The Sister Study
www.SisterStudy.niehs.nih.gov

Investigators

Dale P. Sandler, PI	Epidemiology Branch
Alexandra J. White, Co-Investigator	Epidemiology Branch
Katie M. O'Brien, Co-Investigator	Epidemiology Branch
Jack A. Taylor, Emeritus Investigator (ret.)	Epidemiology Branch
Clarice R. Weinberg, Adjunct Investigator	Biostatistics and Computational Biology Branch

Overview

The Sister Study is a prospective cohort study of environmental and genetic risk factors for breast cancer and other diseases among 50,884 sisters of women who have had breast cancer. Such sisters have about twice the risk of developing breast cancer as other women, thus about 300 new cases of breast cancer are expected to be diagnosed each year. Women were eligible for the study if they were 35 to 74 years of age between 2003-2009, lived in the United States, including Puerto Rico, and had a sister diagnosed with breast cancer but did not have breast cancer themselves. Baseline data on potential risk factors and current health status were collected in telephone interviews and mailed questionnaires. Blood, urine, and environmental samples were collected during a baseline home visit and banked for future use in case-cohort or nested case-control studies of breast cancer or other diseases. Stored samples include whole blood, cryopreserved whole blood or lymphocytes (12% random sample), plasma, serum, urine, toenail clippings, and household dust collected with alcohol wipes. The cohort is being followed prospectively. Contact information and major changes to health are updated annually. Comprehensive follow-up questionnaires administered every 3 years update medical history and changes in exposures. Medical records and pathology reports are sought for women who develop breast and ovarian cancer, and some tumor tissue blocks were also collected. For other cancers, pathology reports are requested. Other self-reported health outcomes are validated for special studies. Analyses assess the effects of environmental and lifestyle exposures and genomic factors on breast cancer risk and risk for other diseases (e.g. heart disease, osteoporosis, other hormonal cancers, and autoimmune diseases). Future studies of environmental and genetic influences on breast cancer prognosis are made possible by continuing to follow women in the cohort who develop breast cancer.

Background and Rationale

Breast cancer is the leading (non-skin) cancer among women with approximately 282,000 diagnoses of breast cancer and 44,000 deaths per year in the United States. Known risk factors explain less than 50% of variation in breast cancer risk and known breast cancer genes account for fewer than 10% of cases. The Sister Study was designed to study environmental and genetic risk factors for breast cancer and other women's health conditions. The study creates a framework for addressing current and future hypotheses as science advances over the follow up period, including studies related to biological mechanisms. Studying sisters of women diagnosed with breast cancer is advantageous because it allows for a smaller cohort size and shorter follow-up than needed to study women in general. These sisters have about twice the risk of breast cancer

as other women and the frequency of relevant genes and shared risk factors will also be higher, increasing the statistical power of the study. This enhances the ability to assess the interplay of genes and environment in breast cancer risk and to identify potential modifiable risk factors. In addition, sisters are often highly motivated to participate in long-term breast cancer research because their family member has experienced the disease so the response rates and compliance are high. The prospective design allows the assessment of exposures before the onset of disease thereby avoiding biases common to retrospective studies.

Recruitment and Enrollment

After a four-city vanguard phase in 2003, nationwide enrollment took place October 2004 through March 2009. Women were eligible if they had a sister diagnosed with breast cancer but did not have breast cancer themselves, were between 35 and 74 years of age, and lived in one of the 50 US states or Puerto Rico. Efforts were made to maximize the inclusion of women who are often under-represented in research, such as Black or Hispanic women, those with low education, and those aged 65 years and older, and to target women with possibly relevant exposures because of their place of residence or occupation. Recruitment activities included outreach to volunteers and breast cancer organizations, networking with communities, direct mailings to specific lists, national media campaigns and the endorsement of the Sister Study by high profile celebrity supporters. Study materials were made available in Spanish in 2005. Additional details can be found in Sandler, et al. 2017 (PMID: 29373861).

Study Population

A total of 50,884 women completed required baseline activities and were fully enrolled in the study, including 8,311 women (16%) who self-identified as Hispanic/Latina or non-White, 8,874 women aged 65 years and older (17%), and 7,805 women with a high school education or less (15%) (**Table 1**). A smaller group of women who completed some but not all study requirements (n=3,066) is being followed passively through record linkage (vital statistics and eventually cancer registries) to assess differences in outcomes for those who did and did not fully enroll. This latter group includes a larger percentage of minority women (36%) and women with lower attained education (20% high school or less); groups of women who were the focus of intense recruitment efforts towards the end of the enrollment period. Additional information about the cohort can be found on the study's website – www.SisterStudy.niehs.nih.gov.

Data Collection

Baseline

Computer-assisted telephone interviews (CATI): Telephone interviews were scheduled in two one-hour sessions to collect information on a broad range of exposures and lifestyle characteristics. Supporting materials, including a list of relevant medications and a chronological life calendar, were provided to help women prepare for the interviews. Topics included demographic and socioeconomic factors, lifestyle and environmental exposures, residential history, medical and medication-use history, reproductive history and hormone use, breast conditions and surgeries, occupational history, and physical activity. Questionnaires focused specifically on early life (before puberty) and reproductive years as well as the time of enrollment.

Table 1: Baseline characteristics of women in the Sister Study

Characteristic	Number	Percent
Total	50,884	
Race and ethnicity		
Non-Hispanic White	42,558	83.6
Non-Hispanic Black/African American	4,600	9.0
Hispanic/Latina	2,377	4.7

Other[a]	1,334	2.6
Age		
35-44	6,578	12.9
45-54	17,520	34.4
55-64	17,912	35.2
65+	8,874	17.4
Education		
High school or less	7,805	15.3
Some college (includes associates/technical)	17,181	33.8
Bachelor's degree	13,714	27.0
Master's or doctoral degree	12,172	23.9
Smoking		
Never smoker	28,552	56.1
Past	18,141	35.7
Current	4,175	8.2
Alcohol consumption		
Never	1,949	3.8
Former	7,730	15.2
Current, < 1 drink/day	34,256	67.4
Current, ≥ 1 drink/day	6,862	13.5
Body Mass Index		
≤25 kg/m^2	19,438	38.2
>25- ≤30 kg/m^2	16,151	31.7
>30 kg/m^2	15,278	30.0
Number of sisters (full or half) with breast cancer		
1	45,706	89.8
2+	5,177	10.2
Mother diagnosed with breast cancer	9,135	18.0

[a]Includes non-Hispanic Asian/Pacific Islanders, non-Hispanic American Indians, and non-Hispanic Other; women who self-identified as Black/African American and another race were included as Black/African American

Self-administered questionnaires: Participants filled out three self-administered questionnaires: use of personal care products; prenatal (*in utero*) exposures and family medical history; and current diet (Block 98 food frequency questionnaire), with supplementary questions on complementary and alternative medicines, childhood diet, special diets, and eating patterns.

Home Visit: Trained female examiners from a national in-home phlebotomy service (EMSI) visited participants' homes (or a mutually agreed upon alternate site such as a doctor's office) to draw blood, measure blood pressure, height, weight, hips, and waist and to retrieve consent forms, self-administered questionnaires and self-collected toenails, dust, and urine. Participants filled out a brief questionnaire on the day of the visit to report information on their diet, medication use, and activities over the past 24 hours. Examiners packed and shipped study samples and forms to the Sister Study Laboratory by FedEx Priority Overnight on the same day as the visit.

Biological Specimen Collection: Nearly all participants provided biological samples. Details of collection and processing can be found on the Sister Study website (https://sisterstudy.niehs.nih.gov/english/images/SIS_SpecimenSummary_20120323_webversion.pdf)

Toenails: Participants collected toenail clippings from each toe unless they had a medical or

physical condition that would prohibit collection. Samples are stored at room temperature.

Dust: Participants collected dust samples from three rooms of their home using pre-packaged alcohol wipes. Wipes are stored in -20° C freezers.

Urine: Participants collected clean-catch midstream first morning urine specimens on the day of the home visit and kept them refrigerated until pick up by the examiner.

Blood: Participants were instructed to fast for at least eight hours prior to their blood draw. Examiners collected approximately 45 ml of blood using six BD Vacutainer® (Becton, Dickinson and Company) tubes, including two EDTA tubes (BD#s 367855 and 366643), two serum tubes (BD# 367820) and two ACD-B tubes (BD# 364816). In the rare event that a blood sample could not be collected due to an unsuccessful phlebotomy, participants were asked to provide a saliva sample using an Oragene™ DNA self-collection saliva kit (DNA Genotek, Ottawa Canada).

DNA:
DNA was extracted from whole blood (90%), clot, or saliva collected at enrollment. Altogether, we have extracted DNA from over 45,000 women thus far. Sister Study DNA Samples have been used in large scale genome-wide association studies (GWAS) including approximately 4,200 women (2,281 cases and 1,906 non-cases) genotyped on the OncoArray panel contributing to the GameOn Initiative (https://epi.grants.cancer.gov/gameon/) and the Breast Cancer Association Consortium (BCAC; https://www.ccge.medschl.cam.ac.uk/breast-cancer-association-consortium-bcac) (e.g., PMID: 39753771, 38951643), with another approximately 4,500 women genotyped via NCI's Confluence Project (https://dceg.cancer.gov/research/cancer-types/breast-cancer/confluence-project). This includes an additional 1,697 incident breast cancer cases, matched non-cases selected specifically for Confluence analyses, and all remaining Black and Hispanic study participants not already selected for GWAS analyses, enhancing our ability to carry out our own gene x environment studies that stratify by race and ethnicity when appropriate. Extracted DNA has also been used to assess DNA methylation in breast cancer cases and randomly selected sub-cohorts, first limited to small sample of non-Hispanic White women (298 cases, 612 subcohort, PMID: 23578854), then a larger sample of non-Hispanic White women (1552 cases, 1224 subcohort, PMID: 30989176) and most recently in both Black and non-Hispanic White women (2,166 women including 999 cases, PMID: 36974720). We refer to the latter as the "2019 case-cohort".

Follow-up
The Sister Study cohort is followed prospectively to identify incident breast cancer and other health outcomes. Participants can report a diagnosis of breast cancer or other conditions at annual updates (selected outcomes) or detailed follow-up (DFU) questionnaires (see schematic below), or they can contact a study helpdesk by telephone, mail, or email. Annual update forms and biennial/triennial follow-up questionnaires are available in English and Spanish. Starting in 2010, all study materials have been available on the web and women have the option of completing follow-up questionnaires on-line, by mail, or over the phone.

Women reporting a diagnosis of lobular carcinoma *in situ* (LCIS), ductal carcinoma *in situ* (DCIS), invasive breast cancer, or ovarian cancer (including peritoneal and fallopian tube cancers) are asked to provide information on their diagnosis and treatment and provide authorization for medical record and tumor tissue sample retrieval. Women with other cancers are asked for pathology reports or permission to retrieve them from medical providers. Protocols for validating other incident conditions reported during follow up are developed as needed.

Annual updates: Women are contacted annually for a brief update or a scheduled detailed follow-up questionnaire. The annual update form collects changes in contact information and allows participants to report major changes in health, including breast cancer. Response rates for the annual updates have been 86% or higher throughout follow-up (range 86%-96%). Through the end of 2023, 5,209 (10.2%) of Sister Study participants were known to be deceased.

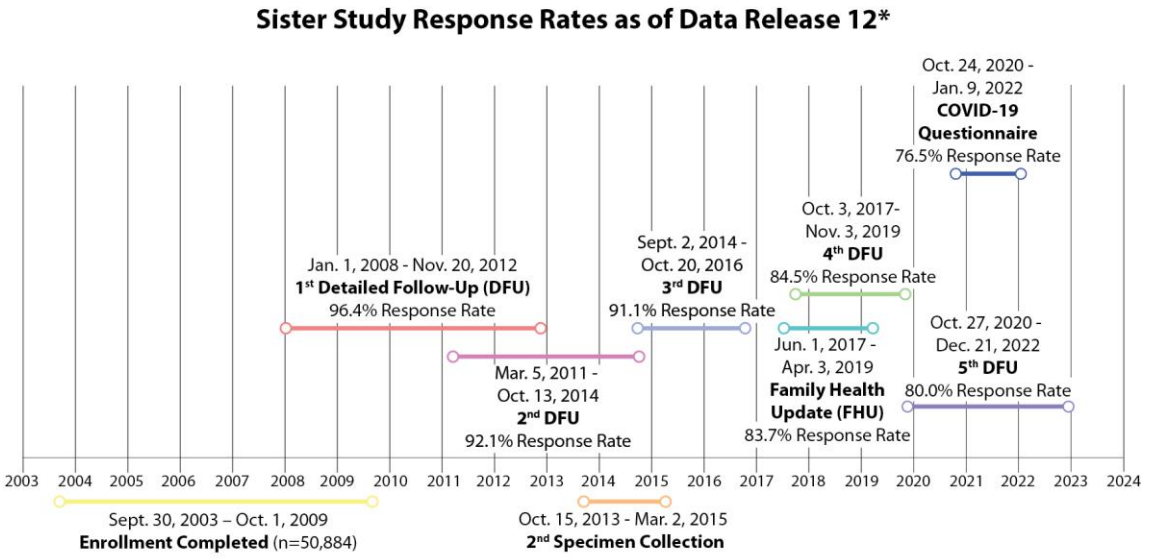


*Figure excludes Annual Health Updates (AHU); includes limited number of 5th DFU questionnaires submitted after Data Release 12 cutoff (10/31/2022).

Detailed follow-up (DFU) questionnaires: More in-depth DFU questionnaires collect information on medical diagnoses and symptoms, changes in environmental exposures and lifestyle, and special topics of interest. For example, the first DFU, completed in July 2012, consisted of three questionnaires: *Health and Medical History*, *Lifestyle*, and the special topic, *Stress and Coping*. Responses were obtained from 48,090 women for an overall response rate of 95%. The special topic for the 2nd DFU (completed April 2014) was *Quality of Life and other related topics.* From the 3rd DFU onward, we included a streamlined reproductive section for participants >60 years of age. A detailed family history questionnaire was distributed in 2017-2018 to collect data on the history of cancer in first and second degree relatives (response rate of 84%), and a special COVID-19 survey was distributed in the fall of 2020 (response rate of 77% through July 2021). Starting with the 3rd DFU (2014) we introducted an advocacy program, which provides more personal attention to those at higher risk for dropping out of the study.

Breast and Ovarian Cancer Follow-up

Women who self-report breast or ovarian cancer are contacted 6 months after diagnosis. They are mailed a packet that includes instructions, cancer definitions, a self-administered questionnaire and authorization forms for requesting medical records and tumor tissue samples. The questionnaire covers information on tumor pathology and treatment in case the medical record is not obtained. We ask women to send a copy of their pathology report if they have one. Medical providers are asked to complete a form about the cancer diagnosis and treatment and/or provide relevant pages from the medical record. They are also asked to send pathology reports, blocks of breast (ovarian) carcinoma and normal breast tissue, or, if not available, diagnostic H&E slides.

As of Sister Study Data Release (12.1), which is complete through October 2022, 4,897 women had reported a diagnosis of incident DCIS or invasive breast cancer. Out of the total incident breast cancer events at that time, medical records or pathology reports were obtained to confirm 4,087 (83.5%) incident breast cancer events, and 2,487 tissue samples have been retrieved. Among women for whom we obtain pathology reports or medical records, the positive predictive value (PPV) of a self-reported breast cancer is 98.1%. As of Data Release 12.1, 327 women had an incident diagnosis of ovarian cancer, including fallopian tube and peritoneal cancers. Medical records or pathology reports were collected for 207 of these cases, with a PPV of 77.6%.

Breast and Ovarian Tissue Microarrays (TMAs) and Tissue Cores: Tumor and normal tissue blocs were used to create TMAs for immunohistochemical staining and to obtain tissue core biopsies. These were prepared at the UNC Translational Pathology Laboratory. When available, TMAs and cores include invasive cancer tissue, co-occurring *in situ* disease, and adjacent normal tissue. The ovarian tissue TMAs are being used in several Ovarian Cancer Cohort Consortium projects, but the breast tissue TMAs have not yet been utilized.

Other incident cancers

In 2010 we began asking women diagnosed with any type of cancer to mail a copy of their pathology report to us, if available, or to sign an authorization form allowing us to request it from their medical provider.

In 2023, we began to match our participants to the tumor registries of 37 states participating in, or cooperating with, the Virtual Pooled Registry-Cancer Linkage System (VPRCLS) (https://surveillance.cancer.gov/research/vpr-cls.html) or as individual registries not part of VPRCLS. This data will be used to improve case ascertainment, provide more complete validation of self-reported cases, and, in some cases, obtain more detailed information on tumor characteristics such as histolology, stage, and grade. Data for 17 states as well as the Seattle area and Puerto Rico will be available to Sister Study researchers starting with data release 13.0 (to be released in late 2025). Another 22-30 states are expected to be available to be included in the subsequent data release (14.0, expected late 2026).

Second Specimen Collection

In 2014-15 we carried out the “Sisters Changing Lives” initiative in which we invited 3,800 women to complete a second home visit for sample collection. Procedures were identical to those at the enrollment visit except an RNA Tempest tube was substituted for one of the baseline whole blood tubes. Women diagnosed with breast cancer by the time of the initiative and a random sample of non-cases were targeted. Samples were obtained for 61% of invited breast cancer cases and 65% of non-cases. A total of 2,434 women participated, of whom 1,227 were cases. This resource allows for studies of changes in biomarkers over time and of changes in biomarkers due to a breast cancer diagnosis.

Family Health Update

A survey with detailed questions about family history of cancer was sent to all participants between June 2017 and April 2019, with a final response rate of 83.7%. The questionnaire focused on cancers with shared genetic risk factors for breast cancer (ovarian, prostate and pancreatic), so that we could calculate individuals’ risk scores according to the BOADICEA model of genetic susceptibility (PMID: 18349832). Data on genetic testing were also collected.

Special COVID survey

In response to the 2020 COVID-19 pandemic, we designed a special questionnaire to collect data

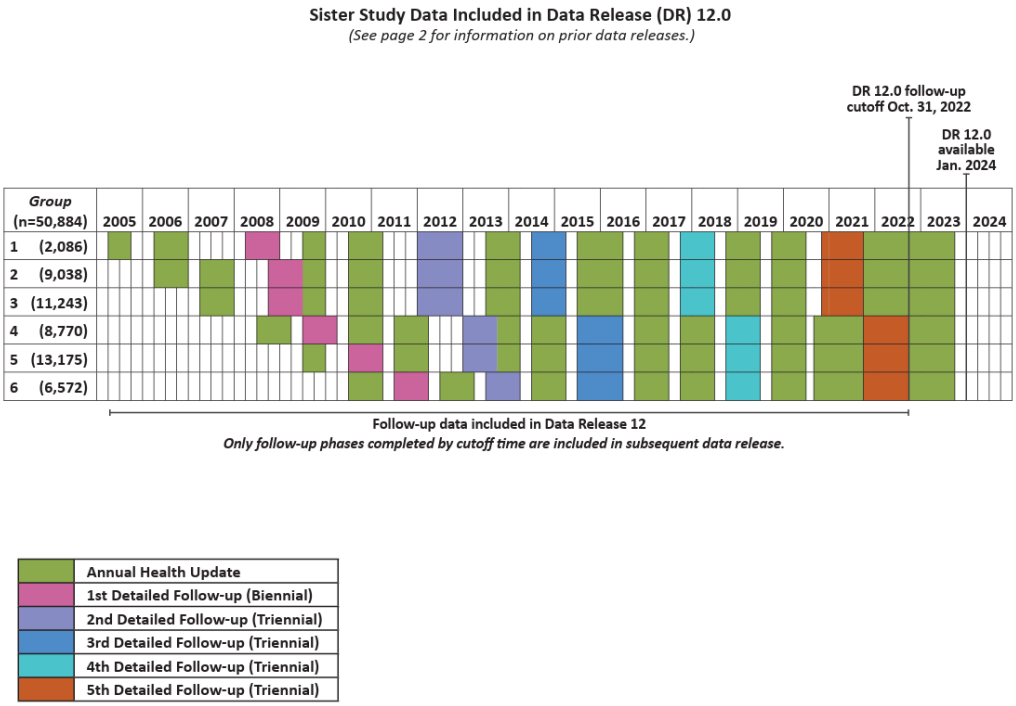
on coronavirus infections, testing, and COVID-related health behaviors. We also included questions about cancer screening or treatment delays, mental health (including stress, anxiety, and sleep health), and many other factors. The survey was sent to all active participants in November 2020, with a 76.5% response rate through July 2021. Several COVID-related questions (e.g. ever infected, vaccine status) were also added to the annual follow-up questionnaire and 5th DFU questionnaire.

ABC collection
A new biomarker collection, referred to as the Anniversary Biospecimen Collection (ABC), was begun in 2024, 20 years after initial open enrollment began. Sister Study participants who consent to ABC are asked to provide blood, urine and stool specimens and complete accompanying questionnaires about their health and exposure history at the time of collection. They will schedule an appointment with a licensed phlebotomist to come to their home or another approved location. The phlebotomist will collect approximately 38 mL of blood (three 10 mL plastic tubes for plasma, one 6 mL plastic tube for buffy coat, and one 2 mL glass tube for whole blood). Women will self-collect six spot urine samples – morning and evening for 3 days – in 100 mL collection cups. Stool samples will be self-collected as smears on 3 fecal occult blood test (FOBT) cards. The fecal sample collection is a collaboration with Dr. Emily Vogtmann, an epidemiologist in the Division of Cancer Epidemiology and Genetics at the NCI. The urine and stool self-collection should ideally be completed on or before the day of the scheduled blood draw so that the phlebotomist can ship all samples together to the SSS laboratory. Alternatively, the participant can pack the urine and stool samples themselves with the provided shipping supplies and contact FedEx for collection. All samples will be aliquoted in the DLH laborator and put in long-term storage at the Experimental Pathology Lab (Durham, NC).

The pilot phase, which prioritized participants included in prior biomarker studies (e.g., Sisters Changing Lives, 2019 case-cohort), as well as a number of volunteer participants identified through the study's Facebook page, successfully collected samples from 481 women by early mid-June 2025 (42% completion, with others still in process). Another 1,602 women were identified to be included in Phase 1, with 28% complete by mid-June 2025. Once those included in above-mentioned ancillary studies have been recruited, we will prioritize enrolling newer breast cancer cases and younger women.

Self Collection Pilot Study. We are also initiating a pilot study to test the feasibility of having participants self-collect blood samples using TAP Micro Select devices (https://yourbiohealth.com/touch-activated-phlebotomy/our-devices/). These use microneedle arrays to draw whole blood samples. We will provide each participant with 2 devices, hoping to collect 0.6 mL per device (1.2 mL total). Once the pilot phase is complete we will determine whether this alternative collection may be useful for obtaining samples from women living outside the phlebotomists' coverage area or those who refuse a home visit. Because women who self-collect will provide very limited blood volume (1.2 mL versus 38 mL) and no plastic-free samples, this protocol is unlikely to be broadly applied.

Data Management and Processing
The first data release was created in 2013. Data releases are issued approximately once per year to incorporate new follow-up data, including updated mortality data from the National Death Index, and changes due to data cleaning. The most recent data (version 12.0) were released in January 2024 and include follow-up through October 31, 2022. Data Release 13 is expected in late 2025.



Data Sharing and Collaboration

In the interest of promoting scientific research on the environmental and genetic risk factors for breast cancer and other diseases, the Sister Study welcomes proposals for collaborative studies from within NIEHS and the wider scientific community. Proposals are reviewed to ensure scientific merit and to protect the integrity of the study and participant confidentiality. Acceptable study topics will take advantage of the unique characteristics of the Sister Study cohort. Information on available data, instructions on how to submit a research proposal, and guidelines regarding the use of data and specimens can be found on the Sister Study Website (For Researchers tab (The Sister Study: For Researchers) or the data portal at ***www.sisterstudystars.org***. This portal tracks study proposals, data requests, specimen use and manuscripts.

Consortia and data pooling

The Sister Study participates in the National Cancer Institute's Cohort Consortium, a group that promotes the pooling of data from individual cohort studies to create high-quality databases large enough to investigate risk factors for rare cancers or to study low-penetrance genetic variants and other factors with small effects in relation to breast and other common cancers. More than 70 international cohorts are included.

Sister Study investigators (Dr. Sandler and former fellow Dr. Hazel Nichols, now at the University of North Carolina) initiated the Premenopausal Breast Cancer Collaborative Group, along with investigators from the Institute of Cancer Research, London. Initial efforts aimed to understand pregnancy- and adiposity-related risk factors, with recently published papers covering topics such as physical activity, hormone therapy, and breast cancer risk prediction. Drs. O'Brien and Sandler have also led projects in the Ovarian Cancer Cohort Consortium (OC3), including studies of genital powder use and an upcoming project on hormone therapy.

The Sister Study also has contributed data to Cohort Consortium studies focused on breast, head and neck, gallbladder and other biliary tract cancers, and thyroid cancers as well as large GWAS and sequencing-based studies of breast and ovarian cancer outside the Cohort Consortium umbrella. This allows us to contribute to research on cancers for which we lack

sufficient power on our own or to contribute to the large efforts needed for gene identification and risk prediction. These include:

- The Confluence Project, NCI
- Biomarkers and Breast Cancer Risk Prediction in Younger Women, NCI
- Diet and Cancer Consortium, NCI Cohort Consortium
- Breast Cancer Association Consortium (BCAC)
- Breast CAncer STratification (B-CAST) Consortium, Netherlands Cancer Institute
- Ovarian Cancer Association Consortium (OCAC)
- Biliary Tract Cancers Pooling Project, Epidemiology and Genomics Research, NCI
- Reproductive and Hormonal Factors and Thyroid Cancers Risk Pooling Project, NCI via Cohort Consortium
- AMH and Breast Cancer Pooling Project (NYU and the NCI Cohort Consortium)
- Collaborative Study to Find Genetic Variants Associated with Variation in Anti-Müllerian Hormone Levels, Exeter University (UK)

The Sister Study also contributes to other meta-analyses and data pooling efforts outside the Cohort Consortium:

- Cancer Risk Estimates Related to Susceptibility Genes (CARRIERS) Consortium, Mayo Clinic
- Trauma and ovarian cancer, Oregon Health and Science University and Moffitt Cancer Center
- Circulating hormones in premenopausal women and subsequent breast cancer risk, NCI and University of Utah
- Polycystic ovarian syndrome and pancreatic cancer, University of Washington and others
- Air pollution and cardiovascular disease, University of Washington

Building on the air pollution and cardiovascular disease pooling project, Drs. White and Sandler lead a sub-consortium studying breast and reproductive cancers.

Geocoding studies

Sister Study enrollment, longest-lived and childhood residences were geocoded in 2011 by the University of Washington allowing linkage to air pollution, census, and other data sources. Follow-up addresses were geocoded through 2017 (completion of the 3rd DFU) as part of the cardiovascular disease collaboration with Dr. Kaufman (University of Washington). In 2021, Dr. White (NIEHS, EB) led an initiative to identify Sister Study participant's interim addresses (post-1980) using the LexisNexis database, and these addresses were also geocoded. In 2024, follow-up addresses obtained through 2022/5th DFU were geocoded to extend the ability to perform linkage efforts to the most recent residences.

Ancillary Studies

Two Sister Study

Dr. Clarice Weinberg (NIEHS, BCBB) led the Two Sister Study, which completed enrollment in December 2010. This is a family-based study of genetic and environmental risk factors for young onset (before age 50) breast cancer. The study recruited the affected sister of Sister Study participants (the sister with breast cancer who was not in the Sister Study) if her diagnosis was before age 50 and within four years of when the Sister Study participants was screened for eligibility. Case-sisters completed the same computer-assisted telephone interviews as their sisters did when joining the Sister Study, provided saliva, dust, and toenail samples, provided detailed information about their breast cancer diagnosis and treatment, and were asked to

authorize retrieval of medical records and tumor samples. In addition, participants invited their parents to provide a saliva sample as a source of DNA for genetic analyses. Over 1,400 young-onset sisters enrolled in the study by completing questionnaires and/or providing saliva samples for DNA. These index cases are the sisters of ~1,700 women in the Sister Study (who also provided questionnaires and samples for DNA). Of their parents, 1,438 provided a saliva sample. About 1,300 of the sisters with young-onset breast cancer completed all study requirements (all questionnaires and saliva sample) and are now being followed prospectively along with Sister Study participants who developed breast cancer after joining the study. This work was funded in part by a grant from the Susan G. Komen for the Cure (grant # FAS0703856).

CDC Special Survey and Survivorship Survey

In response to a CDC mandate under the Young Women's Breast Health Awareness and Support of Young Women Diagnosed with Breast Cancer bill (the 2010 EARLY Act), the Sister Study teamed with researchers from the Epidemiology and Applied Research Branch in the Division of Cancer Prevention and Control at the Centers for Disease Control and Prevention (CDC) to 1) survey breast cancer free Sister Study participants about breast cancer screening practices, family communication about cancer, and the effect of having a sister with breast cancer on participants and their families. About 18,000 women participated in 2012; 2) survey women diagnosed with breast cancer about topics of interest to younger women such as body image, work-life balance, relationships and intimacy, and fertility, as well as impact of cancer on the lives of breast cancer survivors and their families, survivors' quality of life, physical and emotional health, changes in lifestyle and environment, and coordination of cancer treatment and follow-up care. This survey was completed (2012-2013) by 2,537 women with breast cancer in the Sister Study and the Two Sister Study.

Validation of Early Life Factors

Data collection for a validation study of self-reported early life factors was completed in 2012. The aim was to evaluate how accurately women reported the information on early life collected at baseline, including information on their mother's pregnancy. A total of 1,802 of the participants' mothers completed a questionnaire after receiving an invitation from their daughters.

Mammography Initiative

In collaboration with investigators from Columbia University (Dr. Parisa Tehranifar, Dr. Mary Beth Terry), the Sister Study attempted to retrieve digital and film mammography images from a case-control sample of participants age $\leq$60, with a goal of studying factors related to breast density changes over time. Approximately 60% of women contacted for the study provided medical release forms, allowing for the collection of 10,000+ mammograms from more than 1,500 women.

Olfactory Impairment

Dr. Honglei Chen of Michigan State University received grant funding (Department of Defense and Parkinson's Foundation) to study airborne pollutants, the olfactory system, and Parkinson's disease. To support this research, a sample of 3,406 Sister Study participants aged 50-79 completed a special survey about olfaction status and a Brief Smell Identification Test.

Vitamin D biomarkers

Dr. Katie O'Brien (NIEHS, EB) received two grants from the Office of Dietary Supplement Research Scholars' program to evaluate concentrations of vitamin D-related biomarkers in blood samples provided by Sister Study participants. These biomarkers were initially assessed in a breast cancer case-cohort sample, with later assays conducted to measure concentrations in women who contributed a second blood specimen, and a third in Black and Hispanic women from the 2019 case-cohort.

Toenail Metals
Dr. Alexandra White (NIEHS, EB) received funding from the Office of Research on Women's Health (ORWH) to measure concentrations of metals and metalloids in toenails. This was conducted in the 2019 case-cohort. Prior to this, Dr. Weinberg (NIEHS, BCBB) assessed a similar panel of metals and metalloids in toenails collected from young-onset cases and sister-matched controls participating in the Two Sister Study.

Exposome, Metabolome, and Breast Cancer
In collaboration with Dr. Douglas Walker and other investigators from Emory University, Dr. Alexandra White (NIEHS, EB) is leveraging state-of-the-art gas chromatography (GC) and liquid chromatography (LC) coupled with high-resolution mass spectrometry (HRMS) to profile both the internal exposome and metabolome in blood samples collected at enrollment. Recent advancements in omics-scale technologies now allow for the quantification of hundreds of low-abundance environmental chemicals in biologic samples. This effort includes a pilot phase of 200 participants with two samples approximately 6 years apart, with the goal to evaluate temporal trends and stability of the chemicals over time. For the main study, a breast cancer case-cohort sample (1,846 cases, 2,182 random subcohort) was assayed. The aim is to investigate exogenous chemicals (e.g., PFAS, organochlorine pesticides and novel compounds), individually and in combination, in relation to breast cancer incidence.

Overlap of breast cancer biomarker studies
Many of the breast cancer case-cohort samples described above were designed to overlap with one another, such that a large number of breast cancer cases and a large randomly selected subcohort (the 2019 case-cohort) have the following 'omics data available: genomics, epigenomics, metabolomics, and exposomics, plus toenail metals and vitamin D. The Sisters Changing Lives sample has also been included in many of these studies, including epigenomics, metabolomics, exposomics, toenail metals, and vitamin D. These subgroups have been prioritized for the ABC intiaitive, which will allow us to study changes over time (including before and after breast cancer diagnosis) and interactions between factors of interest.

Metabolomics and Type 2 Diabetes
Dr. Chandra Jackson (NIEHS, EB) received a Bench to Bedside grant from NIH to study the role of the metabolome in incident type 2 diabetes. The selected case-cohort sample included 729 women with incident type 2 diabetes (500 non-Hispanic White, 229 Black) and a random sub-cohort of approximately 1300 (500 non-Hispanic White, 800 Black) selected from the subcohort in the 2019 case-cohort sample.

Obesity and Diverticulitis
Dr. Anne Peery is leading a team of NIEHS and University of North Carolina researchers to study metabolic syndrome, diet, and other factors in relation to incident diverticulitis. They will also do a validation study of self-reported diverticulitis in the Sister Study and measure obesity-related biomarkers in serum to see if they are related to diverticulutis. This work is being funded by a grant from the National Institute of Diabetes and Digestive and Kidney Diseases.

Microbiome and menopause
Dr. Emily Vogtmann (National Cancer Institute) and Dr. Sandler (NIEHS, EB) received a grant from ORWH to study the impact of menopause and hormone therapy on the gut microbiome. This grant will help support the collection of the stool samples in the ABC initiative.

Cardiovascular disease in women with breast cancer

Dr. Heather Greenlee (Fred Hutch Cancer Center) received an NIH grant to study cardiovascular disease in women with breast cancer. She plans to develop risk prediction models in other cohorts and then validate those models in the Sister Study.

Heat and DNA methylation

Drs. Dale Sandler (NIEHS, EB), Kaitlyn Lawrence (formerly NIEHS EB, now DLH Inc.) and others received an Intramural Climate Change and Health (ITCCH) award to study the relationship between heat exposure and blood DNA methylation, a type of epigenetic change that can impact gene expression. This will include an analysis of the association of several heat-related exposure metrics and epigenetic markers assessed among Sister Study participants. Supplemental funding received in 2025 will support measurement of several biomarkers of cardiometabolic function in the sample to follow-up effects seen in mouse models, which were funded via phase I of this grant.

Autoimmune diseases

Drs. Jennifer Woo (NIEHS, EB post-doctoral Fellow) and Dale Sandler (NIEHS, EB) are leading an interdisciplinary team of NIH researchers to identify preclinical epigenetic and serological risk profiles of systemic lupus erythematosus and other co-occuring autoimmune diseases. This projects is funded through the Office of Autoimmune Disease Resarch in ORWH. This work will facilitate future research in the Sister Study linking life course social and environmental exposures to epigenetic and immunoproteomic factors in women with autoimmune diseases.

Sister Study Collaborators

Intramural NIEHS

Donna Baird, PhD	Epidemiology Branch (emeritus)
Mary Diaz-Santana, PhD	Biostatistics and Computational Biology
Symielle Gaston, PhD	Epidemiology Branch
Quaker Harmon, PhD	Epidemiology Branch
Chandra Jackson, PhD	Epidemiology Branch
Anne Marie Jukic, PhD	Epidemiology Branch
Suril Mehta, PhD	Division of Translational Toxicology
Alex Montiel-Ishino, PhD	Epidemiology Branch
Christine Parks, MSPH, PhD	Epidemiology Branch
Min Shi, MD, PhD	Biostatistics and Computational Biology Branch
Jack Taylor, MD PhD	Epidemiology Branch (emeritus)
Kyla Taylor, Ph.D.	Division of Translational Toxicology
Brittany Trottier	Hazardous Substances Research Branch
Zongli Xu, PhD	Biostatistics and Computational Biology Branch
Clarice Weinberg, PhD	Biostatistics and Computational Biology Branch
Shanshan Zhao, PhD	Biostatistics and Computational Biology Branch

Past and Current Trainees Using Sister Study Data / Current position

Jared Bailey, MPH	Emory University
Jordyn Brown, MPH	University of North Carolina
Rachel Carroll, PhD	American Institutes for Research
Che-Jung Chang, PhD	Social & Scientific Systems, Inc. / DLH
Dazhe Chen, PhD	Epidemiology Branch / Michigan State University
Helen Chin, PhD	George Mason University
Aimee D'Aloisio, PhD	Social & Scientific Systems, Inc. / DLH
Meklit Daniel	University of Oxford

Maya Deshmukh, MPH	Emory University
Brittany Gedeon	University of North Carolina
Mandy Goldberg, PhD	Epidemiology Branch / Rutgers University
Allyson Gregoire, MPH	Michigan Medicine
Jennifer Ish, PhD	Epidemiology Branch
Mitali Joshi, MS	Johns Hopkins University
Jacob K. Kresovich, PhD	Moffitt Cancer Center
Sydney Lash	University of North Carolina
Kaitlyn Gam Lawrence, PhD	Social & Scientific Systems, Inc. / DLH
Oscar Lopez	Johns Hopkins University
Sharonda Lovett, PhD	Epidemiology Branch
Yilda Macias, MPH	University of Washington
Clare Meernik, PhD	Duke Department of Public Health
Helen Meier, PhD	University of Michigan
Hazel Nichols, PhD	Univ of North Carolina
Nicole Niehoff, PhD	GlaxoSmithKline (GSK)
Kemi Ogunsina, PhD	Epidemiology Branch/Natera
Yong-Moon Park, MD, MS, PhD	Univ Arkansas for Medical Sciences
Molly Rogers	Biostat and Computational Biology Branch
Srishti Shrestha, PhD	Univ. of Mississippi Medical Center
Marina Sweeney, PhD	Social & Scientific Systems, Inc. / DLH
Hana Tekle, MPH	Qlarant
Kristen Upson, PhD	Michigan Statue University
Ann von Holle, PhD	Biostat and Computational Biology Branch/ American Medical Group Association
Emily Werder, PhD	University of North Carolina
Jennifer Woo, PhD	Epidemiology Branch
Jing Xu, PhD	Peking Union Medical College
Jordan Zeldin, MD MS	New York University, Lagone Health

<u>Intramural NIH</u>

Thomas Ahearn, PhD	National Cancer Institute
Lindsey Criswell, PhD	National Human Genome Research Institute/ National Institute of Arthritis and Musculoskeletal and Skin Diseases
Arash Etamadi, PhD	National Cancer Institute
Jared Fisher, PhD	National Cancer Institute
Gretchen Gierach, PhD	National Cancer Institute
Lauren Hurwitz, PhD	National Cancer Institute
Amber Hurson, PhD	National Cancer Institute
Rena Jones, PhD	National Cancer Institute
Alexander Keil, PhD	National Cancer Institute
Cari Kitahara, PhD, MPH	National Cancer Institute
Jill Koshiol, PhD	National Cancer Institute
Peter Kraft, PhD	National Cancer Institute
Erica Loftfield, PhD	National Cancer Institute
Jessica Madrigal, PhD	National Cancer Institute
Mahdi Nalini, PhD	National Cancer Institute
Elisa Pasqual, PhD	National Cancer Institute, International Agency for Research on Cancer
Jongeun Rhee, ScD MS	National Cancer Institute, Murtha Cancer Center Research Program

Minkyo Song, PhD	National Institute on Aging
Rachael Stolzenberg-Solomon	National Cancer Institute
Charlotte Talham, BS	National Institute of Minority Health and Health Disparities
Thi-van-Trinh Tran, PhD	National Cancer Institute
Rebecca Troisi, PhD	National Cancer Institute
Emily Vogtmann, PhD, MPH	National Cancer Institute
Mary Ward, PhD	National Cancer Institute
Nicolas Wentzensen, MD PhD	National Cancer Institute
Faustine Williams, PhD, MPH, MS	National Institute on Minority Health and Health Disparities

Extramural

Christine Ambrosone, PhD	Roswell Park Comprehensive Cancer Center
Chelsea Anderson, PhD	University of North Carolina
Antonis Antoniou, PhD	University of Cambridge
Trevor Barlowe, MD	University of North Carolina
Olga Basso, PhD	McGill University
Amy Berrington de Gonzalez	Institute for Cancer Research
Kimberly Bertrand, ScD	Boston University
Nicholas Boddicker, PhD	Mayo Clinic
Clara Bodelon, PhD	American Cancer Society
Deborah Bookwalter, PhD	Westat, Inc.
Kristen Brantley, PhD	Dana-Farber Cancer Institute
Jessie Buckley, PhD	University of North Carolina
Timothy Buckley, PhD	US Environmental Protection Agency
Isabella Caruso, MPH	University of Massachusetts Amherst
Zichun Cao, PhD	Michigan State University
Jenny Chang-Claude	German Cancer Research Center
Honglei Chen, MD, PhD	Michigan State University
Tess Clendenen, PhD	NYU School of Medicine
Fergus Couch, PhD	Mayo Clinic, Rochester
Douglas Easton, PhD	University of Cambridge
Jessie Edwards, PhD	University of North Carolina
A. Heather Eliassen, ScD	Harvard T.H. Chan School of Public Health
Olivia Fletcher, PhD	Institute for Cancer Research
Montserrat Garcia-Closas, MD PhD	Institute for Cancer Research
Heather Greenlee, ND, PhD, MPH	Fred Hutch Cancer Center
Christopher Haiman, ScD	Keck School of Medicine of USC
Holly Harris, ScD	Fred Hutch Cancer Center
Melissa House, PhD	Social & Scientific Systems, Inc. / DLH
Chunling Hu, PhD	Mayo Clinic
Dezheng Huo, PhD	University of Chicago
Michael E. Jones, PhD	Institute for Cancer Resarch
Joel D. Kaufman, MPH, MD	University of Washington
Roger Milne, PhD	University of Melbourne
Grace Mulholland, PhD	University of North Carolina
Kate Nathanson, MD	University of Pennsylvania Perelman School of Medicine
Hazel Nichols, PhD	University of North Carolina
Julie Palmer, ScD	Boston University
Jihye Park, PhD	GSK
Alpa Patel, PhD	American Cancer Society
Anne Peery, MD	University of North Carolina

Robert Sandler, MD	University of North Carolina
Minouk Schoemaker, PhD	Institute of Cancer Research / IQVIA
Amanda Simanek, PhD	University of WI at Milwaukee
Anthony Swerdlow, MD PhD	Institute of Cancer Research, UK
Parisa Tehranifar, PhD	Columbia University
Lauren Teres, PhD	American Cancer Society
Kathryn Terry, ScD	Harvard Medical School
Mary Beth Terry, PhD	Columbia University
Mary Townsend, ScD	Oregon Health Sciences University
Iain Timmins, PhD	Institute for Cancer Research / AstraZeneca
Britton Trabert, MS PhD	University of Utah
Wei-Lun Tsai, PhD	US Environmental Protection Agency
Shelley Tworoger, PhD	Oregon Health Sciences University
Douglas Walker, PhD	Emory University
Kala Visvanathan, PhD	Johns Hopkins
Wei Zheng, PhD	Vanderbilt University

Sister Study Publications since last review (accepted after September 2021- August 2025)

Approximately 350 Sister Study papers (primary papers and as part of large consortia) have been published **since 2007** (129 since last review). A complete list of papers can be found on the Sister Study Website (https://sisterstudy.niehs.nih.gov/English/articles.htm).

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