

**The Sister Study**  
***Internal and External Consultation, Formal Reviews, and Advisory Groups***

The Sister Study began development in October 1997. The study concept, drafts of the protocol, and various components of the study received extensive formal and informal review. Some reviews were mandated to meet specific administrative milestones; others were designed to better inform the study design or seek advice on “best practices” for a specific aspect of the proposed work. Most recently, the study and its progress received an outstanding evaluation by the NIEHS Division of Intramural Research Board of Scientific Counselors during the review of the Epidemiology Branch in April 2005. Key milestones in the development and review process are summarized below.

November 1997 — Concept reviewed by Interagency Steering Committee for proposed NCI/NIEHS/CDC Collaborative Study of Gene-Environment Interaction in the Etiology of Breast Cancer. Non-NIEHS Steering Committee Members were from CDC, DHHS, NIOSH, and NCI.

1998-1999 — Protocol development and consultation with various experts and consumer groups, e.g., National Breast Cancer Coalition and informal focus groups of different racial, ethnic, and economic backgrounds.

June 1, 1999 — NIEHS Epidemiology Branch Concept Review

1999-2001 — Consultation and external peer review during protocol development from experts at CDC, USEPA, NCI, NIA, DHHS/OWH, and extramural institutions

February 2001 — Reviewed by NIEHS Board of Scientific Counselors and special ad hoc reviewers

December 2001 — Presented for discussion with NIEHS Breast Cancer Interest Group

May 2002 — Presented for discussion at NIEHS Leadership Retreat with NIEHS upper management and senior scientists, National Advisory Environmental Health Sciences Council, and invited outside experts.

June 2002 — Epidemiology Branch Protocol Review and Questionnaire Review

August 2002 — Reviewed for Certificate of Confidentiality

October 2002 — Initial review by NIEHS Institutional Review Board Initial Review

October 2002 through July 2003 — Office of Management and Budget Review

November 2002 — Final External Peer Review

January 2003 — Presented for discussion with National Advisory Environmental Health Sciences Council

January 2003 — Sister Study Minority Recruitment Strategy Meeting with leaders in breast cancer advocacy for minority populations, and experts in recruitment of minority populations for research.

February and July 2003 — NIEHS Division of Intramural Research Contract Review

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