Dear Aspirin for Breast Cancer Trial Participant,

First, thank you for participating in the ABC Trial – a clinical trial that asks an important question: Can taking aspirin every day prevent breast cancer from coming back?

You are receiving this letter because of changes to the ABC Trial Consent Form.

**Why is the consent form being changed?**

The consent form is being changed to let you know the results of a recent study that looked at aspirin use in older adults.

You may have heard recent news reports about this study, called the ASPREE Trial (Aspirin in Reducing Events in the Elderly). This study showed a slight increase in in overall deaths among aspirin users (compared to placebo) and most of the increases in death were from cancer. The study also showed more major bleeding events in those taking aspirin, which we already knew from other studies. Please let your doctor know if you want more information about the ASPREE study.

**Will the results from the ASPREE trial impact the ABC trial?**

We do not believe these results directly impact the study you are participating in, the ABC study of aspirin and breast cancer. We want to point out a number of important differences between the ASPREE and ABC trial.

1. One important difference is the ASPREE trial was in a different patient population. Specifically, ASPREE involved an older population (70 years of age or older if Caucasian and 65 or older if Black or Hispanic). The ABC Trial does not include patients 70 or older at the time of enrollment.
2. Another difference is the history of cancer, fewer than 20% of ASPREE participants had a prior history of any cancer and the number of deaths from breast cancer in the ASPREE trial was very small. All ABC trial participants have a breast cancer diagnosis.
3. There have also been many previous studies looking at aspirin to prevent cardiovascular disease and these have shown decreased deaths from cancer. Many of the studies also use different amounts of aspirin and look at different outcomes (cardiovascular disease, bleeding, cancer recurrence), which leads to different results being reported.

We continue to believe that the ABC Trial will answer an important question about improving breast cancer treatment. Nonetheless, it is important that you talk with your provider about the ASPREE results if you are nearing age 70, as well as any other health concerns you may have. We are changing the Patient Consent Form and you will be asked to sign the new form at your next clinic visit. As always, patients may withdraw from the trial at any time for any reason without any impact on your care.

Please know how much we appreciate your participation in the ABC Trial and your contribution to research to improve breast cancer care.

With gratitude,

Wendy Y. Chen, MD MPH

Study chair of A011502, Aspirin for breast cancer trial