

Supporting Statement B
Attachment 3

Sample Participant Newsletter



The Latest on WHI

The WHI Extension Study is now in the fourth year of data collection, an amazing accomplishment for the nearly 120,000 women enrolled in the study. As of August 2008, over 350 papers on WHI results have been published in scientific journals, with dozens more in various stages of preparation. The data you are providing will continue to impact women around the world, by giving researchers the information they need to answer a broad range of questions about women's health. WHI researchers will continue to analyze these data for many, many years to come, ensuring that your past and current contributions to the science of women's health will have a lasting impact well into the future.

WHI in the Future

As part of the WHI Extension Study, we will continue to collect your health information each year through 2010. This will include a complete update of the medications and supplements that you provided several years ago during the original WHI. Information about the medications you are taking helps researchers learn more about common treatments for chronic diseases and health outcomes. This update will be included in the annual questionnaire packet you receive next year as a participant in WHI.

In recognition of the importance of women's health, the National Institutes of Health (NIH) are considering the possibility of continuing the Women's Health Initiative for additional years of follow-up beyond 2010. This would involve completing annual mailed questionnaires, similar

to what you are doing now. We will keep you informed about this possibility as we learn more.

Focus on Findings in WHI

A few of the many findings published about WHI over the past year are summarized below. WHI participants have let

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us know that they are very interested in knowing about the many findings from WHI, and some have written to us requesting more details on the findings reported in the newsletter. You can find all of the details on the WHI participant website at www.whi.org,

continued, p. 2

- 1 The Latest on WHI**
- 4 Preventing Falls in the Home**
- 6 The Women of WHI**
- 8 Center Information**

INSIDE THIS ISSUE



which has links to the actual publications summarized in the newsletters. If you do not have internet access, your local librarian may be able to help you obtain copies of WHI articles. When you visit your library, be sure to take along the name of the journal, date, and first author of the article you are interested in reading. This information is listed with the summaries of findings in current and past issues of the newsletters. You might also call your local WHI clinical center, to see if they can help you locate this information.

■ **Hormone Therapy Increases Frequency of Abnormal Mammograms and Breast Biopsies** (*Archives of Internal Medicine, Feb. 2008*)

Rowan T. Chlebowski, M.D., Ph.D., principal investigator of the Harbor-UCLA WHI Clinical Center, and other investigators have published new findings from the **WHI Estrogen plus Progestin (E+P) Hormone Trial**. Of the 16,608 women enrolled in the E+P Trial, 8,506 were randomly assigned to take active study pills with combined estrogen plus progestin, while 8,102 took inactive placebo pills. Each woman had a mammogram and breast examination yearly. Biopsies were performed based on their physicians' clinical judgment.

Dr. Chlebowski and his colleagues found that combined estrogen plus progestin hormone therapy appears to increase the risk that women will have abnormal mammograms and breast biopsies,

from that of placebo for at least 12 months after stopping, the investigators reported.

Breast biopsies also were more common among women taking hormones than among those taking placebo (10% vs. 6.1%). "Although breast cancers were significantly increased and were diagnosed at higher stages in the combined hormone group, biopsies in that group less frequently diagnosed cancer (14.8% vs. 19.6%)," the WHI investigators reported.

These findings suggest that mammograms and breast biopsies may be more difficult to interpret for women taking hormones, possibly reducing their ability to diagnose breast cancer. The investigators recommend that health care providers include this information when they discuss risks and benefits with women who are thinking about taking even short-term combined hormone therapy.

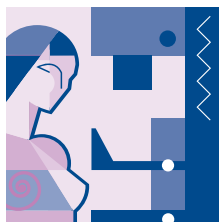
■ **Health Risks and Benefits 3 Years After Stopping Randomized Treatment With Estrogen and Progestin** (*Journal of the American Medical Association, March 2008*)

The **WHI Estrogen plus Progestin (E+P) Hormone Trial** was stopped on July 7, 2002 because results showed that the overall risks exceeded the benefits of taking Estrogen plus Progestin, with women taking E+P at higher risk for heart disease, blood clots, stroke, and breast cancer, but at lower risk for fracture and colon cancer.

After stopping the study pills in the E+P trial, WHI continued to collect follow-up study data from these participants to evaluate the effects of stopping hormone therapy. This summary reports on the health outcomes of E+P trial participants three years after the study pill

intervention was stopped (with a mean average of 2.4 years of follow-up). Follow-up information for this period was available on 95% of the women.

Three years after stopping hormone therapy, women who had taken study pills with active E+P no longer had an increased risk of cardiovascular disease (heart disease, stroke, and blood clots) compared with women on placebo. The lower



Mammograms and breast biopsies may be more difficult to interpret for women taking hormones.

and may decrease the effectiveness of both tests for detecting breast cancer. During the 5.6 years of the E+P trial, mammograms showing abnormal results were more common among women taking hormones than among women taking placebo (35% vs. 23%). After the hormones were stopped, the adverse effect on mammograms decreased somewhat, but remained significantly different





risk of colorectal cancer seen in women who had taken active E+P disappeared after stopping the intervention. The benefit for fractures (broken bones) in women who had taken active E+P also disappeared after stopping hormone therapy. On the other hand, the risk of all cancers combined in women who had used E+P increased after stopping the intervention compared to those on placebo. This was due



E+P hormone therapy should not be used to prevent disease in healthy, postmenopausal women.

to increases in a variety of cancers, including lung cancer. After stopping the intervention, mortality from all causes was somewhat higher in women who had taken active E+P pills compared with the placebo.

Based on these findings, the overall summary of risk and benefits was unchanged, showing that the health risks exceeded the health benefits from the beginning of the study through the end of this three year follow-up. This follow-up confirms the study's main conclusion that E+P hormone therapy should not be used to prevent disease in healthy, postmenopausal women. The most important message to women who have stopped this hormone therapy is to continue seeing their physicians for rigorous prevention and screening activities for all important preventable health conditions.

Low-Fat Dietary Pattern and Risk of Treated Diabetes Mellitus in Postmenopausal Women

(Archives of Internal Medicine, July 2008)

Type 2 diabetes continues to rise in the United States. In women, this form of diabetes rises after menopause, increasing the risk of heart disease and reducing well-being. Fortunately, there are lifestyle changes that can reduce the risk of developing diabetes. Research from the Diabetes Prevention Study in the United States (funded by

the National Institutes of Health) has shown that modest weight loss, exercise, and a low-fat diet may reduce the onset of diabetes in persons who are at risk of developing diabetes.

After an average of 8.1 years of follow-up, a total of 3,342 of the 48,835 **WHI Dietary Study** participants had developed diabetes mellitus being treated by insulin or medications. There was a 4% reduced risk (not statistically significant) of developing diabetes in the low-fat dietary change group compared to participants in the usual diet comparison group. The low-fat dietary change group was asked to reduce their fat intake to 20% of energy and

to increase their vegetable and fruit intake to five or more and grains to six or more daily servings.

Participants who reported a significantly greater reduction in fat intake after the first year had a greater reduction in risk of diabetes. However, this reduced risk was not statistically significant after accounting for weight loss. Participants in the dietary change group lost nearly five pounds after the first year and maintained a lower weight than the comparison group throughout the study. Thus modest weight loss, rather than the proportion of fat, carbohydrate, and protein in the diet, may be what reduced the risk of developing diabetes. Modest weight loss is typical when following a low-fat dietary pattern that is rich in vegetables, fruits, and grains.

After an average of 7 years of follow-up, participants in the low-fat dietary change intervention group maintained a significantly lower fat intake (and minor weight loss) than did participants in the usual diet comparison group. This supports a low-fat dietary eating style that has lots of vegetables, fruits, and grains, as an option for postmenopausal women who are concerned about developing diabetes.



A low-fat eating style is an option for postmenopausal women concerned about diabetes.



Preventing Falls in the Home

Did you know that falls and fall-related injuries are more common than strokes and can have consequences that are just as serious? More than 30% of seniors fall each year, with the chance of falls increasing drastically with age and illness. Of those who fall, 20-30% suffer moderate to serious injuries, leading to problems with daily activities like dressing, bathing, and walking around. The consequences of a fall become more serious as we age — a broken bone can disrupt your lifestyle, and possibly lead to disabilities that make you dependent on a caregiver or lead to nursing home placement.

There are several common health problems and hazards in the home that increase the risk for falling, including:

- problems walking or moving around
- taking 4 or more medications
- foot problems
- unsafe footwear
- a drop in blood pressure when standing up, causing dizziness
- vision problems
- tripping hazards in the home



FALL PREVENTION GUIDE

Follow these steps to help prevent falls in your home:

Take Care of Yourself

- Have your hearing and vision checked on a regular basis.
- Get regular medical checkups. Review your medications with your doctor, to ensure you are taking the appropriate levels and types.
- Take medication as directed and do not skip medications. Failure to properly take medication is a major cause of falls and fall-related injuries.
- Talk with your health care provider about recommending an exercise plan to help you maintain or improve balance, gait, and muscle tone.
- Get plenty of rest, water, and proper nutrition.
- Be aware of how you feel. If you do not feel well, be sure to walk slowly and deliberately, or ask someone to help you.
- Use a cane or walker if one has been prescribed.

Remove Hazards

- Remove throw rugs that slide or fasten them to the floor with carpet tape. If you are buying a rug for the bathroom and kitchen, make sure it has a non-skid backing.
- Keep cords and clutter from pathways.
- Arrange furniture to make sure you have a clear pathway between rooms. Make sure you have 38-42 inches of clearance in your walking path.
- Remove low coffee tables, magazine racks, footstools, floor plants, and anything that is easy to trip over from your walkways.
- Clean up spills right away.
- Use sturdy stepstools with handrails. If you use a ladder, make sure it's secure.
- Make sure that your sidewalks and walkways are level. If they are not, ask for help in having them repaired.





The good news is that by increasing your awareness and making modifications to your home, most falls are preventable. The box below highlights some of the things you can do to make yourself and your home safer. Studies have shown that by taking as many of these steps as possible, you can decrease your likelihood of falling. This is a case where prevention may truly be the best medicine!



If you ever should fall, call 9-1-1, and if any type of cover is in reach, try to keep yourself warm with a blanket or rug.

Even if you are not seriously hurt, be sure to mention the fall to your personal physician, since falling can be a sign of illness or problems with medications.

Protect Yourself and Your House

- Wear safe footwear – shoes or slippers with non-skid soles.
- Hold on to steady furniture if you are unsteady on your feet.
- Be especially careful in the fall “trouble spots” – the bathroom and kitchen. Install grab bars near sinks, toilets, and showers.
- Use a shower chair or transfer bench when getting in and out of the bathtub.
- Keep your home well lit, and turn on the lights when walking through dark rooms or hallways.
- Use nightlights in bathrooms, bedrooms, and hallways.
- Keep a flashlight handy at all times in case of power failure.
- Store lightweight or rarely-used objects on the top shelves of cabinets.
- If you must climb to reach something, use a sturdy step ladder with hand railings.
- Install handrails on both sides of stairways.

- Do not place items on or at the top of stairs, where you can trip over them.
- Add a contrasting color strip to the first and last steps of a stairway to show where the level changes.
- Place phones in several rooms in case you need to call for emergency help.

Outside Your Home

- Make sure outside doors, patios, porches, steps and walkways are well lit.
- Keep outside steps and walkways clear of obstacles and in good condition (for example, have cracks repaired).
- Make sure there are handrails on both sides of exterior steps, and be sure to use them.
- Be extra careful walking outside when the sidewalks are wet, icy, or snowy.



The Women of WHI

In the 1990s, over 160,000 women chose to join the largest study on women's health ever done, and they have been making history ever since! The 160,000 women who joined the original WHI, and the 120,000 who continued in the WHI Extension Study, are a remarkable group of women. They are nurses, doctors, teachers, homemakers, nuns, scientists, volunteers, caregivers, mothers, grandmothers, aunts, sisters – in short, they form a tapestry representing women across the US. Each and every participant has her own story to share – a small number of which we've featured in previous issues of *WHI Matters*, and in the quilt stories on the WHI participant website (www.whi.org). While it is not possible to cover the story of every participant, we will continue to share as many

Inspiring Women for Over 60 Years

Eula Raye Cook started exercising at the age of 12, which was very unusual in the small town in the Blue Ridge Mountains of North Carolina where she was raised. She didn't have any particular inspiration – she just thought it seemed like a good idea at the time – but she did try to inspire her friends to become active with her. At the age of 74, Eula still exercises regularly and can touch her toes with ease, which she attributes to the benefits she's gained from exercising her whole life. She still enjoys playing golf, bowling, and dancing, and is active in the Blue Ridge Senior Games. In September 2008 she participated in Doubles Bowling, the fun walk, and the 5-K Race-Walk, where she won the bronze medal!

As Eula explains, "I raised 5 children and worked full time, and still found time to do my exercises each day. Because of this I have benefited greatly with almost perfect health throughout my life. I'd like to inspire women in WHI to take charge of their health by eating right, keeping active in the right way, and getting plenty of sleep." Eula has been an inspiration to girls since the age of 12, and it clearly continues through today!



"I'd like to inspire women in WHI to take charge of their health by eating right, keeping active in the right way, and getting plenty of sleep."

– Eula Raye Cook



The women of WHI form a tapestry representing women across the U.S.

as we can. Here are just a few of the many interesting and accomplished women of WHI.





WHI Bags Continue to Travel the World

Bonnie Noonan, a Madison clinical center participant, and her well-traveled WHI bag, visited the Great Wall of China in Beijing in 2006. While there, she climbed the great wall, visited the Forbidden City, and saw the initial construction of the Olympic Bird's Nest stadium. She also noticed a flurry of cleaning, painting, and refurbishing going on in Beijing, all in preparation for the 2008 summer games.

Bonnie, the mother of two daughters and six step-children, was employed at the USDA before retiring. When her children were younger, she worked as a Licensed Practical Nurse at the Phantom Lake YMCA camp for several summers, which she greatly enjoyed. Her real passion now is travel; in addition to China, she's visited Ireland, Israel, Hawaii, and Jamaica, and taken cruises to the Caribbean and Alaska. She's in the process of planning the next big trip for her and her WHI bag – to the South American country of Peru!



91-year-old Fashion Model

Marti Serviente, participant at the Newark Clinical Center, recently modeled attire from the 1970s in a Heart Week fashion show at her local mall. When not modeling, she does fundraising walks for the YMCA, donates blood, takes Caribbean cruises, and enjoys spending time with her 5 children, 8 grandchildren, and 9 great-grandchildren.

Marti, whose mantra is “how lucky can I get?” says she's grateful to be living in a time when WHI is available, and that she feels good to be part of such a large study. Like many participants, she feels that her life has been healthier because of the WHI study results. “I'm 91 now”, says Marti, “and I still do aerobics and have an active social life. It's a warm fuzzy feeling to think of so many women, so many places, participating for the good of all.”

Thanks WHI!” We say thank you, Marti, for your contributions to WHI, and for showing us how great 91 can be!



“It's a warm fuzzy feeling to think of so many women, so many places, participating for the good of all.”

– Marti Serviente

Letters

We'd love to hear feedback on the newsletter. We regret that we cannot answer questions about individual medical conditions. Send a letter to:

WHI Matters
Fred Hutchinson Cancer Research Center
1100 Fairview Ave N, M3-A410
P.O. Box 19024
Seattle, WA 98109



Staff Information

WHI Matters is produced by the WHI Coordinating Center at the Fred Hutchinson Cancer Research Center.

Editor: Julie Hunt, Ph.D.
Design: Sunny Bay Design



Stay in Touch

Don't forget to call your local Clinical Center if your address or phone number changes!

Albert Einstein College of Medicine
Bronx, New York • (718) 931-1010

Arizona Prevention Center
Phoenix, Arizona • (800) 341-7672
Tucson, Arizona • (520) 321-7440

Baylor College of Medicine
Houston, Texas • (713) 798-4033

Berman Center for Clinical Research
Minneapolis, Minnesota • (612) 341-7921 or
(800) 789-8380

Brigham and Women's Hospital
Chestnut Hill, MA • (617) 732-9860

Center for Health Research
Portland, Oregon • (503) 335-2400

Charlton Memorial Hospital
Fall River, Massachusetts • (401) 729-2865

Detroit Clinical Center
Detroit, Michigan • (313) 966-8000

Emory University
Decatur, Georgia • (404) 370-7355

Evanston Hospital
Evanston, Illinois • (312) 908-5790

Fred Hutchinson Cancer Research Center
Seattle, Washington • (206) 667-6551

The George Washington University
Washington, DC • (202) 741-2323

Kaiser Permanente – Bay Area Clinic
Oakland, California • (510) 891-3201

Medical College of Wisconsin
Milwaukee, Wisconsin • (414) 805-7040

Memorial Hospital of Rhode Island
Pawtucket, Rhode Island • (401) 729-2865

Nevada Clinical Center
Reno, Nevada • (775) 784-4906

New Jersey Medical School
Newark, New Jersey • (973) 972-2944
New Brunswick, New Jersey • (732) 235-6546

Northwestern University
Chicago, Illinois • (312) 908-5790

Ohio State University
Columbus, Ohio • (614) 688-3563

Rush-Presbyterian St. Luke's Medical Center
Chicago, Illinois • (312) 563-2209

Stanford Women's Health Initiative
San Jose, California • (650) 725-5307

Stony Brook Clinical Center
Stony Brook, New York • (631) 444-9800

South Bay WHI Program
Torrance, California • (310) 222-2217

UAB Preventive Medicine
Birmingham, Alabama • (205) 934-2294

UCLA Women's Health Initiative
Los Angeles, California • (310) 825-9502

UMASS/FALLON Clinical Site
Worcester, Massachusetts • (508) 856-5452

University at Buffalo
Buffalo, New York • (716) 829-3128

University of California, Davis
Sacramento, California • (916) 734-5562

University of California, Irvine
Orange, California • (714) 456-8685

University of California, San Diego
Chula Vista, California • (800) 514-0325
La Jolla, California • (800) 514-0325

University of Cincinnati
Cincinnati, Ohio • (513) 584-6061
or (888) 558-6062

University of Florida
Gainesville, Florida • (352) 392-1920
Jacksonville, Florida • (352) 392-1920

University of Iowa
Davenport, Iowa • (800) 344-3515
Des Moines, Iowa • (515) 241-8989
Iowa City, Iowa • (800) 814-9535

University of Miami School of Medicine
Miami, Florida • (305) 243-4800

University of North Carolina
Chapel Hill, North Carolina • (919) 966-3165
or (800) 342-0770

University of Pittsburgh
Pittsburgh, Pennsylvania • (412) 624-3598
or (800) 552-8140

University of Wisconsin
Madison, Wisconsin • (608) 261-1867

UTHSC
San Antonio, Texas • (210) 567-1850

UT Prevention Center
Memphis, Tennessee • (901) 448-8405

WHI of the Nation's Capital
Washington, DC • (202) 675-4770

WHI of the Triad
Greensboro, North Carolina • (336) 716-2243
Winston-Salem, North Carolina •
(336) 716-2243

Women's Health Hawaii
Honolulu, Hawaii • (808) 441-5555

If you have any questions about the WHI Extension Study, or if your address or phone number changes, please call your WHI clinic at the number listed above. If you have moved to a new area, you should contact the center where you originally joined the study. There are still WHI staff on hand at your clinical center to record address changes and answer your questions. Thank you!



Women's Health Initiative
Clinical Coordinating Center
1100 Fairview Ave N, M3-A410
P.O. Box 19024
Seattle, WA 98109-1024

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