<sup>th</sup>, 2017

Dear, <Participant Name Inserted Here>

**ASPREE clinical trial participants: please stop study medication.**

I am writing to let you know that we are now advising all ASPREE participants to stop taking your trial medication.

The main funding agency of ASPREE, the United States National Institute on Aging (NIA), has been carefully following the outcome data since the start of ASPREE. On reviewing the most recent data, NIA has seen very little difference between the groups taking aspirin or placebo in length of life free of dementia and physical disability since the start of the study treatment.

The NIA has now concluded that it is extremely unlikely that the study would show a benefit for this, the main study outcome. Because of this, the NIA has determined that it is time for all participants to stop taking the study medication that we have provided to you.

However, it is important to note that if your doctor has recommended that you take aspirin -- for example, if you have had a stroke or heart attack -- you should continue to take aspirin.

**For all participants who are still taking study medication, please stop as of today. We ask that you write the date on the enclosed Health Event Report form and PLEASE DO NOT throw away the bottle. On the back of this page, we provide instructions for how to send the medication bottle back to us.**

ASPREE has generated important data that will be analysed during the coming months to identify more information about the risks and benefits of aspirin. We will share this information with you and your doctor as soon as it is available.

***Future ASPREE study visits & phone calls***

Although the trial medication is being ceased, the study is not over. ASPREE study visits and phone calls will continue unchanged through 2017 (except that participants will no longer be taking study medication).

We will continue to be in contact with all our ASPREE trial participants to monitor possible delayed effects of aspirin treatment, such as those on cancer risk and memory. Your ongoing involvement in ASPREE is extremely important to help answer these vital questions.

***Questions & Answers***

We expect that you will have questions about this news and process. To help, we have enclosed a sheet of possible questions with answers that may be helpful. Please feel free to call<INSERT SITE PHONE NUMBER HERE> if you would like to speak with an ASPREE staff member after you receive this letter.

***Thank you***

On behalf of all the study investigators, we would like to again express our gratitude for your participation in ASPREE and your ongoing contribution to its success.

There remains much valuable information to be gained. Your continuing participation will be essential to potentially making a difference to clinical practice and the use of aspirin.

Sincerely,

<INSERT SITE PI NAME AND SIGNATURE HERE> , ASPREE Site Principal Investigator

Anne Murray, M.D., M.S., US ASPREE Principal Investigator

A handwritten signature in black ink that reads "Anne Murray". The signature is written in a cursive, flowing style.

## **INSTRUCTIONS**

### **Health information sheet**

An information sheet with questions about your health is enclosed with this letter. The questions are some of those we normally ask during a phone call or study visit. Please complete this form and enclose in the reply-paid envelope.

### ***If you have a bottle of study medication:***

- Please place the bottle in the enclosed reply-paid envelope.
- Please complete the enclosed Health Event form after recording the date when you stopped taking medication.
- Please place the completed form in the reply-paid envelope with the bottle, and mail it back to us at your earliest convenience.

### ***If you do not have a bottle of study medication:***

- Please complete the enclosed Health Event form.
- Please place the completed Health Event form in the reply-paid envelope and mail it back at your earliest convenience.

### **ASPREE Medication bottle**

Your ASPREE medication has 'ASPREE' on the label, similar to the pictures below. Please return any bottles of ASPREE medication that you may still have, even if you have stopped taking the study medication.



### **ASPREE Information for your doctor or health care provider**

Please feel free to provide this to your doctor or health care provider if you choose. It explains the change in the ASPREE study.