



THE SISTER STUDY

A STUDY OF THE ENVIRONMENTAL AND GENETIC RISK FACTORS FOR BREAST CANCER

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES • NATIONAL INSTITUTES OF HEALTH • DEPARTMENT OF HEALTH AND HUMAN SERVICES

The NIEHS Sister Study is prospectively examining environmental and familial risk factors for breast cancer and other diseases in a cohort of 50,000 sisters of women who have had breast cancer. Such sisters have about twice the risk of developing breast cancer as other women. The frequency of any relevant genes and shared risk factors will also be higher, increasing the statistical power of the study. Sisters are expected to be highly motivated to participate in a long-term study. Studying sisters enhances our ability to assess the interplay of genes and environment in breast cancer risk and to identify potentially modifiable risk factors. The prospective design allows us to assess exposures before the onset of disease thereby avoiding biases common to retrospective studies and creates a framework for testing new hypotheses.

Breast cancer-free sisters aged 35-74 years were recruited in the US and Puerto Rico through health professionals, breast cancer advocates, the Internet, recruitment volunteers, and a national media campaign. Study materials are available in English or Spanish. Recruitment strategies were designed to maximize inclusion of minorities and high-risk women. Data on potential risk factors and current health status were collected in telephone interviews and mail questionnaires. Blood, urine, and environmental samples were collected and banked for future use in nested studies of women who develop breast cancer (or other diseases) and a sample of those who don't. Stored samples include whole blood, cryopreserved lymphocytes (15% random sample), plasma, serum, urine, toenail clippings, and household dust collected with alcohol wipes.

The cohort will be followed prospectively for 10 or more years. Annual tracking and detailed questionnaires performed every two to three years update contact information, vital status, medical history and changes in exposures. Medical records, pathology reports, and tumor tissue blocks and slides are sought for those who develop cancer.

As of 2014, over 2,100 breast cancers have developed and analyses are underway to assess the independent and combined effects of environmental exposures, genetic polymorphisms, and epigenetic changes that affect estrogen metabolism, DNA repair, and response to specific environmental exposures. Future analyses will focus on known and potential risk factors (e.g. smoking, occupational exposures, alcohol, diet, obesity) and include measurement of phthalates, phytoestrogens, metals, insulin, growth factors, vitamins and nutrients, and genes. Ancillary studies will explore risk for other diseases (e.g., heart disease, osteoporosis, other hormonal cancers, and autoimmune diseases). Additional studies will explore genetic and environmental effects on breast cancer prognosis by continuing to follow women in the cohort who develop breast cancer. A related effort, The Two Sister Study enrolled the sisters with breast cancer if they were diagnosed before age 50 and within 4 years of the unaffected sister's enrollment in the Sister Study. Parents of these sister pairs were invited to contribute saliva samples for DNA analysis.

A total of 50,884 women enrolled in the Sister Study between August 2003 and July 2009. Annual and detailed follow-ups are ongoing. A second home visit and sample collection was initiated for women with breast cancer and a random sample of the cohort to evaluate biological changes associated with breast cancer development.

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