

National Institutes of Health Medical Record Department Protocol Coordination Service Center Building 10, Room 1S231B Bethesda MD 20892-1192 Telephone: (301) 496-0744

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