



National Institutes of Health
Medical Record Department
Protocol Coordination Service Center
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July 30, 2002

TO: Dale Sandler, Ph.D.
MSC A3-05

FROM: Theresa Minter, RHIA, Protocol Specialist
Protocol Coordination Service Center, MRD

SUBJECT: Initial Protocol Approval

TITLE: Environmental and Genetic Risk Factors for Breast Cancer

PROTOCOL
NUMBER: 02-E-N271

Your protocol was approved by John I. Gallin, M.D., Associate Director for Clinical Research of the National Institutes of Health on 07/29/2002. The Protocol Coordination Service Center is responsible for assigning the protocol number and maintaining the official record for all intramural on-site and off-site protocols. Your protocol number is **02-E-N271**, and will be due for continuing review on **03/14/2003**.

PCSC will notify you 120 days prior to the review. However, Federal regulation and NIH policy require that you report promptly any unanticipated problems involving risks to subjects or others, or serious harm involving subjects, to your IRB. In addition, substantive changes in research activities, during the period for which IRB approval has been given, may not be initiated by you without prior review and approval by your IRB, except where necessary to eliminate apparent immediate hazard to subjects.

If you have any questions regarding protocol review, approval, or reporting procedures, please contact Jane Lambert, your Protocol Coordinator at (919) 541-5047.

cc: Protocol Coordinator