## HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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HHS Secretary Louis W. Sullivan, M.D., today announced the award of a \$140 million, 15-year contract to launch the National Institutes of Health "Women's Health Initiative," the largest coordinated study of women's health ever undertaken.

The Fred Hutchinson Cancer Research Center in Seattle, Wash., was awarded the contract and named as clinical coordinating center for the initiative. As coordinating center, it will oversee the work of what will ultimately be a network of 45 clinical centers nationwide carrying out the initiative.

"The NIH Women's Health Initiative is a project of national importance that is both unprecedented and overdue," Secretary Sullivan said. "Health research for women is finally moving toward the equal status it deserves."

Dr. Sullivan said the initiative reflects the commitment of President Bush, as well as the leadership of the U.S. Public Health Service under Assistant Secretary for Health James Mason, M.D., and the National Institutes of Health under Director Bernadine Healy, M.D.

The initiative has been in planning and contract competition stages for about 18 months. It will evaluate the effectiveness of various promising interventions in preventing a number of major diseases in older women. The full 15-year project, costing \$625 million, is expected to involve more than 150,000 women.

"For too many years, medical research has paid too little attention to the leading causes of death and disability as they specifically affect women," Secretary Sullivan said. "This is especially true for studies of chronic diseases and their prevention in mature women. The new NIH initiative is an important step toward filling the knowledge gap and correcting the bias that has existed in the design of our research programs."

The initiative will examine treatment and prevention strategies for coronary heart disease, cancer and osteoporosis. It includes both clinical and observational studies.

Dr. Healy said the coordinating center "will function as the central nervous system of the Women's Health Initiative."

"The Seattle project will make certain that each clinical center holds to the highest scientific and administrative standards," she said. "The Hutchinson Center has extensive experience in coordinating large medical research trials, especially dietary interventions. And it has distinguished itself in the management of other NIH clinical trials of women."

The first 15 of the 45 clinical centers will be named early in 1993, while the remaining 30 will probably be named early in 1994. The first 15 centers will develop, implement and refine

the overall program for the initiative, which Dr. Healy called "the most extensive studies of women's health ever conducted."

The objectives of the clinical trials are to test the benefit and risk of hormone replacement therapy, dietary modification, and supplementation with calcium plus Vitamin D on the overall health of post-menopausal women age 50-79. With some overlap of participants in the different studies, approximately 57,000 women will participate in the clinical trials.

The goals of the observational study will be to improve risk prediction of coronary heart disease, breast cancer, fractures and total mortality in postmenopausal women, to examine the impact of changes in characteristics on disease and total mortality; and to create a resource of data and biological samples which can be used to identify new risk factors and/or biomarkers for disease. Some 100,000 women, will be participants in the observational study.

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