

## INFORMED CONSENT

I hereby consent to participate in the Physicians' Health Study. My collaboration will include:

- a) Taking one tablet or capsule daily from the monthly calendar packs I am sent;
- b) Completing, every six months, a brief questionnaire asking about my compliance and my recent health;
- c) Giving Charles H. Hennekens, MD permission to validate, from medical records, any relevant illnesses I report.

I understand that participants *will not be able to choose* their treatment group and that *I will not know* my treatment group, though the daily pills will contain alternate day aspirin (Bufferin, 325 mg), alternate day beta-carotene (Solatene, 30 mg), both or neither.

I further understand that:

- a) In a minority of takers, Bufferin can cause hypersensitivity, dyspepsia or other stomach upset, and it increases the tendency to bleed, particularly in the gastrointestinal tract, although generally at much higher doses than used in this study. If I should experience discomfort and wish to continue taking study medication, I may request a coated preparation.
- b) In doses higher than that given in this trial, Solatene produces yellow pigmentation of the skin and/or occasional looser stools in some individuals, though both effects are completely reversible.

I understand that all information will be kept strictly confidential, that I can contact study personnel if I have any questions, and that I may request other reference material on the possible role of aspirin in cardiovascular disease and beta-carotene in cancer. I further understand that I can withdraw from the study at any time.

I am willing to participate in the Physicians' Health Study to evaluate the possible (but unproven) benefits of aspirin and beta-carotene in healthy people.

Yes

No

Signed \_\_\_\_\_

Date \_\_\_\_\_

WHETHER OR NOT YOU CONSENT TO PARTICIPATE, we shall be grateful if you would complete the questionnaire on the reverse and return it in the reply-paid envelope.

THANK YOU!