

National Heart, Lung, and Blood Institute (NHLBI)

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Sessions on Study Results, Ongoing Extension Study, and Future Research
Scientists and Study Participants Gather at Conference on Scientific Contributions of
the Women's Health Initiative - The Largest Study of Older Women's Health

Many of the nation's leading scientists and experts on women's health will join Women's Health Initiative (WHI) study participants February 28 -- March 1, 2006 at the National Institutes of Health (NIH) campus in Bethesda, MD to celebrate the legacy and probe the findings and future directions of the WHI. The WHI is the largest and most comprehensive study of postmenopausal women's health ever conducted in the United States. From revealing the effects of a low-fat diet and calcium/vitamin D supplements to the dangers of hormone replacement therapy, the study has helped to shape and advance the health care of women for more than a decade.

Conference speakers will closely examine findings from the WHI's clinical trials and observational studies, analyze the study's impact on public health and on national guidelines and recommendations, and discuss not only the ongoing extension study but also future research using stored blood and genetic samples.

Presenters include Elias Zerhouni, M.D., director of the NIH; Elizabeth G. Nabel, M.D., director of the National Heart, Lung, and Blood Institute (NHLBI), which funded the study, and also current director of the WHI; Vivian Pinn, M.D., director of the Office of Research on Women's Health; Bernadine Healy, M.D., who launched the study as the head of NIH in 1991 and Marcia Stefanick, Ph.D., chair of the WHI Steering Committee and principal investigator at the Stanford University clinical center study site. Most of the WHI principal investigators will be presenting at or attending the event. In addition, participants in each of the three clinical trials will share personal accounts of their involvement in the historic study.

"The WHI has replaced conventional wisdom about women's health issues with evidence-

based research findings, and reminded us that there aren't always simple, universal answers to complex questions. It also influenced the ways in which scientific studies involving women are now designed and conducted," said Dr. Zerhouni. "These are just a few of the many contributions from a study that will continue to enhance the lives of women for decades to come."

"The WHI has significantly contributed to our knowledge of disease prevention in postmenopausal women and has challenged many clinical practice and prevention policies," said Dr. Nabel, "Due to the dedication of thousands of women and the widespread release of study findings, the WHI has had a global impact on women's health care and on the lives of generations of mothers, daughters, and granddaughters."

Highlights of the two day conference include:

\* Presentations on the design, implications, and primary results of the recently published Dietary Modification Trial. Speakers include WHI consultant Leslie Ford, M.D., Associate Director of the National Cancer Institute's Division of Cancer Prevention, and WHI principal investigator Ross Prentice, Ph.D., of the Fred Hutchison Cancer Research Center in Seattle. The Dietary Modification trial is the largest-ever clinical trial of a low-fat diet. The study revealed that following an eating pattern lower in total fat did not significantly reduce the risk of breast cancer, heart disease, stroke, or colorectal cancer in healthy postmenopausal women.

\*Sessions on the public health impact and results of the WHI Calcium and Vitamin D trial. Speakers include: WHI consultant Joan McGowan, Ph.D., Director of the Musculoskeletal Diseases Branch at the National Institute of Arthritis and Musculoskeletal and Skin Diseases; Rebecca Jackson and Jean Wactawski-Wende, Ph.D., WHI principal investigator at the University at Buffalo. Released this month, results from the trial revealed that calcium and vitamin D supplements in postmenopausal women have a modest benefit on bone mineral density and prevent hip fractures in certain groups but do not prevent colorectal cancer or other fractures.

\*Sessions on the results and public health impact of the WHI hormone trials and future directions for menopausal hormone research. Speakers include Dr. Stefanick, Barbara Alving, M.D., former director of the WHI, and Jacques Rossouw, M.D., WHI Project Officer. The long-term WHI hormone studies evaluated the effects of menopausal hormone therapy on heart disease, breast cancer, colorectal cancer, and osteoporosis. In 2002, the WHI estrogen-plus-progestin study was stopped because of an increased risk of breast cancer and because, overall, risks from use of the hormones outweighed the benefits. The combination therapy increased the risk for heart attack, stroke, and blood clots but also reduced the risk for hip and other fractures, and colorectal cancer. The study results reverberated throughout the world and significantly changed the treatment of

postmenopausal women. Two years later, the WHI estrogen-alone study was halted because of an increased risk of stroke and no significant effect on the risk of heart disease. Estrogen-alone also increased the risk for venous thrombosis (blood clots deep in a vein). Like the combination therapy, estrogen-alone reduced the risk for hip and other fractures.

\*Sessions on the WHI Extension Study, the impact of WHI on national guidelines and recommendations, and directions for future research on women's health. Speakers include Richard Hodes, M.D., director of the National Institute on Aging; Dr. Nabel, Dr. Pinn, Marian Limacher, M.D., WHI investigator at the University of Florida in Gainesville, and Sally Shumaker, Ph.D. of Wake Forest University School of Medicine and principal investigator of the Women's Health Initiative Memory Study. The WHI Extension Study will follow WHI participants through 2010 and will allow for the collection of longer-term data on the effects of stopping hormones (or making other health changes) on women's health.

\*Sessions on the WHI observational study. Speakers include Teri Manolio, M.D. of NHLBI and the National Human Genome Research Institute, WHI investigator JoAnn Manson, M. D., DrPH of the Harvard School of Public Health and WHI investigator Sylvia Wassertheil-Smoller, Ph.D. of the Albert Einstein College of Medicine in New York City. The observational study yielded important findings on the effects of exercise on cardiovascular disease, breast cancer, and diabetes, including that the duration of exercise increases the degree of protection against disease, and walking is as effective as more vigorous exercise in protecting against breast cancer.

Immediately before the conference, scientists from around the country will discuss proposed studies using WHI blood and DNA samples to determine the factors that contribute to an increased risk of cardiovascular disease, cancer, and fractures in women. WHI investigators are already engaged in a separate genome association study, which will examine the DNA of some 12,000 participants with and without heart disease, stroke, and breast cancer, to determine the genes that predict these diseases.

For more information on the *WHI: A Legacy To Future Generations* conference and for an agenda, please visit, <a href="http://www.nhlbi.nih.gov/whi/references.htm">http://www.nhlbi.nih.gov/whi/references.htm</a>. For more information on the Women's Health Initiative, see <a href="http://www.nhlbi.nih.gov/whi">http://www.nhlbi.nih.gov/whi</a>. Reporters can preregister for the conference or schedule interviews with speakers and participants by calling the NHLBI Communications Office at 301-496-4236 or e-mailing <a href="mailto:nhlbi.news@nhlbi.nih.gov">nhlbi.news@nhlbi.nih.gov</a>. Room J in the Natcher Auditorium on the NIH Campus will be available for press use and registration, and will feature a video feed of the conference proceedings.

NHLBI is part of the National Institutes of Health (NIH), the Federal Government's primary agency for biomedical and behavioral research. NIH is a component of the U.S. Department of Health and Human Services. NHLBI press releases and other materials

including information about women and heart disease are available online at <u>www.nhlbi.</u> <u>nih.gov</u>.



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