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# Your Important Role in the Ongoing WHI Observational Study

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2002

## Historic Hormone Program Results Announced

In July 2002, the WHI asked women in the Estrogen plus Progestin part of the Hormone Program to stop taking their study pills. This announcement surprised doctors, scientists, and women around the world. The reason? After an average of 5 years on treatment some key expected benefits had not emerged, and for women in that study the overall risks outweighed the benefits. More women taking estrogen plus progestin developed breast cancer, heart attacks, strokes, and blood clots in the lungs and legs than did women taking placebo pills. On the positive side, fewer women taking estrogen plus progestin had hip and other fractures (broken bones) and fewer developed colorectal cancer than did women taking placebo pills.

Our results relate to the most commonly used postmenopausal hormone combination in the United States. They have raised questions about the use of this popular treatment for women worldwide. Doctors and scientists are now trying to understand whether these results apply to other hormone combinations. The Estrogen-Alone part of the Hormone Program is continuing because the balance between benefit and risk is still unknown. This study will continue to be monitored closely. Given these findings and the impact they have had on women's health, participation in all parts of the WHI is more important than ever. These surprising findings show that even widespread beliefs sometimes need to be challenged. Other WHI results yet to be discovered will likely be as important in suggesting ways to prevent disease and to help focus future research on women's health.

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## Are all parts of the WHI program continuing?

*Yes!* The women in the Estrogen plus Progestin study will continue to receive study examinations so that we can learn more about the long-term effects of that treatment, even though they are no longer taking study pills. All other parts of the WHI, including the Observational Study, the Dietary Study, the Calcium and Vitamin D Program, and the Estrogen-Alone part of the Hormone Program, are continuing entirely unchanged. The questions asked by these other programs are just as important as those already answered by the Estrogen plus Progestin study and we don't expect to know the results for a few more years. Only by continuing these studies will we discover ways to help prevent

some of the major diseases that affect women.

## Why is continuing the WHI important?

The Estrogen plus Progestin (E-plus-P) part of WHI is a landmark study that has given women definitive information about the risks and benefits of this particular commonly used hormone combination. These results illustrate the need to explore other factors that might reduce a woman's risk of developing breast cancer, heart disease, stroke, and osteoporosis. Now that we've learned that taking this common form of E-plus-P has mixed effects, understanding other influences in women's health is more important than ever. Continuing your WHI participation will help us find other answers!

## **Why is the Observational Study important?**

The purpose of an Observational Study (OS) is to look at how lifestyle factors, personal and family history, use of common treatments, age, and other personal characteristics influence women's health. We are looking at factors such as diet, exercise, smoking, alcohol consumption, and the use of common medications to see if they are associated with disease. The OS is far larger than any other part of the WHI, and will help us understand influences on many diseases that cannot be tested in the other parts of WHI. Findings in the OS may help women make more informed choices about their health and suggest promising ideas for future studies.

As a participant in the Observational Study, you will continue to receive mailed questionnaires annually, just as you always have. Your completion of these questionnaires is now more important than ever.

## **How do the Hormone Program results apply to me if I'm taking or thinking about taking hormones?**

We encourage you to talk with your primary care provider if you have questions about your personal health care. If you would like detailed

information about the findings of the E-plus-P study, we have prepared a special packet of information for your health care provider that we can send to you or directly to your provider. Just phone or write us at the Clinical Center. The information in this packet can help you and your health care provider decide what's best for you.

## **How can I find out more?**

You may find additional details about WHI on the World Wide Web (<http://www.whi.org>). We will update this website as information becomes available, so check back frequently. Over the coming months WHI scientists plan to study the E-plus-P hormone study results in much greater detail. And as findings emerge in other parts of the WHI, we will continue to inform you through mailed newsletters and updates to the study website.

## **Thank you!**

Thank you for taking part in WHI, a landmark study of women's health. The time and effort you have given to the WHI will help to answer many important health questions for postmenopausal women in the United States. We have more work to do and hope that you will continue to be our partner in this effort.

